Procedure file

Basic information

COD - Ordinary legislative procedure (ex-codecision procedure) Regulation 2007/0064(COD)	Procedure completed
Foodstuffs of animal origin: procedures for the establishment of residue limits of pharmacologically active substances Amending Directive 2001/82/EC 1999/0180(COD) Amending Regulation (EC) No 726/2004 2001/0252(COD) Subject 3.10.08 Animal health requirements, veterinary legislation and pharmacy 3.10.10 Foodstuffs, foodstuffs legislation 4.60.04.04 Food safety	

Key players

European Parliament	Committee responsible	Rapporteur	Appointed
	ENVI Environment, Public Health and Food Safety		12/06/2007
		PPE-DE DOYLE Avril	
	Former committee responsible		
	ENVI Environment, Public Health and Food Safety		12/06/2007
		PPE-DE DOYLE Avril	
	Former committee for opinion		
	AGRI Agriculture and Rural Development		08/05/2007
		Verts/ALE GRAEFE ZU BARINGDORF Friedrich-Wilhelm	
	Former committee for opinion on the legal basis		
	JURI Legal Affairs		19/12/2007
		ALDE WALLIS Diana	
Council of the European Union	Council configuration	Meeting	Date
	Agriculture and Fisheries	2917	18/12/2008
European Commission	Commission DG	Commissioner	
	Internal Market, Industry, Entrepreneurship and SMEs	VERHEUGEN Günter	

Key events

17/04/2007	Legislative proposal published	COM(2007)0194	Summary
24/05/2007	Committee referral announced in Parliament, 1st reading		
06/05/2008	Vote in committee, 1st reading		Summary
16/05/2008	Committee report tabled for plenary, 1st reading	A6-0190/2008	
17/06/2008	Results of vote in Parliament		
17/06/2008	Decision by Parliament, 1st reading	T6-0285/2008	Summary

18/12/2008	Council position published	15079/2/2008	Summary
15/01/2009	Committee referral announced in Parliament, 2nd reading		
10/02/2009	Vote in committee, 2nd reading		Summary
12/02/2009	Committee recommendation tabled for plenary, 2nd reading	A6-0048/2009	
01/04/2009	Debate in Parliament		
02/04/2009	Decision by Parliament, 2nd reading	T6-0206/2009	Summary
06/05/2009	Final act signed		
06/05/2009	End of procedure in Parliament		
16/06/2009	Final act published in Official Journal		

Technical information

Procedure reference	2007/0064(COD)
Procedure type	COD - Ordinary legislative procedure (ex-codecision procedure)
Procedure subtype	Legislation
Legislative instrument	Regulation
	Amending Directive 2001/82/EC 1999/0180(COD) Amending Regulation (EC) No 726/2004 2001/0252(COD)
Legal basis	EC Treaty (after Amsterdam) EC 037; EC Treaty (after Amsterdam) EC 152-p4b
Stage reached in procedure	Procedure completed
Committee dossier	ENVI/6/71157

Documentation gateway

Legislative proposal		COM(2007)0194	17/04/2007	EC	Summary
Document attached to the procedure		SEC(2007)0484	17/04/2007	EC	
Document attached to the procedure		SEC(2007)0485	17/04/2007	EC	
Economic and Social Committee: opinion, report		CES1251/2007	26/09/2007	ESC	
Committee opinion	AGRI	PE390.570	22/11/2007	EP	
Committee draft report		PE396.683	07/12/2007	EP	
Amendments tabled in committee		PE400.626	28/02/2008	EP	
Specific opinion	JURI	PE404.727	16/04/2008	EP	
Committee report tabled for plenary, 1st reading/single reading		A6-0190/2008	16/05/2008	EP	
Text adopted by Parliament, 1st reading/single reading		T6-0285/2008	17/06/2008	EP	Summary
Commission response to text adopted in plenary		SP(2008)4439	16/07/2008	EC	

Council statement on its position		16831/2008	10/12/2008	CSL	
Council position		15079/2/2008	18/12/2008	CSL	Summary
Commission communication on Council's position		COM(2008)0912	08/01/2009	EC	Summary
Committee draft report		PE418.216	23/01/2009	EP	
Committee recommendation tabled for plenary, 2nd reading		A6-0048/2009	12/02/2009	EP	
Text adopted by Parliament, 2nd reading		T6-0206/2009	02/04/2009	EP	Summary
Draft final act		03627/2009/LEX	06/05/2009	CSL	
Follow-up document		COM(2015)0056	16/02/2015	EC	Summary

Additional information

National parliaments	IPEX
European Commission	EUR-Lex

Final act

Regulation 2009/470
OJ L 152 16.06.2009, p. 0011 Summary

Foodstuffs of animal origin: procedures for the establishment of residue limits of pharmacologically active substances

PURPOSE: to apply new procedures for establishing residue limits of pharmacologically active substances in foodstuffs of animal origin.

PROPOSED ACT: Regulation of the European Parliament and of the Council.

BACKGROUND: Council Regulation (EEC) No 2377/90 lays down the Community procedure for establishing the maximum residue limits (MRLs) of veterinary medicinal products in foodstuffs of animal origin. However, the current legal framework for MRLs has led to a number of problems. For example, the availability of veterinary medicines has decreased to such an extent that it has created adverse effects on public and animal health as well as on animal welfare. Also, international standards (that have the support of the EU) can not be included into EU legislation without a new scientific assessment by the European Medicines Agency. Control services of Member State haves no points of reference for substances detected in food from third countries and, lastly, the current legislation is intransparent and hence difficult to understand.

CONTENT: the purpose of this proposal, therefore, is to address the shortcomings of the current situation by amending, on substance, the existing legal framework relating specifically to MRLs whilst, at the same time, leaving the overall system of setting maximum residue limits based on scientific assessment intact. In brief the main changes being proposed are as follows:

- to make the assessment of possibilities for extrapolation a compulsory part of the overall scientific assessment and to create a legal basis for the Commission to lay down the principles for applying extrapolation;
- to introduce an obligation to adapt Community legislation to include MRLs set by Codex with the support of the EU;
- to create a specific legal framework and to set MRLs for pharmacologically active substances not intended to be authorised as veterinary medicines in particular for control and purpose and for imported food;
- to rearrange the sequence of articles in order to create a logical structure, differentiating in particular risk assessment and risk management provisions; and
- to integrate, in a separate Commission Regulation, the rules (MRLs, conditions of use, prohibition etc.) relating to individual substances, which can currently be found in 4 annexes of the current basic act.

The proposal provides for significant improvements in terms of simplification ? i.e. the restructuring of the Articles and the integration into a single Annex of all the rules concerning MRLs, conditions of use, prohibition etc. The public authorities, in particular, will benefit from the improved readability of the residue legislation. Consolidating, into one single Regulation all residue limits will make the work of enforcement by control authorities much easier. Further, the timelines for procedural management will be clearly fixed for all parties. International standards supported by the Community would be automatically recognised without the need to submit any specific application at Community level ? thereby avoiding duplication of work.

In addition, veterinarians will have access to a single document in which all relevant information is collated. It will include data on all substances evaluated. Similarly, third countries exporting foodstuffs of animal origin into the Community will benefit from further simplification

and the clarification of Community requirement.

As far as the budget is concerned the proposal will have no impact on the Community budget but could have a negligible (or even no) cost on the European Medicines Agency (EMEA). The proposed Regulation?s financial impact on revenues is uncertain. An increase in applications for authorisations of veterinary medicinal products could lead to an increase of fee revenues for the EMEA. As far as expenditure is concerned, the proposal will not change the principle whereby the system of residue limits is operated by the EMEA and the Commission. Additional scientific assessments will be required for residue limits for control purposes while less assessments will result from the taking over of limits set by Codex alimentarius and from extrapolation requirements. In overall terms the review will thus have a very limited impact on resources which can not be quantified.

Foodstuffs of animal origin: procedures for the establishment of residue limits of pharmacologically active substances

The Committee on the Environment, Public Health and Food Safety adopted a report by Avril DOYLE (EPP-ED, IE) and amended, in the context of the codecision procedure, the proposal for a regulation of the European Parliament and of the Council laying down Community procedures for the establishment of residue limits of pharmacologically active substances in foodstuffs of animal origin, and repealing Regulation (EEC) No 2377/90.

The main amendments are as follows:

-purpose: the Committee emphasises the general purpose of this Regulation, which is that of ensuring food safety;

-reference points for action: this is now defined as the level of a residue of a pharmacologically active substance, established for control reasons in the case of certain substances for which a maximum residue limit has not been laid down in accordance with this Regulation. The Committee wanted to introduce a more precise definition unrelated to the concept of exposure, which could be interpreted as a weakening of the safety requirement. The reference points for action shall be reviewed in the light of any new data concerning the protection of human health and the food chain. In addition, the Committee has introduced a new Article on implementing reference points for action;

-European Food Safety Authority: the risk management recommendations should take into account any relevant scientific findings of the European Food Safety Authority, by way of letters of cooperation;

-extrapolation: in the event of extrapolation between different animal species, a safety factor should be applied when setting maximum residue limits;

-scientific risk assessment: the scientific risk assessment should, inter alia, pay particular attention to the synergetic and cumulative effects of different pharmacologically active substances and to effects on vulnerable categories of people. The risk assessment should comply with the principles for assessing the safety of foodstuffs laid down in Regulation (EC) No 178/2002.

-toxicological, as well as pharmacological or microbiological effects in human beings should be considered;

-equidae: a new clause states that veterinary medicinal products which do not have a maximum residue limit for equidae, which are not included in Annex IV of Regulation (EEC) No 2377/90 or in Article 13(2) of this Regulation, and which are used "off-label", as defined in Article 1(16) of Directive 2001/82/EC, and "under the provisions of the cascade" and not administered intra-muscularly or subcutaneously, shall have a nominal withdrawal period of six months. The Committee stated that peer-reviewed science clearly indicates that no such residues would exist in muscle meat e.g. from oral or intravenous administration after six months, which allows a large safety margin on time. Furthermore, the use of pharmaceuticals containing pharmacologically active ingredients not on "the essential" substances list or the "positive list" for equidae referred to in Article 10(3) of Directive 2001/82/EC and not administered intra-muscularly or subcutaneously, shall have a nominal withdrawal period of six months;

-urgent authorisation: in specific cases where urgent authorisation is required to ensure the protection of human health and animal health and welfare, the Commission may, in accordance with the regulatory procedure with scrutiny, establish a provisional maximum residue limit for a period not exceeding five years;

-requests for an opinion on maximum residue limits: the proposal had stated that the Commission or Member States may forward to the Agency requests for an opinion for substances not intended for use in veterinary medicinal products to be placed on the market in the Community and where no application for such substances has been made. The Committee introduced wording which states that the Commission, Member States or a third party pursuing legitimate interests may forward to the Agency requests for an opinion on MRLs for pharmacologically active substances in certain circumstances which are prescribed in the text. The Committee states that creating possibilities to fix MRLs in the absence of a marketing authorisation would be a powerful tool for availability. It would enable producer's organisations and scientists to submit an application for an MRL and would provide an incentive to pharmaceutical companies to develop veterinary medicinal products - particularly for minor species or minor uses. It would, in particular, address the medicines availability concerns expressed by honey producers and bee keepers.

The text on requests for the Agency's opinion also applies to authorised pharmacologically active substances for which the cost of the procedure for establishing residue limits is disproportionate in relation to the economic revenue from the substance on account of the limited distribution of the animal species or their minor economic significance ('minor uses'). In the event of extrapolation between different animal species, a safety factor shall be applied when setting maximum residue limits. The Commission may, in accordance with the regulatory procedure with scrutiny, establish more precise requirements for the application of this clause;

-requests for review: the text clarifies who may request a review and under what circumstances;

-comitology: defining the methodology of the risk assessment and of risk management will be done in accordance with the regulatory procedure with scrutiny. Moreover, the Committee altered the time limits for the adoption of decisions;

-accelerated procedure for an Agency opinion: a new clause states that, in specific cases where a veterinary medicinal product or a biocidal product needs to be authorised as a matter of urgency for reasons relating to the protection of public health or of animal health or welfare, the

Commission, any person who has requested an opinion, or a Member State may ask the Agency to carry out an accelerated procedure for the assessment of the maximum residue limit of a pharmacologically active substance contained in those products. The Agency shall ensure that the Committee is able to issue its opinion within 150 days following receipt of the application.

-prohibition on placing on the market: Member States shall prohibit the import and placing on the market of food of animal origin containing residues resulting from the illegal administration of pharmacologically active substances which are not subject to a classification in accordance with the Regulation. Accordingly, imports from third countries of food containing residues resulting from the illegal administration of substances whose use is use is banned within the EU shall be prohibited in the interests of public health. Foodstuffs of animal origin containing pharmacologically active substances for which no maximum residue limits have been set may not be placed on the market. Furthermore, if the maximum residue limits or reference quantities established under the Regulation are exceeded, the product shall not be placed on the market as a foodstuff, transformed into foodstuffs or mixed with foodstuffs.

Report: the Commission shall, not later than five years after the entry into force of the Regulation, submit a report which will, in particular, review the experience gained from the application of the Regulation, and, f appropriate, be accompanied by proposals.

Foodstuffs of animal origin: procedures for the establishment of residue limits of pharmacologically active substances

The European Parliament adopted by 660 votes to 13 with 5 abstentions, a legislative resolution amending the proposal for a regulation of the European Parliament and of the Council laying down Community procedures for the establishment of residue limits of pharmacologically active substances in foodstuffs of animal origin, and repealing Regulation (EEC) No 2377/90. The report had been tabled for consideration in plenary by Avril DOYLE (EPP-ED, IE) on behalf of the Committee on the Environment, Public Health and Food Safety.

The amendments - adopted under 1st reading of the codecision procedure ? are as follows:

-purpose: Parliament emphasises the general purpose of this Regulation, which is that of ensuring food safety;

-reference points for action: this is now defined as the level of a residue of a pharmacologically active substance, established for control reasons in the case of certain substances for which a maximum residue limit has not been laid down in accordance with this Regulation. In addition, Parliament introduced a new Article on implementing reference points for action. The reference points for action shall be reviewed in the light of any new data concerning the protection of human health and the food chain;

-European Food Safety Authority: the risk management recommendations should take into account any relevant scientific findings of the European Food Safety Authority, by way of letters of cooperation;

-scientific risk assessment: the principles of risk assessment pursuant to Articles 4 to 8 shall be applied in order to guarantee a high level of health protection.

-toxicological, as well as pharmacological or microbiological effects in human beings should be considered;

-equidae: a new clause states that veterinary medicinal products which do not have a maximum residue limit for equidae, which are not included in Annex IV of Regulation (EEC) No 2377/90 or in Article 13(2) of this Regulation, and which are used "off-label", as defined in Article 1(16) of Directive 2001/82/EC, and "under the provisions of the cascade" and not administered intra-muscularly or subcutaneously, shall have a nominal withdrawal period of six months. Furthermore, the use of pharmaceuticals containing pharmacologically active ingredients not on "the essential" substances list or the "positive list" for equidae referred to in Article 10(3) of Directive 2001/82/EC and not administered intra-muscularly or subcutaneously, shall have a nominal withdrawal period of six months;

-urgent authorisation: in specific cases where urgent authorisation is required to ensure the protection of human health and animal health and welfare, the Commission may, in accordance with the regulatory procedure with scrutiny, establish a provisional maximum residue limit for a period not exceeding five years;

-requests for an opinion on maximum residue limits: the proposal had stated that the Commission or Member States may forward to the Agency requests for an opinion for substances not intended for use in veterinary medicinal products to be placed on the market in the Community and where no application for such substances has been made. Parliament introduced wording which states that the Commission, Member States or a third party pursuing legitimate interests may forward to the Agency requests for an opinion on MRLs for pharmacologically active substances in certain circumstances which are prescribed in the text;

-comitology: defining the methodology of the risk assessment and of risk management will be done in accordance with the regulatory procedure with scrutiny. Moreover, Parliament altered the time limits for the adoption of decisions;

-accelerated procedure for an Agency opinion: a new clause states that, in specific cases where a veterinary medicinal product or a biocidal product needs to be authorised as a matter of urgency for reasons relating to the protection of public health or of animal health or welfare, the Commission, any person who has requested an opinion, or a Member State may ask the Agency to carry out an accelerated procedure for the assessment of the maximum residue limit of a pharmacologically active substance contained in those products. The Agency shall ensure that the Committee is able to issue its opinion within 150 days following receipt of the application;

-placing on the market: a new Article states that if the maximum residue limits or reference quantities established under this Regulation are exceeded, the product shall not be placed on the market as a foodstuff, transformed into foodstuffs or mixed with foodstuffs.

Foodstuffs of animal origin containing pharmacologically active substances for which no maximum residue limits have been set may not be placed on the market;

-import: Member States shall prohibit the import and placing on the market of food of animal origin containing residues resulting from the illegal administration of pharmacologically active substances which are not subject to a classification in accordance with the text. Accordingly, imports from third countries of food containing residues resulting from the illegal administration of substances whose use is use is banned within the European Union shall be prohibited in the interests of public health;

-report: the Commission shall, not later than five years after the entry into force of the Regulation, submit a report which will, in particular,

review the experience gained from the application of the Regulation, and, if appropriate, be accompanied by proposals.

Foodstuffs of animal origin: procedures for the establishment of residue limits of pharmacologically active substances

The Council's common position confirms the objectives and most of the arrangements proposed by the Commission and includes, in part or in their entirety 34 amendments passed at first reading by the European Parliament.

The Council introduced the following amendments to the Commission proposal:

Improvement of the availability of veterinary medicinal products: at the suggestion of the Parliament, amendments were made to a few provisions in order to try to improve the availability of veterinary medicinal products for food producing animals, in particular with regard to minor species and minor uses. More specifically, the Council wanted to clarify the cases in which Member States and the Commission may ask an opinion on MRLs to the Agency. In addition, the Council judged preferable to add provisions on the modalities of financing of MRL evaluations for active substances included in biocidal products. Furthermore, the Council recalled the importance of ensuring a high degree of human health protection and made some changes to insist on this aspect.

Establishment/review and functioning of reference points for action: following a series of Parliament amendments, several provisions were adapted to clarify the Commission proposal regarding in particular the definition of reference points for action and conditions for their establishment and review. Further, the conditions for placing food of animal origin on the market were specified. Likewise the measures to be taken when a forbidden or non authorised substance is found were defined.

Report to European Parliament and the Council: the Council also followed Parliament in asking the Commission to present a report on the experience gained from the application of the regulation, not later than 5 years after its entry into force. In addition, the Council requested that the report considers in particular substances classified under the regulation and having a multiple use.

The Council, like the Commission, could not accept 5 amendments.

Contrary to the Parliament the Council deemed essential to maintain a double legal basis as the proposal is relevant to the functioning of the internal market for products of animal origin included in Annex I to the Treaty. Moreover, the Council could not accept the comitology procedure with scrutiny considering the fixing of MRLs for specific substances to be a purely implementing measure with no quasi-legislative character. Lastly, the Council could not accept the complete deletion of the free circulation clause.

Foodstuffs of animal origin: procedures for the establishment of residue limits of pharmacologically active substances

The Commission fully supports the common position.

Key amendments proposed by the European Parliament in the first reading relating to:

- the availability of veterinary medicinal products,
- the provisions on reference points for action, such as the inclusion of control measures, the clarification relating to the residue levels triggering sanctions by competent authorities and equal treatment of Third country imports and intra-Community trade,
- the clarification of the conditions under which a further scientific assessment by the EMEA is not required when an MRL has been set in the framework of Codex Alimentarius Commission of FAO/WHO, are addressed in the political agreement.

In order to respond to specific availability related amendments, two minor changes to Directive 2001/82/EC on the Community code relating to veterinary medicinal products are included. Furthermore, the Commission has agreed to a Declaration on an assessment of options for a future review of Directive 2001/82/EC.

European Parliament amendments not included in the amended proposal and not incorporated in the common position concern: the legal base of the regulation; the implementing measures as regards to the proposed change to the Standing Committee on the Food Chain and Animal Health; the classification of pharmacologically active substances; the prohibition of the administration of a substance to food-producing animals; the proposed change to the regulatory procedure with scrutiny when fixing individual MRLs; the circulation of foodstuff.

Foodstuffs of animal origin: procedures for the establishment of residue limits of pharmacologically active substances

The Committee on the Environment, Public Health and Food Safety adopted the recommendation for second reading by Avril DOYLE (EPP-ED, IE) approving unamended the Council common position for adopting a regulation of the European Parliament and of the Council 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.

Foodstuffs of animal origin: procedures for the establishment of residue limits of pharmacologically active substances

The European Parliament adopted a legislative resolution approving unamended, under the second reading of the codecision procedure, the Council?s common position with a view to the adoption of a regulation of the European Parliament and of the Council laying down Community

procedures for the establishment of residue limits of pharmacologically active substances in foodstuffs of animal origin and repealing Council Regulation (EEC) No 2377/90.

Foodstuffs of animal origin: procedures for the establishment of residue limits of pharmacologically active substances

PURPOSE: to limit consumer exposure to pharmacologically active substances intended to be used in veterinary medicinal products for food producing animals and residues thereof in foodstuffs of animal origin through Community procedures.

LEGISLATIVE ACT: Regulation (EC) No 470/2009 of the European Parliament and of the Council 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.

CONTENT: the Regulation aims at reviewing and completing existing provisions related to the establishment of Maximum Residue Limits (MRLs) for pharmacologically active substances in foodstuffs of animal origin. The main objective is to improve the availability of veterinary medicinal products for food producing animals whilst ensuring a high level of human health protection.

For the purposes of ensuring food safety, this Regulation lays down rules and procedures in order to establish:

(a) the maximum concentration of a residue of a pharmacologically active substance which may be permitted in food of animal origin ("maximum residue limit");

(b) the level of a residue of a pharmacologically active substance established for control reasons in the case of certain substances for which a maximum residue limit has not been laid down in accordance with this Regulation ("reference point for action").

The main changes planned are as follows:

- an obligation to consider possibilities of extrapolation when scientific evaluation is being carried out to establish a residue limit;
- an obligation for the Community to take over residue limits adopted at Codex Alimentarius level if it did not table any objections when they were adopted;
- the creation of a legal framework for the establishment of residue limits for pharmacologically active substances which are not a priori intended to be used in veterinary medicinal products in the Community;
- the establishment of reference values when necessary for the purposes of control in cases where there is no residue limit.

A further aim of the new Regulation is to simplify current legislation and to improve its legibility.

By 6 July 2014, the Commission shall submit a report to the European Parliament and to the Council. The report shall, if appropriate, be accompanied by relevant proposals.

ENTRY INTO FORCE: 06/07/2009.

Foodstuffs of animal origin: procedures for the establishment of residue limits of pharmacologically active substances

The Commission presented a report on the functioning of Regulation (EC) No 470/2009 of the European Parliament and of the Council laying down Community procedures for the establishment of residue limits of pharmacologically active substances in foodstuffs of animal origin.

This Regulation establishes maximum residue limits and reference values 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 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.

Findings of the questionnaire: in May 2014, a questionnaire about the Regulation was sent to the EMA, national public authorities, businesses and non-business stakeholders.

The following conclusions can be drawn from the findings of the questionnaire:

- 80% of the stakeholders and Member States considered that the scope of Regulation (EC) No 470/2009 was appropriate. 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;
- as regards the scientific risk assessment, the Commission 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. Respondents to the questionnaire said that it would be beneficial if the Commission were to adopt further legal measures on risk management;
- where scientific data are incomplete, Regulation (EC) No 470/2009 allows for the possibility of establishing a provisional MRL classification. This is considered to be one of the most useful elements of the Regulation (90 % of respondents). Moreover, the possibility to allow pharmacologically active substances to be classified as No MRL required where the substance is considered safe at the residue level to be expected in food of animal origin, is considered useful.

Improvements made by the new legislation: the Commission considered that 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 of over 20% compared to the five years preceding the Regulations entry into force, with the number of applications rising from 33 to 40 : this 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 use of the extrapolation principle to extend existing MRLs to other species which was one of the main objectives of revising and introducing Regulation (EC) No 470/2009. 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).

Moreover, each time extrapolation was recommended, it included minor 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, 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.