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IMPACT ASSESSMENT

Accompanying the document

REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

on the manufacture, placing on the market and use of medicated feed and repealing Council Directive 90/167/EEC

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1. PROCEDURAL ISSUES AND CONSULTATION OF INTERESTED PARTIES

1.1. Overview

The purpose of this impact assessment (IA) is to support the changes proposed to the medicated feed legislation in line with the principles set out in the Commission's Work programme 2013[1]. It is related to similar on-going work in the field of veterinary medical products. This review can be considered embedded in the general "Fitness Check Strategy" (assessment of the legal framework).

Giving veterinary medicinal products to sick animals via feed is one of several options for the animal holder. The current IA is concerned with this specific way of administering the veterinary medicinal products and will not elaborate on the other routes of administration, such as: by ointments or tinctures, by injections, oral powders or via drinking water.

Medicated feed is a mixture of feed materials and an authorised medicated premix. Whereas the premix is a veterinary medicine, fully subject to the medicines requirements, the final product is considered a feed.

Directive 90/167/EEC sets out the conditions under which medicated animal feeds may be manufactured, placed on the market and used within the EU. The Directive provides that only authorised medicated premixes may be used to manufacture medicated feed and that precise instructions must be given for the use of such feed. Medicated feed may be supplied to holders of animals only on presentation of a prescription from a veterinarian, subject to certain conditions. Food producing animals that have been fed with medicated feed must not be slaughtered before the end of the legally stipulated withdrawal period for each of the active substances contained in it.

The Health and Consumers Directorate-General has taken the initiative of revising Directive 90/167/EEC which is being done at the same time as the revision of the veterinary medicinal products legislation (Directive 2001/82/EC and Directive 2004/28/EC). The respective roadmap was submitted on 12 September 2012.

A glossary with technical terms and acronyms can be found in Annex 8.0 and full list of relevant legislation and a schema illustrating how medicated feed provisions are embedded into related EU-legislation can be found in Annex 8.1.

1.2. Preparatory work and consultation of interested parties

This IA builds on the results of an external study "Evaluation of the EU Legislative Framework in the Field of Medicated Feed"[2] carried out in 2009/2010 by the Food Chain Evaluation Consortium (FCEC).

1.2.1. Stakeholder consultation

Stakeholders were consulted in the context of the evaluation conducted in 2009/2010, following which internal consultations and discussion with the Member States took place. In addition, during the whole process consultations with the stakeholders were done in the margins of the Advisory Group on the Food Chain and Animal, Plant Health, the Animal Health Advisory Committee and the Advisory Committee on Fisheries and Aquaculture working group on aquaculture. Furthermore, targeted consultations of the International Federation for Animal Health Europe, the European Feed Manufacturers` Federation, the

[1] COM (2012) 629, 23/10/2012

[2] http://ec.europa.eu/food/food/animalnutrition/labelling/medicated_feed_report_20100224.pdf

Federation of Veterinarians in Europe and the EU Farmers and Agri-Cooperatives were undertaken.

Following the stakeholder consultation in the margins of the FCEC evaluation, a new web-based stakeholder survey was organised from 30 March to 31 May 2011, using an Interactive Policy Making questionnaire to collect comments on the policy options.

Finally, focussed interviews with experts from the industry and competent authorities were undertaken mainly to collect data for the assessment of the options.

1.2.2. Member States consultation

In June 2009 a questionnaire was sent to the Member States plus Norway and Switzerland to gather information from the competent authorities on the status quo in the field of medicated feed.

In addition, the Commission has consulted and reported regularly to the working group of Chief Veterinary Officers, the Standing Committee on the Food Chain and Animal Health, Section Animal Nutrition and the Veterinary Pharmaceutical Committee.

1.2.3. Scientific input

Studies, data and scientific opinions from the European Food Safety Authority and the European Medicines Agency have been used as input into this assessment.

1.3. Scrutiny by the Commission Impact Assessment Board

Within the Commission, internal consultation was pursued through an Impact Assessment Steering Group (IASG) involving DG Agriculture, Competition, Employment, Environment, Mare, Research and Innovation, Trade and the Secretariat-General. The IASG was established in 2010 and met five times; in December 2012 a final electronic consultation was undertaken. The IA report was submitted to the IA Board on 12 December 2012. The IAB delivered an opinion on 18 January 2013. A revised IA report considering the board's recommendations was submitted on 12 July 2013 for which a positive opinion was issued on 11 September 2013.

The report was amended in line with the recommendations from the IAB, as follows:

(1) An effort was made to reduce the overlap between the different problem areas and drivers. Furthermore, the issues were explained more in detail and backed by the stakeholder contributions.

(2) Better explain the link to the regulatory framework on coccidiostats: The report better explains the differences between the current regimes for the administration of veterinary medicines via medicated feed and of coccidiostats (feed additives); this concerns approval of manufacturers, provisions about the incorporation into feed and their unintended residues in feed. Furthermore, the analogies in practice are outlined in order to better understand similar measures proposed in the policy options.

(3) The options are more concretely described in order to better indicate how the successive translation into a legal text would be made.

(4) Potential shortcomings of the preferred option, particularly against the criterion of proportionality, are addressed. Furthermore, additional robustness checks have been undertaken and a more detailed presentation of the impacts in the different Member States.

The results are presented now more disaggregated. Concerns of stakeholders were raised in a clearer way and the report indicates how it copes with them. A glossary had been added.

1.4. Consistency with other EU policies and horizontal objectives; Links with other legislation under review

The aim of the review of the medicated feed rules is to harmonise at an appropriate safety level the marketing of medicated feed in the EU and to reflect technical progress in this field. The review of the legislation on medicated feed must be seen in the context of the Commission's efforts to strengthen the internal market, and foster industrial competitiveness, innovation and economic growth.

The project is in line with the Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions, "Commission Work Programme 2012, Delivering European renewal (Building a Union of sustainable growth and solidarity – a single market for growth, and smart regulation and effective implementation".

Medicated feed and antimicrobial resistance

The proposals listed in this impact assessment also aim to implement the actions set out in the Communication from the Commission to the European Parliament and the Council "Action Plan against the rising threats from Antimicrobial Resistance"[3]. Furthermore, the European Parliament called in its resolution on the public health threat of antimicrobial resistance of 27 October 2011[4] on appropriate actions in the field of animal nutrition. Also, the Resolution of the European Parliament of 11 December 2012 on the Microbial Challenge – Rising threats from Antimicrobial Resistance[5] requested a European response to the issue. Additionally, the Council called upon the Commission in its conclusions (Doc 10582/12) on the impact of antimicrobial resistance in the human health sector and in the veterinary sector - a "One Health" perspective - to expedite the review of the medicated feed directive.

Medicated feed and veterinary medicinal products

The revision of the directive on medicated feed is part of the same package as the revision of the veterinary medicinal products legislation. The respective IA tackles amongst others the issue of antimicrobial resistance and the better availability of veterinary medicines with respect to the marketing authorisation of medicines.

Medicated feed is a mixture of feed materials and additives with veterinary premixes authorised under the veterinary medicinal products legislation. Nonetheless, medicated feed is considered a very particular feed, with specific rules on the incorporation of the medicine into the feed.

Member States and the different stakeholders involved in this field have on several times indicated the importance of ensuring that the revision of the medicated feed legislation takes the specificities of the sector into account. This can only be done by an independent approach which builds on the links with the feed legislation and the veterinary medicinal products legislation.

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3 http://ec.europa.eu/dgs/health_consumer/docs/communication_amr_2011_748_en.pdf

4 http://www.europarl.europa.eu/sides/getDoc.do?type=TA&reference=P7-TA-2011-0473&language=EN&ring=B7-2011-0538

5 http://www.europarl.europa.eu/sides/getDoc.do?type=TA&reference=P7-TA-2012-0483&language=EN&ring=A7-2012-0373

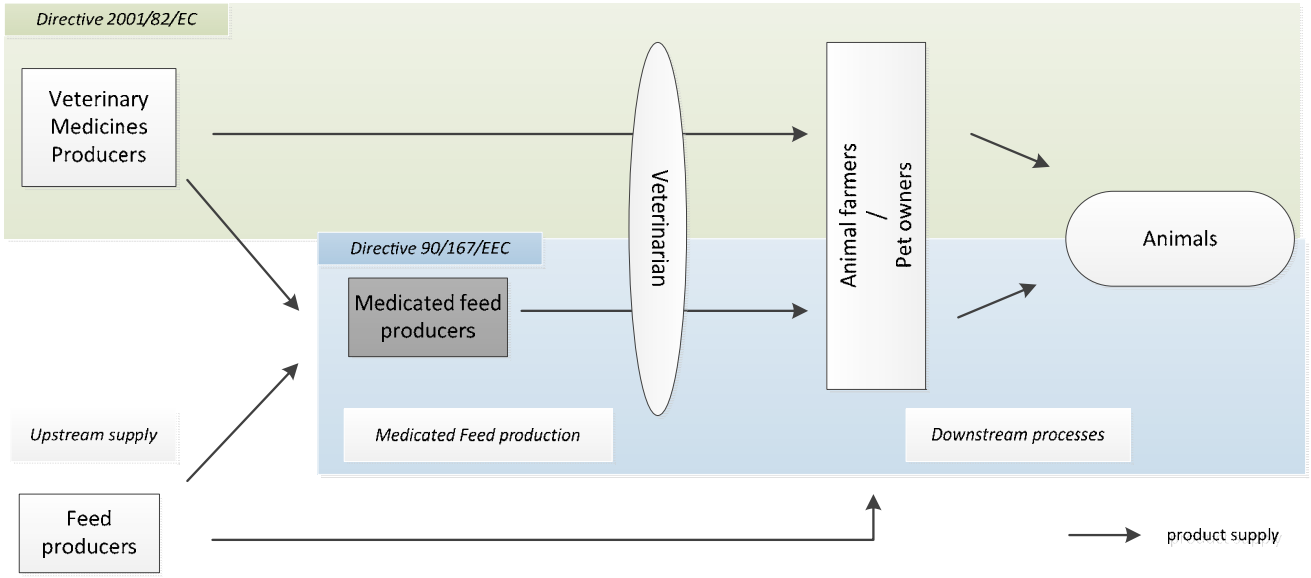
2. PROBLEM DEFINITION

2.1. Context

Farmed animals in the EU are fed with roughage, feed materials and compound feed (mixture of feed materials). If animals are sick and need a treatment, the veterinary medicine can be prescribed by a veterinarian and administered to animals via the following main routes: (1) topically i.e. externally as paste, cream or tincture (2) by injection or (3) orally. The vast majority of medicated feed for farmed animals contains antimicrobials or anti-parasites.

As regards the oral administration of medicine to animals, the animal holders can either (1) add oral medicines themselves to the animal feed or drinking water or (2) use medicated feed into which the medicine is incorporated by an authorised manufacturer. At best, the farmer has a special device[6] to incorporate the "ready to use" powder into his feed but often they just distribute the powders with a scoop. Also top dressing medication is rather common: the farmer sprinkles the dissolved medicine on top of the feed in the manger. The competent control authorities depend on the re-assurance from the farmers that they properly add the veterinary medicine to the feed or drinking water. On the other hand, medicated feed is usually manufactured by feed mills with sophisticated mixing technology and the authorities can verify the mixing quality upon approval of the establishment.

The following schema illustrates the oral administration of medicines to animals:



Medicated feed is generally used to treat animal disease in large groups of animals, particularly pigs and poultry. There is a clear correlation between the level of manufacturing standards and the quality of the treatment via medicated feed. High standards mean good homogenous distribution of the medicine in the feed, good compatibility of the medicine with the feed, and as a result good dosage ensuring an efficient treatment of the animal and low carry-over (sometimes called also "cross contamination") of the medicine into non target animal feed.

The evolution of the quantities of antimicrobials and the quantities of medicated feed used in the EU shows that the decision to use therapeutic antimicrobials is totally independent from the possibility to use medicated feed. Therefore, specific restrictions on medicated feed do not lead to a reduction of the use of antimicrobials in livestock farming because oral alternatives

[6] The quality of homogenisation varies significantly, many use concrete mixers

(ready to use powders mixed in feed, top dressing, via drinking water) or the administration via injection still remain available.

Measures concerning the prescription and availability of all forms of antimicrobial veterinary medicines (including premixes for medicated feed) are addressed in the parallel IA on the review of the veterinary medicines directive.

2.1.1. Costs – Supply – Demand

There are 13.7 mio. animal holdings in the EU.[7] The value of livestock farming output in the EU is €157 bn[8]. The value of the EU's aquaculture which includes production of crustaceans, molluscs, and finfish[9] is estimated to be €3.3 bn. Pet animals represent the second largest type of animals kept in the EU. There are around 64 million cats, 60 mio. dogs, 40 mio. pet birds, 25 mio. small mammals and many millions of ornamental fish. All these farmed animals, aquaculture species and pets may need medication from time to time.

Animal feed (feed materials, additives and compound feed) are the main input into livestock production and the most important cost factor for the famers with an average of 47% of the total production costs. The production of compound feed for food producing animals was 151 mio. t in 2011 resulting in a turnover of €50 bn. More than 110,000 persons are employed in approximately 4,000 production sites. These companies are generally SMEs with a turn over between €10 mio. to €100 mio and 20 to 100 employees. The structure of the pet food sector is similar with 650 plants a turnover of € 13.5 bn (2010)[10]. The production structure is optimised by the industry leading to interregional supply chains of a very broad range of different feed types (dry/wet, complete feed/speciality feed, different target animals, packed in can/bag/poach/treat). Despite its large size, the pet food market in the EU is by and large irrelevant with regard to the use of medicated feed[11].

The EU veterinary medicines market was valued at € 4.3 bn. in 2011. The sales figures by value according to IFAH-Europe include parasiticides (27 %), vaccines (26%), antimicrobials (19%), topical products (7%) and other products (20%).[12] Based on information from the European Group for Generic Veterinary Products, there are no evident differences in the businesses with premixes depending on whether the VMP is a branded or a generic product; in other words: it does not matter for the manufacturing and use of medicated feed whether the veterinary medicine is a generic or a protected brand.

More data on the upstream and downstream activities can be found in Annex 8.2.

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7 Data from Eurostat 2007, Number of farms and heads by economic size of farm (ESU): http://epp.eurostat.ec.europa.eu/cache/ITY_OFFPUB/KS-AF-07-001/EN/KS-AF-07-001-EN.PDF

8 Data from Eurostat 2011

9 Finfish is the aggregate term for freshwater, diadromous and marine fish

10 www.fediaf.org

11 FCEC, chapter 4.6

12 IFAH-Europe annual report 2011. IFAH-Europe (International Federation for Animal Health Europe) is the federation representing manufacturers of veterinary medicines, vaccines and other animal health products in Europe. Its membership covers 95% of the European market for veterinary products and the companies comprise both local medium-size enterprises (SMEs) and international companies

In 18 Member States, oral routes of medication with antimicrobials represented 91% (2010) of the total sales of antimicrobials[13]. The respective share according to the FCEC case study[14] in 2006 for France, United Kingdom and Finland was 88%, 90% and 55%. Premixes for medicated feed manufacture represented in 18 Member States 54% (2010) of orally administered antimicrobials[15]. According to the FCEC case study[16] for France, United Kingdom and seven big manufacturers of veterinary medicines that share was 59%, 70% and 64%, respectively.

Premixes for medicated feed: The number of nationally authorised premixes varies significantly between the Member States from just a few in some Member States to more than 300 in France (see Annex 8.3). Only two premixes have been approved centrally and therefore only medicated feed based on these two medicines can be marketed throughout the EU. For all the other medicated feeds, an authorisation of the respective premix must be obtained in the Member State of destination. The authorisation of veterinary medicines, including premixes for MF, is not covered in this impact assessment but in the parallel one on veterinary medicines which is addressing the fragmented market for VMPs in the EU.

The significance of medicated feed varies drastically amongst EU Member States[17]. In 2008, production figures were highest in Spain (2 - 3 mio t), Italy (1.3 mio t) and France (0.8 - 1 mio. t). The United Kingdom (0,5 mio t), Belgium (0,3 mio t) and the Czech Republic (0,1 mio t) are also quite important producers whereas Germany (12,000 t) and Denmark (12,000 t) are of minor relevance. The share of medicated feed production from the total compound feed output ranges from 9% in some Member States to only 0.1% in Germany[18] (for more data see Annex 8.6).

Table 1: Production of medicated feed (in 000' tonnes) in some Member States and the evolution from 2004-2008

	2004	2005	2006	2007	2008
Belgium	n.a.	n.a.	n.a.	n.a.	300
Czech Republic	92	111	154	149	99
Denmark [(a)]	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
Notes: [(a)] Only medicated feed containing zinc oxides (see country case study Denmark).

In Member States such as France, Poland, Portugal and Spain, where the national system does not result in significant extra-costs for the production, the businesses can market the medicated feed at competitive prices and thus the trend for production and marketing is stable to slightly positive. In Member States where the national system imply high extra costs, the industry either cross-subsidises the medicated feed in order to retain their clients for their

13 See Annex 8.5
14 FCEC, table 9
15 See Annex 8.5
16 FCEC, table 10
17 FCEC, chapter 3.1
18 As medicated feed is mainly produced by the compound feed industry it is commonly put in relation with the compound feed production to see the significance of medicated feed in country. However, this might lead to an overestimation in a country where the farmers purchase relative little compound feed because they pre-dominantly purchase or produce instead the feed materials and mix their own feed.

normal feed sales or they abstain from offering medicated feed because they know that the farmers would not pay the extra costs and instead would use the other routes of medication.

Table 2: Additional costs of manufacturing medicated feed compared with production costs of compound feed in Member States with different national schemes (in €/tonne)

Cost factor (in €/tonne)	**Denmark**	**France**	**Germany**	**United Kingdom**
Additional consumption of fixed capital (additional equipment and buildings)	2.32	0.02	50.5 [(a)]	0.36
Additional labour costs [(b)]	6.33	0.59	12.5	3.17
Additional cleaning costs (costs of flushing/rinsing)	1.75	0.08	n.a.[(c)]	n.a.[(d)]
Cost of tests (homogeneity test, test of drug carry-over, analytical control of concentration of active substance in medicated feed)	1.21	0.12	4.80	0.06
Administrative costs (annual administrative fee)	0.28	0.06	2.50	0.02
Total additional cost of manufacturing medicated feed (excluding cost of the medicine)	***11.89***	***0.87***	***70.33***	***3.62***

Source: FCEC 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.

The manufacture of medicated feed is usually done by the compound feed industry as a special service for their clients that opt, on their veterinarian's advice and prescription, for the medicated feed route. Thus the vast majority of medicated feed production is integrated into the compound feed mills and comes from the approximately 1600 authorised operators (N.B. 4000 compound feed sites in total). The share of turnover of the medicated feed activity in the compound feed industry ranges on average from 3% to 5%. In some specialised feed mills, this value can be up to 30%[19] but these plants usually belong to companies with several production sites, one specialised on medicated feed and the others exclusively ordinary compound feed which makes an overall share of medicated feed for the company in the above mentioned range. Besides these, there are also independent mobile mixers which come with their specifically equipped lorries to the farms. Finally, a rather limited share of the medicated feed[20] is produced in the approximately 5700 farms with specifically authorised premises (N.B. a total 13,7 mio. livestock farmers can potentially administer veterinary medicines to their animals)[21].

The diverging situation in the Member States with respect to numbers of the different kinds of manufacturers of medicated feed and the authorised distributers involved in supplying the market is shown in Annex 8.4. The activities of authorised distributers significantly contribute to a smooth functioning of the medicated feed market. However this activity is not allowed in 11 Member States. Where the national rules for medicated feed manufacturing imply high

19 Source: expert interviews

20 The range according to the expert interviews is between 20t and 2000t per year and based on the assumption of 50t, the total medicated feed production on farm (ex. mobile mixers) would be 0.3 mio t.

21 On farm mixing is frequently done in "integrated farms" where entrepreneurial activity from feed to meat is in one hand (quite common in the EU for poultry); assessment of impacts is more difficult as these data are hardly available.

extra costs, the industry either cross-subsidises the medicated feed in order to retain their clients for their normal feed sales or they abstain from offering medicated feed because they know that the farmers do not pay the high extra costs and use instead the other routes of medication. Thus, for the compound feed industry concerned, the manufacturing of medicated feed cannot generally be considered a business branch to evidently contribute per se to the company's profit. In Member States where the national scheme does not result in significant extra-costs for the production, the businesses can sell the medicated feed at least at cost prices and the trend for medicated feed is stable to slightly positive. As, in these Member States, competition exists between the feed mills but also between feed mills and mobile mixers, medicated feed is at a competitive price compared to the other routes of medication.

An estimation of the total EU production of medicated feed would indicate a range between 4% and 5% which represents a quantity of 6 – 7.5 mio t of medicated feed, creating a total turnover of medicated feed in the order of € 1.6 – 2 bn. This turnover includes the input of the veterinary medicines and the feed. The isolated employment effect, solely for the additional activity "incorporation of the premix into the feed" is estimated to be in the order of less than 1000 manpower units for the total EU[22].

The EU trade in compound feed is not very evident. This is because feed imports and deliveries from the production regions in the EU are usually in the form of bulk raw materials for processing, mixing and compounding close to where the animals are kept. In addition, Member States' regimes are different both for veterinary medicinal products (generally national authorisations) and for medicated feed (no harmonisation at all). This complicates also deliveries in regions close to borders. Thus, the trade in medicated feed within the EU is currently even more negligible than for compound feed.

- The significance of medicated feed for farmed animals varies extremely between the Member States
- It is a niche market with no specialised medicated feed industry. Medicated feed production can be rather considered a service of the compound feed industry to their clients.
- Medicated feed for pets is negligible.
- The national regimes determine the costs for medicated feed production and consequently the supply. The demand is an endogen variable of the specific supply situation in a Member State.
- Trade between the Member States - even in regions near to borders - and also exports and imports of medicated feed are negligible.

2.1.2. Legislative context

Directive 90/167[23] introduced some important and still valid concepts into Community legislation. In particular, it provided that medicated feed had to be manufactured in approved premises in accordance with Community legislation using staff with adequate qualifications. It provides that medicated feed can be made with feed complying with feed law (a.o. Regulation (EC) No 767/2009), issued on the prescription of a veterinarian, with records being retained in the feed mill. However, the Directive gives no indication on what standards to apply in approving plants or the acceptable techniques to produce medicated feed, and whether standards should be technology based or results based.

[22] Based on the labour costs in the survey (FCEC table 6 and Annex 11) a range between 170 and 1040 full time manpower units was calculated.

[23] The interface with other pieces of EU-legislation is illustrated in Annex 8.1.

In addition, while it provides that medicated feed shall be homogenous, it does not define this critically important term and provides no means to do this at EU level. It is silent on the concept of carry-over of medicated feed between batches and provides no mechanism to regulate this. It is vague on whether feed may be prepared in advance of prescription in the feed mill, allowing Member States to interpret it differently. It does not address either the labelling of medicated feed which has both internal market and safety implications. It allows that each individual consignment moving between Member States be accompanied by a (paper) certificate from the Competent Authority of origin. It makes no provision for electronic communication either for prescriptions, feed movement or product information.

The enforcement of the provisions established by the Directive in the EU is regularly checked in audits of the FVO (Food and Veterinary Office, a DG SANCO Directorate). As the Directive is quite general and giving much flexibility to the Member States, those EU-controls for compliance cannot be very concrete in practice. There was only one infringement procedure launched some years ago because one Member State contradicted the EU-Directive in a national legal implementing act.

There are specific additional issues concerning medicated feed for pet animals. This was an unknown concept in 1990 and there is no mention of pet animals in the legislation. Furthermore a provision that the feed mills must keep a record of all individual animal keepers using their feed is valid for local farm deliveries but is a major obstacle for a pet food factory providing specialised medicated feed for pets throughout the EU.

For the manufacture of medicated feed, an authorised premix is mandatory. Veterinary medicines can be approved in the EU centrally or at national level[24]; the latter is still predominant for the medicated feed premixes. The authorisation of veterinary medicines, including premixes, is addressed in the parallel impact assessment on veterinary medicines.

Coccidiostats and histomonostats are considered to be veterinary medicines but their authorisation is regulated under the scope of the Feed Additive Regulation. Thus, authorisation and use of these substances are fully harmonised. Furthermore, in 2009 maximum levels of their unavoidable carry-over in non-target feed were established. Feed additives cannot be directly fed to the animals, but have to be added to feed materials or water. In order to ensure the correct dosage of a coccidiostat to the animal, the incorporation of the additive into the feed materials can be only done by approved feed business operators which apply the HACCP principle. They deliver the formulated complete or complementary feed to the livestock farmer.

- Medicated feed is a specific form of feed but with strong legal links to veterinary medicines.
- The enforcement of the Directive by the EU in practice is rather limited due to its general and vague character.
- The revision of the veterinary medicines regime aims to improve the smooth functioning of the internal market in this area.
- Legislation on feed marketing, feed additives and maximum residues limits of undesirable substances in feed has been fully harmonised.

[24] National authorisations can be expanded to other Member States by a mutual recognition scheme.

2.1.3. Public perception

As a niche in an area between feeding and treating animals, public interest or concern about medicated feed is marginal. However, the often vehement discussions at national and European level about antimicrobial resistance also call for EU-action in the area of medicated feed (see 1.4). Numerous announcements for national action plans in this context show the citizens concern regarding the emergence of multi-resistant bugs.

Furthermore, there are a huge number of pet animals (estimated to number several millions, see Annex 8.13) which suffer from chronic diseases but their owners struggle to administer their medication in the form of pills. On the one hand, a small number of pet owners are aware of medication via ordinary pet food (medicated feed) as a good way of treatment but they do not have regular access to medicated pet food and on the other hand the vast majority of owners are not yet aware of this convenient treatment possibility.

2.1.4. Need for medicated feed production

Evidently, the crucial criterion for the choice of the medication route is the cost situation[25]: Whether medicated feed is a more costly or a more cost efficient route of administering oral VMPs compared to water medication or via ready to use powders depends on

- the manufacturing standards pursuant to the specific Member States` requirements,
- the pricing strategy applied by manufacturers of medicated feed (see 2.1.1) and
- the pricing strategy of the VMP industry for the active substance.

Additional factors are subjective perceptions of cost advantages or effectiveness of the different routes of medication, specific taxation rules, monetary incentives of veterinarians and traditions. Finally, investments in equipment to administer the VMPs via a certain route (e.g. dosing devices or specific storage containers for medicated feed) are sunk cost and thus provide an incentive to continue the practice.

Medicated feed (apart from pets) is not an industry but a small process or service provided within an industry. Individual decisions on pricing of the MF industry are not transparent (largely elaborated in Annex 11 of the FCEC report). In some cases, profit margins for MF can be up to 11% (compared to 6% of non-medicated feed) and in other cases the MF may be cross subsidised by sales of non-medicated feed.
Cost delta for the 2 main oral routes (see 4 case studies in Annex 11 of FCEC report):

- In DK and UK choice depended on the drug prescribed (for some drugs MF-medication was cheaper, for others water medication),
- In FR, MF medication has cost advantage (8-24%),
- In DE water medication is cheaper (10-14%).

Based on the consultations of the concerned stakeholders (feed industry, veterinarians and farmers), the decision of the veterinarian, in coordination with the farmer, depends in the first place on the availability at the price set under the national framework for the various routes of medication (FCEC report p. 42). In the second place, other factors such as perceived convenience, efficacy and safety are also important as is whether investment has already taken place on the farm to use one or another method. On tax, an issue on value added tax (VAT) has an effect in DE but not in other MS. There, the high VAT-rate is charged for the MF in its totality which cannot be reclaimed by some farmers, usually smaller ones that have some tax privileges; but MF is mostly used in bigger holdings with regular taxation. If the farmers buy the feed part and the veterinary drug separately, they only are charged for the VMP with the high VAT-rate. This can only be considered a marginal further cost

[25] See Chapter 4.4 of FCEC report

disadvantage for MF, because only the farmers with that tax privilege cannot reclaim the higher VAT paid.
Several MSs (HU, RO, SI) did note that administration by water/powder was gaining market share over medicated feed which would be a continuation of the current trend. SI related this specifically to the greater regulatory controls on MF than on the alternative routes.

It can be concluded that the farmer's and pet owner's choice for a specific route of medication depends from the supply side i.e. the decision for medicated feed or alternative routes is done based on the specific options offered to him.

2.2. Problem identification, its drivers and consequences

2.2.1. Presence of residues of veterinary medicines in feed

The development of antimicrobial resistance (AMR) is a serious public health risk (more details can be found in Annex 8.9). For the treatment of infections in animals oral medication with antimicrobials is most common. For oral administration of antimicrobials there are several routes, one of them is medicated feed. The FCEC survey and the ESVAC data show that the use of medicated feed has no influence on the overall quantity of antibiotics used in livestock farming (for more details see Annex 8.6). Similarly, the excessive use of antimicrobials can be only satisfactorily addressed in the context of the holistic AMR strategy. The most important element with respect to AMR is the frequency of use and the type of the specific antimicrobial; these issues are addressed in the parallel IA on veterinary medicines.

Concerning medicated feed (i.e. apart from the frequency/quantities of AM-use) AMR can arise from sub-therapeutic (incorrect dosage) or residual (carry-over from a medicated feed) levels of antimicrobials in feed. The issue of incorrect dosage is covered under 2.2.2.

Depending on the active substance, above a certain level (minimum inhibitory concentration, MIC) of the antimicrobial, combined with a longer duration of the exposure of the commensal bacteria in the gut, selective amplification of the resistant subpopulation of the pathogen can be expected.

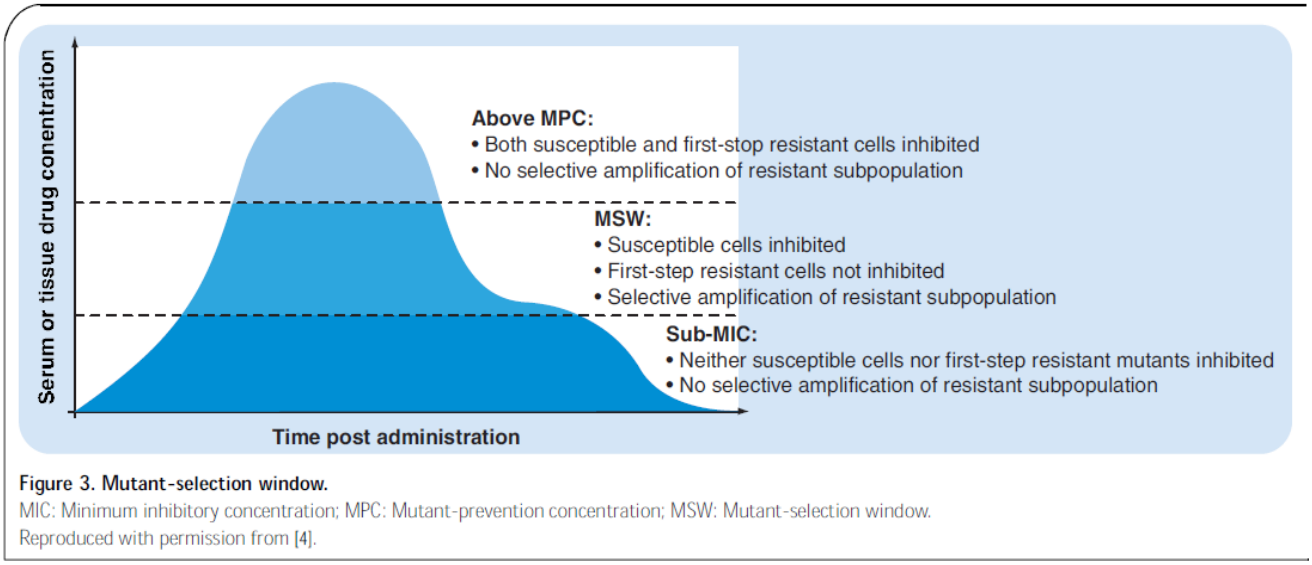

Figure 3. Mutant-selection window.
MIC: Minimum inhibitory concentration; MPC: Mutant-prevention concentration; MSW: Mutant-selection window.
Reproduced with permission from [4].

Figure extracted From (Hesji et al., 2007).

On the other hand, residue levels below the MIC have no evident impact on AMR.

EU ban on antibiotic growth promoters

Administering antibiotics and other antimicrobial agents to animals in doses significantly below the level used for treatment of diseases can have positive impacts on the micro-biota in the intestine of the animals and thus improve zootechnical parameters. Such applications are known as antibiotic growth promoters. However, such sub-therapeutic use of antimicrobials can increase the risk of bacteria becoming resistant and subsequently causing problems in human health. Considering the emerging risk of antimicrobial resistance, the EU decided in 2003 to ban the use of antibiotics in feed for growth promoting purposes from 2006 onwards. EU-controls found residues of antimicrobials in un-medicated feed in the order of those growth promoter levels.

2.2.1.1. Driver 1: Carry-over of veterinary medicines, notably antibiotics, into compound feed

The Food and Veterinary Office found that many Member States had in place measures to avoid or minimise cross-contamination (for details see 8.7). These measures comprised a variety of actions at production level such as using dedicated lines, setting up manufacturing sequences for production or flushing and/or in-depth cleaning of equipment. However, in 18 Member States, feed operators did not ascertain the effectiveness of these measures related to cross-contamination and, therefore, it could not be ensured that they were sufficient. In some countries, cross-contamination tests were not performed at all and the level of cross-contamination was not quantified by operators. In a couple of Member States, the level of cross-contamination measured by these tests was underestimated as samples were taken after the mixer. In a couple of countries, cross-contamination tests were run on a very limited number of samples. In a small number of Member States, the limit of detection of the analytical method used for these tests did not allow to quantify cross-contamination levels lower than 10%. Furthermore, findings of veterinary medicines in feed are reported in the Rapid Alert System for Food and Feed (RASFF)[26] and a list of such notifications can be found in Annex 8.10.

Also the online stakeholder consultation showed an absence of any common ground with respect to carry-over: 42% respondents indicated that tolerance levels exist in their Member State, whereas 30% claimed that a zero tolerance is to be applied and 28% did not know. The large group of undefined responses illustrates that the situation in many Member States is unclear. A further analysis of the 42% respondents showed that in many Member States, even from a formalistic legal point of view, tolerances for VMP residues are officially accepted up to 5% of the therapeutic level which might be, for many antibiotics, above the MIC level. The Belgian compound feed industry claims that due to efforts in recent years the cross contamination had been significantly decreased but even if they consider levels of 10% "very extreme" they are not unrealistic.

16 Member States have no clear rules on the carry-over ("no value", see Annex 8.8). Both competent authorities and MF manufactures have to undergo a burdensome case by case evaluation if residues of veterinary medicine are found in feed. Three Member States have already established tolerance levels which are, on the one hand, arbitrary from a legal point of view and, on the other hand, are more derived from the application of the ALARA (as low as reasonable achievable) principle than from an assessment for public health risks.

The manufacturing of medicated feed cannot totally avoid a carry-over of veterinary medicines into batches of feed that should be free of such substances ("zero tolerance"). This

[26] The RASFF has been set out in Article 50 of Regulation (EC) N° 178/2002. The RASFF is a network which informs the competent authorities in the Member States of the presence of a risk to human health deriving from food or feed. For specific information relating to notifications within the RASFF see http://ec.europa.eu/rasff

carry-over, also called cross contamination, appears even if medicated feed is produced in dedicated lines of the compound feed mill with end of the line mixers (e.g. during transport of feed) or if it is manufactured on the farms where the medicated feed is used. However, the carry-over can be significantly reduced.[27]

2.2.1.2. Driver 2: "Zero tolerance"

From a legal point of view, residues of veterinary medicinal products in ordinary compound feed are not allowed (zero tolerance) i.e. that positive findings of VMPs make the feed not marketable. Eight Member States apply, according to the central authorities, officially a zero tolerance for the carry-over of veterinary medicines. The situation in the Member States is detailed in Annex 8.8. Zero tolerance in the food chain is difficult to implement, thus in practice for VMPs, stakeholders

- try to find "pragmatic solutions" together with the local competent authorities or
- by-pass the rules using other ways of administration.

An example for the unclear, contradictory situation in a Member State where medicated feed is of high importance can be seen from the response of the central Italian authority:

*"… Officially, the national control plan sets a zero tolerance regarding residues of veterinary medicines in feed. In fact the tolerance level is the level of analytical detection related to the accredited laboratory method. Any positive finding has to be followed by corrective actions imposed by local competent authorities (case by case: seizure, destruction, penalties, RASFF notification, procedures of the national control plan of residues in food etc) … From the official control point of view, maximum levels of unavoidable carry-over of VMPs in non-target feed is a necessity. Feed operators are … committed to adopt any measures in order to minimise the carry-over, according to Reg. 183/2005 and Directive 90/167/EEC. However, even in the best situations, carry-over cannot be completely eliminated to zero, as well known. Moreover, Community levels are necessary in order to avoid different practices among Member States, and different standards related to safety of fee*d."

This position of the competent authorities is very unsatisfactory for the business operators as they cannot be sure that, even if they follow the national rules, they are not prosecuted by the authorities in the case of positive findings.

The by-passing of a strict zero tolerance implementation can be increasingly observed in the EU as for the administration of veterinary medicines to animals, several alternatives to MF exist, notably direct use on the farm of oral powders, top dressing or administration via drinking water. However, they entail weaknesses also concerning residual presence of veterinary medicines on the farm mainly due to cross contamination of the equipment used to administer the veterinary medicines. Additional weaknesses are tackled in 2.2.2.

Case studies on AM-use in Germany

- Medicated Feed has no significance in Germany for the administration of antimicrobials to animals
- But, in one Land 92,5% of broilers (generally aged under 40 days) have been treated at least with one antimicrobial, mostly at therapeutically incorrect doses (NRW 2011)
- 76% of the broilers, 97% of the turkeys, 68% of the pigs, 100% of the calves for fattening and 92% of the cattle for fattening have been treated at least with one antibiotic (NI 2011)
- In 62% of the poultry houses, at least one antimicrobial was found in the drinking water though it was not used in the time of sampling (NRW 2012)

[27] "Causes and control of carry-over and cross contamination" W. Strauch (Kraftfutter/feed magazine 04/02); "Avoiding carry-over" W. Strauch and A. Feil (Kraftfutter/feed magazine 4/06); "Avoiding cross contamination, part I" W. Strauch and A. Feil (Kraftfutter/feed magazine 7-8/08); "Avoiding cross contamination, part II" W. Strauch and A. Feil (Kraftfutter/feed magazine 9-10/08)

2.2.1.3. Consequences

- AMR risk in those Member States with generous tolerance levels.
- Burdensome case by case evaluation in Member States where no carry-over level exists and possibility that follow up of positive findings does not fully guarantee public health protection.
- Legal uncertainty for stakeholders in Member States with a "pragmatic" implementation of the zero tolerance.
- Cross contaminations on farms in Member States with a strict application of the zero tolerance due to increased use of less controllable alternatives to medicated feed.
- Unavailability of medicated feed in Member States with strict application of the zero tolerance.

2.2.2. Imprecise dosage of veterinary medicines

The precise dosage of oral VMPs is crucial for an effective group treatment i.e. to ensure that each individual animal gets the correct therapeutic dose. Incorrect dosage may cause toxicity in the animal (too high dosage) or increase the risk that animals are not cured (too low dosage). The animal health problem due to under-dosage is particularly severe for the weak animals because they need the medication in the first place and these individuals already suffer from competing with stronger individuals in their access to feed.

Field study in Germany (DPT 90:12 (2009)
- 96 % of farms used oral powders for group or herd treatment.
- 76% of the oral powders were given via feed, 11% via drinking water, 12% of the farms apply both routes
- 1/3 of farmers dosed the oral powder per hand to the feed
- Only in 18.5% of the samples was the correct therapeutic dose given (in 70.4% there was under-dosage and in 7.4%, an overdose)
- There were severe carry-over problems: 40% of samples had 1-4 unintended active substances of which 20% were at or above the respective therapeutic level.

Conclusion: objective of improving safety in on farm use of medicines, by increasing the regulatory burden for medicated feed alone, has not been achieved.

Report of the French food safety agency (Anses) 2012 (saisine no 2011-SA-0048):
- Significant weaknesses of mixing oral powders into feed by the farmer even if done in compliance with the summary of the product characteristics (SPCs) of the VMP. Oral powders are only first choice under very specific conditions.
- In general, medicated feed with advantages in terms of safe and efficient medication.

Precise dosage is at risk on the one hand if the medicated feed manufacturing does not guarantee a homogeneous incorporation of the medicine into the feed or if the medicated feed intake of animals is lower than expected and on the other hand if less precise routes of dosage (e.g. top dressing of oral powders) are dominating. If the microbes in the animal are exposed to sub-therapeutic dosage of antimicrobials[28], a significant number of pathogens survive the treatment and their presence will stimulate the selection of resistant strains of microbes.

[28] Real AM-concentration below MPC (mutant prevention concentration) and above MIC = MSW (mutant selection window) 2.2.1

The legislation for coccidiostats and other sensitive feed additives does not allow the farmer to add them on their own to the feed. Instead, it requires that this is done by approved feed manufacturers to ensure the homogenous incorporation of these additives into the feed and thus a precise dosage ("premixture obligation"). This is EU wide enforced. However, the oral administration of veterinary medicines ("ready to use powders") can be done by each farmer without any official licensing. And even if the medication is via medicated feed, depending on the rigidity of the respective national regime, the homogeneity of the medicated feed is in various Member States hardly enforced.

2.2.2.1. Driver 1: Preventive costs for medicated feed production in some Member States

Some Member States impose burdensome requirements for the manufacturing of medicated feed in order to avoid misuse of medicated feed leading to costly medicated feed. For example, producers of medicated feed in Germany must comply with pharmacology production standards. This means installing totally separated production lines for compound feed and medicated feed. This involves not only additional investment in a separate medicated feed line but also extra costs for the equipment (materials, technology), the workers and control staff. These extra costs do not apply in other Member States because medicated feed production can be done in the ordinary compound feed production lines. Also in Austria, the national rules impose high burden for the feed industry whereas on-farm manufacturing of medicated feed is implemented at a pragmatic level. Consequently, the manufacturers with the best mixing technology are not operating in this business and all the premixes used are mixed on farm[29] into the feed, apart from the oral powders directly applied via the feed or water. Other Member States where, due to national rules, a trend away from expensive, controlled medicated feed manufacturing to alternative routes of administration can be observed are Luxemburg, Malta, Romania, Bulgaria, Hungary, Greece and Cyprus. In about 1/3 of the Member States the costs for professionally medicated feed can be assumed to be preventive.

As the quantity of veterinary medicines used are independent from the availability of the different routes of administration, such high and thus preventive costs of medicated feed manufacturing result in more use of the other, less precise routes. The oral powders are usually not incorporated into the feed by specific, calibrated devices. The top dressing of the medicines risks that the strong, dominant, animals have an excessive uptake while the weak animals do not have access to feed and are thus deficient. An important percentage of the oral powders is dosed per hand by the farmers (see above) with evident weaknesses concerning precise dosage in group treatments. The authorities in these Member States try to tackle this issue by supporting the investments in dosage devices but there is no hard law to oblige the farmers.

The imprecision of the drinking water route is the quantity of water that is spilled and also the variation of the water quantity drunk by the animals. Furthermore, practical experience from drinking water medication has reported the creation of solid complexes in the pipes, jamming the drinking taps, which can affect the dose precision.

These problems of the oral powder medication cannot be tackled in the margins of the medicated feed legislation but are under the scope of the veterinary medicine law. The leverage on more precise dosage of the livestock in the medicated feed area is to induce for more animals the treatment via medicated feed instead of less precise "ready to use" powders.

[29] 3986 farms were authorised for this activity according to the CIVIC report

2.2.2.2. Driver 2: Poor homogeneity of medicated feed in some Member States

The non-homogeneous mixing of medicines into a quantity of feed means that a part of the feed is under-dosed whereas another part is overdosed. The problem of under-dosage is further aggravated for weak diseased animals.

The homogenous incorporation of the veterinary medicine into the feed is a general requirement for the operators in the EU-Directive. In some Member States this provision is quite diligently implemented by means of explicit measures to achieve and control this. However, in other Member States the requirement is not enforced to this extent.

Medicated feed manufacturers are usually aware of the requirement about homogeneity. However, in nine Member States out of 25 inspected by the FVO, operators did not verify that they achieved homogeneous mixtures. This lack of verification concerned on-farm and mobile mixers, but also a number of feed mills. In some Member States, the verification of the feed homogeneity was only based on visual examinations or on the analysis of only one sample (more details can be found in Annex 8.7). If the competent authority has no willingness or resources to insist on a good homogeneity test, the FVO has no means to conclude non-compliance with the EU-Directive due to missing indicators. Evidence from practical application of the valid homogeneity tests shows that homogeneity cannot be assumed per se by using a certain technology but that each establishment has to be optimised to achieve it.

The evidence produced in France, Germany and Ireland indicates that homogeneity cannot be automatically assumed if the operator merely relies on the technology he installed. Instead, it is crucial to measure recovery rates of the medicine in the finished medicated feed (homogeneity) and residues of medicines in the on target animal feed. Based on these criteria the optimisation of the dosage and mixing process or the concrete design of the flushing regime taking into account the different active substances and feed materials has to be done for each manufacturing site.

2.2.2.3. Consequences

- Ineffective treatment of sick animals as they do not get the therapeutic level of the veterinary medicine (failure of therapy for under-dosed) and residues of the medicines in the animal products (over-dosed animals) both in Member States where medicated feed is displaced by less precise oral powders and in those where homogeneity of medicated feed is not sufficiently ensured.
- Development of antimicrobial resistance as many animals are treated at sub-therapeutic levels (=MSW, see chapter 2.2.1.1), 70% according to the DE-study (see above).

2.2.3. Barriers to expand the production and intra EU trade of medicated feed

Today, each Member State has created its own national system for MF which means in reality an extremely complicated but also costly situation, particularly for the concerned industries:

- 67% of the experts interviewed in the margins of the FCEC survey indicated at least "fairly significant negative consequences" of the different national frameworks for the competitiveness of the manufacturers of medicated feed. The group "Business organisation / enterprise / farmer" called in the online consultation with 86% for "action at EU level instead of national level". Even though a reminder to the subsidiarity and proportionality principles was made in the question the figure in the group of public authorities was 82%.

- The extreme differences in practice between the Member States were addressed by 88% of the respondents to the online consultation who pleaded for more harmonised rules at EU level (results of the online consultation can be found in Annex 8.11).

2.2.3.1. Driver 1: EU-Directive with vague provisions re manufacturing, differently interpreted by the Member States

If the medicated feed industry intends to expand their manufacturing to other Member States they must study and cope with the specific national rules in the Member States. The vague provisions in the EU-Directive about homogeneity, qualification of staff, labelling and record keeping have led to diverging interpretations by the national authorities. In addition, the majority of Member States have mandatory rules for good manufacturing practice in place, in others such rules are only voluntary and a third group does not have them at all (for more details see Annex 8.5). Finally, the character and content of the rules of good manufacturing practice applied varies between Member States. As the manufacturers of medicated feed are pre-dominantly SMEs that cannot afford expensive regulatory affairs departments to research in national manufacturing requirements in potential Member States and the margins in medicated feed are so small (see 2.1.1), the expansion outside the "home" Member State is very limited.

With respect to manufacturing practice, the current Directive only mentions national measures but no European measures. Nonetheless, the European Feed Manufacturers' Guide (EFMC)[30], an industry driven document based on the Feed Hygiene Regulation, whose application by the operators is voluntary, contains since 2009 a chapter on medicated feed manufacturing. However, this soft law measure evidently has not improved the manufacturing of medicated feed. Based on their audits in the Member States, the FVO identifies the following as key weaknesses of the existing voluntary EFMC guide:

"*Once control measures for the reduction of cross-contamination are in place (e.g. flushing, production sequencing, cleaning, etc.), the determination of the level of carry-over as a tool to determine whether these control measures are effective or not is not foreseen; operators flush and take it for granted that this is reducing their carry-over to acceptable limits without any verification.*"

The effectiveness of the control measures should be assessable against the concrete legal limits of the substance concerned (e.g. Directive 2002/32/EC for coccidiostats in non-target feed). This is another main weakness identified by the FVO, that even when operators see a reduction in carry-over, they do not know whether it means that they are in compliance or not.

The determination of the level of carry-over should be done according to a sampling plan where the number of samples and their timing should be determined with the purpose of determining the content of the substance concerned (i.e. the actual level of cross-contamination) in feed placed on the market."

Soft law measures still lack the leverage to change a situation that has intentionally evolved. Neither the Member State Authorities nor the operators for which the EFMC is voluntary can be forced to commit themselves. It can be only an offer to interested parties. As long as strong commitment of specific manufacturers to apply such soft law is missing, manufacturing quality of medicated feed cannot be assured.

[30] http://ec.europa.eu/food/food/animalnutrition/feedhygiene/efmc_1_0_en.pdf

2.2.3.2. Driver 2: Options for Member States' national regimes offered in the EU-Directive

The Directive foresees several measures, which the Member States can chose to apply on their territory, that influence production and deliveries of medicated feed:

- Anticipated (advance/pre-) production of medicated feed
  The feed mill can produce medicated feed based on past sales patterns in advance of receiving the veterinary prescription from the distributor or farmer. The feed mill can optimise the batch sizes according to the expected orders thus reducing costs and the carry-over of the VMPs in non-target animal feed (larger batch production means less problems of carry-over). Another benefit is the timely delivery: if the veterinarian prescribes a veterinary medicine it is usually quite urgent that the animals be treated. If the medicated feed can be dispatched directly upon arrival of the prescription the treatment is more efficient. On the other hand, some Member State fear, that once the medicated feed is produced without prescription, there is a strong incentive to use it by any means. They therefore forbid pre-production.

- Mobile mixers
  Lorries with a specific mixing technology can deliver the feed separate from the premix to the farm and do the manufacturing of the medicated feed on site. The competent authorities have -both when approving the operator and when controlling later in the field- the means to ensure that the respective technology and its application in practice meet the requirements for medicated feed. However, as the precision of the inclusion of the premix into the feed is usually not as good as in specialised feed mills, just a few Member States authorise mobile mixers even though one could cope with this e.g. by setting specific production parameters.

- On-farm mixing
  The farmer himself is approved to produce the medicated feed he needs for his animals on the condition that he meets the respective requirements. It is the competence of the national authorities to enforce this. Some Member States do not allow on-farm manufacturing because they think that the, nationally set, high standards for medicated feed (these are mainly the MS with the "preventive standards") cannot be achieved on the farms. Indeed the quality of medicated feed from specialised feed mills is superior and requires certain technology and production skills. However, it cannot be assumed that *a priori* these conditions cannot be fulfilled by farmers and specific measures and parameters can be foreseen to cope with this. Furthermore, the alternatives applied in these Member States (water, powder) are usually much less safe and efficient.

- Distributors
  Under certain conditions Member States can authorise distributors, apart from the manufacturer, to issue medicated feed to the animal holder. The existence of intermediaries between manufacturers and users increases the flexibility of the system and allows, particularly for medicated feed with small volumes, to be produced remote from the final user. Some Member States forbid the activity of distributors which they consider represent a risk of misuse of medicated feed and because controls would be even more complicated : apart from the manufacturers on their territory they must also control the distributors. However, the risk inherent to internet sales of veterinary medicines for direct use seems much more evident than the risk with the distribution of well controlled medicated feed manufactured in the EU.

The denial of these options decreases the economic viability of the medicated feed route and increases the costs for a treatment via medicated feed[31]. Examples for Member States which

[31] FCEC report chapter 3.5

allow these options are FR, IT, ES, PL and UK and it can be observed that the MF-route is quite important there. The actual combinations of the options chosen by the Member States in their national regimes lead to the fragmentation of the EU market for medicated feed.

2.2.3.3. Consequences

- Barriers to intra EU trade of medicated feed (walling-off), restricted competition and obstacles to the dissemination of innovations.
- High regulatory burden to the industry if they do not limit their business to the local market.
- Unsatisfactory MF manufacturing (poor guides for stakeholders) in MS with lax rules.
- Excessive costs in MS that "gold plated" the MF regime (one after the other MS stop MF production, thereby diverting medication to less controllable routes).

2.2.4. Impossible market access of medicated feed for pets

Generally medicated feed is used for the treatment of larger animal groups in livestock farming. However, for certain veterinary medicinal products the treatment of pets via a medicated feed could be an excellent route allowing owners to provide for their pets medication in the form of prepared feed. Besides, as pets get older and older, many of them with chronic non-transmissible diseases require long term medication, which is not based on antimicrobials. For such pets, the professional incorporation of the medicine into the ordinary food for the animal is an interesting proposition and would also be a major business opportunity. Medicated feed for pets to treat chronic conditions, particularly in older animals or in difficult to medicate animals (especially cats) is potentially a very large and untapped business opportunity. Experiences of pet owners and veterinarians specialised on pets show that it is very difficult to administer a pill or other separately formulated medicine to the pet animal.

2.2.4.1. Driver 1: Unclear scope of the EU-Directive

Today, medicated pet food is only available in three Member States. A combination of factors have resulted in many Member States feeling unable to authorise these products and in the industry believing that there are too many regulatory obstacles to placing products on the market[32]. Several Member States are unsure if the medicated feed legislation can even apply to pets as it is based on old Article 43 of the Treaty (Common Agricultural Policy), thus considered to be applicable only for farmed animals and have therefore been reluctant to approve medicated premixes for pets.

2.2.4.2. Driver 2: National implementation of the Directive

The requirement for a prescription to be available in advance of production (as distinct to delivery) goes against central production and distribution. Several Member States do not allow anticipated manufacturing of medicated feed. Or others do not agree on distributors acting as intermediaries between manufacturer and user, insisting instead on distribution direct from the feed mill to the holder of the animal, which pet food distribution cannot comply with.

[32] Company survey: 9 MS: favourable, 5 MS: opposed, 13 MS: No answer

2.2.4.3. Consequences

- Barriers for innovative companies that want to expand their business in medicated pet food.
- Owners of pets with chronic diseases are prevented from treating them in this comfortable and efficient way.

2.3. Justification for EU action

2.3.1. The choice of legal instrument

The current legislation on medicated feed is a Directive that has been established before the creation of the internal market and that had never been adapted in substance. The national transposition of this legal instrument has given freedom to Member States regarding interpretation and implementation of the legal provisions, but this flexibility has contributed to the problems as laid down in 2.2. With respect to the development of the national systems, the trend over the decades shows that those problems have rather deteriorated instead of improved even though many Member States tried to tackle the problems with national action plans. Thus, the legal instrument is an elementary issue for the different policy options and their evaluation.

2.3.2. Subsidiarity - Conferral

The Member States have established their national regimes for medicated feed under the current Directive which has led to diverging situations in practice and to the problems explained in 2.2. Besides, the Communication from the Commission Europe 2010 "A strategy for smart, sustainable and inclusive growth" identifies the incomplete functioning of the single market as a missing link and a bottle neck for growth in the Union[33]. To achieve a strong single market in the area of medicated feed, there is a need to streamline across the Union the regulatory system and remove inefficiencies and barriers to intra EU trade.

The protection of public health is a competence conferred upon the EU by the Treaty. With respect to the AMR almost all Member States came up with national action plans tackling, at least partially, medicated feed. These national efforts either contain an explicit call for EU-action or they implicitly hint that EU-action would be sensible. Thus, as extensively explained in the impact assessment on veterinary medicines, a holistic EU-Action plan against the rising threats from AMR had been developed. One of the concrete actions is the revision of the medicated feed Directive. Also, the Resolution of the European Parliament on "the Microbial Challenge – Rising threats from Antimicrobial Resistance" demanded a European response to the issue. Additionally, in 2012 the Council called upon the Commission in its conclusions (Doc 10582/12) to expedite the review of the medicated feed directive.

The Directive 90/167 was based on Art 43 of the Treaty establishing the European Economic Community (now article 43 of the TFEU), implementing the Common Agricultural Policy. However, there is evidence that the existing provisions do not deliver the ambition of a functioning internal market. For this, there is a need across the EU to simplify and streamline the regulatory system for the production of medicated feed and remove barriers for new products.[34]

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[33] "A stronger, deeper, extended single market is vital for growth and job creation ... Often, businesses and citizens still need to deal with 27 different legal systems for one and the same transaction."

[34] Examples from company survey: "Medicated premixes for pets are not authorised in the Netherlands as pets are not considered to be under the scope of Directive 90/167. Medicated feed is to be sent directly from the manufacturer to the user in Slovenia." A distribution system from the manufacturer of medicated feed for pets to the individual pet owner is not feasible.

The general and vague requirements in the old Directive are difficult to enforce: The Commission Services have difficulties to police the, unambiguously important, requirement "homogenous incorporation of the veterinary medicine in the medicated feed" in Member States that actually do nothing. Action at EU level would produce clear benefits compared with action at the level of Member States. The EU is in a better position than the Member States to draw up a harmonised and proportionate system to regulate the production and use of medicated feed. A single set of EU rules would reduce the distortions in production conditions for the feed industry and in competitiveness for the livestock farmers. Measures for medicated feed are essentially no more than those already very successfully applied for feed additives, a category of products which is fully harmonised at EU level and which is incorporated in every batch of compound feed and pet food produced. It is not logical that medicines can be included in feed with fewer safeguards that apply to feed additives at present. In the FCEC study, the online consultation and targeted consultations the stakeholders overwhelmingly pleaded for concrete harmonised measures at EU level.

2.3.3. Proportionality of EU action

With a view to ensure proportionality of measures the new legislation should reflect the technological progress in feed manufacturing and feeding techniques and flank the measures taken in the area of veterinary medicinal products. The choice for the new scheme is representing the least onerous way to achieve the objectives. Further is will ensure flexibility of implementation to reflect the regional specificities and variations in livestock farming practices in the EU.

2.4. Small and Medium Enterprises - Micro-enterprises

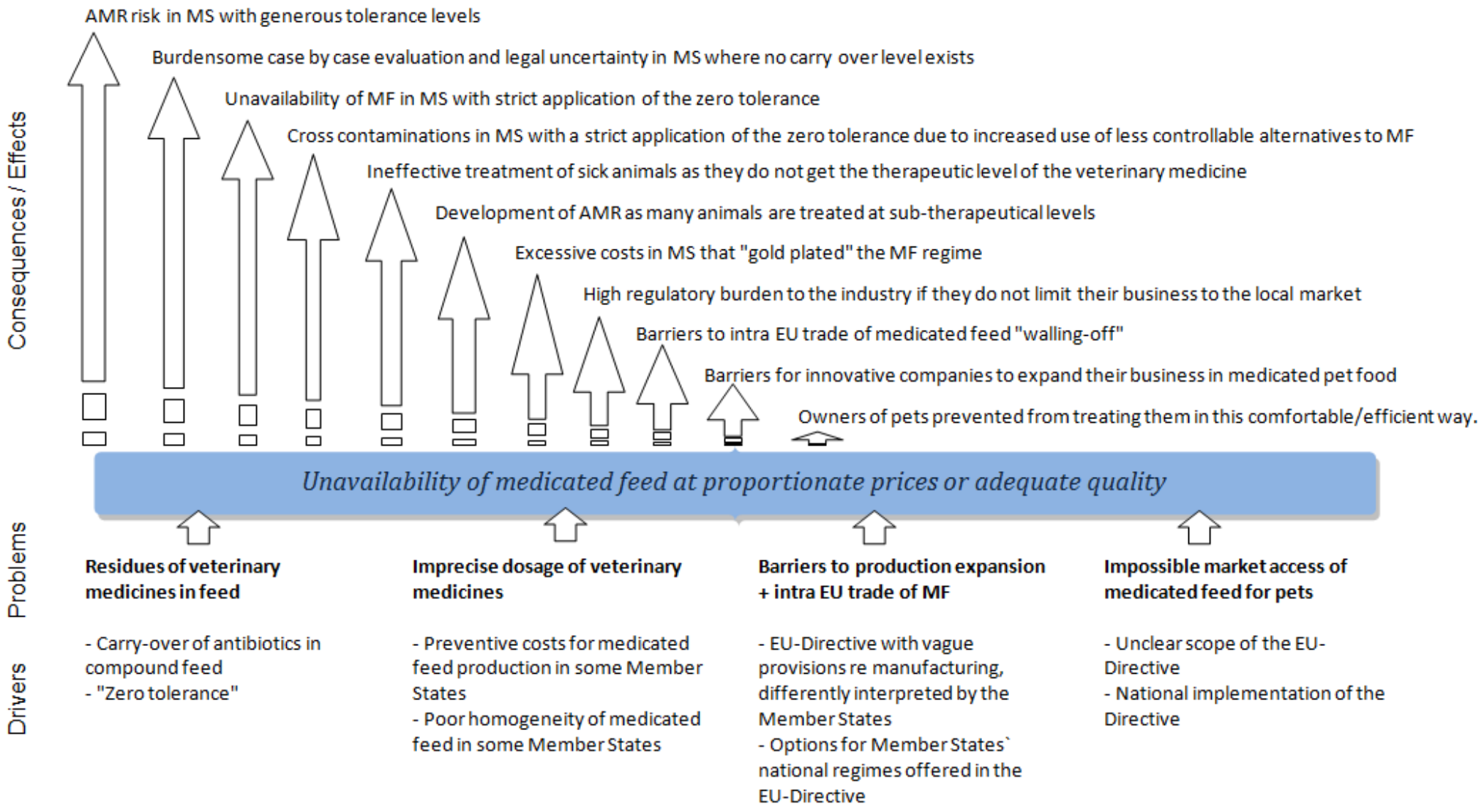
The cross-cutting principles of promoting health, safety and the interests of European consumers are directly embedded in the Treaty. Therefore, as a matter of principle, all EU legislation regarding food safety and public health should apply to all business operators as their impact on the health and safety of citizens is highly significant. The Commission is therefore cautious when considering any exemptions or lighter regimes for SMEs and micro-enterprises for these policy areas, since such exemptions should not undermine the high level of protection which has already been achieved.

The medicated feed business is driven by SMEs and micro-enterprises even if the medicated feed is only one activity of a bigger feed compounder; multinational players are, so far, exceptional. SMEs are reluctant to accept a high regulatory burden and large investments because they cannot realise economies of scale comparable to very large enterprises. Thus, the higher the burden for the manufacturing and the compliance costs, the bigger the disadvantage for the SMEs and micro-enterprises.

It is not proposed to exempt micro-enterprises from the scope of legislation on the production of medicated feed though it may be possible to exempt them from some of the specific requirements, depending on the nature of their business. For example, a mobile mixer could occupy a critical point in the feed supply chain, mixing feed for several hundred farms and would thus have a disproportionate negative impact if this mixing is not done in a correct way. Medicated feed produced by these methods should meet the same standards as a feed mill.

On the other hand, a farmer mixing feed on his own farm for his own animals could be the same enterprise size as a mobile mixer but would have a more limited impact if he failed to meet the same standards. It may be possible in this case to apply more final product characteristics (homogeneity etc.) than detailed process requirements to provide the necessary flexibility for his business, while preserving the essential safety elements.

2.5. Problem Tree



2.6. Forward looking - Baseline

It can be expected that the trends observed above will carry on:

- An unclear situation for the manufacturers in Member States where medicated feed is produced in big volumes continues. The concerned industry is very uncomfortable with a situation where the authorities can always police them e.g. because of carry-over residues or poor homogeneity. The criticism of misuse of medicated feed with antibiotics from these Member States will continue. AMR would stay high in the political agenda.
- The inconsistency between the specific tolerance levels for coccidiostats in feed laid down in Directive 2002/32 and the unclear situation with respect to carry-over of veterinary medicines into feed would persist.
- The current downward trend in use of medicated feed for food producing animals in Member States that stick to very rigid requirements would continue because either the medicated feed route is not offered at competitive prices or the industry does not offer it at all. Measures to optimise the production in terms of safety and economics will continue to be very restricted. On the other hand, the less controllable and less precise routes of medication will become even more important. Even more animals will be treated via the alternative, less controllable routes. This means another inconsistency between the administration of veterinary medicines and the sensitive feed additives for which legislation requires their inclusion into the feed by qualified operator. Consequently, medicated feed survives mainly in those Member States with poorer manufacturing standards.
- As regards pets, little change is expected. The industry cannot develop without changes that would allow them to benefit from the scale of the single market. The pet industry has none of the transport constraints that can apply to compound farm feed as individual volumes are by far smaller (medicated feed for one cat versus for 100 pigs).
- The activity of medicated feed manufacturers will remain limited to the local markets within their "home" Member State. Notwithstanding the huge potential for high quality medicated feed, there is only poor interest in the industry to expand in medicated feed as long as the burden is so high.

In conclusion, AMR is not adequately addressed and less and less animals are treated with high quality medicated feed, even if this would be the first best route of medication.

3. OBJECTIVES

The general objectives of this initiative are
(1) the smooth functioning of a competitive and innovative internal market for medicated feed whilst
(2) ensuring a high level of protection of animal and public health.

For the functioning of the internal market, a level playing field for production, marketing and use of medicated feed across the EU should be established. The harmonised manufacturing standard for the EU should be set at a safe level.

The specific objectives derived from are linked to the problems and drivers identified

- Overcome the zero-tolerance for unavoidable carry-over of veterinary medicines
- Make medicated feed available to farmers and pet owners at a competitive price
- Curb AMR-risk from residual and sub-therapeutic administration of antimicrobials
- Improve animal health by precise dosage of oral veterinary medicines
- Remove barriers for innovative, "novel" medicated feed.

4. POLICY OPTIONS

4.1. Option 1 - Maintain status quo

No EU action is undertaken in the area of medicated feed. Thus, this option can be considered the Baseline Scenario: The existing Directive will keep its general character and still be subject to varying national interpretation and implementation. Different sets of rules for manufacturing and use of medicated feed will apply from one Member State to another. The Member States have a maximum of competence in setting the rules while the responsibility for proper enforcement is also in their hands.

The Commission`s function as guardian of the EU-law would be quite limited because of the vague character of the Directive. The FVO just controls that the general principles established in the Directive are applied by the Member States. As long as enforcement remains only based on the existing medicated feed Directive, efforts to tackle the problems can hardly materialise. In absence of criteria for crucial issues such as homogeneity or residues of veterinary medicines, it is impossible to leverage the controls. Bad and good performers can hardly be detected.

The EFMC and, if applicable, the national guides remain in place simultaneously. The medicated feed Directive requires that operators "comply with hygiene rules and principle of the Member State in question". These rules can span from a pure transfer of the general wording of the EU-Directive to concrete mandatory laws with any kind of guides built therein. Member States will continue to have on their territories different regimes for residues of veterinary medicines in feed, mirroring the full scenario explained in 2.2.1.

4.2. Option 2 - Amend Directive 90/167 combined with "soft law"

The scope of the Directive would be clarified and also extended to cover the production, marketing and use of medicated feed for pets with respect to the objective "remove barriers for innovative MF applications". In addition, the amendment of the Directive would streamline it with the currently revised veterinary medicines legislation to flank the objectives to improve the internal market and the public health. In concrete, the provisions for the intra-EU trade of medicated feed and veterinary medicines would be fully aligned and the legislative measures to fight AMR such as monitoring would be transferred to medicated feed. This could result in a certain incompatibility if the new legislation on veterinary medicines is a Regulation and also because the import procedures for medicated feed are under the scope the horizontal Regulation on official controls on food and feed whereas the import of veterinary medicines is separately regulated.

The intervention logic at EU level in terms of manufacturing standards would charge the voluntary EFMC guide. A stringent reference to the feed hygiene regulation would clarify that the EFMC is also valid for the manufacturing of medicated feed (currently the legal base is only the vague provision in Directive 90/167). In Member States without any guides, the industry could take advantage of the EFMC and in those with voluntary national guides a new benchmark would be established that could challenge the further existence of these.

With respect to the weaknesses of the EFMC as outlined in 2.2.3.1, the Commission would encourage the industry to improve the EFMC in particular by including best practises with respect to minimising the carry-over or the process of incorporation of veterinary medicines. The setting of more concrete parameters about manufacturing would give the FVO a better base to monitor the general objectives of the EU legislation. However, the consequent improvement of the medicated feed manufacturing would be only feasible in those operations

that apply the improved voluntary EU guide. It remains very difficult for control authorities and the FVO to prove that lax manufacturers are not in compliance with the legislation.

The option does not foresee any changes to the technical provisions of the current legislation in terms of manufacturing standards (see 2.2.3). The general character of the provisions and the possibilities for the MS to foresee specific rules on their territory remain.

4.3. Option 3 - New EU Regulation with detailed rules

88% of the stakeholders pleaded for harmonised rules set at EU level. The reasons for this request can be found in all four problems identified: Residues of veterinary medicines in feed, imprecise dosage of veterinary medicines, impossible market access of medicated feed for pets and barriers to intra EU trade of medicated feed. Also the Council and the European Parliament suggested concrete action at EU-level (see 1.4 and 2.3.2) though these focus mainly on EU-measures to curb AMR (see problems 2.2.1 and 2.2.2).

In this option the clarifications concerning the scope and the streamlining with the veterinary medicines in option 2 are undertaken but in the legally directly binding form of a Regulation. Whereas medicated feed for farmed animals is usually produced in bigger quantities for the specific farm and for a short term treatment (often of a microbial disease), medicated pet food would be rather produced more centrally in batches for the treatment of mainly chronically diseased animals kept by many different users. Therefore a specific distribution system will have to evolve in practice and also specific rules for the veterinary prescription have to be foreseen. The validity of the prescription and the quantity prescribed in case of the treatment of a chronic disease in a cat must of course be different from the validity and prescribed quantity of a medicated feed with an antimicrobial to treat an infection in a group of 50 pigs.

Distributors will be allowed in the whole EU to intermediate between the manufacturers and the users of medicated feed which is critically important for medicated pet food. The rather centralised production structure for ordinary pet food could integrate the activity of controlled incorporation of veterinary medicines into dry and wet pet food in existing establishments or certain producers of the relevant veterinary medicines could expand into the manufacture of medicated pet food. The role of the veterinarian as regards the prescription of medical treatments for pets would be unchanged as the pet owners would still have to obtain a prescription from them.

In line with the position of the stakeholders (see following box), precise EU standards for medicated feed in terms of mixing technology and homogeneity will be established in the Regulation, covering all possible manufacturing schemes. Based on best practices in the Member States, homogeneity criteria could be set in an implementing act. Consistent EU-tolerances for the maximum deviation of the labelled concentration of the veterinary medicine in the medicated feed from the actually analysed concentration in a control sample could be established.

Manufacturing schemes – quality and safety (results of online consultation):

- For 79 % of the respondents (4% no idea) anticipated production of MF does not raise concerns in terms of efficient and safe use of the VMPs.
- 67 % of the respondents (20% no idea) believe that mobile mixers can meet the requirements for MF with respect to homogeneity and compatibility of the different components.
- 66 % of the respondents (12% no idea) believe that on-farm manufacture of MF can meet the requirements for homogeneity and compatibility of the different components.

- 41 % of the recorded responses believe that left overs of MF on the farm, e.g. due to a change of treatment might cause problems.

Anticipated medicated feed production, mobile and on farm mixing will be authorised in the EU, while simultaneously tightening the standards for these schemes. Considering that in terms of homogeneity specialised feed mills have advantages over mobile mixers or on-farm manufacturing, the latter are only allowed to use premixes with a higher inclusion rate. Nonetheless, in the margins of the approval by the competent authority, all manufacturers shall be subject to regular verification of product quality, including the verification of homogeneity. Appropriate qualification of the staff, functionality of the equipment particularly the mixing technology and measures to segregate the medicated feed from other feed are other conditions for the approval of the manufacturers.

The issuance of precise veterinary prescriptions and their strict adherence by both the manufacturers and users of medicated feed has to be severely policed by the competent authorities of the Member States to prevent any misuse with medicated feed produced in advance of the prescription is available. Also, these provisions include measures for disposal of medicated feed on farm that is not used e.g. due to a therapy change.[35]

EU wide tolerance levels will be set for the unavoidable carry-over of veterinary medicines in non-medicated feed, based on an assessment of the risk for the animals and the humans with regard to the different types of active substances. For the antimicrobials the risk assessment will take into account the MIC-levels (see 2.2.1). The resulting tolerance level would be a percentage of the therapeutic dose of the veterinary medicine. A similar approach has already been successfully applied for residue levels of coccidiostats[36] (veterinary medicines under the scope of the Feed Additive Regulation). The EU-Authority for the risk assessment could take advantage of the evaluations already undertaken by some Member States. In analogy to the approach for the coccidiostats, the implementing risk management decision would choose the lower level out of the result of the risk assessment and the carry-over levels that following the ALARA-principle[37].

According to the targeted consultations of stakeholders and the online consultation, the establishment of such tolerance levels is strongly recommended to overcome the problems mentioned in 2.2.1. Also 19 out of 22 competent authorities responding to a targeted survey in spring 2013 were in favour of such tolerance levels (see Annex 8.8).

The weaknesses of the voluntary EU-guide that will be sorted out. Product criteria are established that guarantee a safe and efficient manufacturing of medicated feed. The operators have full flexibility how to meet these criteria with their manufacturing process.

The competent authorities in the Member States could concentrate on the control of the concrete product criteria and would be released the task of trying interpret the general Directive. They would be held responsible to ensure that medicated feed is only delivered upon prescription, homogeneity criteria are met by all manufacturers and misuse of medicated feed is avoided. The FVO could in practice check that the Member States efficiently enforce the criteria set in the EU-Regulation, which they are used to in many other areas of food and feed law.

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35 In order to avoid misuse, the recall costs should be priced into the all medicated feed marketed as a levy. Thus, in the concrete case of unused medicated feed the farmer is not confronted with extra costs.

36 OJ L 40, 11.2.2009, p.19 (2009/8/EC)

37 "As low as reasonable achievable": The level for the technically unavoidable carry-over is determined based on the application of good manufacturing practice.

4.4. Discarded Options

4.4.1. Repeal of Directive 90/167

The removal of specific EU-legislation on the manufacture and use of medicated feed would imply that

- for the rules on the manufacturing, marketing and use of medicated feed, the general feed and veterinary medicine legislation is applicable but with a totally unclear status of medicated feed and
- the Member States are totally independent to establish specific requirements for their territory.

Each Member State would be forced to tackle with national rules the evident risks and to render those national regimes consistent with the harmonised legislation on feed and veterinary medicines in order to avoid lacunae and loop holes. Member States would no longer be obliged to approve the establishments. However, feed law requires the approval of compound feed mills once they incorporate feed additives. Proper incorporation of veterinary medicines into feed is at least as sensitive as additives. The production of medicated feed would be conducted on the basis of requirements established in the compound feed legislation. No specific labelling rules for medicated feed would exist. The barriers to intra EU trade of medicated feed and to innovation/dissemination of emerging medicated feed applications would increase. Additionally, the high regulatory burden to the industry (SMEs) that do not want to limit their business to the local market becomes more evident. The administrative burden for the authorities in the Member States increases because they have to cope with their mandate to create and implement national rules specifically for medicated feed in the absence of any EU framework.

Concerning subsidiarity, national authorities would have the full responsibility to regulate particular medicated feed issues within their competence. This is, both with respect to the legislative means and to the substance, a big challenge because in the interlinked areas of feed and veterinary medicines such national structures do not exist.

In conclusion, all the problems identified in 2.2 would deteriorate if the Directive is deleted without substitution.

4.4.2. No-stand-alone medicated feed law

The splitting of the substance to be regulated between already existing legal acts (Feed Hygiene and Feed Marketing Regulations, Directives on veterinary medicines and undesirable substances in feed) would allow the Directive to be repealed without formally creating a new law.

However this option was discarded because of the very particular status of medicated feed: though it is a special form of feed, the link to the veterinary medicines is very strong. This refers to the veterinary prescription but also the pharmacovigilance and other information duties. There is serious concern amongst the authorities in the Member States that strict rules concerning medicated feed would lose their clear status if they are spread over different legal acts in the area of feed and VMPs. In fact, several Member States strongly objected in the consultation to simply adding this legislation to feed law. This is also mirrored in the Resolution of the European Parliament of 11 December 2012 on the Microbial Challenge – Rising threats from Antimicrobial Resistance.

Therefore, a stand-alone legal act for medicated feed is appropriate in order to take into account the sensitivities about this route of medication.

5. ANALYSIS OF IMPACTS

As a result of the problem identification, the major focus of the analysis is on economic and public health impacts.

5.1. Maintain Status quo

This option is the baseline scenario (see 2.6). Neither tangible provisions for the manufacturing nor product criteria for medicated feed would be set at EU-level. The technical provisions for the manufacture of medicated feed remain either vague or subject to specific national rules.

5.1.1. Economic impacts

5.1.1.1. Costs of MF production

National implementation of the general EU-rules still leads to a tremendously different set of economic parameters for the manufacturers of medicated feed. The cost delta between Member States with lesser and more demanding requirements for the manufacturers of medicated feed would be fixed (extra costs from 1 €/t to 70 €/t, see 2.1.1) though the internal market of feed and animal products is fully harmonised. This is heavily criticised by the compound feed industry in the Member States with more demanding standards (they took their consequences) but also by the famers that are deprived of medicated feed as an option to cure their animals.

5.1.1.2. Market access

Mobile mixers and bigger livestock farmers would be still hindered by national rules from producing medicated feed. The trend that fewer animals are treated via medicated feed will continue because either medicated feed is too expensive or not offered at all. The poor availability of medicated feed in many areas is criticised by livestock farmers, explicitly including aquaculture.

Deliveries of medicated feed from one Member State to another would force the producer to comply with potentially significantly different requirements of the Member State of destination. More accentuation on the existing, voluntary EU guidelines for good manufacturing practice could to a limited extent improve the harmonisation of the conditions for MF production in the EU.

For innovative, new applications of medicated feed the marketing environment remains very scattered and exclusive. Industry that wants to expand in these areas complains about this.

5.1.1.3. Compliance and administrative costs

The pre-eminent task of the competent authorities is to control the manufacturing and use of medicated feed. On top of this, each of the national authorities would face the administrative burden to set up or keep updated their existing concrete rules for MF manufacture on their territory, triggered by the increased awareness of the weaknesses of medicated feed manufacturing in many countries as explained in 2.2. Many Member States (those with no

national mandatory guides or with just general references) do not engage in this field because they lack the resources for this task.

Despite the tendency that fewer MF manufacturers have to be authorised and controlled under option 1, the implicit increased use of alternative routes to administer medication by the farmers would probably outweigh the reduced control activities at the manufacturer because more farmers directly administering the veterinary medicines would have to be controlled (no control "bottleneck" in the medicated feed operations[38]). Authorities stated that, in times of scarce resources, they were more likely to prioritise direct control activities than elaborate manufacturing rules.

SMEs with manufacturing activities in medicated feed could potentially market their feed in more than one Member State, not only if they are based close to a frontier or a small Member State. Such enterprises have to cope with a different national scheme for medicated feed in the envisaged Member State which is in contrast to a fully harmonised system for non-medicated feed. This creates considerable cost to comply with the respective national system(s). The compound feed industry continuously raises this issue. The maintenance of the different national systems would also jeopardise the efforts for reduction of administrative burden and centralisation in the field of veterinary medicines.

As the employment in medicated feed production is very limited (see 2.1.1) no significant employment effect is expected because of economic impacts.

5.1.2. Impact on animal and public health

5.1.2.1. Animal health

In MSs with very demanding manufacturing standards for MF, the farmers apply other routes of VMP administration because MF is either not offered by the industry or it is too expensive compared to the other methods of orally administering medicines. These routes (powders added to feed or water by the farmer) have often significant shortcomings (see boxes in 2.2.2): firstly with respect to correct dosage (under and over-dosage due to poor homogenisation); secondly, the problem of veterinary medicines present at residual levels in feed or water for animals for which the VMPs are not intended for. Though the Summary of the Product Characteristics (SPC) of the veterinary medicines gives information on their correct administration this cannot exclude these consequences in practice. In particular when the oral powders are top dressed on feed, animal health is at risk as weak animals in a group often do not get the therapeutic dose because stronger ones push them aside when new "feed" is offered.[39] This aggravates the animal health problem because the weak animals are those who most need the medication in the first place.

[38] The MF route offers a typical bottle neck solution: Whereas the 13,7 mio. livestock farmers in the EU can potentially mix ready-to-use VMPs into the feed or drinking water, only 7281 (thereof 5692 on-farm) are approved to manufacture MF.

[39] In the case of medicated feed, the therapeutic dose of the medicine is homogenously incorporated in 50% of the daily feed uptake of the animal. Thus, even if the strong animals push away the weak ones when new feed is offered, there will be sufficient –medicated- feed for the weaker ones left once the stronger are satisfied.

5.1.2.2. Public health

The respondents of the stakeholder consultation were divided on the question of AMR occurring from the residual traces of VMPs in feed: 28% consider that VMPs residues may increase the occurrence of antimicrobial resistance. 45% consider the contrary and 23% do not know. A closer look shows that 85% of the public authorities (33 respondents) stated carry-over as an AMR-issue whereas only 15% of the "business organisations, enterprises, farmers" (147 respondents). A verification of the qualitative answers shows that the latter mainly opposed to the generalisation "carry-over => AMR" which is in line with the scientific evaluation in 2.2.1 stressing that this depends from the MIC of the medicine.

In the absence of product criteria set at EU level, the majority of the Member States nonetheless abstain from setting stringent rules on the control of carry-over of VMPs in the non-target animal feed ("no value" or with zero tolerance but no strict enforcement).

As detailed in 2.2.1 this increases the risk for AMR development because in those Member States and those with generous tolerance levels the residues of antimicrobials in feed are likely above the MIC and below MPC (MSW). In Member States with a strict enforcement of the zero tolerance, sub-therapeutic dosage of antimicrobials is also frequent due to the weaknesses of the applied alternatives (see 2.2.1 and 2.2.2).

5.1.2.3. Occupational health

Veterinary medicines, in particular antimicrobials, are frequently skin and eye irritants, dermal and inhalation sensitizers or can provoke allergic reactions. The oral powders usually have a high dusting potential which represents a hazard to persons handling them. Exposure by inhalation must be avoided and can in general better be achieved if trained personnel in the feed mills handle the medicines. Qualified staff in a feed mill as a rule are better trained and equipped in this respect than the farming community. In option 1 the number of farmers with direct contact to the pharmaceutical substances is greater to the extent that alternative routes of oral medication (oral powders) are practised. This reinforces the negative effect on occupational health.

5.1.3. Other impacts

5.1.3.1. Animal welfare

As many animals are treated sub-optimally with the VMPs ("weak animal" problem mentioned above and substitution of medicated feed route by injection), option 1 has a slightly negative impact on animal welfare.

5.1.3.2. Environment

Slightly unfavourable environmental impacts can be expected because of poor control on the unintentional release of antibiotics in the environment. Other issues such as waste water or contaminated feed were not raised in any consultation.

5.1.3.3. Subsidiarity

Maintaining the character of the Directive would allow the national authorities to tackle the issues under their competence depending on the respective situation in practice and national actions in related areas. Member States can still decide whether they deem it appropriate to

establish product criteria. In case national programs are established for certain issues, the provisions on Medicated Feed can be consistently integrated. However, national regimes do not exist in manufacturing or marketing feed and also the revision of the veterinary medicines aims to move away from decentralised systems.

5.2. Amend Directive 90/167 combined with soft law

In Option 2 the Directive has the internal market as legal base. It clearly includes pets under its scope and the integration into the legislation for feed and veterinary medicines is modernised. Building up on option 1, there is EU-action to improve the voluntary EFMC with more concrete provisions about best manufacturing practice. However, in Member States with mandatory national regimes the reference to the feed hygiene would not materialise. Furthermore, the missing willingness of operators to apply the voluntary guide jeopardises its success and leads to the difficulty for the control authorities to enforce and police the Directive.

5.2.1. Economic impacts

5.2.1.1. Costs of MF production

The economic parameters for the manufacturers of medicated feed still differ significantly because of the dominant role of the national regimes on the costs of medicated feed thus no significant change to the baseline.

5.2.1.2. Market access and products availability

The clarifications of the legal framework improve the business environment for the stakeholders. In particular, the explicit inclusion of pets into the scope and the clarification that medicated feed can be also given to individual animals opens a window of opportunities for innovative medicated feed.

The short term additional potential for medicated pet food is € 50 mio if all barriers are removed (see Annex 8.12). The inclusion of the pets under the scope of medicated feed would, according to industry surveys, open the market in about one third of the Member States. Consequently, in this option, the potentially additional gross margin from medicated feed for pets could be in the order of € 6 mio thus having a marginally positive employment impact in SMEs.

5.2.1.3. Compliance and administrative costs

Compared to option 1 there is a minimal increase of administrative burden for the national authorities as they need to engage in the assessment of the revision of the EU-guide. On the other hand, several authorities could further reduce their efforts on maintaining national guides for MF manufacturing (Member States where the national law simply establishes the framework and the technical details are up to voluntary guides: BU, CY, ES, FI, IE, NL, PT, RO, SE, SI, UK; FCEC table 32). However, in Member States regulating the MF manufacturing with "hard law", such savings cannot be expected.

For the industry (SMEs), administrative and compliance costs might be slightly smaller because they could rely more on the, then revised, EU-guide as a reference for their manufacturing processes.

5.2.2. Impacts on health

The developments in the past prove that due to unwillingness of Authorities and industry to improve the quality of medicated feed in the Member States with lax manufacturing standards such approach usually fails. The "soft law" option has no leverage to induce more efforts to improve health in those Member States.

5.2.2.1. Animal health

A limited positive impact on animal health can be expected due to the improved adherence to the revised EU guide for good manufacturing but only in the parts of the EU with poor national requirements and no or weak national guides. Thus, more manufacturers in these regions would have an improved homogenisation of the medicated feed with the result that more animals get the correct therapeutic dosage (more efficient treatment). Additionally, pets could be treated more easily thus more efficiently in the Member States that allow medicated feed for pets due to the clarification of the scope.

5.2.2.2. Public health

In addition to the partially improved homogenisation to be expected because of wider application of the revised EU-guide, public health would be slightly improved as the guides could mean better measures to reduce carry-over in place. Both impacts would help that more animals get the correct and less sub-therapeutic dosage which all helps to curb AMR.

5.2.3. Other impacts

Regarding animal welfare, the increased availability of medicated feed for pets, particularly for chronically diseased pets, allows an easy and sure way of medicating, ensuring that pets received the medicine that they need.

On occupational health, the environment and subsidiarity, no other impacts are expected than those outlined for option 1.

5.3. New EU Regulation with detailed rules

Option 3 will lead to full harmonisation of the provisions on manufacture, marketing and use of medicated feed. This will be achieved by compulsory product criteria that

- overcome the impractical zero tolerance,
- reduce administrative burden for the industry linked the existence of 27 different national schemes,
- allow a cost efficient MF production due to economies of scale,
- support the spread of innovative medicated feed applications over the whole EU,
- tackle the hazards of the EU-wide established regime where it might be less rigid than the current national system (e.g. rules for distributors, possibility of anticipated production),
- decrease the use of antimicrobials at sub-therapeutic levels and
- minimise the risk for AMR due to carry-over of antibiotics in feed.

5.3.1. Economic impacts

The significant potential for market expansion and reduction of production costs of medicated feed is more evident than the positive impacts on compliance and administrative costs.

5.3.1.1. Costs of medicated feed production

Overall, a considerable reduction in the costs of manufacturing medicated feed can be expected but these reductions will not be evenly spread:

In MS with low manufacturing standards for MF (those with small additional costs), in particular with respect to homogeneity and carry-over limits, the new EU standard will increase the costs of medicated feed. Assuming that 50% of the current production would be concerned by this upgrade of standard, the additional costs are estimated at € 19 mio (see Annex 8.12). No significant shift from medicated feed to oral powders is expected in these Member States as the implicit price increase for medicated feed is only about 2%[40]. Such price increase does not trigger a change in the farms that are convinced of medicated feed as a good route of treatment and that are equipped for this route. For 25% of the current production no change would result from the new EU standard. The remaining 25% could realise cost reductions as the suppliers of MF in a certain region can choose the most cost efficient production technology (anticipated production, mobile mixers) and profit from economies of scale because the demand for MF will increase once they are able to offer it at a lower price. The resulting cost reductions are € 31 mio which means for the total EU cost reductions of € 12 mio.

As a sensitivity analysis, a second scenario has been calculated in which the percentage of medicated feed production that would be faced with cost increases is 65% (instead of 50%) and the share of current production at very high costs is 10% (instead of 25%). In this scenario the additional costs in the first group would be € 24 mio and the decrease in the second would be € 12 mio resulting EU wide in additional production costs of € 12 mio.

5.3.1.2. Market access – competitiveness

The EU-wide possibility for advance production of MF and the licence for distributors between manufacturers and users increases the marketing potential for the manufacturers because new, innovative applications of medicated feed, such as certain medicated pet food, will not be limited to the respective local markets and specialised manufacturers will have economy of scale to market new innovative niche products. Within the new harmonised EU standard for medicated feed production, the full potential mentioned in 5.2.1.2 could be activated which means only in the area of medicated feed for pets an additional gross margin in the order of € 15 mio in the short term and considerably more beyond. This new revenue in the medicated pet food industry is to be paid by the pet owners in exchange for a more convenient treatment of their pets. Other trade-offs cannot be expected as the volumes of pet food and veterinary medicines for pets remains the same. Furthermore, as there are no evident changes in the production structure for pet food expected, no significant additional transport costs would arise. In practice, medicated pet food would probably to the largest extent be integrated into the existing distribution systems for the veterinary medicines that are currently administered separately from the pet food.

For food producing animals, the lower prices for medicated feed in Member States with currently very high or even preventive national standards make medicated feed more attractive which could lead to a shift from the alternative routes. Experts estimate the potential for additional medicated feed production due to more competitive production conditions to be 30 – 50 % of the current quantities i.e. 2–3,4 mio t. The revenue solely for the inclusion of the

[40] Corresponding to 5,5€ / t MF, calculated based on the necessary additional costs, robustness confirmed by cost delta between Member States with low standards and adequate standards taking into account the implicit possibilities for increased economic feasibility.

veterinary medicine into the feed by an authorised medicated feed manufacturer under the new standards would consequently be in the range of € 11 – 18,6 mio. Assuming that under the competitive internal market environment in option 3 the manufactures can only enforce a profit of 6%, the additional income for the feed operators would be € 12 - 20 mio. There is no trade-off from another actor in the production stream (the quantity of veterinary medicines sold is not influenced) but is an additional cost for the livestock farmer. Either he can reduce any envisaged investments linked to the proper administration via the alternative routes or he benefits from a more efficient treatment of his animals if he did not yet invest in the efficiency of the alternative routes.

5.3.1.3. Compliance and administrative costs

The setting of product criteria at EU-level implies some administrative costs for the national Authorities, the Commission and EFSA. Considering that one can take advantage of existing best practices available in the EU and the experiences with the approach applied for the coccidiostats[41], which did not result in significant increase of costs in EFSA and the Commission, to elaborate product criteria, costs for the EU and involved Member State Authorities would be limited. Indeed, the enforcement of the criteria will reduce the burden for the authorities in a longer term: on the one hand, the control of the concrete criteria is simpler than the interpretation of general principles. On the other hand, the Member States can save resources necessary for the establishment of the national standards, if applicable.

In line with the cost recovery principle established in the chapter on fees of the Regulation 882/2004 on official controls of food and feed[42], the costs of the authorities for the start-up approval of the new manufacturers of medicated feed in this option would be recovered from those manufacturers. This one-off fee would be included by the manufacturers into their cost calculation of the medicated feed, naturally with a negligible price impact.

Further compliance costs for the industry (SMEs) are significantly reduced because they are no longer obliged to follow the different national rules which is particularly relevant for those manufacturers that may wish to market medicated feed in several Member States.

5.3.1.4. Prices of animal products

Feed is the biggest cost factor in livestock farming thus having an evident influence on the prices of the animal products (EU output € 157 bn). Compound feed alone has a turnover of €50 bn. However, even if, as in scenario 2, 65% of the current medicated feed production, an additional 3,4 mio t, shifts from the alternatives routes to medicated feed, charged at €5.5/t, the total cost of the medicated feed would be € 44 mio. This is less than 0.1% of the costs of the livestock production and thus a price effect on the animal products can be excluded.

5.3.2. Impacts on health

5.3.2.1. Animal health

In this option, the use of MF, produced at optimised standards, can be practiced as 'first best route' for the administration of antimicrobials and other veterinary medicines to a significant higher percentage of animals: The reasons for this positive effect are that in Member States

[41] The scientific risk assessment of residue levels for coccidiostats was done by EFSA very diligently (11 opinions issued) and did not lead to an unbearable workload that would have required extra resources.

[42] OJ L 165, 30.4.2004, p. 1–141

with currently preventive standards for medicated feed a substitution from the less precise and less controllable routes can be expected. Secondly, the manufacturing standards in Member States with currently low manufacturing standards will be improved. Both trends result in a significantly higher number of animals treated at the correct dosage which has in the first place a positive impact on animal health.

Besides, the reduced carry-over residues of veterinary medicines in the feed for non-target animals mitigates the animal health risk because there is no indication for these veterinary drugs for the non-target animals receiving such feed.

In the online stakeholder consultation, 39% of the authorities stated that anticipated production may raise concerns in terms of safe and efficient use[43]. A strict enforcement of the requirement that medicated feed can be delivered to the farmer or pet owner only upon presentation of a prescription from a veterinarian minimises the risk that medication is given in a less restrictive way if advance production is allowed in the feed mills and pet food factories.

With respect to mobile mixers and on-farm manufacture of MF, 30% and 33% of the authorities indicated in the online stakeholder consultation concerns that these operators meet the requirements for MF on homogeneity and compatibility of the different compounds[44]. For mobile mixers and on farm manufactures, the competent authority must enforce, when authorising, that the mixing technology complies with the homogeneity criteria. Whereas feed mills with advanced technology (e.g. extra production line for medicated feed production or an end of the line mixer) could use premixes with a lower inclusion rate, for mobile mixers and on-farm manufacturers a restriction to higher inclusion rates might be appropriate.

In the online stakeholder consultation, 73% of the authorities agreed that left overs of MF on the farm might cause problems[45]. Thus, for the rare cases of left-overs of medicated feed on the farm, usually because a change of medication is prescribed before the end of the treatment with the initially prescribed medicated feed, a recall system should be installed. The veterinarian prescribing the new veterinary medicine has a crucial role to ensure that the left-over from the previous prescriptions are disposed of and not given to the animals. With all these measures, any negative health impacts due to the more economically viable rules for manufacture of medicated feed can be eliminated.

5.3.2.2. Public health

With respect to antimicrobials, the risk arising from treatment at sub-therapeutic level is reduced in those countries where the homogeneity requirements for medicated feed are currently poor. This positive impact can be also expected in those regions where, due to preventive requirements for medicated feed manufacturing, the less precise routes of administration are currently dominant. In these countries the farmers might shift to medicated feed which is, under the new regime, more competitive compared to the alternatives.

Furthermore, a significant positive public health impact will be achieved because the carry-over limits are set, EU-wide, below the MICs thus marginalising the risk for the development of AMR both in the Member States with generous tolerance levels or those with unclear situation ("no value").

In addition, the possibility for anticipated production facilitates the industry's task to comply with these carry-over levels because it enables the manufacturing of larger production runs

[43] The figure for the businesses and farmers is just 15%

[44] The figure for the businesses and farmers –not surprisingly- is just 8,5% and 17% (on farm manufacture)

[45] The figure for the businesses and farmers –not surprisingly- is just 38%

with fewer change over points from medicated to non-medicated batches. Consequently, there will be a trend for generally reduced residues of VMPs in feed.

5.3.2.3. Occupational health

Facilitating the use of medicated feed will reduce the number of farmers who have direct contact with antimicrobials in form of oral powders, with a positive effect on occupational health. 82% of the stakeholders agreed in the online consultation that, compared to other methods of oral administration of VMPs, the MF method has a lower risk in terms of direct exposure of staff handling veterinary medicines (e.g. sensitising, allergic or resistance-enhancing properties of VMPs).

5.3.3. Other impacts

5.3.3.1. Animal welfare

Significantly more animals receive the veterinary medicine at the correct therapeutic level and with their "normal" feed thus in a more comfortable manner (pets). Both have a positive impact on animal welfare which is of the same order as found for animal health.

5.3.3.2. Environment

The environmental impacts are positive because of better control on the unintentional release of veterinary medicines in the environment due to the established control measures and because of the expected shift from the less controllable routes of VMP administration.

5.3.3.3. International trade

No significant trade impacts can be expected even in a harmonised internal market for medicated feed for farmed animals, mainly because of the requirements linked to the veterinary prescription and the logistics. If the distribution channels for medicated feed for pets are established there could be an interest for imports into the EU and conversely the development of successful products in Europe could prompt export developments or foreign marketing by European companies.

5.3.3.4. Subsidiarity

The individual Member States lose their flexibility to set the concrete rules for manufacture and use of MF. Several Member States have implemented this flexibility, others did not establish a precise regime. The problems identified in 2.2 show that in both groups of Member States the national competence lead to unsatisfactory results, in particular with respect to imprecise dosage of veterinary medicines and residues of antimicrobials in normal feed (AMR). On AMR the call for EU-measures rather than national ones is prominent, even from the Member States themselves. The envisaged Regulation would by means of setting product criteria for the homogeneity of the medicated feed and the carry over limits in compound feed restrict the EU measures to the minimum and leave it up to the Member States and local operators how these criteria will be met.

The harmonised levels for physical checks of non-animal origin feed imported into the EU[46] (before it was totally up to the Member States to decide the frequency) and the tolerance

[46] Regulation (EC) No 669/2009 (OJ L 194, 25.7.2009, p. 11)

levels for coccidiostats in non-target animal feed set Directive 2002/32/EC clearly delivered an EU added value. Thus, an evident EU value added can be expected due to the establishment of precise criteria in the medicated feed Regulation because the implementation of the objectives can be better guaranteed.

5.3.4. Plausibility check with the views expressed by stakeholders

A summary of the online consultation complemented by the results of targeted consultations can be found in 8.12. There are no fundamental concerns raised by the stakeholders with respect to option 3. Furthermore, the design of option 3 considered in particular the concerns expressed by mainly authorities with restrictive schemes for medicated feed with respect to mobile mixers, on-farm manufacturing of medicated feed, tolerance levels for residues of veterinary medicines, misuse of antibiotics and distribution channels of medicated feed.

The manufacturing industry in the Member States with high national manufacturing standards complains strongly about those regimes. The regulators in the Member States where medicated feed has quasi disappeared are trying with national action plans to solve the problems that occurred consequently to the shift to the alternative routes of treatment. Several authorities noted in the consultations that administration by water or powders was gaining market share over medicated feed linking this specifically to the greater regulatory controls on medicated feed than on the alternative routes.

In the Member States with currently low standards for the medicated feed production, the Authorities suggest to establish tangible product criteria at EU-level. This can be explained by the increased pressure in the context of antimicrobial resistance. Also the feed industry in these Member States supports more concrete, harmonised manufacturing standards even if this means additional production costs. This might also be due to the positive experiences with tolerance levels for coccidiostats in normal feed. The manufacturers of the veterinary medicines (branded and generics) strongly call for this, too. Trade-offs for the veterinarians e.g. due to the potential shift from oral powders to medicated feed have been neither stated by the European Association nor the national associations that have been consulted.

6. COMPARING THE OPTIONS

6.1. Comparing options in terms of economic, health and other impacts

In order to compare the impacts outlined in chapter 5 for the different options, option 1 is calibrated to 0 and the relative change to option 1 is presented in the following table:

		Option 1	**Option 2**	**Option 3**
Economic Impacts	MF production costs* in MS with high standards	0	0	+++
	MF production costs* of MS with low standards	0	0	--
	Market access - competitiveness	0	++	+++
	Administrative and compliance costs*	0	+	++
Health impacts	Animal Health in MS with high standards	0	+	+++
	Animal Health in MS with low standards	0	+	++
	Public Health in MS with high standards	0	+	++
	Public Health in MS with low standards	0	+	+++
	Occupational Health	0	0	+

Other impacts	Animal welfare	0	+	++
	Environment	0	0	+
	Regulatory competence of the MS	0	0	--

* "+(+)" means a (slight) reduction of costs
Magnitude of impact: +++ strongly positive; ++ positive; + slightly positive; 0 none
--- strongly negative; -- negative; - slightly negative

A comparison of the quantified economic impacts of the options shows, due to additional gross margin in medicated pet food, a positive impact of € 6 mio in option 2. Under scenario 1 in option 3, the expected increased costs in Member States with low standards would be overcompensated by the reductions in those with very high standards which would lead together with the additional gross margin in medicated pet food (€ 15 mio) to a total benefit of € 27 mio. In scenario 2 the cost increase exceeds the reductions which results only in a small positive effect (€ 3 mio) resulting from the extra profit in the pet area.

Furthermore, option 3 accounts for an estimated additional turnover (extra costs for medicated feed and profit margin) of € 12 - 20 mio for the medicated feed manufacturers due to the shift from less favourable routes of medication to the use of medicated feed. As explained in 5.3.1.2, it is very difficult to estimate to what extent these extra costs for the farmers can be compensated by interdependent savings on the farms that shift to medicated feed.

Animal Health in Member States with high standards will be improved in option 3 compared to option 2 because of the expected shift from the less controllable routes of medication to medicated feed resulting in more animals getting the correct therapeutic dose. The same result –to a slightly smaller extent- can be expected in the Member States with low standards because the quality criteria for the medicated feed are increased.

The improved public health status in Member States with high standards comes from the more precise dosage of the antimicrobials compared to the currently predominant direct administration by the farmers which means that less animals are exposed to sub-therapeutic levels of antimicrobials (AMR risk). In the Member States with low standards, significant positive impacts on public health can be expected because of the established carry-over limits which assure that the public health risk of the residues of the veterinary medicine in the compound feed is negligible.

6.2. Comparing the options in the light of the objectives

The following table compares the options about their effectiveness to meet the objectives:

		Options		
		1	**2**	**3**
Objectives	Overcome the zero-tolerance for unavoidable carry-over of veterinary medicines	--	--	++
	Curb AMR-risk from residual and sub-therapeutic administration of antimicrobials	--	-	++
	Improve animal health by precise dosage of oral veterinary medicines	--	-	++
	Make medicated feed available to the farmers at a competitive price	0	0	+

	Remove barriers for innovative, "novel" MF applications	--	+	++

Magnitude of impact: ++ strongly positive; + positive; −− strongly negative; − negative; 0 neutral.

6.3. Preferred option

In the light of the assessment above, it is considered that option 3 would have the most positive impacts and provides the best way forward to achieve the objectives for the EU as a whole: Option 3 should have a significant positive impact on cost efficiency and economic growth of the medicated feed manufacturing, also considering innovative applications of veterinary medicines. Trade-offs in upstream and downstream activities are very limited. Animal and public health can be expected to be improved both in Member States with currently lax standards for medicated feed and those with prohibitive standards. Safe tolerance levels for the unavoidable carry-over of veterinary medicines in feed leads to a pragmatic and solid level playing field for the industry and the control authorities.

The interface with the AMR-issue makes it quite evident that the Member States cannot solve the problem on their own and a balanced EU-Regulation would create a value added. Finally, the enforcement and control of the harmonised rules would remain fully in the competence of the Member States.

7. MONITORING AND EVALUATION

The general monitoring of the new legislation on medicated feed is embedded in Regulation 882/2004 on official controls of food and feed. This Regulation foresees that the Member States efficiently implement the requirements in the feed sector and veterinary medicines. The Commission (Food and Veterinary Office) controls the correct enforcement by the Member States. The monitoring would be eased because of the EU-wide establishment of product criteria. Thus, for the evaluation to which extent the objectives of the legislation have been met does not require additional data collection. The national controls according to the Member States` multi-annual control plans (established by Regulation 882/2004) are checked by the Commission Services and thus regulative action could be envisaged if there is evidence for unintended developments.

With respect to the internal market, the following additional indicators could be sourced from representatives of the industry (pharmaceutical and medicated feed). With respect to the considerable numbers of end users (several millions livestock farmers and several millions pet owners with chronically diseased animals) and the limited duties with respect to data collection, the additional indicators should be compiled according to the “bottle neck principle” (acquisition of the data where the fewest operators are involved).

Objective	Potential Indicators	Data Source	Frequency
Competitiveness of medicated feed manufacturing	Share of VMPs sold as premixes	Pharmaceutical industry, EMA	yearly
Competitiveness of medicated feed manufacturing	Quantities of medicated feed produced separated for food producing animals and for pets	Manufacturers of medicated feed	Bi-annual
Competitiveness of medicated feed manufacturing	Price difference medicated feed -compound feed	Manufacturers of medicated feed	Bi-annual

Apart from the potentially new monitoring system established for the use of antimicrobials against the background of AMR which would then cover also the antimicrobials in medicated feed, the approved manufacturers of the veterinary premixes and of medicated feed must in the context of traceability and reporting duties already collect the raw data for the indicators. The additional burden to process this data into the new indicators will therefore be quite limited.

All this data is used for the evaluation that examines whether or not the policies implemented achieve the objectives, in particular with respect to the internal market for medicated feed, the competitiveness of medicated feed production, animal and public health.

8. ANNEXES

8.0. Glossary

AMR: Antimicrobial resistance; phenomena that certain micro-organisms previously sensitive to specific antimicrobial agents overcome this sensitiveness.

Carry-over: the unintentional transfer of VMPs into non-target feed;

EEA: European Economic Area

EFMC: European Feed Manufacturers' Guide; a concrete GMP

EFSA: European Food Safety Authority; independent risk assessment body of the EU

EMA: European Medicines Agency; independent assessment body for medicines

ESVAC: European Surveillance of Veterinary Antimicrobial Consumption, EMA project

EU: European Union

GMP: Good Manufacturing Practice; guidelines to improve feed business operations

HACCP: Hazard Analysis and Critical Control Points; risk management tool for feed business operators

IAB: Impact Assessment Board; quality check entity within the European Commission

MF: Medicated Feed; mixture of a medicated premix with feed which is ready prepared to be directly fed to animals without further processing

Medicated premix: VMP authorised and prepared for the subsequent manufacture of MF

Non-target feed; feed that may contain traces of VMPs due to carry-over that is intended for animals for which no veterinary prescription for such VMPs is issued.

SME: Small and Medium-sized Enterprise

TFEU: Treaty on the Functioning of the European Union

VMP: Veterinary Medicinal Product; substance - presented as having properties for treating or preventing disease in animals - which may be used in or administered to animals with a view either to restoring, correcting or modifying physiological functions by exerting a pharmacological, immunological or metabolic action, or to making a medical diagnosis - which may be used for euthanasia of animals

8.1. List of relevant legislation and schema illustrating how medicated feed provisions are embedded into related EU-legislation

- 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[47]

- Directive 2001/82/EC of the European Parliament and of the Council of 6 November 2001on the Community code relating to veterinary medicinal products[48]

- Regulation (EC) No 470/2009 of the European parliament and of the Council of 6 May 2009 laying down Community procedures for the establishment of residue limits of pharmacologically active substances in foodstuffs of animal origin, repealing Council Regulation (EEC) No 2377/90 and amending Directive 2001/82/EC of the European Parliament and of the Council and Regulation (EC) No 726/2004 of the European Parliament and of the Council[49]

- Regulation (EC) No 183/2005 of the European Parliament and of the Council of 12 January 2005 laying down requirements for feed hygiene[50]

- Directive 2002/32/EC of the European Parliament and of the Council of 7 May 2002 on undesirable substances in animal feed[51]

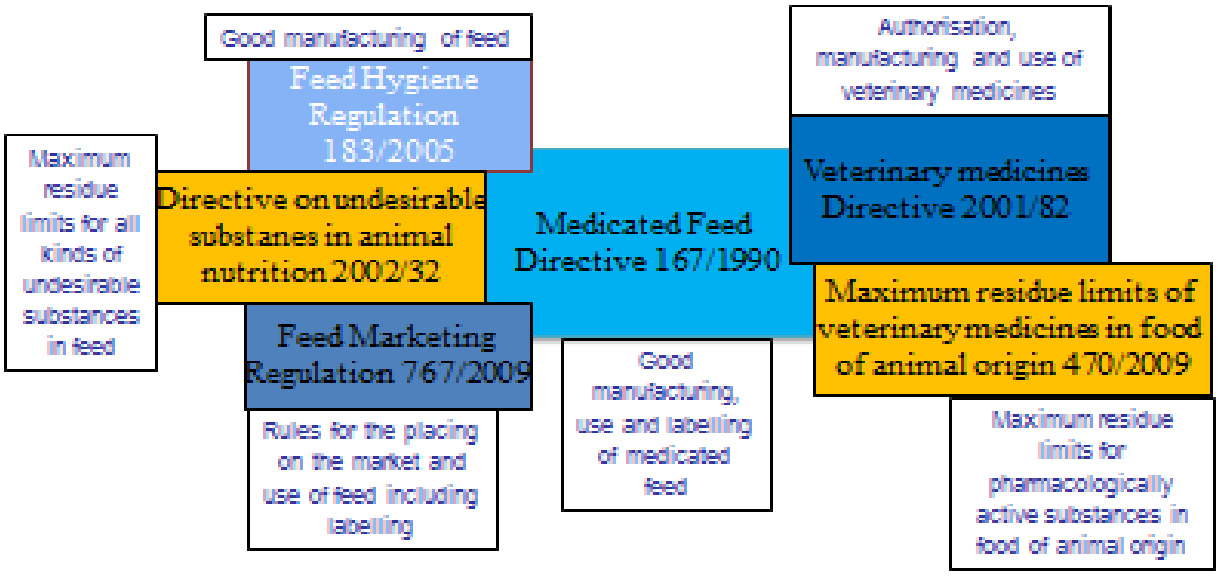
- Regulation (EC) No 767/2009 of the European Parliament and of the Council of 13 July 2009 on the placing on the market and use of feed, amending European Parliament and Council Regulation (EC) No 1831/2003 and repealing Council Directive 79/373/EEC, Commission Directive 80/511/EEC, Council Directives 82/471/EEC, 83/228/EEC, 93/74/EEC, 93/113/EC and 96/25/EC and Commission Decision 2004/217/EC[52]

- 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 [53]

- European Parliament resolution of 27 October 2011 on the public health threat of antimicrobial resistance[54]

- Communication from the Commission to the European Parliament and the Council "Action plan against the rising threats from Antimicrobial Resistance"[55]

[47] OJ L 92, 7.4.1990, p. 42–48
[48] OJ L 136, 30.4.2004, p.58
[49] OJ L 152, 16.6.2009, p.11
[50] OJ L 35, 8.2.2005, p.1
[51] OJ L 140, 30.5.2002, p. 10
[52] OJ L 229, 1.9.2009, p.1
[53] OJ L 31, 1.2.2002, p. 1
[54] http://www.europarl.europa.eu/sides/getDoc.do?type=TA&reference=P7-TA-2011-0473&language=EN&ring=B7-2011-0538
[55] COM (2011) 748


Good manufacturing of feed
Feed Hygiene Regulation 183/2005
Maximum residue limits for all kinds of undesirable substances in feed
Directive on undesirable substanes in animal nutrition 2002/32
Feed Marketing Regulation 767/2009
Rules for the placing on the market and use of feed including labelling
Medicated Feed Directive 167/1990
Good manufacturing, use and labelling of medicated feed
Authorisation, manufacturing and use of veterinary medicines
Veterinary medicines Directive 2001/82
Maximum residue limits of veterinary medicines in food of animal origin 470/2009
Maximum residue limits for pharmacologically active substances in food of animal origin

8.2. Economic data on the upstream and downstream activities

Livestock farming – aquaculture – pets in the EU

Across the EU, most animals are kept in the farming sector with at least 2 billion birds (chickens, laying hens, turkeys, etc.) and 340 mio. mammals (pigs, sheep, goats, cattle, fur animals, etc.). Pet animals represent the second largest type of animals kept in the EU. There are around 64 million cats, 60 mio. dogs, 40 mio. pet birds, 25 mio. small mammals and many millions of ornamental fish. Fewer animals are used for experimentation (public research bodies, animal feeding and zootechnical industries plus pharmaceutical and cosmetic industries): around 12 million animals in the EU, of which most are rodents. There are between 2,000 and 3,000 zoos in the EU and there are an estimated 800,000 captive wild animals. No reliable data could be obtained for circuses or other activities such as animals used in sports, shows, etc.

There are 13.7 mio. animal farming holdings in the EU. The value of livestock farming output in the EU is €157 bn of which pigs and poultry represent 39%. Animal output value represents 41% of the overall agricultural output. In 2011, the EU-27 livestock population produced 48 mio. t of meat (thereof 8.4 mio. t of beef, 23 mio. t of pork and 12.2 mio. t of poultry meat), 150 mio. t of milk and 7.1 mio. t of eggs. According to Eurostat, total aquaculture production in the EU-27 was 1.3 mio. t tonnes live weight. This includes production of crustaceans, molluscs, and finfish. The total value of production is estimated as €3.3 bn.

Feed industry

Animal feedingstuffs, including feed materials and compound feeds, are the main input into livestock production. Within the EU over 470 mio. t of feedingstuffs are consumed by livestock each year. Out of this quantity, 230 mio. t mostly are roughages grown and used on the farm of origin. The balance, i.e. 240 mio. t of feed, includes cereals grown and used on the farm of origin (53 mio. t) and feed purchased by livestock producers to supplement their own feed resources (either feed materials or compound feed).

In 2010, 151 mio. t of compound feed were produced by EU compounders, accounting for 80% of all purchased feedingstuffs. The value of all feedingstuffs used by EU livestock producers including forages produced on the farm is estimated at €79 bn in 2010. This accounts for 37% of all inputs and 60% of the turnover in livestock production. Purchases of compound feed amounted, in 2009, to €42 billion and increased to €44 bn in 2010.

Pet food is produced in the EU in 650 plants with a direct employment of 50.000, annual sales of 8.3 mio tons creating a turnover of € 13.5 bn (2010)[56]. The annual growth rate in the recent years has been 2%.

Trade

The EU is an important player on the world market for animal products. Only for meat and meat preparations, the imports amounted 1.37 mio. t in 2011 and the exports 4.64 mio. t[57]. Also in trade with feed materials of plant origin such as cereals and oil seeds or fruit, the EU plays a major role globally. However, the trade in medicated feed of the EU is negligible.

[56] www.fediaf.org
[57] EUROSTAT 2012

8.3. Number of authorised medicated pre-mixes in the EU

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

Source: Civic consulting

Notes:

(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.

8.4. Number of approved operators for manufacturing and 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	
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 Rep.	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
Unit. Kingdo	734 [q]	10 – 12	640	366

Source: Civic consulting

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).

8.5. Rules of good manufacturing practice of medicated feed

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:

	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: Extracted from Civic Report 3.2 (more details are presented in its Annex 7
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.[58]

- 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.[59]

- 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.[60] This document requires for instance the use of the end-of-line mixing technology to be authorised to produce medicated feed.

- 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.[61]

[58] 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.

[59] 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.*

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

[61] 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.

8.6. Use of veterinary antimicrobials – use of MF

Use of antimicrobials in 18 Member States (year 2010, in tonnes)

Country/MS	Total Antimicrobials Used	Thereof given orally	Thereof given via medicated feed
Austria	63	56	6
Belgium	299	261	60
Czech republic	71	62	23
Denmark	119	78	3
Estonia	8	5	0
Finland	13	5	2
France	997	888	499
Hungary	206	193	135
Ireland	93	62	39
Latvia	7	4	0
Lithuania	16	8	0
Netherlands	461	426	35
Portugal	176	166	133
Slovenia	8	5	1
Spain	1746	1641	1087
Sweden	13	3	0
United Kingdom	456	406	292
All 18 MS	4752	4270	2313

Source: Extracted from ESVAC 2010 tables 1-6 and A1

The evolution of the quantities of antimicrobials and the quantities of medicated feed used in the EU shows that the decision to use therapeutic antimicrobials is totally independent from the possibility to use medicated feed:

In the period from 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, more vaccination and use of VMPs with a higher potency per kg (FCEC, 2.4.2). This is in line with the findings in ESVAC 2010 (see figure 45)

Whereas the overall share of oral application of antimicrobials remains relatively stable, the importance of MF compared to other routes of oral application is decreasing (FCEC, 4.3)

Production figures of MF (FCEC, 3.1) have not changed significantly since 2004. Germany is a special case, reflecting the high relevance of the regulatory framework for the market relevance of MF: Since 2006 the production of MF is only allowed in establishments

authorised under pharmaceuticals law. This has had a severe disruptive effect on the market there. The production volume decreased by 95% (225,000 t in 2004 to 12,000 t in 2008). However, the use of antimicrobials in Germany did not decrease in that period.

Table: Production of medicated feed in several Member States, its relation to the compound feed production, the importance of the different oral routes and the trend:

	Production of medicated feed ('000 tons)	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[e]	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. [f]
Poland	n.a.	n.a.	Medicated feed	Increased very significantly
Portugal	n.a.	n.a.	Medicated feed	Increased fairly significantly
Spain	2,000 [g]	6.6 % [g]	Medicated feed	Remained the same
UK	500	4.0 %	Medicated feed	Decreased fairly significantly[h]

Source: Civic Consulting

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] decrease in 2011 to 2,500 – 3,000 tonnes representing 0.014 % of the total compound feed production.

[f] 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 significantly 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.

[g] 2007 data.

[g] from 2008 to 2011: Remained the same.

8.7. FVO findings re cross-contamination and homogeneity in different Member States[62]

Audit	Concerned operators visited	FINDINGS ON CROSS-CONTAMINATION	FINDINGS ON HOMOGENEITY	RELEVANT CONCLUSIONS
UK 8955-2011	2 approved feed mills (using coccidiostats and other antibiotics) 3 registered feed mills 1 approved mobile mixer	The manufacturers of feed and premixtures visited which were using coccidiostats or medicated premixtures had arrangements in place to minimise cross-contamination of non-target feed with coccidiostats. However, in two establishments visited, the audit team noted that the analytical method used for measuring the level of cross-contamination achieved was not sensitive enough to ensure that it was below the maximum permitted levels set by Directive 2002/32/EC. In one of them, the audit team confirmed that feed for non-target species exceeding maximum permitted levels of cross-contamination for decoquinate was regularly placed on the market. The operator of this establishment was not aware of the applicable legislation and therefore did not take any corrective actions. In the other establishment, cross-contamination was measured just after the mixer and therefore did not take account of the additional contamination occurring in the remaining part of the production process.	The feed mills visited had adequate arrangements in place for ensuring and measuring the homogeneity of the feed produced. However, in one feed mill visited, coefficients of variation (a parameter used to measure homogeneity of feed) ranging from 27 to 50 were measured over a period of nine months in 2011. This issue had been identified by the operator and the feed inspectors but no actions were taken in order to address it.	[...] arrangements in place for minimisation of cross-contamination are not sufficient to ensure compliance with Directive 2002/32/EC [...]. Consequently, the relevant recommendation of report 2009-8092 has not been addressed and important requirements of Annex II to Regulation (EC) No 183/2005 are still not met.
RO 8479-2010	2 approved feed mills (using coccidiostats and other antibiotics) 2 on-farm mixers (1 using antibiotics)	In one of the feed mills visited, one of the production lines was used for production of feed with or without antibiotics and coccidiostats. According to the operator, production sequencing was used to minimise cross-contamination. However, the audit team noted that there was no sequencing procedure in place and no tests had been carried out in order to establish the level of cross-contamination. In one of the on-farm mixers visited, its mixer and production line were used both for production of feedstuffs with or without medicines. Although there was a flushing procedure in place, it was not followed by the operator; the audit team noted that the concerned inspectors from the Unit in charge of Control and the Unit in charge of Feed had recorded in their report that the procedure and its implementation was satisfactory. In the above on-farm mixer, the operator declared that cross-contamination tests were performed twice a year with two samples taken from the mixer; however, the results of the tests were not available for inspectors, who had never questioned this, nor performed any verification in this respect. The audit team noted that samples for the detection of banned antibiotics had been collected by officials; however, they have never collected samples for analysis on antibiotics which were used in the production of medicated feed, for the purpose of establishing the level of cross contamination	The audit team noted that, although homogeneity tests (with amino acids as tracers) were carried out regularly in one of the feed mills visited (with satisfactory results), in the other feed mill and in one on-farm mixer visited, the design of the test was incorrect (they were carried out on the basis of one sample), and in the other on-farm mixer visited no homogeneity test had been carried out. With the exception of the first feed mills mentioned above, homogeneity has never been assessed by the inspectors from the Unit in charge of Control and the Unit in charge of Feed	In most of the establishments visited, there are significant deficiencies in the requirements for HACCP based procedures as well as in the design and implementation of quality control programmes which, in particular, presented shortcomings as regards measures to minimise cross-contamination and homogeneity tests. Moreover, these deficiencies are very often overlooked by the concerned competent authorities during official controls. Therefore, the requirements laid down by Articles 5(2) 6 and 7 of Regulation (EC) No 183/2005 are not met yet and the relevant recommendation of the previous report has not been satisfactorily addressed

[62] For more details: http://ec.europa.eu/food/fvo/index_en.cfm

PT 8942-2011	3 approved feed mills (using coccidiostats and other antibiotics)2 registered feed mills1 approved on-farm mixer	In the three feed mills using coccidiostats and antibiotics visited, some measures to minimize cross-contamination during production were used […].However:• In one feed mill, flushing was not used as a preventive measure. The level of cross-contamination with antibiotics had been found to be satisfactory; however, the audit team noted that this level had only been verified once and using one sample taken from the following production batch (this sample was a pool of 10 samples taken consecutively), with the consequence that the initial part of the production batch could contain a higher level of cross-contamination. The level of cross-contamination of coccidiostats has never been determined.• In another feed mill, flushing procedures were in place. The level of cross-contamination with antibiotics had been found to be satisfactory; however, the audit team noted that this level had only been verified once and using one sample taken randomly from the following production batch.• In the third feed mill, flushing procedures were in place but only to minimize cross-contamination with antibiotics. The feed operator explained that for coccidiostats they had installed an aspiration system aimed at removing residues through the production line (after the use of coccidiostats the manufacturing programme foresees a certain cleaning time during which the production line remains empty and the ventilation system removes the residues left). In this feed mill the level of cross-contamination with coccidiostats was determined once a year by using a coccidiostats (robenidine hydrochloride) as a tracer. Until 2011 such a test was based on the result of only one sample taken randomly from the following production batch. Since 2011, a new sampling procedure has been introduced where three samples have to be taken for each of the three following production batches; subsequently the three samples of each batch are mixed together in one sample and analyzed. The audit team noted that, although the result of the last test was satisfactory, there was no information concerning the collection times of the three samples, and the pooling of samples could result in the initial part of the production batch containing a higher level of cross-contamination without it being detected.The audit team noted that all the above mentioned deficiencies as regards cross-contamination and homogeneity had been overlooked during official controls.	In the two registered feed mills visited the audit team noted that no test on homogeneity had ever been performed.In one approved feed mill visited, homogeneity of compound feed containing coccidiostats or antibiotics was verified twice a year with the use of manganese as a tracer and analysing 10 samples; the results were satisfactory (coefficient of variation between 5% and 10%). However, in the other two approved feed mills visited, the audit team noted that it was tested only by measuring the level of humidity, proteins, ash and fat in a few samples or even only in one (i.e. in one establishment 10 samples were taken but they were subsequently mixed together before the analysis.	The feed establishments visited implement largely satisfactory procedures based on the HACCP principles. However, the technical and organisational measures in place as regards homogeneity and cross-contamination are not satisfactory; therefore, the relevant requirements laid down by Article 5(2) of Regulation (EC) No 183/2005 and specified in its Annex II are not complied with.
PL 8465-2010	3 approved feed mills (using coccidiostats and other antibiotics) 1 registered feed mill 1 approved on-farm mixer 2 registered on-farm mixers	One feed mill visited, which is using coccidiostats, had not performed tests to determine the level of carry-over. They relied on sequencing production to minimise carry-over to feeding stuffs in which additives are not authorised. Flushes were only used in cases where the following feed was one in which the relevant additive was not authorised. Another feed mill using coccidiostats and veterinary medical products had a carry-over of 20% and no adequate measures had been taken to comply with maximum levels of coccidiostats in non target feed. They relied on sequencing production to minimise carry-over to feed in which additives are not authorised. Flushes were only used in cases where the following feed was one in which the relevant additive was not authorised. This practice is not in line with the procedures explained to the audit team by the competent authorities	One approved and one registered feed mill relied on the homogeneity tests that had been carried out by the competent authorities. They did not perform own checks to guarantee homogeneity	The HACCP based procedures required by Article 6(1) of Regulation (EC) No 183/2005 are still absent in several registered feed establishments. Moreover, while the said procedures and quality control measures were in place in approved establishments visited, deficiencies were noted in most of them and official controls overlooked these. Therefore, the relevant requirements of Regulation (EC) No 183/2005 are not satisfactorily met.
FR 8464-2010	2 approved feed mills (producing medicated	According to the competent authorities, the results of the above mentioned own-checks tests for assessing the level of cross-contamination linked to the manufacturing of medicated feed are considered	No negative findings	Quality control and HACCP based procedures are largely satisfactory at large-scale

	feed)2 registered feed mills2 on-farm mixers	to be compliant if the level of cross-contamination in the first batch following the batch of medicated feedingstuffs is less than 5% (of the concentration of the medicine in the medicated feed); from the second batch on, this figure must be less than 1%. In one of the above feed mills, the audit team confirmed that the operator flushed the production lines with 500 kg of feed material after manufacturing medicated feed and this feed material was 20 subsequently used for production of next batch of medicated feed. However, the audit team noted that this flushing material was used, in some cases, for the production of medicated feed which did not necessarily contain the same medicine. The audit team also noted that, in this establishment, the last official sampling discovered traces of oxytetracycline in various feedingstuffs produced several days after its last incorporation. In two departments located in two different regions visited, the audit team noted a similar approach to these issues		feed mills, with the exception of procedures for minimising the carry-over of veterinary medicines, which allow for the presence in medicated feed of up to 5% of another medicinal substance used in a previous production batch; moreover, quality control and HACCP based procedures are either absent or deficient at small-scale feed mills and food recyclers. This is not in compliance with the relevant provisions of Regulation (EC) No 183/2005
EE 7233-2007	2 approved feed mills (using coccidiostats and other antibiotics)	In one feed mill, pre-mixtures containing coccidiostats and other medicinal substances were used for the production of feed. The mission team noted that technical and organisational measures were taken to minimize the risk of cross-contamination arising from the use of such substances. However, the FBO had not verified if such measures were sufficient as the bound carry-over of its equipment was not quantified. Although the FBO stated that he considered the carry-over linked to the mixer as a CCP, no critical limits were defined and no monitoring was in place.	None of the two approved feed mills had carried out homogeneity tests	Shortcomings in relation to essential aspects of feed hygiene requirements laid down in Annex II to Regulation (EC) No 183/2005 were detected by the mission team; in particular, the HACCP systems required by Art. 6 of Regulation (EC) No 183/2005 were incomplete, non-adapted or not fully implemented.
CZ 8087-2009	4 approved feed mills (using coccidiostats) 1 approved on-farm mixer	Feed businesses using coccidiostats as feed additives generally did not flush production lines following manufacture of a compound feed containing coccidiostats. They relied on sequencing production to minimise carry-over to feeding stuffs in which additives are not authorised. Flushes were only used in cases where the following feeding stuff was one in which the relevant additive was not authorised. One feed business visited had been approved to use coccidiostats and medicated feed on the basis of a 2,000 kg flush being used following use of such products to minimise the risk of carry-over. However, the feed business operator informed the mission team that he used a 200 kg flush to minimise carry-over although this had not been validated as being effective	No negative findings	Reasonable measures to avoid carry-over of cocccidiostats were not always taken as required by Annex II to Regulation (EC) No 183/2005.
BG 8478-2010	3 approved feed mills (using coccidiostats) 1 registered feed mill3 registered farms	In one feed mill visited, the approach used for minimising cross-contamination was that for a batch of feedingstuffs with a given active substance, the last production run did not contain any active substance (and, hence, acted as a flushing batch).However, the audit team noted that the effectiveness of this procedure in minimising the level of cross-contamination had not been established; more importantly, the impact of this practice in the homogeneity of the batch, notably as regards the content of the concerned active substance, had never been investigated. The audit team noted that competent authorities were well aware of this practice with which they were not in agreement, and that they have tried to rectify the situation in the past, without success.With the exception of the above, all feed manufacturers visited carried out cross-contamination and homogeneity tests, and had in place flushing procedures to minimise cross-contamination; the audit team noted that these procedures had been subject to adequate controls by the competent authorities over the past years.		The requirements on HACCP based programmes laid down by Articles 6 and 7 of Regulation (EC) No 183/2005 and quality control programmes set out in its Annex II are largely complied with, with the exception of one establishment, where the measures to avoid or minimise cross-contamination were not in place.

BE 8469-2010	3 approved feed mills (using coccidiostats) 2 registered feed mills	All approved feed mills and premixture manufacturers visited where coccidiostats were used, had performed carry-over tests. However, most of these operators were not following their internal procedures which had been designed to minimise the presence of residues of coccidiostats in feed for non-target species. Instead of cleaning the circuit by flushing the required number of times corresponding to their measured level of carry-over, they were using grower, and even in one case, finisher feed to clean their production lines. Some results of carry-over tests indicated levels of residues well above the 3% laid down in Directive 2002/32/EC.	No negative findings	Most of applicable requirements of Annex II to Regulation (EC) No 183/2005 were met by the feed establishments visited. However, weaknesses were identified in certain preliminary steps to the identification of hazards and in the appropriation of HACCP based procedures by certain operators. The measures put in place in order to minimise carry-over of coccidiostats were also very limited.

8.8. Situation about carry-over in the Member States and their position about harmonised tolerance levels.

Member State	1. Tolerance value in place	Comment
AT	Zero	The tolerance level is the level of analytical detection related to the methods of analyses.
BE	(Zero de iuris) Action levels 1% - 3% (for exact values for different molecules consult the Belgian study on carry-over levels)	From a legal point of view, zero-tolerance applies to the presence of residus of medicinal substances in non-target feed. However the Federal food agency (FASFC) and the sector developed initiatives to lower the level of cross contamination as low as reasonable achievable (ALARA). In the convention guideline values are expressed (Annex II) per active substance on what the FASFC considers as ALARA. These values are expressed for antibiotics and paracetamol as a percentage of the minimal authorized dosage, for anthelmintics this is a % of the maximum authorized dosage. So regardless of the actual dose of the active substance 1 maximum level is valid per active substance. The values are not arbitrary but need to comply with three conditions: a. the level of cross contamination may not cause animal health issues. b. The level of cross contamination may not cause an exceeding of the MRL of the products of animal origin c. The level of cross contamination may not provoke an increased antimicrobial resistance selection. the upper bound limit of the cross contamination is never higher than 2,5% for antibiotics or 3% for anthelmintics (this is technical achievable so ALARA).
BU	No value	positive findings are dealt with on a case by case assessment based on which the measures to take are decided
CY	No value	Positive findings are dealt with on a case by case assessment based on which the measures to take are decided
CZ	No value (Min Agri: 0,5% see below)	No national limits for unavoidable carry-over of veterinary medicine in non-target feed is established in the Czech Republic, the competent authority, Institute for State Control of Veterinary Biologicals and Medicines considers each kind of carry-over individually. ⇔ Ministry of Agriculture: 0,5%
DE	Zero	VMP in feed means "not of merchantable quality

DK	No value	No maximum limits. If carry-over is found, the result will be evaluated before action is taken, if necessary.
EE	No value	We have no legal values for residues of VMP in feedingstuffs and the zero tolerance is not officially established. Nevertheless, according to the Estonian Feedingstuffs Act is any positive finding residue of veterinary medicines in feed violation of requirements.
ES	No specific levels established	Maximum level of cross contamination must be justified by the FBO (according to EU regulations where available i.e. coccidiostats). No specific levels have been established for medicated feedingstuffs, despite the presence of non-prescribed drugs in feed is prosecuted under the National Residues Surveillance Scheme. As far as analytical methods are very sensitive, positive findings are dealt with on a case by case assessment based on which the measures to take are decided.
FI	No value	There are no national legislation related to VMP residues in feed in Finland. Positive findings are dealt case by case .
FR	5%	IPM: Thresholds for validation of the manufacturing process: max 5% in the first batch collector and max 1% in the second batch collector.
GR	Zero	No tolerance limits established Limit of detection
HU	Zero	The zero tolerance is laid down in national legislation, in practice, however, at points requiring “zero tolerance” the carry-over limit is defined by the sensitivity of the relevant laboratory method which should be approved by the competent authority.
IE	No value	There is no legal basis in Ireland setting ‘tolerance limits’ for medications in non target feed. ‘Positive findings’ are dealt with on a case by case----corrective actions are carried out by the Competent Authority (CA) . Where appropriate, the ‘positive non-target feed’ will be detained and may be destroyed.
ISLAND	No value	No national limits established
IT	Zero	The Italian national control plan of animal feed, set for zero tolerance regarding residues of veterinary medicines in feed. In fact the tolerance levels is the level of analytical detection related to the LAB accredited method. Any positive finding has to be followed by corrective actions imposed by local competent authorities.
LT	No value	Not regulated

LU	Zero "No value, BUT applying zero tolerance"	We have no legal values for residues of VMP in feedingstuffs and the zero tolerance is not officially established, but in the national regulation regulating the manufacturing of medicated feed is the condition that all recipients, which are used for medicated feed, have to be cleaned after use, in order to avoid any undesirable interaction or cross contamination. Therefore we apply the zero-tolerance and any positive findings have to be withdrawn.
LV	No value	Not regulated
MT	No value (neither 0 nor tolerance)	If for any reason there are positive findings, an investigation is launched => case by case
NL	Shouldn't exceed the MRL's of antibiotics in animal products	The legal status of the current “rule of thumb” used by the Dutch Food and Consumer Product Safety Authority (VWA) is still under discussion, they have introduced an action limit for VMP in non-target feed of **2.5% of the lowest dosage in target feed.**
PL	Zero	Not set in legislation but positive finding => withdrawal
PT	No value	Awaiting confirmation
RO	No value	Romania does not have a national tolerance level, established in national legislation, for carry-over of VMP into non target feed.
SE	No value	If for any reason there are positive findings, an investigation is launched => case by case
SI	Zero	The zero tolerance is laid down in national legislation, in practice, however, at points requiring “zero tolerance” the carry-over limit is defined by the sensitivity of the relevant laboratory method which should be approved by the competent authority.
SK	No value	Slovak national legislation does not lay down exact limits. Institute for State Control of Veterinary Biologicals and Medicaments in Nitra and they evaluate each incident of carry-over individually on following type and significant of veterinary medicine in nontarget feed with help of EU limits for contamination medicinal residues in food.
UK	No value	Carry-over of VMP in non target feed is considered on a case by case basis but generally we inform Feed Business Operators to aim for as low as reasonably possible and at least within the tolerances set for coccidiostats in Commission Directive 2009/8/EC, however, we are also limited to the levels that can be detected.

	2. Support for EU-limits	Reasoning
AT	YES	Yes, we prefer common maximum levels.
BE	YES	YES, we are in favour of an EU harmonisation regarding unavoidable carry-over levels for medicinal substances to non-target feed
BU	YES	
CY	YES	YES, we are in favour to set maximum levels of unavoidable carry-over in a similar way as for coccidiostats and histomonostats.
CZ	YES	Yes, we are in favour to set maximum levels of unavoidable carry-over in a similar way as for coccidiostats and histomonostats.
DE	YES	
DK	?	
EE	YES	Estonia is in favour of establishing maximum levels of unavoidable carry-over of VMPs in non-target feed
ES	YES	
FI	YES	The feasibily has to be evaluated separately. From the feed control point of view, maximum levels would be welcomed .
FR	YES	But maximum RATES of carry-over
GR	YES	
HU	?	
IE	YES	It is recognized that even the best compound feedmill is unable to achieve a 'zero carry-over' at all times. EC Regulation 183/2005 and Directive 90/167 require FBOs to ensure that in the production of feed that hazards are eliminated or minimised to avoid compromising feed safety. FBOs are committed to abide by such regulation. Ireland would welcome the EC setting maximum limits as this would set an equivalent standard for all Member States.
IT	YES	The maximum levels of unavoidable carry-over of VMPs in non target feed is a necessity. The IT national competent authority will welcome that the EC sets these limits for VMP authorised as medicated premix within the EU.
LT	NO	Lithuania would be against establishing maximum levels of carry-over of veterinary medicinal products in non-target feed
LU	NO	In front of the general increase of antimicrobiotic resistance to antibiotics in animals and humans in Europe, setting tolerance levels for residues of VMP in feed, is a contra-productive action. Carry-over is not unavoidable, the producers of medicated feed in Luxembourg have to run after production of medicated feed as many flushing

		batches as needed until there is no more carry-over, before they produce non-medicated feed. […] During the last +/-10 years, we have seen in Luxembourg a very important reduction of manufacturing of medicated feed up to nearly 0 batches of medicated feed/year. Nearly all the pig farmers give VMP to their animals via mixing into drinking water and not into feed. Therefore is no need for setting maximum limits of residues of VMP in feedingstuffs.
LV	?	
MT	YES	
NL	YES	NVWA is in favour with clear MRL's or ML's
PL	NO	No tolerance because AMR!
PT	YES	Taking into consideration unavoidable carry-over/ cross contamination at feed mill level, we are in favour of establishing admissible maximum levels in non target feeds
RO	YES	In principle in favour of establishing maximum levels.
SE	YES	
SI	?	
SK	?	
UK	YES	The UK is in favour of establishing maximum levels of unavoidable carry-over of VMPs in non-target feed in a similar way set for coccidiostats and histomonostats. However, we would ask that tolerances be set based on sound science, taking into consideration the risk to human health and to non-target species health. Consideration should be given to the potential for the development of anti-microbial resistance based on scientific evidence.

Sources: Competent authorities, surveys in 2009, 2011 and 2013

8.9. Medicated feed and antimicrobial resistance

1. Resistance to Antimicrobials

Since the introduction of penicillin in the 1940s antimicrobial medicines, such as antibiotics, have become essential for the treatment of many microbial infections in humans and animals.

These applications are now seriously jeopardized by the emergence and spread of microbes that are resistant to affordable and effective first choice, or "first-line" medicines, rendering the drugs concerned ineffective for the treatment of the infection. This resistance is a natural biological phenomenon but is amplified by a variety of factors. The inappropriate use of therapeutic antimicrobials in human and veterinary medicine, the use of antimicrobials for non-therapeutic purposes as well as the pollution of the environment by antimicrobials is accelerating the emergence and spread of resistant microorganisms. The consequences are severe:

A subset of drug-resistant bacteria is responsible for about 25,000 human deaths annually. In addition to avoidable death, this also translates into extra healthcare costs and productivity losses of at least EUR 1.5 billion[63] per annum.

Common bacteria causing e.g. diarrhoea or respiratory infections in several animal species have become more resistant to commonly used veterinary antimicrobials causing increased suffering and mortality in animals, and consequently, production losses and extra costs as well as occupational hazards to animal keepers.

Resistance was high among gram positive and gram negative bacteria that cause serious infections in man (up to 25% in several Member States) and was growing in bacteria such as Escherichia coli.

This is important in the context of medicated feed since over-use of antibiotics in animals, particularly at low doses has been indicated as one possible source of antibiotic resistance. Once resistance has arisen in bacteria in animals, they can transfer to man or in some cases transfer their resistance to other bacteria which can infect man.

Methicilin resistant Staphylococcus aureus (MRSA) is a major cause of resistant hospital infections. In a 2008 baseline survey coordinated by EFSA, it has been demonstrated that pigs are a major reservoir of a new emerging type of MRSA. A joint ECDC/EFSA/EMA scientific report published in 2009[64] concludes that "the extensive use of antimicrobials for prevention of disease appears to be an important risk factor for the spread of MRSA".

The Commission communicated an action plan to respond to the issue of antimicrobial resistance in November 2011[65]. This recognised the multifaceted nature of the problem and the need to tackle it from many angles. Regarding animal health it concluded that:

The appropriate use of antimicrobials is essential for reducing and preventing AMR and is the cornerstone of EU policy against AMR, both in human and veterinary medicines. Antimicrobials should only be used if necessary and in accordance with best practices.

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[63] ECDC/EMEA JOINT TECHNICAL REPORT The bacterial challenge: time to react. Available from: http://www.ema.europa.eu/docs/en_GB/document_library/Report/2009/11/WC500008770.pdf

[64] Joint scientific report of ECDC, EFSA and EMEA on meticillin resistant Staphylococcus aureus (MRSA) in livestock, companion animals and foods. Available from: http://www.ema.europa.eu/docs/en_GB/document_library/Report/2009/10/WC500004306.pdf

[65] http://ec.europa.eu/dgs/health_consumer/docs/communication_amr_2011_748_en.pdf

The sub-optimal use of therapeutic antimicrobials for animals, in particular under-dosage, can enhance the development of AMR. Efforts to ensure that the medicines are administered to the animals only at the correct therapeutic level are undertaken in the enforcement of the current rules on veterinary medicines and medicated feed but also in the margins of the on-going revision of these legal acts.

Between Member States significant differences exist in the sales of antimicrobials that cannot be explained by the animal husbandry practices.

To respond to this situation, it was important to strengthen the regulatory framework on veterinary medicines and on medicated feed.

2. Use of antimicrobials – use of MF - alternatives

Whereas the oral use of antimicrobials remains relatively stable, the importance of MF, compared to other routes of oral application, is decreasing (FCEC, chapter 4.3). Thus, it can be concluded that the decision to use therapeutic AMs is totally independent from the possibility to use medicated feed.

8.10. Notifications to the Rapid Alert System for Food and Feed of unauthorised veterinary medicines in feed

RASFF Code	Subject
2006.0056	prednisolone, medroxy progesterone acetate (MPA) and dexamethasone in aqueous premixture for farm animals from the Slovak Republic
2012.0982	oxytetracycline (219 µg/kg - ppb) unauthorised in feed for farming trout from Spain, via the Czech Republic
2012.0984	oxytetracycline (605 µg/kg - ppb) in feed for farming trout from Spain, via the Czech Republic
2012.0970	bacitracin (2.22 mg/kg - ppm) in compound feed for rabbits from the Czech Republic
2012.0078	amoxicillin, oxytetracycline, doxycycline, norfloxacin, florfenicol, thiamphenicol, flumequine and chloramphenicol in feed for shrimps from Singapore
2011.0256	zilpaterol (15 µg/kg - ppb) in feed for broilers for fattening from Poland
2008.1202	chloramphenicol in acid casein destined for feed from Ukraine
2008.AIE	chloramphenicol (7.18 µg/kg - ppb) in skimmed milk powder from Ukraine
2008.AEO	chloramphenicol (50.77; 32.99 µg/kg - ppb) in full fat milk powder from Ukraine
2007.0210	tetracycline (traces) and colistin (traces) unauthorised in complete feed for piglets from France
2007.0070	oxytetracycline (1.255 mg/kg - ppm) in single feed for trout from Portugal
2006.0761	oxytetracycline (79.3 mg/kg - ppm) in complete feed for trout from Portugal
2012.0812	chlortetracycline (224 µg/dm²) unauthorised in colostrum for lambs from the United Kingdom
2011.1887	residue level above MRL for oxytetracycline (0.18 mg/kg - ppm) in salmon meal from Chile
2010.1237	tetracycline unauthorised in feed for rabbits from Italy
2011.0257	chloramphenicol (19; 8.2 µg/kg - ppb) in vitamin A complementary feed from China
2011.0058	chloramphenicol (32.6 µg/kg - ppb) in vitamin A / D3 premixtures from China

8.11. Results of the online stakeholder consultation

Response statistics (N=252) for 'Smart Regulation of Medicated Feed How to safeguard public and animal health while increasing the competitiveness of the EU's livestock sector'.

4. ISSUES

4.1. General aspects and MF manufacturing standards

4.1.1. Do you agree that the standards for MF manufacturing have an impact on feed, food and occupational safety? -multiple choices reply- (optional)

	Number of requested records	Requested records (252)	% of total number records (252)	% of total number records (249)
Yes	243	(96.4%)	(96.4%)	(97.6%)
No	1	(0.4%)	(0.4%)	(0.4%)
Do not know	5	(2%)	(2%)	(2%)
N/A	3	(1.2%)	(1.2%)	-

4.1.2. If you represent /are based in a MS, do you think that the way MF is manufactured there, reflects the appropriate safety level in terms of animal and public health? -multiple choices reply- (optional)

	Number of requested records	Requested records (252)	% of total number records (252)	% of total number records (242)
Yes	191	(75.8%)	(75.8%)	(78.9%)
No, too low	18	(7.1%)	(7.1%)	(7.4%)
No, too high	30	(11.9%)	(11.9%)	(12.4%)
Do not know	3	(1.2%)	(1.2%)	(1.2%)
N/A	10	(4%)	(4%)	-

4.1.3. Do you agree that manufacturing standards have an impact on the costs of MF production? -multiple choices reply- (optional)

	Number of requested records	Requested records (252)	% of total number records (252)	% of total number records (246)
Yes	240	(95.2%)	(95.2%)	(97.6%)
No	5	(2%)	(2%)	(2%)
Do not know	1	(0.4%)	(0.4%)	(0.4%)
N/A	6	(2.4%)	(2.4%)	-

4.1.4. The cost of manufacturing MF in a feed mill is higher than for non-medicated compound feed because specific measures have to be taken.

If you represent /are based in a Member State, do you think that, apart from the cost of VMP, the additional costs for manufacturing MF are reasonable? -multiple choices reply- (optional)

	Number of requested records	Requested records (252)	% of total number records (252)	% of total number records (242)
Yes	157	(62.3%)	(62.3%)	(64.9%)
No, too low	7	(2.8%)	(2.8%)	(2.9%)
No, too high	54	(21.4%)	(21.4%)	(22.3%)
Do not know	24	(9.5%)	(9.5%)	(9.9%)
N/A	10	(4%)	(4%)	-

4.1.5. If you represent /are based in a MS, do you think that MF is a practically feasible method for all livestock farmers to administer VMPs to their animals? -multiple choices reply- (optional)

	Number of requested records	Requested records (252)	% of total number records (252)	% of total number records (240)
Yes, for all	122	(48.4%)	(48.4%)	(50.8%)
No, only viable and feasible for very few farming systems	15	(6%)	(6%)	(6.2%)
Not for all, but for the vast majority of farming systems MF is viable and feasible	100	(39.7%)	(39.7%)	(41.7%)
Do not know	3	(1.2%)	(1.2%)	(1.2%)
N/A	12	(4.8%)	(4.8%)	-

4.1.6. The main aim of this initiative is to modernise and harmonise MF production at the appropriate standard. Do you agree that these objectives can only be achieved by taking action at EU level instead of national level (respect of subsidiarity and proportionality principles)? -multiple choices reply- (optional)

	Number of requested records	Requested records (252)	% of total number records (252)	% of total number records (242)
Yes	212	(84.1%)	(84.1%)	(87.6%)
No	23	(9.1%)	(9.1%)	(9.5%)
Do not know	7	(2.8%)	(2.8%)	(2.9%)
N/A	10	(4%)	(4%)	-

4.2 Specific provisions on MF manufacturing

4.2.1. The inclusion rates of the pre-mixes into MF differ currently from MS to MS.

Do you agree that inclusion rates should be the same throughout the EU and depend only on the manufacturing standard (i.e. the quality of the manufacturing practice) of the MF producer? -multiple choices reply- (optional)

	Number of requested records	Requested records (252)	% of total number records (252)	% of total number records (246)
Yes	119	(47.2%)	(47.2%)	(48.4%)
No	120	(47.6%)	(47.6%)	(48.8%)
Do not know	7	(2.8%)	(2.8%)	(2.8%)
N/A	6	(2.4%)	(2.4%)	-

4.2.2. The current rules allow MF to be manufactured before the specific prescription is available in the feed mill (anticipated production of MF). Do you agree that anticipated production of MF may raise concerns in terms of efficient and safe use of the VMPs? -multiple choices reply- (optional)

	Number of requested records	Requested records (252)	% of total number records (252)	% of total number records (246)
Yes	42	(16.7%)	(16.7%)	(17.1%)
No	195	(77.4%)	(77.4%)	(79.3%)
Do not know	9	(3.6%)	(3.6%)	(3.7%)
N/A	6	(2.4%)	(2.4%)	-

4.2.3. Do you agree that the use of more than one pre-mix to manufacture a MF may raise concerns in term of safe and efficient use of VMPs? -multiple choices reply- (optional)

	Number of requested records	Requested records (252)	% of total number records (252)	% of total number records (247)
Yes	45	(17.9%)	(17.9%)	(18.2%)
No	179	(71%)	(71%)	(72.5%)
Do not know	23	(9.1%)	(9.1%)	(9.3%)
N/A	5	(2%)	(2%)	-

4.2.4. MF can be manufactured in feed mills and in specifically equipped mobile mixers. Do you agree that the manufacture of MF in mobile mixers can meet the requirements for MF with respect to homogeneity and compatibility of the compounds? -multiple choices reply- (optional)

	Number of requested records	Requested records (252)	% of total number records (252)	% of total number records (243)
Yes	163	(64.7%)	(64.7%)	(67.1%)
No	32	(12.7%)	(12.7%)	(13.2%)
Do not know	48	(19%)	(19%)	(19.8%)
N/A	9	(3.6%)	(3.6%)	-

4.2.5. Do you agree that on-farm manufacture of MF can meet the requirements for MF with respect to homogeneity and compatibility of the compounds? -multiple choices reply- (optional)

	Number of requested records	Requested records (252)	% of total number records (252)	% of total number records (248)
Yes	164	(65.1%)	(65.1%)	(66.1%)
No	55	(21.8%)	(21.8%)	(22.2%)
Do not know	29	(11.5%)	(11.5%)	(11.7%)
N/A	4	(1.6%)	(1.6%)	-

4.3 Use of MF in practice

4.3.1. A homogenous incorporation of VMP into MF is crucial for the safe and efficient use of MF. Do you agree that transport of MF from the manufacturing feed mill to the farm significantly reduces the homogeneity of feed? -multiple choices reply- (optional)

	Number of requested records	Requested records (252)	% of total number records (252)	% of total number records (245)
Yes	10	(4%)	(4%)	(4.1%)
No	219	(86.9%)	(86.9%)	(89.4%)
Do not know	16	(6.3%)	(6.3%)	(6.5%)
N/A	7	(2.8%)	(2.8%)	-

4.3.2. Sometimes, during a treatment, a change in medication is necessary. Do you agree that, compared to other methods of oral administration of VMPs (e.g. top dressing or on-farm mixing of VMPs), the use of MF reduces the flexibility and thus willingness to change a treatment? -multiple choices reply- (optional)

	Number of requested records	Requested records (252)	% of total number records (252)	% of total number records (241)
Yes	106	(42.1%)	(42.1%)	(44%)
No	127	(50.4%)	(50.4%)	(52.7%)
Do not know	8	(3.2%)	(3.2%)	(3.3%)
N/A	11	(4.4%)	(4.4%)	-

4.3.3. Do you agree that left overs of MF on the farm might cause problems? -multiple choices reply- (optional)

	Number of requested records	Requested records (252)	% of total number records (252)	% of total number records (247)
Yes	103	(40.9%)	(40.9%)	(41.7%)
No	137	(54.4%)	(54.4%)	(55.5%)
Do not know	7	(2.8%)	(2.8%)	(2.8%)
N/A	5	(2%)	(2%)	-

4.3.4. Do you agree that the MF method has advantages in terms of animal welfare over medication that is not administered orally? -multiple choices reply- (optional)

	Number of requested records	Requested records (252)	% of total number records (252)	% of total number records (246)
Yes	227	(90.1%)	(90.1%)	(92.3%)
No	11	(4.4%)	(4.4%)	(4.5%)
Do not know	8	(3.2%)	(3.2%)	(3.3%)
N/A	6	(2.4%)	(2.4%)	-

4.3.5. Do you agree that, prescription rules for VMP and MF should be identical? -multiple choices reply- (optional)

	Number of requested records	Requested records (252)	% of total number records (252)	% of total number records (245)
Yes	226	(89.7%)	(89.7%)	(92.2%)
No	17	(6.7%)	(6.7%)	(6.9%)
Do not know	2	(0.8%)	(0.8%)	(0.8%)
N/A	7	(2.8%)	(2.8%)	-

4.3.6. Would you agree that MF could be prescribed by qualified personnel other than veterinarians, which is already a possibility for the prescription of VMPs? -multiple choices reply- (optional)

	Number of requested records	Requested records (252)	% of total number records (252)	% of total number records (248)
Yes	15	(6%)	(6%)	(6%)
No	231	(91.7%)	(91.7%)	(93.1%)
Do not know	2	(0.8%)	(0.8%)	(0.8%)
N/A	4	(1.6%)	(1.6%)	-

4.4 Public and occupational health

4.4.1. Do you agree that, compared to other methods of oral administration of VMPs to animals, the MF method has a lower risk in terms of direct exposure of staff handling VMPs i.e. with respect to occupational health (e.g. sensitising, allergic or resistance-enhancing properties of VMPs)? -multiple choices reply- (optional)

	Number of requested records	Requested records (252)	% of total number records (252)	% of total number records (244)
Yes	201	(79.8%)	(79.8%)	(82.4%)
No	24	(9.5%)	(9.5%)	(9.8%)
Do not know	19	(7.5%)	(7.5%)	(7.8%)
N/A	8	(3.2%)	(3.2%)	-

4.4.2. Residues of VMPs can be carried over into feed for animals for which the VMPs are not intended. Do you agree that finding of residues of non-prescribed VMPs can be minimised e.g. by flushing or production planning but not totally excluded in practice? -multiple choices reply- (optional)

	Number of requested records	Requested records (252)	% of total number records (252)	% of total number records (243)
Yes	230	(91.3%)	(91.3%)	(94.7%)
No	7	(2.8%)	(2.8%)	(2.9%)
Do not know	6	(2.4%)	(2.4%)	(2.5%)
N/A	9	(3.6%)	(3.6%)	-

4.4.3. If you represent / are based in a MS, are you aware of tolerance levels for carry-over of non-target species VMPs under the current legal framework? -multiple choices reply- (optional)

	Number of requested records	Requested records (252)	% of total number records (252)	% of total number records (233)
Yes	98	(38.9%)	(38.9%)	(42.1%)
No	70	(27.8%)	(27.8%)	(30%)
Do not know	65	(25.8%)	(25.8%)	(27.9%)
N/A	19	(7.5%)	(7.5%)	-

4.4.4. Do you agree that residual traces of VMPs in feed, e.g. from carry-over, can increase the occurrence of micro-organisms resistant to antibiotics? -multiple choices reply- (optional)

	Number of requested records	Requested records (252)	% of total number records (252)	% of total number records (246)
Yes	71	(28.2%)	(28.2%)	(28.9%)
No	115	(45.6%)	(45.6%)	(46.7%)
Do not know	60	(23.8%)	(23.8%)	(24.4%)
N/A	6	(2.4%)	(2.4%)	-

5. INFORMATION ON RESPONDENTS

5.2 Please indicate to what category you belong: -multiple choices reply- (compulsory)

	Number of requested records	Requested records (252)	% of total number records (252)
Citizen	41	(16.3%)	(16.3%)
Non-business organisation	31	(12.3%)	(12.3%)
Business organisation / enterprise / farmers	147	(58.3%)	(58.3%)
A public authority	33	(13.1%)	(13.1%)

	Number of requested records	Requested records (147)	% of total number records (252)	% of total number records (147)
Farmer	11	(7.5%)	(4.4%)	(7.5%)
Veterinarian	30	(20.4%)	(11.9%)	(20.4%)
Manufacturer of MF	45	(30.6%)	(17.9%)	(30.6%)
Wholesaler/trader/importer of MF	5	(3.4%)	(2%)	(3.4%)
Pharmaceutical industry, manufacturer of VMPs	51	(34.7%)	(20.2%)	(34.7%)
Trader of VMPs	0	(0%)	(0%)	(0%)
Researcher	0	(0%)	(0%)	(0%)
Other	5	(3.4%)	(2%)	(3.4%)
N/A	0	-	(41.7%)	-

8.12. Summary of the online consultation complemented by the results of targeted consultations

Pretext: The examination of the responses showed that there were, particularly from the business associations and their affiliates, identical responses. As the consultation does not have the pretence to be a representative survey, such responses have been considered and not rejected.

4.1.1 The vast majority of all the respondents (96%) agree that the standards for MF manufacturing have an impact on feed, food and occupational safety.

27 veterinarians (vets) from a total of 30 respondents also agree that the standards for MF manufacturing have an impact on feed, food and occupational safety.

33 public authorities (PA) of a total of 33 agree that the standards for MF manufacturing have an impact on feed, food and occupational safety.

142 farmers & business (F&B) of a total of 147 have answered "yes" to this question.

The Federation of Veterinarians of Europe commented: Mixing & homogenisation can influence individual doses, efficacy of therapy, withdrawal periods & MRLs//Preparation of different MF mix at the same plants may result to additional MRLs, when standards not respected, & consists an AMR risk //occupational risks.

4.1.2 The majority of the respondents (75%) agree that the way MF is manufactured in their MS of origin reflects the appropriate safety level for MF. Some respondents (12%) consider the safety level of their country too high.

24 vets /30 agree that the way MF is manufactured in their MS of origin reflects the appropriate safety level for MF.

22 PA /33 agree that the way MF is manufactured in their MS of origin reflects the appropriate safety level for MF.

111 F&B/147 have answered "yes" to this question.

4.1.3 The vast majority of the respondents (95%) consider that manufacturing standards have an impact on the costs of MF production.

27 vets /30 and 30 PA/33 consider that manufacturing standards have an impact on the costs of MF production.

141 F&B/147 consider that manufacturing standards have an impact on the costs of MF production.

4.1.4 More than half of the respondents (62%) consider the additional costs for the manufacturing of MF to be reasonable. 20% consider them too high.

19 vets /30 and 20 PA /33 consider the additional costs for the manufacturing of MF to be reasonable.

89 F&B/147 consider the additional costs for the manufacturing of MF to be reasonable.

4.1.5 Less than half of the respondents (48%) consider that MF is a practically feasible method for all farming. 40% consider it to be feasible for the vast majority of farming systems. 6% consider it feasible for very few farming systems.

Half of the responding veterinarians and 18 PA/ 33 consider that MF is a practically feasible method for all farming.

75 F&B/147 replied "yes for all" to this question. 60 F&B replied "Not for all, but for the vast majority of farming systems MF is viable and feasible".

The Federation of Veterinarians of Europe commented: In principal it could be feasible for all livestock farmers, but there are technical difficulties to overcome.

Copa-Cogeca commented: Other “routes” of administration of VMPs may be more appropriate for the treatment of individual animals. It only remains a practically feasible method provided that the farms are well equipped for the management and distribution of MF.

The British Veterinary Association commented that MF is not a practically feasible method for all farming, but for the vast majority of farming systems.

IFAH considers MF as a practically feasible method for all farming and comments: medicated feed assures freedom from stress for livestock in all types of farming settings; there is no stress to animals or staff – especially in major groups, individual dosing would be an enormous exercise, possibly resulting in injuries and certainly inducing a level of stress in the herd or flock; medicated feed is universally suitable; in-feed medication is equally appropriate to all sizes of unit and all types of production systems - intensive or extensive; medicated feed allows an uncomplicated therapy method for all livestock farmers, ensuring the prescribed dose is correctly delivered; from the farmer’s perspective medicated feed allows efficient use of the economic resources at farm level (manpower and equipment).

Germany comments: In principal it could be feasible for all livestock farmers. Manufacturers often make deliveries in quantities that are too large for smaller farms. This leads to longer treatment periods, although according to the German Act on Medicinal Products it is possible to sell medicated feed in smaller quantities, it is, in addition, rarely possible to predict what quantities and concentrations will be needed. Reference is here made to the German Guidelines on the Oral Use of Veterinary Medicinal Products in Livestock regarding feed and drinking water. These guidelines compare the typical characteristics of medicated feed with those of orally administered proprietary medicinal products. For example, the guidelines state that medicated feed does not permit a change of active substance or dosage at short notice. From a pharmaceutical perspective, medicated feed must be classified as low-quality medicine. There is, for instance, a considerable risk of under-dosing. Nevertheless, medicated feed is an indispensable and sensible treatment form for larger farms. On account of their various areas of application, both medicated feed and orally administered proprietary medicinal products are indispensable as well as effective and safe when properly administered.

4.1.6 84% of the respondents would prefer action at EU level for the harmonisation and modernisation of the sector.

25 vets /30 and 27 PA / 33 support EU action instead of action at national level.

124 F&B/147 support EU action instead of action at national level.

4.2.1 The respondents are divided on the issue of inclusion rates. Almost half (47%) agree that inclusion rates should be the same throughout the EU and depend only on the manufacturing standard. The other half (47%) of respondents disagrees with this statement.

13 vets /30 and 31 PA /33 agree that inclusion rates should be the same throughout the EU and depend only on the manufacturing standard.

15 vets /30 disagree with this statement.

88 F&B/147 disagree with this statement. 52 F&B agree that inclusion rates should be the same throughout the EU and depend only on the manufacturing standard.

Copa-Cogeca commented: Achieving a "complete" harmonization is neither a realistic nor a desirable approach: levels may vary depending on animal needs, characteristics of domestic production systems, methods of inclusion, ability of the manufacturer, etc.

The British Veterinary Association commented: However, there must be some flexibility in inclusion rates to achieve the correct dosage rate for a particular group of animals and certain age. For example, a dry sow eats about 1% of its bodyweight/day, a lactating sow, 2.5% and a growing pig 5%. Therefore there needs to be flexibility in the inclusion rate to accommodate this to achieve the correct dose in mg drug/kg bodyweight terms.

IFAH considers that inclusion rates should not be the same throughout Europe and comments: The different inclusion rates in the Member States are based on the established good manufacturing practices within the individual countries. These "country inclusion rates" have been set up based on the technologies used in the feed mills in each Member State. Any European harmonization not respecting these established practices and inclusion rates would necessarily impose significant structural, practical, administrative and financial burdens to the feed industry decreasing the competitiveness of the EU livestock farming sector. An option could be to establish a harmonized range of inclusion rates at EU level, embracing the existing national levels and leaving the implementation up to national decisions governed by tried and tested national inspection procedures.

FEFAC commented: Harmonisation of inclusion rates is not technically feasible as what matters is the amount of the active substance in the final feed, which often depends on the dose prescribed by the veterinarian. This is why for a given medicated premixtures, a range of inclusion rates is suitable to allow the medicated feed manufacturer to incorporate the right dose. However, we believe that a minimum inclusion rate should be established at EU level.

France comments: La réponse n'est ni positive ni négative car la question porte plus sur l'équivalence des normes de production au sein de l'Union européenne :

Une norme harmonisée existe : dans la monographie de la pharmacopée européenne no 07/2010 1037, le taux d'incorporation de 0.5% est posé comme un minimum. Cependant, il est possible d'utiliser un autre taux d'incorporation dans des cas exceptionnels justifiés et autorisés. Le taux d'incorporation est pris en compte dans l'évaluation du dossier d'autorisation de mise sur le marché, ils dépendent de la posologie et de la concentration du principe actif autorisé dans le prémélange. Le taux d'incorporation des prémélanges dépend en grande partie des standards de fabrication pour s'assurer que les animaux reçoivent le traitement approprié. En effet, si chaque animal reçoit le bon traitement, les risques de résidus et d'antibiorésistance s'en trouvent réduits. C'est la raison pour laquelle les standards de production des aliments médicamenteux devraient être harmonisés.

4.2.2 70% of the respondents consider that anticipated production of MF may not raise concerns in terms of efficient and safe use of VMPs. 16% consider that it does raise concerns.

22 vets /30 and 17 PA /33 consider that anticipated production of MF may not raise concerns in terms of efficient and safe use of VMPs.

13 PA /33 consider that anticipated production of MF may raise concerns.

119 F&B/147 consider that anticipated production of MF may not raise concerns in terms of efficient and safe use of VMPs.

The Federation of Veterinarians of Europe commented the following: This system creates possibilities for confusion, accidents & potential fraud. 'Anticipated production of MF' might lead to undue pressure on the market to use the already produced MF. Digital technology potentials should be considered for cases of emergency.

EMA commented: Concerns: Potential that MF not within shelf-life (must be ensured for entire duration of treatment); Risk that if MF available at feed mill with "non-ideal" VMP or not ideal dosage, be prescribed/used; Advantages: Cheaper production, quickly available.

IFAH commented: By pre-manufacturing of medicated feed, there is less time lost between the disease diagnosis by the veterinarian and the treatment of the concerned livestock. Even if this time gap can be reduced by the use of an electronic system (like in Belgium) of prescription transmission, it still takes up to 48 hours from the diagnosis until the actual availability of the medicated feed for the animals. By reducing the time gap between the diagnosis and the actual availability of the medicated feed (see point 1 above), the treatment as such will be more efficient and will reduce economic losses in the concerned livestock holding.In addition, the possibility to pre-manufacture medicated feed prior to a veterinarian prescription will allow the feed manufacturer to structure and organize the production of medicated feed in a more efficient and economic way within the feed mill sector and therefore reduce the cost of production. Anticipated or pre-manufacture of medicated feed allows the feed manufacturer to plan medicated feed production such that he can manage unavoidable carry-over more effectively and comply with high quality standards in terms of homogeneity and stability of the mix.

FEFAC answered "no" to this question and commented: There may be concerns but they are effectively addressed through the principle of "no delivery before the prescription is received". On the other hand, pre-manufacturing may reduce the risk of cross-contamination in facilitating the scheduling for the manufacturing of compound feed batches.

France comments: La préoccupation majeure n'est pas la fabrication à l'avance des aliments médicamenteux mais leur distribution au détail immédiate sur présentation d'une ordonnance. C'est pourquoi il est nécessaire de définir un cadre légal explicitant dans quelles conditions et dans quels cas la fabrication à l'avance des aliments médicamenteux peut être effectuée et quelles sont les mesures appropriées qui doivent être prises en conséquence. Certaines espèces ont besoin d'un traitement approprié pour traiter certaines pathologies. Dans ces cas, il convient d'avoir un aliment médicamenteux spécifique dont la fabrication ne peut être anticipée.

UK comments: There is no concern in the UK because stability testing is carried out on medicated feed. Also the medicated feed cannot be released to the owner of the animals to be treated until a prescription is presented. These conditions must be in place. We believe there are sound health reasons for allowing the manufacture of medicated feed in anticipation of a prescription. If this is not permitted, treatment could be delayed by 24 hours. In addition more efficiency in terms of production scheduling can be achieved.

4.2.3 70% of the respondents consider that the use of more than one pre-mix to manufacture MF may not raise safety and efficiency concerns. 17% consider that it does raise concerns.

20 vets /30 respondents consider that the use of more than one pre-mix to manufacture MF may not raise safety and efficiency concerns.

20 PA /33 consider that the use of more than one pre-mix to manufacture MF may raise safety and efficiency concerns.

115 F&B/147 consider that the use of more than one pre-mix to manufacture MF may not raise safety and efficiency concerns.

EMA commented: Question not entirely clear (meant as use of different premixes (=VMPs) per feeding stuff or VMPplus eg. feed additive, in feeding stuff? Thus answer may be misinterpreted. explanation provided separately.

IFAH commented: With good manufacturing practices for medicated feed, including rules for combinations, and under the authority of the veterinarian prescription, there are no concerns in terms of safe and efficient use of VMPs. The ability to combine premixes in one medicated feed allows the veterinarian to opt for the best treatment. The experience of those countries, where combinations are authorized, shows that this option can help to improve animal health and animal welfare, without compromising safety and efficiency.

Federal Ministry of Food, Agriculture and Consumer Protection of Germany commented: The use of more than one premix raises concerns, yet principally, the possibility to mix in more than one premix per MF should survive. Use of more than one premix (VMP), or the use of a premix and feed additive in the same feeding stuff may increase the risk of incompatibilities between the active substances of the premix, or the active substance of the premix and a feed additive, means the safety or potency might be affected. Within the authorisation process of premixes (VMP), the applicant should substantiate any claims of compatibility. Substances should be listed with which the premix is known to be compatible or incompatible. Mixing different antimicrobials in a MF could support development of antimicrobial resistance. For animal welfare reasons it should be a possibility to allow, only on prescription, based on a decision of a competent veterinarian, the manufacture of MF to use more than one premix in cases if a combination of different active substances is necessary to treat a specific condition.

The Federal Chamber of Veterinary Surgeons in Germany commented: Where several pre-mixes are simultaneously added to medicated feed there is, from

the pharmacological perspective, a risk of unmanageable interactions. Under

German law, the mixing in of a maximum of three pre-mixes with no more than two antibacterial substances is permitted. There are, however, situations in which the treatment necessitates the use of several pre-mixes.

France considers that the use of more than one pre-mix to manufacture MF raises safety and efficacy concerns.

UK comments: There may be concerns, however in the UK we allow this practice and it is the vet's responsibility to check that there are no contra-indications which are set out in the summary of product characteristics of the marketing authorisation. It is recognised that this cannot cover every scenario, however we do not have evidence under our residue surveillance or suspected adverse reactions schemes to suggest a problem.

4.2.4 More than half of the respondents (64%) agree that mobile mixers respect the homogeneity and compatibility requirements to manufacture MF. 20% do not know.12% do not agree with the statement above.

22 vets /30 and 19 PA /33 agree that mobile mixers respect the homogeneity and compatibility requirements to manufacture MF.

101 F&B/147 agree that mobile mixers respect the homogeneity and compatibility requirements to manufacture MF.

Germany comments: it might theoretically be feasible; however this is not realistic in practice. Medicated feed that is manufactured on-farm in mobile mixers is not homogenously blown out when being blown into a storage container because the structure of the feed varies. This results in different feed structures in the storage silo due to the high airspeed, and thus in varying pre-mix concentration in the medicated feed.

4.2.5 More than half of the respondents (65%) agree that on-farm manufacture of MF can meet the homogeneity and compatibility requirements for MF. 20% do not agree with the statement above and 11% do not know.

22 vets /30 and 15 PA /33 agree that on-farm manufacture of MF can meet the homogeneity and compatibility requirements for MF.

11 PA /33 consider that on-farm manufacture of MF cannot meet the homogeneity and compatibility requirements for MF.

106 F&B/147 agree that on-farm manufacture of MF can meet the homogeneity and compatibility requirements for MF.

Federal Ministry of Food, Agriculture and Consumer Protection of Germany commented: In Germany the on-farm manufacturing of a MF is forbidden.

FEFAC comments: Although there is no EU standard for homogeneity, FEFAC answered “yes” to this question, based on the existing practical standards used by the feed manufacturers. However, it must be clear that there cannot be different requirements for compound feed mills vs. on-farm manufacturers and controls should be exerted the same.

4.3.1 The majority of the respondents (86%) consider that transport of MF from the manufacturing feed mill to the farm may not significantly reduce the homogeneity of the feed.

26 vets /30 and 23 PA /33 consider that transport of MF from the manufacturing feed mill to the farm may not significantly reduce the homogeneity of the feed.

136 F&B/147 consider that transport of MF from the manufacturing feed mill to the farm may not significantly reduce the homogeneity of the feed.

4.3.2 Half of the respondents consider that the use of MF does not reduce the flexibility and thus the willingness to change a treatment when compared to other methods of oral administration of VMPs.. Less than half of the respondents (42%) consider that the use of MF reduces the flexibility and the willingness to change a treatment.

Half of the respondent veterinarians and 20 PA /33 consider that the use of MF reduces the flexibility and the willingness to change a treatment.

14 vets /30 consider the contrary.

78 F&B/147 consider MF does not reduce flexibility in changing a treatment.

63 F&B consider that it does reduce flexibility.

4.3.3 The respondents are divided on the question of left overs of MF on the farm. 40% consider that it does not cause problems, whereas 54% considers the contrary.

17 vets /30 consider that left overs of MF on the farm may not cause problems.

11 vets /30 and 24 PA /33 consider that left overs may cause problems.

87 F&B/147 consider leftovers may not raise concerns.

55 F&B consider the contrary.

The Federation of Veterinarians of Europe commented that: left overs represent money & will always be used, for example in animals which do not need medication & where no withdrawal time is considered, eg: weaned piglets. This contributes to irresponsible use of VMP & may be unnecessary increased risk of AMR.

EMA commented: concern of continued administration of "leftovers" to same or other animals when no longer necessary (potential for AMR development and problems re residues in food). If inappropriate disposal it may lead to negative impact on environment.

The Federal Chamber of Veterinary Surgeons in Germany commented: Please refer to the German Guidelines on the Oral use of Veterinary Medicinal Products in Livestock regarding feed and drinking water. The guidelines state that all equipment and facilities that come into contact with medicated feed or feed/drinking water with pre-mixed OA.F (spades, pipes, troughs etc) are subsequently contaminated with the active substance. This can lead to the carryover of the active substance and, possibly, to uninvolved animals absorbing the active substance. Along with the danger of developing antimicrobial resistance, this can also lead to positive residue findings in food as well as to complaints under feed law (cf. the requirements set out in Regulation (EC) No 183/2004). Equipment and facilities that have come into contact with the medicated feed/drinking water must therefore be cleaned by the livestock owner. The livestock owner must take suitable measures to avoid carry-over. This risk is minimised by having separate feed pipes or feeding straight from a trough.

France considers that leftovers may constitute a problem.

Germany comments: A continued administration of “leftovers” to same or other animals, may lead to antimicrobial resistance development or residues in food of animal origin. “Leftovers” disposed of inappropriately, may lead to negative impact on environment.

4.3.4 The vast majority of the respondents (90%) consider that the MF method has advantages in terms of animal welfare over medication that is not administered orally.

23 vets /30 and 29 PA /33 consider that the MF method has advantages in terms of animal welfare over medication that is not administered orally.

134 F&B/147 consider that the MF method has advantages in terms of animal welfare over medication that is not administered orally.

The British Veterinary Association commented: Medicated feed is an essential route for the treatment of fish, whether antiparasitic or antimicrobial and is even used for vaccine boosters. Sick fish cannot be handled and moved easily to be treated by bath administration, and in any case, absorption through the skin is extremely variable and cannot be relied upon as a universal route of administration, even were it feasible for other reasons.

In addition, all licensed products are designed and licensed to be used via the oral route.

4.3.5 The vast majority of the respondents (90%) agree that prescription rules for VMPs and MF should be identical.

28 vets /30 and 28 PA /33 agree that prescription rules for VMPs and MF should be identical.

133 F&B/147 agree that prescription rules for VMPs and MF should be identical.

FEFAC answered "yes" to that question, assuming that the question was meant to tackle harmonisation of the rules for the prescription of e.g. a vaccine or a medicated feed to an animal. If the question was meant to call for the prescription rules for MF to also apply to the delivery of medicated premixtures to compound feed manufacturers, then we would disagree.

UK comments: There should be equivalence rather than the need for them to be identical. In principle, the prescriptions should be the same in that a written prescription must be given if the supplier is not the prescriber. An oral (verbal) prescription would not be appropriate in such a case as information on inclusion rates, dosage and handling precautions will need to be in writing

4.3.6 The vast majority of the respondents (91%) consider that MF should only be prescribed by veterinarians.

29 vets /30 and 28 PA /33 consider that MF should only be prescribed by veterinarians.

134 F&B/147 consider that MF should only be prescribed by veterinarians.

4.4.1 The majority of the respondents (80%) consider that the MF method, compared to other methods of oral administration of VMPs presents lower risks in terms of occupational health.

22 vets /30 and 21 PA /33 consider that the MF method, compared to other methods of oral administration of VMPs presents lower risks in terms of occupational health.

124 F&B/147 consider that the MF method, compared to other methods of oral administration of VMPs presents lower risks in terms of occupational health.

Federal Ministry of Food, Agriculture and Consumer Protection of Germany commented: The risk depends on the conditions on the farm, which equipment is available/used, who is involved in administration of medicine or MF, the number of animals treated, and the availability of alternative medication etc.

UK comments: We have answered yes, but it would depend on the VMP being prescribed for the MF. In the UK we only allow veterinary surgeons to prescribe premixes for medicated feed, including antimicrobials. This should remain the case. The exception is in-feed anthelmintics which can be prescribed by pharmacists and suitably qualified persons which the UK would continue to support.

4.4.2 The vast majority of the respondents (91%) consider that residues of VMPs in non-target feed may not be totally excluded in practice.

26 vets /30 and 30 PA /33 consider that residues of VMPs in non-target feed may not be totally excluded in practice.

136 F&B/147 consider that residues of VMPs in non-target feed may not be totally excluded in practice.

4.4.3 The respondents are divided on the issue of awareness of any tolerance levels for carry-over of non target species VMP's in their MS of origin. 38% are aware of the existence of such tolerance levels, whereas 27% of the respondents claim they do not exist in their country and 25% do not know of their existence.

11 vets /30 say that in their MS there are no tolerance levels.

11 vets /30 say they are not aware of their existence.

6 vets /30 and 19 PA /33 say that such tolerance levels exist in their country.

63 F&B/147 are aware of tolerance levels, 36 say there aren't any and 35 say they are not aware.

IFAH commented: Technically there are no “non target species VMPs”, so we understand the question as asking about existing national carry-over levels of VMPs in non target species feed (medicated feed or other types of feed); There are indeed countries that follow a so-called “zero-tolerance” approach which makes MF production technically impossible, since carry-over is technically unavoidable (see above).Other countries have established carry-over limits in the framework of their national GMP.

France comments: En France, on ne parle pas de seuil de tolérance mais les fabricants doivent se livrer chaque année à une validation des équipements de mélange afin de prouver qu'ils sont en mesure de réduire les contaminations croisées. Les méthodes pour tester les équipements sont décrites dans une décision française du 12 février 2007 relative à la préparation et à la distribution en gros des aliments médicamenteux. "

4.4.4 The respondents are divided on the question of antimicrobial resistance occurring from the residual traces of VMPs in feed.28% consider that VMPs residues may increase the occurrence of antimicrobial resistance. 45% consider the contrary and 23% do not know.

17 vets /30 consider VMPs residues may not increase the occurrence of antimicrobial resistance. 9 vets / 30 consider the contrary.

28 PA /33 consider that residues of VMPs may increase the occurrence of antimicrobial resistance.

81 F&B/147 consider VMPs residues may not increase the occurrence of antimicrobial resistance. 40 F&B do not know and 22 F&B think it may increase AMR.

EMA commented: Residual traces of antibiotics can increase occurrence of resistance; increase depends on many factors eg. active substance, baseline resistance, amount carried over, no. or mass of animals treated; not possible to quantify pharmacological efficient level.

8.13. Aggregated data base and assumptions for the modelling

Medicated Feed for pets:

Based on information from the few companies already in this business (SMEs), the current turnover is estimated to be in the order of € 5 mio. The high willingness of pet owners to pay for the food and treatment of their pets results in a lower price elasticity for pet food. Also innovative market segments allow the supplier to enforce high prices. Therefore, a gross profit margin of 30% is assumed, which is plausible with the cost-price situation of the medicated feed for pets already on the market.

If all limitations for the expansion of medicated pet food are removed, the additional potential for the short term is 10 fold the current volume. The increase could be tremendous for the midterm: Based on estimated numbers of 2,9 mio. chronically diseased dogs and 5,5 mio. chronically diseased cats (no application of antibiotics) in the EU, the potential market is in the order of one billion €.

Segmentation of the current medicated feed production in order of manufacturing standards:

Based on the FCEC-report and additional surveys it can be assumed that roughly half of the current MF-volume is produced at low standards (FR, PT, ES, IT, CZ, PL). The high cost group contains AT, DE, FI, LU, NL, SE, SI.

	Scenario 1	Scenario 2
low standards:	50%	65%
appropriate standards:	25%	25%
very high standards:	25%	10%

Medicated feed manufacturing for food production animals:

To cope with the potential tolerance levels for carry-over of antimicrobials into feed, separated lines in the compound feed mills for medicated feed would be needed. According to an industry survey, plausible additional costs for separated lines (investment in equipment and logistics € 1 mio / site with 20000 t capacity, € 2 mio / site with 50000 t capacity) are estimated at app € 6 / t medicated feed including additional labours costs. The additional equipment for a mobile mixer is estimated to be € 25000 / truck for a yearly capacity of 1000 t. The total additional costs for medicated feed including extra labour are app € 5 / t. These figures have been cross checked with the FCEC-survey.

An industry survey indicates that the recall costs of not used medicated feed from farms would amount € 7-15 / t for logistics and € 100 / t for disposal (land fill). All stakeholders consider residual quantities as extremely exceptional. In case of 1% medicated feed that must be recalled, the cost share to be added to the medicated feed price is € 1 / t .

The cost increase in Member States with low standards is assumed to be for 50% of production € 4 / t and 50% of production € 7 / t.

Considering the current cost delta of almost € 70 / t, cost benefits of € 10 – 25 / t for the current high standard production are realistic. Cost reduction in Member States with very high standards: 50% of production: € 10 / t and 50% of production: € 25 / t.