THE CONTRIBUTION OF THE EUROPEAN FOOD SAFETY AUTHORITY (EFSA) TO NORMATIVE WORK FOR SAFE RECYCLING OF ORGANIC WASTES UNDER PUBLIC HEALTH ASPECTS

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Objective

To guarantee a high standard of health and safety throughout the food chain, based on health rules concerning animal by-products not intended for human consumption.

Background and Legislation

Regulation (EC) No 178/2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority (EFSA) and laying down procedures in matters of food safety, constitutes the cornerstone of the new European legislation on food safety. Adopting the "from farm to table" approach, it aims, by drawing on the latest scientific opinions, to guarantee a high standard of health and safety throughout the food chain. Animal by-products are defined as the entire bodies or parts of bodies of animals or products of animal origin not intended for human consumption, including ova, embryos and sperm. They represent more than 10 million tons of meat per year. These materials are then disposed of or processed and re-used in human food (meat-and-bone meal, fats, gelatin), the cosmetics or pharmaceuticals sectors and for other technical purposes.

Following the food crises of the 1990s, such as the bovine spongiform encephalopathy (**BSE**) epidemic, the role of these by-products in propagating transmissible animal diseases was brought to light. Composed of eight independent scientific experts, the former **Scientific Steering Committee** (SSC) then concluded that products derived from animals declared unfit for human consumption must not enter the food chain. Moreover, the administration to any animal of proteins obtained by processing carcasses of the same species - or cannibalism - may constitute an additional risk of disease propagation.

Consequently the Regulation (EC) No 1774/2002 was adopted by the European Commission (EC) and the European Council **laying down health rules concerning animal by-products (ABP) not intended for human consumption.** These rules apply on the

collection, transport, storage, handling, processing and use or disposal of ABP; the placing on the market and, in certain specific cases, the export and transit of ABP and products derived therefrom.

ABP not intended for human consumption have to be disposed of or may be used by means laid down in detail by this regulation. This regulation sets out the measures to be implemented for the processing of animal by-products. Laying down minimum rules at European level, it gives the Member States the option of taking even more restrictive measures or measures covering products excluded from its scope.

Animal by-products (ABP) not intended for human consumption have to be disposed of or may be used by means laid down in detail in the ABP Regulation (EC) No 1774/2002. With this regulation ABP are divided into three different categories:

Category 1 includes ABP of high risk, e.g. animals killed in the context of TSE eradication measures, animals suspected of being infected by a TSE or specified risk material.

Category 2 includes ABP with a risk in between categories 1 and 3, e.g. animals killed to eradicate an epizootic disease other than TSE or products of animal origin containing residues of veterinary drugs.

Category 3 includes ABP presenting low risk to animals and humans e.g. parts of slaughtered animals fit for human consumption but not intended for human consumption for commercial reasons or former foodstuffs, which are no longer intended for human consumption due to packaging defects.

The Commission has received, from Member States or from the industry, a number of applications being alternative methods for the safe disposal of ABP. Seven of these were forwarded to the SSC requesting scientific evaluation. The SSC adopted two opinions (10-11 April 2003) evaluating in total seven alternative methods.

In summary, the SSC concluded that:

One method ("Bio-Reducer") was not an alternative method as such for safe disposal of ABP but that it concerned a procedure to store ABP in a contained environment;

One method was considered as safe for the disposal of ABP of all three categories under certain circumstances ("alkaline hydrolysis");

The other five methods were regarded as safe only for the disposal of ABP of categories 2 and 3. For those five methods, the SSC concluded that they would probably also have the capacity to safely dispose of ABP of Category 1 but that the applications did not provide

enough information or data supporting this claim. One of those five methods is the High Pressure Hydrolysis Biogas (HPHB) process.
According to these opinions, the methods could be re-assessed after submission of additional information and data from the respective applicants.

The task of EFSA

In this respect, The Scientific Panel on Biological Hazards of EFSA was asked by the EC to reassess certain processes already approved by the SSC for ABP of cat 2 and 3, in view of its ability to safely dispose of Category 1 animal by-products.

Following receipt of an application from the Federal Republic of Germany on a modification of the HPHB process, the Scientific Panel on Biological Hazards of EFSA was requested by the EC to assess this modified method in view of its ability to safely dispose of Category 1 animal by-products. The Scientific Panel on Biological Hazards concluded that the modification of combining the conventional method, fixed by regulation (133°C/20min/3bar) with the HPHB process in a closed system presents no additional risk when disposing of animal by-products of cat 1 (The EFSA Journal, 2003, 11, 1-4).

On April 22nd, 2004, EFSA published an Opinion of the Panel of Biological Hazard on a method of combustion of tallow in a thermal boiler process for safe disposal of category 1 ABP not intended for human consumption. In this assessment the Scientific Panel on Biological Hazards compared the experimental data on submitted alternative tallow combustion method with a reference method and concluded that the method of this applicant was at least equally efficient as the reference method (The EFSA Journal, 2004, 58, 1-4).

Another opinion by this EFSA expert panel was adopted on June 2nd, 2004, on a processing method for biodiesel in terms of TSE safety submitted by a producer. For each of the different steps in the process (rendering, trans-esterification, hydrolyses) a log reduction of TSE infectivity of at least 10^3 is assumed. Experiments have been done on laboratory scale and as the kinetics of prion reduction are not understood at present it is therefore questionable whether these reductions found in all the steps of the process can be added up. However, since the material at the start of the process has already undergone a treatment of 133°C/20min/3bar rendering it may be concluded that the resulting biodiesel, as well as the by-products, do not carry a TSE risk. A bioassay test, which would normally be the final proof of safety, can not be carried out due to the toxicity of the biodiesel (The EFSA Journal, 2004, 23, 1-3).

Addionaly, requests for an Opinion on the „safety vis-à-vis biological risks of the heat treatment process for manure" and „biogas and composting treatment standards" are currently treated by an EFSA Working Group. Requests for assessments on alternative methods of safe disposal of ABP submitted by companies and companies' associations were forwarded by the EC to EFSA (see www.efsa.eu.int; „science", „register of requested opinions").

Applications presented vary in quality and EFSA has to attribute large resources to the examination of dossiers submitted. Therefore, improvements in the quality of dossiers submitted to the EC and forwarded to EFSA were regarded as necessary to facilitate assessment. To this purpose, operators could be assisted by private experts recognised as consultants in the relevant field. Furthermore, assistance could be provided by Member States' authorities to the preparation of dossiers according to standardised rules.

Options for an improvement of the approval/assessment process could be that the EC Directorate General for health and consumer protection (DG) SANCO involvement would be focussed on being informed of ongoing assessments in the preparatory stage, agreeing deadlines on applications when transferring them to EFSA and receiving the scientific assessment by EFSA prior to recognising favourably assessed methods by comitology. EFSA would be involving expert groups rather than the relevant Panel in their internal assessment procedure. Whether applicants would have to pay fees to EFSA was to be decided at a later stage as the necessary legal framework is not yet in place. DG SANCO and EFSA concluded to lay down rules for a facilitated scrutiny of applications in a joint SANCO/EFSA guideline document along the lines set out before.

References

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