COMMISSION OF THE EUROPEAN COMMUNITIES

Brussels, 17.4.2007
SEC(2007) 485

COMMISSION STAFF WORKING DOCUMENT

Accompanying document to 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

EXECUTIVE SUMMARY OF THE IMPACT ASSESSMENT

{COM(2007) 194 final}
{SEC(2007) 484}

Lead DG: DG Enterprise and Industry
Other involved services: DG Health and Consumer Protection
Agenda planning or Work Programme reference: none

Executive summary

This impact assessment report provides a detailed overview of the policy options envisaged by the European Commission with a view to improve the harmonised regulatory framework for residues of veterinary medicinal products in foodstuffs of animal origin. This document is to be read together with 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, repealing Regulation (EEC) No 2377/90, and the accompanying Legislative Financial Statement. The impact assessment outlines the background to the proposal and presents an analysis of all legislative options available and possible impacts that may derive from them.

The current legal framework for MRLs has lead to particular problems:

(1) Availability of veterinary medicines has decreased to an extent that creates adverse effects for public and animal health and animal welfare due to

(2) prohibition of substances used for many years for all food-producing species

(3) lack of applications for new authorisations because of scientific data requirements creating high costs for industry.

(4) International standards supported by the EU cannot be included in Community legislation without a new scientific assessment by the European Medicines Agency.

(5) Control services of Member States have no points of reference in particular for substances detected in food from third countries. In such cases, control authorities have difficulties to decide on compliance and no European Union procedure allows for recourse to a scientific evaluation leading to harmonised residue limits and controls.

(6) The current legislation is difficult to understand. Veterinary practitioners and control personal have difficulties in establishing the legal situation mainly due to different annexes categorising substances in function of their possible use.

The specific objectives of the proposal are

- To improve the level of public health, animal health and animal welfare by increasing the availability of veterinary medicinal products for all food producing animals
- To simplify the existing legislation
- To provide clear references for the control of pharmacologically active substances in food
- To ensure consistency with international standards.

The main policy options considered in the impact assessment are

- To maintain the current legal framework
- To review the existing regulation by incorporating specific legal provisions and amending existing rules to address the specific objectives
- To replace the existing legislation by guidelines.

Maintaining the current legal framework would mean that existing availability problems would be unresolved. The existing practice of only limited use of extrapolation one residue limit to different tissues and species would continue. Consistency with international standards could not be promoted as the current legislation requires new scientific assessment. Moreover, the lack of harmonisation in the area of control would persist with different control levels of Member States without a clear scientific basis. The general lack of clarity of the legislation would not be overcome and risks of erroneous application would continue.

A review provides the chance to overcome the existing shortage of veterinary medicines in the medium and long term by establishing a clear legal basis for extended use of one residue limit for other tissues and species. International standards supported by the European Union could directly be incorporated in European Union legislation. Furthermore, the food industry and third countries would be provided with a clear science-based European Union reference for residues of substances not intended for use in veterinary medicines in the Community. Finally, improved clarity could be achieved with the review of the legislation, in particular by creating one consolidated list of substances with their different classifications. This should result in improved compliance. Overall the administrative burden would be reduced.

The option of replacing the existing legislation by guidelines would create public health risks Deregulation of the internal market and different levels of food safety could lead to crisis in consumer confidence with major economic losses. Self-regulation would result in a reduced administrative burden, but this effect would be offset by enforcement mechanisms to be created under such system.

The assessment of these options shows that option 2 is the option which closely meets the objectives defined by the Commission.