



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

Adopted on 2 June 2004

SUMMARY OF OPINION

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. This regulation divides ABP into 3 categories of risk, where category 1 includes ABP of high risk including Transmissible Spongiform Encephalopathy's and category 3 presents low risk ABP to animals and humans. The former Scientific Steering Committee of the European Commission evaluated alternative methods for the safe disposal of ABP, including the Biodiesel Process which was regarded as safe only for the disposal of ABP of categories 2 and 3.

Following receipt of additional data and further information from SARIA Bio Industries on the Biodiesel Process the Scientific Panel on Biological Hazards of the European Food Safety Authority was asked by the European Commission to reassess the process in view of its ability to safely dispose of Category 1 ABP.

The Scientific Panel on Biological Hazards concludes that the Biodiesel process as described is considered as safe for treatment and use of ABP of category 1.

Key words: Animal By-products, BSE/TSE, prion, biodiesel, rendering

BACKGROUND

Animal by-products (ABP) not intended for human consumption¹ 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 Transmissible Spongiform Encephalopathy (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 European Commission (EC) has received, from Member States (MS) or from industry, a number of applications being alternative methods for the safe disposal of ABP. Seven of these were forwarded to the Scientific Steering Committee (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:

1. 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;
2. One method was considered as safe for the disposal of ABP of all three categories under certain circumstances (“alkaline hydrolysis”);
3. 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 Biodiesel process.

According to these opinions, the methods could be re-assessed after submission of additional information and data from the respective applicants.

TERMS OF REFERENCE

The Commission received further information and data from Saria Bio Industries on the Biodiesel process and the request for approval of this method also for Category 1 ABP.

In the light of the additional data, the EC requested the European Food Safety Authority (EFSA):

1. To re-assess the ability of the “Biodiesel Process” to safely dispose of Category 1 animal by-products.

¹ OJ No L 273 of 10.10.2002, p. 1



2. If the process is considered to present a risk, EFSA is asked to advice on the risks of the use of that process and on possibilities to addressing them.

ASSESSMENT

During a meeting of the Working Group (WG) the submitted documents were discussed and the process was assessed.

For each of the different steps in the process (rendering, transesterification, hydrolyses) a log reduction of TSE infectivity of at least 103 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 degrees Celsius/20 minutes/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 conclusion on safety is only valid if the technical process reflects the conditions of the experimental report.

CONCLUSION

The Scientific Panel on Biological Hazards concludes that the “Biodiesel” process as described is considered as safe for treatment and use of ABP of category 1. This process does not present additional risk in the treatment of ABP of category 1.

DOCUMENTATION PROVIDED TO EFSA

Letter D(2004) KSV/fg/420167 from the EC, requesting a consultation of the re-assessment of the Biodiesel process as a method for safe disposal of ABP of category 1 with annexes.

SCIENTIFIC PANEL MEMBERS

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