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COMMISSION OF THE EUROPEAN COMMUNITIES

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COMMISSION STAFF WORKING DOCUMENT

IMPACT ASSESSMENT

accompanying the

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

{COM(2008)345 final}
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1. EXECUTIVE SUMMARY

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.

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:

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

- 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).

Therefore, 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.

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.

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

- 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.

2. PROCEDURAL ISSUES AND CONSULTATION OF INTERESTED PARTIES

2.1. Overview

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

A number of stakeholders, experts, competent authorities of the Member States and international trading partners have been consulted, bilaterally or collectively. More than 36 European Associations with an interest related to the food chain and animal and public health (ABP producers, processors, traders, users, and consumers) have been given the opportunity on a number of occasions to express their views in accordance with the Commission's minimum standards for consultation. An Inter-Service Steering Group was established. In summary, the reactions towards the proposal were positive. The need for legal certainty and for improving the risk-based approach of the requirements was highlighted.

The Impact Assessment (IA) follows the structure given in the Commission's IA guidelines SEC(2005)791 of 15 June 2005. It aims to consider the environmental, economic and social aspects of policies on ABP in an integrated and proportionate way.

2.2. Consultation of competent authorities

Article 35 of the ABP Regulation requires Member States to inform the Commission of the measures taken to ensure compliance with the Regulation. On the basis of the information received, 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 States in applying the legislation[2]. The report also takes into account the findings of the Commission's Food and Veterinary Office, gathered during inspections carried out in 2004 and 2005 to assess the level of compliance in all 25 Member States.

From December 2005 to September 2006, six working groups and one specialized meeting were held with Member States' experts, in the framework of the Standing Committee on the Food Chain and Animal Health to discuss the issues to be reviewed. Also, over a two-day meeting of the Council Working Party of Veterinary Experts (Public Health) on 10 and 11 November 2005, Member States have examined the Commission's report. The outcome of that meeting supported the Commission's intention to review the legislation concerned.

2.3. Consultation of stakeholders and of consumer organisations

The consultation of stakeholders and consumer organizations targeted the sectors likely to be affected by/or involved in policy implementation. A list of the stakeholders and consumer organizations consulted can be found in Annex I-A.

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[2] http://ec.europa.eu/food/food/biosafety/animalbyproducts/index_en.html

– A three-stage consultation was held via the working group of the Advisory Group on the Food Chain and Animal and Plant Health. The 1st stage (20 February 2006) sought to ascertain stakeholders' perceptions about the nature of the issues identified in the Commission report and to collect views about the possible options to solve them. The 2nd stage (7 September 2006) aimed to sound out stakeholders on the likely acceptability of the preferred option(s). The 3rd stage (20 April – 18 June 2007) collected views on possible impacts of the options. Copies of the minutes are available at

  http://ec.europa.eu/food/food/biosafety/animalbyproducts/index_en.htm

– *Ad hoc* bilateral meetings were held with the representatives of the specific sectors likely to be affected, including key associations (see summary of chronology of main exchanges at Annex I-B).

The stakeholders largely agreed with the need to review the areas identified in the Commission report, particularly those that relate to clarification of the rules and the introduction of a level of flexibility. Whilst consumer organisations were also consulted, no specific comments were received from them.

2.4. Consultation of international partners

From 2002 to 2006 several bilateral discussions have been held with major trading partners (USA, Canada, Japan, Australia, New Zealand, Switzerland, etc), the outcome of which has fed into the review process. Details (dates and broad issues discussed) are given at Annex II.

In line with Article 5(6) of the SPS Agreement, 16 notifications to the WTO/SPS have been made as regards implementing and amending measures. The Commission report has also been notified, with the view to obtaining early comments from international trading partners.

The outcome of the bilateral discussions and responses to the notifications have been considered and as appropriate taken into account in relation to import provisions.

All trading partners consider that the review would be a step in the right direction.

2.5. Inter-Service Steering Group (ISSG)

Given the crosscutting nature of the issues concerned, the Commission set up an ISSG to provide specialized inputs and to bring a wider perspective to the process.

Three meetings of the ISSG were held (20 February, 13 September 2006 and 5 June 2007) in order to obtain other services' views about the issues identified, the possible options and likely impacts.

The services concerned were: AGRI, ENTR, ENV, FISH, RELEX, RTD, SG, SJ and TRADE. As far as possible, the comments expressed by the various DGs represented at the three meetings have been taken into account in this document.

2.6. The European Food Safety Authority (EFSA)

A number of changes being proposed arise from new scientific advice. These changes relate mainly to the use of Category 1 and/or 2 materials for the production of technical / industrial products (biogas, bio-diesel, photo gelatine, fertilizers / soil improvers). The Commission has consulted EFSA concerning aspects of the review that are relevant to its work. A list of opinions is given in Annex III.

2.7. Other opportunities used for consultation

Views were also collected during three workshops – in Greece (May 2006), Italy (June 2006) and Poland (July 2006) – and one Conference in Brussels (September 2006) organized by the Commission as part of the "better training for safer food" initiative, involving the competent authorities of the Member States and of the third countries trading partners and operators.

The workshops and conference highlighted a number of local, regional, third countries and sector specific concerns, which have been considered in completing this report. A report of the workshops and conference is available at:

http://ec.europa.eu/food/food/biosafety/animalbyproducts/index_en.htm

2.8. General on-line consultation

A general consultation addressed to the general public, stakeholders, Member States and third countries has been carried out from 20 April to 18 June 2007 via an Interactive Policy Making online at the following Commission website:

http://ec.europa.eu/yourvoice/ipm/forms/dispatch?form=animalbyproducts

The statistics and a summary of the main findings of this consultation are available in Annex IV. The outcome of this consultation has been used as part of the analysis of impacts.

2.9. Consultation on administrative burden to competent authorities of MS and the industry

A questionnaire was sent to Member States and third countries competent authorities and interested stakeholders in order to gather data concerning the expected potential impact of the review on administrative burden for enterprises, the voluntary sector and public authorities. The addressees had the possibility to respond from 20 April to 18 June 2007. Where possible, the results of this consultation have been used to analyse the impacts of the different proposed options. However, it should be noted that the quality of responses was mixed and it was difficult to get any clear and consistent information on costs. The questionnaire and a summary of the answers received can be found in Annex V.

2.10. Opinion of the Impact Assessment Board

This document has taken into account the recommendations of the Impact Assessment Board as far as possible. As a consequence of the opinion of the Impact Assessment Board, some changes have been introduced in this document, in particular the changes related to information obligations for businesses and public authorities have been listed in order to clarify simplification benefits, though to give exact estimations of these costs for all the affected industrial sectors was not possible due to time constraints as this item is a priority of the Commission Legislative Work Programme for 2007. Though the EU Standard Cost Method has not been used considerable effort to calculate the costs and to get data from Competent Authorities and the industrial sectors affected has been carried out and assumptions have been made when no data was available. As explained under chapter 6, to make extrapolations on these costs from one industrial sector to others is difficult as these costs highly depend on the industrial sectors considered and the type and number of ABP they use as raw material.

To address the question of whether divergence in implementation has led to costs differences which hamper the functioning of the internal market qualitative analyses of the situation has been carried out, though, as for the issue of monetisation of the simplification benefits, data submitted by the Member States and the industrial sectors has not enough quality to make precise indications. Though it was clear that considerable differences between costs of registration in different Member States, it has not been possible to find out whether these divergences are due to the different interpretations of the Regulation by the Member States or to other factors such as the type of premises and the different items considered for the calculations of this costs.

To include further quantification of the problems identified, further effort has been made to collect data on the industrial sector affected. Data on the size, employment and turn over of the affected industrial sectors was available, but the estimation of compliance costs for all the affected industrial sectors was not possible for the reasons already mentioned though some indication of theses costs for the biochemical industry are given under chapter 6.

As regards the procedure and presentation of the document, the benefits of the selected options have been further explained and data sources have been clarified. Further quantification of the problem definition has been included as regards the number of entities and employment for some of the affected industrial sectors.

3. PROBLEM IDENTIFICATION

3.1. Background

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[3] 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.

– The ABP legislation is complex and covers a very broad range of products and industries. The following background information about the current legislation helps to understand the problem identification.

– **Scope of the ABP Regulation.**

The ABP Regulation lays down a general framework for a wide range of stakeholders and industrial sectors such as producers of feeding stuffs, petfood and technical products (organic fertilizers, biogas / bio-fuel, compost, game trophies, cosmetics, medicinal products, medical devices/laboratory reagents, photo gelatine, etc) and for waste operations (incineration, co-incineration plants). The Regulation covers ABP handled within the Community (placing on the market and intra-Community trade), transited through as well as imported into the Community from third countries, and affects small, medium and large operators in EU and third countries.

– **Categorisation of ABP**

The Regulation classifies ABP into 3 categories; with Category 1 material being of the highest risk and Category 3 comprising materials of low or negligible risk. Materials that are not Category 1 or 3 are, by default, placed in Category 2. The categories are described in the box below, along with examples of which ABP falls within which category, allowed uses and means of disposal.

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

Category 1 ABP:	Animals infected or suspected of being infected with transmissible spongiform encephalitis (TSE). ABP from animals treated with hormones; laboratory animals; pet animals
Allowed uses:	Use not allowed, destruction compulsory (generation of energy possible)
Category 2 ABP:	Fallen stock; animals killed due to an epizootic disease (other than TSEs); manure; by default any ABP not categorised as 1 or 3
Allowed uses:	Certain technical uses such as fertilizers or for production of oleochemical products.
Category 3 ABP:	ABP from animals fit for human consumption
Allowed uses:	Feeding purposes and any technical use

– Extent of the industry

It is important to understand the extent and scope of the industries that are affected by the ABP regulation (Diagram 1 highlights some of these industries and the ABPs with which they are linked). The scope of the Regulation is cross-cutting, covering a wide range of industrial sectors. Animal by-products are being used or handled by operators in the field of feed for farmed and pet animals, of technical products (production organic fertilizers, biogas / bio-fuel, compost, game trophies, cosmetic, medicinal products, medical devices/lab reagents, photo gelatine, etc) and of waste disposal / recycling operations (incineration, co-incineration, landfill, etc). As a consequence impacts of each policy issue can vary substantially depending on the type of industry considered. Further information is given in Annex VI, not only on the variety of industries operating on the basis of ABP but also with details of the size and importance of some of these industries. For example,

Gelatine Manufacturers of Europe - 10 European companies with a total of 22 production plants. This accounts for 45 % of the worldwide gelatine production. Gelatine is produced mainly from bones and some parts of hides and skins of bovine, porcine and fish. It is used for food, feed and for technical purposes (e. g. photo and cinema films, x-ray-films).

European Fat Processors and Renderers Association companies process about 15.5 million metric tons ABP per year. It has 483 production units with almost 17000 employees. Raw material comprises mainly of whole carcasses and of any ABP derived during slaughter. Products are meat, bone meal and tallow.

UECBV – European Slaughterhouses and meat Traders Association represents stakeholders for livestock markets, livestock traders and meat traders, slaughterhouses, cutting plants and meat preparation plants, importers and exporters in the 25 Member States and other European countries. UECBV represents some 15,000 firms of all sizes and 230,000 jobs. These stakeholders are main generators of ABP: ABP from live animals (manure, milk, eggs, etc.), ABP derived during slaughtering (specified risk materials, meat not fit for human consumption, etc.) and during further processing (unusable cuts or other parts in meat cutting plants or during meat preparation),

European Oleochemicals & Allied Products Group has 17 members who produce fatty acids. With around 500 mio euro/year turnover the industry represents 10.000 jobs in Europe. Oleochemicals, such as glycerine, are produced mainly from tallow.

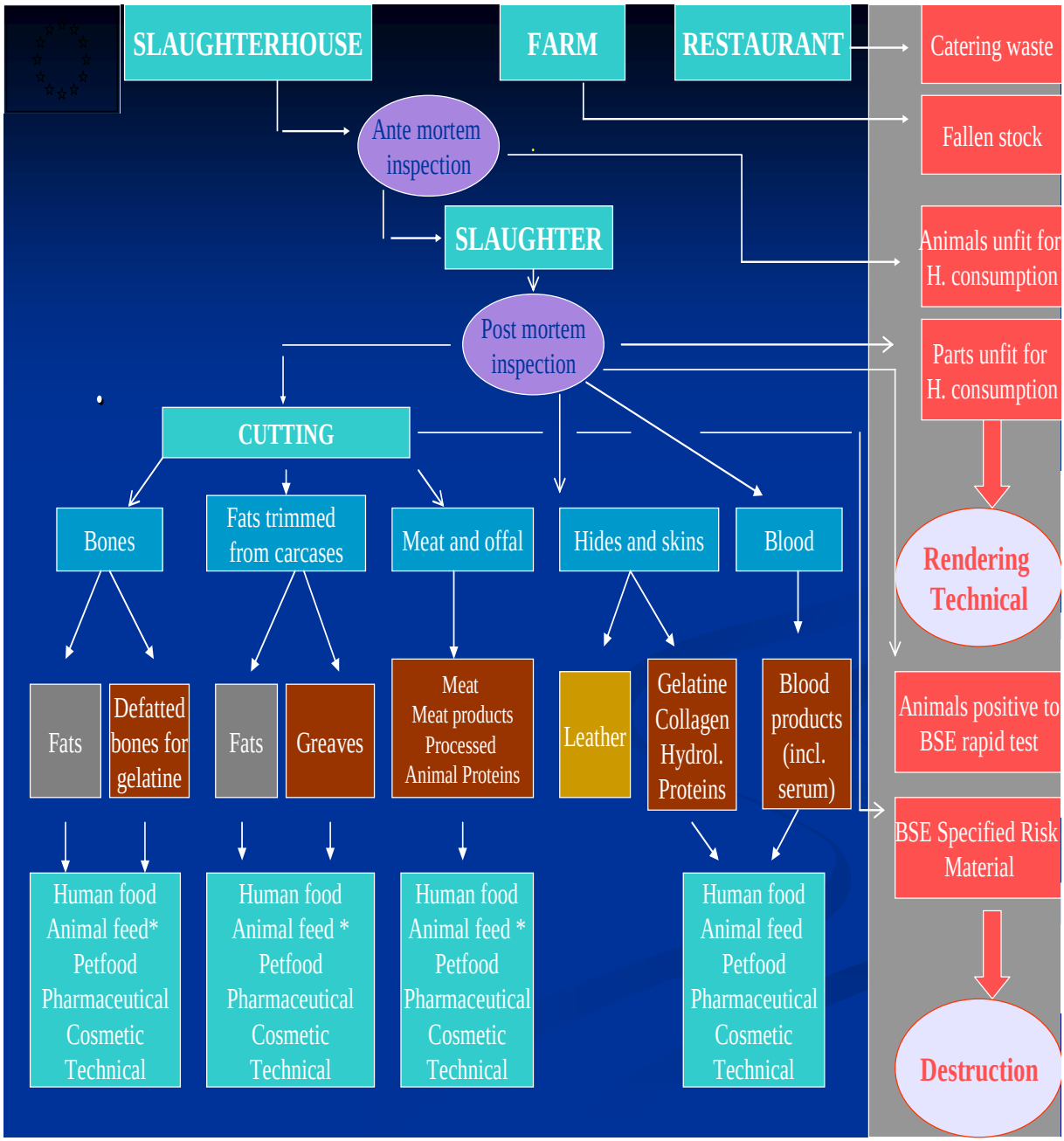
FEDIAF – petfood industry represents the interests of 19 national pet food industry associations and with this the interests of around 450 European pet food producing companies. In 2005, products worth 8.5 Milliard Euro were sold. This industry employs directly 21.000 and indirectly another 30.000 people. Raw material for petfood production are e. g. meat, livers, kidneys, milk products, hides and skins and a large further variety of ABP.

EFPIA – European Federation of Pharmaceutical Industries and Associations

EFPIA represents the pharmaceutical industry operating in Europe through its direct of 30 national associations and 46 leading pharmaceutical companies and 2.100 companies committed. Such products derive mainly from blood products, but also from enzymes (derived e. g. from stomach or intestines) or organs used for medical devices (cardiac valves obtained from hearts, lenses of eyes, parts of the medium or internal ear, etc.).

The European vaccine industry (data submitted by EVM – European Vaccine Manufacturers) is the largest supplier of vaccines in the world, producing approximately 80% of vaccines used worldwide. It is the largest supplier to UNICEF of vital paediatric vaccines, including polio vaccines. ABP used for vaccine production is mainly blood serum, but also pathogens or parts thereof (bacteria, viruses, etc.). **Veterinary products industry:** More than 50.000 fulltime jobs in Europe are dependent on the animal health industry with about 15,000 being in production, marketing, sales, research and development. European sales of animal health care related products amounted to $5.3 billion US in 2005. Such products derive mainly from blood products, but also from enzymes (derived e. g. from stomach or intestines) or medical devices (cardiac valves, parts of eyes or ears, etc.).
EDMA – European Diagnostic Manufacturers Association brings together 20 National Associations in European countries and 29 of the major companies engaged in research, development, manufacture or distribution of in-vitro-diagnostic products. Through its affiliated National Associations, EDMA represents in total more than 500 companies (or over 700 legal entities) across the EU. The market for in-vitro diagnostic products has a value of around 9 billion € per year (2005 figures). The main ABP used is blood serum.
Confederation of National Associations of Tanners and Dressers of the European Community represents companies with more than 3.000 plants (mainly small and medium enterprises). More than 50.000 direct jobs depend on the leather industry that accounts a 8.000 Million Euro turnover/year. This hides and skins used as raw materials represent typically 50-60% of leather production costs
European Cosmetics Industry: The value of output of the EU cosmetics industry is estimated at around €35 billion (in 2004) and the industry employs over 150,000 Europeans directly. Cosmetics are being produced mainly using tallow and derived products, e. g. glycerine, but also enzymes, acids, hormones or colours derived from various animal tissues (skin, intestines, hair, insects, etc.).

Diagram 1: Sectors / industries covered by the Regulation



3.2. The issues / problems that require actions

The current Regulation entered into force on 1 November 2002 (and applied as from 1 May 2003) and lays down strict rules, covering almost everything being a (dead) animal or having been derived from animals and not intended for human consumption. The Commission report of 2005 (see section 2.2) concluded that it has been challenging for all Member States and economic operators to apply the rules laid down by this Regulation. However, compliance has been generally satisfactory and the basic principles of the Regulation have proven to deliver a significant contribution towards achieving the objectives of a high level of protection of public and animal health now achieved in the Community and should be preserved. In order to contribute to the achievement of these objectives, the Commission has, since the entry into force of this Regulation, already carried out a number of actions including the drafting of guidelines and issuing legislation by means of Comitology (the complete list can be found in Annex VIII).

Even though the legislation is working well and generally meets its overall objectives, the subsequent consultations have identified areas where changes need to be considered in order to update the current legislation and to provide legal certainty, as well as simplify and reduce administrative burden. What has been identified is that the products and the industries concerned are wider ranging than foreseeable by the legislators at the time of adoption of the Regulation. In addition, further information on the risks posed by certain ABP material, and the effectiveness of treatment standards in producing a 'safe' product, has become available in the years since adoption of the legislation. Therefore, it is an appropriate time to look again at certain aspects of the legislation. The intention being to focus on ensuring that the current rules are 'risk-proportionate' i.e. they allow trade and competitiveness of the EU industries that deal with ABP without reducing the level of protection for public and animal health.

Whilst there are a number of issues that are likely to be addressed in any revision, there are a few where it has been identified that there might be significant impacts. These are set out below and are the subject of this impact assessment.

3.2.1. Policy issue 1: The scope of the Regulation is not sufficiently clear

The scope of the Regulation is very wide ranging, covering – with only a few exceptions - any animal by-product (i.e. entire bodies, parts of animals and products of animal origin) which is not intended for human consumption. With such a wide scope we need to examine whether the rules are always proportionate to the risk and consideration needs to be given to providing more focus. Specifically in two areas; uncertainty as to when the legislation ceases to apply to ABPs (end of the "life cycle" of an ABP) and difficulties that have arisen due to exceptions from the scope for ABP from wild animals).

<u>Policy Issue 1(a) - For certain ABP it is not clear at which stage of their processing the legislation ceases to apply</u>

Summary

Although the regulation is clear about when materials become an ABP, i.e. when the "ABP life-cycle" starts, it is less clear about when they stop being an ABP, i.e. the life-cycle stops and the Regulation does not apply any more. This means that, technically, products such as leather and clothing made from wool are still subject to the ABP regulation. Whilst for these types of products Member States have adopted a pragmatic approach and not applied the regulation (as there are no obvious risks for public or animal health associated), there are other ABP products where the situation is not so clear. For companies who deal with such products and for the Member States authorities that must ensure proper enforcement, the legal uncertainty due to the lack of a clear definition of the end of the ABP life-cycle can be a major problem, either due to inconsistent enforcement that may lead to health risks and/or distortion of competition or having to apply stringent and disproportionate rules when there is a negligible risk to health from the products in question.

Background

The Regulation classifies certain materials as animal by-products and lays down rules for their handling, channelling and final use. These rules also apply for products containing ABP in addition to other materials. The Regulation, however, does not define the point as from which no further controls of the ABP are needed (the "end point of the life cycle"). It was certainly not the intention of the legislators to subject highly processed products to controls, such as leather shoes (produced from hides and skins), paints (produced with certain milk products) or lubricants (produced from tallow). These products pose a negligible risk to public or animal health and application of the requirements of the ABP Regulation is disproportionate.

Whilst there would potentially be unnecessary costs to operators and competent authorities in applying the Regulation to highly processed products, in reality Member States have adopted a pragmatic approach, acknowledging that such products were not the target of the legislation and, consequently, applying and interpreting the Regulation as not extending to these products.

A higher degree of legal certainty would however avoid different interpretations and a difference in the level of protection throughout Member States. Not least as because the range of products and industries that fall under the ABP Regulation is often not clear cut as it is with products such as shoes and wool clothing. For example, it is possible to treat tallow to the extent that there is a negligible risk (i.e. the ABP life-cycle is 'finished') – but the degree of treatment required will be dependent on whether the tallow is derived from Category 1, 2 or 3 materials. The current ABP Regulation allows the use of Category 3 tallow for production of feed and any technical product including cosmetics, medicinal products and medical devices. Category 1 and 2 tallow and any product derived thereof, are in principle not allowed for such purposes. This poses problems for the tallow derivatives industry, in particular as regards a wide range of items produced for industrial purposes (lubricants, plastics and rubber components, paints, etc).

In the pharmaceutical industry, highly processed ABPs which pose negligible risk are often used, but the companies handling them must anyhow follow the provisions of the ABP Regulation as regards authorization procedures, which are in addition to the already stringent authorization procedures foreseen by the pharmaceutical legislation.

Policy Issues 1(b) - It is not clear whether ABP from wild game are subject to the requirements of the Regulation.

Summary

The ABP Regulation excludes from its scope bodies and parts of wild game which die in nature (either due to natural reasons or through hunting), as long as the wild animals are not suspected of being infected with a communicable disease. However, this means there is uncertainty as to whether ABP from establishments that handle hunted wild game for the placing on the market of wild game meat and other foodstuffs (be these in EU or third country) fall under the ABP Regulation. In this regard, it must be considered that these establishments are indeed covered by the recently revised food hygiene legislation. The major problem relates to import of wild game from outside of the EU and the fact that game handling establishments outside of the EU may not be subject to similar hygiene conditions.

Background

Although a problem of much less magnitude than the previous one, current provisions as regards ABP from wild animals have led to some difficulties of interpretation: the ABP Regulation includes in its scope bodies and parts of farmed game which are slaughtered for human consumption. However, it excludes entire bodies or parts of wild animals if they are not suspected of being infected with diseases communicable to humans or animals (with the exception of certain fish and ABP used to produce game trophies).

The intention of the legislator was to avoid requiring collection and disposal of wild game, which die in nature for natural reasons or through hunting for non-commercial purposes. However, this general exclusion from the scope does not clarify, whether ABP derived from handing wild game in game handling establishments or ABP derived from wild game supplied to the local market by hunters are subject to the requirements of the ABP Regulation. These ABP could pose non-negligible risk to public and/ or animal health. Risks could arise, for example, if these ABP are derived from animals infected with classical swine fever, foot-and mouth disease or tuberculosis, and are then brought into contact with susceptible individuals. Such diseases are absent or rare in most parts of the Community but are common in a certain number of third countries. The lack of clarity of current provisions also has an impact on our import rules.

Furthermore, it must be considered that wild game handling establishments are covered by the recently revised food hygiene legislation. This legislation, in particular Regulation (EC) No 853/2004, contains provisions on the handling of wild game, which obliges operators to ensure hygienic conditions and in particular to prevent contamination of meat from other animal material present.

ABP derived from wild animals may be of economic interest e.g. for the pet food industry but any industry using ABP could also use this source. Currently, certain Member States and parts of the industry are acting on their own responsibility and subject such ABP to adequate safety requirements.

Nevertheless, in order to ensure that these obligations are being met in a consistent way in the EU and in relation to imports, it is preferable to clarify to which extent the rules on ABP are applicable to game-handling operations. Therefore, it is necessary to clarify the scope of the Regulation as regards ABP derived from wild animals, with the aim to ensure legal certainty by harmonising requirements for their control, and in the interest of uniform and adequate protection of human and animal health. By clarifying the provisions applicable to certain commercial hunting operations, consistency with Community food hygiene legislation should also be ensured, while any duplication will be avoided.

3.2.2. Policy Issue 2 – Categorization of ABPs: Categorization of some materials is disproportionate compared to the risk

Summary

The Regulation needs to take account of scientific evidence that has emerged as to the risks of certain ABP. More specifically, the current categorization system is not always risk proportionate for certain ABPs, with this having significant implications for the industries that use these products.

Background

Under the current rules, ABP are classified in accordance with the risk they pose. This may be inadequate in two ways:

- Some of the material is not listed in the category corresponding to the risk

  The risk attached to ABP is in some cases decided by reference to other Community legislation which is based on the assessment of risks to public health (such as the legislation on TSEs) and to the safety of the feed chain (such as legislation on residues). In some cases, this other legislation has been changed since the entry into application of the ABP Regulation to reflect new scientific knowledge (e.g. ruminants below a certain age limit do not have to be tested for BSE and therefore, the classification of the ruminant blood does no longer adequately reflect the risk assessment behind BSE rules).

- Some of the material is not listed at all and therefore by default fall into category 2

  ABP rules establish that any ABP not been defined as Category 1 or Category 3 material falls immediately by default under category 2. The aim of this provision is the protection against any possible unidentified risks that may arise. However, the Regulation only allows a very limited use of category 2 ABP. Since entry into application of the Regulation, more scientific evidence has become available on possible uses of some animal by-products and on the risks attached to them (see box below)

Examples of ABP for which the categorisation is considered as not being risk adequate.

> **Casein**, a by-product derived from milk processing and used for the production of white paints does not fall under any of the ABP listed as Category 1 or 3 and falls also by default under Category 2. As such, its use for technical purposes is limited, which poses great difficulties to the paint industry.
>
> **Insects** are used in the cosmetic industry (as they provide pigments for lipsticks, etc), for pet food and for fish-feed. These ABP fall into Category 2 also by default and are therefore not allowed for those purposes (in order to allow for continued use of these materials, a transitional measure has been adopted under the ABP Regulation (Regulation (EC) No 878/2004)).

Current legislation contains no simple facility for updating the categorisation of ABP other than via the adoption of transitional measures which do not result in a coherent legal framework. Hence, the legislation is not flexible enough to keep up with advancements in scientific knowledge and technology. This means that the legislation is not always risk-proportionate and may to some extent impose unnecessary burdens on the manufacturing industries using these products, .or indeed preventing use of ABP which are safe and of economic value.

3.2.3. Policy issue 3- Duplication of approvals for some type of premises

Summary

Experience has shown that the relationship between the ABP Regulation and other Community sector legislation is not always clear and in some cases at other places they are overlapping. As a consequence, there are legal uncertainties how the requirements laid down in different legal acts are supposed to apply to certain operators. Also, certain operators have to be approved twice by the relevant authorities for similar objectives.

Background

The Regulation requires that all premises handling ABP must be approved and meet the requirements of the ABP Regulation, even if they have also to be approved under other Community sector legislation. As a result, certain premises that are already approved under food/feed legislation (e.g. for the production of tallow, eggs, gelatine, etc) or under technical sector legislation (e.g. on cosmetics, medicinal products and medical devices) must also be approved under the ABP Regulation.

These different sets of rules may result in a duplication of administrative burden for operators as well as different ways of application of the legislation, since different competent authorities might develop different ways of resolving overlaps in the rules. However, as long as food safety and animal and public health protection are guaranteed by the sector legislation, this duplication for operators as well as for competent authorities should be avoided.

Example of types of premises undergoing double approvals

Establishments producing gelatine or collagen for human consumption may decide to deliver their end products also for uses outside the food chain, which fall under the ABP rules (e.g. photographic gelatine). Since they are already approved under food hygiene legislation and comply with the relevant production standards, it should be considered whether a separate approval under ABP rules is necessary for such plants.

Petfood plants may already be approved under Regulation (EC) No 183/2005 on feed hygiene for other manufacturing operations. In this respect, they have to comply with comprehensive requirements as regards hygienic production conditions and the monitoring of risks to public and animal health during their operation. Insofar as the objectives of these rules coincide with the objectives of the ABP Regulation, it would not seem proportionate to require such plants to be approved again under ABP rules.

3.2.4. Policy issues 4 - Derogations of the Regulation do not consider certain specific situations.

Summary

The strict rules of the Regulation on derogations need to take into account specific circumstances. The import of a wide range of ABP is sometimes necessary for research purposes. Under emergency situations, disposal of ABP through the normal channels is not practically feasible. The current rules do not provide for risk-adequate solutions to these problems.

Background

– Import of ABP for research

Current provisions allow the use in the Community of all Categories of ABP for research and scientific purposes under Member States responsibility. However, the importation of Category 1 and 2 materials for such purposes is not allowed even if their use is strictly limited to research/scientific purposes (for example: materials derived from experimental animals are classified as Category 1 material and as such their import is prohibited).

Certain stakeholders are constantly developing new possibilities to use certain ABP classified as Category 1 for testing and research/scientific purposes. The current restriction on imports undermines such development of new products and related technologies and therefore the competitiveness of EU enterprises engaged in research.

Example of ABP used for research purposes:

Research institutes have in the past been engaged in projects which required the use of material from non-farmed animals belonging to species or breeding lines not present in Europe, such as for example non human primates or certain genetically modified mice. Due to such animals being classified as Category 1 material, import of the derived by-products is not permitted. Similar considerations would apply to by-products from animals or materials with BSE or other disease risk which are used for the purpose of tests in Community reference laboratories.

– Disposal in natural disasters

In certain situations the requirements for incineration and landfill of animal carcases, in particular of fallen stock, cannot be applied. The current legislation provides for derogation in three scenarios, namely in the case of (i) dead pet animals, (ii) remote areas with low animal density population and (iii) major outbreaks of highly contagious animal diseases, such as FMD. The derogations have been put in place in order to avoid the risk of spreading diseases or in view of the lack of disposal capacity for a large number of animals which die.

While under the respective contingency plans efforts are necessary to ensure sufficient capacity for the rendering of dead animals in the context of disease control measures, the available rendering or incinerator capacity within a region or country could quickly be overwhelmed and become a limiting factor in the control of a disease, as observed in the case of 1997 CSF and 2001 FMD epidemics.

Similar considerations need to be applied for certain scenarios such as;

- areas where access is practically not possible (eg: due to geographical conditions) or present a risk to health and safety of those charged with the operation, and where there is a unacceptable discrepancy between the requirements for occupational safety and the potential risks to animal health, and

- areas where there is a natural disaster, to which it is equally argued that the derogation should be extended. Examples of this situation are provided in the text box below:

During the fires in Galicia (Spain) in 2006, a total of 130 carcasses of animals had to be brought to the nearest accessible mountain paths where a lorry could drive at a total cost of 33 000 €. To this cost the normal costs for transport to and destruction in the rendering plant have to be added.

In summary, the costs for recovery and disposal, under the conditions of the disaster are five times higher that the costs for the same procedures under normal circumstances.

Similar considerations apply to exceptional circumstances such as extreme heat or floods. As an example, during the extreme heat in France in the summer of 2003, the amount of poultry, fish and porcine cadavers which had to be collected rose by 40% as opposed to the same period in previous years (in total: around 12.000 tonnes more). The additional disposal costs for this quantity of material can be estimated at 3 000 000 €.

3.3. PERSPECTIVES (POSSIBLE EVOLUTION OF THE ISSUE / PROBLEM)

Although a precise evolution of the problem for all different operators and stakeholders involved cannot be predicted, from a general point of view, it can be stated that a lack of legal clarity and consequential different interpretations with respect to the scope and the rules of the Regulation could lead to public and/or animal health risks and different levels of protection across the Community, and distortion of competition for operators.

Insofar as the risk-proportionality of the rules on animal by-products needs to be improved and the rules need to be adapted to possible progress in science and technology, the competitiveness of various industries in the European Union could be undermined as industries outside the EU are not subjected to these requirements. As a consequence manufacturers could move outside the EU with negative impacts on employment and the economy. Advance in medical research could be also negatively affected by the prohibition on imports o ABP for these purposes.

Unnecessary administrative burden would be imposed on EU industries and competent authorities as well as inconsistencies would persist with other EU legislation.

Different interpretations of the scope of the Regulation will lead to potential distortion of competition that hampers the functioning of the internal market and to different levels of protection against public and animal health threats between Member States.

3.4. Subsidiarity test

The project refers to a revision of Regulation 1774/2002 of the European Parliament and of the Council of 3 October 2002 laying down health rules concerning animal by-products not intended for human consumption. Article 152 (2) of the Treaty provides a legal basis for the EU legislative measures on ABP as the primary objective of the Regulation is the protection of public and animal health. The subsidiarity principle applies insofar as the proposal does not fall under the exclusive competence of the Community.

Necessity-test

Significant risks of the spread of diseases to which animals may be exposed and of endangering animal and human health through animal feeding stuffs, were witnessed in recent years in relation to BSE, FMD, CSF and dioxin. Such health risks were identified across the Community and had significant impact on intra-Community trade (such as market failures due to changes in consumption patterns). For this reason particular requirements are needed at Community level as regards the placing on the market of certain ABP, particularly in regions with a poor health status. This would also ensure that products imported from or exported to third countries are of a hygiene standard which is at least equivalent to the minimum hygiene standard applied in the Community.

The current revision, even though not intending to introduce any changes to the basic principles and structure of the way ABPs are handled, has to be done at the Community level as only this way certain issues can be effectively clarified, as well as sufficient flexibility to take account of emerging scientific knowledge about risks associated to the possible uses of ABP can be ensured.

Added-value test

ABP are included in the list of products in Annex I to the Treaty[4]. Their placing on the market constitutes an important source of income for part of the farming population and other concerned sectors. To ensure a smooth functioning of the internal market, rational development in this sector, increase productivity and stimulate competitiveness, animal health and public health rules for the products in question are needed at Community level.

Boundary test

Crises that have occurred in the past show that in the case of a disease outbreak and in the absence of a fully harmonised approach, Member States may be subjected to internal pressure, that may eventually prevent the adoption of the best measures to control the disease, if they are not bound by Community legislation. This may finally lead to the spread of disease and additional costs and losses for the farming, agro- and food-industries as well as for the Member States' and the Community's budgets.

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[4] Annex I to the Treaty establishing the European Community, *List referred to in Article 32 of the Treaty* (list of products subject to the provisions governing CAP).

In addition, in the absence of a harmonised approach, measures restricting trade would be taken at national level, disrupting the functioning of the internal market. This would also have a serious impact on EU exports as the credibility of EU measures would be jeopardized. Member states will have to face third country restrictions to exports themselves, meaning severe trade restrictions as a consequence of animal health problems losing power to negotiate at international level.

In light of these different elements, EU action is justified as it is clear that Member States can not achieve this satisfactorily and that the EU can do it better and more efficiently.

4. OBJECTIVES

The aim of the review is in line with the Commission's strategic objectives and better regulation principles[5], 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.

Therefore, the **general objective** is to review the Regulation on ABP in order to:

- better ensure the safety of the food and feed chain and reinforce consumers' confidence
- facilitate smooth functioning of the internal market,
- increase competitiveness of the EU industries affected by this Regulation

In order to achieve the general objectives, the following **specific objectives** have been established.

- adjust the regulatory framework to the risks posed by animal by-products
- improve legal clarity and,
- adapt requirements to progress in science and technology;

[5] Communication from the Commission - Action plan: "Simplifying and improving the regulatory environment"; COM(2002) 278 final.
Communication from the President in agreement with Vice-President Wallstrom - "Strategic objectives 2005 – 2009, Europe 2010: A partnership for European Renewal, Prosperity, Solidarity and Security"; COM(2005) 12 final.
Communication from President Barroso in agreement with Vice-President Verheugen - "Communication to the Spring European Council: Working together for growth and jobs – A new start for the Lisbon Strategy", COM(2005) 24 final.
Communication from the Commission to the Council, the European Parliament, the European Economic and Social Committee and the Committee of the Region – Proposal for a joint declaration by the Council, the European Parliament and the Commission on the European Union Development Policy – "The European Consensus", COM(2005) 0311 final.

The operational objectives focusing on the problems identified are:

- 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 reinforcing consumers' confidence

- for categorising new products: adjusting the regulatory framework to the risks posed by 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 improving legal clarity, also to contribute to progress in science as regards import of ABP

5. KEY POLICY OPTIONS

As already explained under chapter 3.2, the basic principles of Regulation (EC) No 1774/2002 have proven to deliver a key contribution towards achieving a higher level of public an animal health in the Community and towards preventing food safety and animal health crises such as those which have occurred in the past (BSE, CSF, FMD). The high level of protection against public and animal health risks must be maintained and thus deregulation has not been considered, as it is not an appropriate approach to this very sensitive issue.

To address the problems identified and described under chapter 2, different policy options have been considered and were the subject of an impact assessment. Due to the different nature of the problems identified and the different range of operators affected by each specific issue it was considered more adequate to tackle each issue separately.

The "Do-nothing" approach has been considered for all options as well as the "legislative review" option. Alternatives to the regulatory approach have also been analyzed for some of the issues but for not for the problems that are related to legislative interaction, clarifying derogations or re-categorization as they were considered not relevant due to the reasons explained later in this section.

5.1. Policy issue 1-Clarifying the scope

5.1.1. Policy issue 1 (a) - Determination of the end of the ABP life-cycle

Option (a): Do-nothing

Option (b): Co-regulation

Commission and stakeholders could set a common framework for the adoption of standards based on which the end-point in the manufacturing chain where the rules of the Regulation cease to apply will be established.

Option (c): Legislative review

Two possible sub-options have been identified:

– Exemption of finished products from the Regulation: Finished products which have been processed to a certain extent could be exempted from the Regulation.

– Introduction of a legal basis for the determination of the end of the ABP life cycle. Reduction of controls to products manufactured on ABP basis when technical and scientific considerations allow concluding that this entails no inadequate risks to public and animal health.

5.1.2. Policy issue 1 (b)- Coverage of ABP from wild animals

Option (a): Do-nothing

Option (b): Alternatives to legislative tools

- Self Regulation:

  Stakeholders concerned (such as hunters associations and producers of game meat) could identify for which type of premises it is necessary to apply the controls of the Regulation.

- Co-regulation:

  Commission and stakeholders could set a common framework for the adoption of standards to establish which type of premises must be subjected to the controls of the Regulation.

- Guidance:

  Guidance drawn up by the Commission, as appropriate following scientific advice and/ or consultation with the authorities responsible for enforcement in Member States, could be produced to give orientation when establishments obtaining/processing ABP from wild animals should be subjected to the requirements of this Regulation.

Option (c): Legislative review

To extend the scope to cover all ABP from wild animals which are handled to be placed on the market and allow the competent authority to define conditions to apply to establishments handling such ABP;

5.2. Policy issue 2 - Categorising new products

Option (a): Do-nothing

Option (b): *Alternatives to legislative tools*

Alternatives to the pure regulatory approach have been considered to be not relevant as the issue relates to the strict categorization of the current Regulation and it is not open to modification by non-legal instruments.

Option (c): Legislative review

To reclassify products which pose a low risk for public and /or animal health based on scientific assessment in order to facilitate their use.

5.3. Policy issue 3-Clarifying the approvals / registrations and controls

Option (a): Do-nothing

Option (b): Alternatives to regulatory tools

As this policy issue relates to the need to clarify interaction of different Community legislation non-regulatory tools have been considered to be not relevant and thus their impacts are not been analyzed in this document.

Option (c): Legislative review

To remove duplicated approvals and rely on the provisions already introduced by other Community sector legislation, but maintain certain requirements in order to ensure traceability of these ABP.

5.4. Policy issue 4-Clarifying the derogations

Option (a): Do-nothing

Option (b): Alternatives to regulatory tools

Alternatives to regulatory tools have been considered not relevant for this policy issue as it relates to clarifying the derogations of the Regulation and so their impacts are not assessed in this document.

Option (c): Legislative review

Extending the derogations to:

– Allow the imports of animal by-products for research purposes in line with other EU legislation such as legislation on TSE and

– Extend the possibility to bury and burn carcases of animals in areas (i) affected by natural disasters, (ii) where access is not practically possible or present a risk to health and safety.

6. ANALYSIS OF IMPACTS

6.1. GENERAL REMARKS

This Impact Assessment combines quantitative and qualitative approaches to ensure that adequate consideration is given to a broad range of direct and indirect as well as social, environmental and economic impacts.

The quantitative analysis is based on the results of the consultation, including data supplied by Member States competent authorities, third countries competent authorities and industries and other stakeholders affected.

Consultation on administrative costs. Data limitations and difficulties encountered

The stakeholder consultation carried out by DG SANCO delivered only limited information on financial impacts. Generally stakeholders (both industry and competent authorities) claimed that estimation was very difficult or even impossible for them for different reasons mentioned below (not all of these are applicable to every submission). Based on these data limitations and according to the proportionality principle, the assessment of the options has not been carried out using the Standard Cost Model. Consequently, in order to quantify the impacts, calculations for concrete options have been based on assumptions where appropriate.

As covering quantitative impacts on all industries affected by this proposal was not possible due to lack of accurate data from all of them, some examples of industries have been used to illustrate these analyses.

- The costs to comply with the Regulation are perceived by stakeholders as much higher than administrative costs, and therefore some of them focused their answers on assessing compliance costs. (eg: Cost for slaughterhouses and renderers of the implementation of ABP Regulation were assessed to be 54 mio. Euro/year in a single MS according to data submitted by UECBV). In addition, ABP requirements overlap with other requirements (sectoral rules, Good Manufacturing Practices, environmental legislation etc.) and often is it is difficult to estimate whether or not a given cost occurs only as a result of obligation resulting from ABP rules.

- Even when stakeholders can provide some estimation of overall administrative costs imposed on them by current Regulation it is difficult for them to assess how an eventual change of legislation would affect these costs. The impact of the proposal not only depends on the type of industry considered, but also on the type and category of ABP that they use or process. For example, one single pharmaceutical plant can use more then 80 different ABP, depending on the range of products they produce, while others may only use a few ABP.

- As it was possible not to provide certain information in the questionnaire, many stakeholders provided only partial data.

- Some of the industrial sectors affected by this Regulation are mainly dominated by SME. In most cases these companies do not dispose of precise calculations about costs of these options.

- There are environmental issues related to the use or disposal of ABP. Although this proposal will not introduce changes or requirements on environmental conditions for the use, processing or disposal of ABP, some of the issues could have indirect environmental impacts but these are difficult to predict and are not considered to be of major importance. It has to be noted that the environmental issues related to ABP are regulated by environmental legislation of the EU.

- Data submitted by the competent authorities give an idea of the costs for the administration related with some of the policy issues (ex: costs of registration and inspections of the premises). But costs vary a lot between Member States and even between regions as explained later.

- As the scope of the Regulation leaves room for interpretation, administrative costs of this proposal vary between sectors under the responsibility of different competent authorities. Also it was difficult to obtain disaggregated data on the type of premises to be registered/ or inspected yearly. The lack of disaggregated data makes it difficult to assess the reduction of administrative burden as a consequence of elimination of double approvals as it is not possible to establish the exact number of premises affected by this proposal. In addition, the costs of registration and inspection vary significantly depending on the type of premises and on the Member State. e.g.: registration cost per dossier vary between 16000 € and 75 €. The lack of disaggregate data makes impossible to compare between type of premises but in general approval of technical plants (including petfood plants) is more time demanding and in general costs of authorisation are higher than for other types of premises as co-incineration plants. More detailed examination and discussion of the responses with Member States which had submitted estimations also showed that different bases had been used for calculations, which makes comparisons even more difficult. Some authorities have introduced internal systems of cost calculation throughout the various steps of their control actions that facilitate the submission of data, whereas others supplied rough estimates. In one particular case, these estimates referred to the mere costs of visits necessary prior to granting an approval which were being billed to operators, while general running costs, such as staff salaries, were not being broken down and therefore not included in the estimate on a proportionate basis.

- As a further consequence of the difficulties referred to above, it is also very difficult to assess whether differences in interpretation actually have a significant effect on the proper functioning of the internal market. A Member State may for instance interpret the absence of provisions on suspension of approvals in case of shortcomings in intermediate and storage plants as a lack of legal basis to intervene – and this might be seen as reducing compliance costs for operators since they might not have to seek insure coverage for periods of non-delivery to their customers. However, it is actually more probable that the overall majority of competent authorities would take a different view and intervene based on other provisions of administrative law, thus interpreting the express references to suspension of approvals in provisions such as Article 17 (3) of the Regulation as an illustrative reference (in the particular case, a clarification in the course of the review is however intended).

- It is equally difficult to generalise potential effects of the various options on employment. On the one hand, many sectors operate with technical equipment which does not always require a large amount of manpower to be operational. On the other hand, changes to the possible uses of animal by-products, such as following a risk-based re-categorisation of certain materials, may also have different effects on affected sectors. While more material may e.g. be available to manufacturing sectors, less material would need to be disposed of, with potential effects on employment, which are difficult to quantify.

6.2. ANALYSIS OF IMPACTS

6.2.1. Policy issue 1-Clarifying the Scope of the Regulation

– ***Policy issue 1 (a) - Determination of the end of the ABP life-cycle***

Option (a): Do-nothing

Social Impacts

To do nothing will preserve the current uncertainties regarding the question to which extent products which have been processed on the basis of ABP are subjected to the requirements of the Regulation. As a result, the sectors concerned will comply to a different extent with these requirements. This could lead to public and/or animal health risks and different levels of protection throughout the Community.

Economic impacts

Sectors complying with the requirements face certain compliance costs, e.g. for the setting up of measures guaranteeing traceability and hygiene, as well as continuous monitoring and documentation. If these requirements are being imposed in one part of the Community, while they are not required in other parts of the Community, **competitive disadvantages** are being created with a potential effect on the economic development of the establishments affected. As regards the choice of locations for new establishments, the level of enforcement of the rules of the Regulation could be a decisive factor for economic operators, with potential effects on the distribution of economic development and employment between different regions. The box below provides an example of how been under the scope of the ABP Regulation can affect a certain industry. While it is clear that some industries need to be under the scope of the ABP Regulation, to prevent risks for public or animal health and ensure the safety of the food chain, the do-nothing option would not prevent industries facing different compliance and administrative costs between Member States.

The following data illustrate the economic and social impacts that current Regulation on ABP had for manufacturers of diagnostic tools destined to examine samples e.g. of human or animal blood or tissues, with the aim of detecting the presence of diseases or in conjunction with therapeutic measures (source: EDMA)

- 10-15% increase in cost (Germany),
- problems with non- EU suppliers no longer willing to supply materials due to small volume and problems of complying,
- revalidation of new suppliers (time + costs associated),
- review and cessation of "small-quantity" products lines by manufacturers,
- relocation by EU manufacturers outside the EU,
- loss of employment (estimated up to 5000 employees in Germany)

Option (b): Co-regulation

Social Impacts

Co-regulation would not result either in resolving the legal uncertainties regarding the application of the Regulation along the processing chain of ABP due to the wide-range nature of the issue and industries involved. It also implies difficulties for the Commission to establish a consensus between all the affected operators. This means that a harmonised interpretation of the scope of the ABP Regulation will not be achieved by this option, and as a consequence different levels of protection against public and animal health risks in the Community would continue.

Economic impacts

The sectors participating in the co-regulation would in addition not be compelled to come to horizontal agreements which would result in the same type of rules for the use of ABP by several sectors concerned. As a consequence, **similar differences regarding the competitive situation as for option (a)** could arise.

Option (c): Legislative review

Difficulties for determining the impact of option (c) on administrative and compliance costs:

- Both types of costs vary a lot between Member States and also between industries and plants depending on the type, category, quantity and variety of ABP they use (e.g: a single pharmaceutical plant can use more than 80 types of ABP while a leather plant may use only 3 or 4).

- This option will affect plants using only exempted ABP, so to calculate this costs it would be necessary to know, for each plant/industry, the complete list of ABP they use and the costs of carrying out the tasks that the modification will remove. As a consequence it was not possible to calculate the impact on administrative and compliance costs.

- It can be said that not all the plants/industries producing highly processed products will be affected by the Regulation, so the costs have been calculated for different percentages of plants affected taking as an example the biochemical industry to give an idea of the possible economic impacts that the proposal could have.

- The biochemical industry was used as an example because the best data available are from it. This may be because they are particularly interested in the proposal, as it will have a major impact on them and also because they are larger and more technology-based companies than in other industrial sectors, so for them to assess the costs is not so difficult.

- In addition, ABP requirements overlap with other requirements (sector rules, Good Manufacturing Practices, environmental legislation, etc.) and often it is difficult to estimate whether or not a given cost occurs only as a result of obligation resulting from ABP rules and whether this tasks will continue to be carried out despite the exemption of the ABP they use from the scope of the Regulation.

Economic impacts

Direct impacts:

A legislative review which clarifies the scope of the Regulation will address the issue of legal uncertainty through varying interpretations. It will also provide for a comparable competitive framework for the operators concerned and result in a stable framework for investments and the creation of new employment.

This option will have a positive impact on EU companies having premises, importing and commercialising their products in several/all Member States as they will affect the same requirements for all their processing plants.

The main economic advantages of this option for the industries affected will be the decrease in compliance costs related to the collection, handling, storage, disposal and processing requirements and the obligation to have a system of own checks established under the ABP Regulation. For example the annual costs of having established a system of own checks were estimated in 193800 € for a biochemical plant.

This option would also have positive impacts also in third country enterprises exporting highly processed products if they use ABP exempted from the scope of the Regulation. As an example, the following are the costs estimated by a USA pharmaceutical plant with an annual turnover of more than 250 million €.

- 771 applications for USDA 1774/2002 related inspections for exporting their products to the EU. The annual costs for approval of ABP (40) for export to the EU were estimated to be 82 500 €, including tasks carried out by external staff.

- Cost for carrying out own checks related to ABP obligations were estimated to be 38 900 € annually

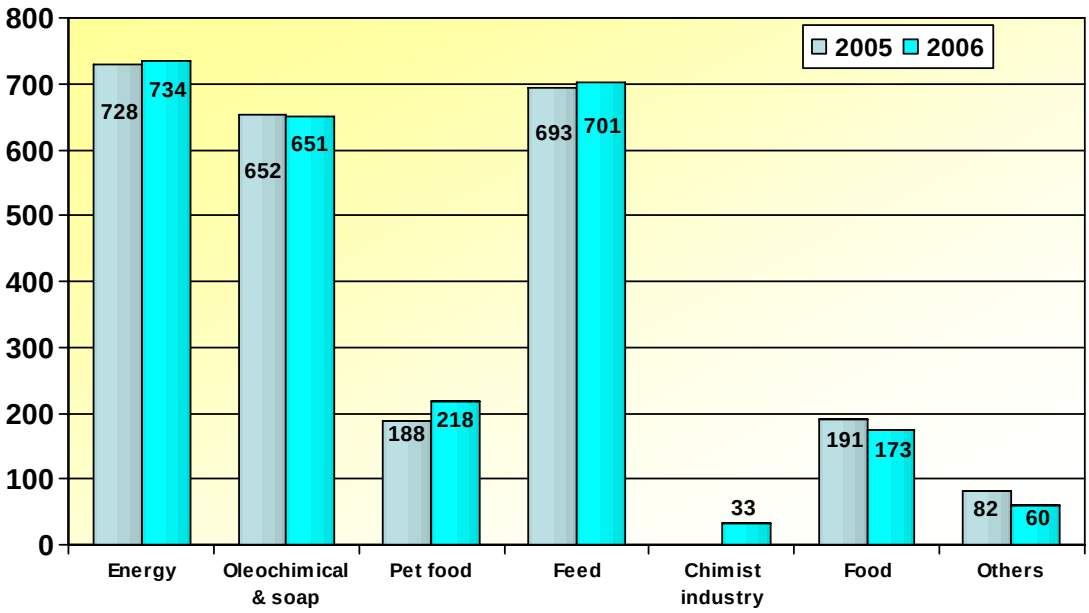
- Cost for identification and labelling 122 200€ (2038 shipment per year to the EU)

The economic and social dimension of the industrial sectors affected by this option is illustrated in Annex VI.

This option would have also **indirect economic impacts** on industries producing certain ABP as their demand for certain uses will increase due to the fact that they will not be subjected to the set of requirements laid down by the Regulation.

An example of this situation would be the fat processing and rendering industry. As illustrated in the graph below the main outlet of animal fats was energy production. If the demand of oleo-chemical industries for the products increases, probably their price will also increase, having positive benefits for the fat processors and renderers (industries producing these ABP) but negative for the rest of the industries using these products for other purposes. At this stage however it is very difficult to make forecast about this as ABP compete with other raw materials used for similar purposes in the market, nevertheless even though price of some components might rise (while others will fall), on average the price of final products are likely to decrease.

Graph 1 Evolution between 2005 and 2006. Main outlets of animal fats (Source EFPRA)



Social impacts

This option will furthermore allow operators and control authorities to focus their resources on the control of those risks which have potentially the greatest negative consequences for public and animal health.

As processed products will be excluded only when scientific evidence shows that they do not pose any risk for animal or public health, the high level of protection against these risks in the community will continue to apply.

Environmental impacts of all options:

None of the options referred to would have direct environmental impacts, since changes to environmental requirements applicable to the disposal, handling and processing of ABP are not being considered for this policy issue.

Indirect environmental impacts are difficult to assess due to the different uses of ABP and the variety of raw materials competing with them in the market for the same uses.

For example, on one hand, as illustrated in graph 1, the largest share of fats outlets in the EU are used for renewable energy production (biomass incineration, tallow combustion, bio-diesel and biogas) helping to save fossil energy and greenhouse emissions. If demand of fats for other uses increases, this might reduce the energetic valorisation of these products.

On the other hand, the EU oleo-chemical industry uses palm oil as a substitute of animal fats when those are not sufficiently available on the market. Production of palm oil is done in virgin areas of tropical rain forest and an increased demand can have negative impacts on the environment, though the quantity of palm oil demanded by the biochemical industry is not assessed to be enough to cause major environmental impacts it is an example that illustrates the complexity of the environmental issues related to the use of ABP.

Impacts on administrative burden:

Option (a) and Option (b) would not imply a change in the administrative burden, however might result in generation of other compliance costs.

Option (c) will have as a consequence reduction on administrative burden for operators and competent authorities of Member States. Approximately 75 % of the Competent authorities and affected industries assessed that option (c) will imply decrease on administrative costs for them, though the exact amount was not calculated due to the difficulties already explained under this chapter.

Reduction on administrative burden for operators:

Under option (c), premises using only ABP exempted would be completely out of the scope of the ABP Regulation while those premises using any ABP included under the scope would have to apply all the requirements and would not be affected by the proposal.

Reduction on administrative burden for operators will arise from the fact that these types of premises using only exempted ABP will not have to comply with the following requirements:

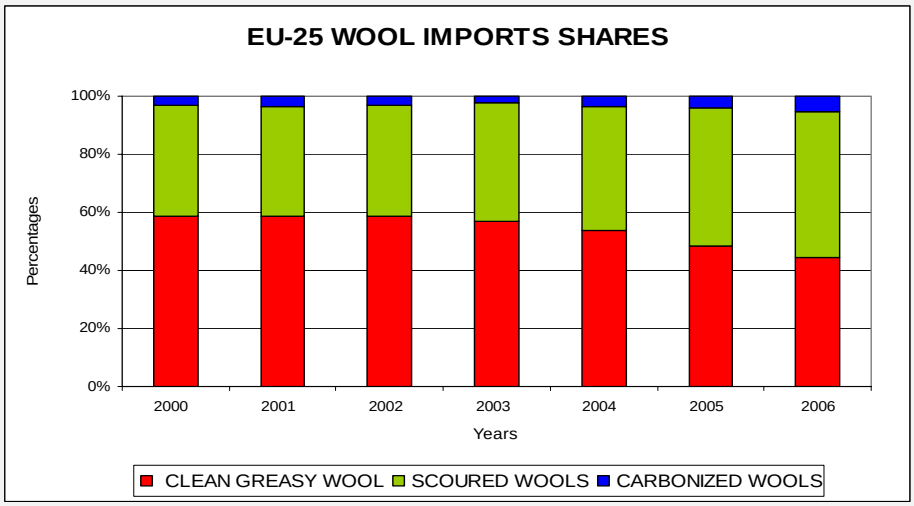
- Submit application for approval of the premises,
- Undergo inspections carried out by competent authorities to demonstrate that they comply with the requirements set out in the Regulation
- Issuing the required documentation for transportation of ABP. Reduction on compliance costs would arise from the fact the premises using only exempted ABP will not have to bear the costs related to the laboratory testing and the certification and permits for imports.

The following example illustrates how the reduction of administrative and compliance cots depends on which category of an ABP (wool) would be excluded from the scope of the Regulation.

Impacts on costs for operators

WOOL

It is estimated that imports of wool with different degree of processing into the EU are divided as follows (source INTERLAINE):



(Explanatory note: Greasy wool: wool shorn from the sheep and packaged usually into bales on the farm of origin. It still contains the grease (fat) and impurities of non-animal origin. Scoured wool: wool washed in hot water and detergent to remove the non-wool contaminants and then dried. Carbonised wool: wool which has been subjected a chemical process to remove material of plant origin from wool using some sort of acid. Usually it follows the scouring process).

If the end of the ABP life-cycle of wool would be determined as to cover only greasy wool, a considerable percentage (currently over 50 % and increasing) of the annual imported volume could be classified as being no longer ABP. This represents over 100.000 tons of wool every year.

Reduction on administrative burden for operators further processing such wool will arise from the fact that they will not have to comply with the requirements laid down in the ABP Regulation as long as they are dealing with only exempted material.

The following is an example of compliance and administrative costs faced by a biochemical plant using ABP. To calculate the reduction of costs it was considered that the plant is only using exempted ABP. It is not possible however to give an estimation of the exact impact because of the lack of data on the exact number of establishments of each industry and the type of ABP they use (if they are using any). It has to be noted, that these assumptions and calculations are based on data submitted by a single company and only focused on the number of companies active in the biochemical sector while this proposal potentially affects a wide range of industries.

Table 2. An estimate of current administrative costs for a plant active in the biochemical industry using ABP (source: answers to the questionnaire on administrative costs by industries):

Information Obligation	Required actions	Regulatory Origin	Average cost per hour (€)	Hours spent on this task	Frequency/Year	Total number of activities	Total cost (€)/year
Gain approval for an establishment by competent authority	Submit a request and supporting documentation for approval	Art 18	190	150-200	Once, prior to production or handling	1	28500-38000 (once)
Laboratory testing	Sample, perform and document lab test	Art 25	190	32/month	continuous	120	72960
Labelling	Label must be attached to products	Annex II Chapter 1	190	580/year	continuous	300	110200
Materials must be imported with proper documentation	Apply for import certificates, permits	Art 29	190	210	continuous	200/year	39900
TOTAL							251560-261060

None of these tasks would have to be carried out by this plant, if they use only products that are out of the ABP regulation requirements so the reduction of costs for this operator could be estimated prior to production 28.500-38.500 € and annually 223.060 €

Although the exact number of affected premises is not known, and the costs showed above are only data from a single company, if we assume that all of all of the estimated biochemical companies (28.600 as explained under chapter 6.3.3) only use exempted ABP and that the costs are similar across the sector, the total reduction of costs would be approximately 2.63,416- 2.245,116 million €. If we assume that only 1% of them would be affected by the proposal, the reduction of costs would be approximately 21-22 million €. But even assuming that only 1% of the premises would be affected by the modification, these costs are probably overestimated, as not all the industries face such a high compliance and administrative costs.

Reduction of administrative burden for competent authorities:

The reduction of administrative burden for competent authorities arises from the fact that they will not have to approve the establishments and carry out inspections to check whether the requirements of the APB regulation are being complied with in these types of premises and also they will not have to authorise them under the ABP Regulation.

Table 3. An estimate of these costs for the competent authorities in relation to one approved establishment is the following (source: answers to the questionnaire for competent authorities on administrative costs):

Information Obligation	Required actions	Regulatory Origin (Art of Reg (EC) 1774/2002)	Average cost per hour (€)	Hours spent on this task	Frequency/Year	Total number of activities	Total cost (€)
Approve entity	Evaluate the submitted request and documentation	Art 18	60	10-30	Once, prior to production or handling	1	600-1800
Official controls	Perform and document official controls	Art 26	60	5-15	1-2	1-2	300-900
List of plants	Keep updated and transmit list of approved plants (for all)	Art 26	60	30	Not defined	Not defined	1800
TOTAL							2700-4500

None of these tasks would have to be carried out for by competent authorities for plants using only exempted ABP, and so the reduction of costs would be approximately once 600-1800 € and annually 300-900 €/ concerning each establishment. Difference in the cost associated with managing the list of establishments would be negligible.

Based on the assumptions explained in the calculation of costs for operators, the reduction for competent authorities would approximately be 23.22-38.7 million € if all the plants would be affected by the proposal, and 0,23-0,38 million € if only 1 % are affected, but same considerations about the over estimation on costs explained in the calculations for the industry apply here.

Impacts on SME

A significant percentage of industries affected are SMEs. Though the impacts will be positive it was also not possible to quantify for the reasons already explained.

Comparison of the two legislative review sub-options:

(1) Exemption of processed finished products from the Regulation

Due to the wide range of materials covered by the Regulation, this sub-option would require to determine under which technical conditions products fall outside the rules. These technical conditions are likely to require adaptation over time due to evolution in science and technology. Therefore, this option would not provide for a flexible basis to adapt to newly emerging health risks.

Exempting processed animal **fat for use as a fuel** or for technical purposes from the scope of the Regulation would remove the controls of the Regulation over processing establishments. However, in case scientific evidence were to become available which would suggest that certain risks to public health are not being eliminated by the processing standards imposed, it would not be possible to impose further treatment steps for the elimination of such risks.

(2) Introduction of a legal basis for the determination of the end of the ABP life cycle.

This sub-option would allow introducing rules which would be more proportionate to the risks arising from specific products maintaining a high level of protection of public and animal health across the EU.

By providing for a legal basis for the adoption of technical standards via implementing rules, this option would allow to react to progress in science, such as new assessments carried out by the European Food Safety Authority or to newly emerging risks.

In the example cited above, a legal basis for the adoption of technical standards would enable the legislator to adopt additional standards which would eliminate the new risk in question as regards animal fat for use in fuel. At the same time, it could very well be the case that the standards for animal fat for technical applications would not have to be adapted if the risk in question is being eliminated by other treatment steps already in place (such as a chemical treatment or the addition of an additive to make the product made out of animal fat usable in a particular technical product).

– ***Policy issue 1 (b) - Coverage of wild animals***

Option (a): Do-nothing

Social impacts (public and animal health): Doing nothing would leave potential risks from animal by-products arising in establishments handling wild game meat for human consumption uncontrolled. Wild animals are a potential source of animal diseases including zoonoses (e.g.: avian influenza) and thus ABP products should be adequately controlled in order to prevent negative impacts for public, animal health and also the economy. Thus, an adequate level of protection against public and animal health risks across the Community would not be ensured.

Possible economic impacts linked to the risks arising from ABP

Through importation of ABP from game animal diseases could be introduced into the EU which could have an enormous financial and socio-economic impact. Example of such diseases are the Classical Swine Fever epidemic in the Netherlands (1997-1998) and the Foot-and-Mouth epidemic in the UK (2001).

Implications were the following:

Community financial contribution during the epidemic of Classical Swine Fever – The Netherlands, 1997-1998

The EU paid a total of 80.5 million € from the "Veterinary Fund" and an additional 570 million € was spent for exceptional market support measures to the Member States affected by CSF under the 1997 and 1998 budget. (Source: Court of Auditors *SPECIAL REPORT No 1/2000* on classical swine fever).

Community financial contribution during epidemic a Foot-and-Mouth Disease epidemic – 2001

Overall, for the 2001 crisis alone the total expenditure declared by all affected Member States (France, Ireland, Netherlands, and the UK) for compensation for slaughter and destruction of animals as well as disinfecting of farms and equipment was about 2,693.4 million €, of which 1,616 million € was claimed for Community reimbursement. Following the decision to reimburse losses related to the FMD crisis of 2001, the EU paid a total of 465.6 million € to Member States from the EU "Veterinary Fund". No exceptional market support measures have been implemented with respect to the FMD crises. (Court of Auditors, *SPECIAL REPORT No8/2004* on FMD)

Option (b): Co-regulation or guidance

Social impacts (public and animal health) and economic impacts:

- **Self-regulation** would not result in a coherent level of protection and legal certainty across the Community because operators are not well organised and the sector does not seem to be well structured and organised to put in place an effective self-regulation framework. In addition, rules adopted by the sectors concerned would not bind the control authorities and could lead to checks being performed to a different extent throughout Member States. As a consequence, risks for public and animal health posed by ABP from wild animals will continue to be uncontrolled as well as the inconsistencies with the Food Hygiene legislation and the competitive situation of operators could vary across the Community.

- **Co-regulation** between the sectors concerned, in particular hunters and game meat processors, and the legislators, could introduce clear rules which would ensure sufficient protection against public and animal health risks. This would also result in a common framework for competition, in particular regarding investments and the creation of new labour. However, since the problem is also linked to the potential import of public and animal health risks from ABP from outside the Community, it is difficult to conceive in which way stakeholders outside the Community could participate to the process and be obliged to follow the rules introduced. This means that the risks that public or animal health threats are being introduced in the Community through the imports of these products will continue.

- **Guidance** issued by the Commission would result in the same adverse effects as those mentioned before with respect to self-regulation.

Option (c) Legislative review

– To extend the scope to cover all ABP from wild animals handled to be placed on the market and allow the competent authority to define conditions to apply to establishments handling such ABP.

Social impacts:

Extension of the scope to ABP from wild animals which are intended to be placed on the market would **increase the level of protection for public and animal health** and ensure that game handling establishments within the Community collect and dispose of ABP arising during their operations in a safe way, in line with the principles of the current food safety and hygiene legislation. As regards imported ABP, the extension of the scope will also result in a higher level of protection.

The option could slightly raise compliance costs for some of these premises as they will have to adapt procedures for handling and disposing ABP. But it has to be noted that being under the scope of the ABP Regulation could have also economic advantages as these establishments would be able to commercialise these products for example for the petfood industry.

Environmental impacts of all options:

Option (a) implies accepting animal health risks arising from the fact that ABP from wild animals are not covered under the Regulation. ABP are a source of animal diseases also affecting the wildlife. In consequence, leaving out of the scope ABP from wild game could have negative environmental consequences. A higher level of protection of animal health and thus the wildlife will arise from option (c) by imposing the disposal or use of ABP in accordance with the rules laid down in veterinary legislation, uncontrolled disposal of ABP would be indirectly prevented.

Impacts on administrative burden of all options:

Option (a) and option (b) will not have impacts on administrative burden.

Option (c) will lead to some additional burden for economic operators affected (establishments handling ABP in the EU and also the same type of establishments in third countries exporting wild game to the EU).

However, since some of the requirements are already applied under the food hygiene legislation (authorisation, inspection) and this legislative review does not intend to duplicate them it can be estimated that there will be no adverse effects on the economic development of the sector or employment. This also implies that option (c) will not imply significant administrative costs for the Competent Authorities as they are already carrying out these requirements under the Food Hygiene legislation.

Option (c) could also have impacts for some third country establishments exporting products. Though they would face some additional compliance costs the advantage for them would be facing the same requirements to export to any EU Member State.

The extension will also not result in adverse effects for the importance of hunting as a social activity, since it does not impose additional burden on hunters supplying wild game meat to game handling establishments in line with the food hygiene legislation. Although it was not possible to obtain the exact number of theses establishments for all Member States there are approximately 452 establishments in 14 of them. It has to be noted that there are significant differences on this number depending on the Member State considered.

6.2.2. Policy issue 2 categorising new products

Option (a): Do-nothing

Option (a) will not provide for a risk-adequate categorisation of certain ABP which pose a low risk. Maintaining the default categorisation means to exclude a wide range of ABP from certain industrial uses when this ABP do not pose any risk for public or animal health and are valuable materials.

Option (b): Alternatives to regulatory tools

Alternatives to regulatory tools have not been considered as they will not address the problem since the strict categorisation which is one of the core elements of the current Regulation is not open to modification or interpretation by non-legal instruments.

Option (c): Legislative review

– To reclassify products which pose a low risk for public and /or animal health based on scientific assessment in order to facilitate their use.

Social and economic impacts

Option (c) will allow resolving the problem. On the basis of scientific advice ABP may be re-classified and their potential uses, whether for feeding purposes or for technical applications, may be determined on a case-by-case basis. This would **ensure a high level of protection of animal and public health**, while eliminating adverse effects on the economic development of the sectors using certain animal by-products.

Some ABP are high quality raw materials and they should be allowed for the widest possible applications as long as they do not pose risks for animal and public health. Allowing the technical use of certain ABP would increase market chances for many companies which would then be able to process such ABP into safe and high quality finished products, resulting in increased competitiveness and reduced operating costs. Additionally, the quantity of ABP which have to be disposed by using high cost rendering processes will be reduced.

Environmental impacts of all options:

No environmental impacts are foreseen for option (a) and (b).

Positive environmental impacts may arise from the fact that certain category 1 and category 2 ABP will be recycled as a raw material instead of been destroyed and thus a more sustainable use of these resources will be achieved.

Impacts on administrative burden:

Option (a) and option (b) will not imply any change on administrative burden.

Option (c) could have negligible impact on administrative burden as similar administrative requirements will apply for these ABP even if they fall into a different category.

The main economic impact for the industries using these ABP is that they will be able to use also categories 1 and 2 ABP and this means a higher quantity of available raw materials. Industrial sectors affected could replace some raw materials for these ABP that are cheaper and to save in production costs. This economic impact will depend on the share of the production costs that these ABP represent for them.

The re-categorization of ABP will have as a consequential impact on the price of raw materials used as a substitute but this is difficult to assess as it will vary for each specific ABP and will depend on the market situation.

The following are some examples of the importance of the use of ABP for certain industrial sectors.

Under the current Regulation, blood from animals other than ruminants which have been declared fit for slaughter is categorised as Category 3 (Article 6 (1) (d)) and may be used for a number of purposes. By contrast, blood from ruminants to which no TSE or other disease risk is attached is classified in a different sub-category of Category 3 (Article 6 (1) (k)) and as such excluded from certain uses, such as use in petfood. However, Regulation (EC) No 999/2001 does not require calves below a certain age limit to be tested for BSE. Therefore, if it were possible to reclassify blood from such calves under the subcategory for animals other than ruminants (Article 6 (1) (d)), such blood could be used for petfood. This option could be beneficial for slaughterhouses specialised on slaughtering calves, as well as regards raw material prices for petfood ingredients. However, due to a wide range of other products available on the market which may be used in petfood, such as material from hormone-treated animals, meat-and-bone meal and animal fat, it is difficult to quantify the precise economic impact of such re-categorization.

6.2.3. Policy issue 3 Clarifying the approvals / registration and controls

Option (a): Do-nothing

Social and economic impacts:

This option means accepting the overlapping between EU legislation and to continue requiring double approval for some premises with the consequent social and economic impacts of the unnecessary burden imposed to operators that undermines competitiveness of the industries affected.

Option (b): Alternatives to regulatory tools

Alternative to regulatory tools have not been considered as they will not address the problem since the issue related to the double approval that some premises are undergoing because of the interaction of different EU legislation.

Option (c): Legislative review: *To remove duplicated approvals and rely on the provisions already introduced by other Community sector legislation, but maintain certain requirements in order to ensure traceability of these ABP*

The social and economic impacts of this option will arise from the reduction on the administrative burden as it is related to eliminating duplication of approvals.

Social impacts

This option would ensure that the establishments concerned remain under the control of the veterinary authorities. In that way, intervention in case of risks to public and animal health would remain a possibility. In order to ensure traceability, minimal requirements, such as a registration requiring information of the veterinary authorities about the use of ABP in certain establishments would be sufficient.

Impacts on administrative burden

This option would remove additional administrative burden (such as costs for the submission of application) from operators of establishments manufacturing products under other Community legislation, without lowering the level of protection against human and animal health risk. In that way, the competitiveness of such operators would be enhanced, with a potentially beneficial effect on the creation of employment.

Furthermore, it would reduce administrative workload for authorities issuing approvals. However, since risks to public and animal health also arise in such establishments and ABP are being delivered to them, the complete removal of controls by the authorities responsible for the application of the ABP Regulation (in many cases veterinary authorities) could create gaps in ensuring traceability of ABP and prevent the authorities from acquiring the necessary knowledge of the potential risks linked to individual establishments. Similarly, they would not be able to intervene in case of shortcomings.

In the case of a **plant manufacturing cosmetic products** which is using animal fat as a starting material, an additional approval under the ABP Regulation would be considered as unnecessary. The provisions of the Community legislation on cosmetics which determine the starting material to be used for the production of cosmetics can be considered as sufficient for the control of risks to public and animal health. However, if the veterinary authorities were unaware of the use of such materials, they would not be able to intervene in case it would appear that a plant manufacturing cosmetics would not sufficiently process the material used to eliminate public and animal health risks. Similarly, if it was to appear that consignments of animal fats were on the market which posed such risks, e.g. due to fraud or other malpractice, they would not be able to take measures to ensure that the cosmetic manufacturer in question does not use such material for the purposes of his production.

The following is an example of administrative costs related to the approval faced by a biochemical plant using ABP. It is not possible however to give an estimation of the exact impact because of the lack of disaggregated data on each type of premises authorised by Member States. It has to be noted, that these assumptions and calculations are based on data submitted by a single company and only focused on the number of companies active in the biochemical sector while this proposal potentially affects a wide range of industries.

Table 4. An estimate of current administrative costs for a company active in the biochemical industry using ABP (source: answers to the questionnaire for industries on administrative costs):

Information Obligation	Required actions	Regulatory Origin	Average cost per hour (€)	Hours spent on this task	Frequency/Year	Total number of activities	Total cost (€)/year
Gain approval for an establishment by competent authority	Submit a request and supporting documentation for approval	Art 18	190	150-200	Once, prior to production or handling	1	28500-38000 (once)
Laboratory testing	Sample, perform and document lab test	Art 25	190	32/month	continuous	120	72960
Labelling	Label must be attached to products	Annex II Chapter 1	190	580/year	continuous	300	110200
Materials must be imported with proper documentation	Apply for import certificates, permits	Art 29	190	210	continuous	200/year	39900
TOTAL							251560-261060

Table 5. An estimate of costs according to the proposal for the same company

Information Obligation	Required actions	Regulatory Origin	Average cost per hour (€)	Hours spent on this task	Frequency/Year	Total number of activities	Total cost (€)/year
Labelling	Label must be attached to products during transport	Annex II Chapter 1	190	580/year	continuous	300	110200
Materials must be imported with proper documentation	Apply for import certificates, permits	Art 29	190	210	continuous	200/year	39900

The impact of change could therefore represent for this given company a reduction of EUR 28.500-38.000 in the cost required prior to approval and around EUR 72.960 annually (or even more depending also on volume of actual production), in total 101.460-110.960 €. Is also possible that some of the companies using highly processed materials as their starting material for production could still further benefit from provisions determining the end of ABP life-cycle and thereby reduce administrative costs even further as explained under chapter 6.3.3.

The number of affected plants is estimated in the in-vitro-diagnostic industry more than 500 companies, in the medicinal and veterinary medicinal industry 46 leading companies and 2.100 committed companies and in the cosmetics sector around 3600 companies with around 6000 production establishments.

If we assume that costs are similar across the sector and that this companies have only one establishment each, the approximated number of companies affected by the proposal would be 8600 and the approximated costs reduced by the proposal would be 872,556-954,256 million €. But even assuming that only 1% of the premises would be affected by the modification, these costs are probably overestimated, as not all the industries face such a high compliance and administrative costs.

The reduction of administrative burden for competent authorities arises from the fact that they will not have to approve the establishments and carry out inspections to check whether the requirements of the APB regulation are being complied with in these types of premises and also they will not have to authorise them under the ABP Regulation.

The estimate of these costs for the approval of a biochemical plant is the following. Similar consideration on the difficulties to calculate the overall costs explained for the industries apply to the administrative costs for competent authorities:

Table 6. An estimate of the current administrative costs for the competent authorities in relation to one approved establishment is the following: (source: answers to the questionnaire for industries on administrative costs):

Information Obligation	Required actions	Regulatory Origin (Art of Reg (EC) 1774/2002)	Average cost per hour (€)	Hours spent on this task	Frequency/Year	Total number of activities	Total cost (€)
Approve entity	Evaluate the submitted request and documentation	Art 18	60	10-30	Once, prior to production or handling	1	600-1800
Official controls	Perform and document official controls	Art 26	60	5-15	1-2	1-2	300-900
List of plants	Keep updated and transmit list of approved plants	Art 26	60	30	Not defined	Not defined	1800
Total							2700-4500

Table 7. An estimate of the administrative costs for the competent authorities according to this proposal for one approved establishment would be:

Information Obligation	Required actions	Regulatory Origin (Art of Reg (EC) 1774/2002)	Average cost per hour (€)	Hours spent on this task	Frequency/Year	Total number of activities	Total cost (€)
Official controls	Perform and document official controls	Art 26	60	5-15	1-2	1-2	300-900
List of plants	Keep updated and transmit list of approved plants	Art 26	60	30	Not defined	Not defined	1800
TOTAL							2200-2700

According to the proposal only the costs associated with the official controls and the management of list of registered plants would still occur due to the obligation to register and control these establishments by the veterinary authority. Depending on later implementing provisions and/or practical arrangements between different sectoral national authorities that cost could vary somewhat but in any case is expected to be similar to or less than the current management of list of approved plants. According to all this the reduction on administrative costs for the competent authorities would be 500-1800 €.

If you assume that the number of plants affected by the proposal would be also 8600, and that costs for carrying out these tasks are similar between competent authorities the approximate reduction of the costs for the competent authorities of this proposal would be 4.3 million € to 15.48 million €.

However, as it has been noted before, these costs not only vary between Member Sates, but as between regions and types of premises to be inspected / approved.

As an example, the following table illustrates the average input of hours needed and the related average costs incurred by regional administrations in Germany (for an average establishment, costs indicated do not include payments for external advice).

The efforts necessary for granting approvals and carrying out inspections vary between different types of plants or establishments. Therefore, since the distribution of establishments varies between regions, the figures indicated may also differ for this reason.

Table 8. Average input of hours needed and the related average costs incurred by regional administrations in Germany (source: answers to the questionnaire for industries on administrative costs):

Land (region)	Hours needed for granting an approval	Costs for granting an approval (€)	Hours normally necessary for carrying out inspections	Costs for carrying out inspections (€)
Baden-Württemberg	35	2000	5	280
Bavaria	10	550	12	720
Berlin	16	770	3	160
Bremen	10	600	2	130
Hessen	4	300	10	700
Lower Saxony	10	700	5	350
Rhineland-Palatinate	11	600	15	870
Saxony-Anhalt	5	250	2	100

Comparing the costs assessed by competent authorities for authorising plants and for carrying out inspections it was found that normally the authorisation costs are approximately three times the inspection costs. Removing the duplication of approvals will allow competent authorities to allocate more financial resources on inspections, and as a consequence prevent public and animal health problems.

Environmental impacts of all options

None of them will have environmental impacts since no changes to the environmental obligations of such establishments are being considered.

6.2.4. Policy issue 4 - Clarifying the derogations

Option (a): Do-nothing

Do-nothing would lead to continuation of the current difficulties for researchers (universities, pharmaceutical industry, etc.) to get certain materials necessary for their studies since importation of ABP of Categories 1 and 2 for research purposes would continue not to be allowed.

With regard to burial and burning of animal carcasses, the current difficulties arising in the case of natural disasters or where access to dead animals is practically impossible would remain. Consequently, the disproportional situation between requirements and risks would remain and even public health risks could be put at stake if animal carcasses would always be required to be collected for disposal (dangerous collection circumstances).

Option (b): Alternatives to regulatory tools

Options (b) will not remedy the problems identified since derogations to the legal requirements are exemptions from the strict rules of the requirements of the Regulation which may only be used under specific circumstances defined by law.

Option (c): Legislative review

Extending the derogations to

– Allow the imports of ABP for research purposes in line with other EU legislation such as legislation on TSE and

– Extend the possibility to bury and burn carcases of animals in areas (i) affected by natural disasters, (ii) where access is not practically possible or present a risk to health and safety.

Social Impacts

To extend derogations to allow the imports of ABP for research purposes would not have any negative impacts on public and animal health as the sale of these products is restricted to professional end users only working in academic, medical, governmental and health care institutions. These products are not intended for general consumer use.

Their channelling to the actual researchers would be subject to import authorization ensuring that they would be used for the purposes foreseen.

– Imports of ABP for research purposes

Research .in the medical field is of major importance to a large number of companies producing vaccines or medicines to cure disease. Some of these Community based companies are world-leading in their field. Improvement of their research activities could result in the development of new products, ensuring or improving health of humans and animals throughout the Community and worldwide.

Vaccine production is a small but critical part of the pharmaceutical marketplace. Europe is a major supplier of these materials to the rest of the world. Continuation of the difficult situation with regard to research possibilities due to import restrictions of materials needed and reduction in vaccine production in Europe could have catastrophic impact on healthcare worldwide and result in significant job losses.

– Burial and burning of carcases

Extending the derogation possibilities on burial and burning of animal carcasses could lead to a better acceptance of Community rules by the public as they would possibly accept this as better adjusting rules to necessities.

Economic impacts

– Imports of ABP for research

Option (c) would bring the provisions of the ABP Regulation in line with other Community legislation, such as Directive 97/78 on import checks and the Regulation 999/2001 concerning TSE. It would also contribute to the competitiveness of research and subsequent innovations in technology carried out in Europe. This could result in investments and in the creation of employment once the results of such research are being commercialized. It could also result in beneficial consequences for human and animal health in the Community and worldwide, leading to reduction of costs for healthcare. This option will have also positive economic impacts for third country companies exporting products needed for research to the EU.

Research is an essential part for the improvement of existing and the development of new medicinal products. Biotech medicines, for example, account for 10 to 15% of the current pharmaceutical market (42 billion Euros in 2002) and comprise the highest growth segment of the market. More than one fifth of the new medicines launched each year are now biotechnology derived. Development of this market, however, is only possible if research is possible. Currently, more than 60 companies are active in this area in Europe.

The situation is similar for the development of human and animal vaccines. In 2002, European companies produced about 80% of the vaccines produced globally. 50% of these were exported to the USA, and about 30% were used in Europe. About 12,000 people in Europe work for vaccine manufacturers. Research and development spend for this segment was $1.5 billion Euro in 2002, with two thirds of all research on vaccines occurring within the EU. The total market for vaccines worldwide in 2002 was 6.3 billion Euros.

– Burial and burning of carcases

With regard to the burial and burning of animal carcasses, this option would allow competent authorities to take more risk-proportionate measures under exceptional circumstances where the normal disposal system cannot be relied on due to the large amount of animal carcasses or the difficulties with respect to recovery. By allowing for swift disposal on site and thus avoiding delays, it would also serve to contain disease-risks arising from the decomposition of animals for other animals and humans.

Environmental impacts

No negative effects on the environment are envisaged by extending the derogation possibilities to importation of Category 1 and 2 ABP for research purposes.

Negative effects on the environment of this option arising from extended burial and burning possibilities would have to be prevented by complementary measures which ensure the protection of air, soil and ground water and previous studies of their situation and characteristics. Such measures could follow the rules applicable to disposal under the current disposal derogations.

Impacts on administrative burden

Option (c) will lead to some additional burden for researchers and authorities when applying for derogation and when deciding on it. However, procedures will be automatic in the case of institutions or companies importing on a regular basis, which diminishes burden.

In the case of burial and burning of animal carcasses, less compliance costs will result from the fact that there transport of the carcasses will not be carried out. However, the evaluation of the situation of the soil, water and air may result in a slight increase of costs for administrations when applying these derogations.

7. COMPARING THE OPTIONS.

7.1. Policy issue 1-Clarifying the scope of the Regulation

7.1.1. Determination of the end of the ABP life-cycle.

Options / Type of impacts	Option 1-Do nothing	Option 2-Coregulation	Option3-Legislative Review	
			(1)	(2)
Social	- [different level of protection against risks]	- [different level of protection against risks]	+ [harmonised level pf protection but not flexible]	++ [harmonised level pf protection and flexible]
Economic	- [distortion of competition] - [limited use of ABP]	- [distortion of competition] - [limited use of ABP]	+ [prevent distortion of competition] + [more use of ABP]	+ [prevent distortion of competition] + [more use of ABP]
Environmental	±	±	±	±

The preferred option

Since the introduction of a legal basis for the determination of the end of the ABP life cycle solution allows for a risk-based determination of the end point for the many different kinds of material covered by the rules, it appears to provide for the best possible solution to the problem as it will imply reduction of administrative burden for operators and competent authorities, decrease of compliance costs for operators while ensuring legal certainty and maintaining a high level protection of public and animal health across the Community.

7.1.2. Coverage of wild animals

Options / Type of impacts	Option A Do nothing	Option B Alternatives to Regulatory tools	Option C Legislative Review
Social	- (continuation of increased risk of introducing epizootic disease into free areas of the Community endangering public and/ or animal health)	= - - (same as Option A, however, with slightly better control possibilities.)	+ (decreased risk for public and human health)
Economic	- (continuation of increased risks of disease introduction and potential economic consequences due to the disease itself and to control measures.)	= - - (same as Option A, however, with slightly better control possibilities.)	- / + (Negative impacts on some establishments due to necessity to comply with ABP rules. Positive impacts on commercialising possibilities)
Environmental	- (depending on a possibly introduced disease and measures to be taken, negative environmental impacts could occur.)	- (same as Option A, however, with slightly better control possibilities.)	+ (Better protection of health of wildlife and of the soil/ water due to prohibition of uncontrolled disposal)

The preferred option

From the conclusions of the analysis of impacts the preferred option will be option (c) although it may imply some costs for the game-handling establishments as option (a) and option (b) will not provide with the necessary level of protection against public and animal health risks and will not solve the inconsistencies that currently exist with the Food hygiene legislation.

7.2. Policy issue 2- Categorising new products

Options / Type of impacts	Option A Do nothing	Option B Alternatives to Regulatory tools	Option C Legislative Review
Social	- (Possibly negative impacts due to reduced valorisation possibilities and consequently employment)	Not relevant (the Regulation does not leave room for guidelines/interpretations)	+ (Possibly increased employment possibilities)
Economic	- (Maintaining the situation of not being able to valorise certain ABP)	Not relevant (the Regulation does not leave room for guidelines/interpretations)	+ (Improved possibilities to valorise ABP, increased market chances, competitiveness and decreased operating costs.)
Environmental	=	Not relevant (the Regulation does not leave room for guidelines/interpretations)	+ (Better valorisation and recycling possibilities of ABP while reduced quantities to be disposed of)

The preferred option

In light of the conclusions of the analysis of impacts the preferred option will be option (c) as option (a) and option (b) will not address the problem that this default categorization poses for the industries using these ABP.

7.3. Policy issue 3. - Clarifying the approvals/registration and controls

Options / Type of impacts	Option A Do nothing	Option B Alternatives to Regulatory tools	Option C Legislative Review
Social	- (continuing with the administrative burden imposed to the operators and competent authorities)	(Not possible due to legal requirements)	+ (will remove administrative burden for operators and competent authorities)
Economic	- (continuing with the administrative burden imposed to the operators and competent authorities)	(Not possible due to legal requirements)	+ (will remove administrative burden for operators and competent authorities)
Environmental	=	(Not possible due to legal requirements)	=

The preferred option

As the problem relates to interaction of different EU legislation and taking into account the conclusions of the impact section, the preferred option would be option (c).

7.4. Policy issue 3-Clarifying the derogations

Options / Type of impacts	Option A Do nothing	Option B Alternatives to Regulatory tools	Option C Legislative Review
Social	- (continuation of possibilities for endangering human health)	= (Not possible due to legal requirements)	+ (probably improvement of human and animal health following results of research. Improvement of risk-proportionate measures and protection of public health)
Economic	- (acceleration of impacts from reduced research possibilities on basic and on applied research in universities and companies)	= (Not possible due to legal requirements)	+ (better possibilities for research, therefore investments and more employment; probably improvement of human and animal health, therefore reduced health care costs
Environmental	±	±	+ (or ± if adequate complementary protection measures are adopted.)

The preferred option

According to the conclusions of the analysis of impacts option (c) would be the preferred option.

7.5. Conclusion

Taking into account all analyses of impacts, the preferred option for all policy issues is the option of the legislative review.

This conclusion also results from the actions taken by the Commission since the adoption and implementation of the ABP Regulation. The difficulties identified have been addressed where necessary and where possible by way of legislative measures taken by the Commission following Comitology procedures as well as by non-legislative tools. A list of these measures and tools is given in Annex 6. Some issues, however, could not be solved this way since they relate to rules fixed by the Articles of the Regulations, which can only be amended by co-decision procedures.

8. MONITORING AND EVALUATION

Monitoring and evaluating the economic, social and environmental effects of EU policies is a core element accompanying the political process. In the area of public and animal health, monitoring and assessing the implementation and effectiveness of action taken are shared between the Community and Member States.

8.1. Community

In accordance with Article 211 of the EC Treaty, it is the duty of the Commission to ensure proper application of Community legislation. In the field of public and animal health, the Commission services, in particular the Food and Veterinary Office (FVO) collect information which serves to evaluate to which extent measures taken have been implemented. The information also helps to identify to which extent the measures taken at Community level effectively address the risks which were identified as requiring action.

The FVO has carried out a series of inspections in the area of ABP in all 25 Member States in 2004-2005 in order to gather information related to the proper implementation of the Regulation. Similar inspections can be envisaged as a way of follow-up in the near to long term.

Furthermore, the Commission collects information regarding the proper implementation of the rules and possible new risks by way of its rapid alert systems (in particular the RAPEX system for consumer products and the RASSF system for food and feed).

In the animal health area, the Community has in place a well functioning system to gather information on the animal health situation in the Community, with particular reference to major animal diseases.

8.2. Member States

Member States are obliged to ensure proper implementation and enforcement of the Regulation. This has implications for both central and local administrative systems and financial resources for carrying out official controls by means of regular inspections and supervision at plants approved in accordance with the Regulation (pet food plants, processing plants, biogas/composting plants, etc).

In certain areas, the Regulation requires that Member States shall report to the Commission and to other Member States on the way they have make use of certain derogations and provide information on national measures taken which are related to the Regulation.

8.3. Communication and Consultation with stakeholders

The Commission will also continue to monitor the improvements made by this review of the Regulation or possible new problems arising through frequent meetings, bilateral exchanges of views, with the industry and other stakeholders concerned by the proposal, including consumers associations. The Commission will continue to collect views from Member States' authorities by regular meetings of the Standing Committee on the Food Chain and Animal Health and from other stakeholders by way of consultations of the Advisory Group on the Food Chain and Animal and Plant Health.

The Commission will also consider the possibility of carrying out a special study to collect information on the effects of the proposed review of the legislation. This study could be based on contacts with a wide range of different stakeholders and cover the aspects identified as requiring modifications now, as well as any potentially new problems. A feasible timing for such an exercise is probably 2-3 years after entry into force of the reviewed legislation.

ANNEX I-A

LIST OF THE STAKEHOLDERS CONSULTED ON THE IMPACT ASSESSMENT

I. Stakeholders consulted through the Advisory Group

1 AIPCE-CEP – Association des Industries do Poisson de l'U.E. (fish)

2 AVEC – Poultry processors and poultry trade association (poultry)

3 BEUC – Bureau européen des Consommateurs (consumers)

4 CEFIC – European Chemical Industry Council (chemical industry)

5 CELCAA – European Liaison Committee for the Agri-Food Trade (agric. Products trade)

6 CIAA – Confederation of the food and drink industries of the EU (agric. product industry)

7 CLITRAVI – Centre de Liason des Industries Transformatrices de Viandes de L'U.E. (meat processors)

8 COPA-COGECA – (farmers)
Committee of Professional Agricultural Organisations in the European Union (COPA) and General Confederation of Agricultural Co-operatives in the European Union (COGECA)

9 ECSLA – European Cold Storage and Logistics Association (cold stores)

10 EDA – European Dairy Association (milk)

11 EFPRA – European Fat Processors and Renderers Association (renderers)

12 EMRA – European Modern Restaurant Association (modern restaurants)

13 EUROCOMMERCE – Retail wholesale and international trade representation to the European Union (retailers)

14 EUROPABIO – European association for bioindustries (bioindustries)

15 FEDIAF – Fédération Européenne de l'Industrie des Aliments pour Animaux Familiers (petfood)

16 FEFAC – Fédération Européenne des Fabricants d'Aliments Composés (feed)

17 FESASS – Féderation Européenne pour la Santé Animale et la Securité Sanitaire (animal health)

18 FVE – Federation of Veterinarians of Europe (veterinarians)

19 HOTREC – Trade association of hotels, restaurants and cafes in the European Union

20 IFAH – International Federation for Animal Health (animal health industry)

21 IFOAM – International Federation of Organic Agriculture Movements (organic agriculture)

22 UAPME – SME – Union Européenne de l'Artisanat et des petites et moyennes entreprises

23 UECBV – Union Européenne du Commerce du Bétail Vivant (meat trade)

24 UGAL – Union of groups of independent retailers of Europe (retailers)

II. Other ABP sector representatives consulted

25 APAG – European Oleochemicals and Allied Products Group (oleochemical industry)

26 Fachverband Biogas e. V. – German Biogas Association (as coordinator for other European organisations)

27 CIBC – Confédération Internationale de la Boucherie et de la Charcuterie (butchers)

28 CCTA – European collagen industry (collagen)

29 COTANCE – Confederation of National Associations of Tanners and Dressers of the European Community (leather industry)

30 DEMETER-International e.V. – Organisation for products of certified biodynamic production (biodynamic producers)

31 EAPA – European Animal Protein Association (protein processors)

32 EBB – European Biodiesel Board (biodiesel producers)

33 ECN – European Compost Network (compost producers)

34 EDFA – European Down and Feather Association (feathers)

35 EDMA – European Diagnostic Manufacturers Association (in-vitro diagnostics industry)

36 EuLA – European Lime Association (lime)

37 FACE – Federation of Associations for Hunting & Conservation of the E.U. (hunters)

38 FEAD – European Federation of Waste Management and Environmental Services (waste management)

39 FEICA – Fédération Européenne des Industries de Colles et Adhésifs (adhesives manufacturers)

40 GME – Gelatine Manufacturers of Europe (gelatine)

41 ISIA – International Serum Industry Association (serum)

42 VOD – Verband organischer Düngemittel (organic fertilisers)

43 INTERLAINE – Umbrella organization for European associations of raw materials suppliers, processors, spinners and weavers of wool and wool textiles.

ANNEX I-B

SUMMARY OF CHRONOLOGY OF MAIN EXCHANGES WITH REPRESENTATIVES OF THE SPECIFIC SECTORS LIKELY TO BE AFFECTED BY THE REVIEW

Bilateral or multilateral meetings have been held with the following industry associations, during which specific aspects related to Regulation (EC) No 1774/2002 have been raised and further discussed (sometimes alongside with issues which may have been considered by way of comitology amendments). The following list gives a non-conclusive overview over these meetings:

18 November 2002	ca. 45 international industry organisations: explanation of the ABP Regulation and discussion of specific aspects
18 December 2002	GME: importation of bones derived from animals treated with growth hormones and/ or containing specified risk materials (SRM) for gelatine production; processing conditions for dicalcium phosphate (by-product from gelatine production)
17 January 2003	FEFAC: connection of the ABP Regulation to the feed ban
12 February 2003	APAG: importation of tallow for pharmaceutical purposes; HACCP in oleochemical plants; separation requirement for Category 2 and 3 ABP
20 February 2002	Medical devices industry: correlation between legislation from DG ENTR and ABP rules
5 March 2003	Photographic industry (Kodak): Importation and use of gelatine produced from animals treated with growth hormones for photographic purposes
25 March 2003	WR²: Discussion of alkali hydrolysis as an alternative treatment method
28 March 2003	European dairy association, International butchers association, GME, APAG, UECBV; Argentina and other organisations and third countries (in total 160 participants): clarification of ABP issues

8 April 2003	Milk industry: Transport of former foodstuffs; use of contaminated milk (Category 2) for petfood production
1 July 2003	Photographic industry (Fuji, Kodak): Importation and use of gelatine produced from animals treated with growth hormones for photographic purposes
4 July 2003	EFPRA: Processing conditions for production of hydrolysed proteins from feather meal
23 July 2003	WR² (alkali hydrolysis industry): Discussion of alkali hydrolysis as an alternative treatment method
28 July 2003	Cotance: application of food, feed and ABP rules on handling and treating of hides and skins
30 July 2003	SARIA (rendering industry): Discussion of an alternative treatment of tallow for production of biodiesel
2 September 2003	Photographic industry (Kodak): Importation and use of gelatine produced from animals treated with growth hormones for photographic purposes
7 October 2003	GME: import requirements for gelatine
13 October 2003	Industry producing adhesives: Possibilities to mark raw materials for adhesive production, in particular as regards milk products
17 October 2003	APAG: use of tallow for biofuel production; possibilities for marking of tallow; labelling requirements for tallow tanks; import certificates for fat derivatives
6 November 2003	EFPRA: Discussion of combustion of tallow in a thermal boiler as an alternative treatment method; marking of ABP

25 November 2003	Milk industry: Use of milk for feeding purposes; Applicability of marking requirements for milk products (casein) derived from animals treated with growth hormones and intended for petfood production
9 January 2004	EFPRA: Marking of ABP; use of hydrolysed feather meal
22-23 Jan. 2004	FEDIAF: use of blood products (plasma)
19 March 2004	Demeter (organic industry): possibilities to use Category 2 and 3 materials for production of their products
30 May 2005	UECBV (overlap with environmental legislation)
26 August 2005	Fur trade industry (import requirements for importation of hides and skins from fur animals)
24 October 2005	SITFA (feather industry): requirements on importation and transportation of feathers
22 November 2005	UECBV (clarification of certain terms, e. g. "fertilisers" or "tallow" , under ABP and under waste legislation; use of residues from biogas and composting; marking of ABP; need to simplify the ABP rules)
29 November 2005	APAG (Presentation and discussion of a study on the effect of oleochemical treatment of tallow on prion activity)
13 January 2006	Cotance (use of hides and skins from "cohort animals")
23 January 2006	FEDIAF (labelling of processed petfood; commercial document for ready-to-sell products; approval of plants only processing pre-treated ABP)
24 February 2006	Photographic industry (use of gelatine by this industry)

16 March 2006	EULA (Lime Association): Discussion of an application for a method allowing production of lime from ABP
20 March 2006	Working Group of the Advisory Group on the Food Chain, Animal and Plant Health (Commission presentation of the intended scope of the review exercise - Present: Advisory Group Members with an interest in ABP, additional stakeholders concerned)
22 June 2006	EULA (treatment requirements for the production of lime; approval requirements for lime producing plants)
28 June 2006	EFPRA (overlap with environmental legislation)
29 June 2006	European Dairy Association (overlap with food and feed hygiene legislation, duplication of approvals under such legislation and ABP rules)
27 July 2006	FEDIAF, EFPRA, EAPA (treatment requirements for porcine blood; differentiation between blood meal and blood products)
10 August 2006	EDMA (interlink with ENTR legislation regarding the manufacture of products for diagnostic purposes)
5 September 2006	EDMA (follow-up meeting of 10/08/2006)
7 September 2006	Working Group of the Advisory Group on the Food Chain, Animal and Plant Health (presentation of a draft proposal for review of the Regulation)
20 September 2006	UECBV, EFPRA, FEFAC, Cotance (classification of ruminant blood; materials to be used in Category 3 processing plants; requirements for dairy products in ABP and in fed and food legislation; etc.)
20 September 2006	Conference on animal by-products, as part of the "Better Training for Safer Food" initiative (provided an opportunity to collect views of Member States, third countries and certain industry sectors – UECBV (slaughterhouses),

	EFPRA (renderers), COTANCE – leather, FEFAC – animal feed)
21 September 2006	COTANCE (request for clarifications with respect to classification of hides and skins)
9 October 2006	VOD (import and labelling conditions for hornmeal, bonemeal and bloodmeal for use in fertilisers)
19 October 2006	EFPRA (see 28 June 2006)
25 October 2006	UECBV (simplification of legislation, risk-based approach for categorisation of animal by-products)
9 November 2006	ISIA (concerns about importation of serum and other products in particular from third countries treating animals with growth hormones)
22 November 2006	Joint informal discussion with EFPRA, UECBV and COTANCE (basis: draft proposal)
8 December 2006	Deutscher Bauernverband (German Farmers Association): Swill feeding; catering waste; use of ABP in composting and biogas production; manure handling; risks from sewage sludge
22 February 2007	FACE (handling of pheasant chicks being reared and then released in the wild for hunting; handling of "damaged game")
27 March 2007	MIV (possibilities to feed milk; categorisation of milk containing prohibited substances; quality management)
19 April 2007	ISIA (categorisation of serum; impacts of Regulation (EC) No 2007/2006)
23 April 2007	CWT (company producing hydrocarbon – oil): Discussion of an application for a method allowing production of industrial oil from ABP
1 June 2007	FACE (questionnaire to the impact assessment)

ANNEX II

SUMMARY OF CHRONOLOGY OF MAIN EXCHANGES WITH INTERNATIONAL PARTNERS LIKELY TO BE AFFECTED BY THE REVIEW

Bilateral or multilateral meting have been held with the following third countries, during which specific aspects related to Regulation (EC) No 1774/2002 were being raised and further discussed (sometimes alongside with issues which were considered by way of comitology amendments):

8 November 2002	USA: Import certificates for gelatine
18 November 2002	Representatives of 63 third countries: explanation of the ABP Regulation and discussion of specific aspects
19 November 2002	USA: marking of pet food; long list of issues, e. g; blood from ruminants; applicability of the ABP Regulation on technical products; use of used cooking oils
10 February 2003	Canada: long list of issues, e. g. categorisation of heads and feet from poultry; hydrolysed proteins for use in pet food; use of grieves derived from gelatine production
12 February 2003	APAG: importation of tallow for pharmaceutical purposes; HACCP in oleochemical plants; separation requirement for Category 2 and 3 ABP
19 February 2003	China: sourcing of materials, e. g. for lanolin production or for cosmetic products
19 February 2003	USA: marking of ABP; ban on international catering waste
23 April 2003	USA: Importation of collagen produced from bovine hides for production of sausage casings
15 September 2003	USA and photographic industry: Discussion of possibilities to import gelatine derived from animals which have been treated with growth hormones for photographic purposes
25 November 2003	Canada: Listing of establishments; request for certain import derogations from the ABP Regulation

3-4 December 2003	USA: Transitional measures and derogations for importation of ABP, e. g. hides and skins and pet food
10 December 2003	Canada: Certification requirements; marking of pet food; game trophies; transit requirements; etc.
10 December 2003	New Zealand: technical conditions on imports
15 January 2004	USA: long list if issues. E. g. import rules for finished products such as paints, lubricants, finished laboratory reagents; used cooking oil for use in animal feed or for technical purposes; use of dead in transit poultry for processing of (Category 3) processed animal protein
17 March 2004	USA: recommendations to refine health regulations for trading in animal products
30 March 2004	USA (conference call): photographic gelatine; certificates for raw ABP; import of bones for gelatine production; treatment requirements for birdseed with tallow; derogation for tallow and for hides
23 June 2004	USA (conference call): blood derived products for laboratory use; certification requirements for dairy products
12 July 2004	USA (conference call): importation of blood products; lists of approved plants; health certification requirements
11 November 2004	USA: import certificates
20 June 2005	USA: Derogation for separation of plants; risk assessment for tallow and gelatine; approval of marking substances; importation of certain intermediate products; exportation of milk replacers; raw milk for research purposes; blood from lagomorphs and rodentia
7 July 2005	USA: Export of gelatine capsules from USA to EU

22 March 2006	Australia: discussion of a list of points submitted by Australia
04 December 2006	Japan: Swill feeding
16 January 2007	Australia, New Zealand, USA, Canada: review of the ABP Regulation; importation of intermediate products; questions on how to trade with products not covered by Regulation (EC) No 2007/2006; clarification request on Category 2 ABP of low risk
20 January 2007	New Zealand: Categorisation of certain ABP

In addition to these meetings a very intense exchange of letters and e-mails has taken place with several third countries where the Commission has tried to clarify uncertainties and to provide help by issuing guidance notes or, where this was not possible by amending existing legislation or by adopting transitional measures, derogations or implementing legislation.

ANNEX III

OPINIONS OF THE EUROPEAN FOOD SAFETY AUTHORITY (EFSA) RELATING TO THE ABP REGULATION

Opinion of the Panel on Biological Hazards of the European Food Safety Authority on the process of "High Pressure Hydrolysis Biogas" (HPHB) as method for safe disposal of category 1 Animal by-Products (ABP) not intended for human consumption. (Question N° EFSA-Q-2003-028).

Opinion of the Scientific Panel on Biological Hazards of the European Food Safety Authority on the safety vis-à-vis biological risk including TSEs of the "application on pastureland of organic fertilisers and soil improvers". (Question N° EFSA-Q-2003-090).

Opinion of the Scientific Panel on Biological Hazards of the European Food Safety Authority on the safety vis-à-vis biological risk including TSEs of the "application on pastureland of organic fertilisers and soil improvers" (Question N° EFSA-Q-2003-090).

Opinion of the Scientific Panel on Biological Hazards of the European Food Safety Authority on the “Assessment of the human and animal BSE risk posed by tallow with respect to residual BSE risk” (Question N° EFSA-Q-2003-099).

Opinion of the Scientific Panel on Biological Hazards of the European Food Safety Authority on the “Quantitative assessment of the human BSE risk posed by gelatine with respect to residual BSE risk” (Question N° EFSA-Q-2003-099)

Opinion of the Scientific Panel BIOHAZ on the “Quantitative assessment of the residual BSE risk posed by di-calcium phosphate (DCP) and tri-calcium phosphate (TCP) from bovine bones used as an animal feed additive or as fertiliser” (Question N° EFSA-Q-2003-099).

Opinion of the Panel on Biological Hazards of the European Food Safety Authority on “Combustion of Tallow in a Thermal Boiler” process for safe disposal of animal by-products as method for safe disposal of category 1 Animal by-Products (ABP) not intended for human consumption (Question N° EFSA-Q-2003 –234).

Opinion of the Panel on Biological Hazards of the European Food Safety Authority on “Biodiesel Process” as a method for safe disposal of category 1 Animal by-Products (ABP) (Question N° EFSA-Q-2004-028).

Opinion of the BIOHAZ Panel on the "safety of collagen and a processing method for the production of collagen" (Question N° EFSA-Q-2004-085).

Opinion of the BIOHAZ Panel on the "BSE risk from cohort animals: bovine hides and skins for technical purposes" (Question N° EFSA-Q-2005-292).

ANNEX IV

STATISTICS OF THE ONLINE QUESTIONNAIRE[6]

Date open: 2007-04-24
End date: 2007-06-19
There are 114 responses

Reply as an individual or on behalf of an organisation, institution or company	**Number of responses**	**% of responses**
Organisation, institution, company	107	(86.3%)
Individual	17	(13.7%)

Type of organisation, institution or company	**Number of responses**	**% of responses**
Organization representing the private sector	42	(39.3%)
Private company	38	(35.5%)
National authority	8	(7.5%)
National NGO	8	(7.5%)
Other contributor	7	(6.5%)
Regional or local authority	3	(2.8%)
International NGO	1	(0.9%)
International organization Academic institution/think tank	0	(0%)

[6] Note: questions were optional for the participants to answer and some have chosen not to answer all of them. Therefore the number of responses given to any particular question varies and does not add up to the number of all the people answering the questionnaire (124). Similarly, the % of responses refers to the number of responses in relation to all the people answering the questionnaire and does not add up to 100%.

Country of residence	Number of responses	% of responses
UK-United Kingdom	53	(42.7%)
BE-Belgium	20	(16.1%)
NL-Netherlands	14	(11.3%)
DE-Germany	11	(8.9%)
Other non-European country	6	(4.8%)
FI-Finland	5	(4%)
DK-Denmark	3	(2.4%)
CZ-Czech Republic	2	(1.6%)
EL-Greece	2	(1.6%)
IE-Ireland	2	(1.6%)
IT-Italy	2	(1.6%)
EE-Estonia	1	(0.8%)
FR-France	1	(0.8%)
PT-Portugal	1	(0.8%)
SK-Slovakia	1	(0.8%)
Other European countries	0	(0%)

RESULTS FROM THE ON_LINE CONSULTATION

A. Determination of the end of the ABP life-cycle

Option (a): Do-nothing	**Number of responses**	**% Responses**
Strongly disagree	37	(29.8%)
Disagree	18	(14.5%)
Agree	14	(11.3%)
Other	14	(11.3%)
Strongly agree	11	(8.9%)

Option (b): Self-regulation, co-regulation or guidance	**Number of responses**	**% Responses**
Agree	36	(29%)
Disagree	30	(24.2%)
Other	11	(8.9%)
Strongly agree	7	(5.6%)
Strongly disagree	6	(4.8%)

Option (c): Legislative review **i. Exemption of finished products from the Regulation**	**Number of responses**	**% Responses**
Agree	39	(31.5%)
Disagree	20	(16.1%)
Other	14	(11.3%)
Strongly agree	8	(6.5%)
Strongly disagree	5	(4%)

Option (c): Legislative review **ii. Introduction of a legal basis for determining the end of the ABP life cycle**	**Number of responses**	**% Responses**
Strongly agree	40	(32.3%)
Agree	28	(22.6%)
Disagree	8	(6.5%)
Other	8	(6.5%)
Strongly disagree	4	(3.2%)

B. Coverage of wild animals

Option (a): Do-nothing	**Number of responses**	**% Responses**
Strongly agree	23	(18.5%)
Disagree	21	(16.9%)
Agree	18	(14.5%)
Strongly disagree	17	(13.7%)
Other	12	(9.7%)

Option (b): Self-regulation, co-regulation or guidance	**Number of responses**	**% Responses**
Agree	49	(39.5%)
Disagree	17	(13.7%)
Other	11	(8.9%)
Strongly disagree	9	(7.3%)
Strongly agree	2	(1.6%)

Option (c): Legislative review **i. To extend the scope to cover all wild animals, but apply only minimal Community controls in line with the Hygiene legislation**	**Number of responses**	**% Responses**
Disagree	30	(24.2%)
Strongly disagree	25	(20.2%)
Agree	16	(12.9%)
Other	13	(10.5%)
Strongly agree	2	(1.6%)

ii. To extend the scope to cover all wild animals, but allow the competent authority to issue a general authorisation	**Number of responses**	**% Responses**
Disagree	41	(33.1%)
Agree	23	(18.5%)
Other	13	(10.5%)
Strongly disagree	6	(4.8%)
Strongly agree	4	(3.2%)

iii. To extend the scope to cover all wild animals, but apply only minimal Community controls in line with the Hygiene legislation and to allow the competent authority to issue a general authorisation	**Number of responses**	**% Responses**
Strongly disagree	23	(18.5%)
Disagree	23	(18.5%)
Agree	18	(14.5%)
Other	15	(12.1%)
Strongly agree	3	(2.4%)

CATEGORISING NEW PRODUCTS AND TECHNICAL USE OF ALL THREE CATEGORIES OF ABP

A. Categorising new ABP

Option (a): Do-nothing	**Number of responses**	**% Responses**
Disagree	34	(27.4%)
Strongly disagree	28	(22.6%)
Agree	7	(5.6%)
Strongly agree	4	(3.2%)
Other	4	(3.2%)

Option (b): Self-regulation, co-regulation or guidance	**Number of responses**	**% Responses**
Disagree	34	(27.4%)
Agree	17	(13.7%)
Other	13	(10.5%)
Strongly disagree	6	(4.8%)
Strongly agree	2	(1.6%)

Option (c): Legislative review **i. To categorise newly the intrinsically low risk products**	**Number of responses**	**% Responses**
Disagree	29	(23.4%)
Agree	28	(22.6%)
Strongly agree	10	(8.1%)
Other	5	(4%)
Strongly disagree	1	(0.8%)

ii. To maintain current default categorization, but create basis for proportional measures to be introduced on a case-by-case basis	Number of responses	% Responses
Disagree	40	(32.3%)
Agree	24	(19.4%)
Strongly disagree	4	(3.2%)
Other	4	(3.2%)
Strongly agree	0	(0%)

iii. To categorise newly intrinsically low risk products and to create a legal basis to categorise further products and proportional measures to be introduced on a case-by-case basis	Number of responses	% Responses
Agree	47	(37.9%)
Strongly agree	23	(18.5%)
Disagree	5	(4%)
Other	4	(3.2%)
Strongly disagree	0	(0%)

B. Technical use of all three Categories of ABP

Option (a): Do-nothing	Number of responses	% Responses
Disagree	35	(28.2%)
Strongly disagree	17	(13.7%)
Agree	11	(8.9%)
Other	7	(5.6%)
Strongly agree	4	(3.2%)

Option (b): Self-regulation, co-regulation or guidance	**Number of responses**	**% Responses**
Disagree	34	(27.4%)
Agree	16	(12.9%)
Other	13	(10.5%)
Strongly disagree	5	(4%)
Strongly agree	1	(0.8%)

Option (c): Legislative review **i. Extending the list of products per category and their possible uses in the Regulation**	**Number of responses**	**% Responses**
Disagree	40	(32.3%)
Agree	20	(16.1%)
Other	9	(7.3%)
Strongly agree	5	(4%)
Strongly disagree	2	(1.6%)

ii. Introduction of the possibility to use any animal by-product for technical uses on a risk based approach	**Number of responses**	**% Responses**
Agree	39	(31.5%)
Strongly agree	37	(29.8%)
Other	3	(2.4%)
Strongly disagree	0	(0%)
Disagree	0	(0%)

CLARIFYING THE APPROVALS / REGISTRATIONS AND CONTROLS

Option (a): Do-nothing	**Number of responses**	**% Responses**
Strongly disagree	36	(29%)
Disagree	22	(17.7%)
Agree	11	(8.9%)
Strongly agree	3	(2.4%)
Other	2	(1.6%)

Option (b): Self-regulation, co-regulation or guidance	**Number of responses**	**% Responses**
Disagree	40	(32.3%)
Agree	13	(10.5%)
Strongly disagree	8	(6.5%)
Other	8	(6.5%)
Strongly agree	1	(0.8%)

Option (c): Legislative review **i. To remove duplicated approvals and rely fully on the provisions already introduced by other Community sector legislation**	**Number of responses**	**% Responses**
Disagree	28	(22.6%)
Agree	14	(11.3%)
Other	11	(8.9%)
Strongly agree	9	(7.3%)
Strongly disagree	3	(2.4%)

ii. To remove duplicated approvals, rely on the provisions already introduced by other Community sector legislation, but require registration for specific businesses	Number of responses	% Responses
Disagree	30	(24.2%)
Agree	16	(12.9%)
Strongly agree	9	(7.3%)
Strongly disagree	7	(5.6%)
Other	6	(4.8%)

iii. To remove duplicated approvals, rely on the provisions already introduced by other Community sector legislation, and require registration in all cases	Number of responses	% Responses
Disagree	32	(25.8%)
Agree	15	(12.1%)
Other	10	(8.1%)
Strongly disagree	6	(4.8%)
Strongly agree	4	(3.2%)

iv. To remove duplicated approvals, rely on the provisions already introduced by other Community sector legislation, require registration in all cases and to create a legal basis allowing introduction of additional requirements	Number of responses	% Responses
Agree	23	(18.5%)
Strongly agree	14	(11.3%)
Disagree	12	(9.7%)
Other	12	(9.7%)
Strongly disagree	8	(6.5%)

CLARIFYING THE DEROGATIONS

Option (a): Do-nothing	**Number of responses**	**% Responses**
Strongly disagree	30	(24.2%)
Disagree	25	(20.2%)
Agree	14	(11.3%)
Strongly agree	5	(4%)
Other	3	(2.4%)

Option (b): Self-regulation, co-regulation or guidance	**Number of responses**	**% Responses**
Disagree	31	(25%)
Agree	16	(12.9%)
Other	10	(8.1%)
Strongly disagree	6	(4.8%)
Strongly agree	4	(3.2%)

Option (c): Legislative review **i. Extending the derogation by allowing Member States to authorise the importation and use all three Categories of ABP for research purposes**	**Number of responses**	**% Responses**
Agree	31	(25%)
Strongly agree	25	(20.2%)
Other	12	(9.7%)
Disagree	5	(4%)
Strongly disagree	0	(0%)

ii. Extending the derogation to provide for burial or burning in more areas affected by special circumstances	Number of responses	% Responses
Agree	29	(23.4%)
Other	21	(16.9%)
Strongly agree	13	(10.5%)
Strongly disagree	4	(3.2%)
Disagree	3	(2.4%)

ANNEX V

QUESTIONNAIRE SENT TO COMPETENT AUTHORITIES OF MEMBER STATES AND STAKEHOLDERS AND NUMBER OF ANSWERES RECEIVED

Type of organisation, institution or company	**Number of responses**
Competent Authorities from Member States	16
Competent Authorities from third countries	1
Organization representing the private sector	7
Private company	10
NGO	0
Other contributor	0
Total	34

ANNEX VI

Examples of the economic and social dimension of the industries affected by the review

EFPRA – European Fat Processors and Renderers Association

EFPRA members process about 15,5 million metric tons (mMT) of animal by-products (raw materials) per year. Of this about 5,5 mMT are Category 1 and 2 and about 10 mMT are Category 3 and food grade material.

The production of rendered products is as follows:

	Protein Meal/PAP*	Rendered Fat
Cat. 1 and 2 (combined)	1.32 mMT	0.92 mMT
Cat. 3 and Food grade (Combined)	2.42 mMT	1.68 mMT
Total	3.75 mMT	2.6 mMT

* Processed Animal Protein

Confederation of National Associations of Tanners and Dressers of the European Community

This confederation represents companies with more than 3.000 plants (mainly small and medium enterprises). More than 50.000 direct jobs depend on the leather industry that accounts a 8.000 Million Euro turnover/year. This hides and skins represent typically 50-60% of leather production costs

Cotance – Leather industry

Hides and skins (HS) make up 50 % of the costs of the whole leather production chain. Of raw HS only 20 % are used for leather production (the rest are heir, splits, etc.). The other 80 % enter into the food chain (e. g; gelatine, collagen, hydrolised proteins), feed and technical products (e. g. fertilisers).

FEDIAF – petfood industry

FEDIAF represents the interests of 19 national pet food industry associations. In all, it represents the views and interests of around 450 European pet food producing companies. FEDIAF members provide a range of products to help ensure long, healthy and active lives of millions of pets in Europe, which are cared for in around 55 million pet keeping households.

FEDIAF members process 5.000.000 ton of raw materials (not only ABP) per year. Yearly, they use about 2.750.000 ton of by-products from European agriculture. In 2005, products worth 8.5 billion Euro were sold with a yearly growth rate of 3 %. This industry employs directly 21.000 people and indirectly another 30.000 people.

As an example, one big company imports from 30 third countries to 160 locations within the EU15; this company has 30.000 associates. Each day, this company processes in just one of the plants 380 to raw materials (ABP, tallow, cereals, vitamins, etc.) while having about 70 lorries of packaging materials.

GME – Gelatine Manufacturers of Europe

GME represents 10 European companies with a total of 22 production plants in Europe. They produce 110.000 ton gelatine per year, which is 45 % of the world production. Worldwide, apart from Europe, Japan, USA and China are the main producers. All producers of bone gelatine in Europe are members of GME.

Photographic industry (Kodak)

Kodak produces all over the world but everywhere to the same standard. In Europe, they have 2 production plants (FR and UK), where they employ about 6000 people and produce products worth 1 billion €. Most of the products produced in Europe are also sold in Europe.

Products of Kodak are in particular photo imaging products (photo films), motion pictures (cinema), x-ray-films and medical devices. Kodak does not produce for the food industry.

Associations representing the use of Serum:

1. **EDMA – European Diagnostic Manufacturers Association**

   EDMA ***membership*** brings together 20 National Associations in European countries and 29 of the major companies engaged in the research, development, manufacture or distribution of IVD products. Through its affiliated National Associations, EDMA represents in total more than 500 companies (or over 700 legal entities) across Europe.

   http://www.edma-ivd.be/

2. **IFAH - International Federation for Animal Health**

   The International Federation for Animal Health (IFAH) is an organisation representing manufacturers of veterinary medicines, vaccines and other animal health products in both developed and developing countries across five continents.

   http://www.ifahsec.org/default.htm

3. **EFPIA – European Federation of Pharmaceutical Industries and Associations**

   EFPIA represents the pharmaceutical industry operating in Europe. Through its direct of **30** national associations and **46** leading pharmaceutical companies, EFPIA is the voice on the EU scene of **2,100** companies committed to researching, developing and bringing to patients new medicines that improve health and the quality of life around the world.

   http://www.efpia.org/Content/Default.asp

4. EVM – European Vaccine Manufacturers

EVM is a specialised group within EFPIA, the professional association of the European pharmaceutical industry. EVM brings together **8 company members**. The group was established in 1991 in order to promote a favourable climate for expanded vaccine protection and improved vaccine coverage in Europe, and to help sustain the innovative research and development capability of vaccine manufacturers in Europe

EVM members:

- Baxter - Austria
- Berna A Crucell Company - Switzerland and Spain
- GlaxoSmithKline Biologicals - Belgium
- Novartis Vaccines - Italy and Germany
- Sanofi Pasteur - France
- Sanofi Pasteur MSD - France
- Solvay Pharmaceuticals - The Netherlands
- Wyeth Vaccines - Belgium

The European vaccine industry:

- is the largest supplier of vaccines in the world, producing approximately 80% of vaccines used worldwide.
- is the largest supplier to UNICEF of vital paediatric vaccines,including polio vaccines
- has developed vaccines specifically designed for the needs of developing countries (e.g., combined paediatric vaccines against diphtheria, tetanus, pertussis, hepatitis B, and invasive Hib disease)
- is working in collaboration with the public sector in joint R&D activities and in clinical trials partnerships to develop vaccines against diseases that particularly burden developing countries (e.g., denguefever, leishmaniasis, rotavirus, HIV, malaria and tuberculosis, among others)
- contributes significantly to Research & Development with over half of all global vaccine R&D being carried out in Europe by EVM member companies

- has production facilities not only in Europe but across the globe through international collaboration and joint ventures

- submits its novel products to a centralised procedure to obtain EU licensing (e.g. all hepatitis B vaccines, hepatitis B-containing combination vaccines, as well as the pneumococcal conjugate vaccines, among others).

http://www.evm-vaccines.org/

5. ISIA – International Serum Industry Association

Use of serum:

Animal serum (a blood-derived ABP) is used extensively in

1. Life science research

2. Production of human and animal vaccines

3. Production of biopharmaceuticals

4. Production of diagnostic products

The use of serum in research is critical in the development of future diagnostic and biologically based therapeutic products, a high growth segment of the healthcare industry

Animal Health Sector:

More than 50,000 full time jobs in Europe are dependent on the animal health industry with ~15,000 being in production, marketing, sales, research and development. European sales of animal health care related products amounted to $5.3 billion US in 2005.

Diagnostic Manufacturing:

Serum is used in the manufacturing of antibodies and antigens for use in diagnostic tests, as well as a component or diluent in the test kits themselves. These diagnostic tests provide critical health care information allowing the potential for global health care savings.

The European market for in vitro diagnostics was 7.8 billion Euros in 2004. Over 550 companies all over Europe serve this market. Several of these companies compete globally, and are market leaders on a worldwide basis.

Reduction in diagnostic test manufacturing in Europe could have significant impact on the healthcare, financial and employment sectors.

Biopharmaceuticals:

Biopharmaceuticals are defined as pharmaceuticals manufactured by biotechnology methods, with the products having biological sources usually involving live organisms or their active components. Biotech medicines account for 10 to 15% of the current pharmaceutical market (42 billion Euros in 2002) and comprise the highest growth segment of the market. More than one fifth of the new medicines launched each year are now biotechnology derived. Biotech medicines have been developed for a wide range of rare and chronic diseases and will continue to provide new breakthroughs in the years to come. More than 60 companies are active in this area in Europe.

Given the uses of serum described above in both research and production it is apparent that the inability to use this material would significantly impact this segment and result in job losses, healthcare concerns and financial woe.

Human vaccines:

In 2002, European companies produced 3.5 billion vaccines doses, which are 80 % of the vaccines produced globally! 50% of these were exported to the USA, and about 30 of these doses were used in Europe. 2.8 billion doses were used for humanitarian purposes. About 12,000 people in Europe work for vaccine manufacturers. Research and development spend for this segment was $1.5 billion Euros in 2002, with two thirds of all research on vaccines occurring within the EU. The total market for vaccines worldwide in 2002 was 6.3 billion Euros.

Vaccine production is a small but critical part of the pharmaceutical marketplace. Europe is a major supplier of these materials to the rest of the world. Reduction in vaccine production in Europe could have catastrophic impact on healthcare worldwide and result in significant job losses.

In summary, serum is a critical component in use in all of the segments detailed above. It is essential for the wellbeing of these industries in Europe that this important intermediate be responsibly imported through clear channels in a way that maintains total traceability

ANNEX VII

List of legislation concerning ABP introduced since October 2002

1. Transitional measures for Member States and Third Countries

1.1. Transitional measures for Member States

- Collection, transport, treatment, use and disposal of former foodstuffs (all Member States). Commission Regulation (EC) No 197/2006 (expiry: 31/7/2009)

- The possibility of on-site burning or burial of ABP (Estonia and Cyprus). Commission Decision 2004/467/EC (Expired on 01/01/2005). Commission Decision 2005/62/EC as amended by Decision 2005/869/EC extended the transitional measures for Cyprus (expired on 1/1/2007).

- Separation of Category 1 and 2 processing plants and the inclusion of ABP establishments in the list of establishments in transition in Latvia. Commission Decisions 2004/464/EC and 2004/476/EC (expired on 31/12/2004).

- Collection, transport and disposal of former foodstuffs. Commission Regulation 813/2003/EC (expired on 31/12/2005).

- Biogas standards (all Member States). Commission Regulation (EC) No 810/2003 as amended by Regulation (EC) No 12/2005 and by (EC) No 209/2006 & by (EC) 185/2007 (expiry: 30 June 2008)

- Composting standards (all Member States). Commission Regulation (EC) No 809/2003 as amended by Regulations (EC) No 12/2005 and by (EC) No 209/2006) & by (EC) 185/2007 (expiry: 30 June 2008)

- Collection of wastewater (Austria, Denmark, France, Finland, Italy, Ireland, Portugal, Spain, Sweden, Estonia and Hungary). Commission Decisions 2003/334/EC and 2004/468/EC (expired on 30/04/2005).

- Manure processing standards (Belgium, France, Finland and Netherlands). Commission Decision 2003/329/EC as amended by Decision 2005/14/EC and by Decision 2006/129/EC (expired on 31/12/2006)

- Feeding catering waste (swill feeding) to animals (Austria and Germany). Commission Decision 2003/328/EC (expired on 31/10/2006).

- Low-capacity incinerators/co-incinerators (Finland and United Kingdom). Commission Decision 2003/327/EC (expired on 31/12/2004).

- Separation of oleo-chemical plants (Belgium, Germany, Italy, Netherlands, Spain, Sweden and United Kingdom). Commission Decision 2003/326/EC (expired on 31/10/2005).

- Total separation between plants handling Category 1, 2 and 3 materials (Finland and France). Commission Decision 2003/325/EC (expired on 30/04/2004 for FR and on 31/10/2005 for FIN).

- Separation of intermediate plants (France and Italy). Commission Decision 2003/323/EC (expired on 30/04/2004).

- Processing standards for mammalian blood (Germany, Italy, Spain and United Kingdom). Commission Decision 2003/321/EC (expired on 31/12/2004).

- Feeding used cooking oil to animals (Ireland and United Kingdom). Commission Decision 2003/320/EC (expired on 31/10/2004).

1.2. Transitional measures for third countries

General transitional arrangements were granted to third countries postponing the application of the import provisions and allowing adequate time for them to adjust to the new requirements and for the Commission to update the import rules. In addition, the following specific transitional measures were granted:

- Import and placing on the market of certain materials of animal origin classified as Categories 1 and 2 intended for technical purposes (all third countries). Commission Regulation 878/2004/EC as amended by Regulation (EC) No 1877/2006 (no expiry date)

- Separation of Category 1, 2 and 3 intermediate plants and the separation of Category 1, 2 and 3 processing plants (Australia, Canada, China and USA). Commission Regulation 780/2004/EC (expired on 31/10/2005).

- Import of gelatine produced from vertebrae bones from Japan and United States to Netherlands, France and United Kingdom intended for making photo films in the EU. Commission Decision 2004/407/EC as amended by Decision 2006/311/EC (no expiry date)

2. Amending Regulations

Eight Regulations have been introduced amending the Articles and/or Annexes:

- Regulation (EC) No 829/2007 has amended certain Annexes relating to production standards and has brought all import certificates into line with the requirements of the TRACES system.

- Importation and transit of certain intermediate products derived from Category 3 material intended for technical uses in medical devices, in vitro diagnostics and laboratory reagents and amending the ABP Regulation. Commission Regulation (EC) No 2007/2006.

- Regulation (EC) No 208/2006 amending Annexes VI and VIII as regards processing standards for biogas and composting plants and requirements for manure

- Regulation (EC) No 416/2005 amending Annex XI as regards the importation from Japan of certain animal by-products intended for technical purposes

- Regulation (EC) No 93/2005 has amended Annexes II and V of the Regulation

- Regulation (EC) No 92/2005 has amended the Regulation as regards biogas transformation and processing of rendered fats.

- Regulations (EC) No 668/2004 and No 416/2005 have introduced some technical amendments to bring the Annexes in line with the text of the Articles and have updated the model of health certificates and introduced new models for the import of certain products that may be used as feed material, pet-food, dogchew and technical products. The list of third countries has been updated accordingly.

- Regulation (EC) No 808/2003 has amended Article 12(3) to allow the incineration of specified risk material and bodies of animals in low-capacity incinerators in line with the SSC opinion and has introduced some other technical amendments to the Annexes.

3. Implementing Regulations

Six implementing Regulations have been introduced:

- Importation and transit of certain intermediate products derived from Category 3 material intended for technical uses in medical devices, in vitro diagnostics and laboratory reagents and amending the ABP Regulation. Commission Regulation (EC) 2007/2006.

- Listing of approved plants in Member States. Regulation (EC) 1192/2006 provides for ways of updating, and communicating to the Commission and other Member States, the list of approved establishments

- Control measures as regards fertilisers and soil improvers. Regulation (EC) No 181/2006 allows the use of organic fertilisers and soil improvers other than manure under certain conditions and amends Annex I

- Processing of ABP of fish origin and commercial document. Regulation (EC) No 93/2005 establishes a specific method for the processing of ABP of fish origin and lays down a harmonised model of commercial document for the transport of ABP.

- Means of use or disposal of ABP. Regulation (EC) No 92/2005 as amended by Regulations (EC) No 2067/2005 & (EC) No 1678/2006 provides for the possibility to dispose of ABP by other alternative methods or recycle them in other ways.

- Use of milk, milk-based products and milk-derived products. Regulation (EC) No 79/2005 allows the direct feeding to farmed animals with dairy products produced to food standards

4. Permanent general derogations

Two permanent / general derogations have been granted:

- Derogation from the intra-species recycling ban for fish (Article 22(2). Regulation (EC) No 811/2003.

- Detailed requirements on how burial and burning should be carried out in accordance with Article 24(1). Regulation (EC) No 811/2003.

5. Permanent specific derogations granted on request from member States

Two measures have been introduced to allow the continual feeding of:

- Feeding of endangered / protected species of necrophagous birds with dead ruminants containing specified risk material (Article 23(2) (Italy, France, Spain, Portugal, Greece and Cyprus). Commission Decision 2003/322/EC, as amended by Commission Decisions 2004/455/EC & 2005/830/EC.

- Fur animals with processed animal protein derived from the bodies or part of bodies of animal of the same species (Finland, Estonia). Commission Decision 2003/324/EC.

6. Guidelines issued to clarify a number of issues

Five guidelines have been issued:

- Guidance note: Interpretation of Regulation 1774/2002/EC - questions from FVO missions (April 2006)

- Guidelines for applications for new alternative methods of disposal or use of ABP (April 2006)

- Frequently asked Questions and Answers on ABP (6 May 2004)

- Guidance on applying the new ABP Regulation in the form of questions and answers clarifying the main concerns raised by Member States and stakeholders (April 2004)

- Guidance note on the application to ABP of Community legislation regarding animal and public health and waste (March 2004, updated in March 2007)

A full list of ABP legislation can be found at:

http://europa.eu.int/comm/food/food/biosafety/animalbyproducts/index_en.htm

ANNEX VIII

List of other Community legislation and policy changes taken into account

Articulation with other Community legislation

TSE

- Current provisions contains a number of TSE-related elements, including -
  - Classification as Category 1 of tissues such as SRM and BSE positive / suspects and animals killed in the context TSE eradication.
  - General requirement for mammalian materials intended for the production of processed animal protein to be pressure-cooked.
  - Ban on the landfill of TSE suspects/positive even after pressure-cooking.
  - Burial or burning of fallen stock only allowed in remote areas (excluding BSE positive).
  - Prohibition on intra-species recycling ("cannibalism").
  - Requirement to filter tallow to maximum 0,15 % in weight to remove the protein fraction.
  - Prohibition on the application to pastureland of organic fertilisers and soil improvers.
- Being a general legal framework, the ABP Regulation ensures that TSE risk materials are disposed of properly; thus, complementing the TSE Regulation. Subject to the TSE feed ban, it foresees the possibility to use processed animal protein of all species in feed, provided that only safe material is used and mammalian derived protein has been treated using the highest processing standard (pressure-cooking) capable to inactivate the TSE agent.
- The proposal suggests no policy changes that would affect the above elements.
- However, as stipulated in the TSE road map, provided the positive trend continues and scientific conditions are in place, it might be envisaged in long term to adapt some of the above provisions to the improving BSE trend.

Waste legislation

There is a concomitant review of waste legislation (shipment and framework).

- *Waste shipment Regulation*

  The co-legislators have recently adopted Regulation (EC) No 1013/2006 on waste shipment, revamping the relevant Community legislation.

  The new Regulation excludes ABP that are controlled by the ABP Regulation. But in Article 59(1) it requires the Commission to complete a review of the relationship between it and the ABP Regulation. If necessary, this review shall be accompanied by appropriate proposals with a view to achieving an equivalent level of procedures and control regime for the shipment of ABP.

  The opportunity is taken to propose some changes to ensure such equivalency, in particular as regards ABP that become waste when mixed with or contaminated by hazardous waste.

- *Waste Framework legislation*

  The Commission has also proposed a review of the basic waste framework law. A proposal for a Directive of the European Parliament and of the Council on waste is at initial stage of co-decision.

  It is proposed to exclude from the scope of the waste framework law ABP that are regulated by the ABP Regulation, except when ABP are foreseen for incineration, landfill or use in biogas or composting plant.

  This is viewed by interests as a further step in the right direction, avoiding duplication and improving the procedural arrangements in applying Community law.

- *Waste incineration*

  The Commission has initiated a study on the incineration of tallow and its impact on the tallow burning industry.

  The study has been finalised at the end of the year 2006, and might result in a co-decision review of the relevant Community provisions.

Cosmetics, medicinal products and medical devices

- *Approval of plants*

  Separate Community legislation governs the manufacturing and placing on the market and export of cosmetics, medicinal products and medical devices (including laboratory reagents).

Current provisions only apply to cosmetics, medicinal products and medical devices (including laboratory reagents) as far as concern the source and starting materials of animal origin that are used in the manufacture of such products. It requires that such starting materials must derive from "Category 3 materials" i.e. materials from animals fit for human consumption following veterinary checks.

When such starting materials are to be imported into the EU, they must meet equivalent conditions set out in the Regulation, ensuring their safety vis-à-vis animal and public health.

Sector legislation has been adapted to reflect these basic conditions.

– It is proposed to recognise that in most cases such sector legislation achieves the objectives of the ABP Regulation; hence, should be relied on, excluding the sector establishments from the need for further approval under the ABP Regulation, unless new risks arise or a comparison of specific provisions of sector legislation with ABP rules shows that no equivalent degree of protection is being ensured.

- *Intermediate products*

– Use of category 3 material

Current provisions require intermediate products to be ‘derived from Category 3 material’. This poses severe problems for the industry, which uses many intermediate products are derived from animals not intended for slaughter for human consumption, sometimes raised specifically for the purpose of producing intermediate products from their tissues, and sometimes under laboratory conditions. These include dogs, mice, rats, snakes, insects, worms and many other species, whose by-products are classified as Category 1 or 2 because they are not intended for human consumption and are not slaughtered in a slaughterhouse. As such they cannot be used.

– It is proposed to adapt the provisions, avoiding disruption of trade in /importation of intermediate products derived from such animal species kept for non-food purpose.

– Hormone derived materials

Also, in some countries, particularly Australia and the NAFTA countries, growth hormones are regularly used on farmed animals intended for human consumption.

Community law does not allow such animals to enter the human food chain. However, it does not seem necessary to prevent the use of tissues derived from such animals to produce intermediate products. Nevertheless, these animals can only be classed as Category 1 and therefore intermediate products derived from is prohibited by the Regulation.

Restricting the sourcing to only those animals that have not been fed with growth hormones could, according to industry sources, cut off supplies of a large number of vital intermediate products. For instance, it is estimated that more than 70% of biopharmaceutical and diagnostic products currently produced within the Community are derived from or use intermediate products sourced in Australia and North America. The vast majority, if not all, of these would have been fed with growth hormones and would automatically be classified as Category 1.

– It is proposed to adapt the provisions, avoiding disruption of trade in /importation of intermediate products derived from animals fed growth hormones.

– Countries from which intermediate products may be imported

Current provisions require intermediate products to come from only listed third countries. However, that list concerns countries where the importation of fresh meat /products of animal origin intended for food is allowed.

The listing would seem inappropriate given that some of the products concerned are not derived from meat producing species (dogs, mice, rats, snakes and many other species).

– It is proposed to readjust the listing accordingly, also reducing the level of burden resulting from control and inspections at Border Inspection Posts.

– Estimates of the potential impact on industry

According to the industry, sales of in-vitro diagnostic products in the EU are worth some 9.4 billion Euros and the industry employs around 100,000 people. As an example the industry estimates a 10-15% increase in costs in Germany as a result of the application of current interim measures, leading to a number of negative impacts on the industry, including an estimated 5000 jobs lost (see enclosed the industry's economic impact data).

Other policy

The proposal also takes into account recent law changes in the field of food/feed hygiene and animal nutrition. Being a framework law, the ABP Regulation ensures that by-products from food production are properly handled and used or disposed of; so as to avoid any direct or indirect source of contamination for food. The ABP Regulation complements the general rules for the handling of by-products from food production in food establishments, set down in Regulation (EC) No 852/2004, which, in particular, provides for its disposal in a hygienic and environmental friendly way. In addition, rules related to certain food activities have already been more specifically addressed in the ABP legislation to cover certain practices, such as the possible use of hides and skins for gelatine or collagen production, or the direct use of certain dairy products for feed purposes. The proposal suggests no policy changes that would affect the above elements. It might, however, adapt some of the provisions to improve basing of the rules on possible risk while ensuring the current high level of public and animal health.