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

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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 Regulation's 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.