Medicated feed: manufacture, placing on the market and use

2014/0255(COD) - 10/09/2014 - Legislative proposal

PURPOSE: to ensure a high level of protection of human and animal health, providing adequate information for users and strengthen the effective functioning of the internal market.

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

ROLE OF THE EUROPEAN PARLIAMENT: the European Parliament decides in accordance with the ordinary legislative procedure and on an equal footing with the Council.

BACKGROUND: livestock production occupies a very important place in the agriculture of the Union. There are **13.7 million animal holdings** in the EU. The value of livestock farming output in the EU is EUR 157 billion.

In addition, the protection of animal health constitutes one of the general objectives of EU food law.

The rules concerning medicated feed have significant influence on the keeping and on the rearing of animals, including non-food producing animals, and on the production of products of animal origin.

Council Directive 90/167/EEC constitutes the Union’s regulatory framework for the manufacture, placing on the market and use of medicated feed.

Experience with the application of Directive 90/167/EEC has shown that further **measures should be taken** to strengthen the effective functioning of the Internal Market and to explicitly give and improve the possibility to treat non-food producing animals by medicated feed.

IMPACT ASSESSMENT: the impact assessment identified the following main axes along which the system has to change in order to answer the stakeholders concerns: residues of veterinary medicines in feed, imprecise dosage of veterinary medicines, impossible market access to medicated feed for pets and barriers to intra EU trade of medicated feed. The impact assessment concluded that an EU Regulation with detailed rules would have the most positive impacts and would provide for the best way forward to achieve the objectives for the EU.

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CONTENT: the proposed Regulation seeks to **update the current legislation on medicated feed** by repealing Directive 90/167/EEC which sets out the conditions under which medicated animal feed may be manufactured, placed on the market and used within the EU.

The main elements of the proposed Regulation include:

Scope: the scope of the proposed Regulation covers the manufacture, placing on the market and use of medicated feed for use in pets and in food-producing animals within the Union. It does not apply to veterinary medicinal products used as the medicinal component of medicated feed (previously called "medicated premixes"), which are dealt with under the veterinary medicinal products legislation.

Manufacture, composition, placing on the market and use of medicated feed: the proposal:

- ensure that the general manufacture requirements laid down in Regulation (EC) No 183/2005 apply;
- stipulates that medicated feed may only be manufactured from veterinary medicinal products authorised under the veterinary medicinal products legislation;
- sets rules for the approval of feed business operators and rules they need to comply with in order to manufacture medicated feed;
- lays down rules for the homogenous incorporation of the veterinary medicinal products into the medicated feed and requirements in order to avoid carry-over of active substances from veterinary medicinal products into non target feed.

Labelling: the proposal provides that as regards labelling, the general provisions laid down in Regulation (EC) No 767/2009 on the placing on the market and use of feed should apply and that it be subject to specific labelling requirements in order to provide the user with the information necessary to correctly administer the medicated feed. It should also ensure that:

- specific rules for the prescription, the validity of the prescription, the use of medicated feed containing antimicrobials in food-producing animals and the quantities required for the treatment of animals with medicated feed are laid down;
- manufacturers, distributors and users of medicated feed are keep daily records for the effective tracing of medicated feed;
- for veterinary medicinal products authorised at national level, the Regulation sets Intra-Union rules for trade of medicated feed in order to prevent distortions in competition.

DELEGATED ACT: the proposal contains provisions empowering the Commission to adopt delegated acts in accordance with Article 290 of the Treaty on the Functioning of the European Union.