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Subject : 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
- Progress report

I. INTRODUCTION

1. On 17 April 2007, the Commission submitted to the Council the abovementioned proposal based on Article 152 (4) (b) of the EC Treaty (codecision).
2. The Economic and Social Committee and the Committee of the Regions were consulted.
3. The proposal aims at reviewing existing provisions related to the establishment of Maximum Residue Limits (MRLs) for pharmacologically active substances in foodstuffs of animal origin. The main changes foreseen are:

- 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 the Codex Alimentarius Commission when these were adopted with the support of the Community;
- to create a specific legal framework to establish MRLs for pharmacologically active substances not intended for use in veterinary medicinal products (VMPs) in the EU;
- to provide clear references for control purposes in cases where MRLs have not been set, via the establishment of Reference Points for Action (RPAs).

In addition, the proposal provides for some improvements in terms of simplification and better regulation.

II. STATE OF PLAY

4. The European Parliament has appointed Avril Doyle (EPP-ED, IE) as rapporteur. Examination of the text within the Committee on the Environment, Public Health and Food Safety is expected to start only on 19 December 2007.
5. The Economic and Social Committee delivered its opinion on 26 September 2007. The Committee of the Region indicated that it would not deliver any opinion on the issue.
6. At Council level, the Working Party of Veterinary Experts (Public Health) discussed the proposal on 15 June, 20 July, 19 and 27 September, 19 and 31 October, 19, 20 and 29 November 2007.

A large majority of delegations welcomed the proposal and indicated their support to it in general. However, many of them stressed the need for further clarification/discussion on several of its articles. In particular, the four new elements of the proposal presented above were identified as key issues requiring an in-depth examination.

The clarification provided by the Commission and some drafting suggestions made by the Presidency¹ permitted to address many concerns raised by delegations, in particular on two of the key issues - extrapolation and adoption of Codex MRLs.

On the remaining two key issues, the Presidency stated the need for further work at expert level. Likewise, some other points of the original proposal are still subject to technical discussion. A draft legislative text is presented in the Addendum to the present report.

1) Substances not intended for use in VMPs to be placed on the EU market:

Article 9

This article foresees the possibility for Member States and the Commission to request, under certain conditions, an opinion from the Agency (EMEA) on MRLs for substances not intended to be used in VMPs to be placed on the market in the Community.

Many delegations stressed the need to clarify the scope (i.e. the substances covered) as well as the procedures applicable. Following the explanation given by the Commission representative, most of them expressed a reservation on the inclusion of biocidal products in the proposal. In particular:

- they questioned the expediency of permitting that only Member States or the Commission - and not operators - may ask the Agency for an opinion on MRLs for these products;
- they queried whether these products would fall under the sphere of responsibilities of the Agency;

¹ The Commission representative maintained, at that stage, a general reservation on the changes made to the initial Commission's proposal. Furthermore, some of these changes are still subject to scrutiny reservation from a few delegations. DK and UK maintained a parliamentary reservation on the entire proposal.

- they raised concerns regarding administrative consequences for the Agency (workload and costs) and possibly the Members States (payment of fees and provision of necessary data).

2) **Reference points for action (RPAs): Articles 17 and 18**

The proposal foresees the possibility for the Commission to establish on a case by case basis, RPAs for control purposes for substances for which MRLs have not been set (namely forbidden and not authorised substances). RPAs would be set at levels below which human exposure to that residue through food is considered negligible and may be subject to a risk assessment by EFSA.

Many delegations acknowledged that RPAs would represent an improvement compared to the current Minimum Required Performance Limits : they would apply to imported foodstuffs as well as to those produced within the EU, the distinction between MRLs and RPAs would become clearer and controls among Member States would be harmonised.

However a need was stated to better clarify the cases in which RPAs would be set.

Furthermore, some delegations expressed concerns on the wrong signal these RPAs could give to consumers and operators inside and outside the Community: as they would be used to control mainly substances forbidden or not authorised in the Community, RPAs could be interpreted as being a tolerance level for such substances.

Finally, many delegations asked for a systematic risk assessment of the RPAs before they are used. As a consequence, they consider that foodstuffs containing a residue of a forbidden substance at the level of the RPA cannot enter the food chain if it is not ascertained that this limit is safe for the consumer. These delegations prefer in this case a zero tolerance approach.

3) **Additional technical issues to be further examined**

Some of the technical issues to be examined are closely linked to the outcome of discussion on RPAs and biocidal products (e.g. definition of MRLs). Others, raised by some delegations, will require additional discussion at expert level; they refer in particular to:

- dual use substances (e.g. substances used in pesticides and veterinary medicinal products) for which it can happen that different MRLs are set in different pieces of legislation making controls difficult;
- the risk assessment when the metabolism and the depletion can not be evaluated;
- the prohibition of administration to food producing animals of substances not yet evaluated;
- the type and content of an urgent procedure for establishment of MRLs.
