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## COVER NOTE

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From:	Secretary-General of the European Commission, signed by Mr Jordi AYET PUIGARNAU, Director
date of receipt:	16 February 2015
To:	Mr Uwe CORSEPIUS, Secretary-General of the Council of the European Union

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Subject:	REPORT FROM THE COMMISSION TO THE EUROPEAN PARLIAMENT AND THE COUNCIL on the functioning of 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

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Delegations will find attached document COM(2015) 56 final.

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Encl.: COM(2015) 56 final



Brussels, 16.2.2015  
COM(2015) 56 final

**REPORT FROM THE COMMISSION TO THE EUROPEAN PARLIAMENT AND  
THE COUNCIL**

**on the functioning of 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**

# **REPORT FROM THE COMMISSION TO THE EUROPEAN PARLIAMENT AND THE COUNCIL**

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## **I. INTRODUCTION**

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 (hereinafter: 'Regulation (EC) No 470/2009')<sup>1</sup> establishes maximum residue limits and reference values ('reference points for action') for pharmacologically active substances present in food obtained from animals.

A maximum residue limit (MRL) is the maximum concentration of a residue of a pharmacologically active substance which may be permitted in food of animal origin. A reference point for action (RPA) is the level of residue of a pharmacologically active substance established for monitoring purposes in the case of certain substances for which a maximum residue limit has not been laid down.

Regulation (EC) No 470/2009 entered into force on 6 July 2009. Article 28 thereof requires the Commission to report to the European Parliament and the Council on the experience gained from applying the Regulation by 6 July 2014, i.e. after it has been in force for five years.

## **II. BACKGROUND AND DATA COLLECTION**

### **1. Background**

The use of veterinary medicines on food-producing animals may leave residues in food derived from those animals that can be harmful to humans. While the pharmacological effects of medicinal products are necessary for the effective treatment of animals, consumers should be protected from them.

The process for establishing a maximum residue limit begins with an application to the European Medicines Agency (EMA). The EMA's Committee for Medicinal Products for Veterinary Use (CVMP) assesses the data in the application and prepares the EMA's opinion. On the basis of this opinion, the Commission drafts an implementing act in consultation with Member States.

Since the mid-1960s, national authorities in the Member States have imposed safety requirements on veterinary medicinal products intended for food-producing animals to ensure that food derived from treated animals is safe for human consumption. In order to facilitate a harmonised approach to the scientific assessment of residues and to avoid barriers to the free movement of food of animal origin, the Council adopted Regulation (EEC) No 2377/90 of 26 June 1990 laying down a Community procedure for the establishment of maximum residue limits of veterinary medicinal products in food of animal origin.<sup>2</sup> That Regulation was subsequently repealed and replaced by Regulation (EC) No 470/2009.

Regulation (EC) No 470/2009 was established with the aim of tackling the following problems which were identified as a result of applying Regulation (EEC) No 2377/90:

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<sup>1</sup> OJ L 152, 16.6.2009, p.11.

<sup>2</sup> OJ L 224, 18.8.1990, p.1.

- the legislation was difficult to understand owing to its complex system for categorising substances;
- substances used safely for many years in veterinary medicines for food-producing animals were suddenly banned;
- the detailed scientific data required for establishing MRLs created a high cost burden for industry and contributed to a decrease in applications for authorisations for new veterinary medicines;
- international standards supported by the EU could not be included in EU legislation without further scientific assessment by the EMA;
- the monitoring authorities in the Member States had no reference values for many substances, in particular those detected in food from outside the EU. In such cases, it was difficult for regulatory authorities to establish compliance and there was no EU-level procedure for conducting a scientific evaluation that could lead to harmonised residue limits and controls.

In addition, one of the main problems in the veterinary sector at the time of drafting Regulation (EC) No 470/2009 was the lack of availability of authorised veterinary medicines.

Regulation (EC) No 470/2009 ensures that substances intended for use on food-producing animals are assessed for their harmful potential and that consumers of food of animal origin are adequately protected. It helps to determine ‘withdrawal periods’ when granting marketing authorisations for veterinary medicinal products. A withdrawal period is a period after treatment during which an animal must not be slaughtered or during which milk, eggs or honey must not be taken for human consumption, to ensure that maximum residue limits are not exceeded. Under Directive 2001/82/EC<sup>3</sup>, pharmacologically active substances intended for use on food-producing animals must have MRLs before a marketing authorisation for the related veterinary medicinal product can be granted. A lack of MRLs which apply to certain animal species will lead to a lack of authorised veterinary medicines for treating those species. It is therefore vital that as many pharmacologically active substances as possible are evaluated in accordance with Regulation (EC) No 470/2009.

All the pharmacologically active substances that have been assessed in accordance with Regulation (EC) No 470/2009 are listed and classified in alphabetical order in Commission Regulation (EU) No 37/2010<sup>4</sup>, which was adopted on the basis of Article 27 of Regulation (EC) No 470/2009. This Regulation contains two separate tables: one for authorised substances, and one for prohibited substances.

Commission Regulation (EU) No 37/2010 has been amended over 40 times by Commission implementing regulations amending or adding MRLs. Currently, 641 pharmacologically active substances are listed in Table 1 and nine pharmacologically active substances are listed in Table 2 (prohibited substances). In addition, food additives with a valid E number which are approved for human consumption are classified as ‘No MRL required’.<sup>5</sup>

## 2. Data collection

In May 2014, a questionnaire about Regulation (EC) No 470/2009 was published on the ‘Your Voice in Europe’ website and paper versions were sent to the EMA, national public authorities, businesses and non-business stakeholders.

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<sup>3</sup> Directive 2001/82/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to veterinary medicinal products (OJ L 311, 28.11.2001, p.1).

<sup>4</sup> Commission Regulation (EU) No 37/2010 of 22 December 2009 on pharmacologically active substances and their classification regarding maximum residue limits in foodstuffs of animal origin (OJ L 15, 20.1.2010, p.1).

<sup>5</sup> See the ‘food additives’ section of Table 1 in the Annex to Regulation (EU) No 37/2010.

The number of responses received is indicated in the table below (respondents declared themselves to be ‘business’ or ‘non-business’):

<b>THE ‘YOUR VOICE IN EUROPE’ SURVEY SAMPLE</b>		
<b>PUBLIC AUTHORITIES</b>	<b>BUSINESSES</b>	<b>NON-BUSINESS</b>
32 (67%)	11 (23%)	5 (10%)

The responses received came from a broad cross-section of the various stakeholders involved in MRL policy:

- Public authorities – from 24 Member States (i.e. 86% of the Member States) and from some non-EU countries;
- Businesses;
- Non-business.

A full list of respondents can be found in Annex I.

The findings of the questionnaire were presented to stakeholders and Member States and they were given the opportunity to comment on the following occasions:

- 27 June 2014: at the Animal Health Advisory Committee – for stakeholders (industry, veterinarians and consumers).
- 2 July 2014: at the Standing Committee on Veterinary Medicinal Products – for Member States and the EMA.

### **III. FINDINGS OF THE QUESTIONNAIRE**

The following conclusions can be drawn from the findings of the questionnaire. The responses to the questionnaire are provided in graph form in Annex II.

#### **1. Scope**

For the purpose of ensuring food safety, Article 1 of Regulation (EC) No 470/2009 states that the Regulation lays down rules and procedures in order to establish (i) the maximum concentration of a residue of a pharmacologically active substance permitted in food of animal origin (MRL – maximum residue limit), and (ii) the level of a residue of a pharmacologically active substance for which an MRL has not been laid down (RPA – reference point for action).

When stakeholders and Member States were asked if the scope of Regulation (EC) No 470/2009 was appropriate, 80% responded positively. As regards possible improvements to the scope of the Regulation, a minority of respondents said that the scope may need to be adjusted with regard to scientific assessment and to risk management, e.g. in relation to the development of new biological products.

#### **2. Scientific risk assessment and risk management procedures**

An organisation wishing to have an MRL established or amended must submit an application to the EMA along with sufficient data to demonstrate the safety of the pharmacologically active substance, including the depletion of its residues in animals, and the details of analytical methods for detecting the substance and its metabolites.

The basic principle for setting MRLs is that the residue of the substance consumed in food of animal origin must not exceed the acceptable daily intake (ADI). The ADI is established by the EMA on the basis of the scientific information available and indicates the level of the substance or its metabolites which would not affect human health. On the basis of the CVMP's opinion, a Commission regulation establishing the MRL is adopted, supplementing or amending the classification contained in Regulation (EU) No 37/2010.

The scientific risk assessment examines the metabolism and depletion of pharmacologically active substances in relevant animal species, the type of residues, and the amount thereof that may be ingested by human beings over a lifetime without an appreciable health risk expressed in terms of ADI.

The scientific risk assessment is a key element of Regulation (EC) No 470/2009 and so it is essential that it achieves its purpose. The Commission has received positive feedback regarding this provision and the current methods of establishing MRLs and ADIs, with 80 % of respondents stating that there was an adequate balance between food safety and the availability of veterinary medicines.

In addition, the scientific risk assessment may take into account monitoring and exposure data if the metabolism and depletion of the substance cannot be assessed. This specific provision in Article 6(3) of Regulation (EC) No 470/2009 is considered useful (75 % of respondents).

EMA opinions must include a scientific risk assessment and risk management recommendations. Article 13(2)(a) of Regulation (EC) No 470/2009 requires the Commission to adopt measures regarding the methodology of the risk assessment and the risk management recommendations. Respondents to the questionnaire said that it would be beneficial if the Commission were to adopt further legal measures to implement this requirement.

### **3. Classification of pharmacologically active substances: special cases**

Where scientific data are incomplete, Regulation (EC) No 470/2009 allows for the possibility of establishing a provisional MRL classification. This is laid down in Article 14(2)(b) and (4) and is considered to be one of the most useful elements of the Regulation (90% of respondents). The provisions of Article 14(2)(b) and (4) are used in situations where there is no health risk associated with the lack of data, e.g. the analytical method proposed by the applicant for monitoring of residues does not fulfil the criteria for a confirmatory method but is appropriate for monitoring purposes. This provisional MRL classification is particularly appreciated as it does not delay the filing of an application for a marketing authorisation of a veterinary medicinal product.

Article 14(2)(c) allows pharmacologically active substances to be classified as 'No MRL required'. Under Regulation (EC) No 470/2009 there is no need to establish an MRL if the substance is considered safe at the residue level to be expected in food of animal origin. This classification is considered useful since it explicitly acknowledges the absence of consumer safety concerns associated with a specific substance.

### **4. Number of applications**

A 2011 survey, *Benchmarking the Competitiveness of the Global Animal Health Industry*,<sup>6</sup> showed that since Regulation (EC) No 470/2009 entered into force in 2009, the negative impact of MRL legislation on companies has slightly decreased.

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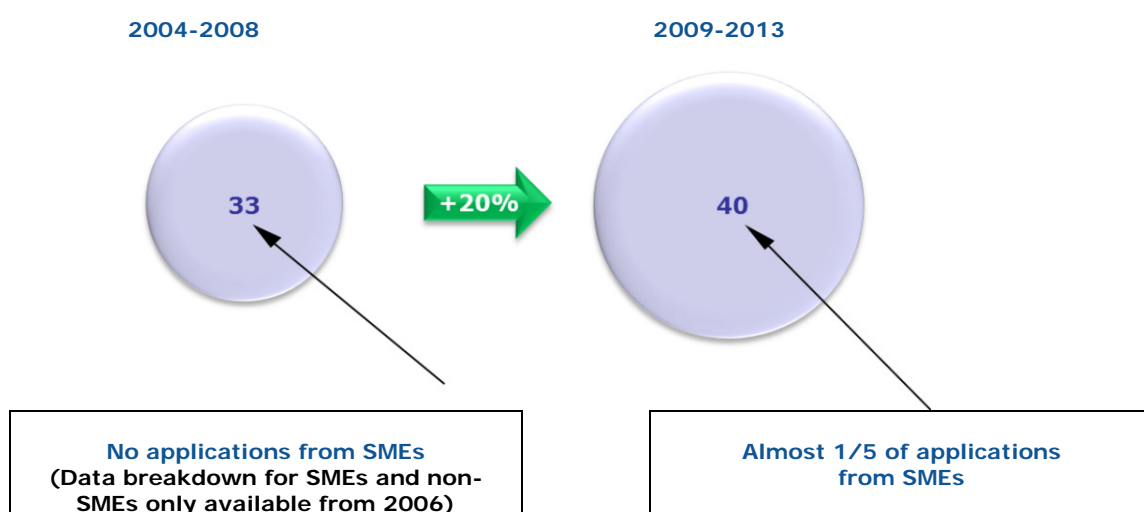
<sup>6</sup> BioBridge Ltd., (2012) 'Benchmarking the Competitiveness of the Global Animal Health Industry', 2011 Survey for IFAH-EUROPE.

Between 2009 and 2013, the number of applications for establishment of MRLs submitted to the EMA increased by over 20% compared to the five years preceding the Regulation's entry into force, with the number of applications rising from 33 to 40. Furthermore, since the entry into force of Regulation (EC) No 470/2009, almost 20% of the applications submitted have come from SMEs.

Overall, the increase in the number of applications is encouraging, as it shows that there is a certain amount of innovation in veterinary medicinal products and confirms that SMEs are willing and able to place veterinary medicines on the market in the EU.

The diagram below illustrates the number of applications for an EMA opinion submitted under the Council Regulation (EEC) No 2377/90 (between 2004 and 2008) and under the Regulation (EC) No 470/2009 (between 2009 and 2013):

**Number of applications for an EMA opinion submitted from 2004–2008 and from 2009–2013  
(Article 3 of Regulation (EC) No 470/2009)**



## 5. Extrapolation

In order to address concerns about the lack of availability of veterinary medicines for food-producing animals, an extrapolation principle was included in Article 5 of Regulation (EC) No 470/2009. It stipulates that a maximum residue limit established for substances in a particular food can be used for establishing the MRL for another food obtained from the same or another species. For every MRL application, the EMA will consider whether an established MRL can be extrapolated, without additional data, to other foods or other species.

Since 2009, the EMA has recommended the extrapolation of 13 substances to additional animal species or foods (e.g. fin fish, goats and poultry species). About 70% of the extrapolations occurred between 2012 and 2013. Moreover, each time extrapolation was recommended, it included minor species.

Member States, veterinarians and industry representatives have stated that the extrapolation principle has a good impact on the availability of authorised veterinary medicinal products – especially when it results in MRLs for minor species. It has reduced the research, expenditure and risks associated with developing new products as the applicant does not need to provide additional data.

The adoption of an implementing measure by the Commission would provide additional clarity to the EMA and businesses and may promote the use of this provision.

The table below summarises MRL extrapolation between 2009 and 2013:

Year	Substance(s) for which extrapolation was recommended	Animal species	Minor species
2009	Tildipirosin	From bovine, pigs to goats	Yes
2010	Isoeugenol	From salmon to (other) fin fish	Yes
2011	Fenbendazole	From all ruminants, pigs, horses and chicken to all (other) food producing species, except fish	Yes
	Monepantel	From sheep milk to goats milk	Yes
2012	Eprinomectin	From cattle and sheep to goats	Yes
	Diclazuril	From chicken to all (other) poultry species	Yes
	Manganese carbonate	From bovine to all (other) food producing species	Yes
	Neomycin	Modification to bovine MRLs to all (other) food producing species	Yes
	Phoxim	From bovine, sheep, pigs and chicken to (all other full food producing species)	Yes
2013	Butafosfan	From cattle and porcine to all (other) mammalian food producing species	Yes
	Chloroform	All ruminants, porcine to all (other) mammalian food producing species	Yes
	Triptorelin acetate	Porcine to all (other) food producing species	Yes
	Lufenuron	Atlantic salmon and rainbow trout to other Fin fish	Yes
2014 (January - April)	Barium selenate	Bovine/ovine to all (other) food producing species	Yes

## 6. Codex Alimentarius

The Codex Alimentarius Commission was created in 1963 by the Food and Agriculture Organisation of the United Nations (FAO) and the World Health Organisation (WHO) to develop food standards. Codex Alimentarius's role is to protect the health of consumers, ensure fair practices in the international food trade and promote the coordination of all work on food standards undertaken by international governmental and non-governmental organisations.

The EU and the Member States draw up EU position papers on issues discussed by the Codex Alimentarius Commission. Consistency between international standards and EU legislation on residue limits in food has been further enhanced by Regulation (EC) No 470/2009.



Under Article 14(3)(b) of Regulation (EC) No 470/2009, MRLs can be laid down in the EU following a Codex Alimentarius decision, provided that the scientific data taken into consideration are made available to the EU Delegation before the Codex decision is made. In this case, an additional assessment by the EMA is not required. Over 80% of respondents to the questionnaire said this provision was useful as it offers the veterinary pharmaceutical industry greater certainty that the EU will adopt Codex MRLs and provides an incentive for developing new medicinal products. However, it should be noted that this provision has not yet been used.

### **7. Controlling and monitoring veterinary medicinal products from third countries**

The Commission or a Member State can request an opinion from the EMA on a substance used in a veterinary medicine authorised in a third country but not in the EU. This facilitates the harmonised approach to the control of residues in imported products of animal origin. In the questionnaire, 90% of respondents felt that applying for an opinion was useful for monitoring and controlling residues in animal products.

### **8. Rules on placing food of animal origin on the market**

Article 23 of the Regulation (EC) No 470/2009 states that food of animal origin containing residues of pharmacologically active substances can be placed on the market only if it complies with an established MRL. 70% of respondents consider this provision appropriate. Although the provision works well in general, respondents have argued that additional provisions, such as expanding MRLs to other species or tissues and providing less stringent provisions for bulking agents, could improve the legislation without adversely affecting consumer safety.

### **9. Reference points for action**

Allocating MRLs for pharmacologically active substances is one of the many measures taken to ensure food safety. In addition, articles 18, 19 and 20 of Regulation (EC) No 470/2009 lay down rules on establishing reference values for the control of residues in food of animal origin for prohibited or non-authorised substances.

The Commission can establish RPAs under Regulation (EC) No 470/2009 for pharmacologically active substances that are prohibited or currently not authorised under EU legislation. The RPAs constitute, like MRLs, a reference value for monitoring residues in food of animal origin. A food product cannot legally be placed on the EU market if an RPA has been exceeded. The setting of RPAs should, however, in no way serve as a pretext for allowing the illegal use of prohibited or non-authorised substances to treat food-producing animals (cf. Recital 25 of Regulation (EC) No 470/2009).

The respondents to the survey were of the opinion that establishing RPAs would help to ensure the effectiveness of checks on food of animal origin imported into or placed on the EU market as they would have established reference values for potential action to be taken. So far, no RPAs have been established by the Commission under the Regulation (EC) No 470/2009.

## **IV. CONCLUSIONS**

Regulation (EC) No 470/2009 has achieved its purpose of protecting public health and safeguarding animal health and welfare.

Regulation (EC) No 470/2009 has contributed to an increase in the number of MRL applications and in the use of the extrapolation principle to extend existing MRLs to other species. This was one of the main objectives of revising Council Regulation (EEC) No 2377/90 and introducing Regulation (EC) No 470/2009. This in turn has helped to safeguard public health as consumer exposure to pharmacologically active substances is limited because clear reference values are provided for the monitoring of residues in food. The increase in the number of established MRLs has also helped to

protect animal health, as a lack of MRLs for certain species leads to a lack of authorised veterinary medicines to treat diseases in those species. Recently, accessibility was further improved by means of an online MRL database.

Overall, Member States, businesses, non-business stakeholders and the EMA regard their experience with Regulation (EC) No 470/2009 as positive. Nonetheless, as it can be seen in Annex II, the views on particular issues may vary between different stakeholders. This can be explained notably by their differing perspectives when applying the Regulation No 470/2009 (e.g. competent authorities versus pharmaceutical companies or veterinarians).

Substantial improvements have been made compared to the previous legislation on establishing MRLs. The drafting of implementing measures as required by Article 13 of Regulation (EC) No 470/2009 should bring further improvements.

At the same time, it is important to note that the true impact of Regulation (EC) No 470/2009 will only become clear as experience is gained in the longer term. Furthermore, it should be pointed out that it would be wrong to expect Regulation (EC) No 470/2009 to solve all the issues in the veterinary medicines sector. The lack of availability of veterinary medicinal products in the EU is being addressed in the amendments to the relevant legislation for which the Commission adopted a proposal on 10 September 2014, and which are currently being discussed in European Parliament and Council.

**ANNEX I**  
**List of respondents to the survey**

**I. PUBLIC AUTHORITIES**

1. AUSTRIA: Bundesministerium für Gesundheit (BMG);
2. BELGIUM: Agence Fédérale des Médicaments et des Produits de Santé (AFMPS) / Agence Fédérale pour la Sécurité de la Chaîne Alimentaire (AFSCA);
3. CROATIA: Ministarstvo Poljoprivrede;
4. CYPRUS: Υπουργείο Γεωργίας, Φυσικών Πόρων και Περιβάλλοντος, Κτηνιατρικές Υπηρεσίες;
5. CZECH REPUBLIC: Ústav pro Státní Kontrolu Veterinárních Biopreparátů a Léčiv (USKVBL) / Státní Veterinární Správa (SVS);
6. DENMARK: Fødevarestyrelsen (FVST);
7. EUROPEAN UNION: Committee for Medicinal Products for Veterinary Use (CVMP);
8. FINLAND: Jord- och skogsbruksministeriet;
9. FRANCE: Ministère de l'Agriculture;
10. GERMANY: Bundesamt für Verbraucherschutz und Lebensmittelsicherheit (BVL) x2;
11. Institut für Hygiene und Umwelt; Bundesministerium für Ernährung und Landwirtschaft (BMEL);
12. GREECE: Εθνικός Οργανισμός Φαρμάκων (EOF);
13. IRELAND: Department of Agriculture Food & the Marine (DAFM) & The Irish Medicines Board (IMB);
14. ITALY: Ministero della Sanità;
15. LATVIA: Pārtikas un veterinārais dienests (PVD);
16. LITHUANIA: Valstybinė Maisto ir Veterinarijos Tarnyba (VMVT);
17. MALTA: Gvern ta' Malta;
18. NETHERLANDS: Ministerie van Economische Zaken;
19. POLAND: Urząd Rejestracji Produktów Leczniczych (URPL);
20. PORTUGAL: Direção-Geral de Alimentação e Veterinária (DGAV);
21. ROMANIA: Institutul pentru Controlul Produselor Biologice si Medicamentelor de Uz Veterinar (ICBMV);
22. SLOVAKIA: Štátna Veterinárna a Potravinová Správa (ŠVPS) / Ústav štátnej kontroly

veterinárnych biopreparátov a liečiv (USKVBL);

23. SLOVENIA: Vlada Republike Slovenije;
24. SPAIN: Agencia Española de Medicamentos y Productos Sanitarios (AEMPS); Ministerio de Sanidad, Servicios Sociales e Igualdad (MSSSI);
25. SWEDEN: Lakemedelsverket;
26. TURKEY: T.C. Gıda Tarım ve Hayvancılık Bakanlığı;
27. UNITED KINGDOM: Department for Environment Food & Rural Affairs (DEFRA);
28. UNITED STATES OF AMERICA: Food and Drug Administration (FDA) Health and Human Services (HHS).

## **II. BUSINESSES**

1. Bayer
2. CEVA
3. Elanco Animal Health
4. IFAH-Europe
5. KLIFOVET AG
6. Laboratoire Boiron
7. Laboratoire TVM
8. Novartis
9. Sea Food Alliance
10. The Danish Agriculture & Food Council
11. TSGE Consulting Ltd

## **III. NON-BUSINESS**

1. Bundestierärztekammer (BTK)
2. Private veterinarian
3. European Coalition on Veterinary Homeopathy (ECVH)
4. European Federation of Honey Packers and Distributors (FEEDM)
5. Federation of Veterinarians of Europe (FVE)

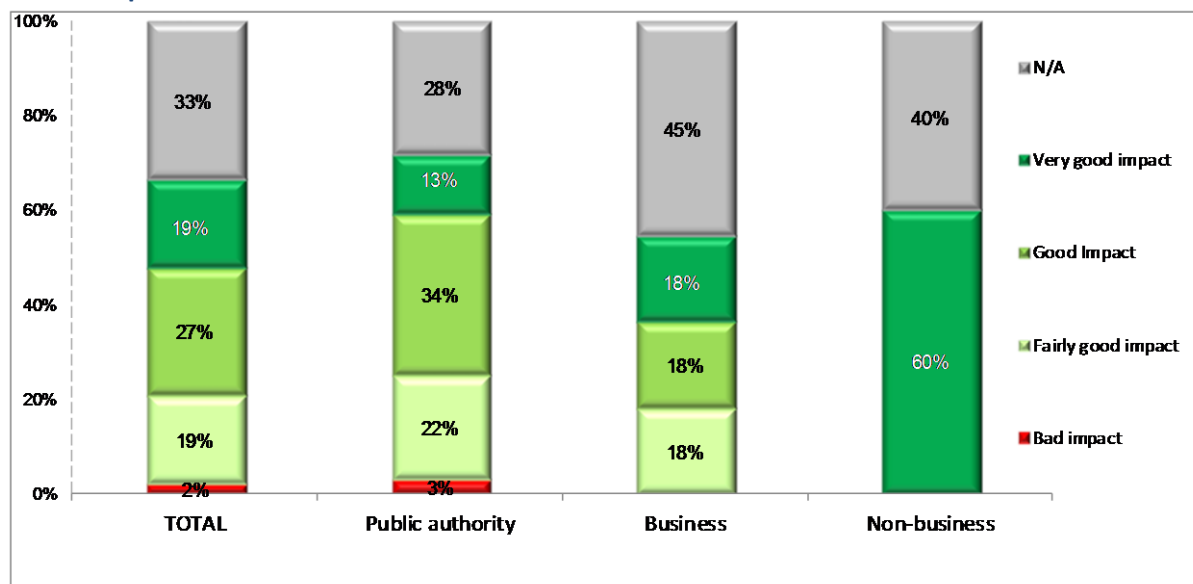
**ANNEX II**  
**Findings of the questionnaire**

<b>Legend to the graphics</b>	
<b>Total</b>	
<b>Public authority</b>	
<b>Business</b>	
<b>Non-business</b>	
<b>Yes</b>	
<b>No</b>	
<b>N/A (not applicable)</b>	
<b>Very adequate balance</b>	
<b>Adequate balance</b>	
<b>Somewhat adequate balance</b>	
<b>No adequate balance</b>	
<b>Very good impact</b>	
<b>Good impact</b>	
<b>Fairly good impact</b>	
<b>Bad impact</b>	
<b>Very useful</b>	
<b>Useful</b>	
<b>Somewhat useful</b>	
<b>Not Useful</b>	

## 1. Impact of extrapolation

**Q1. Extrapolation is the principle of using MRLs established for substances in a particular foodstuff for another foodstuff derived from the same species or in one or more species for other species (Article 5 of Regulation EC No 470/2009).**

**In your view, what is the impact of extrapolation on the availability of authorised veterinary medicinal products?**



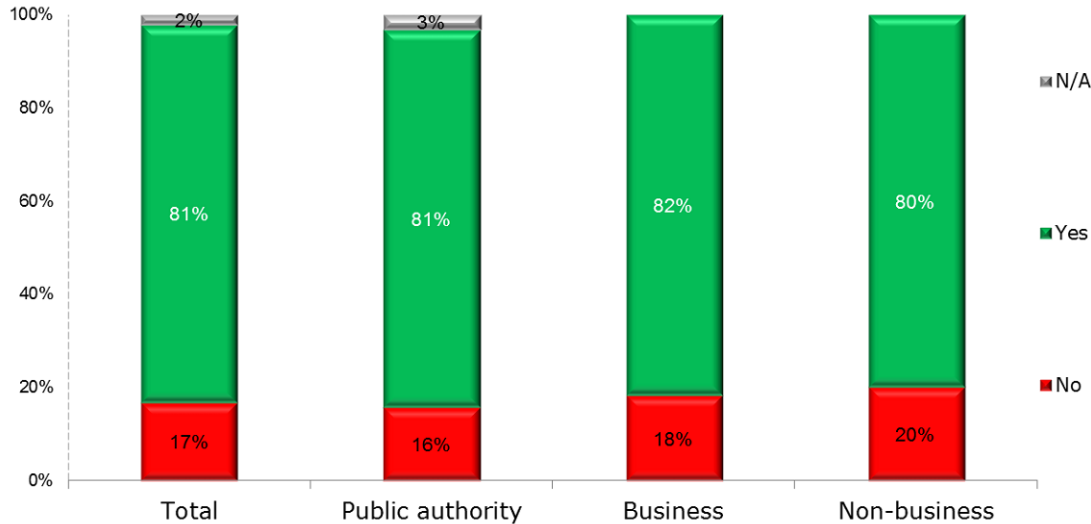
## 2. List of substances established for multiple purposes

Substance(s) established for multiple purpose	PPP		Biocidal product		Feed additives	
	Yes	No	Yes	No	Yes	No
Alphacypermethrin	X					
Amitraz	X					
Azamethiphos	X					
Coumaphos	X					
Cyfluthrin	X					
Cyhalothrin	X					
Cypermethrin	X					
Deltamethrin	X					
Diazinon	X					
Diflubenzuron	X		X			
Permethrin	X					
Phoxim	X					
Teflubenzuron	X					
Tau fluvalinate	X					
Thiabendazole	X					
Diclazuril					X	
Halofuginone					X	

Lasalocid					X	
Monensin					X	

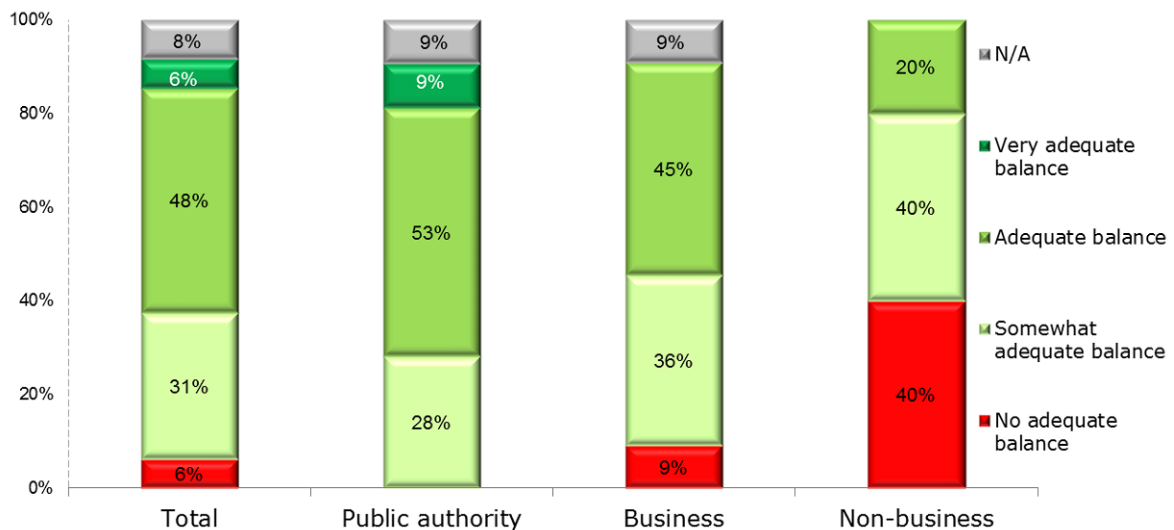
### 3. Scope of Regulation (EC) No 470/2009

Q18. Do you consider the scope of Regulation EC No 470/2009 as defined in Article 1 appropriate?



### 4. Food safety and availability of veterinary medicinal products

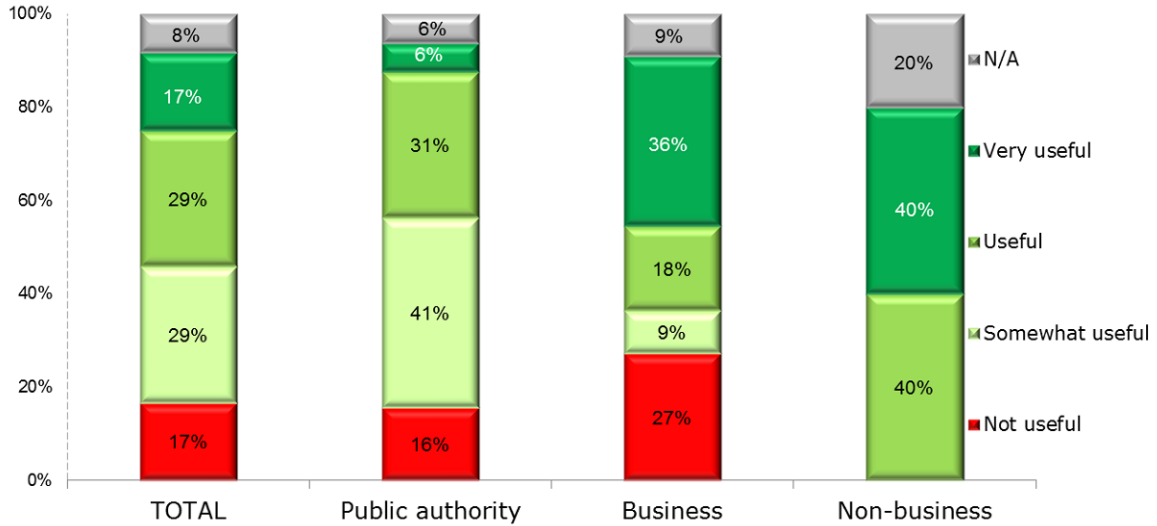
Q5. Do you think that the current methods to establish MRLs and Acceptable Daily Intakes (ADI) achieve an adequate balance between food safety and the availability of veterinary medicinal products (Article 6 of Regulation EC No 470/2009)?



**5. Scientific risk assessment of pharmacologically active substances**

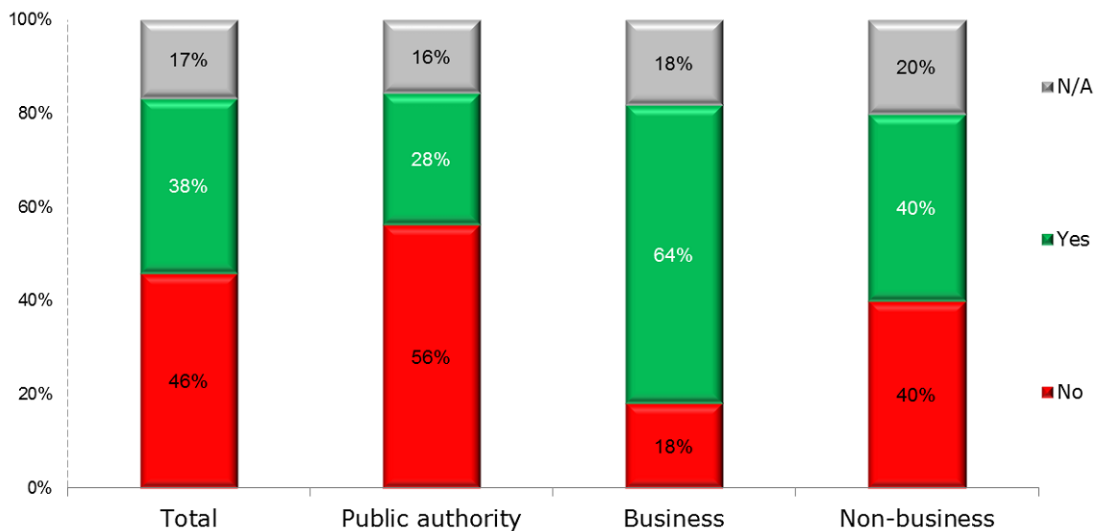
**Q3. The scientific risk assessment of pharmacologically active substances may take into account monitoring data or exposure data, if the metabolism and depletion of the substance cannot be assessed (Article 6(3) of Regulation EC No 470/2009).**

**Do you consider these provisions in the Regulation useful?**



**6. Scientific risk assessment and risk management**

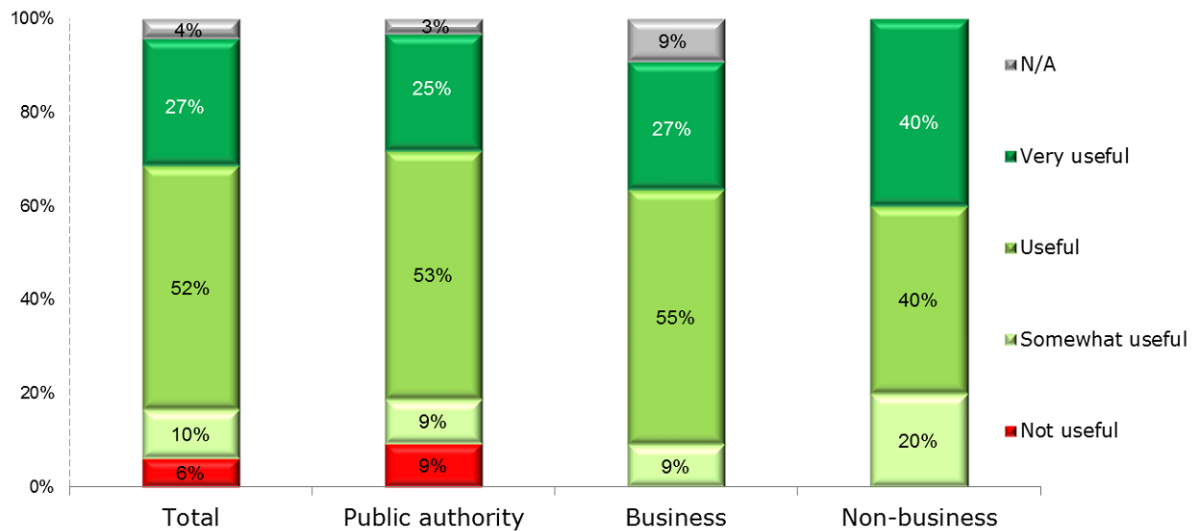
**Q4. An opinion of the Agency shall consist of a scientific risk assessment and risk management recommendations (Article 6 and 7 of Regulation EC No 470/2009). Do you consider that the Commission should adopt an implementing measure (Article 13(2)(a) of Regulation EC No 470/2009) providing further guidance for the implementation of Article 6 and 7?**





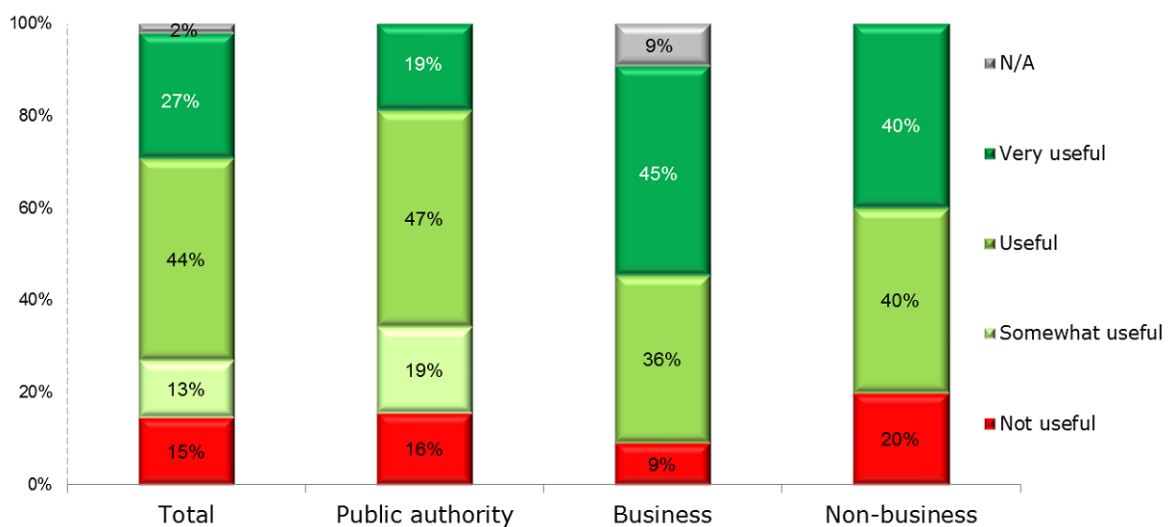
## 7. Establishment of provisional MRLs

**Q9. A MRL must be established for pharmacologically active substances (Article 14 of Regulation EC No 470/2009) intended for use in veterinary medicinal products. Is the possibility of establishing provisional MRL classification, where scientific data are incomplete, useful (Article 14(2)(b) of Regulation EC No 470/2009)?**



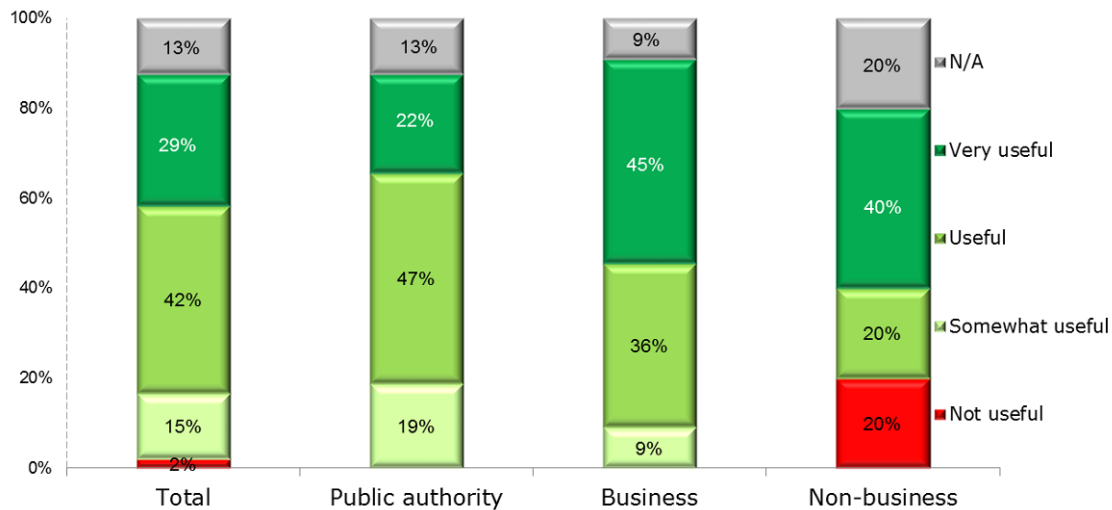
## 8. Establishment of MRLs in the EU based on Codex Alimentarius

**Q7. A MRL shall be laid down pursuant to a decision by Codex Alimentarius Commission if the Union supported this decision (Article 14(3)(b) of Regulation EC No 470/2009). Please indicate whether you consider the establishment of MRLs in the Union based on a Codex Alimentarius decision a useful procedure.**



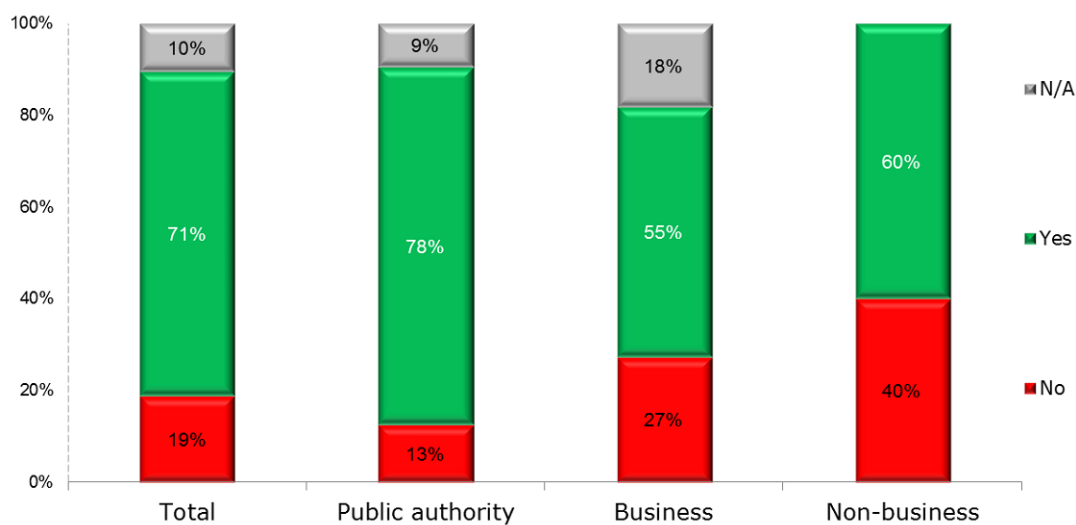
**9. Controlling and monitoring residues in animal products**

**Q6. An opinion of the Agency may be requested by the Commission or a Member State where a substance in a veterinary medicinal product is authorised in a third country but not in the Union (Article 9(1)(a) of Regulation EC No 470/2009). Do you consider this request for an opinion useful in order to be able to control and monitor residues in animal products?**



**10. Provisions related to placing on the market**

**Q16. Article 23 of Regulation EC No 470/2009 specifies that food of animal origin can be placed on the market if it complies with an established MRL. Do you consider the provisions in Article 23 (a) and (b) related to the placing on the market sufficient to cover all situations?**



## 11. Controls on food of animal origin imported into or placed on the EU market

**Q14. When it is deemed necessary to ensure the functioning of controls of food of animal origin imported or placed on the EU market the Commission may establish Reference Points for Action (RPA) for residues from pharmacologically active substances (Article 18 of Regulation EC No 470/2009). Are you aware of problems related to controls where the establishment of a RPA would have been useful?**

