Food Safety:

From the Farm to the Fork

The new Animal By-Products Regulation: Guidance Document

On 3 October 2002 the EU adopted Regulation (EC) No 1774/2002 governing Animal By-Products (ABPs). The Regulation lays down strict animal and public health rules for the collection, transport, storage, handling, processing and use or disposal of all ABPs. These rules will apply throughout the EU from 1 May 2003.

The scope and objectives of the Regulation were examined at a conference organised by the Directorate General for Health and Consumer Protection (SANCO) on 13 November 2002 in Brussels, which was attended by more than 150 people (stakeholders, representatives from Missions of third countries and Member States Permanent Representations). The questions and answers below are largely based on the issues raised at that conference.

1. What is the definition of an Animal By-Product?

Article 2 of the Regulation defines an animal by-product (ABP) as any part of an animal carcass, or any material of animal origin, not intended for human consumption. All products of animal origin would be considered to be ABP if they were not intended for human consumption. The important point is the intention. Much of the carcass of an animal slaughtered for human consumption will be despatched for human consumption, but some parts will not be. This is not necessarily because they are not fit for human consumption; it may simply be that there is no market for them. So, for example, in parts of Europe where cow tongues are considered a delicacy that part of a cow carcass may be considered as meat. In parts of Europe where there is no market for cow tongues they will be ABP. Animal products become ABP as soon as it is decided that they will not be used for human consumption.

2. Why do Animal By-Products need to be regulated by the EU?

The use of certain animal by-products (ABPs) in animal feed can spread BSE and other animal diseases or spread chemical contaminants such as dioxins. ABPs can also pose a threat to human health if not properly disposed of. The EU has, of course, already taken steps to regulate high risk animal by-products – or specific risk material – and exclude it from the food chain. However a comprehensive approach to regulating ABPs is seen by the

European Commission as an essential for ensuring a high level of health protection in the EU. Food, animal feed and ABPs can circulate freely in the EU's internal market, so effective regulation can only take place at EU level.

3. How soon will the new rules be applied?

The disposal infrastructure in most Member States is suitably developed and they will easily phase in the new requirements by 1 May 2003. But the Commission recognises that some Member States will not be able to meet that deadline. Either they have a shortage of the necessary facilities or simply their ABP disposal industry is specifically designed to meet local circumstances. Therefore, where appropriate and justifiable, Article 32 of the Regulation allows a possible one-off temporary relaxation of the strict measures. This can be used to allow less developed industry sectors or those with specific problems in adapting time to acquire the necessary facilities. Such a relaxation will be subject to strict conditions to be established by the Commission.

4. Which sectors are likely to be given extra time to implement the new rules?

Member States are acquainted with the local conditions of the industry and have been asked to assess the likely effects of the Regulation on the industry and to submit appropriate requests for transitional measures. Interested Member States have submitted requests, covering swill feeding, feeding of used cooking oils, material from wastewater, compost and biogas plants, rendering plants and their separation from slaughterhouses, separation of category 2 and 3 oleo-chemical plants, manure processing plants, low capacity incinerators and disposal of blood.

The Commission is already analysing the requests, where necessary in consultation with technical and scientific experts, in order to establish the minimum interim health requirements for discussion in the working groups of the Standing Committee on the Food Chain and Animal Health, which is a Committee made of experts from Member States. The first of such working groups is foreseen on 19 December 2002, and the adoption would be expected before the application of the Regulation on 1 May 2003. The Commission cannot at present predict the outcome of the Committee, but is committed to make every effort, where appropriate and justified, providing for suitable non-renewable transitional measures.

At the same time, the Commission is preparing permanent implementing measures for the various Articles as well as reviewing the Annexes. A single piece of Regulation will be

proposed covering the transitional and permanent implementing measures, repealing all current separate legislation governing ABP not intended for human consumption.

5. What is the scope of the provisions on material collected from wastewater (sludge)?

The animal material covered by the provisions in Articles 4(1)(d) and 5(1)(b) is only animal material collected from primary treatment, namely animal material retained in the filters and skimming of solids such as sludge from the primary physico-chemical treatment process onsite. It is believed that this material can easily be collected and disposed of in accordance with the Regulation, but if necessary, the Commission is ready to clarify further by defining the scope of the provisions in Annex I.

The Regulation requires that all materials collected when treating wastewater from rendering plants processing category 1 material – such as cadavers of potentially BSE infected animals and slaughterhouses in which BSE specified risk material is removed – must be disposed of by incineration, co-incineration or landfill following sterilisation. The only exception to this rule is where such wastewater contains no specified risk material or part of such material. This is in line with current opinions of the Scientific Steering Committee.

Bearing in mind that the existing EU legislation including the TSE Regulation does not deal with the issue of disposal of material collected from wastewater, the new rules on wastewater from facilities handling category 1 materials are necessary as this type of material may be contaminated with the BSE agent. Its disposal in urban wastewater treatment plants should be prevented to avoid possible dissemination of the BSE agent into the environment. Since sewage sludge from urban waste water treatment plants is commonly used on agricultural land as organic fertiliser without having undergone any effective sterilisation, there may be a potential risk of spreading BSE this way. Lord Phillips (2000) highlighted the potential risk of spreading BSE in the UK through this practice in the BSE Inquiry report.

6. What is the meaning of "complete separation of building" between a processing plant and a slaughterhouse required by Annex V, Chapter I(1)(a) of the Regulation?

The background to this requirement is the need to avoid cross-contamination or substitution (voluntary or otherwise) between "material intended for human consumption", "material intended for animal consumption" and "material destined for disposal or recovery".

When the Regulation was being negotiated in the European Parliament and the Council the legislators ruled out the possibility of using "part of the building", and have instead emphasised the need for "completely separate building". The Regulation is not descriptive as to the premises construction arrangements needed to ensure the objectives of the requirement are achieved. Nonetheless the Commission believes that "completely separate" implies some level of physical and geographical separation between a processing plant and a slaughterhouse.

7. How will the requirement of "complete separation of building" be enforced?

Processing plants must be approved by the competent authority (see Articles 13 and 17 of the Regulation). In order to be approved processing plants must meet the required level of separation. The need for such level of separation is in line with the key principle of the Regulation, aiming to achieve the dedication of facilities throughout the disposal chain from collection, transport, storage, handling, processing to the use or disposal of the 3 categories of ABP. In line with this principle, any mixture of low risk material (e.g. category 3) with high risk material (e.g. category 1) is considered as high risk (i.e. category 1). Also when mammalian material is mixed with non-mammalian, then the mixture is considered to be mammalian. The need for dedication, coupled with the ban on intra-species recycling, severely restricts the "time-sharing" of the facilities for processing different animal species such as poultry or fish and porcine material intended for processed animal protein.

8. Will every slaughterhouse need to have an approved ABP processing plant?

No. A processing plant approved by the competent authorities in a Member State would be allowed to process ABP from several slaughterhouses.

9. Can Animal By-Products be used in organic fertiliser and soil improvers?

Article 22(1)(c) prohibits the application to pastureland of organic fertiliser or soil improvers, other than manure. Pastureland is defined in Annex I as "land covered by grass or other herbage and grazed by farmed animals". This prohibition is in line with current EU ban on the feeding of meat and bone meal, and is intended to avoid the possible risk that may be related to direct grazing or use of grass as silage or hay by farm animals

The use on other types of lands of, for instance, biogas or compost treated category 2 and 3 ABP is allowed on condition that –

- In the case of category 2 material (other than manure, digestive tract content separated from the digestive tract, milk and colostrum if the competent authority does not consider them to present a risk of spreading any serious transmissible disease), it has been pre-treated to method 1 (133 ºC/20'/3 bars) (Article 5(2)(c)(ii)); and
- In the case of category 3 material, it has been treated to the standards set in Chapter II (13), Annex VI (70 ºC/60') with or without pre-treatment.

Detailed implementing rules will be fixed by an EU administrative decision (comitology) following scientific advice. It is still possible that the spreading of certain organic fertilisers (e.g. digestion residues, compost or pressure-treated category 3 material) on pastureland may be allowed, provided that, for instance, animals are not allowed to graze for a certain period of time after spreading.

10. Will the Regulation allow the use of horns, bladder, intestines, skull and mesentery as soil improvers?

The Regulation (Articles 5(2)(c)(i) and 6(2)(d)) allows the use of ABP (including horns, bladders, etc) for the production of 'technical products' intended for purposes other than human or animal consumption, including organic fertilisers and soil improvers. The prohibition in Article 22(1)(c)) referred to in the question above, however, applies. The use of organic fertilisers or soil improvers on lands other than pasturelands is possible under EU implementing measures to be laid down. Pending the adoption of such measures, Member States may adopt or maintain national rules (Article 35(3)).

The TSE Regulation (EC) No 999/2001 provides that specified BSE risk material such as skull of bovine, ovine or caprine animals above 12 months of age, and intestines and mesentery of bovine animals of all ages must be disposed of by an appropriate method and cannot be used as fertiliser. The ABP Regulation maintains this requirement and further stipulates that specified risk material can not be used for the production of technical products.

11. Why does processed mammalian protein need pressure-cooking even when it is intended for petfood?

ABP are classified into 3 categories. Category 1 - can be incinerated or processed to any method 1-5 and then incinerated or co-incinerated, or landfilled (except TSE positive or suspect animals) following method 1 (Article 4). Category 2 - can be incinerated or processed to any method 1-5 and then incinerated or co-incinerated, or landfilled or treated in bio-gas/composting plant or used as organic fertilisers or soil improvers following pressure-

processing method 1 (Article 5). Category 3 - can be incinerated or processed to any method 1-5 (or method 7 in the case of non-mammalian) and then incinerated, co-incinerated or landfilled or used as organic fertilisers or soil improvers, or treated in biogas or composting plants without pre-processing (Article 6). Category 3 can also be recycled into processed animal protein and other processed products for animal feeds (Annexes VII and VIII).

The pressure processing of category 3-mammalian material concerns processed animal protein and other processed products that could be used as feed material. For reasons of control, it has been agreed not to make difference between category 3 plants producing processed animal protein for use in petfood and those producing processed animal protein for feedingstuffs for other animals. Generally products such as digestion residues and compost can not possibly be used as feed material; hence, there is no requirement for pre-treatment.

The use of atmospheric pressure processing (methods 2-5 or 7) for mammalian processed animal protein intended for petfood could be acceptable if it was possible to exclude any risk of illegal use or contamination of feedingstuffs intended for other animals, in particular ruminants. But at present the possible risks and control problems of having on the market mammalian processed animal protein and processed products that have been treated to different standards can not be ignored. The Commission has no plans to relax the rules in this area.

12. Why does Article 22 of the Regulation ban the intra-species recycling of ABP?

A ban on feeding mammalian materials (including ruminant material) back to ruminant animals has been in place in the EU since 1994. That ban was introduced in the light of the clarification brought by the independent scientific committees of leading experts that the BSE epidemic was spread and sustained *via* the recycling of BSE infected cattle material. The EU's Scientific Steering Committee and Member States' national advisory scientific bodies such as the UK's Spongiform Encephalopathy Advisory Committee have advised that the ruminant intra-species-recycling ban be extended to non-ruminant animals. So the new Regulation seeks to address the possible risk inherent in recycling potential infectivity due to the absence of barrier within species, which may be induced by the practice of intra-species recycling.

13. What are the implications of the intra-species recycling ban for the EU's trading partners?

In general terms the Regulation requires that the conditions for the importation of ABP from non-EU countries shall be no more or less favourable than those applicable to the production and marketing of those products in the EU. The European Commission does not foresee, at present, any implications for third countries' export to the EU arising from the ban on cannibalism. Even so, given the recent discovery of BSE cases in countries outside the EU, the Commission is encouraging all its trading partners – and especially those with the greatest potential risk of BSE – to adopt similar safeguard measures to reduce the possible risks.

14. Does the Regulation allow the use of hides and skins from fallen stock for leather?

Hides and skins from fallen stock would be classified as category 3 material , unless they come from TSE positive/suspect animals (article 4(1)(a)) or animals showing clinical signs of any disease communicable through that product to human or animals (see Article 6(1)(k)). As such they can be used for technical purposes such as leather production, but not, for instance, for gelatine or collagen production (see Commission Decision 2001/25/EC).

This is in line with current EU rules on TSE, which stipulate that all parts of the body (including hides) from TSE positive animals or animals having reacted positively to a rapid TSE test must be destroyed (see Regulation (EC) No 999/2001, Article 13 and Annex III). This implies that where a TSE test is being applied to fallen stock, hides from those animals or batches of hides must be kept separate (under official supervision) until the results of the tests are known. This is to ensure identification and traceability for the purpose of recall and appropriate disposal should tests show that to be necessary.

Nonetheless, the wording of Annex VIII, Chapter VI (5)(a) on imports implies that the import of fresh or chilled hides and skins from fallen stock is prohibited. The Chapter only allows import of the hides and skins from animals referred to at article 6(1)(b) or (c), i.e. animals that have at least passed ante-mortem inspection.

15. What are the implications of the Regulation for imports of milk/products (casein)?

Current rules (Annex I of Directive 92/118/EEC) allow import of casein not intended for human consumption only if it (i) comes from third countries listed in Annex (B-C) to Decision 95/340/EC, (ii) has undergone a pasteurisation treatment sufficient to produce a negative phosphatase test, and (iii) is accompanied by a health certificate (model in Decision 95/341/EC). Additional conditions apply to third countries with foot and mouth disease

outbreak or where vaccination for foot and mouth disease has been carried out in last 12 months (Decision 95/342/EC). The list of establishments is not yet harmonised (bilateral agreements apply). The ABP Regulation maintains these conditions (Annex VII, Chapter V – specific requirements, Annex XI – list of third countries, Annex X, Chapter 2A-C – model of health certificate), but also requires the listing of approved establishments (Article 29(4)).

16. What are the implications of the Regulation for imports of raw material for the petfood and pharmaceutical industry?

Current EU rules (Directive 92/118/EEC, Annex I, Chapter 10) allow import from third countries listed in the Annex to Decision 79/542/EEC, if accompanied by a health certificate, whose model is not yet harmonised (bilateral agreements apply). These requirements are maintained by the ABP Regulation (Annex VIII, Chapter XI). A model health certificate is also laid down in Annex X, Chapter 8.

17. What are the implications of the Regulation for imports of Tallow?

Some commentators have claimed there may be import problems relating to the uncertainties about the list of specified risk materials, until the determination of BSE status of third countries is completed. The European Commission does not accept this analysis. Current transitional measures on specified risk material apply to import of products such as tallow covered by Regulation (EC) No 999/2001. These measures continue to apply until the determination of the BSE status. Before adopting the final BSE status of countries exporting to the EU, it is intended to review the permanent list of specified risk material, as laid down in Annex V to Regulation (EC) No 999/2001. The Commission cannot at this stage predict the definitive list of specified risk material that will apply in the various categories until after determination of BSE status. However, it will most likely be similar to that laid down in the transitional measures and will be based on the BSE risk identified in the country.

18. What are the implications of the Regulation for imports of Hooves and horns?

Commission Decision 94/446/EC, as amended by Decision 97/197/EC lays down the requirements for the importation of bones and bone products, horns and horn products and hooves and hoof products, excluding meals thereof, for further processing not intended for human or animal consumption. These requirements are recasted in the ABP Regulation, which further restricts the use on pastureland of organic fertiliser and soil improvers (see answers to questions 9 and 10 above).

Article 6(2)(d) allows the use of safe ABP (including hooves, horns, etc) for the production of 'technical products' intended for purposes other than human or animal consumption, including organic fertilisers and soil improvers. In the light of the restriction in Article 22(1)(c) on the application to pastureland of organic fertilisers and soil improvers, the importation of hooves, horns, etc is allowed under the following conditions –

- for hooves, horns, etc intended for game trophies, Chapter VII of Annex VIII applies.
- for hooves/hoof products, horns/horn products, etc intended for use other than feed material, or organic fertilisers and soil improvers , Chapter X of Annex VIII applies.
- for hooves/hoof products, horns/horn products, etc intended for use as organic fertilisers or soil improvers on lands other than pasturelands, EU implementing measures are still to be laid down and, pending the adoption of such measures, Member States may adopt or maintain national rules (bilateral agreement applies) (Article 35(3)).

19 Does the Regulation ban the use of catering waste – including used cooking oils –in animal feeds?

The Regulation (Article 1(2)(e)) does not apply to catering waste, unless it (i) comes from means of transport operating internationally, (ii) is destined for animal nutrition or (iii) is destined for use in a biogas plant or for composting. Catering waste from international means of transport is classified as category 1 material, and must continue to be disposed of in accordance with environmental legislation. The feeding of catering waste produced domestically (category 3) to farmed animals is prohibited; but this can be used in biogas or composting to produce gas or bio-fertiliser.

As indicated in the Commission White Paper on Food Safety, the full traceability of animal feed ingredients is one of the key principles to guarantee a high level of food safety. For example, it is now agreed that the lack of a mechanism for traceability allowed recent dioxin crisis to develop and expand throughout the whole food chain. This is also true for the recent foot and mouth disease and swine fever crisis. So EU Member States have agreed to prohibit the feeding of catering waste, including used cooking oils from restaurants and catering facilities, to animals as traceability of these products can not be guaranteed.

The ban on the feeding of catering waste (as swill) including used cooking oils to farmed animals applied in all Member States from 1 November 2002, except in three Member States (two Member States may continue the feeding of swill and one Member State may continue

the feeding of used cooking oil) because they had requested transitional measures before then and pending adoption of strict interim minimum conditions by the Commission.

The Regulation provides for a possible temporary relaxation of the ban on the use of category 3 catering waste in feed for a limited period of time for Member States where appropriate control systems are in place prior to the application of the Regulation, under strictly controlled conditions to be established by the Commission following the opinion of the Standing Committee on the Food Chain and Animal Health. Officials from the Commission have already carried out visits to the 3 Member States concerned to ascertain the adequacy of the existing systems and to collect the necessary data to enable the preparation of minimum interim measures.

20. What is the definition of "catering waste"?

The European Commission considers that catering waste is waste from premises on which food is produced for direct consumption. This includes restaurants, catering facilities and kitchens, including central and household kitchens. It may include sandwich bars or sandwich factories that are producing food for direct consumption but not retail outlets such as supermarkets or food factories that are producing products for retail sale. In the interim, this distinction is necessary to prevent the feeding of waste from cutting plants, butchers' shops etc as swill, while permitting waste from as many food serving premises as possible to continue to be fed as swill during possible transitional period.

21. Can catering waste still be used in composting and biogas treatment?

As a consequence of recent foot and mouth disease the European Parliament and Council requested that catering waste be included in the scope of the Regulation to avoid potential spread of animal diseases. The Commission accepted this request on condition that such inclusion would not hinder the development of new rules on environmental protection, avoiding any negative impact on current national policies in particular as regards biodegradable waste. Therefore, the Regulation does not lay down rules for the treatment of catering waste that is subject to composting or biogas treatment. Instead it establishes (in Article 6(2)(g)) that pending the adoption of EU rules, composting and biogas production from catering waste may continue in accordance with existing national rules. It also includes a legal basis to request the advice of an independent scientific body to evaluate the effectiveness of conventional biological treatments to inactivate pathogens of concern for animal and public health. However, high risk catering waste from international means of

transport remains subject to the strict rules of the Regulation to ensure its traceability and proper disposal.

The processing standards in Chapter II(C), Annex VI of the Regulation relate to the approval requirements pertaining to biogas and composting plants set out in Article 15. These processing standards do not affect the provision in Article 6(2)(g), which specifically exempts catering waste (other than from means of transport operating internationally), when it is the only ABP used as raw material for a biogas or composting plant (see the answer to question 20, above). The Commission will consider modifying the wording in paragraph 14 of Chapter II(c) of Annex VI in order to avoid possible confusion.

As announced in its Communication "Towards a Thematic Strategy for Soil Protection" (COM(2002) 179), the Commission has given a commitment that by the end of 2004 a Directive on biodegradable waste, including catering waste, will be prepared with the aim of establishing rules on safe use, recovery, recycling and disposal of this waste and of controlling potential contamination.

22. Does the Regulation foresee alternative disposal processes, equipment and systems for ABP?

The Regulation (Articles 4(2)(e), 5(2)(g) and 6(2)(i)) provides for the approval of alternative disposal processes, equipment and systems in the light of scientific (and technological) development, in accordance with the procedures of the Standing Committee on the Food Chain and Animal Health following consultation of the appropriate Scientific Committee. These alternatives may either supplement or replace those currently approved.

The Commission welcomes scientifically proven initiatives to develop safer alternatives, and is receiving an increasing number of requests for opinions on the safety with regard to TSE risk of alternative disposal processes, equipment and systems. To assist an efficient handling of the requests, the Scientific Steering Committee has prepared a Framework for the assessment of the risk from different options for the safe disposal or use of ABP. People or organisations working on such initiatives are advised to submit a dossier describing the process, and giving evidence of any risk assessments carried out proving its safety. Submissions should be structured in accordance with the 5 key components of the Framework, covering:

- the identification and characterisation of the risk materials;

- the TSE risk reduction by the particular process;
- the degree of risk containment;
- the identification of interdependent processes; and
- the intended end-use of the product.

The Commission is already analysing in details a number of processes, equipment or systems that have been submitted to ascertain their safety vis-à-vis human health (workers, general public), animal health and the environment. The processes, equipment or systems range from non-conventional systems of rendering, incineration, biogas, composting to a combination of processes (alkali hydrolysis, gasification, biodiesel production, etc), and must at least meet the equivalent final standards set for the products before a decision can be taken to approve them. Where necessary, the Scientific Steering Committee and industry will be consulted for opinion and further information, respectively. The Regulation does not permit the use of a given alternative process, equipment or system until it has been thoroughly assessed and approved.

23. What are the rules on burial in remote areas, in cases of dead pet animals or diseases outbreaks?

The ABP Regulation (Article 24), like the TSE Regulation 999/2001 (Annex XI (8)), provides for derogation permitting the burial or burning of ABP in remote areas and in the case of dead pet animals, except where they may have died of a TSE. This article also allows the burial on farm of origin of ABP – other than materials from confirmed or suspected TSE cases – where a widespread outbreak of an OIE List A disease leads to lack of disposal capacity, or where the competent authority rules out transport for fear of propagating diseases. The derogation is designed for exceptional circumstances; it must be considered as the minimum requirement and preclude the risk of transmission of animal diseases such as TSE, taking into account environmental aspects. It must also be approved and verified by the competent authority.

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