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Evaluation of the EU Legislative Framework in the Field of Medicated Feed

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Final Report

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Food Chain Evaluation Consortium (FCEC)

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Contents

Acronyms

COPA-COGECA: Committee of Professional Agricultural Organisations and General Confederation of Agricultural Co-operatives in the European Union

DG: Directorate General

EMEA: European Medicines Agency

FCEC: Food Chain Evaluation Consortium

FEDIAF: European Pet Food Industry Federation

FEFAC: European Feed Manufacturers Federation

FVE: Federation of Veterinarians of Europe

IFAH: International Federation for Animal Health

LSU: Livestock units

MS: Member State/s

PCV: Porcine Circovirus

PMWS: Postweaning Multisystemic Wasting Syndrome

PRRS: Porcine Reproductive and Respiratory Syndrome Virus

ToR: Terms of Reference

VMP: Veterinary Medicinal Product

Executive Summary

The European Commission is in the process of revising Directive 90/167/EEC which sets out the conditions under which medicated animal feeds may be prepared, placed on the market and used within the Community. DG Health and Consumers commissioned Civic Consulting of the FCEC this study to evaluate the production and use of medicated feed in the EU. Key conclusions of the study include:

⇒ *Size and recent evolution of the medicated feed market vary drastically amongst Member States.* Production trends vary by country, with three Member States reporting a decrease in use of medicated feed over the last 5 years, four reporting an increase in use and two reporting no change. All in all, there is considerable uncertainty with regard to production of medicated feed since official statistics are rare.

⇒ *The number of authorised medicated pre-mixes varies significantly across countries.* Innovation in the market for medicated pre-mixes seems to be limited and treatments via medicated feed appear to be based on pre-mixes containing rather old active substances. This is reflected in the small number of medicated pre-mixes newly authorised per year in many countries. *Antimicrobials are by far the most important VMPs currently used for the production of medicated feed.* This strong emphasis on antimicrobials is reflected in the number of authorised medicated pre-mixes: In many countries around three quarters of all authorised pre-mixes are antimicrobials.

⇒ *Whereas the share of oral application of antimicrobials remains relatively stable, the importance of medicated feed compared to other routes of oral application is decreasing.* Medicated feed is still the most common way of oral administration of antimicrobials for animals in some Member States for which detailed data is available, and possibly also in the EU as a whole, according to sales data from a sample of seven VMP producers (when measured as share of total tonnage of active substances). However, medicated feed loses importance compared to other routes of oral administration, such as water medication and top dressing/mixing of ready-to-use veterinary medicine into feed.

⇒ *The additional costs of mixing medicated feed are comparatively low if national demand allows feed manufacturers to realise economies of scale.* The case studies conducted in Denmark, France, Germany and the United Kingdom reveal that it is between 0.4 % (France) and 25 % (Germany) more costly to manufacture medicated feed than compound feed (not considering the costs of the active substances used). Additional production costs of medicated feed are more significant in countries where production levels are low and producers are not able to realise economies of scale, especially if in addition the technology used for the production of medicated feed requires significant investments (e.g. end-of-line mixer, as is the case in Germany).

⇒ *There is no generally valid economic rationale for farmers to prefer a specific way of administering oral veterinary medicines, be it through medicated feed or water medication.* Whether medicated feed is a more costly or a more cost efficient alternative of administering oral VMPs compared to water medication depends on the pricing strategy applied by manufacturers of medicated feed, the active substance used and the specific Member State. Case studies in Denmark, France, Germany and the UK indicate that cost differences are generally in the range of plus or minus 25 % in both directions. Only in France water medication is – for the three active substances scrutinized – always more expensive than medicated feed. As objective and systematic price comparisons are hardly feasible for farmers, their choices between alternatives ways to administer oral VMPs depend on a variety of factors, including perceived cost advantages, specific rules concerning VAT (in Germany), monetary incentives of veterinarians, tradition, and assumptions or experiences with the effectiveness/efficiency of the route of administration.

⇒ *There is no indication that different ways of administering oral veterinary medicines lead to significant differences regarding occupational safety, public health and environmental consequences, if safety and handling instructions are properly observed.* In situations where the latter cannot be guaranteed, medicated feed can be expected to provide a safer way of administering oral VMPs than top dressing and mixing ready-to-use VMPs in the feed by farmers. A main advantage of medicated feed is that it ensures homogeneity and stability of the VMP in the feed and reduces the number of people handling highly concentrated veterinary medicines. In absence of relevant surveillance data and scientific research on the issue a final conclusion, however, cannot be made.

1. Introduction

1.1. Aim of the study

The oral administration of veterinary medicinal products (VMPs) via feed is one option for the animal holder. Directive 90/167/EEC sets out the conditions under which medicated animal feeds may be prepared, placed on the market and used within the Community.

The global objective of this Directive is to safeguard public health from any dangers arising from the use of medicated feeds for animals intended for food production, and to prevent distortions in competition in the keeping and rearing of farm animals, by laying down conditions regarding the preparation, placing on the market and use of medicated feeds and regarding intra-Community trade in those products.

In the light of significant progress in scientific and technical knowledge made in this field the European Commission is in the process of revising Directive 90/167/EEC.

For this purpose DG SANCO has commissioned Civic Consulting of the FCEC this study to evaluate the production and use of medicated feed in the EU, taking particular attention to the additional costs of manufacturing medicated feed compared with manufacturing compound feed and to the costs of using medicated feed for farmers.

1.2. Acknowledgements

Civic Consulting would like to express its gratitude to all supporters, without whom this study would not have been possible; we would like to thank the feed manufacturers' associations, associations of cooperatives and farmers' associations and manufacturers of VMPs, as well as competent authorities, feed mills, farmers, veterinarians and experts who provided valuable inputs through in-depth interviews and an EU-wide survey. We are very grateful for the support provided by the European stakeholder organisations FEFAC, Copa-Cogeca, IFAH-Europe and FEDIAF. Finally, we thank DG SANCO of the European Commission for the support provided throughout the study.

2. Background - animal husbandry in the European Union

The following section summarises the background of medicated feed production in the EU. A description of the holding of animals in the EU and recent trends is followed by an overview of the production of animal products and a discussion of the regional prevalence of intensive production systems. Finally, this section provides recent trends concerning key farm inputs relevant for the study, namely compound feed and veterinary medicinal products.

2.1. Holding of animals

The European Union is one of the major livestock producing regions in the world. In 2008, the value of livestock production amounted to 152 billion Euro; that were 40 % of the total EU agricultural output.[1] In 2007, total EU livestock was 132.6 million livestock units (LSU).[2] Cattle accounted for 48.3 % of total livestock, sheep, goats and equidae for 10.4 %, pigs for 27.8 % and poultry and rabbits for 13.5 %. France, Germany, Spain, the United Kingdom and Poland are the major livestock producing countries representing about 60 % of the holding of livestock in the EU.[3]

Figure 1 below depicts the trends in livestock holding between 1995 and 2008. Whereas cattle, sheep and goat livestock have declined slightly, the number of pigs has remained nearly the same.[4] The size of the EU pig herd was around 160 million animals in the period 2000-2007. In 2008 the numbers declined by more than 4 % to about 153 million pigs. Major pig producing countries are Germany, Spain, France, Poland and Denmark.[5]

[1] European Feed Manufacturers Federation (FEFAC) 2008.

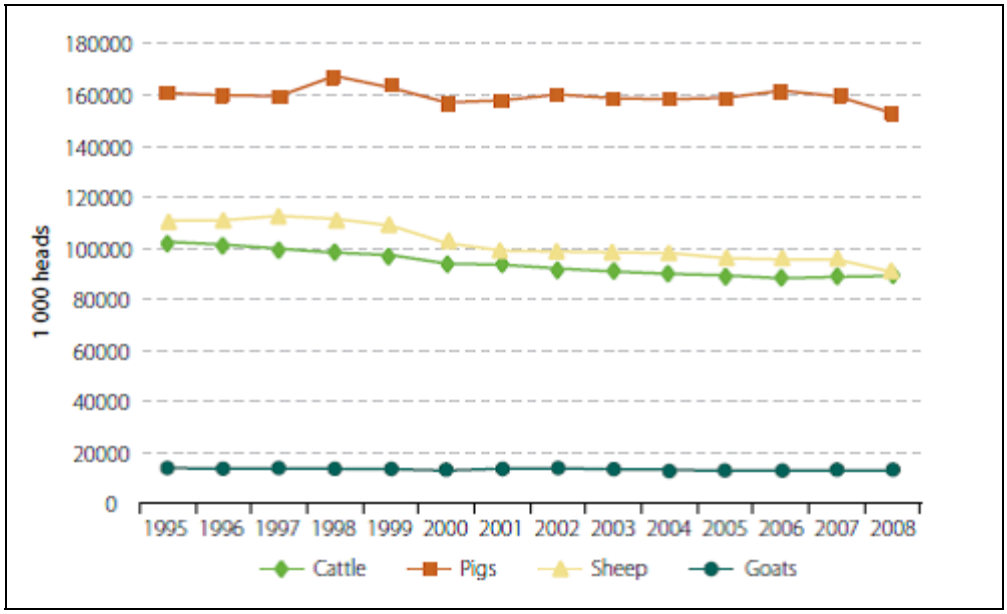
[2] The livestock density index provides the number of livestock units (LSU) per hectare of utilised agricultural area. The LSU is a reference unit which facilitates the aggregation of livestock from various species and ages. The Eurofarm LSU coefficients, which are at the basis of this indicator, are established by convention (originally, they were related to the animals' feed requirements, the reference being a dairy cow with an annual yield of 3000 kg milk, without additional concentrated feedingstuffs). In the interpretation of the livestock density index, the limits of this theoretical unit are to be taken into account. The livestock species aggregated in the LSU total, for the purpose of this indicator, are: equidae, cattle, sheep, goats, pigs, poultry and rabbits.

[3] France: 22.5 million LSU; Germany: 17.95 million LSU; Spain: 14.33 million LSU; United Kingdom: 13.88 million LSU; Poland: 10.74 million LSU (2007 data, see Eurostat 2009a).

[4] Eurostat 2009a.

[5] Germany: 26.7 million; Spain: 26.3 million; France: 14.8 million; Poland: 14.2 million; Denmark: 12.2 million (2008 data, see Table 17 in Annex 3). Production of slaughter pigs is most important in Germany, Spain, Poland, France and Denmark. Major producers of piglets are Spain, Germany, Poland, Denmark, France and the Netherlands. See Eurostat 2008.

Figure 1: Number of livestock in the EU by main species



Source: Eurostat 2009a.

As the figure above illustrates, the number of cattle shows a slight decline; numbers were down to 88.8 million in 2008 from 90.2 million in 2004. France, Germany, the United Kingdom, Italy, Spain and Ireland are major producing countries.[6] In 2008, the number of dairy cows was 22.5 million in the EU; this was a slight increase compared to 2007 (22.3 million) but a slight decrease from the 23.3 million dairy cows in 2004.

The number of sheep declined remarkably between 2004 (98.2 million) and 2008 (89.9 million). Sheep production is most important in the United Kingdom (21.9 million) and Spain (20 million), which represent nearly 47 % of EU production.[7] The number of goats was 11.8 million in 2007.[8] Goats are mainly kept in Greece (41 %), Spain (22 %) and France (11 %).[9]

In 2007, 1,443 million poultry were kept in the EU, including 780 million broilers, 469 million laying hens and 194 million other poultry.[10] Poultry production is concentrated in France (19 %), Spain and the United Kingdom (12 % each), Italy and Poland (10 % each) and Germany (8 %).[11]

Besides farm animals, there are also a large number of pets in the European Union. The European Pet Food Industry Federation (FEDIAF) estimates that about 200 million pets live in the EU, including 60 million cats, 56 million dogs, 35 million birds, 9 million aquaria and 40 million other animals.[12] For Germany alone, for instance, it is estimated that about 23.1 million pets live in private households, including about 8.2 million cats, 5.5 million dogs, 6.2 million small animals, 3.4 million ornamental birds and 4.3 million fish.[13]

[6] France: 19.4 million; Germany: 13 million; United Kingdom: 9.9 million; Italy: 6.5 million; Spain: 6 million; Ireland: 6 million (2008 data, Table 19 in Annex 3).

[7] See Table 17 in Annex 3.

[8] Eurostat 2009a.

[9] 2005 data, see Eurostat 2008.

[10] See footnote 8.

[11] See footnote 9.

[12] See Table 21 in Annex 3.

[13] See Figure 9 Annex 3.

2.2. Production of animal products

Products of animal origin include a wide spectrum of products destined for human consumption or other purposes (such as pet foods, leather etc.). Food products of animal origin include fresh meat (beef, pork, poultry, game), meat products, aquaculture products, milk and milk products[14] and other products such as eggs, honey and royal jelly, gelatin, lard and rendered fat.[15]

The Eurostat slaughter index describes the trends for cattle, pigs, sheep and goats meat production in terms of tonnes of animals slaughtered (see Figure 11 in Annex 3). According to this index, the weight of pigs slaughtered increased by 16.5 % between 1995 and 2008. It rose rapidly between 1997 and 1999, then dropped slightly until 2001, and slowly picked up until 2007. In 2008 production fell again by 1 %.[16] In 2008 production of pig meat was 22.6 million tonnes of carcass weight.[17]

Total cattle slaughter in the EU was 8.1 million tonnes in 2008.[18] The weight of cattle slaughtered fell between 1995 and 2001 by about 9 %; since then production slightly recovered and fall again several times so that production numbers in 2008 were similar to those in 2001.[19]

Between 1995 and 2008, meat production in the EU has also fallen in terms of tonnes of animals slaughtered for sheep (-18.2 %) and goats (-21 %).[20] In 2008 production of sheep and goats meat was down to 1 million tonnes of carcass weight.[21] Production of poultry meat was 10.8 million tonnes of carcass weight in 2007.[22]

2.3. Production systems

There is a wide spectrum of different animal production systems in the EU. Even in egg production which is characterised by a comparatively high degree of standardisation, four different production systems were set out in Council Directive 1999/74 laying down minimum standards for the protection of laying hens: eggs from caged hens, barn eggs, free-range eggs and organic eggs. The picture is much more complex in other sectors of animal production where the heterogeneity of production systems is much larger. The German *Kuratorium für Technik und Bauwesen in der Landwirtschaft (KTBL)*, for instance, describes and assesses 139 different animal production systems.[23] Nonetheless, despite the large number of existing production systems, the basic distinction between intensive (or conventional) and extensive (including organic) production systems seems to be most relevant with regard to the use of medicated feed. Typical characteristics of intensive livestock production are:[24]

- The bringing together of large numbers of animals, often from diverse backgrounds, and confining them to limited spaces, at high density;

[14] See in Annex 3 tables 22 to 25 and Figure 10 on meat production in the EU and Figure 8 on production of milk products.

[15] http://ec.europa.eu/food/animal/animalproducts/index_en.htm; downloaded November 3, 2009.

[16] See footnote 8.

[17] See Table 22 in Annex 3.

[18] See Table 23 in Annex 3.

[19] See footnote 8.

[20] See footnote 8.

[21] See Table 24 in Annex 3.

[22] See Table 25 in Annex 3.

[23] KTBL 2006.

[24] Murphy et al. 1999.

- Asynchronous turnoff of animals for sale and the introduction of new animals;
- The care of large numbers of animals by few, sometimes inadequately trained, personnel;
- Elaborate housing systems with complex mechanical services for ventilation, feeding, waste disposal, and cleaning;
- Limitation of the husbandry system to one species;
- Manipulation of natural biological rhythms (artificial daylight, estrus synchronization, etc.);
- Use of very large batches of premixed, easily disgestible feed;
- Improved hygienic conditions;
- Isolation of animal populations.

Extensive production systems can be distinguished from conventional production systems with regard to all or some of the above-mentioned aspects. Since the differentiation between intensive and extensive livestock production describes a continuum, a clear distinction is difficult due to the existence of a large number of semi-intensive as well as semi-extensive production systems. Even intensity of organic farming which is one manifestation of extensive livestock production varies slightly between different private (Demeter, Bioland etc.) and public (mainly organic production in accordance with Regulation (EC) 834/2007) certification standards.

Due to these difficulties in identifying and differentiating specific production systems, regional prevalence of production systems is often characterised through using livestock density as a proxy, i.e. the number of animal per area in a specific Member State or region. Livestock density is very diverse throughout the European Union. It is highest in Belgium, the Netherlands and Denmark; Germany, Ireland and Slovenia come next. A closer look reveals that the density also varies significantly within the EU Member States so that regional livestock densities can be much higher than national averages (for instance, Catalonia compared to Spain, Brittany compared to France or the Weser-Ems region compared to German average). Differences can be observed with regard to main production areas of pigs and cattle. Pig production, for instance, is strongly concentrated in some parts of Spain and the United Kingdom, northwestern France, northern Italy, parts of central and eastern Europe and a sickle shaped area along the North Sea including Belgium, the Netherlands, northwestern Germany and Denmark.[25] Dairy production is often (but not always) located in different regions including, for instance, Ireland, some western parts of the United Kingdom and the Baltic states.[26]

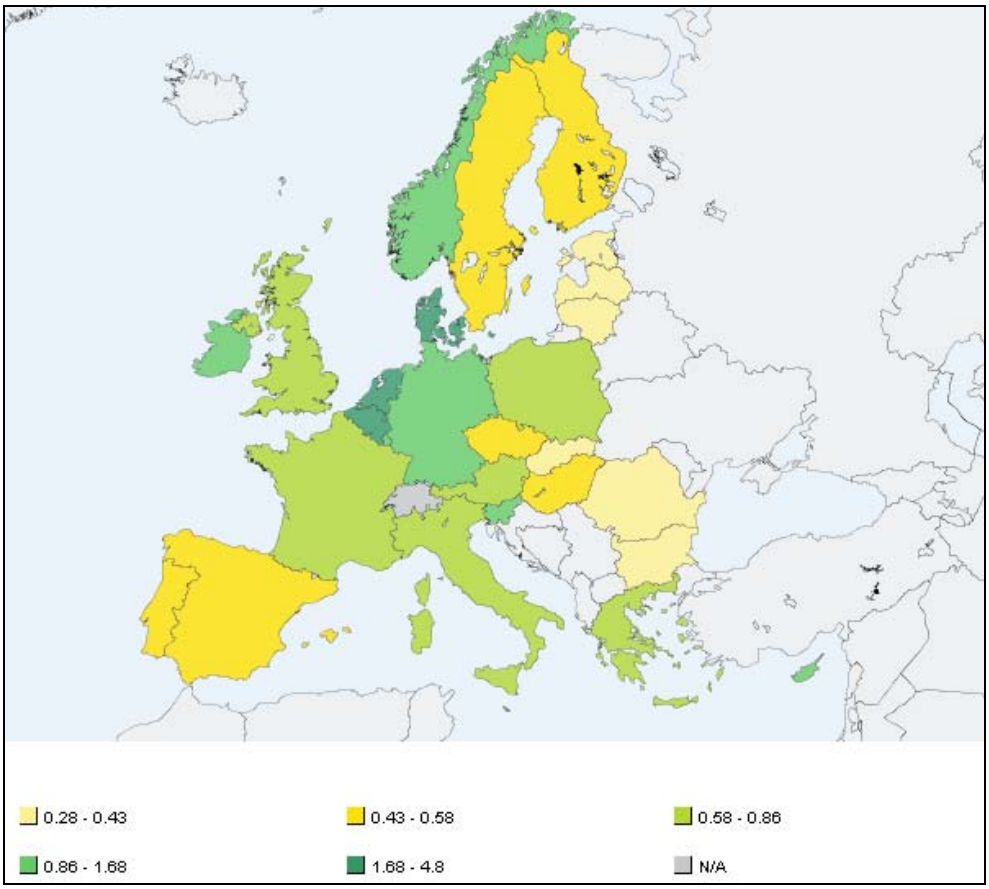
The following figure illustrates livestock density as measured by the livestock densitity index:[27]

[25] See Figure 13 in Annex 3.

[26] See Figure 14 in Annex 3.

[27] The livestock density index provides the number of livestock units (LSU) per hectare of utilised agricultural area (Eurostat, retrieved from http://epp.eurostat.ec.europa.eu in September 2009).

Figure 2: Livestock density index[28] (2007)



Source: Eurostat (retrieved from http://epp.eurostat.ec.europa.eu in September 2009).

It is often assumed that intensive production is predisposed for the use of medicated feed due to, for instance, higher stocking densities and breeding selection criteria that do not adequately take into account animal health and fitness. Although this is generally true and pig and poultry, which are hold in intensive production systems, are the most relevant species in terms of overall quantity of medicated feed used, more in-depth analyses will show that the situation is more complex (see below, section 4.1).

2.4. Farm inputs

Farm inputs that are relevant in the context of this study are compound feed and veterinary medicinal products, which are the basis for the production of medicated feed.

2.4.1. Sales of compound feed

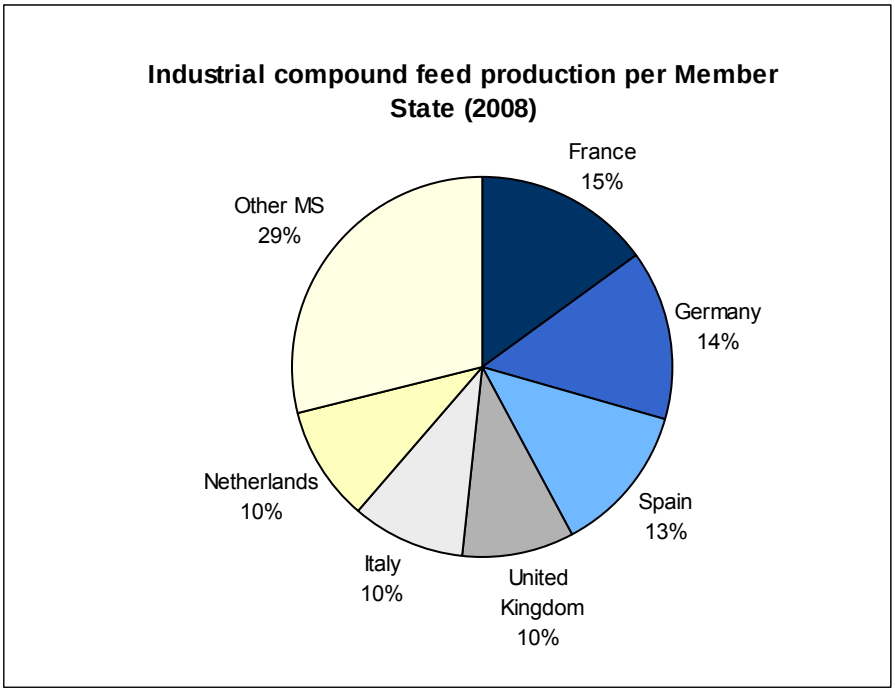
Production figures of compound feed very much parallel the sales figures in each Member State. This means the major livestock producing countries are also major producers of industrial compound feed. This situation is due to high transportation costs of compound feed. The regional character of the industry is emphasised by a decision of the German antitrust agency to

[28] See footnote 2.

consider, with reference to the concept of relevant markets, the compound feed market to be a regional market where farmers are supplied by compound feed mills located in that region.[29]

As a consequence of the regional market structure, France, Germany and Spain are not only the biggest livestock producers but also leading manufacturers of compound feed.[30] The United Kingdom, Italy and the Netherlands come next (see Figure 3).[31] In 2008, the total industrial production of compound feed in the EU was 151 million tonnes and the number of production sites was approximately 4,500.[32] Other important animal feedingstuffs in the EU are roughages grown and used on the farm of origin (228 million tonnes in 2008) and cereals grown and used on the farm of origin (51 million tonnes in 2008).[33]

Figure 3: Industrial production of compound feed per MS, as share of total EU production (2008)



Source: European Feed Manufacturers Federation (FEFAC) 2008.
Note: Data include medicated feed but do not include home mixing. Data do not include Luxembourg, Greece and Malta.

Industrial compound feed production in the EU grew rapidly in the 1960s and early 1970s with growth rates around 7.5 % per year. Then growth rates slowed down. Since 1995 industrial compound feed production has remained largely stable except the additional production that was brought by EU enlargement.[34] Total turnover of the EU compound feed industry was 41.6 billion

[29] Bundeskartellamt 2008.

[30] France: 22.4 million tonnes; Germany: 21.3 million tonnes; Spain: 20.3 million tonnes (2007 data, see Table 26 in Annex 4)

[31] United Kingdom: 14.3 million tonnes, Italy: 14.2 million tonnes; Netherlands: 13.7 million tonnes (2007 data, see Table 26 in Annex 4)

[32] See footnote 1.

[33] See footnote 1.

[34] See footnote 1.

Euro in 2007. In the same year compound feed amounted to 53 % of the value of all feedingstuffs used for livestock production.[35]

2.4.2. Sales of veterinary medicinal products

According to Directive (EC) 2001/82, veterinary medicinal products (VMPs) are defined as follows:

> "*Any substance or combination of substances presented for treating or preventing disease in animals. Any substance or combination of substances which may be administered to animals with a view to making a medical diagnosis or to restoring, correcting or modifying physiological functions in animals …*".

Similar definitions can be found in national laws, for instance Article 1 of the Dutch Veterinary Medicinal Products Act. The most important substance groups in the VMP market include antibiotics,[36] products against endoparasites, endectoparasites and ectoparasites, hormones, cardiacs and non-steroidal antiphlogistics.[37] IFAH-Europe reports total sales of animal health products in the European market of 4.3 billion Euro in 2008.[38] The European animal health market represents about 37 % of the world market.[39] The sales figures by value reported by IFAH-Europe for the year 2008 include vaccines (26.3 %), antimicrobials (19.9 %), parasiticides (27.4 %), topical products (6.8 %) and other products (19.6 %).[40]

Information about sales of VMPs in the EU are, at least in parts, incomplete and inconsistent. For this reasons, in addition to evaluating published information on the sales of VMPs, a survey of producers has been conducted in the framework of this study in coordination with IFAH-Europe. The survey covered 9 IFAH-Europe corporate members, which account for a large share of the animal health market for veterinary medicines in Europe, as well as other companies producing veterinary medicines, including generic producers. A total of eleven responses were received, of which six from IFAH-Europe member companies. Data provided included total sales of therapeutic antimicrobials for oral use, which are the most important

[35] See footnote 1.

[36] Antibiotics are chemical substances produced by various species of microorganisms (bacteria, fungus, actinomycetes) that suppress the growth of other microorganisms and may eventually destroy them. The term antimicrobials includes antibiotics as well as other antimicrobial substances, for instance herbs, that are neither chemical nor produced by microorganisms (Brunton, Lazo and Parker 2006). For definitions of various forms of VMPs see also Regulation (EC) 1831/2003.

[37] SRU 2007.

[38] International Federation for Animal Health (IFAH) 2009. Data based on a survey of 2008 sales statistics of 14 IAFH-Europe and European Animal Health Study Centre (CEESA) Member companies. 20 % is added for non-participating companies. Data cover Austria, Belgium, Switzerland, Cyprus, Germany, Denmark, Spain, France, Great Britain, Greece, Hungary, Ireland, Netherlands, Poland, Portugal and Slovakia.

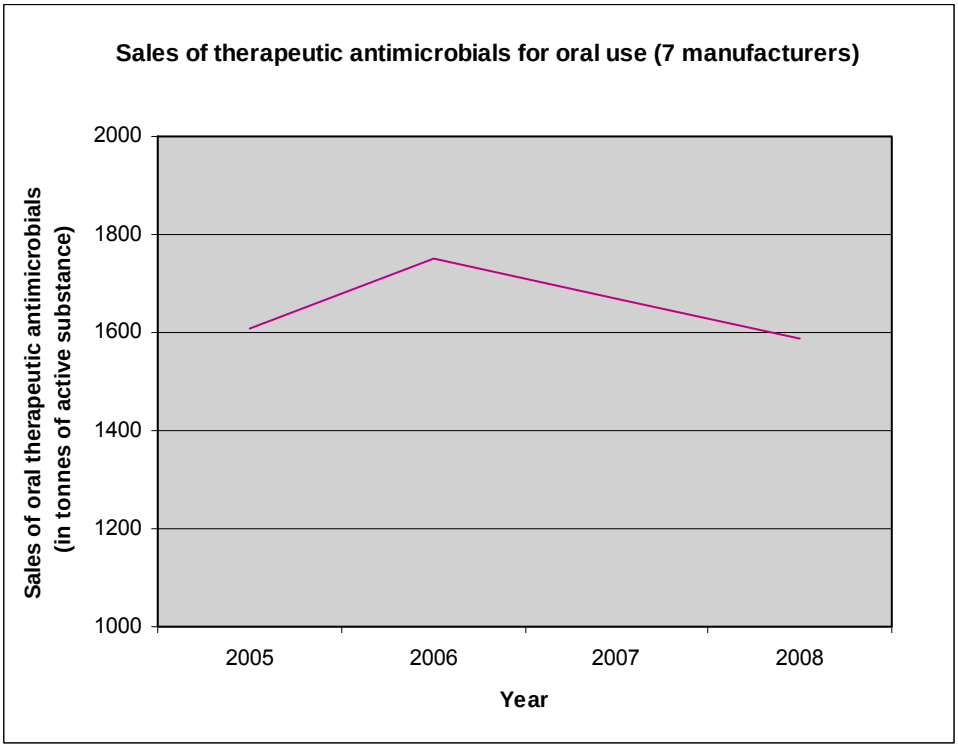
[39] Data include West Europe (32.5 % of the world market) and East Europe (4.6 % of the world market). According to the categorisation used in IFAH 2009, West Europe includes Andorra, Austria, Belgium, Denmark, Faeroe Islands, Finland, France, Germany, Gibraltar, Greece, Greenland, Holy See, Iceland, Ireland, Italy, Liechtenstein, Luxembourg, Malta, Monaco, Netherlands, Norway, Portugal, San Marino, Spain, Sweden, Switzerland and the United Kingdom; and East Europe includes Albania, Armenia, Republic of Azerbaijan, Belarus, Bosnia and Herzegovina, Bulgaria, Croatia, Czech Republic, Czechoslovakia, Estonia, Georgia, Hungary, Kazakhstan, Kyrgyzstan, Latvia, Lithuania, Macedonia, the former Yugoslav Republic of Macedonia, Republic of Moldova, Poland, Romania, Russian Federation, Serbia and Montenegro, Slovakia, Slovenia, Tajikistan, Turkmenistan, Ukraine, Uzbekistan and Yugoslavia SFR.

[40] IFAH-Europe 2009. IFAH-Europe (International Federation for Animal Health Europe) is the federation representing manufacturers of veterinary medicines, vaccines and other animal health products in Europe. It represents both corporate members and national animal health associations in Europe. According to IFAH-Europe, these associations comprise both local medium-size enterprises (SMEs) and international companies, and its membership covers 95% of the European market for veterinary products.

group of VMPs used in medicated feed. This category of VMPs includes antibiotics as well as other antimicrobial substances and is the group of veterinary medicines for which the most published data is available, because several Member States monitor their use. The further analysis therefore focuses on antimicrobials.

Figure 4 below depicts the EU sales data concerning therapeutic antimicrobials for oral use received from seven manufacturers[41] of veterinary medicines, showing a decline in sales of therapeutic antimicrobials for oral use between 2005 and 2008 when measured in tonnes of active ingredients, with the highest sales figures reported for 2006.

Figure 4: Trend in the sales of therapeutic antimicrobials for oral use (7 manufacturers)



Source: Civic Consulting survey of manufacturers of VMPs.
Note: Data concerns total of therapeutic antimicrobials for oral use sold as veterinary medicines in the EU by the responding manufacturers.

The seven manufacturers that provided relevant data accounted for a total of 1,670 tonnes of active substances of antimicrobials for oral use sold as veterinary medicines in the EU in 2007. This equals roughly five times the sales of antimicrobials for oral use for animals in the UK in the same period, or slightly more than the combined sales of such active ingredients in the UK and France. The data is therefore only partially representative for the EU market, and has to be interpretated with care: Firstly, several major producers of veterinary medicines that are member of IFAH-Europe declined to provide data. Secondly, no reliable data on generic producers is available, and according to IFAH-Europe oral antibiotics are mainly administered under generic forms.[42] Thirdly, potency differences between different antimicrobials have to be taken into account when evaluating market trends, and decreasing quantities of antimicrobials

[41] Of the eleven answers received, four did not provide relevant data.

[42] According to IFAH-Europe oral antibiotics administered under generic forms include tetracyclines, amoxicillin, TMP/sulfamides, enrofloxacin, tilmicosin, tiamulin for powder and premixes.

are in some cases compensated by higher potency of products. In the United Kingdom, for example, total consumption of antimicrobials in tonnes of active substance declined by 12 % between 2002 and 2007 whereas consumption declined by only 1 % in potency units.

A complementary source concerning sales of antimicrobials are reports on the use of antimicrobials that are published by Denmark, Finland, France, Germany,[43] Sweden, the Netherlands, and the United Kingdom (see Annex 5). According to these reports, sales of antimicrobials vary remarkably between EU Member States, from 1,349 tonnes of active ingredients in France to less than 20 tonnes in Sweden and Finland.

Table 1: Sales of therapeutic antimicrobials in selected Member States for food and non-food producing animals (in tonnes of active ingredient)

	2002	2003	2004	2005	2006	2007
Denmark	96	103	113	113	115	121
Finland	13.2	13.1	13.4	13.6	14.1	n.a.
France	1,337	1,309	1,278	1,325	1,263	1,349
Netherlands	406	394	453	508	542	590
Sweden	17.3	16.0	16.1	16.4	17.2	17.1
United Kingdom	440	435	454	446	405	387

Sources: National reports on the use of antimicrobials. For detailed sources, see Table 28 in Annex 5.
Notes: Data refer to sales of therapeutic antimicrobials only and do not include antimicrobials used as feed additives for the years 2002-2005, i.e the years preceding the ban on the use of antibiotics as growth promoters in feed, which entered into effect on January 1, 2006 (since then, antibiotics are only allowed to be added to animal feed for veterinary purposes).
For Denmark and Finland, data refer to food producing animals only.

In the period 2002 to 2007 sales of therapeutic antimicrobials remained stable or increased in Denmark, Finland, France, the Netherlands and Sweden. In the only country where during this period a significant decrease of sales was noted in the available reports, the United Kingdom, this appears to be mainly due to decreasing livestock production but may also be influenced by management measures such as switch from 21 days to 28 days of weaning for piglets[44] and vaccination strategies such as PCV2 vaccination. Sales of microbials therefore appear to be strongly influenced by the relevance and trends of animal production in different countries. This is illustrated by the reduced sales of antimicrobials in the UK, but also by the increased sales of antimicrobials in Member States that have increased or intensified livestock production, such as the Netherlands.[45]

[43] The report provides figures on total sales of antimicrobials for veterinary use for 2003 and 2005 only (724. 2 and 784.4 tonnes respectively) (see GERMAP 2008). Other sources estimate that the use of antibiotics for application to farm animals in Germany vary between 669 tonnes (in 2003) and more than 2,100 tonnes (April 2000 to July 2001) (see SRU 2007).

[44] According to Directive 2008/120/EC of 18 December 2008 laying down minimum standards for the protection of pigs (Annex 1, Chapter II C), "No piglets shall be weaned from the sow at less than 28 days of age unless the welfare or health of the dam or the piglet would otherwise be adversely affected."

[45] See Table 1 and Table 17 in Annex 3.

3. Production of medicated feed in the European Union

3.1. Annual production

The significance of medicated feed in terms of production varies drastically amongst EU Member States. In 2008, production figures were highest in Spain (2 to 3 million tonnes according to the national feed manufacturers' association), Italy (1.3 million tonnes) and France (0.8 to 1 million tonnes). Belgium (300,000 tonnes) and the Czech Republic (99,000 tonnes) are also quite important producers whereas Germany (12,000 tonnes) and Denmark (12,000 tonnes) are of minor relevance. In some countries such as Slovenia medicated feed is hardly used by farmers. All in all, there is considerable uncertainty with regard to production of medicated feed since official statistics are rare. Some of the numbers presented here are based on estimates of the production numbers of a few large feed manufacturers.

Table 2: Production of medicated feed in the EU (in 000' tonnes) [(a)]

	2004	2005	2006	2007	2008
Belgium	n.a.	n.a.	n.a.	n.a.	300
Czech Republic	92	111	154	149	99
Denmark [(b)]	n.a.	0.01	3	9	12
France	800 - 1,000	800 - 1,000	800 - 1,000	800 - 1,000	800 - 1,000
Germany	225	150	80	20	12
Italy	n.a.	n.a.	1,085	1,260	1,330
Spain	2,600	2,500	2,200	2,000	2,000 – 3,000
United Kingdom	n.a.	n.a.	n.a.	n.a.	500

Source: Civic Consulting survey of national feed manufacturers' associations, associations of cooperatives and farmers' association.
Notes:
(a) Data for the Czech Republic, Spain and the United Kingdom include on-farm mixing.
(b) Estimates of sales of medicated feed containing zinc oxides only (see country case study Denmark).

The relevance of medicated feed is highest in Italy where its market share – measured by dividing the production of medicated feed by the production of compound feed – is above 9 %. In other major producing countries market shares are between 3 % and 7 % (see Table 3 below). The market relevance of medicated feed is very low in Denmark (0.2 %) and Germany (0.1 %).

Production figures in several countries for which data is available have not changed significantly since 2004. In some cases increases of production can be observed (e.g. Italy), whereas other countries show slightly decreasing numbers (Spain, Czech Republic). In the Czech Republic decreasing production numbers of medicated feed may be due to decreasing livestock production.

Denmark and Germany are special cases and reflect the high relevance of the regulatory framework for the market success of medicated feed:

- In 2005 Denmark authorised zinc oxide as veterinary medicine; since then production figures of medicated feed show a steady increase. Feed containing zinc oxide is by far the most important medicated feed in Denmark.[46]
- In Germany new feed regulation after the outbreak of the BSE crisis – medicated feed is now treated as a VMP and regulated by the pharmaceuticals law (*§ 13 Arzneimittelgesetz*) – has contributed to a sharp decline in production. According to the Deutscher Verband Tiernahrung (DVT), most of the compound feed manufacturers in Germany are still not able to meet the obligations for getting an authorisation for producing medicated feed. Production volume went down drastically from 225,000 tonnes in 2004 to only 12,000 tonnes in 2008 (see table above). Another possible reason for this development is the abolishment of the assignment of production (*Herstellungsauftrag*) for veterinarians in 2006.

Other factors that may affect the relevance of medicated feed in a given country besides trends in livestock production and legislative requirements include the degree to which alternative ways of orally administering VMPs such as 'top dressing' are allowed and accepted by farmers, the outbreak of new animal diseases (such as PMWS, circovirus and PRRS in swine), the implementation of vaccination strategies[47] and the introduction of management procedures for improving animal health (for instance, switch from 21 days to 28 days weaning of piglets).[48]

In countries for which figures on medicated feed production are not available, an assessment of of the evolution of the use of medicated feed by national feed manufacturers' associations gives some indication on production trends (see table below and survey results presented in Annex 10). The feed manufacturers' associations from Belgium and Portugal report a fairly significant increase of the use of medicated feed over the last five years while the British and the Dutch associations report a decreasing use of medicated feed in their countries. The Polish association of feed manufacturers reports a very significant increase in the use of medicated feed over the last 5 years (see table below).

Table 3 below summarizes the production and market shares of medicated feed in 2008 in selected Member States, describes the most common routes of oral administration and highlights the evolution of the use of medicated feed over the last five years.

[46] The volume of medicated feed produced in 2008 with medicated pre-mixes containing zinc oxides represented 95% of the total use of medicated pre-mixes in 2008 (see case study Denmark in Annex 11).

[47] For instance, PCV2 vaccine was reported to have contributed to the decrease in the use of medicated feed in the United Kingdom (see case study United Kingdom in Annex 11).

[48] See footnote 44.

Table 3: Medicated feed in the EU (2008)

	Production of medicated feed ('000 tonnes)	Production of medicated feed as percentage of production of compound feed [a]	Most common route of oral administration of VMPs [b]	Evolution of the use of medicated feed over the last 5 years [b]
Belgium	300	4.8 %	Top dressing/ incorporation of ready-to-use VMPs in the feed and mixing into water	Increased fairly significantly
Czech Republic	99	3.4 %	Medicated feed and mixing into water	Decreased fairly significantly
Denmark	12 [c]	0.2 % [c]	Top dressing/ incorporation of ready-to-use VMPs in the feed and mixing into water	Increased very significantly [d]
France	800 – 1,000	3.5 % – 4.4 %	Medicated feed	Remained the same
Germany	12	0.1 %	Top dressing/ incorporation of ready-to-use VMPs in the feed and mixing into water	Decreased very significantly
Italy	1,330	9.1%	Medicated feed and mixing into water	n.a. [e]
Poland	n.a.	n.a.	Medicated feed	Increased very significantly
Portugal	n.a.	n.a.	Medicated feed	Increased fairly significantly
Spain	2,000 [f]	6.6 % [f]	Medicated feed	Remained the same
UK	500	4.0 %	Medicated feed	Decreased fairly significantly

Source: Civic Consulting surveys of national feed manufacturers' associations, associations of cooperatives and farmers' associations and case studies.

Notes:

(a) Ratios based on figures of compound feed production and medicated feed production as provided by national feed manufacturers' associations. Compound feed production figures include medicated feed. Data for the Czech Republic, Spain and the United Kingdom include on-farm mixing.

(b) Assessments of stakeholders, as provided through the survey and during the case studies.

(c) Estimates of sales of medicated feed containing zinc oxides only.

(d) The increase in the use of medicated feed in Denmark is due to the authorisation of zinc oxides as veterinary medicine in 2005.

(e) Inconsistent data were obtained from stakeholders. An Italian farmers' association reported that the use of medicated feed remained the same over the last five years. However, industrial production figures of medicated feed in Italy (estimated on basis of a sample representing 35 % of total industrial production) show an increase in production during the period 2006 – 2008 (see Table 2). According to the Italian feed manufacturers association (ASSALZOO), while the industrial production of medicated feed increased during the period 2006 – 2008, the total production of medicated feed (including on-farm mixing) decreased fairly signifcantly over the same period. The reduction of on-farm production of medicated feed in favour of industrial production may be explained by the good payment condition (180 days) granted to farmers by feed producers, according to the association.

(f) 2007 data.

The data on production of medicated feed and productions trends presented in this section lead to the following conclusion:

1. **Size and recent evolution of the medicated feed market vary drastically amongst Member States.** In 2008 production figures were highest in Spain (2 to 3 million tonnes according to the national feed manufacturers' association), Italy (1.3 million tonnes) and France (0.8 to 1 million tonnes). The United Kingdom (500,000 tonnes), Belgium (300,000 tonnes) and the Czech Republic (99,000 tonnes) are also quite important producers whereas Germany (12,000 tonnes) and Denmark (12,000 tonnes) are of minor relevance. Production trends vary by country, with three Member States reporting a decrease in use of medicated feed over the last 5 years, four reporting an increase in use and two reporting no change. All in all, there is considerable uncertainty with regard to production of medicated feed since official statistics are rare.

3.2. Rules of good manufacturing practice

Art. 4 of Directive 90/167/EEC of 26 March 1990 laying down the conditions governing the preparation, placing on the market and use of medicated feedingstuffs in the Community stipulates that "…the manufacturing process [of medicated feedingstuffs] must conform to the rules of good manufacturing practice". Most of the 26 Member States (and Norway) for which data was available have rules of good manufacturing in place. Only five Member States do not have rules of good manufacturing practice established, according to the competent authorities. Where rules of good manufacturing practice exist, they are often mandatory (see table below). In major markets where production of medicated feed is significant, rules on good manufacturing practice generally exist and are reported to be mandatory. However, in Spain, the largest EU market for medicated feed, officially published rules on good manufacturing practices did not exist until very recently.

Table 4: Rules of good manufacturing practice

	Rules of good manufacturing practice	Details
AT	✓	Rules in force include the *Fütterungsarzneimittelbetriebsordnung 2006, BGBl II Nr. 394/2006* and others (see Annex 7) [(a)]
BE	✓	The concrete application of the rules is mandatory by law. [(b)]
BG	✓	Medicated feed manufacturers are required to apply the GMP and HACCP of the Bulgarian feed manufacturers association. [(a)]
CY	✓	The concrete application of the rules is not mandatory by law. [(a)]
CZ	✓	The concrete application of the rules is mandatory by law. [(a)]
DE	✓	The concrete application of the rules is mandatory by law. [(a)]
DK	✓	In Denmark the manufacturing process must conform to the rules of good manufacturing practice of the EU GMP on the rules governing medicinal products in EU; however, some exceptions from these rules are allowed. [(a)]
EE		No rules of good manufacturing practice exist in Estonia. [(a)]
ES	✓	A new Royal Decree amending Royal Decree 109/1995 which introduces hygiene rules in compliance with Council Regulation 183/2005 is officially available since September 2009 and it includes an approach to rules of good manufacturing practice and specific requirements for Intermediate (feed) products among other considerations. [(a)]
FI	✓	The concrete application of the rules is not mandatory by law. [(a)]
FR	✓	The concrete application of the rules is mandatory by law. [(a)]

GR	✓	Commission Directive 91/412/EEC has been implemented in Greece by the 94/313314/GMD Greek Ministerial Decision. Circular 98/310584 refines particular matters. (a)
HU	✓	The concrete application of the rules is mandatory by law. (a)
IE	✓	The Regulations in Ireland transposing EU Directive 90/167 are entitled 'European Communities (Animal Remedies and Medicated Feedingstuffs) Regulations 1994'. Regulation 6(1)(e) of the aforementioned regulations gives effect to Article 4(1d) of the Directive. (a)
IT	✓	*Circolare 23 gennaio 1996 n.1* and the document "Production of medicated feed, measures for reducing cross- contaminations" provide indications about the way to put into practice the requirements of national and Community law. Most requirements of these guidelines are mandatory by law. (a)
LT		There are no approved rules for good manufacturing practise for medicated feed in Lithuania. (a)
LU		No rules of good manufacturing practice exist in Luxembourg. (a)
LV		There are no rules for good manufacturing practice in Latvia. (a)
NL	✓	Rules are established in the GMP Standards by the Product Board Animal Feed. The concrete application of the rules is not mandatory by law. (a)
NO	✓	The concrete application of the rules is mandatory by law. (a)
PL	✓	The principles of good practice for medicated feed (production and distribution) are included in national regulations. (a)
PO	✓	The concrete application of the rules is not mandatory by law. (a)
RO	✓	The concrete application of the rules is not mandatory by law. (a)
SE		No specific rules for good manufacturing practice are established in Sweden. (a)
SI	✓	The concrete application of the rules is not mandatory by law. (a)
SK	✓	The concrete application of the rules is mandatory by law. (a)
UK	✓	There are no nationally approved Industry Codes in the UK. However manufacturers are required to comply with the Veterinary Medicines Regulations. (a)

Note: More details are presented in Annex 7 of this report.
Sources:
(a) Competent authority.
(b) National feed manufacturers' association.

The character of the rules of good manufacturing practice applied varies between Member States. This is illustrated by the following examples:

- In Denmark the manufacturing process must conform to the rules of good manufacturing practice of the EU GMP on the rules governing medicinal products in EU, but some exceptions from these rules are allowed.[49]
- In France manufacturers of medicated feed must follow the requirements applicable for pharmaceuticals establishments. For the production of medicated feed, the presence of a veterinarian or a pharmacist in the feed mill is not required to be permanent, but must occur at least 2 times a month. Feed mills must conduct a series of mandatory tests.[50]
- In Germany, the pharmaceutical law applies for the production of medicated feed. Rules of good manufacturing practice for medicated feed relate to the EU GMP on the rules governing medicinal products in the EU. An expert group responsible for surveillance and control in the federal states has produced a leaflet on the application of these guidelines.[51] This document requires for instance the use of the end-of-line mixing technology to be authorised to produce medicated feed.

[49] Rules governing the production of medicated feed by feed mills are described in the executive orders number 1228, 1251 and 1254 implementing Directive 90/167/EEC.

[50] Rules governing the production of medicated feed by feed mills are described in the *Décision du 12 février 2007 fixant les bonnes pratiques de fabrication et de distribution en gros des aliments médicamenteux (BPFDAM)*. The application of these rules is mandatory by law.

[51] *Merkblatt für die Antragstellung auf Erteilung einer Erlaubnis zur Herstellung von Fütterungsarzneimitteln aus Arzneimittel-Vormischungen nach § 13 Abs. 1 des Arzneimittelgesetzes.*

- In the United Kingdom manufacturers of medicated feed are required (in accordance with Articles 6 and 7 of EC Regulation 183/2005) to document and implement a HACCP plan, which identifies the risk of cross-contamination of non-target feed with medicinal pre-mixes. To this end, manufacturers have to define a cross-contamination matrix which, when followed, ensures that cross-contamination is minimised or avoided. The cross-contamination matrix specifies the order of mixing that can take place (scheduling) and, where necessary, where and how flushing of the production line must take place.[52]

Further details on rules on good manufacturing practice put into place in Member States are provided in Annexes 7 and 11.

This review of rules of good manufacturing practice in Member States leads to the following conclusion:

2. **In the large majority of Member States rules on good manufacturing practice with regard to production of medicated feed are in place.** Only five Member States do not have rules of good manufacturing practice established. In major markets where production of medicated feed is significant, rules on good manufacturing practice generally exist and are reported to be mandatory.

3.3. Medicated pre-mixes

3.3.1. VMPs used for the production of medicated feed

Antimicrobials are by far the most important VMPs authorised as medicated pre-mixes. In many countries around three quarters of all authorised pre-mixes are antimicrobials: For instance, this is the case for 75 % of authorised pre-mixes in Bulgaria, 71 % of authorised pre-mixes in Finland, 85 % of authorised pre-mixes in Germany, and 74 % of authorised pre-mixes in the United Kingdom (for more details, see Annex 7).

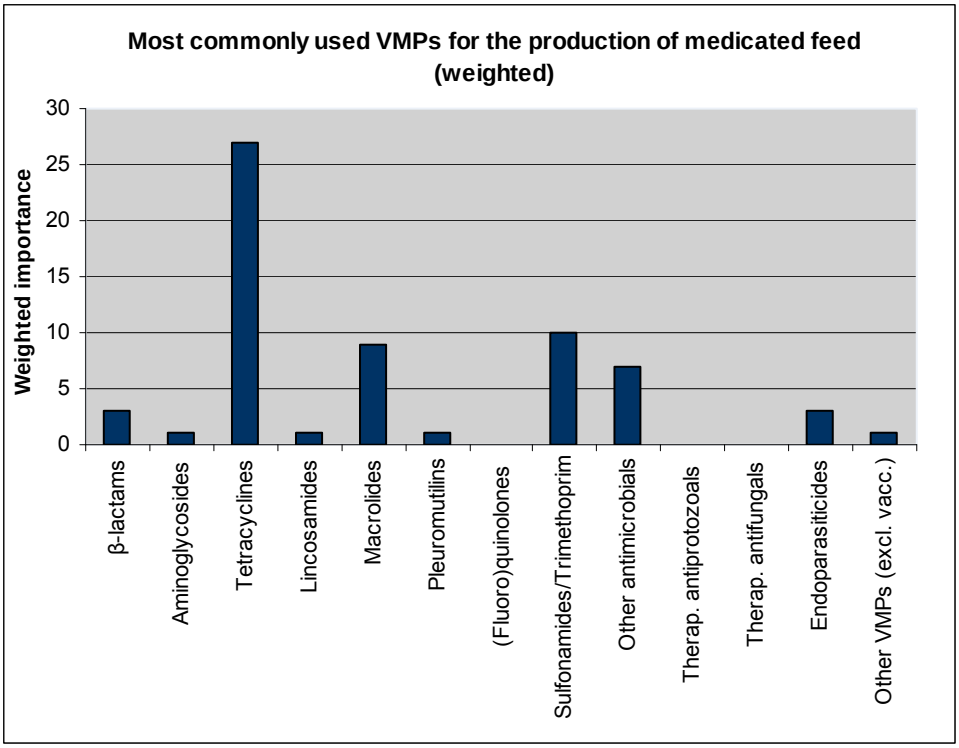
The key role of antimicrobials for the production of medicated feed is confirmed by national feed manufacturers' associations. According to the assessment of feed manufacturers' associations, tetracyclines are by far the most commonly used VMP for the production of medicated feed (see also Figure 5 below). The most frequently mentioned VMPs are all antimicrobials and are ranked as follows:

[52] Where cross-contamination is identified as a Critical Control Point (CCP), tests of drug carry-over must be conducted to verify that the measures put in place to control that risk, are effective. Manufacturers must also conduct further quality control tests, including a mixer dispersion (homogeneity) test. Manufacturers must also test a number of samples each year to control the level of medicinal active ingredient in medicated feeds. Manufacturers of medicated feed are required to comply with the Veterinary Medicines Regulations which implements 90/167 and 183/2005 and guidance is provided in Veterinary Medicines Guidance Notes 21 and 22 on the Veterinary Medicines Directorate website. Complying with the Regulations is mandatory.

1. Tetracyclines
2. Sulfonamides/Trimethoprim
3. Macrolides
4. Other antimicrobials (incl. β-lactams, Aminoglycosides, Pleuromutilins, Lincosamides)

Veterinary medicines other than antimicrobials were hardly listed among the three most commonly used VMPs for the production of medicated feed by manufacturers, with the exception of endoparasiticides (including anthelmintics). This group of VMPs was assessed by the Belgian feed manufacturers' association as being the most commonly used VMP for the production of medicated feed in this country. However, no other association mentioned endoparasiticides among the three most commonly used VMPs for the production of medicated feed.

Figure 5: Most commonly used VMPs for the production of medicated feed



Source: Civic Consulting survey of national feed manufacturers' associations, associations of cooperatives and farmers' associations, Q 10, N= 12.
Note: Weights refer to the order of importance of VMPs, as assessed by stakeholders, i.e. VMPs mentioned as most commonly used are given a weight of 3, VMPs mentioned as second most commonly used are given a weight of 2, and VMPs mentioned as third most commonly used are given a weight of 1.

This leads to the following conclusion:

3. **Antimicrobials are by far the most important VMPs currently used for the production of medicated feed.** The most commonly used antimicrobials are tetracyclines, reported from nine feed manufacturers' associations to be the most commonly used VMP for the production of medicated feed in their country. Other antimicrobials that are listed among the three most commonly used VMPs include sulfonamides/trimethoprim, macrolides and other antimicrobials (incl. β-lactams, aminoglycosides, pleuromutilins, lincosamides). This strong emphasis on antimicrobials is reflected in the number of authorised medicated pre-mixes: In many countries around three quarters of all authorised pre-mixes are antimicrobials.

3.3.2. Authorisation of medicated premixes

Medicated pre-mixes are Veterinary Medicinal Products and authorised as such. Therefore several authorisation procedures are available: [53]

- The *centralised procedure* allows applicants to obtain a marketing authorisation that is valid throughout the EU. This centralised (or "Community") authorisation procedure, is mandatory for certain types of veterinary medicines and optional for others. When a company wishes to place on the market a medicinal product that is eligible for the centralised procedure, it sends an application directly to the European Medicines Agency, to be assessed by the Committee for Medicinal Products for Veterinary Use (CVMP). The procedure results in a Commission decision, which is binding on all EU Member States, to authorise the product. Centrally-authorised products may be marketed in all Member States.
- The *mutual recognition procedure* is applicable to the majority of conventional medicinal products and based on the principle of recognition of an already existing national marketing authorisation by one or more Member States. As soon as one Member State decides to evaluate the medicinal product (at which point it becomes the "Reference Member State"), it notifies this decision to other Member States (which then become the "Concerned Member States"), to whom applications have also been submitted. Concerned Member States will then suspend their own evaluations, and await the Reference Member State's decision on the product. As soon as the assessment is completed, national marketing authorisations are granted in the reference and in the concerned Member States.
- The *decentralised procedure* is also applicable to the majority of conventional medicinal products. As the mutual recognition procedure it is based on recognition by national authorities of a first assessment performed by one Member State. The difference lies in that it applies to medicinal products which have not received a marketing authorisation at the time of application.
- The *national procedure* is available for medicinal products to be marketed in one Member State only.
- *Referral procedures* may be initiated on the basis of the following articles of Directive 2001/82/EC (as amended):[54]

[53] See European Medicines Agency (http://www.emea.europa.eu/index/indexv1.htm) and DG Enterprise and Industry (http://ec.europa.eu/enterprise/pharmaceuticals/procedure/cproc_en.htm).

- Article 33 of Directive 2001/82/EC ("Mutual Recognition and Decentralised referral"): initiated because of disagreement between Member States within the framework of the mutual-recognition or decentralised procedure;
- Article 34 of Directive 2001/82/EC ("Divergent decision referral"): initiated in order to obtain harmonisation within the Community of the conditions of authorisation for products already authorised by Member States;
- Article 35 of Directive 2001/82/EC ("Community interest referral"): initiated in cases involving the interests of the Community or concerns relating to the protection of human or animal health or the environment;
- Articles 39 and 40 of Directive 2001/82/EC ("Follow-up referrals");
- Article 78 of Directive 2001/82/EC ("Pharmacovigilance urgent measures"): initiated when, as a result of the evaluation of veterinary pharmacovigilance data, a Member State considers that a marketing authorisation should be suspended, withdrawn or varied to restrict the indications or availability, amend the posology, add a contraindication or add a new precautionary measure.

Whenever such a referral is initiated, a scientific evaluation of the matter is undertaken by the Committee for Medicinal Products for Veterinary Use (CVMP) of the EMEA. These referrals lead to an opinion, from which the Commission issues a single decision addressed to all Member States.

A number of factors are taken into account during the marketing authorisation procedure including quality, safety, stability, efficacy and consequences for the environment. A Maximum Residue Limit (MRL) must also be established for medicines for food producing species.

Medicated pre-mixes are usually based on old active substances and therefore have been mostly authorised through the national procedure, although this procedure is now used rarely. Only two pre-mixes have been authorised via the centralised procedure so far.[55] The table below gives an overview over the number of authorised medicated pre-mixes in the Member States. [56]

[54]See European Medicines Agency (http://www.ema.europa.eu/htms/vet/referral/background.htm). See also http://ec.europa.eu/enterprise/sectors/pharmaceuticals/files/eudralex/vol-6/a/vol6a_chap3_rev09-2007_en.pdf.

[55] Interview European Medicines Agency. The two pre-mixes authorised via the centralised procedure are Aivlosin and Econor.

[56] In case of dispute regarding intra-Community trade in medicated feeds, in particular as concerns recognition of the similar nature of the pre-mix, the Member States concerned or the Commission may submit the dispute to assessment by an expert (see Article 10 (2) of Directive 90/167/EEC).

Table 5: Number of authorised medicated pre-mixes in the EU

	2004	2005	2006	2007	2008
Austria	41	43	44	48	57
Belgium	n.a.	23	24	27	34
Bulgaria	1 *(1)*	3 *(2)*	6 *(3)*	11 *(5)*	22 *(12)*
Cyprus	24	24	27	31	38
Czech Republic	53	55	60	61	66
Denmark	12	13 *(1)*	16 *(3)*	16	15 *(1)*
Estonia	23	22	20	21	17
Finland	10	10	11	12	12
France	*(1)*	*(15)*	*(7)*	*(8)*	312 (a) *(3)*
Germany	60	55	61	65	64
Greece	34	34	30	39	36
Hungary	n.a.	n.a.	n.a.	n.a.	n.a.
Ireland	*(5)*	*(4)*	*(6)*	*(7)*	*(11)*
Italy	87	92	96	100	103
Latvia	*(2)*	*(4)*	*(5)*	*(2)*	*(2)*
Lithuania	*(2)*	*(1)*	*(0)*	*(3)*	21 (b) *(0)*
Luxembourg	5	7	7	9	12
Netherlands	n.a.	n.a.	n.a.	n.a.	52 (c)
Norway	3	4	4	4	4
Poland	n.a.	n.a.	n.a.	n.a.	58 (d)
Portugal	*(3)*	*(2)*	*(2)*	*(5)*	157 (e) *(12)*
Romania	53 *(14)*	53 *(8)*	63 *(15)*	60 (f) *(6)*	59 (g) *(8)*
Slovakia	n.a.	n.a.	n.a.	n.a.	n.a.
Slovenia	23	21	20	14	11
Spain	*(11)*	*(7)*	*(10)*	*(13)*	*(8)*
Sweden (h)	18	17	14	14	14
United Kingdom	55 *(1)*	60 *(7)*	50 *(0)*	53 *(3)*	53 *(4)*

Source: Competent authorities.

Note: **New authorisations** of medicated pre-mixes per year are indicated in brackets.

(a) Data refers to the total number of authorised medicated pre-mixes as of August 2009. The total number of medicated pre-mixes authorised (312) includes 19 medicated pre-mixes for which authorisations are currently suspended.
(b) Data refers to the number of authorised medicated pre-mixes as of August 2009.
(c) Data refers to the number of authorised medicated pre-mixes as of August 2009. According to the competent authority, due to the authorisation system used in the Netherlands, it is not possible to reproduce lists of VMP of precedent years.
(d) The competent authority provided a list of 58 authorised pre-mixes.
(e) Data refers to the number of authorised medicated pre-mixes as of August 2009.
(f) Figure includes 6 medicated pre-mixes prohibited for food producing animals.
(g) Figure includes 3 medicated pre-mixes prohibited for food producing animals.
(h) Figures relate to the number of medicated pre-mixes reported to be in use to the Swedish Board of Agriculture.

In 2008 leading countries with regard to the number of authorised medicated pre-mixes were France (312 pre-mixes, including 19 for which authorisations are currently suspended), Portugal (157), Italy (103), the Czech Republic (66), Germany (64), Austria (57), and the United Kingdom (53). A closer look at the data reveals that the development is not uniform throughout

the EU. In some, mainly new Member States a quite rapid increase of the total number of authorised medicated pre-mixes can be observed, starting, however, from a low level. For example, between 2004 and 2008, the total number of authorised medicated pre-mixes in Bulgaria rose from 1 to 22, in Cyprus from 24 to 38. A rapid increase was also noted in Luxembourg, where the number of authorised medicated pre-mixes available rose from 5 to 12 in the same period. But there are also countries in which the number of authorised medicated pre-mixes has grown only slowly (for instance, the Czech Republic), has hardly changed (for instance, Greece and Finland) or has declined (for instance, Slovenia and Sweden).

The number of medicated pre-mixes newly authorised per year is small in many countries. In France, few new authorisations have been granted in recent years: 1 (2004), 15 (2005), 7 (2006), 8 (2007) and 3 (2008). The situation is similar in the United Kingdom where the number of newly authorised medicated premixes varies between 1 and 7 per year. Between 2004 and 2008, 15 medicated premixes were newly authorised whereas 17 authorisations expired in the United Kingdom.[57] This may reflect the fact that treatments via medicated feed are very standard and new medicated pre-mixes are usually not very innovative, new authorisations often concern generic products containing old active substances.[58] The duration of the authorisation process and the costs of placing a new medicated pre-mix on the market[59] might also discourage manufacturers to develop new medicated pre-mixes.

This leads to the following conclusion:

4. **The number of authorised medicated pre-mixes varies significantly across countries.** In 2008 leading countries with regard to the number of authorised medicated pre-mixes were France (312 pre-mixes, including 19 for which authorisations are currently suspended), Portugal (157), Italy (103), the Czech Republic (66), Germany (64), Austria (57), and the United Kingdom (53). Innovation in the market for medicated pre-mixes seems to be limited and treatments via medicated feed appear to be based on pre-mixes containing rather old active substances. This is reflected in the small number of medicated pre-mixes newly authorised per year in many countries.

3.4. Additional costs of producing medicated feed for feed manufacturers compared to producing compound feed

To better understand trends in the market for medicated feed, Civic Consulting has analysed the additional costs of producing medicated feed for feed manufacturers compared to producing compound feed. The results are presented in Annex 11, and are summarised in the following paragraphs.

[57] See case study United Kingdom in Annex 11.

[58] Interview with the French competent authority.

[59] According to the French competent authority, the process of placing a medicated pre-mix on the market can take up to two years (including time spent for the preparation of the application and carrying out studies, the filing of the application and the time needed for processing the application). Only the application for a national marketing authorisation can amount to 10,000 Euro and the total costs of placing a new medicated pre-mix on the market can amount to 1,000,000 Euro for only one species (including cost of studies for preparation of the authorisation dossier). The costs for placing a generic medicated pre-mix on the market were estimated by the same source to be 200,000 – 300,000 Euro.

The production of medicated feed increases product variety for feed mills, and this has implications for their costs. Product variety is a typical cost driver in manufacturing industries. The resulting costs are often labelled complexity costs.[60] Not taking into account opportunity costs, two categories of complexity costs can be distinguished. The first category consists of one-off set-up costs, for instance costs for product development, marketing authorisation procedures, additional machinery and buildings (storage buildings etc.), or tests of new products. The second category includes ongoing variable costs stemming from additional quality assurance, higher logistic and storage costs due to more complex product handling procedures, or additional documentation or training of employees.[61] This distinction has been used successfully for cost analyses in the agribusiness sector, and has also been applied for this study.[62]

Typical cost factors that contribute to the additional costs of manufacturing medicated feed compared to manufacturing compound feed include:

- Costs of measures related to management of risk of drug carry-over (cleaning, flush batches, tests of cross contaminations and carry-over, additional equipment such as conveyors and elevators to reduce the risk of carry-over);
- Costs of mandatory quality control of medicated feed (for instance, checks of the concentration, homogeneity tests and other analytical controls);
- Costs of getting authorisation to manufacture medicated feed (administration fees; audits);
- Costs of administration of prescriptions;
- Higher transport costs because of small quantities and a limited number of authorised feed mills.[63]

In four case studies – Denmark, France, Germany, and the United Kingdom – we have scrutinised these costs in detail with collaboration of feed mills. Additional costs of producing medicated feed (compared to the costs of producing compound feed) were collected according to the following cost categories:

- Additional consumption of fixed capital;
- Additional labour costs;
- Additional cleaning costs;
- Cost of tests (including homogeneity tests, tests of drug carry-over, analytical control of concentration of active substance in medicated feed); and
- Additional administrative costs (annual administrative fee).

Additional costs for transporting of medicated feed to farms were not included in the analysis, as these costs are not always borne by the feed mill. Also, the cost of the active substance is not considered, as this varies depending on the VMPs used.

[60] Schuh 2005.

[61] Homburg and Daum 1997.

[62] See e.g. Gawron and Theuvsen (2008), and Annex 11 for an overview of the methodology of the case studies.

[63] In Denmark, for instance, only ten feed mills are authorised to manufacture medicated feed from all authorised medicated pre-mixes; another five feed mills are only allowed to use zinc oxides (See case study Denmark in Annex 11).

The results of the case studies indicate a wide spectrum of additional production costs of medicated feed, reaching from 0.87 Euros per tonne up to 70.33 Euros per tonne (see following table).

Table 6: Additional costs of manufacturing medicated feed compared with production costs of compound feed (in Euro/tonne)

Cost factor	Denmark	France	Germany	United Kingdom
Additional consumption of fixed capital (additional equipments and buildings) (in Euro/tonne)	2.32	0.02	50.5 [(a)]	0.36
Additional labour costs [(b)] (in Euro/tonne)	6.33	0.59	12.5	3.17
Additional cleaning costs (costs of flushing/rinsing) (in Euro/tonne)	1.75	0.08	Not applicable [(c)]	Not applicable [(d)]
Cost of tests (homogeneity test, test of drug carry-over, analytical control of concentration of active substance in medicated feed) (in Euro/tonne)	1.21	0.12	4.80	0.06
Administrative costs (annual administrative fee) (in Euro/tonne)	0.28	0.06	2.50	0.02
Total additional cost of manufacturing medicated feed (not including cost of the active substances) (in Euro/tonne)	***11.89***	***0.87***	***70.33***	***3.62***

Source: Civic Consulting (see Annex 11)
Notes:

(a) In the case of Germany, the additional consumption of fixed capital includes 50 Euro of depreciation cost per tonne of medicated feed for the end-of-line mixer and 0.5 Euro of depreciation cost per tonne of medicated feed for storing of medicated pre-mixes.
(b) Additional labour costs for medicated feed production include the labour costs for a veterinarian/pharmacist, where applicable, and the share of labour costs of staff members performing tasks related to the production of medicated feed (e.g. production manager, quality control officer and feed mill workers).
(c) Because of the use of an end-of-line mixer, there is no need to clean the production line following medicated feed production.
(d) In the feed mill selected for the case study, most flushed materials are used to produce medicated feeds.

Differences in additional costs per tonne are largely related to the production volume. This is obvious in Germany, where manufacturers currently only have a very small output of medicated feed (12,000 tonnes per year) compared to their actual production capacities. These producers are not able to realise economies of scale and, at the same time, suffer from overcapacities. Costs of overcapacities are reflected by calculating 50 Euros of depreciation per tonne of medicated feed in the feed mill scrutinised in Germany, which are related to the requirement to use end-of-line mixing technology (see case study Germany in Annex 11) and a low volume of production. An output similar to the quantities produced in France would bring depreciation down to less than 1 Euro per tonne. Therefore, the cost figures from France and UK can be assumed to be more realistic from the perspective of mass production of medicated feed than the cost figures from Germany. With the notable exception of Germany, the most significant cost factor for producing medicated feed are additional labour costs, which are caused by the administrative requirements for handling medicated feed, as well as the production and cleaning process.

According to FEFAC, the European Feed Manufacturers' Association, the gross margin for medicated feed is between 2 % and 11 %, compared to between 2 % and 6 % for compound feed. Therefore, sales prices of medicated feed are mainly determined by production costs. Although detailed data on the costs of production of compound feed was not available, average sales prices of compound feed and the quoted gross margin rates allow estimating the additional costs of producing medicated feed as percentage of the production costs of compound feed (see table below). Depending on whether the cost figures from France or UK are taken into account, additional costs for the production of medicated feed (not considering the costs of active substances) vary between 0.4 % (France) and 2 % (United Kingdom).

Table 7: Additional costs of manufacturing medicated feed compared with production costs of compound feed (in %)

	Denmark	France	Germany	United Kingdom
Sale price of a tonne of compound feed (in Euro, excluding VAT) [(a)]	196	248	290	189
Production cost of a tonne of compound feed (in Euro, excluding VAT) [(b)]	188	238	278	181
Additional cost of manufacturing medicated feed (in Euro, excluding VAT)	11.89	0.87	70.33	3.62
Total cost of manufacturing medicated feed (in Euro, excluding VAT)	199.89	238.87	348.33	184.62
Additional production costs of medicated feed (in %) compared to compound feed	***6.3%***	***0.4 %***	***25.3%***	***2.0 %***

Source: Civic Consulting. For more detailed analysis of costs of manufacturing medicated feed, please refer to Annex 11.
Note:
(a) The table presents sales prices of compound feed for pigs of similar quality and composition as the one used for the production of medicated feed in the respective country/feed mills visited.
(b) An average gross margin rate of 4% is substracted from the sale price of a tonne of compound feed to obtain the production cost of a tonne of compound feed. Additional cost of manufacturing medicated feed does not include the cost of the active substance.

As is illustrated by the example of Germany, where differences in additional costs for manufacturing medicated feed are partly related to the requirement to use an end-of line mixer, the legislative framework can have influence on the competitiveness of feed manufacturers. Governments influence the regulatory framework of the production of medicated feed as well as its substitutes (for instance, on-farm mixing of medicated feed or prescriptions of oral VMPs by veterinarians). These aspects are most relevant if competing manufacturers are subject to different national legislative frameworks. The survey of national feed manufacturers' associations has revealed that four of the 12 responding associations perceive very significant and four associations fairly significant negative consequences of different national legislative frameworks in the field of medicated feed on the competiteveness of feed manufacturers. Competitive effects may be most relevant in border regions where manufacturers of medicated feed from different countries compete against each other (as it is the case, for instance, in the

Dutch-German border region).[64] However, due to the regional character of the feed industry, these effects are likely to be limited.

The analysis presented in this section leads to the following conclusion:

5. **The additional costs of mixing medicated feed are comparatively low if national demand allows feed manufacturers to realise economies of scale.** The case studies conducted in Denmark, France, Germany and the United Kingdom reveal that it is between 0.4 % (France) and 25 % (Germany) more costly to manufacture medicated feed than compound feed (not considering the costs of the active substances used). Additional production costs of medicated feed are more significant in countries where production levels are low and producers are not able to realise economies of scale, especially if in addition the technology used for the production of medicated feed requires significant investments (e.g. end-of-line mixer, as is the case in Germany). Differences in the national legislative frameworks can have influence on the competitiveness of feed manufacturers. However, due to the regional character of the feed industry, these effects are likely to be limited.

3.5. On-farm production of medicated feed

Medicated feed is usually produced by feed mills approved by the competent authority. However, under a derogation provided in Article 4(2) of Directive 90/167/EC, Member States may authorise farms to manufacture medicated feed from authorised medicated pre-mixes. On-farm production of medicated feed is therefore regulated under the medicated feed legislation, in contrast to other ways of using veterinary medicines on farms. Mixing ready-to-use oral VMPs into water, 'top dressing' of feed (i.e. sprinkling of ready-to-use VMPs on the feed) and the incorporation of ready-to-use VMPs into the feed by the livestock farmer are practices that are not regulated by Directive 90/167/EEC. Strict procedures to incorporate the medicine, for instance in terms of homogeneity, are not required in these cases, and related practices are only regulated under the veterinary medicines legislation (for medicated feed, both the veterinary medicines legislation and the medicated feed legislation apply). The following paragraphs focus exclusively on the production of medicated feed on farms from authorised pre-mixes. Practices related to ready-to-use VMPs will be discussed at a later stage (see section 4.3).

On-farm production of medicated feed is practiced in Austria, Cyprus, France, Greece, Hungary, Ireland, Italy, Latvia, Lithuania, Portugal, Slovenia, Spain, Sweden and the United Kingdom, and a total of 5,697 on-farm producers of medicated feed have been authorised, according to data of competent authorities.[65] Other countries have refrained from making use of the derogation in Article 4(2) of Directive 90/167/EC.

The case studies conducted in France and the UK illustrate rules applying for on-farm production of medicated feed in these countries.

- According to the Veterinary Medicines Directorate (VMD), there are currently 640 farms in the United Kingdom that are authorised to manufacture medicated feed. On-farm mixing is allowed provided the mixer is approved.[66] Mixers must comply with the

[64] Civic Consulting, information reported by a German feed mill interviewed during the case study.

[65] See Table 29 in Annex 7, providing data from all EU Member States except Malta.

[66] Either by the Animal Medicines Inspectorate (AMI) of the Veterinary Medicines Directorate or the Department of Agriculture and Rural Development in Northern Ireland (DARDNI).

conditions of Regulation 183/2005, in particular Annex II of that Regulation and operate in accordance with Schedule 5 of the Veterinary Medicines Regulations.[67] On-farm producers mixing medicated feeds for feeding solely to their own livestock are only permitted to incorporate medicines at a rate of at least 2 kg/tonne.[68]

- In France, currently 19 farms are authorised to produce medicated feed. These authorisations concern large pig farms (with more than 350 productive sows), which produce significant volumes of medicated feed (at least 2,000 to 3,000 tonnes per year), similar to what is produced by the smallest feed mills in France. Authorisations for on-farm production are delivered by the Veterinary Services Directorates of the "*départements*". Similar to the rules applicable for feed mills, rules for on-farm production include, for example, the control of the medicated feed production by a pharmacist or a veterinarian and the obligation to conduct homogeneity tests and tests of drug carry-over. Medicated feed can be produced for animals breeded on the farm only; sale of on-farm produced medicated feed to other farms is not allowed.[69]

More details concerning on-farm mixing are presented in Table 29 of Annex 7.

This leads to the following conclusion:

6. **On-farm production of medicated feed is practiced in 14 Member States under a derogation provided in Article 4(2) of Directive 90/167/EC.** In Austria, Cyprus, France, Greece, Hungary, Ireland, Italy, Latvia, Lithuania, Portugal, Slovenia, Spain, Sweden and the United Kingdom a total of 5,697 on-farm producers of medicated feed have been authorised, according to data of competent authorities**.** Rules for on-farm producers of medicated feed are similar to the rules for the production of medicated feed in feed mills, but additional requirements may apply.

4. Use of medicated feed in the European Union

4.1. Use of medicated feed for different production systems and animal species

The use of medicated feed is most common in intensive livestock production – that was the unanimous opinion of all national feed manufacturers' associations, associations of cooperatives and farmers' associations that answered to the survey and had an opinion on this issue. 16 of 23 responding organisations (70%) marked that the use of medicated feed is most common in their country in intensive production, none marked that this is the case in semi-intensive and extensive production, and the remaining 7 organisations marked "don't know" or did not provide an answer. In total, responses from 14 EU countries were received, accounting for 86% of the EU livestock production. The fact that medicated feed is most common in intensive livestock production does, however, not mean that it is irrelevant in other production systems, as

[67] See case study UK (Annex 11).

[68] If medicines' inclusion rates are less than 2 kg/tonne, the farmer must purchase the product as an intermediate product (premixture), for inclusion at a rate of at least 2 kg/tonne, according to VMD.

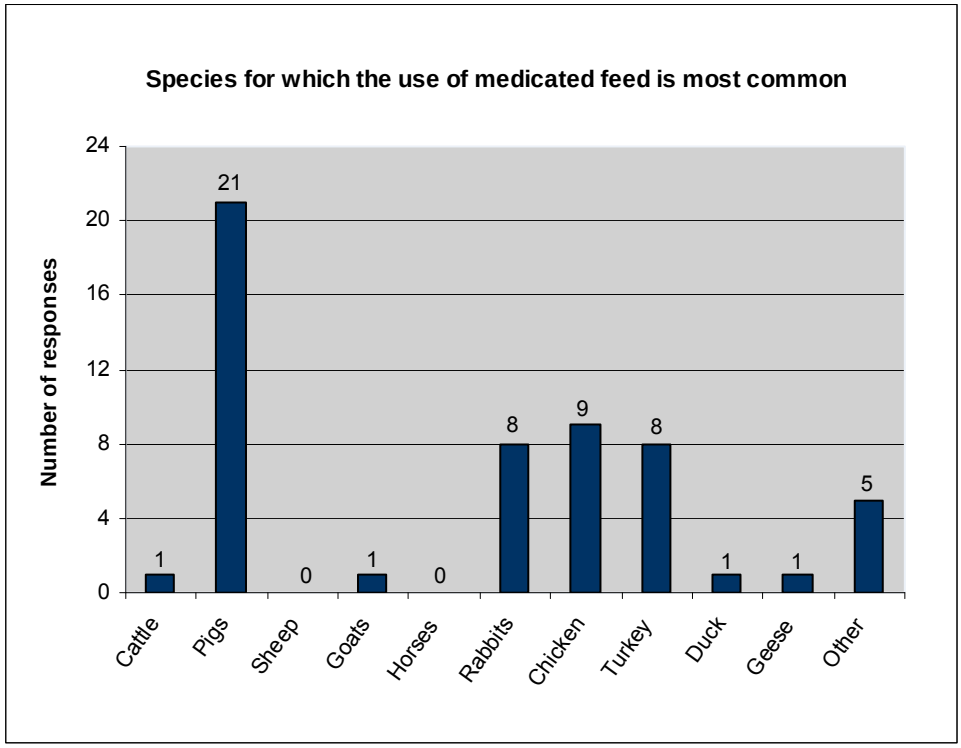
[69] Conditions for on-farm mixing are described in the *Arrêté du 9 juin 2004 relatif aux bonnes pratiques de préparaton extemporanée des médicaments vétérinaires*. See case study France (Annex 11).

was emphasized by several stakeholder organisations. For example, the Portuguese feed manufacturers' associations *(Associação Portuguesa dos Industriais de Alimentos Compostos para Animais – IACA*) considered medicated feed to be practically the only way to treat animals in extensive production systems such as iberic pigs.

Some respondents also commented that the use of medicated feed is not so much dependent on which production system prevails but on animal species, age of animals or the size of groups of animals.

The use of medicated feed is most common for pigs. This is confirmed by market data on the use of medicated feed by species (for countries for which such data is available), expert interviews and survey results. The following graph presents stakeholder opinions concerning the question for which species the use of medicated feed is most common (multiple answers were possible):

Figure 6: Species for which the use of medicated is most common



Source: Civic Consulting survey of national feed manufacturers' associations, associations of cooperatives and farmers' associations, N= 23 (multiple answers possible).

Besides pigs, chicken, turkeys and rabbits are most frequently considered by stakeholders to be among the species for which the use of medicated feed is most common.[70] Other species mentioned include game, fish and fur animals. For example, the National Farmers Union Scotland reported that 90 % of all game feed in Scotland is being medicated.

Data on production figures of medicated feed by species are only available for the United Kingdom and France (see following table).

[70] The answers by country are provided in Table 37 in Annex 10.

Table 8: Production of medicated feed by species in the UK and France

	Production of medicated feed (in tonnes)	
Species	**UK** (total market, 2005) [(a)]	**France** (sample of 97 feed mills, 2007) [(b)]
Pigs (include sows, piglets and pigs)	335,970	178,847
Rabbits	n.a.	154,118
Game	90,000	7,479
Poultry	45,915, including: *37,573 (broilers)* *4,983 (layers and pullet rearers)* *3,359 (turkeys)*	142,556, including: *7,302 (chicken)* *43,805 (layers)* *65,082 (turkey)* *2,267 (guineafowl)* *20,940 (palmipeds)* *3,160 (quals)*
Sheep	22,488 (lamb and ewe)	9,729 (sheep and goat)
Cattle	n.a.	8,073
Fish	n.a.	924
Horses	n.a.	7

Source:
(a) Estimates provided by the Agricultural Industries Confederation. Figures include medicated feeds produced on-farm and by feed mills. Figures do not include anticoccidials, except for game and sheep.
(b) Coop de France nutrition animale and SNIA (2009). *Aliments médicamenteux, résultats de l'enquête sur les production 2007*. The survey results are based on a sample of 107 production sites (40% of the total production of compound feed), of which 97 manufacture medicated feed.

The table confirms that pigs are the most important species for the use of medicated feed, accounting for 68% of total production in the UK (2005) and 35% of production of a sample of 97 feed mills in France (2007). It also confirms the importance of the poultry sector for the medicated feed market. It is interesting, however, that the second most important species in terms of use of medicated feed is very different in both countries, namely game in the UK and rabbits in France, which illustrates the importance of national meat consumption preferences for the medicated feed market.

This leads to the following conclusion:

7. **The use of medicated feed is most common in intensive production, especially of pigs.** Medicated feed for pigs accounts for 68% of medicated feed production in the UK (2005) and 35% of medicated feed production of a sample of feed mills in France (2007). Chicken, turkeys and rabbits are also frequently considered by stakeholders to be among the species for which the use of medicated feed is most common. However, differences between Member States can be significant, illustrating the importance of national meat consumption preferences for the medicated feed market.

4.2. Control systems for the use of medicated feed in the MS

The use of VMPs and medicated feed is regulated in all EU Member States in the sense that their use is not free but requires a prescription by an (authorised) veterinarian.[71] In many cases farmers have to document the quantities of medicines which are used on-farm, and the quantities that farmers are allowed to store are often limited.

Compliance with legislation on the prescription, storage, use and administration of VMPs and medicated feed on farms has to be enforced through regular controls of veterinarians and farmers. In EU Member States this task is delegated to national or regional competent authorities. Examples for control procedures in place for the use of medicated feed include the following:[72]

- In Denmark farms and the number of animals are registered centrally. Prescriptions of veterinarians are registered electronically in a central database. Data are, for example, collected on volumes of medicines used at farm level, regional level and by species (and, in some cases, by individual animals) as well as on medicines prescribed by veterinarians.
- In France on-farm controls of the use of medicated feed are done by the veterinary services of the state. The public agents control the identification of animals, feed, animal welfare and veterinary medicines, including medicated feed. In pork production 5 % of all farms are subject to routine controls per year. Additional target controls may take place in case of, for instance, residues in foodstuffs in slaughterhouses.
- In Germany there is surveillance during all steps of production and distribution of medicated feed. The surveillance is the duty of the federal states (*Länder*). The *Länder* are responsible for the control of the production sites, transportation, animal production and also for site visits. Germany has also implemented a risk-oriented control strategy of veterinarians and livestock farmers.

Table 33 in Annex 6 gives a more detailed overview of procedures EU Member States have implemented to control the use of medicated feed on farms.

4.3. Importance of medicated feed compared to alternative ways of oral administration

The main substitutes to medicated feed are ready-to-use oral veterinary medicines and non-oral routes of administration such as parenteral and intramammary routes. In the case of oral administration, two alternatives to medicated feed exist for the application by farmers: mixing ready-to-use veterinary medicines into water and top dressing/mixing of ready-to-use veterinary medicine into feed. Both alternatives are not regulated by Directive 90/167/EEC, and consistent data to assess their current relevance and possible changes in preferences of farmers for using medicated feed or one of the mentioned alternatives exists only to a limited extent. The data that is available concerns antimicrobials, the most important VMPs for the production of medicated feed (see section 3.3.1 above).

Table 9 below shows the sales of antimicrobials for oral admistration as percentage of total sales of antimicrobials for food and non-food producing animals in Finland, France and the UK, the

[71] Directive 90/167/EEC says in the preamble: "the supply of medicated feedingstuffs to stockfarmers may only be on prescription of a veterinarian".

[72] See case studies in Annex 11.

only countries for which such data is available for the period 2003 to 2007. The table indicates that in Finland and France oral antimicrobials have slightly increased their market shares, and in the UK the share has slightly decreased. However, changes are very slight and may not indicate long term trends.

Table 9: Sales of antimicrobials for oral administration as percentage of total sales of antimicrobials for food and non-food producing animals in Finland, France and the UK

	2003	2004	2005	2006	2007
Finland [(a)]	*52%*	*56%*	*57%*	*55%*	*n.a.*
France [(b)]	*87%*	*88%*	*88%*	*88%*	*89%*
United Kingdom [(c)]	*91%*	*91%*	*91%*	*90%*	*89%*

Sources:

(a) Finish Food Safety Authority (Evira) (2007). *FINRES-Vet 2005-2006 - Finnish veterinary antimicrobial resistance monitoring and consumption of antimicrobial agents*.

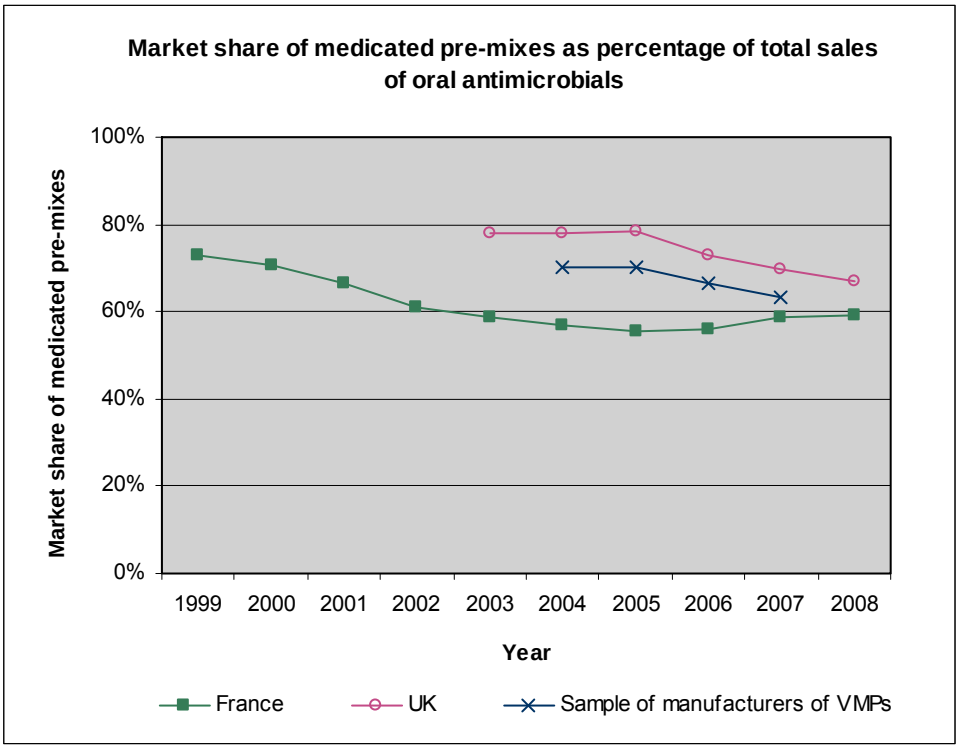
(b) Agence française de sécurité sanitaire des aliments (AFSSA) (2009). *Suivi des ventes de médicaments vétérinaires contenant des antibiotiques en France en 2007*.

(c) Veterinary Medicines Directorate (2009). *Sales of antimicrobial products authorised for use as veterinary medicines, antiprotozoals, antifungals, growth promoters and coccidiostats, in the UK in 2008*.

Whereas the overall share of oral application of antimicrobials remains relatively stable, the importance of medicated feed compared to other routes of oral application is decreasing, according to the available data (see Figure 7 below). The graph shows multi-annual data concerning the relative importance of medicated pre-mixes of antimicrobials, for which data from the UK and France could be evaluated. In addition, the graph provides EU sales data obtained from a sample of seven producers of VMPs (see section 2.4.2), which allowed to calculate the proportion of active substances for the production of medicated pre-mixes as part of total sales of antimicrobials for oral use in the period 2005 to 2008.[73]

[73] This includes both the amount of active substances used for medicated pre-mixes produced by the company and the amount of active substances sold to pre-mix manufacturers for the production of medicated pre-mixes.

Figure 7: Market share of medicated pre-mixes as percentage of total sales of oral antimicrobials



Source: Civic Consulting survey of manufacturers of VMPs and reports on sales of VMPs containing antimicrobials published by the competent authorities of France and the United Kingdom (seeTable 9).

The same data is presented in absolute figures in the following table, focusing on the period 2004 to 2007. Only taking into account this period, total sales of antimicrobials for oral administration in France (when measured in tonnes of active substance) have increased slightly, whereas the relative importance of pre-mixes for the production of medicated feed remained overall stable (with a slight decrease followed by a slight increase). In contrast, in the UK both total sales of antimicrobials for oral administration and relative importance of medicated feed decreased. Finally, the sample of seven VMP manufacturers first shows an increase and then a decrease of total EU sales of antimicrobials, with a steadily decreasing share of active substances for the production of medicated pre-mixes. When interpreting this data, it is important to recall the limitations of the sample of VMP producers described in section 2.4.2 above: Not all relevant producers are covered and as the sales figures are provided in tonnes of active substances, differences in the potency of active substances are not considered.

Table 10: Sales of antimicrobials by route of oral administration in selected Member States

	2003	2004	2005	2006	2007
France [(a)]					
Total sales of antimicrobials for oral use (in tonnes of active substance)	1,144	1,126	1,172	1,106	1,204
Thereof medicated pre-mixes (in tonnes of active substance)	671	641	652	621	705
Medicated pre-mixes as percentage of total	*59 %*	*57 %*	*56 %*	*56 %*	*59 %*
United Kingdom [(b)]					
Total sales of antimicrobials for oral use (in tonnes of active substance)	394	414	405	363	345
Thereof medicated pre-mixes (in tonnes of active substance)	*307*	*323*	*317*	*264*	*241*
Medicated pre-mixes as percentage of total	*78 %*	*78 %*	*78 %*	*73 %*	*70 %*
Sample of seven manufacturers of VMPs [(c)]					
Total sales of antimicrobials for oral use (in tonnes of active substance)	n.a.	1,608	1,753	1,670	1,586
Thereof for the production of medicated pre-mixes (in tonnes of active substance)	*n.a.*	*1,127*	*1,227*	*1,112*	*1,008*
Active substances for the production of medicated pre-mixes as percentage of total	*n.a.*	*70%*	*70%*	*67%*	*64%*

Sources:
(a) Agence française de sécurité sanitaire des aliments (AFSSA) (2009). *Suivi des ventes de médicaments vétérinaires contenant des antibiotiques en France en 2008.*
(b) Veterinary Medicines Directorate (2009). *Sales of antimicrobial products authorised for use as veterinary medicines, antiprotozoals, antifungals, growth promoters and coccidiostats, in the UK in 2008*.
(c) Civic Consulting survey of manufacturers of VMPs.
Note: Data include sales of antimicrobials for both food and non-food producing animals.

Medicated feed is therefore still the most common way of oral administration of antimicrobials for animals in some Member States for which detailed data is available, and possibly also in the EU as a whole, according to sales data from a sample of seven VMP producers (when measured as share of total tonnage of active substances). However, medicated feed loses importance compared to other routes of oral administration.

This leads to the following conclusion:

8. **Whereas the share of oral application of antimicrobials remains relatively stable, the importance of medicated feed compared to other routes of oral application is decreasing.** Medicated feed is still the most common way of oral administration of antimicrobials for animals in some Member States for which detailed data is available, and possibly also in the EU as a whole, according to sales data from a sample of seven VMP producers (when measured as share of total tonnage of active substances). However, medicated feed loses importance compared to other routes of oral administration, such as water medication and top dressing/mixing of ready-to-use veterinary medicine into feed. These alternatives to medicated feed are not regulated by Directive 90/167/EEC.

4.4. Additional costs of using medicated feed compared to the costs of administering ready-to-use oral veterinary medicines for farmers

One possible reason for the decreasing relevance of medicated feed experienced in some Member States are costs. Since most farming business mainly produce commodities which have a very limited potential for product differentiation or serving market niches, there is a very strong cost focus in agriculture, including livestock production.[74]

Whether or not the use of medicated feed is more expensive than the administration of ready-to-use oral veterinary medicines through, for instance, mixing into water or top dressing is disputed among stakeholders. Four associations of cooperatives and farmers' associations responding to our survey assessed that there is no cost disadvantage of medicated feed compared to its substitutes.[75] This view is mainly shared in those countries in which medicated feed is the most important way of administering veterinary medicines, i.e. in France and the United Kingdom among the case study countries. It is also shared by other stakeholders such as the Danish Ministry of Food, Agriculture and Fisheries under the assumption that there is no overmedication of animals that do not have diseases but are fed with medicated feed. Some stakeholders argue that water medication is more expensive than medicated feed because it requires additional equipment such as a dosing system. It is also assumed that medicated feed is more convenient since it can simply be put out in feeders or troughs and left.

But there are also strongly contrasting views: The Danish Pig Production association perceives a cost disadvantage of more than 50 % of medicated feed. In Denmark water medication is increasingly used as products for mixing into water are said to be cheaper than medicated feed. The sceptical view concerning the cost efficiency of medicated feed is shared by the German Association of Veterinarians (*Bundestierärztekammer*) that sees a clear cost disadvantage of medicated feed.[76]

To understand cost differences between medicated feed and alternative ways of oral administration better, four case studies have been conducted in the framework of this study to assess the costs of medication through medicated feed and water medication as its most important substitute from a farmer's perspective. For this aim, data was collected in four Member States (Denmark, France, Germany and the UK) concerning relevant costs factors and a detailed cost assessment. The cost assessment considered several issues to make results comparable, that are detailed in Annex 11. They include:

- The *prices of active substances* vary between Member States and between modes of administration. For example, a water soluble form of an active substance may differ in price compared to the form of the same active substance used in a pre-mix. Cost comparisons therefore covered several active substances;
- *Pricing strategies for medicated feed* differ significantly across feed mills. Even though additional costs of feed mills for producing medicated feed were analysed in depths (see section 3.4 above), we only rarely had access to data indicating how these cost differences affected sales prices of medicated feed. Feed mills may only charge a share of the additional cost of manufacturing medicated feed to farmers, or the full costs, or even apply an additional margin for medicated feed. Therefore different pricing scenarios are considered.

[74] Theuvsen and Inderhees 2008.

[75] See Annex 10.

[76] BTK 2008.

The table below presents the results of the cost comparisons for different pricing scenarios and active substances.[77] Costs for farmers are presented as index values, with the costs of a treatment via medicated feed being set at 100 for each active substance and each scenario.[78]

Table 11: Costs of treatment with medicated feed and water medication from a farmer's perspective (index values, treatment with medicated feed = 100)

	Medicated feed			Water medication		
	Amino-glycosides (Apramycin)	Macrolides (Tylosin)	Macrolides (Tilmicosin)	Amino-glycosides (Apramycin)	Macrolides (Tylosin)	Macrolides (Tilmicosin)
Denmark						
Scenario 1 – Fully cross-subsidised price	Set at 100 for each active substance and each scenario			111	73	n.a.
Scenario 2 – Cost price				108	71	n.a.
Scenario 3 – Price with gross margin of 6%				106	70	n.a.
France						
Scenario 1 – Fully cross-subsidised price	Set at 100 for each active substance and each scenario			123	110	124
Scenario 2 – Cost price				122	110	123
Scenario 3 – Price with gross margin of 6%				120	108	121
United Kingdom						
Scenario 1 – Fully cross-subsidised price	Set at 100 for each active substance and each scenario			113	98	226
Scenario 2 – Cost price				112	97	223
Scenario 3 – Price with gross margin of 6%				110	96	220
Germany						
Scenario 1 – Fully cross-subsidised price	Set at 100 for each active substance and each scenario			107	107	127
Scenario 2 – Cost price				89	88	105
Scenario 3 – Price with gross margin of 6%				87	86	103

Source: Civic Consulting (see Annex 11). Notes: The different pricing scenarios are defined as follows:
Scenario 1 – Fully cross-subsidised price: It is assumed that the feed mill charges no extra cost for mixing the medicine with the feed, i.e. the medicated feed is sold at a price below its production cost and the total additional cost of producing medicated feed is subsidised by the additional price charged on other products.
Scenario 2 – Cost price: It is assumed that the feed mill charges the full amount of the additional cost of mixing the medicine with the feed without making any profit on the additional cost.
Scenario 3 – Price with gross margin of 6%: It is assumed that the feed mill charges a margin of 6% on the total production cost of medicated feed.
The costs of water medication include the costs of the medicine as well as the costs of equipments required to prepare the medicinal solution (e.g. dosing pump), labour costs (in terms of time spent for the preparation of the solution) and the costs of a tonne of compound feed of similar quality and composition as the one used for the production of medicated feed, to account for the additional nutrition value of medicated feed compared to water medication.
The data for Germany refers to dataset A (two datasets were obtained, see Annex 11).
Cost calculations exclude VAT.

[77] For more details see case studies in Annex 11.

[78] The price of medicated feed varies depending on the active substance. An index value of 100 for medicated feed for all active substances therefore does not mean that the price of the medicated feed is the same for all active substances. However, the index value of medicated feed was set to 100 for each active substance to facilitate price comparisons per active substance between the two alternatives of oral administration of medicines.

The results of the cost analyses can be summarised as follows:

- In Denmark, cost differences between the two routes of oral administration depend on the active substance prescribed; Apramycin is more cost efficiently administered through medicated feed (cost savings between 6 % and 11 % depending on the feed mill's pricing strategy), whereas a treatment with Tylosin is up to 30 % cheaper through water medication. The pricing strategy of the feed manufacturer does not have any influence on which alternative is more cost efficient;
- In France, water medication is between 8 % and 24 % more expensive than medicated feed. The latter is always cheaper than water medication regardless which pricing strategies the feed manufacturer applies;
- In the United Kingdom water medication is 10 % to 13 % more expensive than medicated feed in the case of administration of Apramycin and 120 % to 126 % more expensive than medicated feed in the case of Tilmicosin. Water medication provides a slight cost advantage (between 2 % and 4 %) in case of administering Tylosin.
- In Germany, water medication is up to 27 % more expensive for farmers as long as feed manufacturers cross-subsidise medicated feed (pricing strategy 1). However, as soon as they charge additional costs of mixing to farmers, water medication is cheaper than medicated feed for Apramycin and Tylosin. The cost advantage of water medication in these cases is comparatively low (between 11 % and 14 %).[79]

In Denmark and Germany, the number of feed mills producing medicated feed is low. This may result in additional transport costs (not considered here) and further increase the costs of medicated feed for farmers. An additional cost factor that is not included in the calculation and is relevant in Germany are fiscal regulations concerning VAT. In Germany the VAT rate applicable to medicated feed is the same as for veterinary medicines, i.e. 19%, while the VAT rate for compound feed is 7%. In the case of top dressing, farmers therefore pay different tax rates for the carrier feed (7% VAT) and the ready-to-use VMPs they use (19%). In contrast, for medicated feed, i.e. the pre-mix and the carrier feed, the 19% VAT rate applies on the overall sales price. This is irrelevant for VAT-registered farms that opt for the regular VAT regulation, because they can claim back VAT. However, in Germany farmers may choose between the regular VAT regulation and a specific regulation for agricultural producers that applies taxation according to average values (*Umsatzsteuerpauschalierung*). If farmers opt for taxation according to average values, they have an incentive to buy input factors with a lower VAT rate since in this case the VAT on input factors is not reimbursed by the tax authorities but instead part of the farmers' input costs (see case study Germany in Annex 11). Similar unintended financial incentives caused by the VAT regime were not encountered in the other case study countries Denmark, the UK and France, where farmers are generally registered for VAT, and therefore can claim it back.

In general, it seems unlikely that farmers base their choice of the route of administration on cost comparisons as have been presented above. The case studies conducted during the course of this study revealed the difficulty of systematically collecting data on prices of active substances and of obtaining cost data on medicated feed and water medication which are comparable. Put in other words: The market for medicated feed and possible alternatives is far from being transparent. Objective and systematic price comparisons are hardly feasible for farmers. Farmers' choices between alternatives ways to administer oral VMPs therefore depend on

[79] This calculation is based on dataset A for Germany that is based on the costs of active substances provided by a manufacturer of VMPs. A second dataset B was provided by a German distributor of VMPs. With dataset B, water medication is always cheaper when treating animals with Tylosin. Medicated feed is only more cost efficient in the cases of Tetracyclines and Sulfonamides/Trimethroprim if feed mills cross-subsidise prices (see Annex 11).

perceived costs and benefits, as well as other factors. The case studies revealed several factors that may influence farmers' perceptions of costs and benefits and the incentive structures of relevant actors:

- *Convenience*: In Denmark water medication is more convenient for pig farmers since the veterinarian is allowed to make a prescription for the next 35 days whereas medicated feed may have to be re-ordered regularly due to storage constraints at the farm and also creates additional transport costs since only a limited number of feed mills are authorised for its production.
- *Effectiveness*: The National Pig Association (NPA) from the United Kingdom and other stakeholders stress qualitative differences between medicated feed and its alternatives. The NPA emphasizes that top dressing cannot guarantee that the medicine is evenly distributed in the feed, and that each animal receives the right amount of active substance. On the other hand, the Danish Pig Production stresses that ill animals do not eat very much but still drink a lot; therefore, water medication is supposed to work better.
- *Safety*: According to the UK Veterinary Medicines Directorate, unknown compatibility of the ready-to-use VMP with the water or feed makes it very difficult to define the shelf-life of feed to which veterinary medicine has been added via top dressing. Besides safety, this also is feared to affect the efficacy.
- *Incentives for veterinarians*: In Denmark, veterinarians are not allowed to be commercially involved in the distribution of or be otherwise engaged in the distribution of VMPs. Therefore, the veterinarian has no financial interest in prescribing VMPs. The situation is different in other countries such as Germany. In this country, veterinarians were previously (before 2006) allowed to commission the production of medicated feed to feed mills and sell this service to the farmer (*Herstellungsauftrag)*. Since the abolishment of this possibility, veterinarians can only prescribe medicated feed and the distribution of medicated feed is done via companies holding a manufacturing permit in line with § 13 of the German pharmaceutical law, excluding the veterinarian from any financial benefit. By contrast, veterinarians are allowed to sell ready-to-use veterinary medicines directly to the farmers and therefore have a financial incentive to do so.

Other factors such as tradition and the availability of equipments to administer ready-to-use VMPs on the farm (e.g. dosing pump to administer medicines via water) also influence farmers' decisions. Once relevant dosing equipment has been purchased, these are sunk (and, therefore, financially irrelevant) investments and provide an incentive to continue the practice.

This analysis leads to the following conclusion:

9. **There is no generally valid economic rationale for farmers to prefer a specific way of administering oral veterinary medicines, be it through medicated feed or water medication.** Whether medicated feed is a more costly or a more cost efficient alternative of administering oral VMPs compared to water medication depends on the pricing strategy applied by manufacturers of medicated feed, the active substance used and the specific Member State. Case studies in Denmark, France, Germany and the UK indicate that cost differences are generally in the range of plus or minus 25 % in both directions. Only in France water medication is – for the three active substances scrutinized – always more expensive than medicated feed. As objective and systematic price comparisons are hardly feasible for farmers, their choices between alternatives ways to administer oral VMPs depend on a variety of factors, including perceived cost advantages, specific rules concerning VAT (in Germany), monetary incentives of veterinarians, tradition, and assumptions or experiences with the effectiveness/efficiency of the route of administration.

4.5. Consequences of the use of ready-to-use oral veterinary medicines compared to the use of medicated feed

4.5.1. Consequences on the competitiveness of livestock farmers

The competitiveness of livestock production very much depends on cost efficiency. Competitive situation and market environment differ by livestock species and this section therefore focuses on the pig sector, the most important sector in terms of medicated feed consumption. Cost analyses of pork production in various countries show that the production costs at the farm level vary significantly. Low-cost producers such as Brazil have average production costs of around 1 Euro per kg of slaughter weight, high-cost producers such as Austria, the United Kingdom and Sweden are, at least on average, close to 1.60 Euro per kg of slaughter weight.[80] European pig producers therefore potentially face strong competition from more cost-efficient producers from non-EU countries, although pork import from non-EU countries is limited by import tariffs and sanitary barriers. In 2008, the EU-27 was the second world pork producer after China, with more than double the production of the USA, the third largest world producer. Trade with third countries has risen and could further increase in the future. But 94% of the outlets of EU pig production are in the EU and almost the entire supply of the domestic market (more than 99.5%) comes from the EU.[81] In spite of the protection currently enjoyed, pig producers are on average not very profitable. Especially during times of low pig prices, there is a permanent pressure to reduce costs and to choose the most cost efficient way of production. Therefore, even small cost differences can result in an avoidance of less cost efficient alternatives by pig farmers.

Cost analyses show that about 50 % of the total costs of pig production are feed costs. In these cost calculations, costs for VMPs and veterinarians are typically part of "other costs" that amount to 10 % to 15 % of total costs of pig production.[82] Therefore, feed costs are one of the

[80] Gaus and Haxsen 2003.

[81] ADHB Meat Services et al 2009: The Impact of Increased Operating Costs on Meat Livestock in the EU, Study prepared for the European Parliament.

[82] Gaus and Haxsen 2003; Haxsen and Beckhove 2004.

major and veterinary and VMP costs one of the minor cost drivers in pig production. A crude calculation on basis of total EU sales figures of farm inputs indicates that total sales of antimicrobials (the most commonly used VMP for medicated feed) equal approximately 2 percent of total sales of compound feed in value terms.[83] Therefore, any cost increase of antimicrobials and their application has only very limited consequences for overall pig production costs. In addition, as has been outlined before, whether the use of ready-to-use oral veterinary medicines is less costly than medicated feed depends on a variety of factors, including the pricing strategy applied by manufacturers of medicated feed, the active substance used and the specific conditions of the Member State. Cost differences (in both directions) are often minor, are difficult to assess for farmers and may be evened out in the long run, because cost advantages of a particular method for the administration of one active substance may be balanced by similar disadvantages for another active substance (see previous section). The consequences of the use of ready-to-use oral veterinary medicines compared to the use of medicated feed produced from pre-mixes on the competitiveness of pig production in the EU can therefore be expected to be very limited.

This is also likely to be the case for other species, although for specific situations where local conditions and the choice of active substances used leads to clear cost advantages for a specific way of administration of the veterinary medicines, effects on competitiveness cannot be excluded.

This leads to the following conclusion:

10. **The consequences of the use of ready-to-use oral veterinary medicines compared to the use of medicated feed on the competitiveness of pig production in the EU can be expected to be very limited.** Cost differences between the different ways of administration of oral veterinary medicines are often minor and may be evened out in the long run, because cost advantages of a particular method for the administration of one active substance may be balanced by similar disadvantages for another active substance. This situation is likely to be similar for other species, although for specific situations where local conditions and the choice of active substances leads to clear cost advantages for a specific way of administration of veterinary medicines, effects on competitiveness cannot be excluded.

4.5.2. Consequences for occupational safety

Regardless of how oral VMPs are administered, all products undergo a risk analysis during the authorisation process. This also includes occupational or user safety. Despite authorisation processes taking occupational safety into account, it is a widely shared view among stakeholders that top dressing and mixing into water or feed of ready-to-use VMPs result in a more direct and more frequent contact with concentrated veterinary medicines. This exposes farmers and farm workers to the potential risks of contamination through, for instance, inhalation of dust or skin contact. The development of allergic reactions is one potential consequence of this.

Nonetheless, it is also stressed by stakeholders that staff who are well trained, are made aware of best practices of handling concentrated VMPs and use – whenever necessary – personal protective equipment such as gloves or face masks can avoid these risks and, as a consequence,

[83] In the EU total sales of compound feed were 36.1 billion Euros in 2006 (FEFAC 2007), total sales of antimicrobials around 0.70 billion Euros (IFAH-Europe 2007).

are not exposed to greater risks than with medicated feed. If precautionary measures are taken the risk of farmers and farm workers are not larger that those of workers in feed mills. But since in feed mills a much smaller number of people handles VMPs, it is expected to be easier to adequately train these people and to operate in full compliance with relevant health and safety regulations. Furthermore, in a feed mill it is easier to guarantee that adequate equipment for handling concentrated VMPs is available. So, although the occupational risks farmers and farm workers are exposed to can, at least in principle, be controlled through adequate training, some respondents see advantages of medicated feed with regard to user safety due to an easier to control environment in feed mills.

It can be concluded that due to authorisation processes taking into account safety aspects and safety instructions given to farmers, mixing into water and top dressing/mixing into feed of ready-to-use veterinary medicines do not imply occupational safety risks, if adequate precautions are taken. However, the number of persons handling highly concentrated veterinary medicines clearly increases through on-farm application of ready-to-use VMPs and therefore the risk of mishandling and unintended exposure of farm workers increases. This risk is mitigated through the use of medicated feed.

4.5.3. Consequences for public health

The arguments provided by stakeholders with regard to public health issues are similar to the arguments brought forward in the previous discussion of occupational safety. If farmers and farm staff have the required training, are aware of the potential risks to public health and do not act opportunistically with regard to, for instance, withdrawal periods,[84] water medication and top dressing do not create any additional public health problems compared to the use of medicated feed. Furthermore, it is assumed that increasing farm sizes due to structural changes in agriculture contribute to a more professional handling of ready-to use oral medicines and prevention of over-dosing. In combination with authorisation processes including risk analyses, in the end no differences with regard to public health are expected in this view.

Nonetheless, several respondents admit that there might be difficulties with correctly handling concentrated VMPs on farms. Typical problems with the use of ready-to-use medicines at the farm level are considered to be wrong dosing (over- or under-dosing) of VMPs and poor mixing homogeneity. Mixing inhomogeneity is mainly a technical problem resulting from inadequate equipment used on farms. Unlike in feed mills, homogeneity and stability tests are not performed on farms when ready-to-use medicines are used.

Wrong dosing can be the result of human error (especially miscalculations), a lack of awareness but also of opportunistic behaviour (for instance, conscious over-dosing or other non-compliance with veterinarians' prescriptions or ignoring withdrawal periods). A lack of "will" or "skill" of farmers or farm workers can contribute to developing antibiotic resistance or lead to residues in end products.

Furthermore, cross contaminations are considered to be more likely on farms than in feed mills where adequate measures against cross contamination have been implemented. Therefore, the German Ministry of Food, Agriculture and Consumer Protection (BMELV) is preparing guidelines for farmers and veterinarians with regard to handling ready-to-use VMPs on farms.

The above-mentioned problems are avoided by medicated feed that is said to guarantee correct dosage and homogeneity. Without doubt, all problems that can occur on a farm – lack of skill or awareness, opportunistic behaviour, cross contaminations – can also occur in a feed mill. But it

[84] The withdrawal period is the waiting time that must elapse before treated animals can be slaughtered or their products, such as milk and eggs, collected.

is often considered that it is easier to monitor and inspect feed mills than controlling the administration of water medication by thousands of farmers and that more adequate measures for avoiding cross contaminations are set up in feed mills.

Despite the generally positive assessment of medicated feed, there are also some respondents that refer to potential advantages of water medication and, in some cases, also top dressing. It is reported that water administration allows a stricter targeting of the medication and an easier and quicker withdrawal and, as a consequence, an all in all smaller consumption of veterinary medicines and a reduced risk of residues in food products.

There is no research data available that would allow to provide an evidence-based judgment on possible public health consequences of using medicated feed compared to alternative ways of administration. The European Medicines Agency emphasized in an interview that possible public health consequences have to be judged on a case by case basis. According to EMEA, public health issues very much depend on, for instance, animal species, active substances, dosing and type of disease to be treated. Therefore, generalisations with regard to effects on public health are considered to be difficult.

Some data concerning residues resulting from the use of medicated feed are available from the UK Veterinary Medicines Directorate. They indicate that the use of medicated feed only in exceptional cases leads to positive residue results. In a five years period approximately 53 samples showed positive residue results likely to have resulted from medicated feeds. This compares to a total of 12,128 samples taken in the species that have shown positive residue results.

Table 12: Positive residue results from medicated feeds in the United Kingdom

	2004	2005	2006	2007	2008
Total number of samples taken in the species that have shown positive residue results	1,855	2,987	2,354	3,104	1,828
Positive residue samples	8	15	9	12	9

Source: UK Veterinary Medicines Directorate.

Unfortunately, similar data is not available from the UK for other ways of oral administration. The competent authority of Norway communicated that "no specific signals [were] detected by the Norwegian Medicines Agency via the pharmacovigilance system" regarding safety aspects of both medicated feed and alternative ways of oral administration. The competent authority of Hungary reported results of samples taken in feed production plants for monitoring of cross-contamination in 2007, where 11 out of 302 samples proved to be positive. Cross-contamination through medicated feed was also established through the feeding system in the animal farm. No data was provided concerning cross-contamination caused by other ways of oral administration, but the authority judged water medication to be "effective and therefore … to be supported". Competent authorities from the other 24 responding countries did not provide any surveillance data that would allow to compare possible consequences for public health caused by the use of medicated feed and the use of other ways of oral administration of VMPs.

In conclusion, it is therefore only possible to point out potential differences of the different ways of application of VMPs concerning public health consequences based on general considerations, focusing on the risk of inhomogeneities and risk of overdosing. Homogeneity problems are less relevant for medicated feed and water medication with adequate equipment and controls. Top dressing/mixing into feed of ready-to-use VMPs at the farm is likely to lead more often to homogeneity problems, especially if mixing is done manually. The risk of

unintended overdosing is clearly the least for medicated feed, as long as the feed mill is well equipped and staff adequately trained. For both water medication and top dressing/mixing into feed of ready-to-use VMPs the risk of overdosing is higher because of the much larger number of people involved that need to be trained and the lack of testing of resulting mixtures of VMPs with feed or water. Although therefore general considerations point to certain advantages for the administration of oral VMPs through medicated feed, a final view on possible public health consequences of the different ways of application of oral medicines requires scientific research at farm level and an analysis in Member States whether or not the frequency of positive residue results correlate with different application practices of VMPs.

4.5.4. Environmental consequences

Environmental consequences of the application of human and veterinary medicines are an area of serious concern, as low levels of pharmaceutical residues have been found in aquatic environments of developed and developing countries, both caused by the production of active substances and their use, and environmental concentrations of antimicrobials may contribute to antibiotic resistance. This general problem of the use of veterinary medicines is, however, out of the scope of this study, which focuses only on the extent to which the various ways of administration of oral veterinary medicines differ in their consequences.

Compared to occupational and public health-related risks, possible environmental consequences of the different ways of application of oral VMPs are considered less relevant by stakeholders. Some respondents do not see any additional environmental risks of water medication and top dressing compared to using medicated feed. Other respondents refer to the precautionary measures taken during the authorisation procedure, including, for instance, ecotoxicity studies and studies of residues of active substances that have to be performed before a medicated pre-mix is authorized.

Potential environmental risks in principle relate to all situations where active substances are emitted to the environment. This can result from accidents, improper storage of VMPs at the farms (to the extent that storage is allowed), improper disposal of leftovers or packaging material, unintended losses, or residues in the excrements of animals, especially in case of overdosing.

The different ways of administering oral veterinary medicines can have an influence of the mentioned factors:

- *Accidents* with highly-concentrated VMPs can occur in feed mills during the production of medicated feed. At farm-level, they can only occur only through other ways of administration;
- *Improper storage, improper disposal of leftovers or packaging material* can occur with medicated feed and with highly-concentrated VMPs;
- *Unintended losses* can occur with all ways of administration through leakage. Water medication can result in losses through water that is not consumed by animals or if animals play with water.
- *Residues in the excrements of animals*, especially in case of overdosing, may occur with all ways of administration;

Again, if safety and handling instructions are properly observed, the differences between medicated feed and alternative ways of administering oral VMPs are expected to be insignificant with regard to environmental consequences. However, in absence of scientific research on the issue, a final conclusion cannot be made.

This leads to the following conclusion:

11. **There is no indication that different ways of administering oral veterinary medicines lead to significant differences regarding occupational safety, public health and environmental consequences, if safety and handling instructions are properly observed.** In situations where the latter cannot be guaranteed, medicated feed can be expected to provide a safer way of administering oral VMPs than top dressing and mixing ready-to-use VMPs in the feed by farmers. A main advantage of medicated feed is that it ensures homogeneity and stability of the VMP in the feed and reduces the number of people handling highly concentrated veterinary medicines. In absence of relevant surveillance data and scientific research on the issue a final conclusion, however, cannot be made.

4.6. Medicated feed for non-food producing animals

There is a clear difference between farm animals and pets regarding the use of veterinary medicines. Pets are typically not hold in large numbers; therefore, the risk of infections is much lower and individual treatment is easily feasible in case of an infection. Furthermore, the weight of pets is generally much lower; therefore the required quantities of active substances are much smaller. As a consequence, despite its large size, the pet market is by and large irrelevant with regard to the use of medicated feed, although there is a widespread lack of data. Only one of the 12 national feed manufacturers associations responding to our survey sees a market potential for medicated feed for non-food producing animals, two marked “no” and most associations did not know (see Annex 10). None of the 11 manufacturers of VMPs responding sees a potential market. The European Pet Food Industry Federation (FEDIAF) was also contacted to explore the current use of medicated feed for pets and the existence of a potential market in this respect. However, FEDIAF and its member associations do not include medicated feed for pets in the scope of their work and could therefore not provide any data.

Annex 1: Glossary

In this study the following key definitions are used:

Feed (or 'feedingstuff'): Any substance or product, including additives, whether processed, partially processed or unprocessed, intended to be used for oral feeding to animals.[85]

Compound feed: Mixture of feed materials, whether or not containing feed additives, for oral animal feeding in the form of complete or complementary feed.[86]

Medicated feed: Any mixture of a veterinary medicinal product or products and feed or feeds which is ready prepared for marketing and intended to be fed to animals without further processing, because of its curative or preventive properties or other properties as a medicinal product.[87]

Veterinary medicinal product (VMP): Any substance or combination of substances presented for treating or preventing disease in animals. Any substance or combination of substances which may be administered to animals with a view to making a medical diagnosis or to restoring, correcting or modifying physiological functions in animals is likewise considered a veterinary medicinal product.[88]

Veterinary Medicinal Products may be administered orally via the following routes:

1. Through medicated feed produced by feed mills approved by the competent authority in line with Article 4(1) of Directive 90/167/EEC and manufactured from authorised medicated pre-mixes;

2. Through medicated feed produced by farms that are authorised to manufacture medicated feed from authorised medicated pre-mixes (on-farm mixing) in line with Article 4(2) of the Directive;

3. Through ready-to-use oral veterinary medicines administered by farmers through water, top dressing of feed, and mixing of powders into feed (not regulated by this Directive).

Ready-made veterinary medicinal product (alternatively also called 'ready-to-use veterinary medicine': Any veterinary medicinal product prepared in advance which does not comply with the definition of proprietary medicinal products and which is marketed in a pharmaceutical form which may be used without further processing.[89]

Authorised medicated pre-mix: Any pre-mix for the manufacture of medicated feedingstuffs as defined in Article 1 (2) of Directive 81/851/EEC which has been granted an authorisation in

[85] Regulation (EC) no 178/2002 of the European Parliament and of the Council of 28 january 2002 laying down the general principles and requirements of food law, establishing the European food safety authority and laying down procedures in matters of food safety.

[86] European Commission (2008). Proposal for a regulation of the European Parliament and of the Council on the placing on the market and use of feed.

[87] European Commission (2008). Commission staff working document. Accompanying document to the regulation of the European Parliament and of the Council on the placing on the market and use of feed. Impact Assessment.

[88] Directive 2001/82/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to veterinary medicinal products.

[89] See footnote 88.

accordance with Article 4 of that Directive.[90] According to the European Pharmacopoeia Supplement 6.8 (December 2009), pre-mixes for medicated feedingstuffs for veterinary use are mixtures of one or more active substances, usually in suitable bases that are prepared to facilitate feeding the active substances to animals. They are used exclusively in the preparation of medicated feedingstuffs.

Carry-over: Contamination of a material or product with another material or product that originates from previous use of equipment.[91]

Food producing animal: Any animal that is kept for the production of food for human consumption including animals that are not consumed but that belong to species that can be normally consumed in the Community.[92] Horses are considered to be food producing animals.

Non-food producing animals: Animals kept or bred but not used for human consumption such as fur animals, pets and animals kept in laboratories, zoos or circus.[93]

Pet or pet animal: Animal belonging to species nourished, bred or kept, but normally not consumed by humans in the Community. [94]

[90] Council Directive 90/167/EEC of 26 March 1990 laying down the conditions governing the preparation, placing on the market and use of medicated feedingstuffs in the Community.

[91] European Feed Manufacturers Federation (2007). *European Feed Manufacturers Guide (EFMC) - A community guide to good practice for the EU industrial compound feed and premixtures manufacturing sector for food producing animals.*

[92] See footnote 86.

[93] See footnote 86.

[94] See footnote 86.

Annex 2: Methodological approach

Methodological tools employed for this study include:

- Desk research and collection of available information;
- Interviews;
- Surveys of the following stakeholder groups:
  - Compound feed manufacturers' associations;
  - Associations of cooperatives manufacturing compound feed;
  - Farmers' associations; and
  - Manufacturers of veterinary medicinal products (VMPs).
- Four case studies (in Denmark, France, Germany and the United Kingdom) aimed in particular to collect cost data, focusing particularly on the costs of using medicated feed and water medication for farmers, and the additional costs of producing medicated feed for manufacturers.

The methodological tools are described in more detail below:

Literature research

Relevant scientific literature and reports were reviewed and evaluated concerning the research issues. The literature collected is listed in Annex 12.

Interviews with stakeholders

Exploratary interviews

Several exploratory interviews were conducted with relevant key stakeholders, of which two were group interviews (see Table 13). The main objective of these interviews was to acquire insight into stakeholder opinions on the main issues relevant for the study. Interviewees were selected so as to be representative of the different stakeholder groups that have an interest in the issue of medicated feed and which may be affected, directly or indirectly, by a revision of Directive 90/167/EEC. The exploratory interviews involved the following stakeholder groups: farmers and cooperatives (COPA-COGECA), manufacturers of veterinary medicines (IFAH-Europe), feed manufacturers (FEFAC) and veterinarians (FVE). The views of the feed manufacturers were heard during a group discussion that involved the EU-level association (FEFAC) but also three national associations of feed manufacturers, from Belgium, France and Germany (see table below). All interviews were conducted face-to-face in Brussels. Two representatives of the national associations of feed manufacturers participated in the group discussion via conference call.

Table 13: Overview of exploratory interviews

Organisation	Stakeholder groups	Persons interviewed	Date of interview
Committee of Agricultural Organisations in the European Union - General Committee for Agricultural Cooperation in the European Union (COPA-COGECA)	EU farmers and cooperatives association	Mr Derrien, Policy Adviser Ms Di Rubbo, Policy Adviser Mr. Zitty, Policy Adviser	16 June 2009
International Federation for Animal Health (IFAH-Europe)	EU association of manufacturers of veterinary medicines	Declan O' Brien, Managing Director	16 June 2009
European Feed Manufacturers' Federation (FEFAC)	EU association of feed manufacturers	Mr Döring, Secretary General Arnaud Bouxin, Deputy Secretary General Erik Hoeven, BEMEFA [(a)] Xavier Gautier , SNIA [(b)] Peter Radewahn, DVT [(c)]	17 June 2009
Federation of Veterinarians of Europe (FVE)	EU association of veterinarians	Jan Vaarten, DVM Executive Director	17 June 2009

Notes:
(a) BEMAFA: *Association Professionnelle des Fabricants d'Aliments Composés pour Animaux /Beroepsvereniging van de Mengvoederfabrikanten* (Belgium)
(b) SNIA: *Syndicat National des Industriels de la Nutrition Animale* (France)
(c) DVT: *Deutscher Verband Tiernahrung e.V.* (Germany)

In-depth interviews

In addition, in-depth interviews were conducted with national feed manufacturers' associations, farmer's associations, feed mills and farmers as well as with the competent authorities of the four case study countries, i.e. Denmark, France, Germany and the United Kingdom. These interviews were conducted either face-to-face or by phone.

Supplementary interviews were conducted with representatives of the European Medicines Agency (EMEA), manufacturers of VMPs, as well as with a distributor and a manufacturer of dosing pumps used in water medication.

Table 14: Number of stakeholders interviewed (in-depth interviews)

Stakeholder groups	Number of interviews
Competent authorities	4
Farmers' associations	4
Farmers	2
National feed manufacturers' associations	4
Feed mills	4
Manufacturers of VMPs	2
Distributors/manufacturers of equipment	2
Exploratory interviews with key stakeholders	4
Total	*26*

Surveys

On the basis of the information collected during the inception phase, a survey covering the 27 MS was developed to collect data on current production figures and their recent developments; the alternatives to VMP-administration via medicated feed commonly used; and other relevant issues.

We circulated the following two complementary surveys, respectively targeted at:

- Feed manufacturers' associations, associations of cooperatives and farmers' associations; and
- Manufacturers of VMPs.

The questionnaires were developed in close cooperation with stakeholders and the Commission. The accuracy and clarity of the questions was tested prior to circulation by sending draft questionnaires to a small sample of feed manufacturers through FEFAC, and to two VMP manufacturers. Comments were taken into account and integrated in the final versions of the questionnaires.

The two questionnaires were designed to specifically target different stakeholder groups. However, the questionnaires also contained a number of complementary questions aimed at assessing issues for all stakeholder groups (e.g. related to the use of medicated feed, existence of a potential market for non-food producing animals, possible consequences of administration of ready-to-use oral veterinary medicines compared to the use of medicated feed). These questions allowed for the triangulation of data obtained from different stakeholders.

In addition, a list of questions was circulated in June 2009 by the European Commission to competent authorities.

These surveys are described in more detail in the following sub-sections.

Survey of feed manufacturers' associations, associations of cooperatives and farmers' associations

The questionnaire to feed manufacturers' associations, associations of cooperatives and farmers' associations is divided into 3 sections. The first section concerned all stakeholders while the other two sections were targeted at specific stakeholder groups in Member States (feed manufacturers' associations and farmers' associations). The specific aims of this questionnaire were to collect data on:

- Production figures of medicated feed and compound feed, and other issues relevant for compound feed manufacturers and cooperatives manufacturing compound feed, including additional costs of manufacturing medicated feed compared with manufacturing compound feed;
- The legal situation concerning the on-farm use of medicated feed, and other relevant issues for farmers, including costs of using medicated feed compared with ready-to-use oral veterinary medicines (e.g. through water, top dressing of feed, mixing of powders into feed).

This questionnaire was circulated to the relevant national associations via the EU-level associations (i.e. FEFAC for the feed manufacturers' associations and COPA-COGECA for associations of cooperatives and farmers' associations).

The questionnaire to feed manufacturers' associations, associations of cooperatives and farmers' associations is included in Annex 8.

The number of responses received by stakeholder group is presented in Table 15.

Table 15: Number of respondents by stakeholder group

Respondents	Questionnaires received	Member States covered
National feed manufacturers' associations	10 [(a)]	9
Associations of cooperatives and farmers' associations	13	10
Total	*23*	*13*

Notes:
(a) In addition, two cooperatives manufacturing compound feed answered the questions related to the production of medicated feed (section B of the questionnaire addressed to feed manufacturers' associations). See Annex 10 on the survey results.

Responses to the survey of national feed manufacturers' associations, associations of cooperatives and farmers' associations are broken down by country in Table 16.

Table 16: Number of respondents by country

Country	Questionnaires received
Belgium	1
Czech Republic	1
Denmark	2
Finland	1
France	3
Germany	3
Italy	2
Netherlands	1
Poland	1
Portugal	1
Slovenia	1
Spain	1
Sweden	1
United Kingdom	4
Total	*23*

Survey of manufacturers of veterinary medicinal products

The main objective of this survey was to collect data on sales of VMPs for all routes of oral administration in tonnes of active substances over the last 5 years in the EU. The questionnaire to manufacturers of VMPs was sent directly to members of IFAH-Europe. Manufacturers that were not members of IFAH-Europe were also contacted, including generic producres. The questionnaire to manufacturers of VMPs is included in Annex 9.

Survey of competent authorities

A list of questions to Heads of Delegation of the Standing Committee on the Food Chain and Animal Health, Section Animal Nutrition, was circulated in June 2009 by the European Commission to collect information on the number of approved operators for the placing on the market of medicated feed, the number of authorised medicated pre-mixes, rules for good manufacturing practice, national implementation and official controls, and on experiences with the practice of oral administration of VMPs. This information complemented the data collected by Civic Consulting. All Member States except Malta provided an answer.

Case studies

Selection of case study countries

During the inception phase we selected a sample of case study countries identified for in-depth analysis on basis of the following criteria:

- Share of animal production in the EU;
- Different situations concerning the use of medicated feed;
- Different situations concerning national requirements for the manufacturing of medicated feed.

Based on these criteria and the information and data collected, a list of possible candidates for case study countries was prepared. The list of countries was discussed with the Commission and it was agreed to focus on Denmark, France, Germany and the United Kingdom.

Objectives of case studies

The case studies aimed in particular to collect cost data, focusing particularly on the costs of using medicated feed and water medication for pig farmers, and the additional costs for manufacturers of producing medicated feed. Based on the analysis of the national reports on sales of antimicrobial products, discussions with stakeholders during the exploratory interviews, and with the European Commission, it was agreed that swine is the most relevant specie for the study.

Data collection took into consideration the perspectives of both manufacturers of medicated feed and farmers using medicated feed:

- *From the perspective of the manufacturers of medicated feed:* Information on additional production costs of medicated feed was collected and additional production costs of medicated feed compared with the production costs of compound feed were calculated.
- *From the perspective of the farmers:* Information on the costs of administering medicines via medicated feed and via water was collected in order to compare the costs of the two routes of oral admistration of medicines. Cost data are indicated per head of treated animal.

In case study countries selected relevant stakeholders were contacted for in-depth interviews (i.e. national feed manufacturers' associations, farmers' associations, feed mills and farmers, as well as the competent authorities) to collect both cost data and background information on the country (see Annex 11, which presents the methodological approach for and results of the case studies).

Annex 3: Animal husbandry within the EU

Table 17: Number of pigs (1,000)

	2004	2005	2006	2007	2008
Austria	3,125	3,170	3,139	3,286	3,064
Belgium	6,319	6,253	6,304	6,200	6,208
Bulgaria	943	933	1,013	889	784
Cyprus	471	430	453	467	465
Czech Republic	2,915	2,719	2,741	2,662	2,135
Denmark	13,407	12,604	13,613	13,170	12,195
Estonia	354	352	341	375	364
Finland	1,435	1,440	1,435	1,427	1,400
France	15,150	15,123	15,009	14,969	14,796
Germany	26,335	26,989	26,821	27,113	26,719
Greece	994	952	1,033	1,038	1,061
Hungary	4,059	3,853	3,987	3,871	3,383
Ireland	1,754	1,671	1,620	1,575	1,605
Italy	8,972	9,200	9,281	9,273	9,252
Latvia	436	428	417	414	384
Lithuania	1,073	1,115	1,127	923	897
Luxembourg	77	77	87	86	78
Malta	77	73	74	77	66
Netherlands	11,140	11,000	11,220	11,710	11,735
Poland	17,396	18,711	18,813	17,621	14,242
Portugal	2,348	2,344	2,296	2,374	2,340
Romania	6,495	6,604	6,815	6,565	6,174
Slovakia	1,149	1,108	1,105	952	749
Slovenia	534	547	575	543	432
Spain	24,895	24,889	26,219	26,061	26,290
Sweden	1,920	1,797	1,662	1,728	1,703
United Kingdom	4,787	4,726	4,731	4,671	4,550
Total EU 27	158,559	159,108	161,929	160,039	153,067

Source: Eurostat (retrieved from http://epp.eurostat.ec.europa.eu in September 2009).

Table 18: Number of dairy cows (1,000)

	2004	2005	2006	2007	2008
Austria	538	534	527	525	530
Belgium	571	548	532	524	518
Bulgaria	369	348	350	336	315
Cyprus	26	25	24	24	24
Czech Republic	429	437	417	407	400
Denmark	569	558	555	551	568
Estonia	117	113	109	103	100
Finland	318	313	309	296	288
France	3,947	3,895	3,799	3,759	3,794
Germany	4,287	4,164	4,054	4,087	4,229
Greece	150	152	168	150	154
Hungary	304	285	268	266	263
Ireland	1,122	1,101	1,087	1,088	1,105
Italy	1,838	1,842	1,814	1,839	1,831
Latvia	186	185	182	180	170
Lithuania	434	417	399	405	395
Luxembourg	41	41	46	40	46
Malta	8	8	8	8	7
Netherlands	1,502	1,486	1,443	1,490	1,587
Poland	2,730	2,755	2,637	2,677	2,697
Portugal	338	324	307	306	301
Romania	1,566	1,625	1,639	1,573	1,483
Slovakia	202	199	185	180	174
Slovenia	134	120	113	117	113
Spain	1,057	1,018	942	903	888
Sweden	401	391	385	366	366
United Kingdom	2,054	2,007	2,005	1,977	1,903
Total EU 27	23,302	22,918	22,315	22,267	22,450

Source: Eurostat (retrieved from http://epp.eurostat.ec.europa.eu in September 2009).

Table 19: Number of cattle (1,000)

	2004	2005	2006	2007	2008
Austria	2,051	2,011	2,003	2,000	1,997
Belgium	2,657	2,604	2,607	2,573	2,538
Bulgaria	680	630	637	611	574
Cyprus	60	58	56	56	56
Czech Republic	1,368	1,352	1,390	1,367	1,358
Denmark	1,616	1,572	1,579	1,545	1,570
Estonia	250	252	245	241	238
Finland	952	945	929	903	907
France	18,948	18,930	18,902	19,124	19,366
Germany	13,031	12,919	12,677	12,707	12,988
Greece	640	665	683	682	682
Hungary	723	708	702	705	701
Ireland	6,212	6,192	6,002	5,902	5,935
Italy	6,515	6,460	6,340	6,577	6,486
Latvia	371	385	377	399	380
Lithuania	792	800	839	788	771
Luxembourg	184	184	186	193	196
Malta	19	20	19	19	18
Netherlands	3,759	3,746	3,673	3,820	3,996
Poland	5,200	5,385	5,281	5,406	5,564
Portugal	1,443	1,441	1,407	1,443	1,439
Romania	2,808	2,861	2,934	2,819	2,684
Slovakia	540	528	508	502	488
Slovenia	451	453	454	480	470
Spain	6,653	6,464	6,184	6,585	6,020
Sweden	1,552	1,533	1,516	1,517	1,505
United Kingdom	10,745	10,545	10,335	10,075	9,910
Total EU 27	90,220	89,641	88,463	89,037	88,837

Source: Eurostat (retrieved from http://epp.eurostat.ec.europa.eu in September 2009).

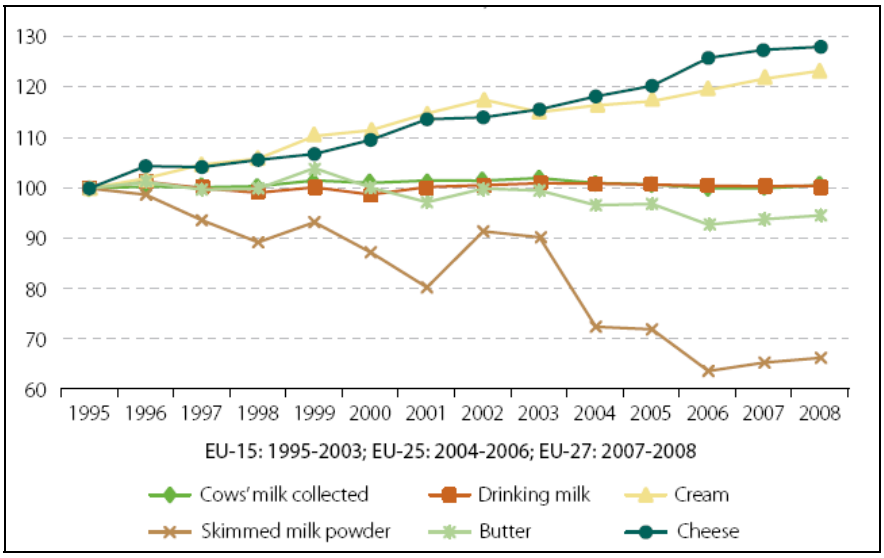
Table 20: Number of sheep (1,000)

	2004	2005	2006	2007	2008
Austria	327	326	312	351	333.2
Belgium	-	-	-	-	-
Bulgaria	1,693	1,602	1,635	1,526	1,475
Cyprus	279	269	272	292	267
Czech Republic	155	163	169	184	-
Denmark	88	84	98	98	-
Estonia	42	49	58	74	62
Finland	72	84	88	90	94
France	8,898	8,760	8,494	8,285	7,781
Germany	2,138	2,036	2,017	1,926	1,920
Greece	9,241	8,745	8,976	8,984	8,994
Hungary	1,397	1,405	1,298	1,232	1,236
Ireland	4,557	4,257	3,826	3,531	3,423
Italy	8,106	7,954	8,227	8,237	8,175
Latvia	39	42	41	54	67
Lithuania	22	29	37	43	48
Luxembourg	7	9	9	8	8
Malta	14	15	12	12	13
Netherlands	1,700	1,725	1,755	1,715	1,545
Poland	311	318	301	316	270
Portugal	3,541	3,583	3,549	3,356	3,145
Romania	7,425	7,608	7,678	8,469	8,882
Slovakia	321	321	333	347	n.a.
Slovenia	119	129	132	131	139
Spain	22,736	22,514	22,452	22,194	19,952
Sweden	456	480	506	521	521
United Kingdom	24,524	23,730	23,429	23,676	21,856
Total EU 27 [(a)]	98,208	96,236	95,703	95,653	89,872

Source: Eurostat (retrieved from http://epp.eurostat.ec.europa.eu in September 2009).

Note: (a) Data not available for all 27 Member States.

Figure 8: Collection of cows' milk and production of milk products in the EU



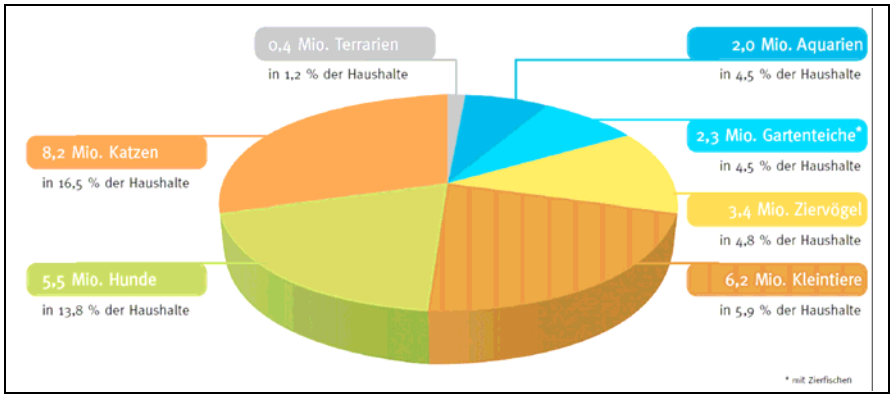
Source: Eurostat 2009, p. 102.

Table 21: Number of pets in the EU

	Number of pets in the EU (in millions, 2004)
Cats	60
Dogs	56
Birds	35
Aquaria	9
Others	40

Source: The European Pet Food Industry Federation (FEDIAF), available at: http://www.fediaf.org/gentree.htm.

Figure 9: Number of pets in Germany



Source: Industrieverband Heimtierbedarf 2009.

Table 22: Production of pig meat (in 1,000 tonnes of carcass weight) [(a)]

	2004	2005	2006	2007	2008
Austria	516	509	505	531	526
Belgium	1,032	1,013	1,006	1,063	1,056
Bulgaria	78	75	75	76	73
Cyprus	55	55	53	55	59
Czech Republic	426	380	359	360	336
Denmark	1,809	1,793	1,749	1,802	1,707
Estonia	38	38	35	38	40
Finland	198	204	208	213	217
France	2,311	2,274	2,263	2,281	2,277
Germany	4,308	4,500	4,662	4,985	5,111
Greece	137	130	123	122	119
Hungary	487	454	489	499	460
Ireland	204	205	209	205	202
Italy	1,590	1,515	1,556	1,603	1,606
Latvia	37	38	38	40	41
Lithuania	97	106	106	99	76
Luxembourg	11	11	10	10	10
Malta	8	9	8	8	9
Netherlands	1,287	1,297	1,265	1,290	1,318
Poland	1,923	1,926	2,071	2,091	1,888
Portugal	315	327	339	364	381
Romania	512	466	468	491	455
Slovakia	165	140	122	114	102
Slovenia	35	32	34	33	31
Spain	3,076	3,168	3,235	3,439	3,484
Sweden	294	275	264	265	271
United Kingdom	720	706	697	739	740
Total EU 27	21,669	21,645	21,948	22,819	22,596

Source: Eurostat (retrieved from http://epp.eurostat.ec.europa.eu in September 2009).

Note: (a) This indicator expresses the total carcass weight of pigs slaughtered in slaughterhouses and on the farm, whose meat is declared fit for human consumption.

Table 23: Production of cattle meat (in 1,000 tonnes of carcass weight) [(a)]

	2004	2005	2006	2007	2008
Austria	206	204	215	216	221
Belgium	281	267	269	273	267
Bulgaria	31	30	23	22	20
Cyprus	4	4	4	4	4
Czech Republic	97	81	80	79	80
Denmark	150	136	129	130	128
Estonia	15	13	14	15	15
Finland	91	87	87	89	83
France	1,580	1,554	1,510	1,532	1,518
Germany	1,263	1,167	1,193	1,185	1,210
Greece	62	58	61	58	57
Hungary	38	32	34	35	32
Ireland	563	546	572	581	537
Italy	1,151	1,114	1,111	1,127	1,059
Latvia	22	20	21	23	21
Lithuania	48	53	47	56	48
Luxembourg	11	10	9	9	10
Malta	1	1	1	1	1
Netherlands	381	396	384	386	378
Poland	298	306	355	365	386
Portugal	119	118	105	91	109
Romania	235	207	195	211	190
Slovakia	26	26	21	23	20
Slovenia	40	37	38	36	37
Spain	714	715	670	643	658
Sweden	142	136	137	134	136
United Kingdom	731	762	847	882	862
Total EU 27	8,299	8,083	8,132	8,204	8,090

Source: Eurostat (retrieved from http://epp.eurostat.ec.europa.eu in September 2009).

Note: (a) This indicator covers the carcass weight of bovine animals (calves, bullocks, bulls, heifers and cows) slaughtered in slaughterhouses and on the farm, whose meat is declared fit for human consumption.

Table 24: Production of sheep and goats meat (in 1,000 tonnes of carcass weight) [(a)]

	2004	2005	2006	2007	2008
Austria	8	7	0	0	8
Belgium	3	3	1	1	1
Bulgaria	20	24	23	21	21
Cyprus	7	7	7	7	7
Czech Republic	1	1	2	2	2
Denmark	2	2	2	2	2
Estonia	0	0	1	1	0
Finland	1	1	1	1	1
France	132	129	129	127	118
Germany	49	50	44	44	43
Greece	125	118	114	111	110
Hungary	1	1	1	1	1
Ireland	72	73	70	66	59
Italy	63	62	62	61	60
Latvia	0	0	0	0	1
Lithuania	1	1	1	1	1
Luxembourg	0	0	0	0	0
Malta	0	0	0	0	0
Netherlands	15	14	16	18	15
Poland	3	2	1	2	2
Portugal	12	12	13	14	12
Romania	60	61	64	73	65
Slovakia	1	2	1	1	1
Slovenia	0	0	0	0	0
Spain	245	238	226	207	166
Sweden	4	4	4	5	5
United Kingdom	314	332	330	325	326
Total EU 27 [(b)]	1,139	1,144	1,113	1,091	1,027

Source: Eurostat (retrieved from http://epp.eurostat.ec.europa.eu in September 2009).

Note: (a) This indicator covers the carcass weight of sheep, including lambs, and goats slaughtered in slaughterhouses or elsewhere whose meat is declared fit for human consumption.
(b) Data not available for all 27 Member States.

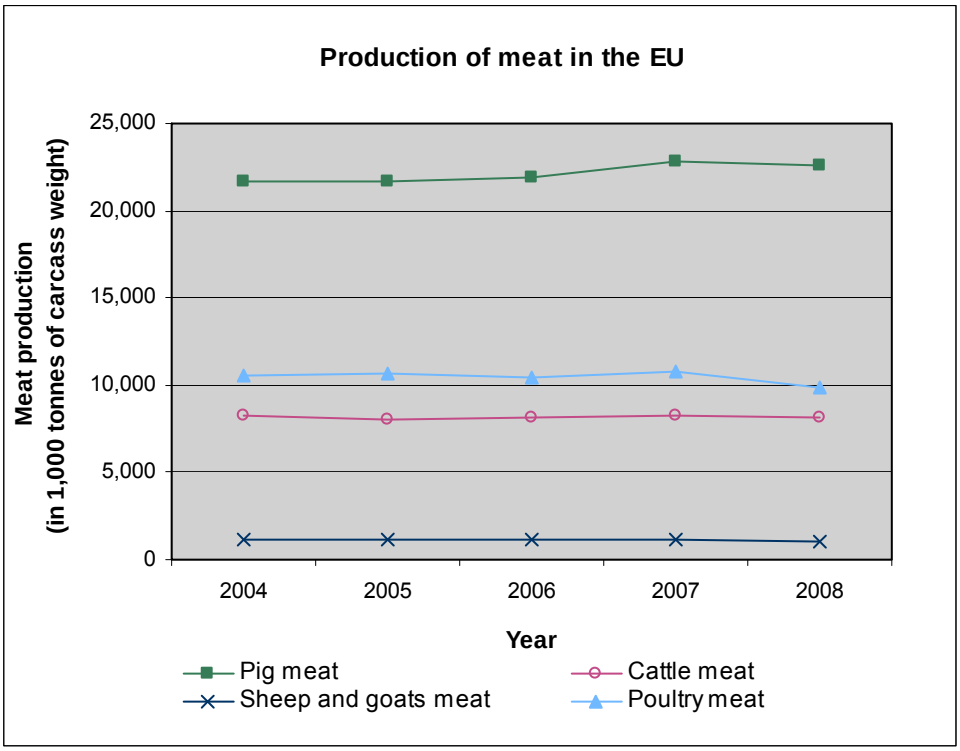
Table 25: Production of poultry meat (in 1,000 tonnes of carcass weight) [(a)]

	2004	2005	2006	2007	2008
Austria	107	107	102	109	109
Belgium	-	-	-	-	-
Bulgaria	85	98	107	116	91
Cyprus	32	33	27	29	29
Czech Republic	232	241	231	217	210
Denmark	188	186	170	171	176
Estonia	15	14	13	12	13
Finland	87	87	87	95	101
France	1,840	1,797	1,722	1,716	1,706
Germany	989	994	1,009	1,087	1,192
Greece	161	163	154	162	-
Hungary	384	375	385	376	388
Ireland	142	142	130	122	117
Italy	1,001	1,013	919	1,029	1,116
Latvia	14	17	21	21	23
Lithuania	49	57	66	68	71
Luxembourg	0	0	0	0	0
Malta	6	5	4	5	5
Netherlands	637	671	661	721	-
Poland	919	1,036	1,058	1,143	1,186
Portugal	248	251	247	271	284
Romania	300	292	266	305	-
Slovakia	90	92	94	84	78
Slovenia	52	53	48	59	59
Spain	1,268	1,287	1,261	1,328	1,375
Sweden	94	104	102	104	114
United Kingdom	1,564	1,582	1,517	1,454	1,433
Total EU 27 [(b)]	10,505	10,698	10,399	10,805	9,876

Source: Eurostat (retrieved from http://epp.eurostat.ec.europa.eu in September 2009).

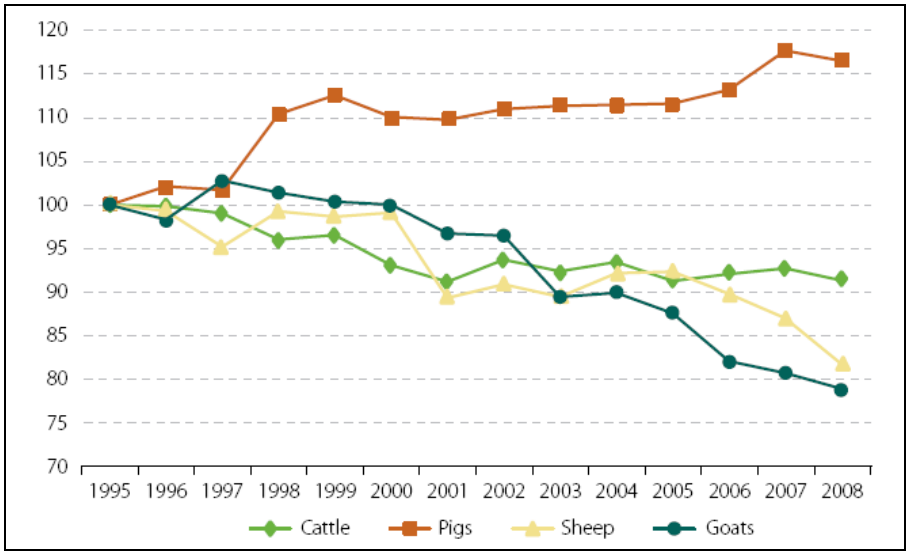
Note: (a) Total carcass weight of poultry slaughtered whose meat is declared fit for human consumption. The following poultry is included: hens, chicken, ducks, turkey, guinea fowls, geese. This indicator covers mainly the production of gallinaceae including broilers.
(b) Data not available for all 27 Member States.

Figure 10: Meat production in the EU



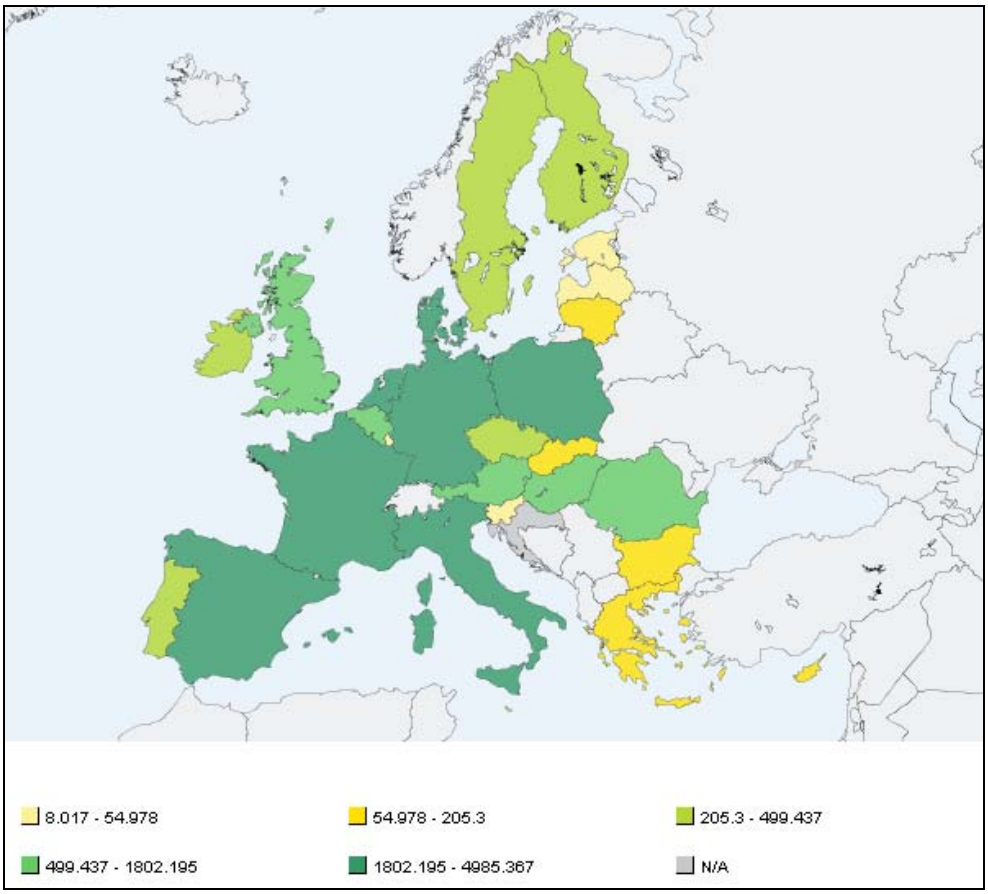
Source: Eurostat (retrieved from http://epp.eurostat.ec.europa.eu in September 2009).

Figure 11: Slaughter index (in tonnes) by species, EU



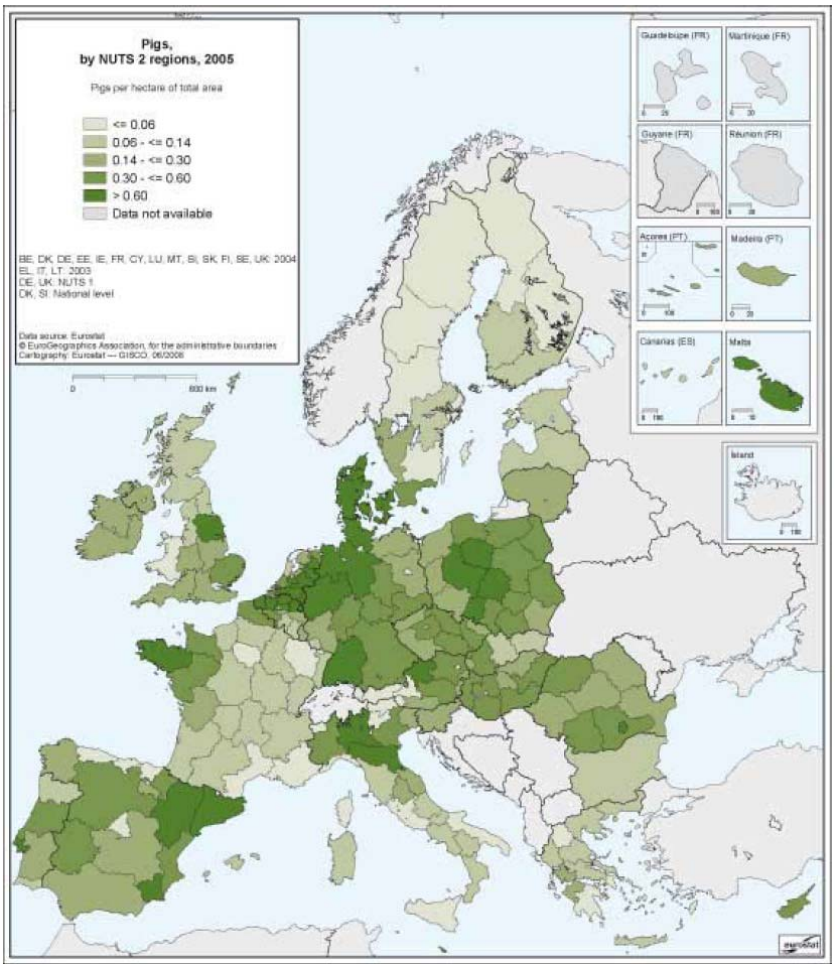
Source: Eurostat 2009.

Figure 12: Gross indigenous production of pig meat in 2007 (in 1,000 tonnes of carcass weight)



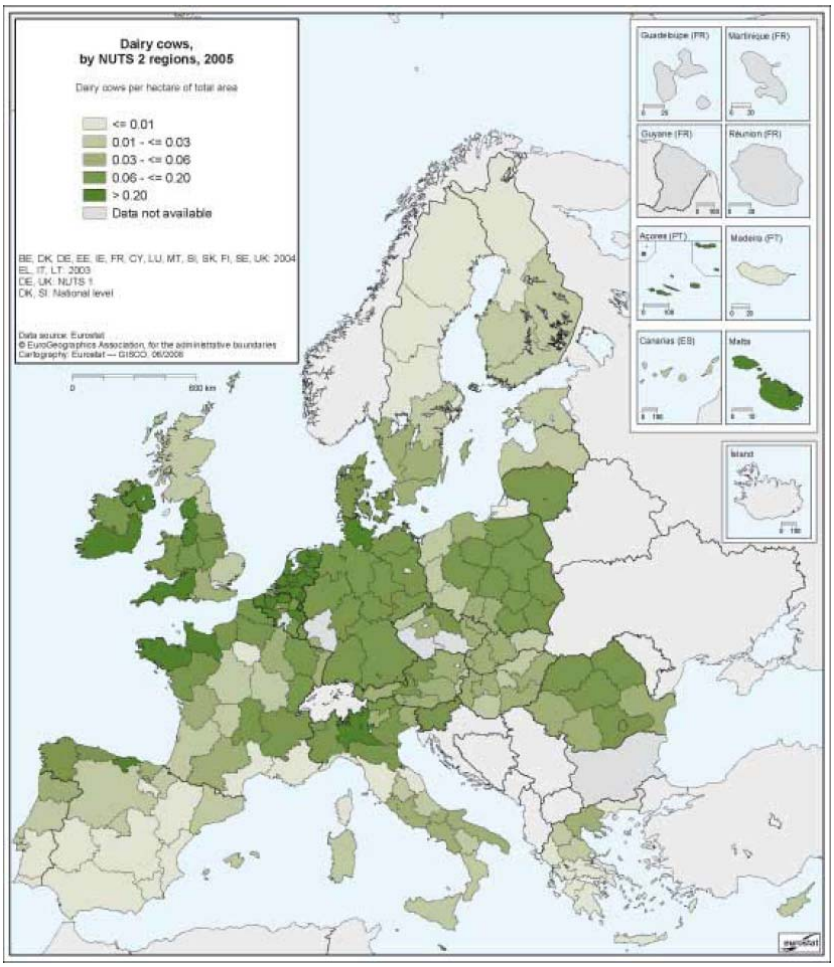
Source: Eurostat (retrieved from http://epp.eurostat.ec.europa.eu in September 2009).

Figure 13: Pigs per hectare of total area (2005)



Source: Eurostat (2009b).

Figure 14: Dairy cows per hectare of total area (2005)



Source: Eurostat (2009b).

Annex 4: Production of feed

Table 26: Industrial compound feed production (in 1,000 tonnes)

	2000	2001	2002	2003	2004	2005	2006	2007
Austria	1,011	1,029	1,085	1,124	1,136	1,140	1,200	1,286
Belgium	6,303	6,365	6,291	6,150	6,347	5,994	5,958	6,242
Bulgaria	561	555	475	480	613	669	685	710
Cyprus	240	238	230	234	220	283	290	289
Czech Republic	3,362	3,599	3,206	3,259	3,155	2,981	2,962	3,117
Denmark	6,128	6,045	5,782	5,562	5,630	5,329	5,206	5,205
Estonia	187	212	221	206	227	223	212	218
Finland	1,299	1,321	1,369	1,399	1,415	1,453	1,417	1,405
France	23,157	23,315	22,789	22,609	22,320	22,016	21,616	22,362
Germany	19,636	19,474	19,695	20,009	20,139	19,449	20,304	21,310
Hungary	5,288	5,564	5,610	5,123	4,759	4,500	4,456	4,180
Ireland	3,517	3,575	3,821	3,740	3,590	3,628	3,966	3,605
Italy	11,662	12,063	13,378	13,464	14,264	14,000	13,700	14,200
Latvia	169	173	200	233	239	191	208	203
Lithuania	327	327	327	244	284	299	355	520
Netherlands	14,655	14,251	13,349	12,846	13,078	12,979	13,491	13,730
Poland	4,270	4,598	4,741	5,559	5,464	5,276	6,341	7,053
Portugal	3,835	3,850	3,940	3,780	3,800	3,805	3,450	3,620
Romania	1,570	1,603	1,682	1,745	1,853	2,045	2,329	2,713
Slovakia	1,318	1,249	1,344	1,279	1,082	1,002	1,069	990
Slovenia	526	526	504	503	501	484	474	495
Spain	17,125	18,486	19,648	19,425	20,339	20,988	19,218	20,300
Sweden	2,371	2,418	2,361	2,324	2,241	2,146	2,109	2,190
United Kingdom	13,647	13,998	13,674	13,718	14,085	13,770	14,115	14,341
Total EU 27 [(a)]	**142,164**	**144,834**	**145,722**	**145,015**	**146,781**	**144,650**	**145,131**	**150,284**

Source: European Feed Manufacturers Federation (FEFAC) 2007b.

Note: (a) No data available for Greece, Luxembourg and Malta.

Table 27: Compound feed industry turnover (current value of production in millions of Euro)

	2000	2001	2002	2003	2004	2005	2006
Austria	255	260	265	275	290	305	330
Belgium	1,536	1,639	1,591	1,622	1,780	1,620	1,635
Bulgaria	-	-	-	-	-	-	-
Cyprus	-	-	-	-	40	50	53
Czech Republic	-	-	-	-	631	675	549
Denmark	1,151	1,254	1,250	1,132	1,151	1,067	1,022
Estonia	-	-	-	-	45	44	42
Finland	340	325	331	330	328	323	318
France	5,640	5,850	5,680	6,356	6,400	6,300	6,350
Germany	3,897	3,855	4,168	3,881	4,500	4,020	3,940
Hungary	-	-	-	-	1,190	1,200	1,220
Ireland	714	725	832	818	820	788	900
Italy	4,000	4,300	4,500	4,500	5,100	4,900	4,950
Latvia	-	-	-	-	60	38	52
Lithuania	-	-	-	-	61	65	63
Netherlands	3,285	3,620	3,284	3,110	3,400	3,120	3,500
Poland	-	-	-	-	1,226	1,398	1,720
Portugal	956	960	945	945	950	951	906
Romania	-	-	-	-	-	-	-
Slovakia	-	-	-	-	185	198	201
Slovenia	-	-	-	-	115	115	115
Spain	3,750	4,030	4,120	4,418	5,183	5,860	4,896
Sweden	550	570	540	500	510	465	500
United Kingdom	2,926	3,115	2,960	2,936	2,714	2,680	2,840
Total EU [(a)]	**29,000**	**30,503**	**30,466**	**30,823**	**36,679**	**36,182**	**36,102**

Source: European Feed Manufacturers Federation (FEFAC) 2007b.

Note: (a) EU-12 until 1993, EU-15 from 1994 until 2003, EU-25 from 2004. No data available for 2007. No data available for Bulgaria, Greece, Luxembourg, Malta and Romania.

Annex 5: Data on sales of veterinary medicinal products

Table 28: Sales of antimicrobials in selected Member States for food and non-food producing animals (in tonnes of active ingredient)

	2002	2003	2004	2005	2006	2007
Denmark [(a)]	96	103	113	113	115	121
Finland [(b)]	13.8	13.2	13.1	13.4	13.6	14.1
France [(c)]	1,337	1,309	1,278	1,325	1,263	1,349
Netherlands [(d)]	406	394	453	508	542	590
Sweden [(e)]	17.3	16.0	16.1	16.4	17.2	17.1
United Kingdom [(f)]	440	435	454	446	405	387

Note: For Denmark and Finland, data refer to food producing animals only.

Sources:

(a) DANMAP (2008). *DANMAP 2008 - Use of antimicrobial agents and occurrence of antimicrobial resistance in bacteria from food animals, foods and humans in Denmark* and communication with Central Veterinary Institute of Wageningen UR, Lelystad

(b) Finish Food Safety Authority (Evira) (2007). *FINRES-Vet 2005-2006 - Finnish veterinary antimicrobial resistance monitoring and consumption of antimicrobial agents* and communication with the Finnish Medicines Agency

(c) Agence française de sécurité sanitaire des aliments (AFSSA) (2009). *Suivi des ventes de médicaments vétérinaires contenant des antibiotiques en France en 2008.*

(d) Fabrikanten en Importeurs van Diergeneesmiddelen In Nederland (FIDIN). *Antibioticarapportage 2002, 2003, 2004, 2005, 2006 and 2007* (available at: http://www.fidin.nl/686/Antibioticumbeleid.html).

(e) National Veterinary Institute Sweden (2008). *SVARM 2007 - Swedish Veterinary Antimicrobial Resistance Monitoring.*

(f) Veterinary Medicines Directorate (2008). *Sales of antimicrobial products authorised for use as veterinary medicines, antiprotozoals, antifungals, growth promoters and coccidiostats, in the UK in 2007.*

Annex 6: EC questionnaire

EUROPEAN COMMISSION
HEALTH & CONSUMERS DIRECTORATE-GENERAL

Directorate D - Animal Health and Welfare
D2-Feed

SANCO
25. 06. 2009

Brussels,
SANCO/D2/WT/ci/ D(2009)420169

NOTE FOR THE ATTENTION OF THE HEADS OF DELEGATION OF THE STANDING COMMITTEE ON THE FOOD CHAIN AND ANIMAL HEALTH SECTION ANIMAL NUTRITION

Subject: Revision of Directive 90/167 on medicated feed

I refer to the discussions at the last meeting of the Standing Committee on the Food Chain and Animal Health, section Animal Nutrition, on 19 June 2009 concerning the revision of the medicated feed Directive.

The oral administration of veterinary medicinal products (VMPs) via feed is one option for the animal holder. Directive 90/167/EEC sets out the conditions under which medicated animal feedingstuffs may be prepared, placed on the market and used within the Community.

In line with requests from the Member States and the stakeholders, the Commission services launched the preparatory works for the proposal of a legal act to streamline the provisions for medicated feed with the other pieces of feed legislation.

In this context Member States are asked to deliver information available to them on the following issues to the Commission:

(1) Number of approved operators in your country for the placing on the market of medicated feed:

Manufacturing establishments:

↳thereof mobile mixers:

↳thereof on farm producers (Art. 4(2)):

Distributors (Art. 9(2)):

(2) Authorised medicated pre-mixes (Art. 3)

Number in 2004

2005

2006

2007

2008

Commission européenne, B-1049 Bruxelles / Europese Commissie, B-1049 Brussel - Belgium. Telephone: (32-2) 299 11 11.
Wolfgang Trunk, Office: F101 00/58. Telephone: direct line (32-2) 298 63 75. Fax: (32-2) 296 36 15.

If possible indicate in detail the main groups of VMPs currently authorised in the medicated pre-mixes.

(3) Rules for good manufacturing practice (Art. 4 (1d))

Are such rules established in your Country (if yes, please indicate the link to their publication)?

If yes, is their concrete application mandatory by law?

(4) National implemention and official controls

How is the implementation of the Directive organised in your Country especially in terms of
- authorisation of establishments and medicated pre-mixes and
- official controls on the compliance with the legal provisions.

(5) Experiences with the practice of oral administration of VMPs:

What kind of experiences are available in your Authority concerning safety aspects in the field of manufacturing and use of VMPs via medicated feed?

What kind of experiences are available in your Authority concerning safety aspects in the field of the oral use of VMPs in other ways of administration such as through water, top dressing or incorporation of ready-to-use VMPs in the feed by the livestock farmer?

We would appreciate to have your replies by fax to SANCO-unit D2 (0032 2 2963615) or by email to wolfgang.trunk@ec.europa.eu before end of July 2009. On question (5) additional comments are welcome as well at a later date.

For further questions please contact directly Wolfgang Trunk (tel.: 0032 2 2986375) or Ana-Maria Cucuteanu (0032 2 2999588).

Yours sincerely,

Willem PENNING

cc: Ms P Testori-Coggi, Mr. B. Van Goethem, Mr E. Poudelet, Mr M. Scannel, A. Laddomada Mr W. Penning, Ms C. Garau, Mr S. Giraud, Ms N. Robinson, Mr L. Terzi, Mr W. Trunk, Mr M. Terberger (DG ENTR)

Annex 7: Responses of competent authorities to EC questionnaire

Table 29: Number of approved operators for the placing on the market of medicated feed

	Number of approved manufacturing establishments			Distributors (Art. 9(2))
	Total number	Thereof mobile mixers	Thereof on farm producers (Art. 4(2))	
Austria	3,986 [a]	n.a.	3,986	0 [b]
Belgium	63	10	0	0 [c]
Bulgaria	6	0	n.a.	n.a.
Cyprus	47	0	47	16 [d]
Czech Republic	71 [e]	0	0	13
Denmark	15	0	0	4
Estonia	6	0	0	0 [f]
Finland	15 [g]	0	0	1
France	247 [h]	0	19	241 [i]
Germany	31 [j]	3	0	0
Greece	n.a.	4	1	0
Hungary	133	0	0 [k]	0 [l]
Ireland	84	0	62	22
Italy	~ 1000	0	~ 700 [m]	~ 230
Latvia	7	0	5 [n]	0
Lithuania	n.a.	n.a.	2	n.a.
Luxembourg	2	0	0	0
Netherlands	115	0	0	1
Norway	2	0	0	28 [n]
Poland	56	0	0	71
Portugal	n.a.	37	9	22
Romania	17	n.a.	n.a.	9
Slovakia	30	0	0	53
Slovenia	8	0	1	0
Spain	543	0	175	652
Sweden	63 [p]	0	50	0
United Kingdom	734 [q]	10 – 12	640	366

Source: Survey of competent authorities.

Notes:

(a) No manufacturer (feed mill) is authorised for manufacturing and placing on the market of medicated feed at present. For 3 manufacturers the authorisation procedure is in progress.
(b) No distributor of medicated feed is authorised at present; the authorisation procedure is in progress for one distributor.
(c) This is not foreseen in national rules.
(d) Includes 14 commercial mills/distributors and 2 distributors.
(e) 71 manufacturers are approved; this corresponds to 81 manufacture sites.
(f) 13 distributors (Art. 9(1)) are approved by the competent authority. There are no authorised distributors for sepecial cases of medicated feedingstuffs (Art. 9(2)).
(g) Includes 3 establishments manufacturing medicated feed for food producing animals and 12 establishments manufacturing medicated feed for fur animals.
(h) 164 establishments have both the status of manufacturer and distributor. 64 establishments have the status of manufacturers of medicated feed only.
(i) 64 establishments have the status of manufacturers of medicated feed only. No mobile mixers have been approved. 77 establishments have the status of distributors only.
(j) Includes 5 enterprises which currently do not make use of the permit, 10 enterprises with limited permit and 3 mobile mixers.
(k) Small units producing medicated feed on-the-spot do not exist, however, large plants authorized by the competent authority, producing medicated feed exclusively for the purposes of their own establishments or even for placing on the market do exist. In the latter case they are located separately from the animal holding, even if located on the same site.
(l) Medicated feed is placed on the market only by the manufacturing establishments.
(m) There are also approximately 948 farmers that are approved for using “intermediate products” for the exclusive requirements of their own farm. “Intermediate products” are medicated feed that contain multiple of daily dosage of VMP (max 20 times) and are intended to production of medicated feed ready to use.
(n) Farms producers include 4 fur animal farms and 1 pig farm.
(o) Includes both wholesalers and distributors (both approved Premix and Zink).
(p) Includes 13 feed mills.
(q) Includes 94 feed mills. Additionally, 39 establishments manufacture intermediate products from medicated pre-mixes intended to be mixed into final feed (Art. 3 1. first indent).

(n.a.: no information available)

Table 30: Number of authorised medicated pre-mixes in the EU

	2004	2005	2006	2007	2008
Austria	41	43	44	48	57
Belgium	n.a.	23	24	27	34
Bulgaria	1 *(1)*	3 *(2)*	6 *(3)*	11 *(5)*	22 *(12)*
Cyprus	24	24	27	31	38
Czech Republic	53	55	60	61	66
Denmark	12	13 *(1)*	16 *(3)*	16	15 *(1)*
Estonia	23	22	20	21	17
Finland	10	10	11	12	12
France	*(1)*	*(15)*	*(7)*	*(8)*	312 (a) *(3)*
Germany	60	55	61	65	64
Greece	34	34	30	39	36
Hungary	n.a.	n.a.	n.a.	n.a.	n.a.
Ireland	*(5)*	*(4)*	*(6)*	*(7)*	*(11)*
Italy	87	92	96	100	103
Latvia	*(2)*	*(4)*	*(5)*	*(2)*	*(2)*
Lithuania	*(2)*	*(1)*	*(0)*	*(3)*	21 (b) *(0)*
Luxembourg	5	7	7	9	12
Netherlands	n.a.	n.a.	n.a.	n.a.	52 (c)
Norway	3	4	4	4	4
Poland	n.a.	n.a.	n.a.	n.a.	58 (d)
Portugal	*(3)*	*(2)*	*(2)*	*(5)*	157 (e) *(12)*
Romania	53 *(14)*	53 *(8)*	63 *(15)*	60 (f) *(6)*	59 (g) *(8)*
Slovakia	n.a.	n.a.	n.a.	n.a.	n.a.
Slovenia	23	21	20	14	11
Spain	*(11)*	*(7)*	*(10)*	*(13)*	*(8)*
Sweden (h)	18	17	14	14	14
United Kingdom	55 *(1)*	60 *(7)*	50 *(0)*	53 *(3)*	53 *(4)*

Source: Competent authorities.

Note: **New authorisations** of medicated pre-mixes per year are indicated in brackets.

(a) Data refers to the total number of authorised medicated pre-mixes as of August 2009. The total number of medicated pre-mixes authorised (312) includes 19 medicated pre-mixes for which authorisations are currently suspended.
(b) Data refers to the number of authorised medicated pre-mixes as of August 2009.
(c) Data refers to the number of authorised medicated pre-mixes as of August 2009. According to the competent authority, due to the authorisation system used in the Netherlands, it is not possible to reproduce lists of VMP of precedent years.
(d) The competent authority provided a list of 58 authorised pre-mixes.
(e) Data refers to the number of authorised medicated pre-mixes as of August 2009.
(f) Figure includes 6 medicated pre-mixes prohibited for food producing animals.
(g) Figure includes 3 medicated pre-mixes prohibited for food producing animals.
(h) Figures relate to the number of medicated pre-mixes reported to be in use to the Swedish Board of Agriculture.

Table 31: Main groups of VMPs currently authorised in the medicated pre-mixes

	Main groups of VMPs currently authorised in the medicated pre-mixes.
Austria	-
Belgium	Antibiotics, anthelmintics, anti-inflammatory agents
Bulgaria	75% antibacterial substances; 25% antiparasitic substances
Cyprus	-
Czech Republic	Antibiotics (chlortetracycline, penicilin, sulfonamide, macrolide, pleuromutiline, chinolon, linkosamid) Antiparazitic Zinc, antipyretics
Denmark	Today, in total 17 medicinal pre-mixes are authorized. Medicinal substances: Acetylvaleryltylosin, apramycin sulphate, Yersenia vaccine, Chlortetracycline, Oxolin acid, Valnemulin Hydrochloride, Ivermectin, Florfenicol, Paracetamol, Doxycyclin hyclate, Tilmicosin phosphate, Amoxicillin, Sulfadiazin and Trimethoprim, Tylosin phosphate
Estonia	Anti-infectious agents and antiparasitics
Finland	From the authorised pre-, there are 10 belonging to the group "QJ" (*microbial* medicines) and 4 to the group "QP" (agents acting against ectoparasites)
France	Antibiotics: polypeptides, sulfamides, macrolides, penicillins, tetracyclines, aminosides, quinolones, with principally colistine, oxytetracycline, chlortetracycline, apramycine, tylosine, sufadimethoxine trimethoprim (TMP sulfa), tiamuline, tilmicosine, lincospectine. Antiparasitics: flubendazole, oxybendazole, decoquinate Antifungals: parconazole
Germany	Of 61 premixes authorised in Germany there are currently 52 antibiotic substances and 9 antiparasitic substances
Greece	The main groups of VMPs currently authorised in the medicated pre-mixes are antibacterials that belong to penicillins, tetracyclines or sulphonamides+trimethoprim, and anthelminthics (benzimidazoles, ivermectin). To a lesser extent there are also aminoglycosides, macrolides, polymyxins, tiamulin and florfenicol.
Hungary	-
Ireland	-
Italy	Antibiotics
Latvia	The main groups of Veterinary medicinal products currently authorised in the medicated pre–mixes are: antibacterials, antiparasitcals, nonsteroidal anti- inflammatory drugs.
Lithuania	-
Luxembourg	1 anti-inflammatory, 3 anthelmintics, 8 antibacterial
Netherlands	-
Norway	NSAID – 1 (ATCvet QM), Antibacterial – 3 (ATCvet QJ), Antiparasitical – 1 (ATCvet QP)
Poland	-
Portugal	-
Romania	The premixtures contain antibiotics, chimiotherapics and antiparasitic substances and most frequently found in curently authorized medicated premixtures substances are: amoxicillin, lincomycin, tiamulin, florfenicol and ivermectin.
Slovakia	-
Slovenia	-
Spain	-

Sweden	-
United Kingdom	2009: Antimicrobials: 37 Anthelmintics: 6 Antiprotozoal anticoccidial: 2 Gastroint – bloat treatments: 2 Antimycotic – treatment of ringworm in horses: 1 Anti inflammatory – pyrexia in pigs: 1 Ectoparaciticide – treatment of salmon louse: 1 = 50

Source: Survey of competent authorities.

Table 32: Rules of good manufacturing practice (Art. 4(1d))

	Are rules of good manufacturing practice (Art. 4(1d)) established in your Country? If yes, is their concrete application mandatory by law?
Austria	Following rules are in force: • Fütterungsarzneimittelbetriebsordnung 2006, BGBl II Nr. 394/2006 • § 6 Tierarzneimittelkontrollgesetz, BGBl I Nr. 28/2002 • Tiergesundheitsdienst-Verordnung 2005, BGBl II Nr. 443/2005 • TAKG-Ausbildungsverordnung, BGBl II Nr. 194/2002 • Kundmachung betreffend Leitlinien im Sinne des § 6 Tierarzneimittelkontrollgesetz idgF über die Herstellung von Fütterungsarzneimitteln am landwirtschaftlichenBetrieb, GZ 74200/11-IV/B/5/07
Belgium	The main principles and ideas of Directive 90/167/EEC on medicated feed were transposed into Belgian legislation by way of the Royal Decree of 21 december 2006 (repealing the Royal Decree of 30 march 1995). This "framework" decree describes the general rules as regards the production, the distribution and the use of medicated feed. Link: *https://portal.health.fgov.be/portal/page?_pageid=56,513318&_dad=portal&_schema=PORTAL* Besides this framework Decree, the Royal Decree of 21 february 2006 (art. 5 + annex III) fixes the precise conditions for approval of establishments manufacturing medicated feed. Annex III contains rules on good manufacturing practices for medicated feed. Link: *http://www.favv.be/sp/pa/doc/alim_ani/KB-21-02-2006.pdf* It is obvious that the application of the rules described in the abovementioned Decrees are mandatory by law. Further on, the FASFC (Food Agency) has elaborated specific instructions and a protocol for the production of medicated feed at time of delivery on farm via mobile mixers (fixed on a truck). For more details, see *http://www.favv.be/sp/pa/aliment-ani_fr.asp#dosage* (go to subtitle: "Appareil de dosage de précision pour l'incorporation à la ferme de prémélanges médicamenteux dans les aliments composés"). Finally, the compound feed sector in Belgium has developed a sectorial GMP Guide for the production and trade in compound feedingstuffs. This guide is publically available at *http://www.ovocom.be/GMP2008.aspx?lang=fr.* In part A of this guide there is a specific chapter on the "production of compound feedingstuffs" (ref. AC-02) which also contains some specific rules concerning the production of medicated feedingstuffs (see point 13).
Bulgaria	The Bulgarian feed manufacturers association has prepared Guidelines on application of Good Manufacturing Practices and HACCP system in feed establishments. The Guidelines include specific requirements for medicated feed. Guidelines are distributed on paper. Medicated feed manufacturers are required to apply the GMP and HACCP, regulated in Ordinance No 20 of medicated feed. Control is assigned to the National Veterinary Service (NVS).
Cyprus	A Guidance for Good Practice of Manufacturing medicated feedingstuffs was established in 2006 and the revised document is available at the Veterinary Services website: http://www.moa.gov.cy/vs The application is not mandatory by law
Czech Republic	The link to their publication: • Act No.378/2007 Coll. on Pharmaceuticals and on Amendments to Some Related Acts (the Act on Pharmaceuticals) - in particular section 73, paragraph 2 and section 64 Comment: definition in section 2 paragraph 2, b) of Act No.378/2007 Coll. „…. veterinary medicinal product shall mean medicated feedingstuffs and not additives". Medicated feedingstuffs are (in accordance with Dir. 2001/82/EC, in later amendments, Article.1, point 6. which is transposed to the Czech law - Act No.378/2007 Coll. on pharmaceuticals) considered as medicines

	in the Czech Republic. • Decree No.229/2008 Coll. about manufacture and distribution of medicaments (rules for good manufacturing and distribution practice) – in particular Good manufacturing Practice (GMP) for Medicated Feedingstuffs - Part Five - Section 29 and Part Three (general GMP rules) of decree. The application is mandatory by law.
Denmark	No.
Estonia	We do not have national rules for good manufacturing practice.
Finland	The Finnish Food and Drink Industries's Federation has published a national guide to good practise for the industrial compound feed and premixtures manufacturing sector for food producing animals. The guide is compiled by the Finnish Food and Drink Industries' Federation (Elintarviketeollisuusliitto ry). The guide has been published in internet http://www.etl.fi/julkaisu/PDF/FFMC_05_02_2009.pdf . The guide is based on the EFMC community guide. The section regarding good practise for medicated feed will be revised once the EFMC guide has been finalised for that particular area. The application is not mandatory by any law.
France	La fabrication industrielle et la préparation par l'utilisateur ("préparation à la ferme") sont soumises en France à des bonnes pratiques de fabrication ou de préparation. Ces dispositions sont prévus par deux articles législatifs (articles L. 5142-3 et L. 5143-1 du Code de la santé publique) qui prévoient que les principes de ces bonnes pratiques soient pris par décision du directeur général de l'AFSSA: Ces bonnes pratiques sont fixées par: • Décision du 12 février 2007 relative aux bonnes pratiques de fabrication et de distribution en gros des aliments médicamenteux • Arrêté du 9 juin 2004 relatif aux bonnes pratiques de préparation extemporanée des médicaments vétérinaires (arrêté interministériel pris antérieurement à la disposition législative précitée, article L. 5143-1, qui prévoit désormais une décision du directeur général de l'AFSSA).
Germany	Fütterungsarzneimittel unterliegen in Deutschland dem Arzneimittelgesetz und den darauf gestützten Verordnungen. Danach gilt für die Herstellung Teil I des EG-GMP-Leitfadens, wobei die sich nach dem Stand der Wissenschaft ergebenden Besonderheiten von Fütterungsarzneimitteln zu berücksichtigen sind. Die Expertenfachgruppe „Fütterungsarzneimittel" der für die Überwachung zuständigen Länder hat für die Anwendung des GMP-Leitfadens das „Merkblatt für Antragstellung auf Erteilung einer Erlaubnis zur Herstellung von Fütterungsarzneimitteln aus Arzneimittel-Vormischungen nach § 13 Abs. 1 des Arzneimittelgesetzes" entwickelt. Link: http://www.zlg.de/download/AM/EFG/EFG14/Merkblatt_Stand_060613.pdf
Greece	Commission Directive 91/412/EEC (of 23 July 1991 laying down the principles and guidelines of good manufacturing practice for veterinary medicinal products) has been implemented in Greece by the 94/313314/GMD Greek Ministerial Decision. Circular 98/310584 refines particular matters.
Hungary	In Hungary the production conditions of medicated feed, such as provisions for medicated premixes to be used for the production of medicated feed are laid down in national legislation which is obviously mandatory. The following pieces of legislation apply currently to the field: • Decree of the Minister of Agriculture and Rural Development 50/2006. (VI. 28.); • Decree of the Minister of Agriculture and Rural Development 43/2003. (IV. 26.); • Decree of the Minister of Agriculture and Rural Development 44/2003. (IV. 26.);
Ireland	The European Communities (Animal Remedies and Medicated Feedingstuffs) Regulations 1994 (S.I. 176 of 1994) transposed EU Directive 90/167. Regulation 6(1)(e) gives effect to Art 4 (1d).
Italy	Circolare 23 gennaio 1996 n.1 and the document "Production of medicated feed, measures for reducing cross- contaminations" in the Ministry LSPS' website at the following link: http://www.ministerosalute.it/alimenti/sanita/documenti/fen_cont_crociata.pdf

	The above mentioned documents provide mainly indications about the way to put into practice the requirements of national and Community law, the most requirements of these guidelines are mandatory by law.
Latvia	There are not elaborated rules for good manufacturing practice in Latvia.
Lithuania	There are no approved rules for good manufacturing practise for medicated feed in Lithuania yet.
Luxembourg	None
Netherlands	These rules are established as from 1992 in the GMP Standards by the Product Board Animal Feed, a statutory regulatory industrial organisation. The current standard is the GMP+-Certification Scheme Animal Feed Sector 2006 (http://www.pdv.nl/english/kwaliteit/GMP_2006/page2398.php) Companies in the animal feed sector can join voluntary. However, app. 95% of the companies active in any way animal feed in The Netherlands have joined this scheme. Worldwide over 10.000 companies are certified according to these standards.
Norway	The rules can be found under: http://www.lovdata.no – Regulations on Medicated Feedingstuffs and EU GMP. *Their concrete application is mandatory by law.* Requirements for starting materials ("pure substances"): Before the feed mill signs a contract with a manufacturer, it must be proven that the manufacturer is qualified: 3 different lots with different batch numbers (minimum 2 different batch numbers) of the starting material should be tested according to the European Pharmacopea (Ph. Eur.). For each shipment, when purchased directly from original active substance manufacturer: -Sealed shipment to avoid ID testing -Batch number on each unit -Certificate of Analysis for each shipment -Requirements in the Ph. Eur. must be fulfilled -The manufacturer must be audited -Full reanalyses must be done yearly -Written contract with manufacturer, specifying quality, terms/conditions, shipment details If the substance is purchased from a wholesaler/agent, each shipment must be tested according to Ph. Eur. Requirements for testing of finished product (medicated feed): Each batch to be analysed. Preferably complete finished-product-control, as a minimum quantitative determination of active ingredient. Level of testing should be in accordance with GMP (Good Manufacturing Practice) and general requirements for manufacturing of non-sterile medicinal products.
Poland	The Chief Veterinary Inspectorate has prepared Instruction of the Chief Veterinary Officer of 23 October 2007 No. GIWpuf-700pl./96/2007 *on standardization of principles of conduct of the bodies of the Veterinary Inspection within the territory of the Republic of Poland while supervising manufacture, trade, distribution and use of medicated feedingstuffs in animal nutrition.* Moreover, due to execution of Polish-Danish project PL2005/IB/AG/09/TL "Strengthening veterinary administration in the scope of control over animal feedingstuffs and soil fertilizers" the Polish Veterinary Administration had training materials containing, among others, guidelines for Good Manufacture Practice and the HACCP system in the scope of manufacture and placing on the market feedstuffs and medicated feedingstuffs prepared. Medicated feedingstuffs manufacture plants are obliged to perform internal control, within which they collect samples of medicated feedingstuffs for analyses for homogeneity and active substance content in 1 g of the feedinfstuff. Similar analyses are performer by the Veterinary Inspection within official control.
Portugal	This can be found under: http://www.dgv.min-agricultura.pt/medicamentos_veterinarios/docs/alimento-medicamntoso-Normas_orientativas_documentacao_para_o_fabrico_e_distribuicao.pdf

	Their concrete application is: "Just for orientation"
Romania	In Romania, the legislation in the field of veterinary medicinal products forces the producers to meet the requirements of the Community Guide of Good Manufacturing Practices for medicinal products of human and veterinary use published on EC website (http://ec.europa.eu/enterprise/pharmaceuticals/eudralex/vol4_en.htm). This guideline, containing in annex 4 specific provisions for medicated premixtures, was translated by the Competent Authority and published with the assistance of the National Association of Veterinary Products Manufacturers. Furthermore, as far as the manufacture of feed is concerned, there is, at national level, a voluntary Guideline of Good Manufacture Practices for compound feed production, published under the National Sanitary Veterinary and Food Safety Authority supervision.
Slovakia	Observance of rules EEC 91/412 GMP about medicaments with consequence of keeping guidelines GMP IV part 1 (article 4) – premixes registered like medicaments, with keeping ANNEX VICH Q2 about treatments of stability. Slovak law No. 140/1998 Z.z. about medicaments and sanitary tools Slovak law No. 39/2007 Z.z. about veterinary care Slovak government Regulation 41/2004 Z.z. of preparation, operating and application in the market medicated feed.
Slovenia	Most feed manufacturers are members of the Feed Manufacturers' Section of the Chamber of Commerce and Industry of Slovenia, which in turn is a member of the European Compound Feed Manufacturers' Federation (FEFAC). Members of this Section are bound to comply with the FEFAC Guidelines in manufacturing the compound feedingstuffs and premixes. However, the adherence to the Guidelines is not mandatory under law.
Spain	There are not official published rules for good manufacturing practice. These rules should be implemented by the manufactures according to their specific premises. The CA must verify, by inspection, the efficacy of such practices. In particular homogeneity, stability and suitability for conservation and marketing should be checked by random sampling (art. 18. Real Decreto 157/1995, de 3 de febrero, sobre condiciones de preparación, de puesta en el mercado y de utilización de los piensos medicamentosos) However Spanish authorities are now in the process of amending the Regulation currently in practice (Real Decreto 109/1995) in order to achieve the requirements of Annex II of Council Regulation 183/2005. In particular, medicated feedingstuffs manufactures must have comply with the HACCPP principles especifically designed for medicated feedingstuffs. This new Royal Decree amending Royal Decree 109/1995 which introduces hygiene rules in compliance with Council Regulation 183/2005 will be officially available from 1st September and it includes an approach to such rules and specific requirements for Intermediate (feed) products among other considerations.
Sweden	No specific rules for good manufacturing practice are established in Sweden.
United Kingdom	There are no nationally approved (by the CCA) Industry Codes in the UK. According to Annex IV of the EFMC there are no nationally approved codes for farmers. However manufacturers are required to comply with the Veterinary Medicines Regulations 2008 which implements 90/167 and 183/2005 and guidance is provided in Veterinary Medicines Guidance Notes 21 and 22 on the VMD website. Complying with the Regulations is mandatory. http://www.opsi.gov.uk/si/si2008/pdf/uksi_20082297_en.pdf http://www.vmd.gov.uk/General/VMR/vmgn.htm In addition, feed mills have access to industry guides related to the Agricultural Industries Confederate (AIC) or the Universal Feed Assurance Scheme (UFAS) and farmers to the guides related to the NFU or the various Farm Assurance Schemes. These are voluntary guides and are not approved by the CCA. http://www.agindustries.org.uk/content.output/93/93/Trade%20Assurance/Trade%20Assurance%20Schemes/UFAS.mspx

Source: Survey of competent authorities.

Table 33: National implementation and official controls

	How is the implementation of the Directive organised in your country, especially in terms of authorisations of establishments and medicated pre-mixes and official controls on the compliance with the legal provisions?
Austria	In accordance with Austrian legislation medicated feedingstuffs are defined as veterinary medicinal products and therefore under the responsibility of the Federal Ministry of Health as competent authority. The official controls and registrations of distributors and feed mills producing medicated feed are carried out by the Federal Office for Safety in Healthcare. The inspection focuses on the implementation of the rules laid down in the *Fütterungsarzneimittelbetriebsordnung* 2006. Farmers are registered by the District Administrative Authority for on-farm mixing of medicated feed provided they are members of the Animal Health Service, have a contract with a veterinary practitioner and have participated in a training program. The District Administrative Authority (official veterinarians) is responsible for the control of the use of medicated pre-mixes and feed on farms. The controls at the farms are carried out by means of checklists including following issues: − daily documentation of manufacturing (type and amount of medicated premixes, used feed, manufactured and stored medicated feed) − existence of veterinarian receipt and instruction − storing of medicated feed − existence of registration for manufacturing medicated feed − check of mixing machine (e.g. hygiene) − training
Belgium	In Belgium, the competences in the field of medicated feed and pre-mixes are divided as follows: − the Federal Agency for Medicines and Health Products (FAMHP) is responsible for the authorisation of medicated pre-mixes, which are clearly considered to be veterinary medicinal products; − the FAMHP is also responsible for the control on the production and distribution of veterinary medicinal products, including medicated pre-mixes; − the Federal Agency for the Safety of the Food Chain (FASFC) is responsible for the approval of establishments manufacturing medicated feed; − the FASFC is also responsible for the control on the production (including prescription), distribution and use of medicated feed. These controls are performed at the level of the producers and users of medicated feed and include both inspections (to check provisions on traceability, notification, infrastructure, installation, hygiene, labelling, documentation, …) and sampling/analysis (to check guarantees active substance level and carry-over to non- medicated feed).
Bulgaria	Control of medicated feed is assigned to the National Veterinary Service under the Veterinary Act. Performance of control activities related to the medicated feed is monitored in compliance with Directive 90/167/EEC transposed into the Bulgarian legislation through the above mentioned Ordinance No 20, Regulation (EC) No 882/2004 and some specific provisions of Directive 2001/82/EEC in the manufacture of medicated premixes, which are by definition veterinary medical products. Medicated premixes manufacturers are granted licenses for manufacture under the principles valid for the production of veterinary medical products (VMP). There are no benefits in terms of output in comparison with other similar pharmaceutical forms. By law, the producer is required to comply with GMP for the production of VMP. Checks for compliance with GMP are made in 2-years intervals, if the quality of the products is not under suspicion. With the checks GMP – certificates of the producers are renewed. Implementing of the obligations by the producer is controlled by a veterinarian, designated by an Order of the Director of RVS, through planned inspections of the system of self control – GMP and HACCP as well as periodic checks of the results of the manufacturer's laboratory tests for homogeneity and stability of the medicated feed

	till expiry date.
Cyprus	The Veterinary Medicinal Products (Medicated FeedingStuffs) Regulations 136/2006 is the National Legislation and it is fully harmonized with the Council Directive 90/167/EC of 26 March 1990. These Regulations have entered into force in 27/07/2001 and were amended on 31/03/2006. Regarding the Regulations, the application for authorization for Manufacturing and Distribution of Medicated Feedingstuffs should be submitted to the Council of Veterinary Medicinal Products and the authorization is issued if the establishment is in compliance with the provision of the law. The authorisation of Medicated Premixes is accomplished under the National Legislation «The Veterinary Medicinal Products (Control of Quality, Registration, Supply, Manufacture, Administration and Use) Law N 10(I) of 2006», which is fully harmonized with the Directive 2001/82/EC as amended by the Directive 2004/28/EC. The inspectors make controls to the establishment before and after the authorisation to assure that the provision of the Regulations are implemented. They also make sampling. If the establishment is not in compliance with the provision of the law, they impose penalties: Administrative penalty: 1. Recommendations. 2. In case of a continuation of the violation, a penalty of €342 shall be applied for each day the infringement is been continued. 3. The Council of VMPs is responsible for the examination violations with a maximum penalty of € 42715 Offences*:* 1. A person who manufactures and/or distributes MFs, or imports MFs from third countries without the relevant authorization, is guilty of offence that can lead to prison for up to 5 years or/and to a € 85430 penalty. 2. Suspend / withdrawn of Manufacturing /Distribution Authorization of MFs
Czech Republic	According to Directive 90/167/EEC medicated feedingstuffs (MFs) manufacturer in the CR (EU) has to have license for MFs production, issued by competent authority - the Institute for the State Control of Veterinary Biologicals and Medicaments (USKVBL). Manufacturer has to meet requirements of Directive 90/167/EEC which is transposed to the Act No. 378/2007 Coll., on Pharmaceuticals in CR and corresponding degrees, especially No. 229/2008 Coll. (rules of good manufacturing and distribution practice for medicines – GMP, GDP) and degree No.54/2008 Coll. about prescription in later amendments and degree No.344/2008 Coll. about using, prescription and outgoing of medicinal products in connection with veterinary care administration. Basic principles for MFs manufacturers: • appropriate premises • appropriate equipment, qualified and validated (homogeneity and cross-contamination) – program of decontamination • sufficient number of employees with proper qualification • documentation (SOPs and batch records) • qualified person (= Medicated Feed Manager) According to the Czech legislation it is obligatory for MFs manufacturer to have a qualified person (QP) responsible for production and releasing of MFs batches, taking and storage of MFs samples, homogeneity and cross contamination testing, SOP system, batch records etc. Facilities for MFs production has to match all requirements for feedingstuffs manufacture – there is a link up to the Regulation No.183/2005/EC. For MFs production only feedingstuffs or combinations thereof that comply with Community provisions (Act No. 91/1996 Coll., on feedingstuffs, in later amendments, and corresponding Decrees in CR) have to be used. Currently we have 71 MFs registered manufactures (81 sites) in Czech Republic and thereof 7 manufacturers are authorized to produce also medicated premixes (medicinal products according Dir. 2001/82/EC). There are 66 authorized medicated premixes in the Czech Republic at this

	time. There is a system for licensing and regular inspections – each site has to be approved by national authority (based on application for license and provided documentation and based on results of pre-approval inspection) responsible for veterinary medicaments. The licensed manufacturer is after approval inspected at least once per two years (interval never exceeds three years). Usually the inspection takes one day, but for bigger manufacturers it can take two days. During the inspection all main parts of GMP for MFs are subject of inspection (premises for storage of medicated premixes, samples and medicated feedingstuffs; production premises; production equipment; quality assurance; documentation; batch records and batch release; training and qualification of employees; technology validation and control – cross-contamination, homogeneity; results of sample analyses; frequency of sampling, etc.) MFs manufacturers are obliged to report (quarterly) production quantity of MFs and consumption of medicated premixes (active substances) to the competent authority (USKVBL) in the CR. Medicated premixes require marketing authorization as other veterinary medicinal products. Based on an application for marketing authorization all relevant parts of dossier are checked and if in compliance with requirements the marketing authorization can be issued. Quality of medicated premixes is checked within national market surveillance program – each product with marketing authorization is sampled by the NCA inspectors and analysed in OMCL laboratory, frequency of sampling depends on risk analysis and varies between 3 – 8 years.
Denmark	Directive 90/167 is implemented in the following Danish regulation: • Bekendtgørelsen nr. 1251 af 12. december 2005 om fremstilling og forhandling m.v. af foderlægemidler til dyr (http://lms-lw.lovportaler.dk/ShowDoc.aspx?docId=bek20051251-full) • Bekendtgørelsen nr. 1254 af 12. december 2005 om fremstilling og forhandling m.v. af foderlægemidler til fisk m.m. (http://lms-lw.lovportaler.dk/ShowDoc.aspx?docId=bek20051254-full) • Bekendtgørelse nr. 1228 af 12. december 2005 om indførsel af visse foderlægemidler til dyr og fisk (http://lms-lw.lovportaler.dk/ShowDoc.aspx?docId=bek20051228-full) A manufacturing authorisation is granted for the manufacturers of VMP. A marketing authorisation is granted for the MAH (Marketing Authorisation Holder) of the premix. Every company importing, exporting, producing, storing or handing out premixes or medicated feed have to be authorised by the Danish Medicines Agency. The official control of the manufacturing of VMP is conducted by the Inspectorate at the Danish Medicines Agency, including sampling and analytical control.
Estonia	*Authorisation of establishments and official controls:* Enterprises engaged in the manufacture of medicated feedingstuffs shall approval for the manufacture of medicated feedingstuffs pursuant to the Feedingstuffs Act. To obtain approval for an enterprise, a person who wishes to engage in manufacture of medicated feedingstuffs shall submit to the Veterinary and Food Board (hereinafter 'the Board') an application. Documents to be attached to the application for obtaining approval for an enterprise shall include the self-check plan and documents certifying observance of the HACCP principles and compatibility of construction works; cleaning and disinfection plan, pest control plan and technological diagram of the handling process along with the parameters essential from the perspective of feedsafety and a brief specification of the technology. Medicated feedingstuffs may only be manufactured from those pre-mixes for medicated feedingstuffs concerning which the State Agency of Medicines has issued marketing authorisation for a veterinary medicinal product and which hae been registered at the State Agency of Medicines as veterinary medicinal products and on the basis of a prescription for medicated feedingstuffs issued by a veterinarian in accordance with Regulation No 21 of the Minister of Agriculture of 23 February 2005 "Conditions and procedure for the use of medicinal products and medicated feedingstuffs for the prevention and treatment of animal disease". Requirements for menufacture of medicated feedingstuffs are regulated on the Regulation No. 150 of the Minister of Agriculture of 10 December 2007 "Requirements for handling of medicated feedingstuffs". State inspection over compliance with requirements shall be conducted by the Board. According

	to the inspection plan, the number of inspections is partially determined by taking into consideration a minimum frequency for approved establishments (three inspections per year for manufacturers). The four feed inspectors work in the field. The geographical area for which they are responsible varies between four and five countries. The inspection plan is drawn up for one year and details the inspections, samples and analyses to be carried out. Each inspector is allocated a number of samples and inspections. Analyses to be performed on official samples are also detailed so that each inspector knows what substances to look for. During the inspection they control prescription for medicated feedingstuffs issued. By a veterinarian, self-check plan, packaging and labelling of medicated feedingstuffs and register of medicated feedingstuffs (manufactured and placed on the market) *Authorisation of medicated pre-mixes and official controls* Pre-mixes for medicated feedingstuffs are any veterinary medicinal products which are manufactured for the purpose of manufacture of medicated feedingstuffs. Veterinary medicinal products are medicinal products which are designated by the manufacturer to be used only on animals. A person wishing to obtain or renew a marketing authorisation in respect of a medicinal product shall submit a corresponding application together with supplementary documentation to the State Agency of Medicines. A applicant wishing to obtain marketing authorisation in respect of a medicinal product must prove by scientific methods that the medicinal product, if used for its intended purpose, is safe and effective according to the requirements of modern medical science, that the quality f the medicinal product conforms to the requirements provided by Medicinal Products Act, entered into force 1 March 2005 and legislation issued on the basis thereof. Supplementary documentation to be attached to the application and those should be in compliance with the requirements provided for in Annex I of Directive 2001/82/EC of the European Parliament and of the Council of the 6 November 2001 on the Community code relating to veterinary medicinal products. State supervision over compliance with the requirements provided by Medicinal Products Act and legislation established on the basis thereof shall be exercised by the State Agency of Medicines and, according to the competence, the Board. The Board shall execute supervision over the use of medicinal products and medicated feedingstuffs by veterinarians and breeders producing animal products.
Finland	As regards authorisation of establishments, the Directive has been implemented by Feed Act 86/2008 and the Decree No. 10/EEO/2008 (previously No 13/EEO/1998) of the Ministry of Agriculture and Forestry. Section 5, point 6 of the Feed Act defines “medicated feedingstuff”: Medicated feedingstuff is any mixture of a veterinary medicine or veterinary medicine and feed, which is manufactured for placing on the market and intended to be fed to animals, because of its curative or preventive properties or other properties as a medicinal product. The section 13 in the Feed Act concerns medicated feedingstuff. Only such medicine can be used for manufacturing of medicated feed, which has been approved by the centralised EU procedure or for which the national authority (National Agency for Medicines in Finland) has granted the marketing authorisation or other permission for expenditure according to the Medicines Act (395/1987). The manufacturer or supplier of the medicated feedingstuff has to keep records. Medicated feedingstuffs have to be stored, packaged and transported properly. The manufacturer or supplier of medicated feedingstuff is allowed to supply them to holder or possessor of animal based on a prescription from a veterinarian only. In addition what is said above, the general provisions regarding compound feed apply to medicated feedingstuffs. Decree No 10/EEO/2008 set additional provisions for manufactures of medicated feedingstuffs (conditions for manufacturing, record keeping, organising of business, disposal of medicated feedingstuffs and import). The Decree does not apply to farms or other holdings of animals where medicine and feed is mixed to be used only for the animals of that farm/ holding. In order to be authorised, the manufacture of medicated feedingstuffs shall have:

	• premises and technical equipment suitable for production of medicated feedingstuffs; • adequate lock-up storage facilities for storing of medicines; • premises and equipment for quality control and monitoring of manufacturing; • written quality control plan, which includes a section of laboratory used for quality control; • staff whose knowledge of and qualifications in manufacturing medicated feedingstuffs are adequate; • the person responsible for manufacturing, storing, disposal and quality control with adequate education; • written procedure based on the HACCP principles in line with Feed Hygiene (183/2005); Regulation. In order to be authorised, the supplier of medicated feedingstuffs shall have: • premises suitable for storing of medicines; • staff whose knowledge of and qualifications in selling and disposal of medicated feedingstuffs are adequate; • the person responsible for storing and disposal of medicated feeding stuffs with adequate education; • written quality control plan. As regards official controls on the compliance with the legal provisions, the Finnish Food Safety Authority Evira is responsible for the licensing of manufacturers and distribution outlets for medicated feedingstuffs, and for their control. The license for feedmills and fur animal feed processing plants authorised to manufacture medicated feedingstuffs when certain requirements are fulfilled, is valid for undetermined time. During an audit, the whole production process is verified. Feedmills manufacturing medicated feedingstuffs are inspected once a year and the fur animal feed processing plants according to a risk based control plan about every two years by Evira. Evira maintains a list of approved manufacturers and dealers of medicated feedingstuffs. The feedmills are also controlled by taking official samples.
France	Le contrôle du respect des bonnes pratiques par les établissements autorisés à produire industriellement les aliments médicamenteux est assure par des vétérinaires agents de L'Etat, pour le compte de l'AFSSA, selon un rythme fixé réglementairement de 3 ans pour les établissements fabricants et de 4 ans pour les établissements de distribution. Cette périodicité des inspections est fixée par l'autorité compétente en France qui est l'Agence Française de sécurité sanitaire des aliments.
Germany	Die Umsetzung der Richtlinie 90/167/EWG erfolgte durch das Arzneimittelgesetz (AMG) und die darauf gestützten Verordnungen. In § 13 des AMG ist die Erlaubnispflicht verankert, die grundsätzlich für alle gewerblichen Hersteller von Arzneimitteln und somit auch für die Hersteller von Fütterungsarzneimitteln gilt. Die Überwachung der Einhaltung der betrieblichen Anforderungen erfolgt durch die zuständigen Behörden der Bundesländer. Die behördlichen Kontrollpflichten ergeben sich aus § 64 AMG, der für Arzneimittelhersteller in der Regel eine Kontrollfrequenz von 2 Jahren vorsieht. Die Überwachung der Fütterungsarzneimittel verschreibenden Tierärzte sowie die der Tierhalter ist ebenfalls in § 64 AMG festgeschrieben. Tierärztliche Hausapotheken sind ebenfalls in der Regel alle 2 Jahre zu kontrollieren, die Kontrollen der Tierhalter sind nach einem risi-koorientierten Ansatz für jeden Betrieb gesondert festzulegen und durchzuführen. Basis für die Kontrollen sind Verfahrensanweisungen (VAW), die Bestandteil des gemeinsamen Qualitätssicherungssystems der Länder (QS-L) sind: • VAW 071102 „Vorbereitung, Durchführung und Nachbereitung von Inspektionen im Bereich GMP" • VAW 071121 „Überwachung von tierärztlichen Hausapotheken" • VAW 071122 „Arzneimittelrechtliche Überwachung bei Haltern von Tieren, die der Lebensmittelgewinnung dienen" sowie

	• VAW 071143 „Erstellen eines risiko- und zeitabhängigen Inspektionsplanes für die Überwachung von Haltern von Tieren, die der Gewinnung von Lebensmitteln dienen“. Link: http://www.zlg.de/cms.php?PHPSESSID=d8219edd43d6aee1a9a1085951eada31&mapid=77 Arzneimittel-Vormischungen müssen, wie andere Tierarzneimittel auch, nach den nationalen bzw. gemeinschaftlichen Vorschriften zugelassen werden (AMG; RL 2001/82/EG bzw. VO 726/2004/EG). Bei der Zulassung von Arzneimittel-Vormischungen werden die üblichen Zulassungsanforderungen an Tierarzneimittel zu Grunde gelegt. Zusätzlich sind die im Anhang 1 zur Richtlinie 2001/82/EG (Titel I, Teil 2 G) geforderten Unterlagen vorzulegen (Einmischrate, Angaben zur Herstellung, zur Kompatibilität/Eignung der Mischfuttermittel, zur homogenen und stabilen Verteilung im Fütterungsarzneimittel und zur vorgesehenen Haltbarkeit des Fütterungsarzneimittels). Die Zulassung von Arzneimittel-Vormischungen erfolgt wie im Falle von anderen nicht immunologischen Tierarzneimitteln in Deutschland durch das Bundesamt für Verbraucherschutz und Lebensmittelsicherheit (BVL).
Greece	For the authorisation of establishments the 98/310584/GMD Greek Ministerial Decision[95] is applied, while for the authorisation of medicated pre-mixes the 2006/282371/GMD Greek Ministerial Decision[96] is followed. Regarding the official controls, a quality assurance system is applied according to which inspections are conducted every 3 years.
Hungary	In Hungary an authorization is to be obtained for the production of medicated feed. Only authorized VMPs and intermediary products containing an authorized medicated premix can be used. Controls on the labelling and on the production of medicated feeds are organized on the basis of the annual plan on feed control, sampling and analysis. Establishments manufacturing medicated feed are ranked into the highest risk category. Therefore, their official control is the most frequent. A section in the plan is dedicated to the official sampling and analysis of medicated feed. The guaranteed levels of VMPs, cross contamination, presence of banned or not authorized substances are in the focus point of those analyses.
Ireland	Under the European Communities (Animal Remedies and Medicated Feedingstuffs) Regulations 1994, the incorporation of an animal remedy in an animal feedingstuff or the possession of a feedingstuff in which an animal remedy has been incorporated and the placing on the market of a medicated feedingstuff is prohibited except under a licence granted by the Minister. Prior to the granting of a licence for the manufacture of medicated feedingstuff, a premises is inspected to ensure that it is in compliance with National Legislation. Furthermore the premises must be approved as a food business operator under Regulation (EC) No. 183/2005. Licences (with conditions attached) to manufacture medicated feed are granted for a period of 3 years. During the validity period of licences, the licencees are obliged to forward laboratory tests every 6 months/annually (depending on the size of the operation) to demonstrate efficacy of both the mixing and flushing procedures at a premises. Premises are also subject to inspection/s during validity period of licences. The Irish Medicines Board is the competent authority in Ireland for the licensing of animal remedies including premixes. Before a premix can be authorised for use, an application must be made to the Irish Medicines Board and this must contain all the necessary data supporting its quality safety and efficacy.
Italy	In Italy the establishments that produce or deliver medicated feed, are approved by the Ministry LSPS, alone or in cooperation with the Ministry of Economic Development, after an establishment’s inspection carried out by the ASL - local veterinary service (for distributors) or by the “Provincial Commission” (for producers).

[95] 98/310584/GMD Greek Ministerial Decision concerning the acceptance and application of Council Directives 81/851/EEC (EU/L317), 81/852/EEC (EU/L317), 90/167/EEC (EU/L92), 90/676/EEC (EU/L373), 90/677/EEC (EU/L373), 93/40/EEC (EU/L214), 93/41/EEC (EU/L214), as well as the acceptance and application of Commission Directive 92/18/EEC (EU/L97).

[96] 2006/282371/GMD Greek Ministerial Decision concerning the harmonisation of the Greek legislation to the Community law in the area of the production and distribution of the veterinary medicinal products, in compliance to Directives 2001/82/EC and 2004/28/EC of the European Parliament and of the Council on the Community code relating to veterinary medicinal products.

	Ordinary official control on production and distribution of medicated feed are carried out by local veterinary service - LVS. The PNAA (national control plan on animal nutrition) provides to LVS the lowest frequency of inspection, required for this category of feed operators: • Producers: 1 time a year • Distributors: 1 time every 2 years The PNAA also gives to the Regional veterinary services, the minimum number of official feed' samples to be carried out, on the regional territory.
Latvia	Authorization of establishments and medicated pre-mixes and official controls are carried out by inspectors of the Food and Veterinary Service.
Lithuania	Authorization of establishments is carried out by the counties SFVS according "Requirements for manufacture, distribution into market and usage of medicated feed" approved by the Order of director of SFVS from 231011200N4o Bl-80 (O.G., 2004,N o 22-688) with the amendments done by the Order of director of SFVS from 301061200N8 o B1-359 (O.G., 2008, No 83-3334). Authorization of medicated pre-mixes is done by SFVS after the assessment of quality, safety and efficacy carried out by the National Food and Veterinary Risk Assessment Institute. Authorization of medicated pre-mixes as well as authorization of veterinary medicinal products is carried out according "Requirements for manufacture, authorization and distribution into market in Lithuania" approved by the Order of director of SFVS from 291101200N5 o. Bl-594 (O.G. ,2005, No I 3I-4754) with the last amendments done by the Order of directors of SFVS 23110/2008N o B 1-540 (O.G., 2008, No 1,28-4912). These requirements are in line with Directive 200ll82lBc and Directive 20041281F,C. It is not allowed to distribute into market in Lithuania veterinary medicinal products and medicated pre-mixes if there is no authorization certificate issued by SFVS for particular product. The list of authorized veterinary medicinal products and medicated pre-mixes can be found in the Register of veterinary medicinal products on the website of SFVS (http : //vetlt 1 . vet. ltlvrl). Official control of approved medicated feed manufacturing establishments is carried out by the counties SFVS in accordance with the annual feed monitoring and control plans and in respect to classification of feed business operators according to the risks. The controls are carried out at the frequencies established by SFVS for official control of feed business operators.
Luxembourg	The authorisations are given by the minister of Health. Official controls are carried out by three different governmental institutions: Division de la Pharmacie et des Médicaments, Administration des Services Techniques de l'Agriculture (ASTA), Administration des Services Vétérinaires (ASV). Feed manufactures allowed to produce medicated feed are inspected at least once a year and feed samples are analysed to verify the absence of cross contamination. Feed samples are taken at all the types of establishments (Feed manufactures allowed to produce medicated feed, feed manufactures not allowed to produce medicated feed, retailers, mobile mixers, farms) to verify that there is no cross contamination of VMP.
Netherlands	Establishments can apply for an authorisation to manufacture medicated animal feed or medicated pre-mixes. An authorisation is only granted to those establishments that are certified according to the standard GMP B 1: Production & Processing of Feed for Productive Livestock (http://www.pdv.nl/lmbinaries/gmp_b01_-uk-.pdf) with the scope manufacturing of compound feed or manufacturing of pre-mixes. Medicated premixes and manufacturers of veterinary medicines are assessed and approved by a governmental body called the Medicines Evaluation Board. The Veterinary Medicinal Products Unit of The Medicines Evaluation Board (MEB) assesses and monitors the efficacy, risks and quality of veterinary medicines (http://www.cbg-meb.nl/cbg/en/default.htm) Establishments that manufacture medicated animal feed (using medicated pre-mixes) are both checked by the competent Dutch authority, the Food and Consumer Product Safety Authority (http://www.vwa.nl) and by the independent, accredited, certification body. The certification body will assess their GMP B 1 (see above) based quality assurance system and issue a GMP certificate following a successful approval assessment. The assessment will include the inspection with the compliance of the demands of Directive 90/167/EEC when the establishment has applied for an authorisation to manufacture medicated feed.

	The past years the Food and Consumer Safety Authority (VWA) and the General Inspection Service (AID) did a survey on the way medicated feed was prescribed and produced. First this survey (starting in 2002) was focussed on the prescription behaviour of veterinary practitioners. The result of this survey was an increase in the compliance on the level of truthful and complete filling in of prescription for medicated feed. The last years 3 surveys took place on the quality of medicated and the level of carry over. One of these surveys in 2006 showed that the analysed content of antibiotics in feed not always corresponded with the prescription of the antibiotics. In order to confirm these results a survey took place on the content of Oxyteracycline in medicated feed. The result of this survey showed a variation in contents of Oxytetracyline within one batch of medicated feed. This variation might be due to insufficient mixing. The average content seemed to be corresponding with the prescriptions, unless two batches were overdosed. These overdoses were due to production failure of the VMP. This survey of 2007 focussed also on the carry-over in the feed used for flushing the production line. The content in this feed materials varied between 14 and 54 mg/kg.
Norway	*Authorisation of establishments*: Manufacturing Licences and Wholesalers Licences *Authorisation of medicated pre-mixes*: Medicated premixes are defined as medicinal products which require Marketing Authorisation by the Norwegian Medicines Agency according to the National regulation of 22.12.1999 on medicinal products § 3-1. *Official controls on the compliance with the legal provisions:* GMP Inspection every two years and GDP inspection every three to five years.
Poland	*The scheme of approval of manufacture plants of medicated feedingstuffs intended for trade – Art. 16 of the Act on feedingstuffs:* An entity interested in manufacture of medicated feedingstuffs intended for trade shall submit an application for approval to a province veterinary officer competent for the territory of the place of performing activities. The application shall be accompanied by relevant documentation. A province veterinary officer shall perform control over fulfilment of the requirements referred to in the Act on feedingstuffs and Regulation of the Minister of Agriculture and Rural Development of 1 February 2007 *on detailed requirements during manufacture and trading medicated feedingstuffs intended for trade and intermediate products* (Journal of Laws No. 27, item 183). In the event of meeting by the entity all requirements, the province veterinary officer shall issue an administrative decision approving the entity's activities in the area of manufacture of medicated feedingstuffs intended for trade. Prior to approval of a manufacturing plant of medicated feedingstuffs intended for trade, the province veterinary officer shall issue on a one-off basis a permit for manufacture of a test batch of medicated feedingstuffs a sample of which is taken in order to determine homogeneity and active substance content in 1 g of the feedingstuff. In case of obtaining a positive result of the examination, the manufacturing plant shall receive an approval for manufacture of medicated feedingstuffs and the feedingstuff may be placed on the market. *The scheme of approval of holdings producing medicated feedingstuffs not intended for trade - Art. 17 of the Act on feedingstuffs:* In case of granting approval for holdings manufacturing from an intermediate product medicated feedingstuffs for the entity's own purposes, a principle similar to that used while approving a manufacturing plant of medicated feedingstuffs intended for trade is applied. Detailed requirements concerning manufacture of medicated feedingstuffs not intended for trade have been specified in Regulation of the Minister of Agriculture and Rural Development of 1 February 2007 *on medicated feedingstuffs not intended for trade* (Journal of Laws No. 24, item 157). Additionally, the process of maufacture of medicated feedingstuffs not intended for trade may be also managed by a person who has passed an exam carried out by a province veterinary officer in order to check their knowledge of issues concerning production of medicated feedingstuffs from an intermediate product. The detailed scope of issues included in the exam has been specified by Regulation of the Minister of Agriculture and Rural Development of 31 January 2007 *on the exam on knowledge of*

	issues concerning manufacture of medicated feedingstuffs from an intermediate product (Journal of Laws No. 27, item 182). *The scheme of approval of distributors of medicated feedingstuffs - Art. 20 of the Act on feedingstuffs:* An entity interested in distribution of medicated feedingstuffs shall submit an application alongside relevant documentation to the Chief Veterinary Officer. The Chief Veterinary Officer shall order a province veterinary officer competent for the territory of the place of performing activities to perform control over meeting the requirements referred to in the Act on feedingstuffs and in Regulation of the Minister of Agriculture and Rural Development of 1 February 2007 on *requirements concerning placing on the market medicated feedingstuffs intended for trade and intermediate products by a distributor* (Journal of Laws, No. 27, item 184). Following the control, the province veterinary officer shall issue an opinion concerning fulfilment of the requirements by the entity. This opinion shall be the basis for issuing by the Chief Veterinary Officer an administrative decision approving the entity for carrying out activities in the area of distribution of medicated feedingstuffs. The Chief Veterinary Officer shall maintain a register of entities dealing with manufacture and distribution of medicated feedingstuffs. This register is updated on an ongoing basis and generally available on the website of the Chief Veterinary Inspectorate *www.wetgiw.gov.pl* *Principles for use of medicated feedingstuffs:* In case of determining by a veterinary officer providing services in the area of veterinary medicine and looking after a herd of animals the necessity to use medicated feedingstuffs, he/she shall issue an order to manufacture medicated feedingstuffs. The template of an order has been specified in Regulation of the Minister of Agriculture and Rural Development of 31 January 2007 *on the template of an order for placing on the market medicated feedingstuffs and intermediate products* (Journal of Laws, No. 24, item 155). A veterinary officer shall issue an order only in reference to a particular disease case filling in part A of the document in 5 copies. Then, he/she keeps one copy of this order and passes the other copies to the owner of treated animals for which the medicated feedingstuff is intended. The order is then sent to a medicated feedingstuffs manufacturing plant which on its basis starts manufacture of medicated feedingstuffs. Once the production has been completed, the medicated feedingstuffs manufacturing plant fills in Part B of the order, keeps the original of the order, and sends one copy of the document alongside the medicated feedingstuffs to the receiver - the owner of treated animals. Moreover, the manufacturing plant of medicated feedingstuffs intended for trade passes a copy of the order to the veterinary officer who has issued the order and the district veterinary officer on whose area the medicated feedingstuff has been used. An order for manufacture of medicated feedingstuffs is valid for 3 days. Point 3 of Instruction of the Chief Veterinary Officer of 23 October 2007 No. GIWpuf-700pl./96/2007 *on standardization of principles of conduct of the bodies of the Veterinary Inspection within the territory of the Republic of Poland while supervising manufacture, trade, distribution and use of medicated feedingstuffs in animal nutrition.*specifies in detail the principles for official control and approval of entities indending to conduct activities in the area of manufacture and distribution of medicated feedingstuffs. Additionally, there have been compiled control lists having in regard standardization of princliples for conduct of bodies of the Veterinary Inspection within the territory of the Republic of Poland while supervising manufacture, trade, distribution and use of medicated feedingstuffs in animal nutrition.
Portugal	Artigo 120.º DL 148/2008 de 29 de Setembro Plano Nacional de Controlo de Utilização de Medicamentos Veterinários
Romania	The authorization of operators from the field of animal nutrition is made by the county Sanitary Veterinary and Food Safety Directorates (regional competent authorities) and the official controls are carried out by the National Sanitary Veterinary and Food Safety Authority (central competent authority) and the county Sanitary Veterinary and Food Safety Directorates (regional competent authorities).
Slovakia	*Authorisation of establishments and medicated pre-mixes:* Each manufacturer of medicated feed must have application system of HACCP and must have duty of regular check medicated feed in contracted laboratory with regards Slovak Regulation

	41/2004 Z.z. After any change have duty of validation machinery or process by GMP IV and VICH. *Official controls on the compliance with the legal provisions* Regular check by pharmaceutical inspection Regional Veterinary Authorities with Institute for State Control of Veterinary Biologicals and Medicaments by methodic of State Veterinary Authorities Slovak Republic in Bratislava
Slovenia	*Brief description of how veterinary medicinal products are distributed from wholesale level to end user:* VARS: Distribution of veterinary medicinal products requiring veterinary prescription and of thosw which might be dispensed without the veterinary prescription takes place from the wholesaler to the pharmacies, veterinary organisations and (specialised stores). VMPs are not available on the free market in the regular shops. Veterinary practitioners provide VMPs to the agricultural holdings under their care dispense/ sell the VMPs in the veterinary prescription so that the animal keeper may obtain the relevant VMP in the pharmacy. In accordance with Article 29 of VCCA, medicated feed shall be produced by establishments only, which are complying with the required conditions and holding the authorisation of VARS for carrying out such an activity, using the approved medicated premixes only. Medicated feed shall comply with the conditions for the placing on the market, be identified as required and used in the prescribed manner only (the latter is prescribed in the implementing regulations - "Rules"). In accordance with Article 4(1) of the Rules on the registration and approval of establishments of feed business operators (UL RS 114/03), with pertaining amendments, the approval is compulsory for establishments producing medicated feed. The latter shall, in addition to the conditions laid down in the Regulation 183/2005/EC, comply with the conditions referred to in the Rules on the conditions for the productions of, trade in and use of medicated feed. The Rules on the conditions for the production of, trade in and use of medicated feed are laying down the conditions for the production, identification, placing on the market, und use of medicated feed, the form and contents of the veterinary prescription, trading in medicated feed and territory of the EU, and controls. In accordance with Article 4 of the Rules: (1) Medicated feed shall be produced from the approved premixes only. An establishment, which is registered for the production of medicated feed from the approved medicated premixes in compliance with the Rules governing the conditions to be met by establishments in the field of animal nutrition, may purchase the approved medicated premixes for the production of medicated feed directly from the legal or natural person carrying out the wholesale trade in medicinal products. (2) An establishment, which is registered for the production of medicated feed, may prepare intermediate products from the approved medicated premixes for the subsequent preparation of medicated feed. (3) An establishment, which is registered for the production of medicated feed may, based on the veterinary prescription issued by the veterinarian treating the animals and at his/her responsibility, produce medicated feed from several approved premixes, provided that a specifically approved therapeutic agent in the form of an approved premix does not exist for the relevant disease and animal species under treatment. (4) An establishment, which is registered for the production of medicated feed may, based on the veterinary prescription issued by the veterinarian treating the animals and at his/her responsibility, produce medicated feed in compliance with the Rules on the off-label use of medicinal products for the treatment of animals and on the animal treatment records. (5) An agricultural holding shall obtain medicated feed from the veterinarian treating the animals only. (6) The procedure and conditions applicable to the granting of marketing authorisation for the trade in medicated premixes are laid down in the Medicinal Products an Medicinal Devices Act, and in the Rules on the marketing authorisation for the trade in veterinary medicinal products. In accordance with Article 5 of the Rules:

	(1) Aveterinarian may, along with the service rendered, dispense the approved premixes for the preparation of medicated feed, to the agricultural holdings only, which are registered for the production of medicated feed for the holding's own rearing needs, in compliance with the Rules on conditions tobe met by establishments in the animal nutrition sector. (2) Agricultural holdings, which have been registered for the production of medicated feed, shall prepare medicated feed in compliance with the instructions of the veterinarian, who shall in every particular case prescribe the medicated feed using the form, which as Annex 3 constitutes an integral part of these Rules. The form is printed in thressfold, where the original and a copy shall be obtained by the agricultural holding and one copy shall be kept by the veterinarian. The copy obtained by the agricultural holding shall be used as report to the relevant VARS Regional Office, in accordance with Article 6(4) of these Rules. ARSMPMD: VMP wholesale authorisation is granted by the Agency (ARSMPMD/JAZMP). Wholesalers may sell medicinal products to legal entities and natural persons only, who are holding the retail of wholesale authorisation, and to pharmacies. Notwithstanding the preceding provisions, the wholesalers may sell veterinary medicinal products to the veterinary and other organisations performing veterinary activities according to the veterinary regulations, and to authorised manufacturers of medicated feedingstuffs within the scope of the authorisation. (Medical Products Act (ZZdr-1, Article 73(2)(4))) *Brief description of official controls on the compliance with the legal provisions:* In accordance with Article 14 of the The Rules on the conditions for the production of, trade in and use of medicated feed, the controls of production of, trade in and use of medicated feed are carried out by VARS. Compliance with the requirements of these Rules is verified by VARS by regular inspection and control intended to verify whether the medicated feed is used in compliance with the conditions of use, and whether the withdrawal periods are complied with, by checks on samples at all stages of production of, trade in and use of medicated feed and by checks on samples of medicated feed at agricultural holdings and in slaughterhouses. VARS carries out checks on the implementation of internal controls in the production of medicated feed and on the homogeneity, contamination, cross-contamination, stability and storage of medicated feed.
Spain	Medicated premixes are considered VMP and they are authorised by the Competent Authorities (Agencia Española del Medicamento y Productos Sanitarios). However, medicated feedingstuffs are under the supervision of the feed authorities (as far as they are considered feed). Authorisation of establishments is carried out by the CA of the Autonomous Regions, which are also responsible for the official controls on the compliance with the legal provisions.
Sweden	*Authorisation of establishments*: Administrated at the Swedish Board of Agriculture. The process differs between establishments on farm level or manufacturing. Farm level: During the registration of the establishment to the public register, the feed business operator notifies the Board if they will use medical products in the feed. If so, a control is needed of relevant facts in Art 1. A veterinary inspector conducts the physical control on the farm and a written report goes to the administrator at the Board. If the farm copes with the requirements the establishment receive an approval. The first approval run for one year and after that is it prolonged for three years. Manufacturing establishments: During the registration of the establishment, the feed business operator notifies the Board if they will use medical products in the feed. If so, a control is needed of relevant facts in Art 1. The control is done by inspectors from the Board and a written report goes to the administrator at the Board. If the establishment cope with the requirements the establishment will get an approval. The first approval run for one year and after that is it prolonged for three years. *Authorisation of medicated pre-mixes* This is done by the Medical products agency in Sweden. *Official controls on the compliance with the legal provisions*

	Primary production: The County Administrative Boards conduct the official controls on the farms. Manufacturing establishments: The control is conducted by the Swedish Board of Agriculture.
United Kingdom	*Authorisation of establishments* The Animal Medicines Inspectorate (AMI) of the Veterinary Medicines Directorate (VMD) are responsible for inspecting and authorising establishments mixing authorised pre-mixes into intermediate products or into medicated feedingstuffs and distributors supplying medicated feedingstuffs in Great Britain. In Northern Ireland these duties currently fall to the inspection team at the Department of Agriculture and Rural Development (Northern Ireland) (DARDNI). *Authorisation of medicated pre-mixes* The VMD is responsible for the assessment and authorisation of medicated pre-mixes in accordance with the requirements of the Veterinary Medicines Regulations (VMR) which implement Directive 2001/82/EC. The VMD is responsible for the drafting and implementation of the VMR. *Official controls on the compliance with the legal provisions* The AMI of the VMD and DARDNI carry out official controls on compliance in accordance with the VMR in the UK. In recognition of the more up to date manufacturing and official control requirements for feed additives authorised under Regulation 1831/2003, the UK has implemented the feed additive EU Regulations for medicated feeds also. Therefore the VMR implements EU Regulations 178/2002, 882/2004 and 183/2005 for medicated feeds. Those articles from Directive 90/167 specific to medicated feeds are also implemented in the VMR. The AMI consists of a team of 5 regional inspectors. All AMI inspectors hold a formal qualification in agriculture/science and are required to have spent at least 3 years at management level in the animal feed/animal health industry prior to appointment. Inspectors are qualified ISO 9000:2000 auditors and have undertaken a course in HACCP. Two new inspectors have recently been recruited. They will attend the relevant courses within 12 months of appointment. Establishments manufacturing medicated feed are separated into 4 Categories. In addition there is a further category for approval of distributors supplying medicated feed. Inspections are performed upon application and thereafter between every 12 months and 24 months depending on the risk rating of the establishment. Authorisation is renewed annually. Frequency of inspection is based on the risk of the activity carried out by the establishment, i.e. manufacture of a medicated feed using any level of inclusion and for selling on to a large number of customers is deemed to be more of a risk than a farmer mixing into feed for his own use on farm. Although the farmer would still be expected to comply with Annex II of 183/2005, the complexity of inspection and equipment for example would not be the same as that for a large feed mill. In accordance with the requirements of 882/2004, the AMI is due to move to a more fully risk based inspection programme in 2010. In preparation for this, since October 2008, the AMI inspectors have been completing a document at each inspection to gain information regarding the risk rating of the establishment. In Northern Ireland, the Department of Agriculture and Rural Development, Northern Ireland carry out official controls in accordance with the VMR. They use the same inspection regime and categories of establishments as the AMI.

Source: Survey of competent authorities.

Table 34: Experiences with the practice of oral administration of VMPs

	What kind of experiences are available in your Authority concerning safety aspects in the field of manufacturing and use of VMPs via medicated feed? What kind of experiences are available in your Authority concerning safety aspects in the filed of the oral use of VMPs in other ways of administration such as through water, top dressing or incorporation of ready-to-use VMPs in the feed by the livestock farmer?
Austria	The requirements for the feed mills – laid down in the Fütterungsarzneimittelbetriebsordnung 2006 – are high; at present no feed mill is approved for manufacturing medicated feed. Taking into account the rules concerning registration of the establishments and training of the responsible persons the manufacturing and application of medicated feed at farm level is safe.
Belgium	*Production of medicated feed – Safety aspects:* In general, the administration of veterinary drugs to animals via medicated feedingstuffs is considered to be a safe and well controllable (homogenous) system for mass-medication of farm animals. However, problems with carry-over of medicinal substances to subsequent batches of non-medicated feed are well known and sometimes difficult to avoid (currently legal zero-tolerance applies). Therefore we see a trend towards: - addition of premixture at the very end of the production line (just before feed is loaded to truck) in order to avoid contamination of whole line ; - dedicated production lines for medicated feed ; - development of mobile production units fixed on a truck (see also question 3): need for a specific approval by the FASFC and under the responsibility of an approved producer of medicated feed. This "mobile" production at time of delivery at the farm keeps out the VMP's of the production plant (and consequently carry-over is avoided). Regarding homogeneity of medicated feed, the FASFC checks the frequence and results of homogeneity testings performed by the feed manufacturers. Concerning the guarantees in active substance level, control is done by sampling and analysis. Concerning the prescription of medicated feedingstuffs, in Belgium currently is running a trial project (in collaboration with Bemefa/Apfaca and supervised by the FASFC) that concerns the electronic prescription of medicated feed (prescription is made electronically by the veterinarian and sent directly by GPS to the feed producer). This as an alternative for the "paper" prescription. The objective is to obtain a reduction of administrative burden (paper work for both veterinarian and manufacturer) and general simplification (electonical storage of data, fast transmission of prescription to manufacturer, …). Based on the results of this trial project, Belgium will consider to create a legal basis for this electronic prescription of medicated feed. *Oral use of VMPs on farm:* On-farm mixing (e.g. by mixing with feed or via top dressing) : the use of VMP's (e.g. powders) other than medicated pre-mixes is considered to be out of scope of the rules concerning medicated feed. This is explicitly mentioned in the Royal Decree of 21.12.2006 (see question 1), art. 2 : "The present Decree does not apply to the mixing of a VMP, other than a medicated pre-mix, with a quantity of feed that is limited to the daily ration of an animal or a group of animals to be treated." This means that such an oral administration of VMP's is covered by the general rules on the use of VMP's. It is the responsibility of the prescribing veterinarian to choose the best method for oral administration of VMP's (other than medicated pre-mixes) on farm. Legislation does not explicitely exclude on farm mixing with feed or top dressing for the production of a daily ration, however administration via top dressing is never recommended in the leaflet or package insert (section "instructions for use") approved by the FAMHP. Of course there are big question marks as regards the homogeneity (and consequently safety and efficacy) of these methods. Certain VMP's (other than medicated pre-mixes) are specifically approved by the FAMHP or the EMEA for administration via the drinking water.

Bulgaria	In implementation of control on following the regulations related to the activities of production, storage, issue, transportation and use of medicated feed NVS through the feed safety control plan controls: 1. Medicinal substances put in the production of VMP, which is prohibited and punishable with administrative penalty under the provisions of the Veterinary Law 2. Observing withdrawal periods when using medicated feedingstuffs; 3. With the exception of medicated premixes, production of medicated feed from VMP is prohibited, 4. Top dressing" of the VMPs on feed is prohibited- production of medicated feed is possible only by using of medicated premixes. 5. Samples of feed are taken from the place where animals are fed. 6. According to the European and Bulgarian legislation, water is not defined as feed. In Bulgaria there are VMP licensed for use, which package leaflet indicates that they can be included in drinking water, but not in feed. National Veterinary Service prepares and implements a National Monitoring Program of residues control (under Directive 9623/EEC), which ensures compliance with the legislation concerning the monitoring of residues of VMPs in products of animal origin intended for human consumption.
Cyprus	*Experiences concerning safety aspects in the field of manufacturing and use of VMPs via medicated feed:* According to our experience the weak-sick animals are not treated properly with MFs because they cannot receive the individual dose of VMPs through the MFs, so the expected effectiveness is low. *Experiences concerning safety aspects in the field of the oral use of VMPs in other ways of administration such as through water, top dressing or incorporation of ready-to-use VMPs in the feed by the livestock farmer:* Concerning the pharmaceutical forms, the top dressing administration is not used in Cyprus and the use of VMPs in water must be administered properly under suitable conditions, in order to have the expected efficacy. Otherwise the results will be the same with MFs.
Czech Republic	Two principle methods for oral administration of VMPs need to be distinguished in our experience, namely administration in the drinking water and administration in the feed. The administration especially of antimicrobials in the drinking water seems to be much better method for administration of veterinary medicines in most cases, especially in cases of acute disease outbreaks. Despite both feed and water consumption decline, the decline in feed consumption is usually much bigger than the decline in water consumption in the acute phases of disease outbreaks. Administration via the drinking water allows for better targeting and more effective and safe treatment in our opinion. Mass medication with orally administered antimicrobials to animals is in general considered as the most problematic way of treatment with respect to development of antimicrobial resistance. Based on our experience with the prescription practice for the medicated feeds, veterinary drugs (especially antimicrobials) administered orally in the form of medicated feed are in a number of cases used as a replacement of good farming/herd management practices. We do not have comparable figures available for the other types of oral administration (use in the drinking water, individual use in the feed) but we can assume that the situation for these oral administration methods the situation will very similar. Czech Republic prohibited the off-label use of the medicated pre-mixes (prescription, manufacture of medicated feeds) in the feed mills and off-label use of the medicated feeds at the farms in order to ensure proper use of medicated feeds. Despite of this measure introduced in 2003, we still identify cases of misuse / abuse of medicated pre-mixes and medicated feeds. One of the crucial issues when the discussion of the oral administration of veterinary medicinal products is concerned is the decision making process with respect to the use of the most appropriate therapy. Unfortunately, economic pressure in food producing animals moves the decision making process for the drug selection from the professional basis to the economical basis

	and issues like price of the medicinal product or withdrawal period play an import role when decisions are made which product will be used. In our opinion, measures are needed to improve the knowledge of farmers of the possible consequences and professional development training for vets is needed as well. Oral administration of veterinary medicinal products brings specific risks with respect to adverse effects. Those seen in practice in the Czech Republic are toxicities resulting from the interaction of drugs administered via medicated feeds with residues of other drugs / feed additives present in the medicated feed because of the mistakes in the manufacture and/or due to the cross contamination. Most serious cases were reported for turkey and pigs. Cleansing / cross contamination and homogeneity are two principle issues which require high degree of official supervision where manufacture /placing on the market of medicated feeds is concerned. Rules and requirements for cleansing of the mixers / transport pathways and for cross-contamination need to be more stringent for medicated feedingstuffs when compared with the most feed addtitives. In summary: - (mass) oral administration of VMPs is an important and for the modern intensive farming unsubstitutable way of administration of veterinary medicinal products to animals, - such administration brings however high level of different risks (e.g. antimicrobial resistance, adverse reactions) which justify higher level of surveillance, - when decision on the use of a substance is to be made, the legislation should provide that such decisions are made on professional grounds leading to the choice of the most safe and effective treatment available, - an EU wide analysis of the prescription customs is desirable and the future measure should ensure that the use of veterinary medicinal products is based on the professional and scientific grounds and the economical factors do not dictate the choice of the product to be used; it is however recognized that because of the international trade wider solution may be needed, - Medicated feeds should be treated as medicinal products in the EU with high level of official surveillance with respect to their manufacture, placing on the market and proper use.
Denmark	-
Estonia	We do not have any experiences concerning safety aspects in the field of manufacturing and use of VMPs via medicated feed.
Finland	As regards safety aspects and use of VMPs via medicated feed, the National Agency for Medicines (NAM) performs pharmacovigilance surveillance of VMPs by collecting the data of adverse events based on veterinarians' or users' written reports. During 2004-2008 NAM has received only one report of an adverse event concerning premixes. There has been no need for actions from NAM's part.
France	-
Germany	-
Hungary	*Experiences concerning safety aspects in the field of manufacturing and use of VMPs via medicated feed:* In some cases products are not properly labelled (e.g.: coccidiostats still labelled as drugs). The volume of the flushing material is sometimes less than prescribed in the authorization document. In 2007 302 samples were taken in the production plants for monitoring of cross contamination and 11 thereof proved to be positive. Cross contamination was also established through the feeding system in the animal farm. The recipe is sometimes not filled in properly or, – when only intermediary products are sought – is missing. Unauthorized substances do not constitute a problem in Hungary, as can be seen in the diagrams set out in page 50-51 of the 2007 annual report on the feed control in Hungary available at http://www.oevi.hu/uzemlistak/jelentes.pdf. In some cases we have experienced misuse of

	medicated feed, where it was being used for preventive purposes rather than treatment. *Experiences concerning safety aspects in the field of the oral use of VMPs in other ways of administration such as through water, top dressing or incorporation of ready-to-use VMPs in the feed by the livestock farmer:* There are products to be administered through water. This way of administration proves to be effective and therefore is to be supported. Medicated feed production is slowly decreasing because of water-based medication. Top dressing does not constitute a real problem as it can not be and is not used for producing medicated feed (a couple of cases a year).
Ireland	*Experiences concerning safety aspects in the field of manufacturing and use of VMPs via medicated feed:* One of our principal concerns relates to "carry over" of medicated feed to non-medicated feed in the manufacturing plant. The amount of 'flush' required will depend on the type of manufacturing plant and factors such as its age etc. The adequacy or otherwise of the volume of flush is assessed by testing the first non medicated feed manufactured post the manufacture of medicated feed. Handling of the 'flush' material and its subsequent incorporation into a similar medicated feed and production of a homogenous final feed is another issue. This can be difficult to achieve and can involve alteration to the lay-out of the manufacturing plant. We have encountered difficulties regarding the recoverability of the active ingredient (VMP premix) in the final feed. This needs to be carefully monitored. The effects of heat in the manufacture of pelleted feed and the recoverability of the active ingredient in the final feed is another area that requires monitoring. *Experiences concerning safety aspects in the field of the oral use of VMPs in other ways of administration such as through water, top dressing or incorporation of ready-to-use VMPs in the feed by the livestock farmer:* Top dressing by its nature is difficult to monitor. Our concerns in this area and in regard to the administration of VMPs through water are that only animals prescribed the treatment receive the treatment i.e. that there is no cross-contamination and also that the animals receiving the treatment are in receipt of the treatment in accordance with the product specifications. Regarding the in-corporation of ready to use VMPs by the livestock farmer i.e home mixing, the main issues here relate to the production of a homogenous mix and the prevention of carry-over/cross-contamination of non-medicated feed.
Italy	-
Latvia	Safety aspects regarding use of VMPs via medicated feed and water is set down by veterinarian.
Lithuania	Medicated feed is controlled by the local SFVS according "Requirements for manufacture, distribution into market and usage of medicated feed" approved by the Order of director of SFVS from 231011200N4 o 81-80 (O.G., 2004, No 22-688) with the amendments done by the Order of director of SFVS from 301061200N8o 81-359 (O.G. 2008,N o. 83-3334), which are in line with Directive 90116l7E EC on medicated feed. It should be taken into account that at the moment there are no approved medicated feed manufacturing establishments which would supply medicated feed into the market in Lithuania. There are only two approved medicated feed manufacturing establishments (farms), which produce medicated feed for their own needs. Veterinary medicinal products can be administrated through water with the supervision of private veterinarian and according to the requirements that are stated in the instructions of use of veterinary medicinal products. It should be mentioned that official control of feed in general, medicated feed and veterinary medicinal products carried out by SFVS is consistent and covers all stages of handling of feed and veterinary medicinal products.
Netherlands	*Experiences concerning safety aspects in the field of manufacturing and use of VMPs via medicated feed:* Establishments that manufacture medicated feed are concerned about the safety of their workers. VMPs are added manually into the feed mixer during the manufacturing process. Workers can get into contact with small amounts of VMPs. For this raison safety precautions are necessary. The development of resistance to antibiotics is a major topic for the feed manufacturers. In one case a worker developped a MRSA infection.

	Another issue feed manufactures are worrying about is the carry-over of VMP into feeds which are not intended to be medicated. During the production process of medicated feed a small amount (a few percent) of the feed stays behind on the production line. Although the production line is flushed contamination of other feeds manufactured on the same production line is almost inevitable. Very small amounts of VMP may trigger resistance to antibiotics on farm level. *Experiences concerning safety aspects in the field of the oral use of VMPs in other ways of administration such as through water, top dressing or incorporation of ready-to-use VMPs in the feed by the livestock farmer:* Administration of VMP through water is considered as rather safe and effective. When the water pipes are cleaned thoroughly after a treatment coarse there is little risk for carry-over of VMPs. Animals which are sick sometimes stop eating but almost never stop drinking. This means that administration of VMP's by drinking water may be more effective then the administration of medicated feed. This may also possibly minimize the risk of antibiotic resistance. The water piping on the farm has to be adjusted for administration of VMP to drinking water. Not all farmers have made the necessary adaption's to their drinking water system. The fact that not all VMPs are available in a soluble form is limitating the administration of medicated drinking water. VMP treatment by drinking water is common practice in Dutch poultry farming. At Dutch pig farms medicated feed is still customary, although more and more drinking systems for VMP are coming into place. From administration through top dressing or incorporation of ready-to-use VMPs in feed by the livestock farmer no recorded experiences are available.
Norway	*Experiences concerning safety aspects in the field of manufacturing and use of VMPs via medicated feed:* No specific signals detected by the Norwegian Medicines Agency via the pharmacovigilance system. The Norwegian Medicines Agency is of the opinion that the Norwegian operators (manufacturers/distributors etc) in this sector are serious and law abiding. All concerned products are POM, and regarding medicinal products for fish there is a double reporting system to the Norwegian Food Safety Authority (responsible for food safety and veterinarians' good veterinary practice); veterinarians must report all prescriptions for fish and pharmacies/feed mills/wholesalers must report all sales of medicines (incl. medicated feed) for fish. This enables good level of control. *Experiences concerning safety aspects in the field of the oral use of VMPs in other ways of administration such as through water, top dressing or incorporation of ready-to-use VMPs in the feed by the livestock farmer:* No specific signals detected by the Norwegian Medicines Agency via the pharmacovigilance system.
Poland	As results from the histherto experience the validity period of an order (only 3 days) is the biggest problem for enterpreneurs. However, experts from both the Chief Veterinary Inspectorate and the Ministry of Agriculture and Rural Development are in favour of preserving this provision. In the course of approving entities intending to conduct activities consisting in trade of medicated feedingstuffs it was determined that the entities were not aware about meeting the requirements by a distributor of medicated feedingfstuffs. Hence, over 50% of the applications were rejected due to failing to meet the requirements. The next problem for entrepreneurs are the so called warehouse transfers between medicated feedingstuffs manufacturing plants belonging to the same holding. The Chief Veterinary Inspectorate is in opinion that until a change of the provisions has been made such warehouse transfers may not take place. The next important issue is prophylaxis and metaphylaxis. This applies in particular to eradication of parasitic diseases by means of medicated feedingstuffs. It seems reasonable to make in regulations developed in future a clear division between medicated feedingstuffs the use of which results from a disease process manifesting itself in clinical symptoms and treatment of subclinical states, i.e. in prophylaxis of disease units the occurrence of which in the course the manufacture process is unavoidable.

	Issues concerning cleaning technological lines following manufacture of medicated feedingstuffs need to be made more specific as well. Moreover, it seems reasonable to make the principles of conduct with medicated feedingstuffs which remain in the holding and have not been used up in order to treat animals for which they were intended more specific. It seems from the Polish experience that it was a very apt decision to place supervision over medicated feedingstuffs at the level of a province veterinary officer, who is also responsible for supervision over trade and use of veterinary medicated products. It increased the importance of supervision and contributed to effective law enforcement.
Portugal	-
Romania	In Romania, the most frequent oral administration of veterinary medicinal products is via drinking water. At national level, the approach is to replace the VMP administration via medicated feed with parenteral administration and with administration in drinking water. As regards the safety aspects, until now, there were not notifications concerning adverse reactions or quality defects for medicated premixtures at the National Sanitary Veterinary and Food Safety Authority.
Slovakia	*Experiences concerning safety aspects in the field of manufacturing and use of VMPs via medicated feed:* Evaluation by inspection is by meaning of guidelines GMP. *Experiences concerning safety aspects in the field of the oral use of VMPs in other ways of administration such as through water, top dressing or incorporation of ready-to-use VMPs in the feed by the livestock farmer:* Application and treatments of any medicaments is observant by keeping evidence in book of operation by EU Regulation 2377/90.
Slovenia	*Experiences concerning safety aspects in the field of manufacturing and use of VMPs via medicated feed:* Business activities in medicated feedingstuffs are conducted by the same feed business operators (FBOs), who are carrying out the business activities involving the conventional feed. From the poit of view of FOBs, this is just a specific activity within the feed business sector, as such feed is intended for animals as any other. The manufacture, storage and placing on the market of the medicated feed are all feed business activites and, as such, fall within the scope of the Regulation (EC) No 183/2005. Requirements for the manufacture of medicated feed in Directive 90/167/EC and Regulation 183/2005/EC are similar; an essential difference is in the conditions applicable to the placing on the market and use of medicated feed. The latter is feasible on the basis of a veterinary prescription only. It should be noted also that in Slovenia these particular areas are regulated within the national veterinary legislation. This means that the control of manufacture, trade in and use of, etc. of medicated feed, as well as control of compliance with the requirements of Annex II to Regulation 183/2005/EC in the FBO establishments are conducted by official veterinarians. Frequency of official checks in FBO establishments is in proportion with the risks involved, taking into account the results of the FBOs' own checks. Risk analyses are performed in the FBO establishments in the regular intervals, on which basis the frequency of controls is determined, and the controls include also the medicated feed risk criteria. *Experiences concerning safety aspects in the field of the oral use of VMPs in other ways of administration such as through water, top dressing or incorporation of ready-to-use VMPs in the feed by the livestock farmer:* VMPs in water for watering are advantageously used with poultry, and there have been no reports of any specific problems in this regard. From year to year, however, a downward trend has been noticed in the number of registrations of medicated premixes, which is probably due to the fact that there apply certain conditions for the use of medicated premixes in feed (Regulation 183/2005/EC, Directive 90/167/EC), whilst there are no additional requirements in place for the use in feed of the orally administered powdered substances. We would wish that with the VMPs registered for the use in feed as orally administered powdered

	substances there would apply the "rules of conduct" which would be as clear as those on the use in feed of medicated premixes. We would like to take this opportunity to point at the non-harmonisation of legislation on the use feed additives and premixes in feed (and water for watering) with the legislation on the use of VMPs through feed and water for watering in the form of orally administered powdered substances and water-soluble powdered substances. Whilst for the admixture of VMPs and use thereof through feed and water for watering (excluding medicated premixes) there apply no specific conditions, the FBOs and animal keepers intending to use a feed additive through feed or water for watering are compelled to comply with the requirements of Annex II to Regulation 183/2005/EC (HACCP). We believe that, as far as the "safety aspects" are concerned, it is imperative to equalise the conditions of use applicable for VMPs with the conditions of use applicable for feed additives. Thus, food safety would be secured and VMP residues in food avoided.
Spain	For the oral administration of VMP to a large amount of animals, it is considered that the medicated feed manufactured by an authorised stablishment is the best way to warranty the dosage, homogeneity and stability of the VMP. The reason is that Feed manufactured must comply with HACCPP principles to warranty such requirements. However, farmers do not usually have the appropriate equipment to warranty the safe administration of VMP for collective treatments. Thus, for individual or low number of animals to be orally treated, top dressing or ready to use VMP would be preferred but, for collective treatments, medicated feedingstuffs seems to be more appropriate.
Sweden	*Experiences concerning safety aspects in the field of manufacturing and use of VMPs via medicated feed:* On manufacturing level the experience are generally speaking good with few findings concerning overdosing or cross contamination. The handling and documentation are in general included in the companies GMP:s and HACCP:s. For the majority of the approved establishments the production also is covered by a certification. During the last years the feed operators had started to limit the use of VMPs to a small number of establishments due to the stricter classification in the control system and the risk for bad publicity from cross contamination. *Experiences concerning safety aspects in the field of the oral use of VMPs in other ways of administration such as through water, top dressing or incorporation of ready-to-use VMPs in the feed by the livestock farmer:* There is an insignificant collected knowledge regarding this since the field veterinarians handle this. Some use occurs of medical product in wet feed to pigs and fur animals, with no negative effects reported.
United Kingdom	*Experiences concerning safety aspects in the field of manufacturing and use of VMPs via medicated feed:* 1. Suspected Adverse Reaction Scheme The VMD runs a Suspected Adverse Reaction Scheme (SARS) related to all veterinary medicinal products including medicated feedingstuffs. This would include any safety reports on medicated feeds. There has been very few SAR reports on medicated feed during the past 5 years. This is the total sum of adverse reactions for medicated feed. 2004 1 2005 0 2006 1 2007 0 2008 1 = 3 in 5 years 2. UK National Statutory Residues Surveillance Scheme The VMD runs the UK National Statutory Residues Surveillance Scheme. The following information is the result of positive residue results in samples taken from the

	animal which is likely to have resulted from medicated feedingstuffs. In relation to the number of samples taken in the species that have shown positive results, this is a low result over 5 years. Positives — No of Samples taken in the positive species 2004: 8 — 1,855 2005: 15 — 2,987 2006: 9 — 2,354 2007: 12 — 3,104 2008: 9 — 1,828 = 55 *approximately* in 5 years, out of 12,128 samples taken in the species that have shown positive results. Note: Nine of the above results are phenylbutazone. We are unable to confirm how all these cases were administered to animals but some are certainly via feed. *Experiences concerning safety aspects in the field of the oral use of VMPs in other ways of administration such as through water, top dressing or incorporation of ready-to-use VMPs in the feed by the livestock farmer:* Regarding oral administration and medicated feedingstuffs, the UK complies with the EU Directives and Regulations. Article 3.1. of Directive 90/167 "Member States shall prescribe that, as regards the medicinal component, medicated feedingstuffs may be manufactured from authorised medicated pre-mixes only." In the UK medicated feedingstuffs must be manufactured from authorised medicated pre-mixes. Veterinary medicinal products which are authorised as pre-mixes must be incorporated and fully mixed into feed as indicated on the summary of product characteristics for the marketing authorisation. Feed mills and farmers mixing the products must be approved by the AMI before they may do so. We do not permit veterinary medicinal products which are not authorised for incorporation (e.g. powders for top dressing, soluble products intended for drinking water) to be mixed into feed. We do not allow pre-mixes to be sprinkled on top of feed (top dressing) unless a veterinary practitioner makes a clinical decision that this is necessary. As a result of an FVO mission in 2002, it was recommended to the UK that the use of pre-mixes as top dressing was illegal and that the UK should take steps to try to ensure that this practice did not take place. The UK wrote to stakeholders and vets informing them of this position. We are unaware of any products other than premixes being mixed into feed; therefore, we have had no resulting safety aspects regarding this use. It is the UK's view that veterinary medicinal products should only be used in accordance with the directions on the marketing authorisation's Summary of Product Characteristics. If data has not been presented and assessed to mix the product into feed, we believe it is an illegal administration of the product. Similarly, farmers mixing any VMP into feed must be approved in accordance with EU medicated feedingstuffs legislation.

Source: Survey of competent authorities.

Annex 8: Questionnaire to national feed manufacturers' associations, associations of cooperatives and farmers' associations

CIVIC CONSULTING

MEDICATED FEED IN THE EUROPEAN UNION
*
SURVEY OF NATIONAL FEED MANUFACTURERS' ASSOCIATIONS, ASSOCIATIONS OF COOPERATIVES AND FARMERS' ASSOCIATIONS

Please fill in questionnaire no later than

31 July 2009

and return this questionnaire by email in Word-Format (.doc) to
medicatedfeed@civic-consulting.de
Please do not pdf the questionnaire

The oral administration of Veterinary Medicinal Products (VMPs) via feed is one option for the animal holder. Directive 90/167/EEC sets out the conditions under which medicated animal feedingstuffs may be prepared, placed on the market and used within the Community.

The Directorate General for Health and Consumers of the European Commission has commissioned a study to evaluate the EU legislative framework in the field of medicated feed. As the significance of medicated feed in terms of production varies drastically amongst the Member States, this survey is intended to evaluate the current production figures and their recent developments, the alternatives to the VMP-administration via medicated feed commonly used, and other relevant issues.

The information you provide through this questionnaire will be crucial for the review and possible revision of Directive 90/167/EEC. We therefore greatly appreciate your contribution.

If you have any further questions, do not hesitate to contact:

Rémi Béteille (medicatedfeed@civic-consulting.de) Phone: +49 30 2196 2287; Fax: +49 30 2196 2298

IMPORTANT INFORMATION:

This questionnaire is divided in 3 sections. Section A concerns all stakeholders while section B and C are targeted at specific stakeholders groups in EU Member States.

If your members are manufacturers of compound feed, please answer sections A and B.

If your members are farmers, please answer sections A and C.

If your members include both manufacturers of compound feed and farmers, please answer sections A, B and C.

Please note the following definitions and clarifications:

Veterinary Medicinal Products (VMPs) may be administered orally via the following routes:

1) *Through medicated feed produced by feed mills approved by the competent authority in line with Article 4(1) of Directive 90/167/EEC and manufactured from authorised medicated pre-mixes;*
2) *Through medicated feed produced by farms that are authorised to manufacture medicated feed from authorised medicated pre-mixes (on-farm mixing) in line with Article 4(2) of the Directive;*
3) *Through ready-to-use oral veterinary medicines administered by farmers through water, top dressing of feed, and mixing of powders into feed (not regulated by this Directive).*

Authorised medicated pre-mix is defined in Directive 90/167/EEC as any pre-mix for the manufacture of medicated feedingstuffs as defined in Article 1 (2) of Directive 81/851/EEC which has been granted an authorisation in accordance with Article 4 of that Directive.

A. SECTION FOR ALL STAKEHOLDERS

1. Please identify yourself:

a. Please identify the name of your organisation:

Please specify

b. Please identify the type of your organisation:

Please select from the dropdown menu *If Other, please specify*

c. Please identify the country in which you are located:

Please specify

d. Please specify the total number of members of your organisation:

Please specify

e. Please specify the market share of your members in your national market:

Please specify

f. Questionnaire completed by:

Name, position, contact details

2. Is medicated feed the most commonly used route of oral administration of Veterinary Medicinal Products (VMPs) in your country?

- ☐ Yes
- ☐ No
- ☐ Don't know

If No: Please specify the route of oral administration of ready-to-use VMPs which is currently the most commonly used in your country:

Please select from the dropdown menu *If Other, please specify*

Comments

3. **How did the use of oral Veterinary Medicinal Products evolve in your country over the last five years?**

   a. Please assess the evolution of oral administration of Veterinary Medicinal Products in your country over the last five years (i.e. total of medicated feed and ready-to-use veterinary medicines administered by farmers through water, top dressing, etc.):

Please select from the dropdown menu

Comments

   b. Please assess the evolution of the use of medicated feed in your country over the last five years:

Please select from the dropdown menu

Comments

4. **In your view, what are the factors that may explain the recent evolution of the use of medicated feed in your country?**

Please specify

5. **What are the possible consequences, if any, of administration of ready-to-use oral veterinary medicines by farmers (i.e. through water, top dressing of feed, mixing of powders into feed) compared to the use of medicated feed?**

   a. What are possible direct consequences for occupational safety (e.g. for workers on livestock farms)?

Please specify

   b. What are possible consequences for public health (food safety, indirect implications on human health)?

Please specify

   c. What are possible environmental consequences?

Please specify

6. **In your view, in which production system is the use of medicated feed most common in your country?**

Please select from the dropdown menu

Comments

7. Please mark species for which the use of medicated feed is most common in your country:

- ☐ Cattle
- ☐ Pigs
- ☐ Sheep
- ☐ Goats
- ☐ Horses
- ☐ Rabbits
- ☐ Chicken
- ☐ Turkey
- ☐ Duck
- ☐ Geese
- ☐ Other *Please specify*

Comments

B. SECTION FOR ASSOCIATIONS OF COMPOUND FEED MANUFACTURERS AND COOPERATIVES MANUFACTURING COMPOUND FEED ONLY

8. What is the number of authorised medicated pre-mixes[1] in your country? Please specify the total number of authorised medicated pre-mixes for the following years:

	2004	2005	2006	2007	2008
Total number of authorised medicated pre-mixes					

Comments

9. What was the total production of medicated feed and of compound feed over the last 5 years in your country? Please specify in tonnes.

Please specify the market for which you provide data:

- ☐ Whole national market (members and non-members, preferred)
- ☐ Production figures for your members only *Please specify market share*
- ☐ Other *Please specify*

	2004	2005	2006	2007	2008
Total production of medicated feed (in tonnes)					
Total production of compound feed (not including medicated feed) (in tonnes)					

Comments

10. What are the Veterinary Medicinal Products (VMPs) most commonly used by your members for the production of medicated feed?

a. Most commonly used VMP for the production of medicated feed:

Please select from the dropdown menu
If Other VMP, please specify

b. Second most commonly used VMP for the production of medicated feed:

Please select from the dropdown menu
If Other VMP, please specify

[1] In line with Article 3 of Directive 90/167/EEC

c. Third most commonly used VMP for the production of medicated feed:

Please select from the dropdown menu *If Other VMP, please specify*

11. Do rules of good manufacturing practice[2] for medicated feed exist in your country?

- ☐ Yes
- ☐ No
- ☐ Don't know

If Yes: Please specify if the application of the rules is mandatory by law:

- ☐ Mandatory by law
- ☐ Voluntary
- ☐ Don't know

Comments, if possible attach relevant information

12. What are the additional costs of manufacturing medicated feed compared to manufacturing compound feed for your members (not considering the costs of the active substances)?

a. Please specify which of the following additional costs are the most relevant:

- ☐ Costs of measures related to management of risk of drug carry-over
- ☐ Costs of legislative requirements to conduct homogeneity tests and other analytical controls
- ☐ Costs of mandatory official quality control of medicated feed
- ☐ Administration fee to obtain authorisation to manufacture medicated feed
- ☐ Other costs. *Please specify*

Comments

[2] In line with Article 4(1d) of Directive 90/167/EEC

b. If the costs of producing a tonne of compound feed were 100, what would be the costs of producing a tonne of medicated feed?
Please estimate the percentage for each cost factor including all inputs such as labour, utilities, maintenance, depreciation of capital goods[3] etc. (costs of the active substances are, however, excluded):

Cost factor		***Costs for producing medicated feed in % of costs of producing compound feed***
Cost of producing compound feed		100
Additional costs medicated feed	Cost of measures related to management of risk of drug carry-over	
	Cost of legislative requirements to conduct homogeneity tests and other analytical controls	
	Cost of mandatory official quality control of medicated feed	
	Other costs *Please specify*	
Total cost of producing medicated feed *(not including costs of the active substances)*[4]		(must be more than 100)

Comments

13. In your view, what are the negative consequences, if any, of different national legislative frameworks in the field of medicated feed on the competitiveness of manufacturers/cooperatives in the EU?

a. Please assess negative consequences, if any, of different national legislative frameworks in the field of medicated feed on the competitiveness of manufacturers/cooperatives.

Please select from the dropdown menu

Comments

b. In your view, are negative consequences, if any, of different national legislative frameworks in the field of medicated feed on the competitveness of manufacturers/cooperatives particularly relevant for specific regions or sectors?

☐ Yes
☐ No
☐ Don't know

If Yes: Please specify negative consequences of different national legislative frameworks in the field of medicated feed on the competitiveness of manufacturers/cooperatives for specific regions or sectors.

Please specify

[3] E.g. end-of-line mixer and other capital equipment acquired exclusively for the production of medicated feed to avoid carry over.
[4] Total costs, consisting of costs for producing compound feed and additional costs of producing medicated feed. For example, if total cost is 125, this means that medicated feed is 25% more costly to produce than compound feed.

14. What were your members' total production of medicated feed for non-food producing animals[5] over the last 5 years in your country? Please specify in <u>tonnes</u>.

Please specify the market for which you provide data:

☐ Whole national market (members and non-members, preferred)
☐ Production figures for your members only *Please specify market share*
☐ Other *Please specify*

	2004	**2005**	**2006**	**2007**	**2008**
Total production of medicated feed for non-food producing animals (in tonnes)					

Please specify the species of non-food producing animals for which your members sold medicated feed during the period 2004-2008

Comments

15. In your view, is there a demand (potential market) for medicated feed for non-food producing animals in your country?

☐ Yes
☐ No
☐ Don't know

Comments

[5] Non-food producing animals kept or bred but not used for human consumption such as fur animals, pets and animals kept in laboratories, zoos or circus.

C. SECTION FOR FARMERS' ASSOCIATIONS ONLY

16. What are the measures in place for the control of the use of medicated feed in your country?

Please specify

17. Please describe the legal situation concerning the on-farm use of Veterinary Medicinal Products in your country.

a. Is on-farm mixing under the feed legislation (i.e. the authorisation of the manufacture of medicated feed on farms in line with Article 4(2) of Directive 90/167/EEC) allowed in your country?

- ☐ Yes, on-farm mixing under feed legislation allowed
- ☐ No, not allowed
- ☐ Don't know

If Yes: Please specify the number of farms that are authorised to manufacture medicated feed in your country:[6]

Please specify

Please specify the conditions for on-farm mixing in your country:

Please specify

b. Is administration of ready-to-use oral veterinary medicines prescribed by a veterinarian, e.g. through water, top dressing of feed, mixing of powders into feed, restricted in your country?[7]

- ☐ Yes, administration of prescribed ready-to-use oral vet. medicines by farmers restricted
- ☐ No, administration of prescribed ready-to-use oral vet. medicines by farmers not restricted
- ☐ Don't know

If Yes: Please specify the restrictions:

Please specify

[6] In line with Article 4(2) of Directive 90/167/EEC

[7] Restrictions could include technical requirements for the administration through water, the prohibition of specific practices, etc.

18. Is the use of medicated feed in general[8] more expensive per treated animal than the administration of ready-to-use oral veterinary medicines (e.g. through water, top dressing of feed, mixing of powders into feed)?

☐ Yes
☐ No
☐ Don't know

If Yes: Please provide an estimate concerning additional costs of using medicated feed:

Please select from the dropdown menu *If more than 20%, please specify percentage*

If needed, specify the type of medicated feed you are referring to, and possible reasons for the difference

19. In your view, what are negative consequences, if any, of different national legislative frameworks in the field of medicated feed on the competitiveness on farmers?

a. Please assess negative consequences, if any, of different national legislative frameworks in the field of medicated feed on the competitiveness of farmers.

Please select from the dropdown menu

Comments

b. In your view, are negative consequences, if any, of different national legislative frameworks in the field of medicated feed on the competitiveness of farmers particularly relevant for specific regions or sectors?

☐ Yes
☐ No
☐ Don't know

If Yes: Please specify negative consequences of different national legislative frameworks in the field of medicated feed on the competitveness of farmers for specific regions or sectors.

Comments

[8] "In general" refers to most commonly used types of medicated feed/active substance used by farmers in your country.

Annex 9: Questionnaire to manufacturers of veterinary medicinal products

MEDICATED FEED IN THE EUROPEAN UNION
*
SURVEY OF MANUFACTURERS OF VETERINARY MEDICINAL PRODUCTS

Please fill in questionnaire no later than

31 July 2009

and return this questionnaire by email in Word-Format (.doc) to medicatedfeed@civic-consulting.de. Please do not pdf the questionnaire

The oral administration of Veterinary Medicinal Products (VMPs) via feed is one option for the animal holder. Directive 90/167/EEC sets out the conditions under which medicated animal feedingstuffs may be prepared, placed on the market and used within the Community.

The Directorate General for Health and Consumers of the European Commission has commissioned a study to evaluate the EU legislative framework in the field of medicated feed.

As the significance of medicated feed in terms of production varies drastically amongst the Member States, this survey is intended to evaluate the current production figures of medicated pre-mixes and of VMPs administered orally and their recent developments.

The information you provide through this questionnaire will be crucial for the review and possible revision of Directive 90/167/EEC. We therefore greatly appreciate your contribution.

If you have any further questions, do not hesitate to contact:

Rémi Béteille (medicatedfeed@civic-consulting.de) Phone: +49 30 2196 2287; Fax: +49 30 2196 2298

Please note the following definitions and clarifications:

Veterinary Medicinal Products (VMPs) may be administered orally via the following routes:

1) *Through medicated feed produced by feed mills approved by the competent authority in line with Article 4(1) of Directive 90/167/EEC and manufactured from authorised medicated pre-mixes;*
2) *Through medicated feed produced by farms that are authorised to manufacture medicated feed from authorised medicated pre-mixes (on-farm mixing) in line with Article 4(2) of the Directive;*
3) *Through ready-to-use oral veterinary medicines administered by farmers through water, top dressing of feed, and mixing of powders into feed (not regulated by this Directive).*

Sales data concerning VMPs for "all routes of oral administration" refer to the total sales of VMPs administered via these three routes.

Authorised medicated pre-mix is defined in Directive 90/167/EEC as any pre-mix for the manufacture of medicated feedingstuffs as defined in Article 1 (2) of Directive 81/851/EEC which has been granted an authorisation in accordance with Article 4 of that Directive.

All views you express in this questionnaire will only be quoted anonymously. Data will not be used for any purposes other than for this study and will only be published in an aggregated form. The data that you provide in this survey will not be transmitted to third parties.[1]

[1] If required, Civic Consulting will also provide a signed statement of confidentiality in the format requested by individual respondents.

1. Please identify yourself:

a. Please identify the name of your company:

Please specify

b. Please identify the country in which you are located:

Please specify

c. Questionnaire completed by:

Name, position, contact details

2. What were your company's total sales of Veterinary Medicinal Products (VMPs) for all routes of oral administration over the last 5 years in the EU? Please specify in tonnes of active substances.[2]

EU sales of VMPs for oral administration in tonnes of active substances

Active substances	**2004**	**2005**	**2006**	**2007**	**2008**
β-lactams for oral use					
Aminoglycosides for oral use					
Tetracyclines for oral use					
Lincosamides for oral use					
Macrolides for oral use					
Pleuromutilins for oral use					
(Fluoro)quinolones for oral use					
Sulfonamides/Trimethoprim for oral use					
Other therapeutic antimicrobials for oral use					
Total of therapeutic antimicrobials for oral use					
Thereof for medicated pre-mix production[3]					
Therapeutic antiprotozoals for oral use					
Thereof for medicated pre-mix production[3]					
Therapeutic antifungals for oral use					
Thereof for medicated pre-mix production[3]					
Endoparasiticides (incl. anthelmintics) for oral use					
Thereof for medicated pre-mix production[3]					
Coccidiostats for oral use					
Thereof for medicated pre-mix production[3]					
Other VMPs for oral use *(excluding vaccines)*					
Thereof for medicated pre-mix production[3]					
Total sales of VMPs for oral use *(excluding vaccines)*					
Thereof for medicated pre-mix production[3]					

Comments

[2] For years until 01/01/2006, data for therapeutic antimicrobials should not include antimicrobials administered as feed additives.

[3] This includes both the amount of active substances used for medicated pre-mixes produced by your company and the amount of active substances sold to pre-mix manufacturers for the production of medicated pre-mixes.

3. Please provide the following data concerning the sales of your company in the EU in 2008.

a. What were your total sales of VMPs for all routes of oral administration in the EU in 2008 in Euro (excluding vaccines)?

Please specify

b. Please specify which percentage of your total sales of VMPs for all routes of oral administration in the EU in 2008 (in Euro, excluding vaccines) was related to the sales of medicated pre-mixes.

Please select from the dropdown menu *If more than 50%, please specify percentage*

Comments

4. What were your company's total sales of Veterinary Medicinal Products (VMPs) for all routes of oral administration for non-food producing animals[4] over the last 5 years in the EU? Please specify in tonnes.

	2004	2005	2006	2007	2008
Total sales of VMPs for oral administration for non-food producing animals (in tonnes)					

Please specify the species of non-food producing animals for which your company sold VMPs (for oral administration) during the period 2004-2008

Comments

5. In your view, is there a demand (potential market) for medicated feed for non-food producing animals in the EU?

☐ Yes
☐ No
☐ Don't know

Comments

[4] Non-food producing animals kept or bred but not used for human consumption such as fur animals, pets and animals kept in laboratories, zoos or circus.

6. Please specify total sales of <u>therapeutic antimicrobials for all routes of oral administration</u> for selected MS over the last 5 years. Please specify in <u>tonnes of active substances</u>. [5]

	2004	2005	2006	2007	2008
Belgium					
Total amount of antimicrobials for oral use					
Thereof for medicated pre-mix production[6]					
Denmark					
Total amount of antimicrobials for oral use					
Thereof for medicated pre-mix production[6]					
Estonia					
Total amount of antimicrobials for oral use					
Thereof for medicated pre-mix production[6]					
France					
Total amount of antimicrobials for oral use					
Thereof for medicated pre-mix production[6]					
Germany					
Total amount of antimicrobials for oral use					
Thereof for medicated pre-mix production[6]					
Hungary					
Total amount of antimicrobials for oral use					
Thereof for medicated pre-mix production[6]					
Italy					
Total amount of antimicrobials for oral use					
Thereof for medicated pre-mix production[6]					
Netherlands					
Total amount of antimicrobials for oral use					
Thereof for medicated pre-mix production[6]					
Poland					
Total amount of antimicrobials for oral use					
Thereof for medicated pre-mix production[6]					
Romania					
Total amount of antimicrobials for oral use					
Thereof for medicated pre-mix production[6]					
Spain					
Total amount of antimicrobials for oral use					
Thereof for medicated pre-mix production[6]					
United Kingdom					
Total amount of antimicrobials for oral use					
Thereof for medicated pre-mix production[6]					

Comments

[5] For years until 01/01/2006, data for therapeutic antimicrobials for all routes of oral administration should <u>not</u> include antimicrobials administered as feed additives.

[6] This includes both the amount of <u>active substances used for medicated pre-mixes produced by your company</u> and the amount of <u>active substances sold to pre-mix manufacturers for the production of medicated pre-mixes</u>.

7. Please specify total sales of endoparasiticides for all routes of oral administration for selected Member States over the last 5 years. Please specify in tonnes of active substances.

	2004	2005	2006	2007	2008
Belgium					
Total amount of endoparasiticides for oral use					
Thereof for medicated pre-mix production[7]					
Denmark					
Total amount of endoparasiticides for oral use					
Thereof for medicated pre-mix production[7]					
Estonia					
Total amount of endoparasiticides for oral use					
Thereof for medicated pre-mix production[7]					
France					
Total amount of endoparasiticides for oral use					
Thereof for medicated pre-mix production[7]					
Germany					
Total amount of endoparasiticides for oral use					
Thereof for medicated pre-mix production[7]					
Hungary					
Total amount of endoparasiticides for oral use					
Thereof for medicated pre-mix production[7]					
Italy					
Total amount of endoparasiticides for oral use					
Thereof for medicated pre-mix production[7]					
Netherlands					
Total amount of endoparasiticides for oral use					
Thereof for medicated pre-mix production[7]					
Poland					
Total amount of endoparasiticides for oral use					
Thereof for medicated pre-mix production[7]					
Romania					
Total amount of endoparasiticides for oral use					
Thereof for medicated pre-mix production[7]					
Spain					
Total amount of endoparasiticides for oral use					
Thereof for medicated pre-mix production[7]					
United Kingdom					
Total amount of endoparasiticides for oral use					
Thereof for medicated pre-mix production[7]					

Comments

[7] This includes both the amount of active substances used for medicated pre-mixes produced by your company and the amount of active substances sold to pre-mix manufacturers for the production of medicated pre-mixes.

8. In your view, in which production system is the use of medicated feed most common in the EU?

Please select from the dropdown menu

Comments

9. Please mark species for which the use of medicated feed is most common in the EU:

- ☐ Cattle
- ☐ Pigs
- ☐ Sheep
- ☐ Goats
- ☐ Horses
- ☐ Rabbits
- ☐ Chicken
- ☐ Turkey
- ☐ Duck
- ☐ Geese
- ☐ Other *Please specify*

Comments

10. What are the possible consequences, if any, of administration of ready-to-use oral veterinary medicines by farmers (i.e. through water, top dressing of feed, mixing of powders into feed) compared to the use of medicated feed?

a. What are possible direct consequences for occupational safety (e.g. for workers on livestock farms)?

Please specify

b. What are possible consequences for public health (food safety, indirect implications on human health)?

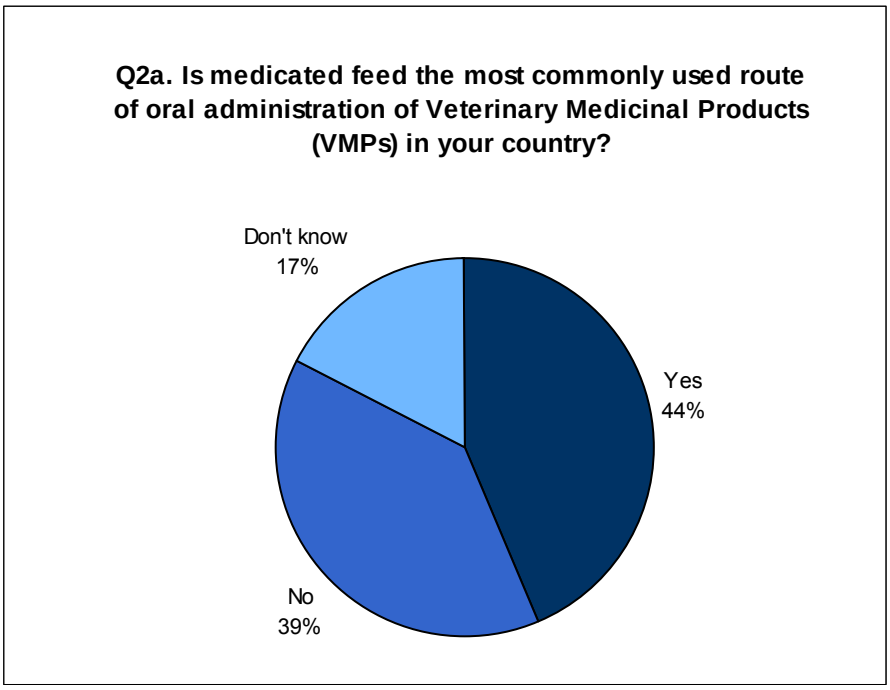
Please specify

c. What are possible environmental consequences?

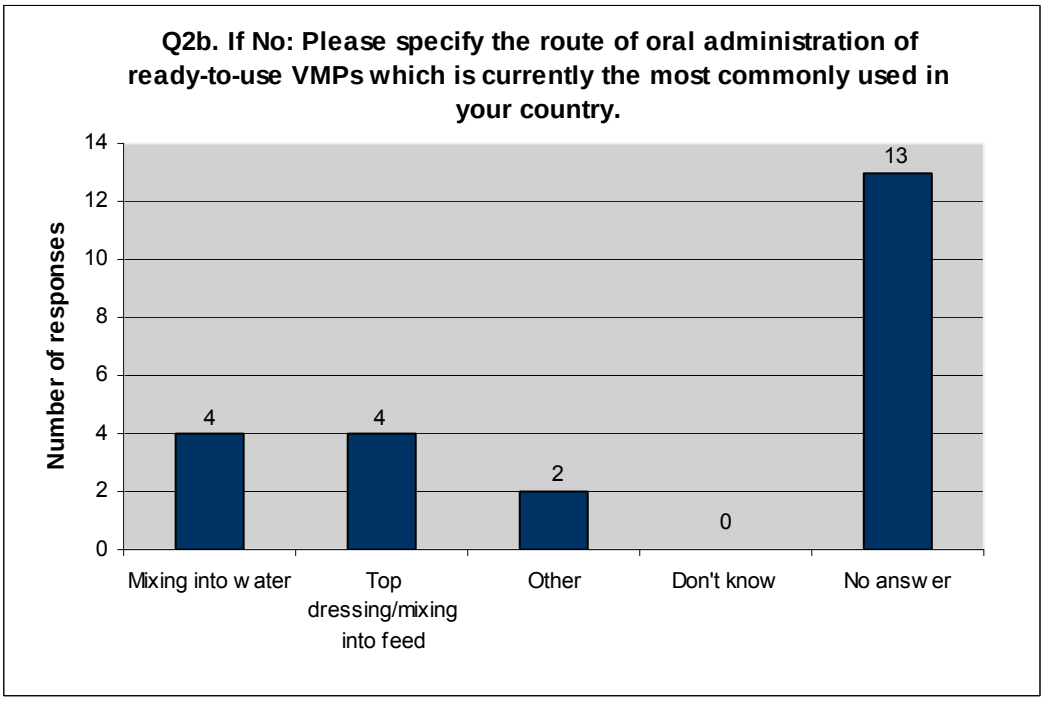
Please specify

Annex 10: Results of survey of national feed manufacturers' associations, associations of cooperatives and farmers' associations

A. Section for all stakeholders



Source: Civic Consulting survey of national feed manufacturers' associations, associations of cooperatives and farmers' associations, N= 23.

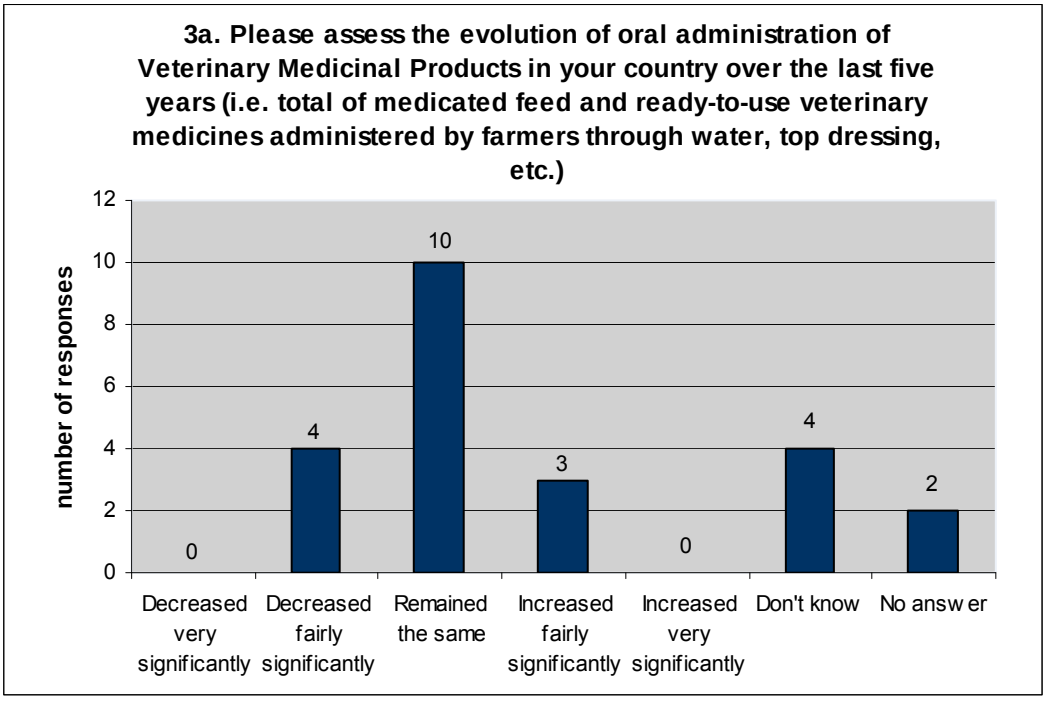


Source: Civic Consulting survey of national feed manufacturers' associations, associations of cooperatives and farmers' associations, N= 23.

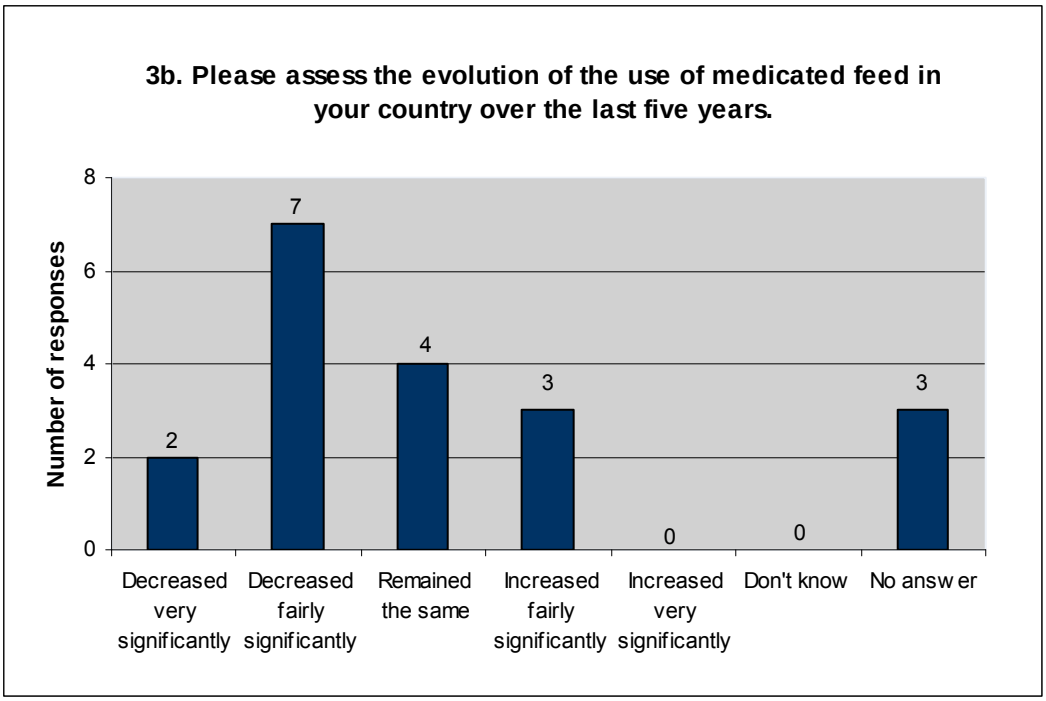
Table 35: Stakeholders' opinions by Member State concerning the most commonly used route of oral administration of VMPs (Q 2)

	Medicated feed	Mixing into water	Top dressing/ incorporation of ready-to-use VMPs in the feed
Czech Republic	√	√	
Denmark		√	√
France	√√		
Germany			√√√
Italy	√	√	
Portugal	√		
Spain	√		
United Kingdom	√√√	√	

Source: Civic Consulting survey of national feed manufacturers' associations, associations of cooperatives and farmers' associations, N= 18 (5 stakeholders did not provide any answer to the question and some respondents provided more than one answer).



Source: Civic Consulting survey of national feed manufacturers' associations, associations of cooperatives and farmers' associations, N= 23.



Source: Civic Consulting survey of national feed manufacturers' associations, associations of cooperatives and farmers' associations, N= 19.

Table 36: Stakeholders' opinions by Member State concerning the evolution of the use of oral VMPs over the last five years (Q 3b)

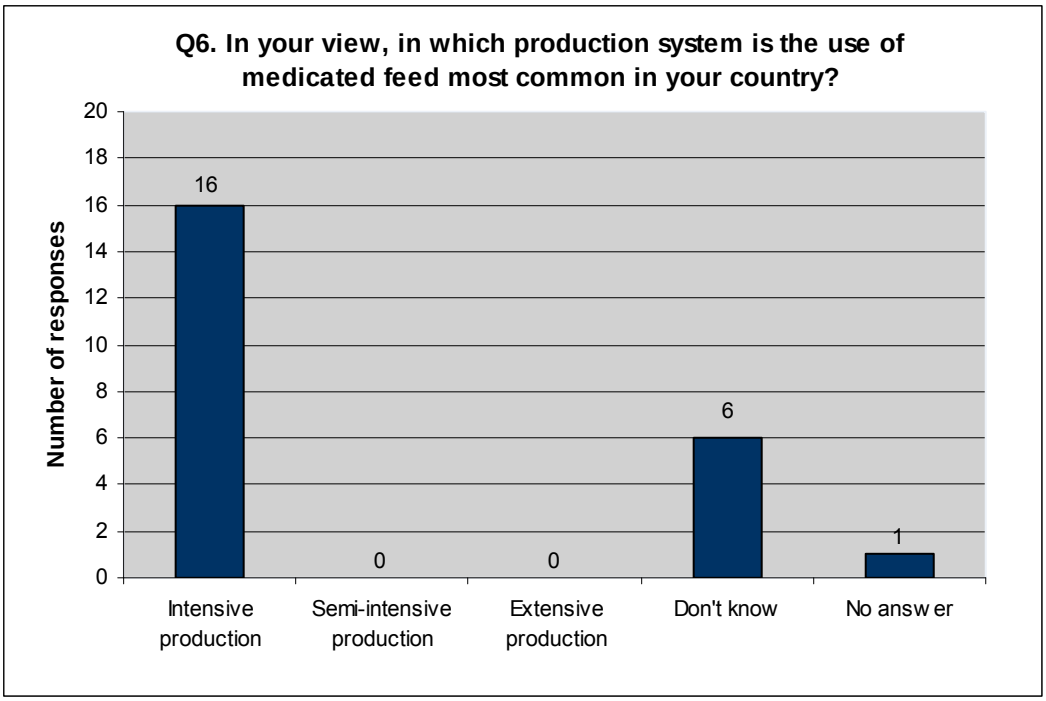
	Evolution of oral administration of VMPs	Evolution of the use of medicated feed
Belgium	Remained the same	Increased fairly significantly
Czech Republic	Remained the same	Decreased fairly significantly
Denmark	Increased fairly significantly	Increased very significantly [(a)]
Finland	Remained the same	Increased fairly significantly
France	Remained the same	Decrased fairly significantly
Germany	Increased fairly significantly	Decreased very significantly
Italy	Remained the same	n.a. [(b)]
Netherlands	Decrased fairly significantly	Decrased fairly significantly
Poland	Remained the same	Increased very sigificantly
Portugal	Increased fairly significantly	Increased fairly significantly
Spain	Remained the same	Remained the same
United Kingdom	Decreased fairly significantly	Decreased fairly significantly

Source: Civic Consulting survey of national feed manufacturers' associations, associations of cooperatives and farmers' associations, N= 19.

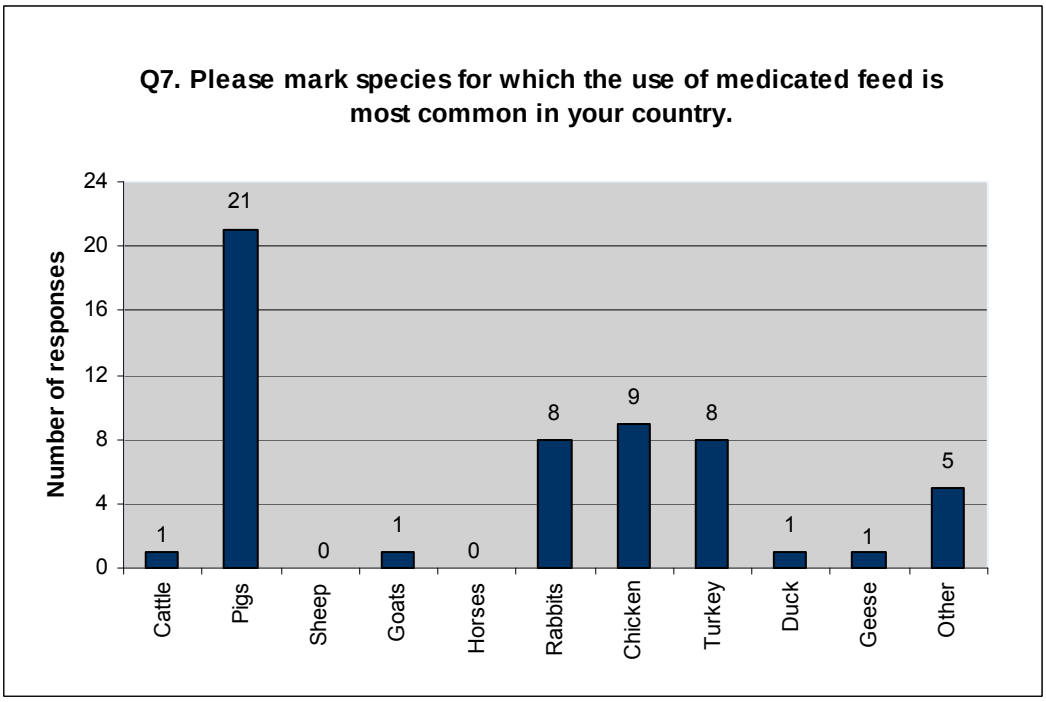
Notes:

(a) The increase in the use of medicared feed in Denmark is due to the authorisation of zinc oxides as veterinary medicine in 2005.

(b) Inconsistent data were obtained from stakeholders. An Italian farmers' association reported that the use of medicated feed remained the same over the last five years. However, production figures of medicated feed in Italy (estimated on basis of a sample representing 35 % of total production) show an increase in production during the period 2006 – 2008.



Source: Civic Consulting survey of national feed manufacturers' associations, associations of cooperatives and farmers' associations, N= 23.



Source: Civic Consulting survey of national feed manufacturers' associations, associations of cooperatives and farmers' associations, N= 23 (multiple answers possible).

Table 37: Stakeholders' opinions by Member State concerning species for which the use of medicated feed is most common (Q 7)

	Cattle	Pigs	Sheep	Goats	Horses	Rabbits	Chicken	Turkey	Duck	Geese	Other
Belgium		√				√					
Czech Republic		√					√				
Denmark		√√									
Finland		√									
France		√√				√√		√√			Game
Germany		√√√									
Italy	√	√√				√√	√	√	√	√	
Netherlands		√		√		√	√				
Poland		√					√	√			
Portugal		√				√	√	√			Fish
Spain		√				√	√				
Sweden		√									Fur and aqua-culture
United Kingdom		√√√√					√√√	√√√			Game

Source: Civic Consulting survey of national feed manufacturers' associations, associations of cooperatives and farmers' associations, N= 23 (multiple answers possible).

B. Section for Associations of Compound Feed Manufacturers and Cooperatives manufacturing Compound Feed only

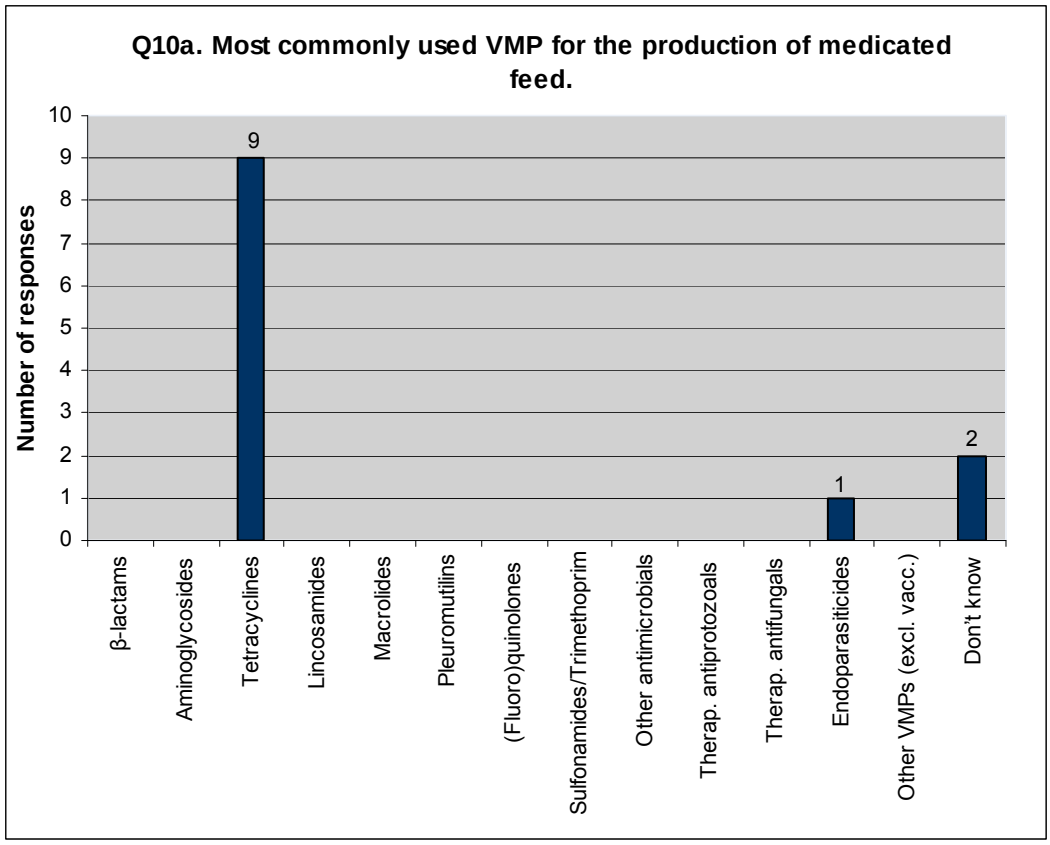
Q9. What was the total production of medicated feed and of compound feed over the last 5 years in your country? Please specify in tonnes.

	2004	2005	2006	2007	2008
Belgium					300
Czech Republic	92	111	154	149	99
Denmark [(a)]	-	0.01	3	9	12
France	800 - 1,000	800 - 1,000	800 - 1,000	800 - 1,000	800 - 1,000
Germany	225	150	80	20	12
Italy			1,085	1,260	1,330
Spain	2,600	2,500	2,200	2,000	2,000 – 3,000
United Kingdom					500

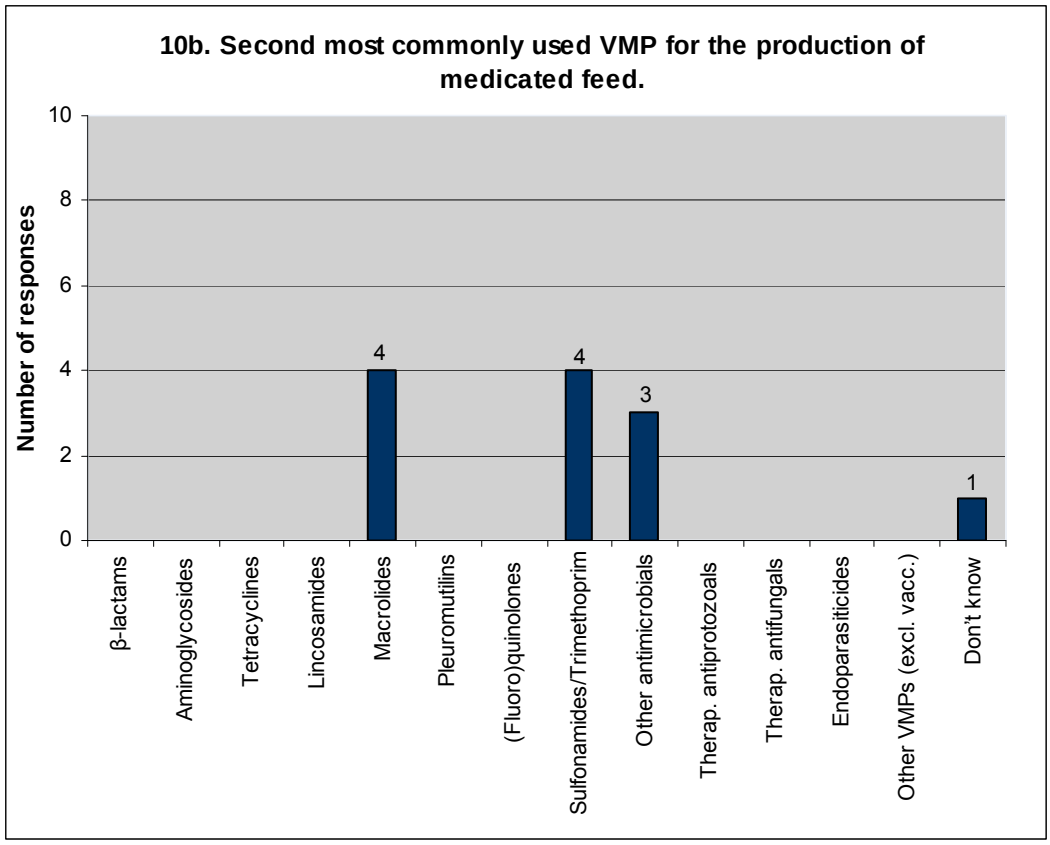
Source: Civic Consulting survey of national feed manufacturers' associations, associations of cooperatives and farmers' association, N=8.

Note:

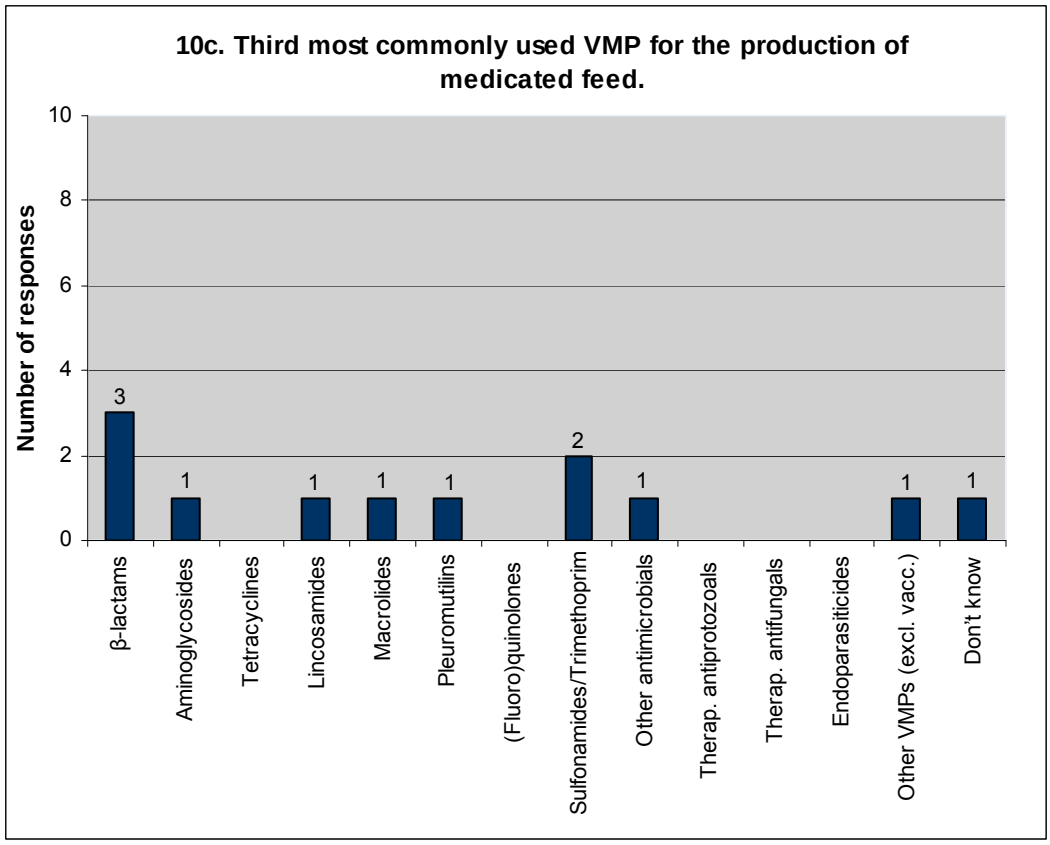
(a) Figures relate to total sales of medicated feed containing zinc oxides only. Calculated on basis of total sales of medicated pre-mixes containing zinc oxides (as provided by the Danish Register of Veterinary Medicines, VetStat) and on the assumption that 3 kg of pre-mix with zinc oxides are used per tonne of compound feed (see country case study Denmark).



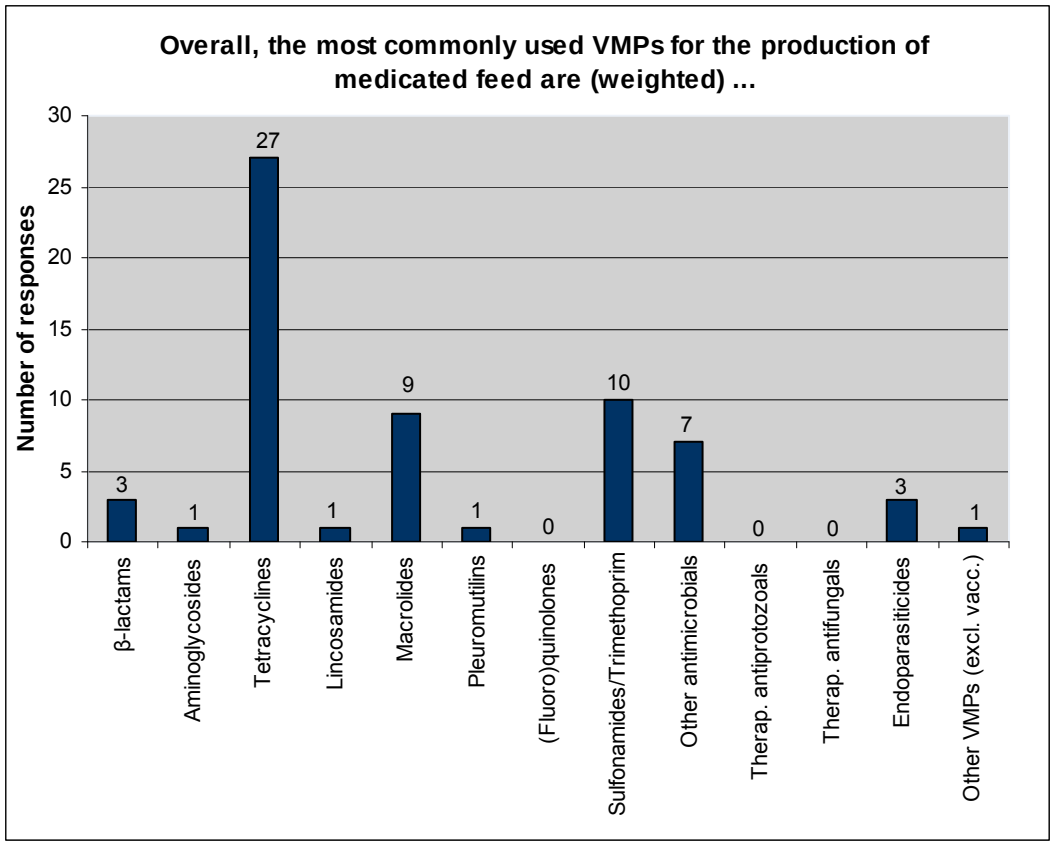
Source: Civic Consulting survey of national feed manufacturers' associations, associations of cooperatives and farmers' associations, N=12.



Source: Civic Consulting survey of national feed manufacturers' associations, associations of cooperatives and farmers' associations, N= 12.



Source: Civic Consulting survey of national feed manufacturers' associations, associations of cooperatives and farmers' associations, N= 12.

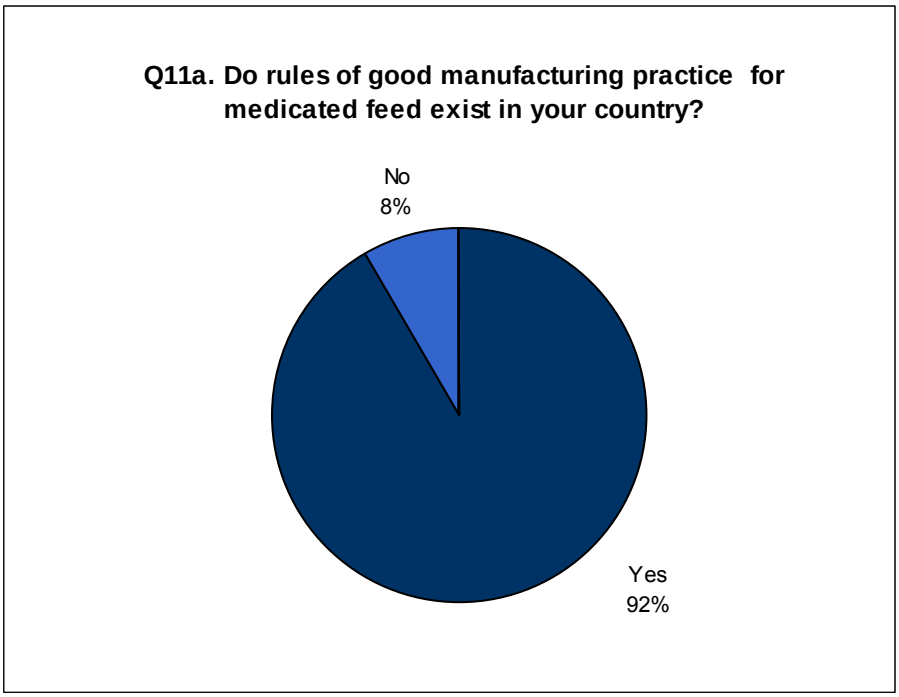


Source: Civic Consulting survey of national feed manufacturers' associations, associations of cooperatives and farmers' associations, Q 10, N= 12.
Note: Weights refer to the order of importance of VMPs, as assessed by stakeholders, i.e. VMPs mentioned as most commonly used are given a weight of 3, VMPs mentioned as second most commonly used are given a weight of 2, and VMPs mentioned as third most commonly used are given a weight of 1.

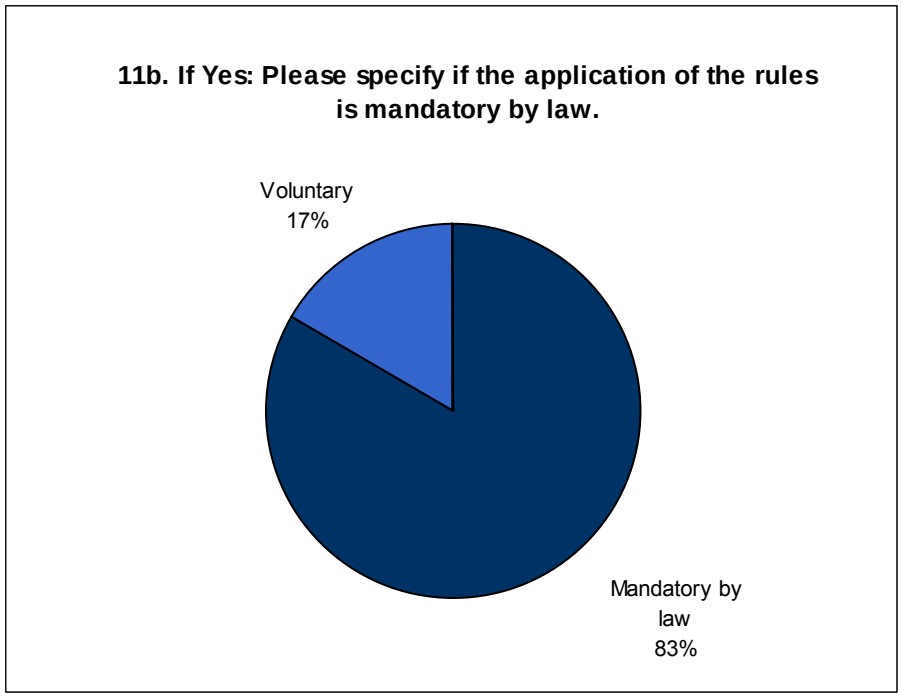
Table 38: Stakeholders' opinions by Member State concerning the Veterinary Medicinal Products (VMPs) most commonly used for the production of medicated feed (Q 10)

	β-lactams	Aminoglycosides	Tetracyclines	Lincosamides	Macrolides	Pleuromutilins	(Fluoro)quinolones	Sulfonamides/ Trimethoprim	Other antimicrobials	Therapeutic Antiprotozoals	Therapeutic Antifungals	Endoparasiticides (incl. Anthelmintics)	Other VMPs (excluding vaccines)
Belgium								√	Colistin sulfate			√	
Czech Republic			√		√			√	Penicil-lins				Zinc oxides
Denmark					√	√							
France		√	√√		√√			√	Amino-glyco-sides				
Germany			√					√	Colistin				
Italy	√		√					√					
Portugal			√		√				Poli-mixines				
Spain			√	√					√				
United Kingdom	√√		√√					√√					

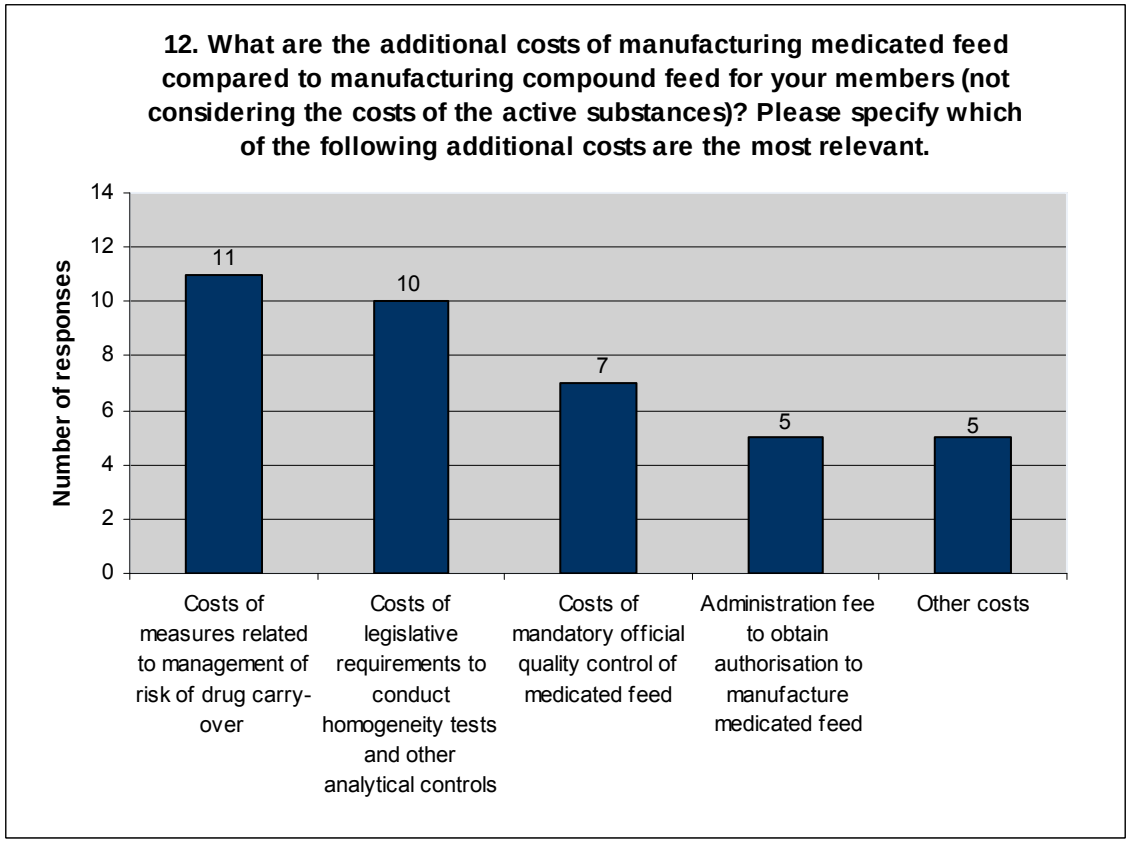
Note: Table includes the three VMPs most commonly used (without reference to rank allocated), as reported by stakeholders.
Source: Civic Consulting survey of national feed manufacturers' associations, associations of cooperatives and farmers' associations, N=12.



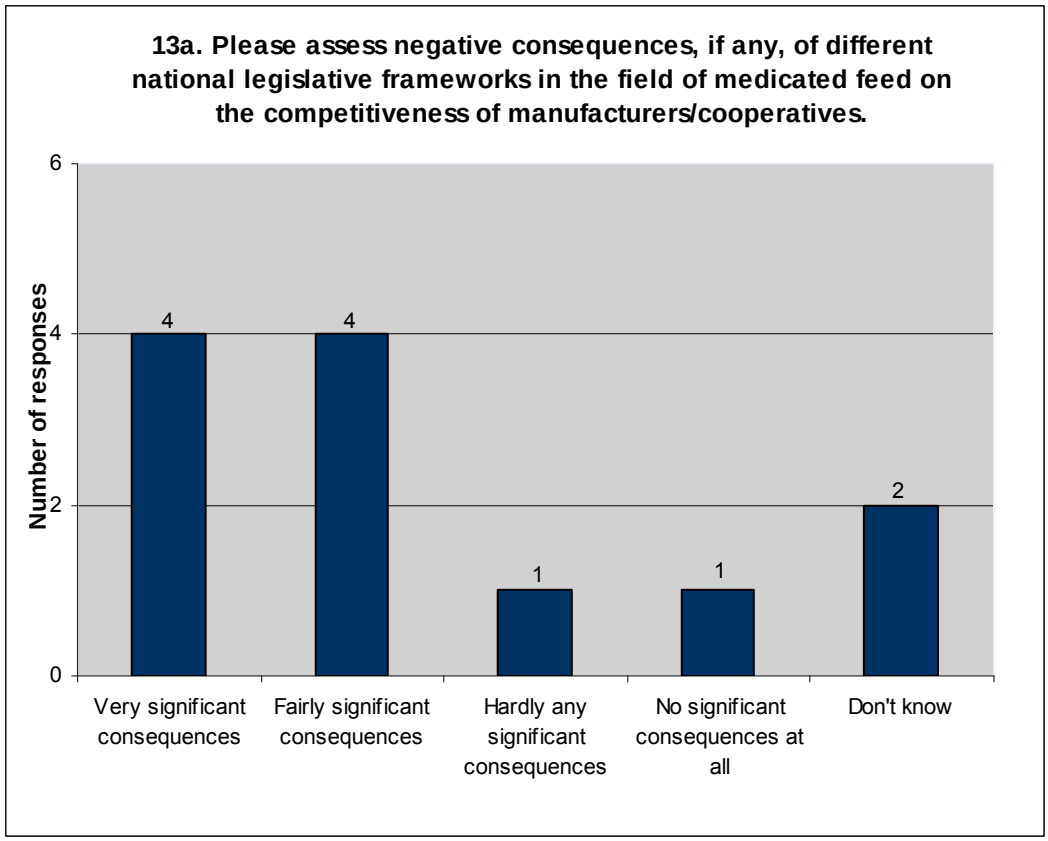
Source: Civic Consulting survey of national feed manufacturers' associations, associations of cooperatives and farmers' associations, N= 12.



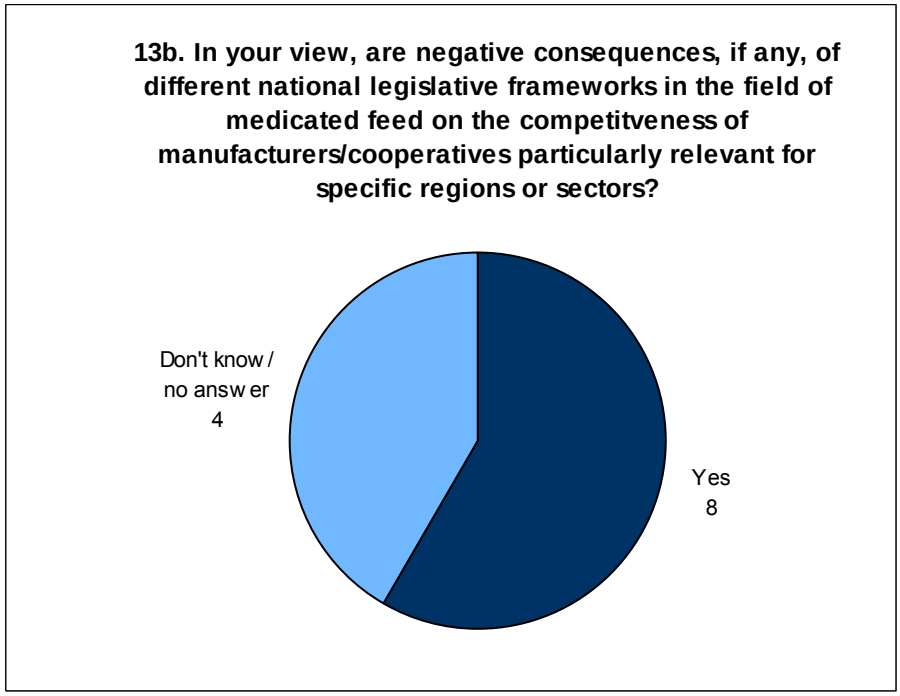
Source: Civic Consulting survey of national feed manufacturers' associations, associations of cooperatives and farmers' associations, N= 12.



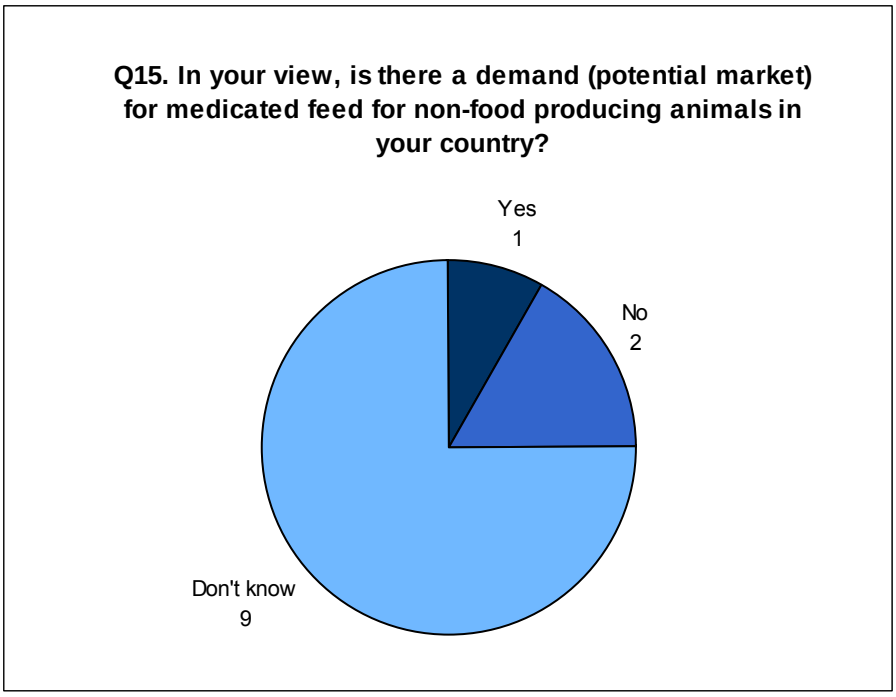
Source: Civic Consulting survey of national feed manufacturers' associations, associations of cooperatives and farmers' associations, N= 12 (multiple answers possible).



Source: Civic Consulting survey of national feed manufacturers' associations, associations of cooperatives and farmers' associations, N= 12.

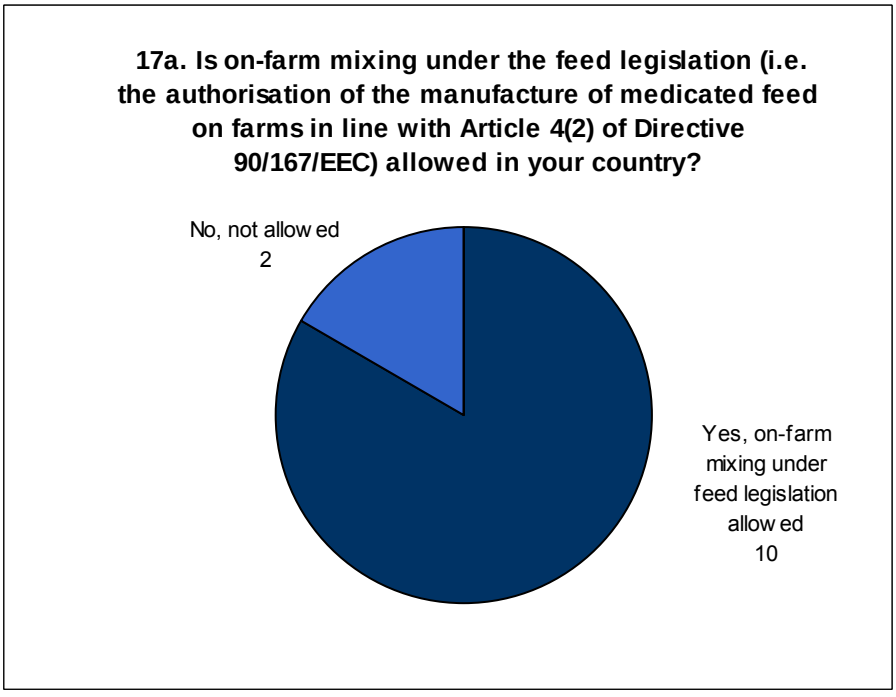


Source: Civic Consulting survey of national feed manufacturers' associations, associations of cooperatives and farmers' associations, N=12.



Source: Civic Consulting survey of national feed manufacturers' associations, associations of cooperatives and farmers' associations, N=12.

C. Section for Farmers' Associations only

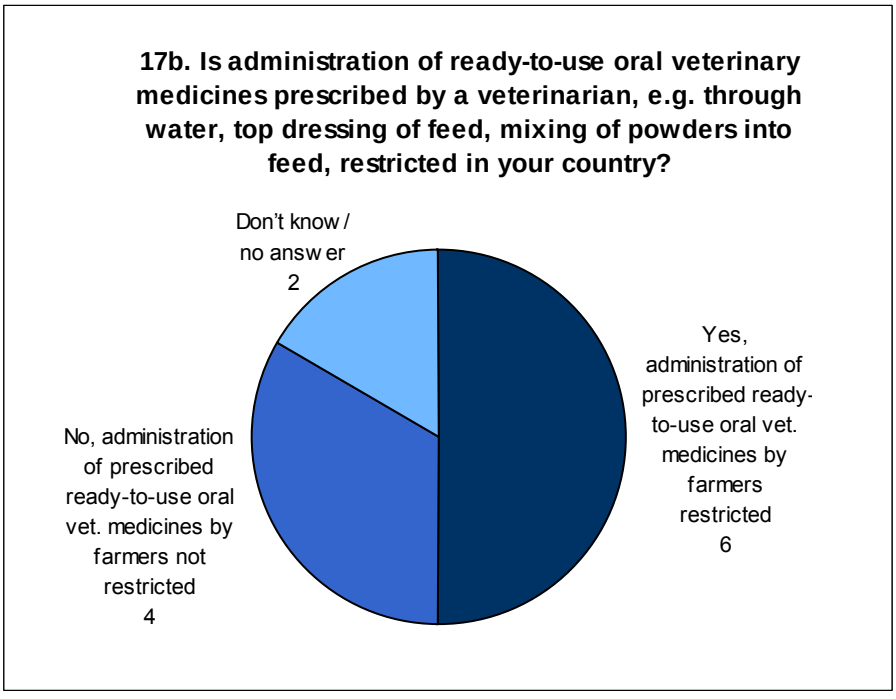


Source: Civic Consulting survey of national feed manufacturers' associations, associations of cooperatives and farmers' associations, N=12.

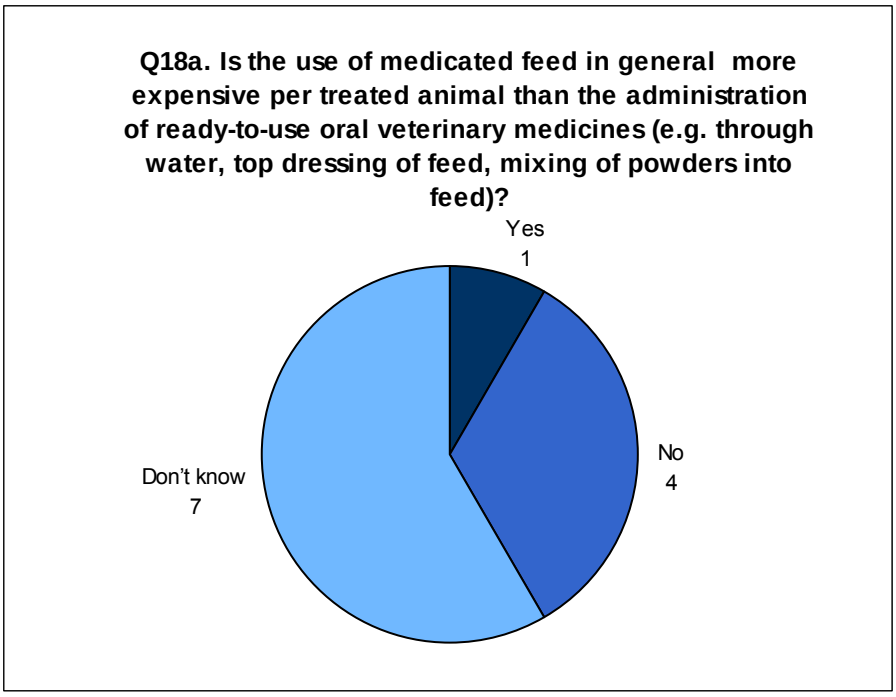
Table 39: Stakeholders' responses by Member State to the question: "Is on-farm mixing under the feed legislation (i.e. the authorization of the manufacture of medicated feed on farms in line with Article 4(2) of Directive 90/167/EEC) allowed in your country?" (Q 17a)

	Yes	No
Denmark		√
Finland	√	
France	√	
Germany		√
Italy	√	
Netherlands	√	
Slovenia		√
Sweden	√	
United Kingdom	√	

Source: Civic Consulting survey of national feed manufacturers' associations, associations of cooperatives and farmers' associations, N=12 (several responses were received for the UK and France).



Source: Civic Consulting survey of national feed manufacturers' associations, associations of cooperatives and farmers' associations, N=12.

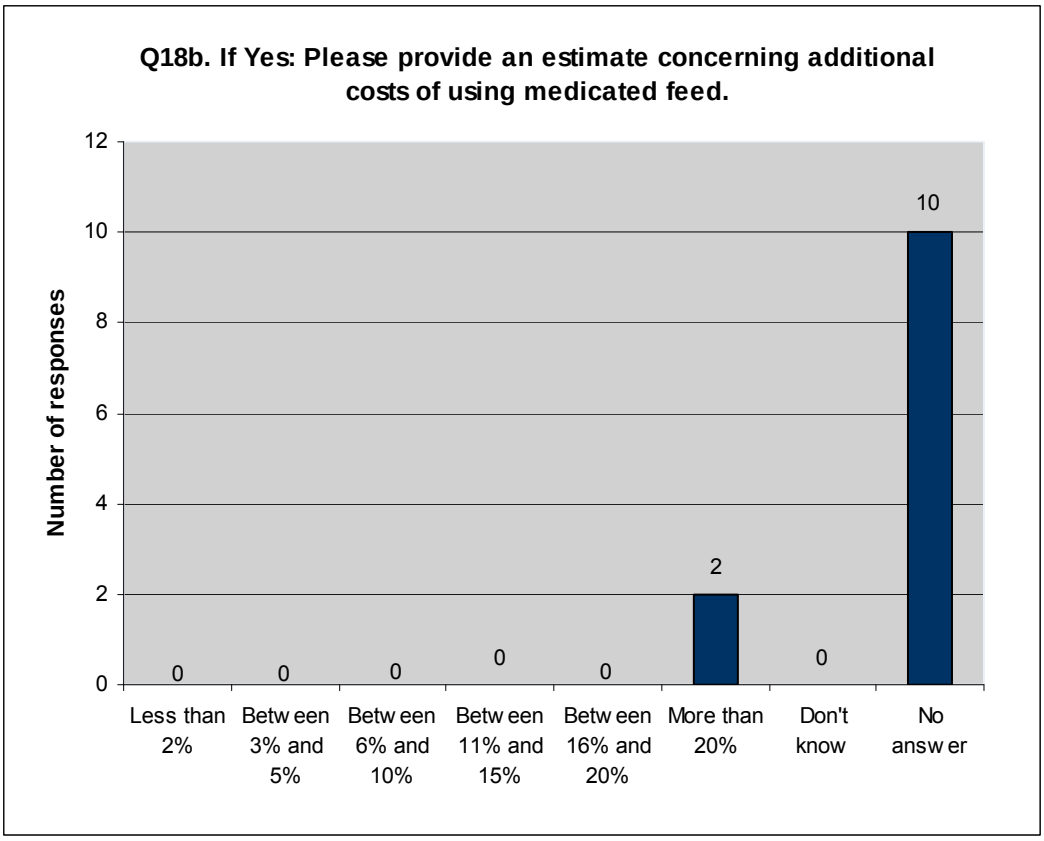


Source: Civic Consulting survey of national feed manufacturers' associations, associations of cooperatives and farmers' associations, N=12.

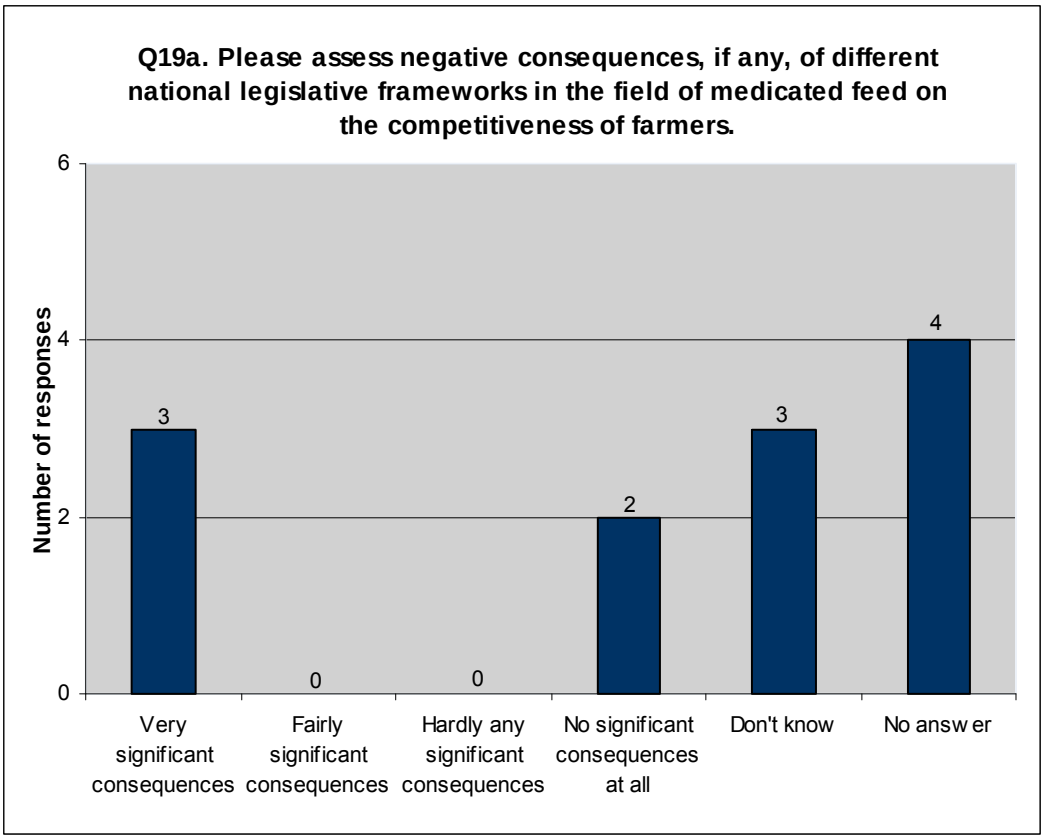
Table 40: Stakeholders' responses by Member State to the question: "Is the use of medicated feed in general more expensive per treated animal than the administration of ready-to-use oral veterinary medicines (e.g. through water, top dressing of feed, mxing of powders into feed)" (Q 18a)

	Yes	No	Don't know
Denmark	√		
Estonia			
Finland		√	
France		√	√
Germany			√
Italy			√
Netherlands		√	
Slovenia			√
Sweden			√
United Kingdom		√	√√

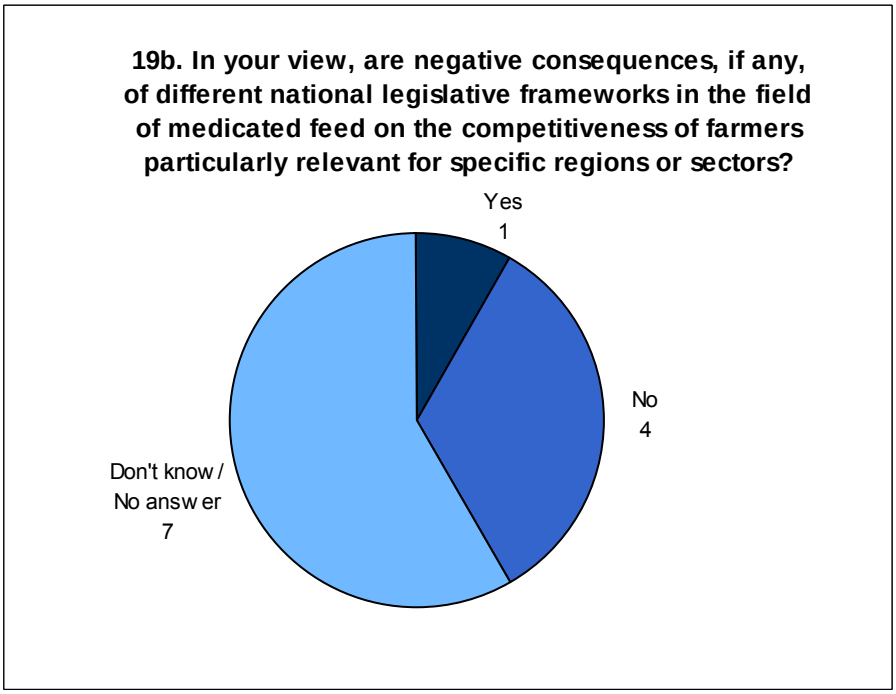
Source: Civic Consulting survey of national feed manufacturers' associations, associations of cooperatives and farmers' associations, N=12.



Source: Civic Consulting survey of national feed manufacturers' associations, associations of cooperatives and farmers' associations, N=12.



Source: Civic Consulting survey of national feed manufacturers' associations, associations of cooperatives and farmers' associations, N=12.



Source: Civic Consulting survey of national feed manufacturers' associations, associations of cooperatives and farmers' associations, N=12.

Annex 11: Case studies

1. Key issues considered for case studies

In practice, a number of issues needed to be considered to calculate additional production costs of medicated feed for manufacturers and cost differences between medicated feed and the alternatives of oral administration of VMPs for farmers. These issues are outlined below, along with the approaches used to resolve them:

Issue 1: Difficulty comparing additional costs of manufacturing medicated feed between case study countries

Issue

Feed mills selected in case study countries have different cost structures, partly caused by different production volumes of medicated feed. This leads to difficulties when comparing costs between feed mills.

Resolution

The study focused on the additional costs of producing medicated feed compared to the costs of producing compound feed (i.e. on the cost differential). Additional costs of producing medicated feed for feed mills focused on the production process and did not include transport costs of the medicated feeds to the farms. Additional costs of producing medicated feed were collected according to the cost factors presented in the table below.

Table 41: Cost factors for the production of medicated feed compared with the costs of the production of compound feed

Cost factors
Additional consumption of fixed capital
Additional consumption of fixed capital related to additional equipment
Additional consumption of fixed capital related to additional buildings
Additional labour costs
Additional cleaning costs
Cost of tests (including homogeneity tests, tests of drug carry-over, analytical control of concentration of active substance in medicated feed)
Additional adminitrative costs (annual administrative fee)

Note:
(a) Annual depreciation costs were calculated on the basis of data on replacement costs of capital collected during interviews in case study countries. A useful life of 20 years was applied to buildings (e.g. storage room for medicated pre-mixes) in all case study countries.

In order to compare cost data across case study countries, additional costs of manufacturing medicated feed were calculated per tonne of medicated feed.

It was not possible to quantify opportunity costs in a systematic way in all case study countries; these costs could therefore not be included in the cost calculations.[97] Similarly, interest on capital tied up in storage of medicines and costs related to export certifications were not taken into consideration.

Cost data for Denmark and the United Kingdom were converted in Euro using ECB exchange rates.[98]

Issue 2: Difficulty comparing additional costs of producing medicated feed with the costs of producing compound feed

Issue

Data on production costs of compound feed were not directly available. To be able to compare additional costs of producing medicated feed with the costs of producing compound feed, it was therefore necessary to first estimate the costs of producing compound feed.

Resolution

Production costs of compound feed were calculated on the basis of sale prices of compound feed of similar quality and composition as the one used for the production of medicated feed, and an estimate of the gross margin (i.e. the difference between sales revenue and production costs) applied by feed mills, using the following formula:

$$\text{Production costs of compound feed} = \text{Sale price of compound feed} * (1 - \% \text{ gross margin rate})$$

The average gross margin for compound feed is assumed to amount to 4%.[99] Sale prices of compound feed were provided by feed mills interviewed during the case studies, as indicated in the table below:

[97] Opportunity cost is defined at the value of a resource in its best alternative use (see European Commission, Directorate General Regional Policy 2008). Opportunity costs may arise from the fact that the production line may be stopped and cleaned between two sequences of production of medicated feed to prevent risk of drug carry-over. According to one feed mill, production of medicated feed would cut overall production by 33%. Similarly, transport of medicated feed may also result in opportunity costs, as medicated feeds may not be transported together in the same lorry with compound feeds or with food intended for human consumption. Delivery of medicated feeds may therefore result in sub-optimal delivery routes and sub-optimal use of transport capacities.

[98] The following exchange rates were used: 1 Pound sterling = 1.0812 Euro (conversion rate as of October 7, 2009 as provided by the ECB, available at: http://www.ecb.int/stats/exchange/eurofxref/html/index.en.html); 1 Danish Krone = 0.1343 Euro (conversion rate as of October 7, 2009 as provided by ECB, available at: http://www.ecb.int/stats/exchange/eurofxref/html/index.en.html).

[99] According to the European Feed Manufacturers' Federation (FEFAC), the gross margin for compound feed is between 2 and 6 %.

Table 42: Sale prices and production costs of a tonne of compound feed of similar quality and composition as the one used for the production of medicated feed in case study countries

	Denmark	France	Germany	United Kingdom
Sale price of a tonne of compound feed (in Euro, excluding VAT)	196	248	290	189
Production cost of a tonne of compound feed (in Euro, excluding VAT)	188	238	278	181

Source: Civic Consulting, data collected from feed mills and national feed manufacturers' associations interviewed in case study countries.
Note: The table presents sale prices of compound feed for pigs.

Issue 3: Difficulty obtaining prices of medicated feed

Issue

It was difficult to collect data on prices of medicated feed excluding the cost of active substances (i.e. on prices charged by feed mills to farmers for mixing the medicine with the feed). In addition, pricing strategies of medicated feed appear to differ significantly across feed mills.[100]

Resolution

To be able to compare costs for farmers across case study countries, a number of assumptions were made, and it is on these assumptions that cost results were obtained.

Interviews in case study countries revealed that pricing strategies of feed mills concerning medicated feed can be grouped into the following three pricing scenarios:

- *Scenario 1 – Fully cross-subsidised price (price of compound feed + price of active substance only)*:

  It is assumed that the feed mill charges no extra cost for mixing the medicine with the feed, i.e. the medicated feed is sold at a price below its production cost and the total additional cost of producing medicated feed is subsidised by the additional price charged on other products.[101]

- *Scenario 2 – Cost price (price of compound feed + price of active substance + cost of mixing the medicine with the feed):*

  It is assumed that the feed mill charges the full amount of the additional cost of mixing the medicine with the feed without making any profit on the additional cost.

[100] For example, feed mills may charge only a share of the additional cost of manufacturing medicated feed, or an average production cost for a mix, and apply this to all feeds manufactured whether the feed is medicated or not, while others may apply a margin on their additional production costs of medicated feed.

[101] Feed mills do not usually subsidise the total cost of manufacturing medicated feed, as revealed by the interviews conducted in case study countries. The share of the additional cost that is subsidised may vary significantly across feed mills. The fully-subsidised price scenario, however, provides an indication of the lowest price that can be offered for a tonne of medicated feed.

- *Scenario 3 – Price with gross margin of 6% (price of compound feed + price of active substance + margin of 6% on total production cost of medicated feed):*

  It is assumed that the feed mill charges a margin of 6% on the total production cost of medicated feed.[102]

Issue 4: Difficulty comparing costs of using medicated feed and water medication for pig farmers between case study countries

Issue

Farms may differ, e.g. in terms of size, number of treatments administered per year and equipment used for the administration of veterinary medicines via water. In addition, medicated feed and water medication do not have the same nutritional value; associated costs cannot therefore be compared directly.

Resolution

To be able to compare costs for farmers across case study countries, a number of assumptions were made, and it is upon these assumptions that cost results were obtained.

(a) General assumptions on pigs

The assumptions that were made concerning pigs are presented in the table below.

Table 43: Assumptions concerning pigs

Criterion	Assumption
Pig live weight	30 kg
Number of pigs treated per treatment	100
Number of pigs on farm	1,000
Production cycle of a pig	6 months
Average daily medicated feed intake per pig	1.5 kg (for a pig of 30 kg)
Average number of treatments per pig during production cycle	2.4

Source: Civic Consulting, data collected during case studies.

(b) Active substances administered to pigs

Information on duration of treatments and dosage of active substance was provided by a VMP manufacturer, a German distributor of VMPs and a veterinarian (see Table 44). Costs on active substances were provided by a VMP manufacturer active in the four case study countries and by a German distributor of VMPs.

[102] According to the European Feed Manufacturers' Federation (FEFAC), the gross margin for medicated feed is between 2 and 11 % . 6 % was considered to be a realistic average value.

Table 44: Dosage and duration of treatments

Active substance	Dosage of active substance per day (in mg/kg of pig weight)	Duration of treatment (in days)
Aminoglycosides (Apramycin)	12.5	7
Macrolides (Tylosin)	25.0	10
Macrolides (Tilmicosin)	20	5
Tetracyclines	85	5
Sulfonamides/ Trimethoprim	30	5

Source: VMP manufacturer, German distributor of VMPs and veterinarian.

(c) Equipment used by farmers

- Equipment used for medicated feed

It is assumed that farmers do not use any special equipment to store and administer medicated feed in addition to the equipment usually used to feed pigs.[103]

- Equipment used for water medication[104]
  - Dosing pump

In water medication a dosing pump is used to inject the medicine into the water system. A hydraulic dosing pump *Dosatron D25RE5* is considered for the calculation. The recommended price of the pump in the four case study countries amounts to 565,68 Euro (excluding VAT) and the average useful life of the pump is considered to be 8 years.[105]

  - Mixer container:

A mixer container is used to prepare the stock solution according to the veterinarian's prescription. The price of a 100-litre mixer container with a continuous stirrer is estimated to amount to 465 Euro (excluding VAT) in the four case study countries. The average useful life of a container is assumed to be 25 years.

(d) Labour costs

Labour costs relate to the time spent adding the veterinary medicine to the carrier (i.e. feed or water). The table below presents the average time spent adding the veterinary medicine to the carrier, as reported by interviewees in case study countries.

[103] It is, for example, assumed that farmers do not use a separate silo to store medicated feed.

[104] Depreciation of equipment is calculated per pig using the straight-line depreciation method and assuming that each item of equipment is used to treat 480 pigs per year. It is assumed that one pump and one container are sufficient to treat the 1,000 pigs on the farm. On basis of the assumption that a pig lives 6 months, a pump can serve 2,000 pigs per year. As it is assumed that, of 1,000 pigs, 100 pigs receive a treatment; 200 pigs therefore receive a treatment every year (see a above). On the assumption that the average number of treatments per pig is 2.4, the total number of pigs treated per year therefore amounts to 480.

[105] Data provided by Dosatron International (manufacturer of dosing pumps).

Table 45: Time spent to add the veterinary medicine into the carrier

	Medicated feed	Top dressing/ incorporation of ready-to-use VMPs in the feed
Time spent adding the veterinary medicine to the carrier (in minutes/day of treatment) per 100 pigs treated	0	15 mins

Source: Civic Consulting, data collected during case studies.

Labour costs were calculated on the basis of hourly labour costs provided by the agri-info portal.[106]

Table 46: Labour costs in case study countries

	Denmark	France	Germany	United Kingdom
Hourly labour costs of farm workers (in Euro, 2009)	16.1	11.2	10.9	10.0

Source: Agri-info portal (available at: http://agri-info.eu/english/t_wages.php).
Note: As data on labour costs were available on the agri-info.eu website for the year 2007 only, estimates for 2009 were obtained using a GDP deflator index as provided by the World Economic Outlook Database (April 2008) of the International Monetary Fund (available at: https://www.imf.org/external/pubs/ft/weo/2009/01/weodata/weorept.aspx?sy=2007&ey=2014&scsm=1&ssd=1&sort=country&ds=.&br=1&pr1.x=61&pr1.y=10&c=128%2C132%2C134%2C112&s=NGDP_D&grp=0&a=#download).

(e) Total costs of using medicated feed or water medication

The cost of using medicated feed corresponds to the sale price of medicated feed, which includes the costs of the carrier feed and the cost of the medicine. In contrast, the cost of using water medication includes the cost of the medicine as well as the costs of equipment needed to prepare the medicinal solution (e.g. dosing pump) and labour costs (in terms of time spent preparing the solution), but does not include the cost of feed. To obtain cost data that are comparable between the two routes of administration, the price of a tonne of compound feed of similar quality and composition as the one used for the production of medicated feed (see issue 2) was therefore added to the costs of water medication, taking thereby into account the additional nutritional value of the medicated feed.

[106]The portal agri-info provides information on wages and working conditions in agriculture in Europe on the basis of a survey of agricultural trade unions. This research has been carried out by IG BAU, EFFAT and PECO-Institute, with financial support from the European Commission (see www.agri-info.eu).

2. Case study Denmark

2.1. Key results

In Denmark top dressing, mixing of ready-to-use veterinary medicine into feed and water are more commonly used than medicated feed. Even though the production of medicated feed has increased since 2005, following the authorisation of zinc oxides as veterinary medicine, medicated feed production remains limited in Denmark.[107]

Additional production costs of medicated feed

The additional cost of producing medicated feed compared with the production cost of compound feed amounts to 11.89 Euro per tonne. The additional cost is mainly due to additional labour costs, which amount to 53% of the total additional cost. Costs of cleaning the production line after production of medicated feed constitute 15% of the total additional cost, while costs related to tests (i.e. homogeneity test, test of drug carry-over and analytical control) represent 10% of the total additional cost. The cost of additional equipment used for the production of medicated feed (to dose and transport the medicated pre-mix from the weighing equipment to the mixer) corresponds to 17% of the total additional cost. It can be concluded that it is 6 % more costly to produce medicated feed than compound feed (see Table 50).

Cots of using medicated feed for farmers

In Denmark the cost advantage of treating animals via medicated feed rather than via water medication seems to depend on the active substance. Under all scenarios it is less expensive to administer Apramycin via medicated feed than via water but it is more expensive to administer Tylosin via medicated feed than via water.

Table 47: Costs of treating via water medication compared with the costs of treating via medicated feed (index values)

	Medicated feed			**Water medication**		
	Aminoglycosides (Apramycin)	Macrolides (Tylosin)	Macrolides (Tilmicosin)	Aminoglycosides (Apramycin)	Macrolides (Tylosin)	Macrolides (Tilmicosin)
Scenario 1: *Fully cross-subsidised price*	Set at 100 for each active substance and for each scenario.			111	73	n.a.
Scenario 2: *Cost price*				108	71	n.a.
Scenario 3: *Price with gross margin of 6%*				106	70	n.a.

Source: Civic Consulting.

[107] Data on total production of medicated feed are not available in Denmark. However, the volume of medicated feed produced in 2008 with medicated pre-mixes containing zinc oxides, which represented 95% of total use of medicated pre-mixes in 2008 (compared with 0.6% in 2005), is estimated to amount to 12,000 tonnes. When excluding medicated pre-mixes containing zinc oxides, the volume of medicated pre-mixes used to produce medicated feed decreased from 6.9 tonnes in 2005 to 1.9 tonnes in 2008.

2.2. Production of medicated feed

Data on total production of medicated feed are not available in Denmark. However, the volume of medicated feed produced in 2008 with medicated pre-mixes containing zinc oxides, which represented 95% of the total use of medicated pre-mixes in 2008, is estimated to be 12,000 tonnes. Even if the production of medicated feed has increased since 2005 following the authorisation of zinc oxides as veterinary medicine, medicated feed production remains limited in Denmark.[108]

Table 48: Production of medicated feed

Production of medicated feed					
	2004	2005	2006	2007	2008
Total sales of medicated pre-mixes over the last five years (in tonnes of active substances) (a)	4.7	7.0 (0.041)	11.3 (7.6)	30.9 (26.4)	37.5 (35.5)
Total sales of medicated feed containing zinc oxides over the last five years (in '000 tonnes) (b)	-	0.01	2.5	8.8	11.8
Total production of compound feed (in '000 tonnes) (c)	5,630	5,319	5,205	5,206	4,960
VMPs used for the production of medicated feed	According to the Danish Plant Directorate of the Danish Ministry of Food Agriculture and Fisheries, the medicinal substances used in authorised medicated pre-mixes include: ❑ Acetylvaleryltylosin, ❑ Apramycin sulphate, ❑ Yersenia vaccine, ❑ Chlortetracycline, ❑ Oxolin acid, ❑ Valnemulin Hydrochloride, ❑ Ivermectin, Florfenicol, Paracetamol, ❑ Doxycyclin hyclate, ❑ Tilmicosin phosphate, ❑ Amoxicillin, ❑ Sulfadiazin and Trimethoprim, ❑ Tylosin phosphate.				
Medicated pre-mixes authorised for the production of medicated feed	The numbers of medicated pre-mixes authorised for the period 2004-2008 are as follows: ❑ 2004: 12				

[108] While medicated pre-mixes with zinc oxides represented 0.6 % of the total volume of medicated pre-mixes used in medicated feed production in 2005, they amounted to 94.9 % in 2008. Excluding medicated pre-mixes containing zinc oxides, the volume of medicated pre-mixes decreased from 6.9 tonnes in 2005 to 1.9 tonnes in 2008.

(Art. 3 of Directive 90/167/EEC)	❑ 2005: 13 (one new medicated pre-mix was authorised) ❑ 2006: 16 (three new medicated pre-mixes were authorised) ❑ 2007: 16 (no new medicated pre-mix was authorised) ❑ 2008: 15 (one new medicated pre-mixes was authorised, and two were cancelled)
Number of approved operators for the placing on the market ofmedicated feed	Operators authorised to manufacture medicated feed in Denmark can be grouped as follows: ❑ Manufacturing establishments: 15 (d) ❑ Distributors: 4 There are no mobile mixers or farm producers in Denmark. Every company importing, exporting, producing, storing or handing out pre-mixes or medicated feed has to be authorised by the Danish Medicines Agency (*DKMA*).
Rules of good manufacturing practice (Art. 4 (1d) of Directive 90/167/EEC)	The rules governing the production of medicated feed by feed mills are described in the executive order numbers 1228, 1251 and 1254 implementing Directive 90/167/EEC.(e) In Denmark the manufacturing process must conform to the rules of good manufacturing practice of the EU GMP on the rules governing medicinal products in EU; (f) however, some exceptions from these rules are allowed. (g)
On-farm mixing (Art. 4(2) of Directive 90/167/EEC)	On-farm mixing under the feed legislation (Art. 4(2) of Directive 90/167/EEC) is not allowed in Denmark.
Official controls on the compliance with the legal provisions of the Directive 90/167/EEC	The control of the production of pre-mixes and medicated feeds is the responsibility of the *DKMA*. In Denmark, manufacturers of medicated feeds are audited every two to three years by the *DKMA*. Audits can be normal routine audits or audits in connection with a new application for a license. If serious non-compliance is found at a manufacturer of medicated feed, the license can be restricted or suspended. The Danish Plant Directorate regulates drug carry-over in samples of feeds.

Notes:

(a) Source: Danish Register of Veterinary Medicines (VetStat). Volumes of sales of medicated pre-mixes containing zinc oxides are indicated in brackets.

(b) Volumes of sales of medicated feed containing zinc oxides are based on an estimate of 3 kg of pre-mix per tonne of compound feed.

(c) Source: Statistics Denmark (available at: http://www.statbank.dk). Data include medicated feed.

(d) 5 feed mills are authorised to manufacture medicated feeds with zinc oxides only. The others are authorised to manufacture medicated feed from all authorised medicated pre-mixes.

(e) See *Bekendtgørelsen nr. 1251 af 12. december 2005 om fremstilling og forhandling m.v. af foderlægemidler til dyr* (available at: http://lms-lw.lovportaler.dk/ShowDoc.aspx?docId=bek20051251-full), *Bekendtgørelsen nr. 1254 af 12. december 2005 om fremstilling og forhandling m.v. af foderlægemidler til fisk m.m (available at*: http://lms-lw.lovportaler.dk/ShowDoc.aspx?docId=bek20051254-full) and *Bekendtgørelse nr. 1228 af 12. december 2005 om indførsel af visse foderlægemidler til dyr og fisk* (available at: http://lms-lw.lovportaler.dk/ShowDoc.aspx?docId=bek20051228-full).

(f) See http://ec.europa.eu/enterprise/pharmaceuticals/eudralex/vol4_en.htm.

(g) For example, there is no requirement for analysis for every batch produced, and reduced requirements for clean facilities. These exceptions and the Danish implementation of the EU GMP on rules governing medicinal products in the European Union can be found in the executive orders implementing Directive 90/167/EEC (see (e) above).

Table 49: Additional costs of manufacturing medicated feed compared with production costs of compound feed (in Euro)

Additional costs of manufacturing medicated feed compared with production costs of compound feed (in Euro) [(a)]		
Cost factor	**Description of cost factor**	**Additional cost/tonne (in Euro)**
Additional consumption of fixed capital related to medicated feed production		
Additional equipments used for medicated feed production	This includes the cost of the equipment used to dose and transport the medicated pre-mix from the weighing equipment to the mixer.	2.02
Additional buildings used for medicated feed production	Storage room for medicated pre-mixes.	0.30
End-of-line mixer	End-of-line mixers were reported as not used in Denmark.	Not applicable
Additional labour costs for medicated feed production		
Veterinarian/pharmacist	Not applicable.	Not applicable
Other labour costs	Additional labour costs relate to additional tasks related to medicated feed production (e.g. administration of prescriptions, control of production, cleaning of equipment, handling of premixes).	6.33
Additional cleaning costs for medicated feed production		
Costs of flushing/rinsing	This additional cost includes the cost of raw materials and cost of disposing of materials once flushed through the production line.	1.75
Cost of tests		
Homogeneity test	The number of tests and the methods of analysis are defined by feed mills themselves.	1.21
Test of drug carry-over		
Analytical control of concentration of active substance in medicated feed		
Administrative costs		
Annual administrative fee	Feed mills producing medicated feed pay an annual fee amounting to 15,366 Danish Krone (regardless of the volume of the medicated feed production).	0.28
Total additional cost of manufacturing medicated feed (not including cost of the active substances)		***11.89***

Notes:
(a) Costs are based on an annual production of 7,431 tonnes of medicated feed.
(b) However, during inspections of feed mills, agents of the *DKMA* evaluate the entire set-up, and further requirements can be imposed on the feed mills.

The additional cost of producing medicated feed compared with the production of compound feed amounts to 11.89 Euro per tonne. The additional cost is mainly due to additional labour costs, which amount to 53% of the total additional cost. Costs of cleaning the production line after production of medicated feed constitute 15% of the total additional cost while costs related to tests (i.e. homogeneity test, test of drug carry-over and analytical control) represent 10% of the total additional cost. The costs of additional equipment used for the production of medicated

feed (to dose and transport the medicated pre-mix from the weighing equipment to the mixer) correspond to 17% of the total additional cost.

Differences between production costs of medicated feed and production costs of compound feed are presented in the table below.

Table 50: Additional costs of manufacturing medicated feed compared with production costs of compound feed (in %)

Additional costs of manufacturing medicated feed compared with production costs of compound feed (in %)				
	Production costs of compound feed (in Euro/tonne) [(a)]	Additional cost of medicated feed (in Euro/tonne)	Total production cost of medicated feed (in Euro/tonne)	Additional production costs of medicated feed (in %/tonne)
Production costs	188	11.9	199.9	6.3 %

Note:
(a) A gross margin of 4% is deducted from the sale price of a tonne of compound feed, of similar quality and composition as the one used for the production of medicated feed (196 Euro, excluding VAT, according to the feed mill interviewed), to obtain the production cost of a tonne of compound feed.

According to the table above, it is 6% more costly to produce medicated feed than compound feed.

The table below presents the range of prices to which medicated feed may be sold to farmers according to three pricing scenarios.[109]

Table 51: Sale price of medicated feed

Sale price of medicated feed (excluding cost of active substance)		
	Additional sale price of medicated feed/tonne (excluding cost of active substance) (in Euro, excluding VAT)	Sale price of a tonne of medicated feed [(a)] (in Euro, excluding VAT)
Scenario 1: *Fully cross-subsidised price*	0.0	196.1
Scenario 2: *Cost price*	11.9	208.0
Scenario 3: *Price with gross margin of 6%*	16.8	212.9

Note:
(a) Figures are based on a sale price of a tonne of compound feed of similar quality and composition as the one used for the production of medicated feed of 196 Euro (in Euro, excluding VAT).

[109] The three scenarios are as follows (see also Annex 2 on the methodological approach):
- *Scenario 1 – Fully cross-subsidised price* (price of compound feed + price of active substance only): It is assumed that the feed mill charges no extra cost for mixing the medicine with the feed, i.e. the medicated feed is sold at a price below its production cost and the total additional cost of producing medicated feed is subsidised by the additional price charged on other products.
- *Scenario 2 – Cost price* (price of compound feed + price of active substance + cost of mixing the medicine with the feed): It is assumed that the feed mill charges the full amount of the additional cost of mixing the medicine with the feed without making any profit on the additional cost.
- *Scenario 3 - price with gross margin of 6%* (price of compound feed + price of active substance + margin of 6% on total production cost of medicated feed): It is assumed that the feed mill charges a margin of 6% on the total production cost of medicated feed.

2.3. Use of medicated feed

In Denmark top dressing, mixing of ready-to-use veterinary medicine into feed and water are more commonly used than medicated feed.

Table 52: Use of medicated feed

Use of medicated feed	
Current use of medicated feed	In Denmark top dressing, mixing of ready-to-use veterinary medicine into feed and water are more commonly used than medicated feed.
Recent evolution of the use of VMPs and medicated feed	The use of medicated feed has increased over the last five years in Denmark. This is due to the authorisation of zinc oxides as veterinary medicine in 2005. (a)
Measures in place for the control of the use of medicated feed	Farms and the number of animals are registered centrally. Prescriptions of veterinarians are registered electronically in a central database. Data are, for example, collected on volumes of medicines used at farm level, regional level and by species (and, in some cases, by individual animals) as well as on medicines prescribed by veterinarians. (b)

Notes:
(a) See Table 48.
(b) Data on medicines prescribed by veterinarians have been registered since 2001by the VetStat programme at the Veterinary Institute (Technical University of Denmark). Some statistics are available online. See: http://www.vet.dtu.dk/Dyrlaegen/Antibiotika/VetStat/Opgoerelser.aspx. The Danish Integrated Antimicrobial Resistance Monitoring and Research Programme (DANMAP) issues an annual report that presents the annual consumption of antimicrobial agents and the occurrence of resistance in different reservoirs. See: DANMAP (2008). *Use of antimicrobial agents and occurrence of antimicrobial resistance in bacteria from food animals, foods and humans in Denmark* (available at: http://www.danmap.org/pdfFiles/Danmap_2008.pdf).

2.4. Costs of using medicated feed compared with the costs of using water medication in pig production

The table below presents costs of treating pigs via medicated feed and via water medication[110] as index values for three active substances and for the three pricing scenarios.[111]

[110] The price of water medication includes the cost of the medicine as well as the cost of the equipment required to prepare the medicinal solution (e.g. dosing pump) and labour costs (in terms of time spent for the preparation of the solution). Compared with water medication, medication via feed involves a carrier (feed) with a significant nutritional value and which constitutes an important share of the total price of the medicated feed. To obtain cost data that are comparable between the two routes of administration, the price of a tonne of compound feed of similar quality and composition as the one used for the production of medicated feed was therefore added to the costs of water medication (see Annex 2 on methodological approach).

[111] See footnote 124 and Annex 2.

Table 53: Costs of treating via water medication compared with the costs of treating via medicated feed (index values)

	Medicated feed			Water medication		
	Aminoglycosides (Apramycin)	Macrolides (Tylosin)	Macrolides (Tilmicosin)	Aminoglycosides (Apramycin)	Macrolides (Tylosin)	Macrolides (Tilmicosin)
Scenario 1: *Fully cross-subsidised price*	Set at 100 for each active substance and for each scenario.			111	73	n.a.
Scenario 2: *Cost price*				108	71	n.a.
Scenario 3: *Price with gross margin of 6%*				106	70	n.a.

Source: Civic Consulting.

In Denmark the cost advantage of treating animals via medicated feed rather than via water medication seems to depend on the active substance. Under all scenarios, it is less expensive to administer Apramycin via medicated feed than via water but it is more expensive to administer Tylosin via medicated feed than via water.

2.5. Sources of information

Organisations that have provided information for the Denmark case study are as follows:[112]

- The Danish Plant Directorate of the Danish Ministry of Food Agriculture and Fisheries
- Danish Medicines Agency (*DKMA*)
- The Danish Grain and Feed Trade Association (*DAKOFO*)
- Danish pig production
- One feed mill

[112] Interviews took place in September and October 2009.

3. Case study France

3.1. Key results

In France medicated feed is the most commonly used route of oral administration of veterinary medicines. Water medication is authorised but top dressing or mixing of ready-to-use veterinary medicine into feed is not allowed. According to estimates from the French feed manufacturers association (*SNIA*), the production of medicated feed remained stable at around 800,000 – 1,000,000 tonnes per year over the period 2004 to 2008.

Additional production costs of medicated feed

The additional cost of producing medicated feed compared with the production cost of compound feed amounts to 0.87 Euro per tonne. The additional cost is primarily fuelled by additional labour costs, which account for 67% of the total additional cost. Most of these labour costs are related to expenditure for the veterinarian/pharmacist (51% of the total additional cost), who, according to the French legislation, must visit the feed mill at least twice a month during the periods of effective production of medicated feed.[113] Costs of cleaning the production line after production of medicated feed represent 9% of the total additional cost while costs of tests (i.e. homogeneity test, test of drug carry-over and analytical control) correspond to 15% of the total additional cost.

It is 0.4% more costly to produce medicated feed than compound feed (see Table 57).

Cost of using medicated feed for farmers

In France, medicated feed is less expensive than water medication for the three active substances considered under the three pricing scenarios.

Table 54: Costs of treating via water medication compared with the costs of treating via medicated feed (index values)

	Medicated feed			**Water medication**		
	Aminoglycosides (Apramycin)	Macrolides (Tylosin)	Macrolides (Tilmicosin)	Aminoglycosides (Apramycin)	Macrolides (Tylosin)	Macrolides (Tilmicosin)
Scenario 1: *Fully cross-subsidised price*	Set at 100 for each active substance and for each scenario.			123	110	124
Scenario 2: *Cost price*				122	110	123
Scenario 3: *Price with gross margin of 6%*				120	108	121

Source: Civic Consulting.

[113] See Ministère de l'Agriculture et de la Pêche (2007). *Décision du 12 février 2007 fixant les bonnes pratiques de fabrication et de distribution en gros des aliments médicamenteux*.

3.2. Production of medicated feed

In France feed mills that produce medicated feed are considered to be pharmaceutical establishments. The production of medicated feed is therefore placed under the control of a pharmaceutical manager (a veterinarian or a pharmacist). According to estimates from the French feed manufacturers' association (*SNIA*), the production of medicated feed remained stable at around 800,000 – 1,000,000 tonnes per year over the period 2004 to 2008.

Table 55: Production of medicated feed

Production of medicated feed					
	2004	2005	2006	2007	2008
Total production of medicated feed over the last five years (in 000' tonnes) [(a)]	800 - 1,000	800 - 1,000	800 - 1,000	800 - 1,000	800 - 1,000
Total production of compound feed (in 000' tonnes) [(b)]	22,320	22,017	21,616	22,372	22,560
VMPs used for the production of medicated feed	According to the competent authority, the main groups of veterinary medicines authorised for the production of medicated pre-mixes in France are as follows: ❑ Antibiotics: polypeptides, sulfamides, macrolides, penicillins, tetracyclines, aminosides, quinolones, with principally colistin, oxytetracycline, chlortetracycline, apramycin, tylosin, sufadimethoxine trimethoprim (TMP sulfa), tiamulin, tilmicosin, lincospectine. ❑ Antiparasitics: flubendazole, oxybendazole, decoquinate ❑ Antifungals: parconazole Medicated pre-mixes are bought and sold under the control of a pharmacist or veterinarian.				
Medicated pre-mixes authorised for the production of medicated feed (Art. 3 of Directive 90/167/EEC)	Marketing authorisations for medicated pre-mixes are delivered by the French Agency for Veterinary Medicinal Products (*ANMV*). The numbers of new authorisations of medicated pre-mixes for the period 2004-2008 are as follows: ❑ 2004: 1 new medicated pre-mix authorised ❑ 2005: 15 new medicated pre-mixes authorised ❑ 2006: 7 new medicated pre-mixes authorised ❑ 2007: 8 new medicated pre-mixes authorised ❑ 2008: 3 new medicated pre-mixes authorised As of August 2009, the total number of medicated pre-mixes authorised amounts to 312, including 19 medicated pre-mixes for which authorisations are currently suspended. 293 pre-mixes are therefore currently sold on the French market.				
Number of approved operators for the placing on the market of medicated feed	In France, the *ANMV* approves operators according to the following 3 categories: ❑ Manufacturers of medicated feed, ❑ Distributors of medicated feed, and ❑ Importers of medicated feed. As of August 2009: ❑ 164 establishments have both the status of manufacturer and distributor. ❑ 64 establishments have the status of manufacturer of medicated feed only. No mobile mixers have been approved. ❑ 77 establishments have the status of distributor only. ❑ No establishment has the status of importer.				

Rules of good manufacturing practice (Art. Art. 4 (1d) of Directive 90/167/EEC)	The rules governing the production of medicated feed by feed mills are described in the *Décision du 12 février 2007 fixant les bonnes pratiques de fabrication et de distribution en gros des aliments médicamenteux (BPFDAM).*(c) The application of these rules is mandatory by law. Manufacturers of medicated feed must be authorised by the *ANMV* and must follow the requirements applicable to pharmaceutical establishments. For the production of medicated feed, the presence of a veterinarian or a pharmacist in the feed mill is not required to be permanent, but must occur at least twice a month. Feed mills must conduct a series of mandatory tests, as described in the *BFDAM*: (c) ❑ Homogeneity test (annual), ❑ Test of drug carry-over (annual), and ❑ Analytical control of concentration of active substances in medicated feeds produced. Medicated feed production is also referred to in the Guide for Good Manufacturing Practice for Compound Feed published by the French feed industry.(d) Its application is voluntary.
On-farm mixing (Art. 4(2) of Directive 90/167/EEC)	In France, 19 farms are authorised to manufacture medicated feed. These authorisations cover large pig farms (those with more than 350 productive sows). These farms produce significant volumes of medicated feed (at least 2,000 to 3,000 tonnes per year), which is similar to that produced by the smallest feed mills. Authorisations for on-farm mixing are provided by the Veterinary Services Directorates of the *départements*. Conditions for on-farm mixing are described in the *Arrêté du 9 juin 2004 relatif aux bonnes pratiques de préparaton extemporanée des médicaments vétérinaires.*(e) Rules for on-farm mixing are similar to those applicable to feed mills, including, for example, the control of the medicated feed production by a pharmacist or a veterinarian and the obligation to conduct homogeneity tests and tests of drug carry-over. Medicated feed can be produced only for animals bred on the farm (i.e. sale of medicated feed to other farms is not permitted).
Official controls on the compliance with the legal provisions of the Directive 90/167/EEC	The monitoring of the observance of good practice by establishments authorised to produce medicated feed is undertaken by state veterinarians (public agents), on behalf of the French Agency for Food Safety (*AFSSA)*. This is done once every three years for manufacturing establishments and once every four years for distributors. (f)

Notes:

(a) Estimates provided by the French feed manufacturers association (*Syndicat National de l'Industrie de la Nutrition Animale -SNIA*), based on data gathered through a survey of manufacturers of medicated feed.

(b) Data provided by the French feed manufacturers association (*Syndicat National de l'Industrie de la Nutrition Animale - SNIA*). Figures include medicated feeds.

(c) See: Ministère de l'Agriculture et de la Pêche (2007).

(d) See: Coop de France Nutrition Animale, SNIA (2008). *Guide de Bonnes Pratiques de la Fabrication d'Aliments Composés pour Animaux.* The Guide has been validated by the French administration, i.e. the administration agreed with the content of the document and considers that it constitutes the standards to be met, without making its application mandatory.

(e) See: Ministère de la Santé et de la Protection Sociale, Ministère de l'Agriculture, de l'Alimentation, de la Pêche et des Affaires Rurales (2004). *Arrêté du 9 juin 2004 relatif aux bonnes pratiques de préparaton extemporanée des médicaments vétérinaires*.

(f) Source: AFSSA (2008). *Décision du 17 septembre 2008 fixant la périodicité des inspections des établissements pharmaceutiques vétérinaires*.

Table 56: Additional costs of manufacturing medicated feed compared with production costs of compound feed (in Euro)

Additional costs of manufacturing medicated feed compared with production costs of compound feed (in Euro) [a]		
Cost factor	**Description of cost factor**	**Additional cost/tonne (in Euro)**
Additional consumption of fixed capital related to medicated feed production		
Additional equipment used for medicated feed production	No equipment specifically acquired for the production of medicated feed could be identified.	0.00
Additional buildings used for medicated feed production	Storage room for medicated pre-mixes.	0.02
End-of-line mixer	The use of end-of-line mixers was reported to be very limited in France.	Not applicable
Additional labour costs for medicated feed production		
Veterinarian/pharmacist	The legislation specifies that for the production of medicated feed, a veterinarian or a pharmacist must be present at least twice a month. [b]	0.45
Other labour costs	Additional labour costs include the additional tasks performed by the Production Manager and by the Quality Control Officer. [c]	0.14
Additional cleaning costs for medicated feed production		
Costs of flushing/rinsing	This includes the cost of raw materials and cost of disposing of materials once flushed through the system. [d]	0.08
Cost of tests		
Homogeneity test	Homogeneity testing must be carried out once a year, regardless of the volume of medicated feed produced. [e]	0.04
Test of drug carry-over	Testing of drug carry-over must be carried out once a year, regardless of the volume of medicated feed produced. [f]	0.04
Analytical control of concentration of active substance in medicated feed	The number of analytical tests to be carried out depends on the annual volume of medicated feed produced. [g]	0.04
Administrative costs		
Annual administrative fee	Feed mills producing medicated feed pay an annual fee amounting to 2,000 Euro to *AFSSA* (regardless of the volume of the medicated feed production).	0.06
Total additional cost of manufacturing medicated feed (not including cost of the active substances)		***0.87***

Notes:

(a) Costs are based on an annual production of 35,000 tonnes of medicated feed.
(b) It is considered that the veterinarian spends 2 full days per month working for the feed mill, at a daily fee of 650 Euro.
(c) It is considered that the Production Manager and the Quality Control Officer each spend 1 full day per month on tasks related to medicated feed production. Total labour costs for both positions amount to 5,000 Euro per year.
(d) It is estimated that the cost of burning the flushed materials amounts to 100 Euro per tonne and that the cost of the flushed material amounts to 130 Euro per tonne.
(e) The cost of a homogeneity test is estimated to be 1,500 Euro.
(f) The cost of a test of drug carry-over is estimated to be 1,500 Euro. The procedure to be followed by feed mills is described in detail in the *BPFDAM*. See Ministère de l'Agriculture et de la Pêche, 2007.
(g) The rules concerning the frequency of the analytical control are described in detail in Ministère de l'Agriculture et de la Pêche, 2007. A feed mill producing 35,000 tonnes of medicated feed per year would carry out at least 24 tests per year to monitor the concentration of the active substance in the medicated feed. The total cost for the 24 tests is estimated to amount to 1,500 Euro.

The additional cost of producing medicated feed compared with the production costs of compound feed amounts to 0.87 Euro per tonne. The additional cost is primarily fuelled by additional labour costs, which amount to 67% of the total additional cost. Most of these labour costs are related to expenditure for the veterinarian/pharmacist (51% of the total additional cost), who, according to the French legislation, must visit the feed mill at least twice a month during the periods of effective production of medicated feed.[114] Costs of cleaning the production line after production of medicated feed represent 9% of the total additional cost, while cost related to tests (i.e. homogeneity test, test of drug carry-over and analytical control) correspond to 15% of the total additional cost.

Differences between production costs of medicated feed and production costs of compound feed are presented in the table below.

Table 57: Additional costs of manufacturing medicated feed compared with production costs of compound feed (in %)

Additional costs of manufacturing medicated feed compared with production costs of compound feed (in %)				
	Production costs of compound feed (in Euro/tonne) [(a)]	Additional cost of medicated feed (in Euro/tonne)	Total production cost of medicated feed (in Euro/tonne)	Additional production costs of medicated feed (in %/tonne)
Production costs	238	0.9	238.9	0.4%

Note:
(b) A gross margin of 4% is deducted from the sale price of a tonne of compound feed for pigs, of similar quality and composition as the one used for the production of medicated feed (248 Euro, excluding VAT, according to the French feed manufacturers association, *SNIA*), to obtain the production cost of a tonne of compound feed.

According to the table above, it appears that it is 0.4% more costly to produce medicated feed than compound feed (see Table 57).

The table below presents the range of prices to which medicated feed may be sold to farmers according to three pricing scenarios.[115]

[114] See Ministère de l'Agriculture et de la Pêche (2007).

[115] The three scenarios are as follows (see also Annex 2 on the methodological approach):
- *Scenario 1 – Fully cross-subsidised price* (price of compound feed + price of active substance only): It is assumed that the feed mill charges no extra cost for mixing the medicine with the feed, i.e. the medicated feed is sold at a price below its production cost and the total additional cost of producing medicated feed is subsidised by the additional price charged on other products.
- *Scenario 2 – Cost price* (price of compound feed + price of active substance + cost of mixing the medicine with the feed): It is assumed that the feed mill charges the full amount of the additional cost of mixing the medicine with the feed without making any profit on the additional cost.
- *Scenario 3 - price with gross margin of 6%* (price of compound feed + price of active substance + margin of 6% on total production cost of medicated feed): It is assumed that the feed mill charges a margin of 6% on the total production cost of medicated feed.

Table 58: Sale price of medicated feed

Sale price of medicated feed (excluding cost of active substance)		
	Additional sale price of medicated feed/tonne (excluding cost of active substance) (in Euro, excluding VAT)	Sale price of a tonne of medicated feed [(a)] (in Euro, excluding VAT)
Scenario 1: *Fully cross-subsidised price*	0.0	248.0
Scenario 2: *Cost price*	0.9	248.9
Scenario 3: *Price with gross margin of 6%*	6.2	254.2

Note:
(a) Figures are based on a sale price of a tonne of compound feed of similar quality and composition as the one used for the production of medicated feed of 248 Euro (in Euro, excluding VAT).

3.3. Use of medicated feed

In France medicated feed is the most commonly used route of oral administration of veterinary medicines. Top dressing or mixing of ready-to-use veterinary medicine into feed is not allowed.

Table 59: Use of medicated feed

Use of medicated feed	
Current use of medicated feed	In France medicated feed is the most commonly used route of oral administration of veterinary medicines. While water medication is permitted, top dressing or mixing of ready-to-use veterinary medicine into feed is not allowed. Medicated feeds are primarily produced for the pig industry. [(a)]
Recent evolution of the use of VMPs and medicated feed	Over the last 5 years sales of oral forms of antibiotic remained stable, despite a slight increase in tonnage between 2006 and 2007. This increase essentially results from an increase in sales of medicated pre-mixes of 14% (85 tonnes). In 2008, the consumption of medicated pre-mixes came back to the level of 2006 to amount to 618 tonnes. When considering the period 2002 – 2008, the consumption of medicated pre-mixes containing antimicrobials decreased by 8 %.[(b)] No data are available concerning total sales of VMPs in France.
Measures in place for the control of the use of medicated feed	Administration of medicated feed is subject to a prescription by a veterinarian. The use of medicated feed is controlled by the state veterinary services (public agents). 2 types of controls exist: • Routine (5% of pig farms are inspected every year), • Targeted (for example, in cases of residues in foodstuffs found in slaughterhouses).

Notes:
(a) Source: Coop de France nutrition animale and SNIA (2009). *Aliments médicamenteux, résultats de l'enquête sur les production 2007*. The survey results are based on a sample of 107 production sites (40% of the total production of compound feed), of which 97 manufacture medicated feed. According to this survey, 35.2% of medicated feeds were produced for pigs in 2007. Medicated feeds for rabbits and poultry represented respectively 30.3% and 27.8% of the total medicated feed production of the sample.
(b) Source: AFSSA (2009). *Suivi des ventes de médicaments vétérinaires contenant des antibiotiques en France en 2008*.

3.4. Costs of using medicated feed compared with the costs of using water medication in pig production

The table below presents costs of treating pigs via medicated feed and via water medication[116] as index values for three active substances and for the three pricing scenarios.[117]

Table 60: Costs of treating via water medication compared with the costs of treating via medicated feed (index values)

	Medicated feed			Water medication		
	Aminoglycosides (Apramycin)	Macrolides (Tylosin)	Macrolides (Tilmicosin)	Aminoglycosides (Apramycin)	Macrolides (Tylosin)	Macrolides (Tilmicosin)
Scenario 1: *Fully cross-subsidised price*	Set at 100 for each active substance and for each scenario.			123	110	124
Scenario 2: *Cost price*				122	110	123
Scenario 3: *Price with gross margin of 6%*				120	108	121

Source: Civic Consulting.

In France medicated feed is less expensive than water medication for the three active substances considered and under the three pricing scenarios.

3.5. Sources of information

Organisations that have provided information for the French case study are as follows:[118]

- *Ministère de l'alimentation, de l'agriculture et de la pêche, Direction générale de l'alimentation, Service de la prévention des risques sanitaires de la production primaire, Sous-direction de la santé et de la protection animales, Bureau des intrants et de la santé publique en élevage*
- *Agence Francaise de Sécurité Sanitaire des Aliments - Agence Nationale du Médicament Vétérinaire* (*AFSSA-ANMV*)
- *Syndicat National de l'Industrie de la Nutrition Animale*
- *Coop de France nutrition animale*
- *FNSEA - Fédération nationale des syndicats d'exploitants agricoles*
- One feed mill
- One pig farm

[116] The price of water medication includes the cost of the medicine as well as the cost of the equipment required to prepare the medicinal solution (e.g. dosing pump) and labour costs (in terms of time spent for the preparation of the solution). Compared with water medication, medication via feed involves a carrier (feed) with a significant nutritional value and which constitutes an important share of the total price of the medicated feed. To obtain cost data that are comparable between the two routes of administration, the price of a tonne of compound feed of similar quality and composition as the one used for the production of medicated feed was therefore added to the costs of water medication (see Annex 2 on methodological approach).

[117] See footnote 124 and Annex 2.

[118] Interviews took place in July and September 2009.

4. Case study Germany

4.1. Key results

In Germany veterinary medicines are administered mainly in ready-to-use form. According to estimates from the German feed manufacturers association (*DVT*), the production of medicated feed decreased by 95% between 2004 and 2008 (from 225,000 tonnes to 12,000 tonnes).

Additional production costs of medicated feed

The additional cost of producing medicated feed compared with the production cost of compound feed amounts to 70.33 Euro per tonne. The cost of the end-of-line mixer represents the highest cost factor, accounting for 71% of the total additional cost. Additional labour costs represent 18% of the total additional cost, while costs related to tests correspond to 7% of the total additional cost.

It is 25 % more costly to produce medicated feed than compound feed (see Table 64).

Cost of using medicated feed for farmers

In Germany the cost advantage of medicated feed compared with water medication depends both on the pricing strategy employed by the feed mill and on the active substance. Under the three scenarios, medicated feed is less expensive than water medication in the case of administration of Tilmicosin but more expensive in the case of Tylosin (dataset B). For the other active substances, medicated feed is less expensive than water medication under scenario 1, whereas medicated feed is more expensive or as costly as water medication under scenarios 2 and 3.

Table 61: Costs of treating via water medication compared with the costs of treating via medicated feed (index values)

	Medicated feed						**Water medication**					
	Aminoglycosides (Apramycin)	Macrolides (Tylosin) (dataset A)	Macrolides (Tylosin) (dataset B)	Macrolides (Tilmicosin)	Tetracyclines	Sulfonamides/ Trimethoprim	Aminoglycosides (Apramycin)	Macrolides (Tylosin) (dataset A)	Macrolides (Tylosin) (dataset B)	Macrolides (Tilmicosin)	Tetracyclines	Sulfonamides/ Trimethoprim
Scenario 1: *Fully cross-subsidised price*	Set at 100 for each active substance and for each scenario.						107	107	81	127	103	122
Scenario 2: *Cost price*							89	88	71	105	87	100
Scenario 3: *Price with gross margin of 6%*							87	86	70	103	85	98

Source: Civic Consulting.

4.2. Production of medicated feed

In Germany medicated feed is classified as a veterinary medicinal product. Therefore, the German pharmaceutical law (*Arzneimittelgesetz*) applies to the production of medicated feed. The production of medicated feed is subject to a permit, granted by the *Länder*, as is the case for all other medicinal products. According to estimates from the German feed manufacturers' association (*DVT*), the production of medicated feed decreased by 95% between 2004 and 2008 (from 225,000 tonnes to 12,000 tonnes).

Table 62: Production of medicated feed

Production of medicated feed					
	2004	2005	2006	2007	2008
Total production of medicated feed over the last five years (in 000' tonnes) [(a)]	225	150	80	20	12
Total production of compound feed (in 000' tonnes) [(b)]	20,098	19,623	20,306	21,310	21,826
VMPs used for the production of medicated feed [(c)]	According to the competent authority, from 61 premixes authorised in 2009, there are 52 antibiotic and 9 antiparasitic substances.				
Medicated pre-mixes authorised for the production of medicated feed (Art. 3 of Directive 90/167/EEC) [(c)]	The numbers of medicated pre-mixes authorised in Germany for the period 2004-2008 are as follows: ❑ 2004: 60 ❑ 2005: 55 ❑ 2006: 61 ❑ 2007: 65 ❑ 2008: 64				
Number of approved operators for the placing on the market of medicated feed [(c)]	Enterprises with manufacturing permit (*Herstellungserlaubnis*) according to § 13 of the German pharmaceutical law: 31 This includes: ▪ 5 enterprises which currently do not make use of the permit ▪ 10 enterprises with limited permit ▪ 3 mobile mixers				
Rules of good manufacturing practice (Art. Art. 4 (1d) of Directive 90/167/EEC) [(c)]	In Germany, manufacturers of medicated feed are considered to be pharmaceutical companies. Consequently, the pharmaceutical law applies to the production of medicated feed. Rules of good manufacturing practice for medicated feed relate to the EU GMP on the rules governing medicinal products in the EU.[(d)] An expert group responsible for surveillance and control in the federal states has written a leaflet on the application of these guidelines: "*Merkblatt für die Antragstellung auf Erteilung einer Erlaubnis zur Herstellung von Fütterungsarzneimitteln aus Arzneimittel-Vormischungen nach § 13 Abs. 1 des Arzneimittelgesetzes*".[(e)] This document requires, for example, the use of the end-of-line mixing technology in order for manufacturers to be authorised to produce medicated feed.				
On-farm mixing (Art. 4(2) of Directive 90/167/EEC) [(c)]	On-farm mixing is not allowed in Germany. In 2001, the Commission (as a consequence of an inspection of the FVO) urged a ban on-farm mixing in Germany (*Hofmischung*).				

Official controls on the compliance with the legal provisions of the Directive 90/167/EEC [c]	There is surveillance during all steps of production and distribution of medicated feed. In Germany the surveillance is the duty of the federal states (*Länder*). The *Länder* are responsible for the control of the production sites, transportation, animal production and also for site visits.

Notes:
(a) Estimates provided by German feed manufacturers association, *Deutscher Verband Tiernahrung* (*DTV*).
(b) Data provided by *DTV*.
(c) Source: Bundesministerium für Ernährung, Landwirtschaft und Verbraucherschutz.
(d) See: http://ec.europa.eu/enterprise/pharmaceuticals/eudralex/vol4_en.htm.
(e) See: http://www.zlg.de/download/AM/EFG/EFG14/Merkblatt_Stand_060613.pdf.

Table 63: Additional costs of manufacturing medicated feed compared with production costs of compound feed (in Euro)

Additional costs of manufacturing medicated feed compared with production costs of compound feed (in Euro) [a]		
Cost factor	**Description of cost factor**	**Additional cost/tonne (in Euro)**
Additional consumption of fixed capital related to medicated feed production		
Additional equipment used for medicated feed production	No additional equipment other than the end-of-line mixer (see below) was identified.	0
Additional buildings used for medicated feed production	Storage room for medicated pre-mixes.	0.50
End-of-line mixer [b]	Includes costs of end-of-line mixer, storage containers and transport equipment.	50.0
Additional labour costs for medicated feed production		
Labour costs for veterinarian/feed mill worker [c]	Additional labour costs relate to additional tasks related to medicated feed production (e.g. administration of prescriptions, control of productions, handling of premixes).	12.5
Additional cleaning costs for medicated feed production		
Costs of flushing/rinsing	Not applicable. [d]	Not applicable
Cost of tests		
Homogeneity test [e]	This includes the total cost of tests.	4.80
Test of drug carry-over		
Analytical control of concentration of active substance in medicated feed		
Administrative costs		
Annual administrative fee	An audit is carried out every second year by the national surveillance authority (2,500 Euro per audit).	2.50
Total additional cost of manufacturing medicated feed (not including cost of the active substances)		***70.33***

Notes:
(a) Costs are based on an annual production of 500 tonnes of medicated feed.
(b) This also includes the costs of running and maintaining the end-of-line mixer (0.03 Euro/tonne).

(c) It is considered that one hour of work, involving both the veterinarian and a feed mill worker, is required for a delivery of 3 tonnes of medicated feed. Additional labour costs are based on an average wage of 37.5 Euro per hour (including social contributions). The work includes both technical and administrative tasks.
(d) Because of the use of an end-of-line mixer, there is no need to clean the production line following medicated feed production.
(e) Each 30th unit of production is tested and each sample is tested twice. The cost of the homogeneity test amounts to 110 Euro.

The additional cost of producing medicated feed compared with the production cost of compound feed amounts to 70.33 Euro per tonne. The cost of the end-of-line mixer represents the highest cost factor, accounting for 71% of the total additional cost. Additional labour costs represent 18% of the total additional cost, while costs related to tests correspond to 7% of the total additional cost.

Differences between production costs of medicated feed and production costs of compound feed are presented in the table below.

Table 64: Additional costs of manufacturing medicated feed compared with production costs of compound feed (in %)

Additional costs of manufacturing medicated feed compared with production costs of compound feed (in %)				
	Production costs of compound feed (in Euro/tonne) [(a)]	Additional cost of medicated feed (in Euro/tonne)	Total production cost of medicated feed (in Euro/tonne)	Additional production costs of medicated feed (in %/tonne)
Production costs	278	70.3	348.3	25.3 %

Note:
(a) A gross margin of 4% is deducted from the sale price of a tonne of compound feed for pigs, of similar quality and composition as the one used for the production of medicated feed (290 Euro, excluding VAT, according to the French feed manufacturers association, *SNIA*), to obtain the production cost of a tonne of compound feed.

According to the table above, it is 20 % more costly to produce medicated feed than compound feed.

The table below presents the range of prices to which medicated feed may be sold to farmers according to three pricing scenarios.[119]

[119] The three scenarios are as follows (see also Annex 2 on the methodological approach):
- *Scenario 1 – Fully cross-subsidised price* (price of compound feed + price of active substance only): It is assumed that the feed mill charges no extra cost for mixing the medicine with the feed, i.e. the medicated feed is sold at a price below its production cost and the total additional cost of producing medicated feed is subsidised by the additional price charged on other products.
- *Scenario 2 – Cost price* (price of compound feed + price of active substance + cost of mixing the medicine with the feed): It is assumed that the feed mill charges the full amount of the additional cost of mixing the medicine with the feed without making any profit on the additional cost.
- *Scenario 3 - price with gross margin of 6%* (price of compound feed + price of active substance + margin of 6% on total production cost of medicated feed): It is assumed that the feed mill charges a margin of 6% on the total production cost of medicated feed.

Table 65: Sale price of medicated feed

Sale price of medicated feed (excluding cost of active substance)		
	Additional sale price of medicated feed/tonne (excluding cost of active substance) (in Euro, excluding VAT)	Sale price of a tonne of medicated feed [(a)] (in Euro, excluding VAT)
Scenario 1: *Fully cross-subsidised price*	0.0	290.0
Scenario 2: *Cost price*	70.3	360.3
Scenario 3: *Price with gross margin of 6%*	81.0	371.0

Note:
(a) Figures are based on a sale price of a tonne of compound feed of similar quality and composition as the one used for the production of medicated feed of 290 Euro (in Euro, excluding VAT).

4.3. Use of medicated feed

In Germany veterinary medicines are administered mainly in ready-to-use form: i.e. via top dressing/mixing into the feed and mixing into water.

Table 66: Use of medicated feed

Use of medicated feed	
Current use of medicated feed	In Germany veterinary medicines are administered mainly in ready-to-use form.
Recent evolution of the use of VMPs and medicated feed	The administration of VMPs (i.e. total of medicated feed and ready-to-use veterinary medicines administered by farmers via water and top dressing) increased fairly significantly over the last five years in Germany. One reason for the decrease in the use of medicated feed in the last five years may be the increase in the VAT rate applicable to medicated feed. In Germany the combination of a taxation system that allows taxation on average values (*Umsatzsteuerpauschalierung*) and a VAT rate of 7% on oral powders as opposed to a VAT rate of 19% on medicated feed may increase the cost advantage of oral powders relative to the cost of medicated feed (see main report). According to information from *BMELV*, another reason might be a lack of incentives for veterinarians to prescribe medicated feed compared with ready-to-use veterinary medicines. Before 2006, veterinarians were allowed to contract the production of medicated feed to feed mills and sell this service to the farmer (*Herstellungsauftrag*). With the abolition of this regulation, veterinarians can only prescribe medicated feed, and the distribution of medicated feed is done via companies holding a manufacturing permit in line with § 13 of the German pharmaceutical law. By contrast, veterinarians are allowed to sell ready-to-use veterinary medicines directly to farmers.
Measures in place for the control of the use of medicated feed	There is monitoring during all steps of production and distribution of medicated feed. In Germany the monitoring is the duty of the federal states (*Länder*). The *Länder* are responsible for the control of the production sites, transportation, animal production and also for site visits.

4.4. Costs of using medicated feed in pig production compared with the other routes of oral administration of VMPs

The table below presents costs of treating pigs via medicated feed and via water medication[120] as index values for three active substances and for the three pricing scenarios.[121]

Table 67: Costs of treating via water medication compared with the costs of treating via medicated feed (index values)

	Medicated feed						Water medication					
	Aminoglycosides (Apramycin)	Macrolides (Tylosin) (dataset A)	Macrolides (Tylosin) (dataset B)	Macrolides (Tilmicosin)	Tetracyclines	Sulfonamides/ Trimethoprim	Aminoglycosides (Apramycin)	Macrolides (Tylosin) (dataset A)	Macrolides (Tylosin) (dataset B)	Macrolides (Tilmicosin)	Tetracyclines	Sulfonamides/ Trimethoprim
Scenario 1: *Fully cross-subsidised price*	Set at 100 for each active substance and for each scenario.						107	107	81	127	103	122
Scenario 2: *Cost price*							89	88	71	105	87	100
Scenario 3: *Price with gross margin of 6%*							87	86	70	103	85	98

Source: Civic Consulting.

In Germany the cost advantage of medicated feed compared with water medication depends both on the pricing strategy employed by the feed mill and on the active substance. Under the three scenarios, medicated feed is less expensive than water medication in the case of administration of Tilmicosin but more expensive in the case of Tylosin (dataset B). For the other active substances, medicated feed is less expensive than water medication under scenario 1, whereas medicated feed is more expensive or as costly as water medication under scenarios 2 and 3.

[120] The price of water medication includes the cost of the medicine as well as the cost of the equipment required to prepare the medicinal solution (e.g. dosing pump) and labour costs (in terms of time spent for the preparation of the solution). Compared with water medication, medication via feed involves a carrier (feed) with a significant nutritional value and which constitutes an important share of the total price of the medicated feed. To obtain cost data that are comparable between the two routes of administration, the price of a tonne of compound feed of similar quality and composition as the one used for the production of medicated feed was therefore added to the costs of water medication (see Annex 2 on methodological approach).

[121] See footnote 124 and Annex 2.

4.5. Sources of information

Organisations that have provided information for the German case study are as follows:[122]

- Ministry of Food, Agriculture and Consumer Protection (*BMELV*)
- German Farmers' Association (*Deutscher Bauernverband*)
- One manufacturer of VMPs
- One feed mill
- One pig farm

[122] Interviews took place between July and September 2009.

5. Case study United Kingdom

5.1. Key results

In the United Kingdom medicated feed is the most commonly used route of oral administration of veterinary medicines. Top dressing is allowed but but its use remains limited.

Additional production costs of medicated feed

The additional cost of producing medicated feed compared to the production cost of compound feed amounts to 3.62 Euro per tonne. Additional labour costs represent 88% of the total additional cost. Additional building costs amount to 10% of the total additional cost while costs related to tests (i.e. homogeneity test, test of drug carry-over and analytical control) correspond to 2% of the total additional cost.

It is 2% more costly to produce medicated feed than compound feed (see Table 71).

Cots of using medicated feed for farmers

In the United Kingdom the cost advantage of treating animals via medicated feed rather than via water medication seems to depend on the active substance. Under the three scenarios, water medication is more expensive than medicated feed for Apramycin and Tilmicosin, but slightly less expensive in the case of a treatment with Tylosin.

Table 68: Costs of treating via water medication compared with the costs of treating via medicated feed (index values)

	Medicated feed			**Water medication**		
	Aminoglycosides (Apramycin)	Macrolides (Tylosin)	Macrolides (Tilmicosin)	Aminoglycosides (Apramycin)	Macrolides (Tylosin)	Macrolides (Tilmicosin)
Scenario 1: *Fully cross-subsidised price*	Set at 100 for each active substance and for each scenario.			113	98	226
Scenario 2: *Cost price*				112	97	223
Scenario 3: *Price with gross margin of 6%*				110	96	220

Source: Civic Consulting.

5.2. Production of medicated feed

Sales of pre-mixes containing antimicrobials have declined by 21% from 2003 to 2007.[123] Feed mills mixing medicated feed are not classed as pharmaceutical establishments in the UK.

Table 69: Production of medicated feed

Production of medicated feed					
	2004	2005	2006	2007	2008
Total sales of medicated pre-mixes over the last five years (in tonnes of active substances) (a)	323	317	264	241	228
Total production of compound feed (in 000' tonnes) (b)	14,085	13,770	14,115	14,341	n.a.
VMPs used for the production of medicated feed	As of September 2009, 50 medicated pre-mixes are authorised for medicated feed production in the UK, according to the Veterinary Medicines Directorate (VMD). These 50 medicated pre-mixes can be grouped according to the following categories: ❑ Antimicrobials: 37 ❑ Anthelmintics: 6 ❑ Antiprotozoal anticoccidial: 2 ❑ Gastroint – bloat treatments: 2 ❑ Antimycotic – treatment of ringworm in horses: 1 ❑ Anti inflammatory – pyrexia in pigs: 1 ❑ Ectoparaciticide – treatment of salmon louse: 1				
Medicated pre-mixes authorised for the production of medicated feed (Art. 3 of Directive 90/167/EEC)	The VMD is responsible for the assessment and authorisation of medicated pre-mixes in accordance with the requirements of the Veterinary Medicines Regulations (VMR), which implement Directive 2001/82 related to Veterinary Medicinal Products. The VMD is responsible for the drafting and implementation of the VMR. The numbers of authorised medicated pre-mixes for the period 2004 – 2008 are as follows: ❑ 2004: 55 (one new medicated pre-mix was authorised, one authorisation expired) ❑ 2005: 60 (seven new medicated pre-mixes, including 2 EU centralised products, were authorised, ten were expired) ❑ 2006: 50 (no new medicated pre-mixes were authorised, and none was expired) ❑ 2007: 53 (3 new medicated pre-mixes were authorised, 5 were expired) ❑ 2008: 53 (4 new medicated pre-mixes were authorised, 1 was expired)				
Number of approved operators for the placing on the market of medicated feed	Establishments approved to manufacture medicated feed in the UK can be grouped as follows: ❑ Mobile mixers – included in the figures below, but of those figures below, estimated: 10 – 12 ❑ On-farm producers (Art. 4(2)): 640 ❑ Distributors: 366				

[123] No data are available neither on total medicated feed production nor on total sales of pre-mixes used for the production of medicated feeds. Only sales data of antimicrobial active substances used for medicated feed production are available. Source: VMD.

	❑ Feed mills: 94 Additionally in the UK establishments manufacture intermediate products from medicated pre-mixes intended to be mixed into final feed. ❑ Feed mills manufacturing intermediate products: 39 The Animal Medicines Inspectorate (AMI) of the VMD is responsible for inspecting and authorising establishments mixing authorised pre-mixes into intermediate products or into medicated feed and distributors supplying medicated feed in Great Britain. In Northern Ireland these duties currently fall to the inspection team at the Department of Agriculture and Rural Development Northern Ireland (DARDNI).
Rules of good manufacturing practice (Art. Art. 4 (1d) of Directive 90/167/EEC)	Manufacturers are required to comply with the Veterinary Medicines Regulations, which implement 90/167 and 183/2005, and guidance is provided in Veterinary Medicines Guidance Notes 21 and 22 on the VMD website. Complying with the Regulations is mandatory. (c) In Schedule 5 of the Veterinary Medicines Regulations, manufacturers of medicated feed are required (in accordance with Articles 6 and 7 of EC Regulation 183/2005) to document and implement a Hazard Analysis Critical Control Point (HACCP) plan, which identifies the risk of cross-contamination of non-target feed with medicinal pre-mixes. To this end, manufacturers must define a cross-contamination matrix which, when followed, ensures that cross-contamination is minimised or avoided. The cross-contamination matrix specifies the order of mixing that can take place (scheduling) and, where necessary, where and how flushing of the production line must take place.(d) Where cross-contamination is identified as a Critical Control Point (CCP), tests of drug carry-over must be conducted to verify that the measures put in place to control that risk are effective. Manufacturers must also conduct further quality control tests, including a mixer dispersion (homogeneity) test. Manufacturers must also test a number of medicated feed samples each year to control the level of medicinal active ingredient in medicated feeds. There are no nationally approved Industry Codes in the UK. Feed mills have access to industry guides related to the Agricultural Industries Confederation (AIC) or the Universal Feed Assurance Scheme (UFAS), and farmers to the guides related to the National Farmers' Union (NFU) or the various Farm Assurance Schemes. (e) These guides are voluntary.
On-farm mixing (Art. 4(2) of Directive 90/167/EEC)	In the UK 640 farms are authorised to manufacture medicated feed. On-farm mixing is allowed in the UK provided the mixer is approved by AMI or DARDNI. Mixers must comply with the conditions of Regulation 183/2005, in particular Annex II of that Regulation, and operate in accordance with Schedule 5 of the Veterinary Medicines Regulations.(c)
Official controls on the compliance with the legal provisions of the Directive 90/167/EEC	The AMI of the VMD and DARDNI carry out official controls on compliance in accordance with the VMR in the UK. In recognition of the more up-to-date manufacturing and official control requirements for feed additives authorised under Regulation 1831/2003, the UK has also implemented the feed additive EU Regulations for medicated feeds. Therefore, the VMR implements EU Regulations 178/2002, 882/2004 and 183/2005 for medicated feeds. Those articles from Directive 90/167 specific to medicated feeds are also implemented in the VMR. The AMI consists of a team of 5 regional inspectors. All AMI inspectors hold a formal qualification in agriculture/science and are required to have spent at least 3 years at management level in the animal feed/animal health industry prior to appointment. Inspectors are qualified ISO 9000:2000 auditors and have undertaken a course in HACCP. Inspections are performed upon application and thereafter between every 12 months and 24 months depending on the risk rating of the establishment. Authorisation is renewed annually. Frequency of inspection is based on the risk of the activity carried out by the establishment, i.e. manufacture of a medicated feed using any level of inclusion and for selling on to a large number of customers is deemed to be more of a risk than a farmer mixing into feed for their own use on a farm. Although the farmer would still be expected to comply with Annex II of 183/2005, the complexity of inspection and equipment for example would not

	be the same as that for a large feed mill. In accordance with the requirements of 882/2004, the AMI is due to move to a more fully risk-based inspection programme in 2010. In preparation for this, since October 2008 the AMI inspectors have been completing a document at each inspection to gain information regarding the risk rating of the establishment. In Northern Ireland, DARDNI carries out official controls in accordance with the VMR. It uses the same inspection regime and categories of establishment as the AMI.

Notes:

(a) Data include sales of antimicrobial active substances used for production of medicated feed only. Source: Veterinary Medicines Directorate (2009). *Sales of antimicrobial products authorised for use as veterinary medicines, antiprotozoals, antifungals, growth promoters and coccidiostats, in the UK in 2008*. According to the Agricultural Industries Confederation (AIC), the total production of medicated feed amounted to approximately 500,000 tonnes in 2008 (including on-farm mixing).

(b) The dataset do include home-mixed diets as seen in the two columns labelled compound (industrial) and home mix.

(c) Source: FEFAC, Feed & Food Statistical Yearbook 2007. European Feed Manufacturers Federation (FEFAC) (2008). *Feed & Food - Statistical Yearbook 2007*.

(d) See: The Veterinary Medicines Regulations 2009 (available at: http://www.opsi.gov.uk/si/si2009/pdf/uksi_20092297_en.pdf). Also see: http://www.vmd.gov.uk/General/VMR/vmgn.htm

(e) See: Veterinary Medicines Directorate (2008). *Documented Procedures & HACCP Plan Guidance for Manufacturers of Feedingstuffs containing Veterinary Medicinal Products/Specified Feed Additives.*

(f) See, for example, Agricultural Industries Confederation (2009). *Universal Feed Assurance Scheme, Compound Feeds Code of Practice* (available at: http://www.agindustries.org.uk/content.output/93/93/Trade%20Assurance/Trade%20Assurance%20Schemes/UFAS.mspx).

Table 70: Additional costs of manufacturing medicated feed compared with production costs of compound feed (in Euro)

Additional costs of manufacturing medicated feed compared with production costs of compound feed (in Euro) [a]		
Cost factor	**Description of cost factor**	**Additional cost/tonne (in Euro)**
Additional consumption of fixed capital related to medicated feed production		
Additional equipment used for medicated feed production	No specific additional equipment for the production of medicated feed was identified.	0.00
Additional buildings used for medicated feed production	This includes costs of storage of medicated feeds and flushed materials re-used in medicated feed production (storage bins) and cost of storage of medicated pre-mixes (dispensary).	0.36
End-of-line mixer	End-of-line mixers were reported as not used in the UK.	Not applicable
Additional labour costs for medicated feed production		
Veterinarian/pharmacist	Not applicable	Not applicable
Other labour costs	Additional labour costs relate to additional tasks related to medicated feed production (e.g. administration and control of the manufacture of medicated feeds, organisation of medicated feed production, cleaning of equipment, handling of pre-mixes).	3.17
Additional cleaning costs for medicated feed production		
Costs of flushing/rinsing	In the feed mill selected for the case study, most flushed materials are used to produce medicated feeds.	Not applicable
Cost of tests		
Homogeneity test	A homogeneity (mixer efficiency) test must be carried out at least annually and the results assessed to determine the efficiency of the mixing equipment and procedures. [b]	0.02
Test of drug carry-over	Where cross-contamination is identified as a Critical Control Point (CCP), tests of carry-over must be conducted to verify that the measures put in place to control that risk are effective.	0.02
Analytical control of concentration of active substance in medicated feed	The number of samples to be taken for analysis of medicinal content should be based on the following formula: Number of samples = Square root of 1% of the medicated feed produced per annum (minimum 1 sample per annum). [c]	0.02
Administrative costs		
Annual administrative fee	Feed mills producing medicated feed pay an annual fee amounting to £610 (regardless of the volume of the medicated feed production). [d]	0.02
Total additional cost of manufacturing medicated feed (not including cost of the active substances)		***3.62***

Notes:

(a) Costs are based on an annual production of 35,000 tonnes of medicated feed.

(b) Veterinary Medicines Directorate (2008). *Documented Procedures & HACCP Plan Guidance for Manufacturers of Feedingstuffs containing Veterinary Medicinal Products/Specified Feed Additives*. According to the UFAS Compound Feed Code of Practice (voluntary), sampling and analysis to check efficiency of mixing and (where needed) in plant carry-over must be carried out at intervals of no more than 6 months. Sampling and testing to establish carry-over of residues of specified feed additives and medicinal substances must be carried out as indicated by HACCP procedures. Agricultural Industries Confederation (2009). *Universal Feed Assurance Scheme, Compound Feeds Code of Practice*.

(c) Veterinary Medicines Directorate (2008). *Documented Procedures & HACCP Plan Guidance for Manufacturers of Feedingstuffs containing Veterinary Medicinal Products/Specified Feed Additives.*

(d) Fee corresponds to the standard fee payable in Great Britain for application for the approval of an establishment to manufacture feedingstuffs using specified feed additives and veterinary medicinal products directly at any concentration, or using premixtures, and the subsequent annual fee. See: The Veterinary Medicines Regulations 2009.

The additional cost of producing medicated feed compared with the production cost of compound feed amounts to 3.62 Euro per tonne. Additional labour costs represent 88% of the total additional cost. Additional building costs amount to 10% of the total additional cost while costs related to tests (i.e. homogeneity test, test of drug carry-over and analytical control) correspond to 2% of the total additional cost

Differences between production costs of medicated feed and production costs of compound feed are presented in the table below.

Table 71: Additional costs of manufacturing medicated feed compared with production costs of compound feed (in %)

Additional costs of manufacturing medicated feed compared with production costs of compound feed (in %)				
	Production costs of compound feed (in Euro/tonne) [(a)]	Additional cost of medicated feed (in Euro/tonne)	Total production cost of medicated feed (in Euro/tonne)	Additional production costs of medicated feed (in %/tonne)
Production costs	181	3.6	184.6	2%

Note:
(a) A gross margin of 4% is deducted from the sale price of a tonne of compound feed, of similar quality and composition as the one used for the production of medicated feed (189 Euro, excluding VAT, according to the feed mill interviewed), to obtain the production cost of a tonne of compound feed.

In the UK, it is 2% more costly to produce medicated feed than compound feed. The table below presents the range of prices to which medicated feed may be sold to farmers according to three pricing scenarios.[124]

Table 72: Sale price of medicated feed

Sale price of medicated feed (excluding cost of active substance)		
	Additional sale price of medicated feed/tonne (excluding cost of active substance) (in Euro, excluding VAT)	Sale price of a tonne of medicated feed [(b)] (in Euro, excluding VAT)
Scenario 1: *Fully cross-subsidised price*	0.0	189.0
Scenario 2: *Cost price*	3.6	192.6
Scenario 3: *Price with gross margin of 6%*	7.9	196.9

Note:
(a) Figures are based on a sale price of a tonne of compound feed of similar quality and composition as the one used for the production of medicated feed of 189 Euro (in Euro, excluding VAT).

[124] The three scenarios are as follows (see also Annex 2 on the methodological approach):
- *Scenario 1 – Fully cross-subsidised price* (price of compound feed + price of active substance only): It is assumed that the feed mill charges no extra cost for mixing the medicine with the feed, i.e. the medicated feed is sold at a price below its production cost and the total additional cost of producing medicated feed is subsidised by the additional price charged on other products.
- *Scenario 2 – Cost price* (price of compound feed + price of active substance + cost of mixing the medicine with the feed): It is assumed that the feed mill charges the full amount of the additional cost of mixing the medicine with the feed without making any profit on the additional cost.
- *Scenario 3 - price with gross margin of 6%* (price of compound feed + price of active substance + margin of 6% on total production cost of medicated feed): It is assumed that the feed mill charges a margin of 6% on the total production cost of medicated feed.

5.3. Use of medicated feed

In the UK, medicated feed is the most commonly used route of oral administration of veterinary medicines. Top dressing is allowed but but its use remains limited.

Table 73: Use of medicated feed

Use of medicated feed	
Current use of medicated feed	In 2007 a total of 335 tonnes of antimicrobials were sold for use in food animals, of which 241 tonnes (72%) were sold for medicated feeds.(a) According to the National Pig Association, the use of medicated feed in pig production has fairly decreased over the last 5 years in the UK.(b)
Recent evolution of the use of VMPs and medicated feed	Sales of medicated pre-mixes with antimicrobials have declined by 21% between 2003 and 2007, but medicated feed remained the preferred method of administering antimicrobials to food producing animals during the same period.
Measures in place for the control of the use of medicated feed	The keeper of the animals may only be supplied with and use a medicated feed that has been manufactured by an approved manufacturer and in accordance with a valid prescription from a veterinary surgeon (as set out in Schedule 5 of the VMR).

Notes:

(a) Source: Veterinary Medicines Directorate (2008). *Sales of antimicrobial products authorised for use as veterinary medicines, antiprotozoals, antifungals, growth promoters and coccidiostats, in the UK in 2007*.

(b) According to the National Pig Association, the decrease in the use of medicated feed in pig production may be explained by an improvement in herd health over the last 2 years due to PCV2 vaccination (against wasting diseases). The switch to a weaning period of 4 weeks (28 days instead of 21 days) and the use of zinc oxide to control E. coli infections may also have contributed to the reduction in medicated feed use.

5.4. Costs of using medicated feed in pig production compared with the other routes of oral administration of VMPs

The table below presents costs of treating pigs via medicated feed and via water medication[125] as index values for three active substances and for the three pricing scenarios.[126]

[125] The price of water medication includes the cost of the medicine as well as the cost of the equipment required to prepare the medicinal solution (e.g. dosing pump) and labour costs (in terms of time spent for the preparation of the solution). Compared with water medication, medication via feed involves a carrier (feed) with a significant nutritional value and which constitutes an important share of the total price of the medicated feed. To obtain cost data that are comparable between the two routes of administration, the price of a tonne of compound feed of similar quality and composition as the one used for the production of medicated feed was therefore added to the costs of water medication (see Annex 2 on methodological approach).

[126] See footnote 124 and Annex 2.

Table 74: Costs of treating via water medication compared with the costs of treating via medicated feed (index values)

	Medicated feed			Water medication		
	Aminoglycosides (Apramycin)	Macrolides (Tylosin)	Macrolides (Tilmicosin)	Aminoglycosides (Apramycin)	Macrolides (Tylosin)	Macrolides (Tilmicosin)
Scenario 1: *Fully cross-subsidised price*	Set at 100 for each active substance and for each scenario.			113	98	226
Scenario 2: *Cost price*				112	97	223
Scenario 3: *Price with gross margin of 6%*				110	96	220

Source: Civic Consulting.

In the United Kingdom the cost advantage of treating animals via medicated feed rather than via water medication seems to depend on the active substance. Under the three scenarios, water medication is more expensive than medicated feed for Apramycin and Tilmicosin, but slightly less expensive in the case of a treatment with Tylosin.

5.5. Sources of information

Organisations that have provided information for the UK case study are as follows:[127]

- Veterinary Medicines Directorate (VMD)
- Agricultural Industries Confederation (AIC)
- National Farmers' Union (NFU)
- National Pig Association
- One feed mill

[127] Interviews took place in September and October 2009.

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Annex 13: Terms of reference

EUROPEAN COMMISSION
HEALTH AND CONSUMERS DIRECTORATE-GENERAL

Animal health and welfare
Feed

Brussels,
D2 D(2008)

EVALUATION OF THE EU LEGISLATIVE FRAMEWORK
IN THE FIELD OF **MEDICATED FEED**

1. CONTEXT OF THE ASSIGNMENT

The oral administration of veterinary medicinal products (VMPs) via feed is one option for the animal holder. Directive 90/167/EEC sets out the conditions under which medicated animal feedingstuffs may be prepared, placed on the market and used within the Community. The deadline for the Member States (MS) for the transposition of these rules ended on 30th September 1991.

The global objective of this Directive is to safeguard public health from any dangers arising from the use of medicated feedingstuffs for animals intended for food production, and to prevent distortions in competition in the keeping and rearing of farm animals, by laying down conditions regarding the preparation, placing on the market and use of medicated feedingstuffs and regarding intra-Community trade in those products;

The Directive provides that:

- Only authorised medicated pre-mixes may be used to manufacture medicated feedingstuffs and that precise instructions must be given for the utilisation of such feedingstuffs;
- Producers must have adequate premises and staff whose knowledge of and qualifications in mixing technology are adequate;
- The manufacturer shall have premises which have been previously approved by the competent national authorities;
- Good manufacturing practice guidelines should be developed by MS;
- Producers shall also be responsible for the quality of the products placed on the market;
- Medicated feedingstuffs may be supplied to holders of animals only on presentation of a prescription from a veterinarian subject to certain conditions;
- Where medicated feedingstuffs are administered to animals intended for human consumption, treated animals must not be slaughtered before the end of the legally stipulated withdrawal period for each of active substances contained in it.

2. SCOPE OF THE EVALUATION

2.1. Legal instrument to be analysed:

Council Directive 90/167/EEC of 26 March 1990 laying down the conditions governing the preparation, placing on the market and use of medicated feedingstuffs in the Community[1] and its transposition acts by the MS.

2.2. Other legal instruments related to Directive 90/167:

- Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety[2]

- Directive 2001/82/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to veterinary medicinal products[3]

- Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency[4]

- Regulation (EC) No 183/2005 of the European Parliament and of the Council of 12 January 2005 laying down requirements for feed hygiene[5]

- Regulation on the placing on the market and use of feed materials and compound feed (Revision of Dir. 79/373/EEC, 82/471/EEC, 93/74/EC and 96/25/EC in process)

- Regulation (EC) No 882/2004 of the European Parliament and of the Council of 29 April 2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules[6]

- Regulation (EC) No 2377/90 of the European Parliament and of the Council laying down a Community procedure for the establishment of maximum residue limits of veterinary medicinal products in foodstuffs of animal origin[7]

- Directive 96/23 of 29 April 1996 on measures to monitor certain substances and residues thereof in live animals and animal products[8].

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1 OJ, L 92, 7.04.1990, p. 42
[2] OJ L 31, 1.02/2002, p.1
[3] OJ L 311, 28.11.2001, p. 1
[4] OJ L 136, 30.04.2004, p. 1
[5] OJ L 35, 8.02.2005, p.1
[6] OJ L 165, 30.04.2004, p. 6
[7] OJ L 224, 18.08.1990, p. 1
[8] OJ L 125 , 23.05.1996, p.1

2.3. Period to be examined in the evaluation

Data to be collected and analysed in the study will cover the period between the last year available (probably 2008) and at least the 3 precedent years.

2.4. Geographical scope of the evaluation

The evaluation shall cover the 27 MS of the European Union. To the limit of the data collection/creation, the evaluator could make reference to the situation of the specific MS. In this case the consultant will collect a robust and representative sample of stakeholders' assessments of the issues in scope of this evaluation across all the 27 MS. By doing so, the regional specifics resulting from cultural, traditional or organisational differences should be considered in order to reach the important actors in all the MS. The evaluator will strive to represent 80% or more of the animal production in the EU.

3. OBLIGATIONS OF THE CONTRACTOR

3.1 General objectives of the contract

The main purpose of the present contract is to establish the economical, social and environmental consequences of the use of medicated feed in the EU.

The word "consequences" used in this document should consider the perspectives of the different stakeholders (i.e. farmers, pet owners, consumers` organisations, animal welfare organisations, veterinarians, etc.) and take into account the following dimensions:

- The *economic* evaluation shall take particular attention of the consequences on the competitiveness of manufacturers of medicated feed and the livestock farmers taking into account production costs in detail. Further, if appropriate the consequences on specific regions or sectors shall be described.
- *Social* consequences to be considered shall include public health in terms of food and feed safety but as well potential indirect implications on human health. Besides, occupational safety and qualification of workers in the feed mills shall be taken into account;
- *Environmental* consequences shall be considered if necessary.

3.2 Task 0 – Planning and methodology

This task will include a written and oral presentation on the detailed planning of the study, including methodology, data sources and contacts to be used during the overall study. Annex I provides a list of potential stakeholders.

3.3 Task 1 – General Presentation of the animal husbandry systems within the EU

This task will include a presentation of the main economic figures characterising the holding of animals in the EU including a short analysis of the current situation and evolution in the last years (Number of different animal species including pets, production of animal products, consumption (in quantities and prices) of feed and VMPs, etc.). In the area of food producing animals the evaluation should for the main animal products characterise the most important production systems in animal husbandry and their regional prevalence.

3.4 Task 2 – In depth analysis

3.4.1 *Task 2.1: Use of medicated feed in the MS*

The significance of medicated feed in terms of production varies drastically amongst the MS. This task will evaluate the current production figures and their recent developments. In particular for the MS where medicated feed is only used to a very limited extend, the alternatives to the VMP-administration via medicated feed will be exposed in an adequate way. Also, the evaluator will describe the control system (competent authority) for the use of medicated feed in the different MS.

3.4.2 Task 2.2: VMPs administered via medicated feed

Article 3 of Directive 90/167/EEC provides that medicated feed may be manufactured from authorised medicated pre-mixes only. This task will determine the main VMPs currently used for the production of medicated feed. Furthermore, the dynamics in authorisations of medicated premixes will be evaluated.

3.4.3 Task 2.3: Medicated feed for pets

The legal basis for Directive 90/167 is Article 43 EEC dealing with the Common Agricultural Policy on which public health measures could be based when linked to agriculture, thus covering only food producing animals in its scope. Evaluation is needed on the appropriateness of the use of medicated feed to non food producing animals.

3.4.4 Task 2.4: Good manufacturing practice for medicated feed

Article 4 of Directive 90/167/EEC provides that medicated feed must be manufactured in compliance with rules on good manufacturing practice. Based on this, some MS have established detailed codes in their national legislation. This task will evaluate the current situation with respect to codes of good manufacturing practice i.e. the existence of mandatory or voluntary national codes and their level of detail.

3.4.5 Task 2.5: Production costs for medicated feed

Due to the provisions to be complied with in the different MS the production costs of medicated feed are higher than those for compound feed. This task will include an analysis of the additional costs of medicated feed in different MS and for the most important types of medicated feed. Ideally, the additional costs are indicated per treated animal.

3.4.6 Task 2.6: On-farm production of medicated feed

The on-farm production of medicated feed is allowed in some MS. This task will describe the situation throughout the Community including the conditions for on-farm mixing. The additional costs for the farmer are assessed including their breakdown on the animal to be treated.

3.5 Task 3 – Conclusion and executive summary

This task will include a summary of the main findings and the overall conclusions based on the findings and evidence of the study. This part will not exceed 10% of the overall volume of the final document. The task should also mention if, among the various stakeholders consulted during the study, other concerns than the factors listed in the study were raised. In these cases, the contractor will shortly describe the corresponding positions of the stakeholders. The contractor will also provide an executive summary, not exceeding 1 page at the front of the final version.