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COMMISSION STAFF WORKING DOCUMENT

Accompanying document to the

Draft proposal for a Regulation of the European Parliament and the Council laying down health rules as regards animal by-products not intended for human consumption (Animal by-products Regulation)

SUMMARY OF THE IMPACT ASSESSMENT

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SUMMARY OF THE IMPACT ASSESSMENT

1. POLICY CONTEXT AND CONSULTATION OF INTERESTED PARTIES

The item is part of the Commission agenda planning /work programme (reference 2005/SANCO/058).

In response to a number of crises affecting the safety of public and animal health as regards products of animal origin - in particular linked to Transmissible Spongiform Encephalopathy (TSE), dioxin, Classical Swine Fever (CSF) and Foot and Mouth Disease (FMD) - the Community has adopted a series of measures to protect public and animal health, from "farm to fork". Among several pieces of legislation concerning animal and public health, Regulation (EC) No 1774/2002 laying down health rules concerning animal by-products (ABP) not intended for human consumption[1] consolidated, simplified and replaced 19 previous legal acts. It introduced stricter rules concerning the approval of certain premises, the channelling and traceability of certain products and the implementation of several processing parameters for strictly risk-related categories of ABP, in order to guarantee the safety of final products intended for feed or technical uses.

Since the entry into force of the Regulation a continuous process of communication and consultation with stakeholders has been initiated and maintained by the Commission in order to identify possible issues or areas where problems could arise (see Annex I and Annex II) including inspections of the Food and Veterinary Office to monitor the implementation of the ABP rules by competent authorities of Member States. Based on the information submitted by Member States and the outcome of FVO inspections, the Commission, on 24 October 2005, submitted a report, COM (2005) 521, to the European Parliament and the Council describing the experience of all 25 Member Sates in applying the legislation. In addition, a general on-line consultation was carried out and a questionnaire on administrative costs sent to competent authorities, affected industries and stakeholders, including third country partners, in order to gather data on the possible impacts of this initiative on administrative burden. An Inter-service Steering Group comprising several Directorates-General was created in order to guide work and provide specialized input for this Impact Assessment. This group has met three times during the development of this impact assessment.

[1] OJ L 273, 10.10.2002, p. 1.

The legislation is working well and generally meets its overall objectives. However, the consultations have identified areas where changes need to be considered in order to update the current legislation and to provide legal certainty, simplify it and thus reduce administrative burden. In particular, the need emerged to clarify certain issues and to ensure flexibility to take account of emerging scientific knowledge about risks associated to the possible uses of ABP. Consequently a revision is being considered, which does however not envisage any changes to the basic principles and structure of the way the use, processing, disposal, traceability and channelling of ABP not intended for human consumption are regulated in the European Union. Whilst there are a number of issues that need to be addressed, the areas which could have major impacts, and which are the focus of this impact assessment, are:

- the lack of clarity in the scope of the Regulation. Specifically it is not clear when products are not longer considered as ABP, and so the requirements of the Regulation cease to apply, nor the extent to which ABP from wild game is covered;

- the categorization of ABP is not always proportionate to the risk they pose,

- some of the premises that fall into the scope of this Regulation have to undergo a double approval (under the ABP legislation and under other sector legislation)

- and the fact that current Regulation does not consider some important issues as regards derogations (impact of ABP for research, natural disasters).

2. GENERAL OBJECTIVES

The **general objectives** of this initiative remain the same as for the current legislation, i.e. to protect human and animal health and ensure food safety, to reinforce consumers' confidence in the safety of the food and feed chain, to facilitate smooth functioning of the internal market, and to increase competitiveness of the EU industries affected by this Regulation.

3. OPERATIONAL OBJECTIVES

Specific objectives were identified and these are to review the Regulation on ABP in order to adjust the regulatory framework to the risks posed by animal by-products, improve legal clarity and adapt requirements to progress in science and technology.

To achieve these specific objectives, operational objectives were established focusing on the problems identified as:

- for the scope of the Regulation: adjusting the regulatory framework to the risks posed by animal by-products by determining to which processed products the rules apply, thereby preventing gaps or overlapping of legislation and reinforcing consumers' confidence,

- for categorising new products: adjusting the regulatory framework to the risks posed by new animal by-products and improving legal clarity,

- for clarifying approvals/ registrations and controls: improving legal clarity and avoiding any unnecessary burdens,

- for clarifying the derogations: adjusting the regulatory framework to the risks posed by animal by-products and contributing to progress in science as regards import of ABP.

The aim of the initiative is in line with the Commission's strategic objectives and better regulation principles, namely to improve and make the measures more effective and efficient, reducing unnecessary burden for operators as far as protection of public and animal health and food safety are not undermined.

4. OPTIONS CONSIDERED

To address the problems identified during the process, different options were considered except deregulation as the current legislation has proven to be an efficient tool to achieve a high level of protection against public and animal health risks.

The social, economic and environmental impacts of all options were analyzed during the impact assessment process. The analysis has remained mainly qualitative due to the limited data that the questionnaire delivered (as further explained under chapter 6). Although it was not possible to use the Standard Cost Model, an estimation of administrative costs has been carried out for some policy options as far as available data could be used. The following is a summary of the conclusions from the analyses carried out:

- The no-change option, which is based on continuing with the current situation for all the issues was considered not adequate as it would not solve the problems that currently exist as regards the level of protection of public and animal health, the distortion of competition and the functioning of the internal market .

- The use of non/soft regulatory tools was also considered for clarifying the scope of the Regulation while for the rest of the identified issues the use of these tools was considered not relevant, . The results of the impact analyses concluded that the use of non-regulatory tools would not solve the problem of legal uncertainty when interpreting the scope of the ABP Regulation

- The final option considered was a legislative revision of the current Regulation.

5. CONCLUSION

Following the impact analysis, the overall conclusion was that the best option to respond to the problems identified in the evaluation was to carry out a legislative revision of the current Regulation. This legislative review would solve the issues of different interpretations on the scope of the regulation and the derived problems as distortion of competition and different levels of protection against risks for public and animal health. It will also provide for a more risk-based categorisation of ABP, will clarify the derogations and would imply a reduction of administrative burden by eliminating double approvals for some types of premises.