

International Report

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Saria Bio-Industries

German Renderer Proves Animal Fats are Safe for Biodiesel

Since October 1, 2000, specified risk materials (SRMs) have been excluded from the feed chain in the European Union (EU). Fats and proteins derived from SRMs must be destroyed. Due to the fact that not every EU region or plant could guarantee a safe SRM separation, non-SRMs (so called "low risk material") and SRMs are often processed together, leading to more fats and proteins being destroyed.

Graz, Austria.

Since November 1, 2002, European Commission Regulation 1774/2002, referred to as the animal by-products regulation (ABPR), has been in force. It developed three categories of raw material based on its potential risk and sets standards as to how to treat and use these categories. Category 1 fats, which are mainly SRMs, must be destroyed while Category 2 and 3 fats can be used in

Category 2 and Category 3 low-risk fats, but not for Category 1 fats (SRMs). Nevertheless, the commission published a proposal for a regulation (SANCO 2153/2003) that allows the use of Category 1 fat under certain conditions (i.e., exclusion of fats from transmissible spongiform encephalopathy (TSE)-positive or TSE-suspect cases, including BSE, scrapie, chronic wasting disease, etc.).

Saria immediately began new tests in order to prove that the biodiesel process is safe even for fats of TSE-positive cases. These results were sent to the commission in December 2003.

The scientific assessment was made very quickly and published by the newly formed European Food Safety Authority (EFSA) on June 2, 2004 (www.efsa.eu.int/science/biohaz/biohaz_opinions/471_en.html). The EFSA concluded that the production of biodiesel, including the by-products potassium sulphate and glycerine, is safe for the treatment of Category 1 fats. A new proposal for the regulation on alternative uses is expected at the end of the year.

Saria's Role

All testing was carried out at the Fraunhofer Institute of Molecular Biology and Applied Ecology (IME) in Schmallenberg, Germany, by Dr. Bjorn Seidel. The biodiesel process was downscaled to laboratory scale. The aim of the second experiment in 2003 was to examine the efficiency of every single step to reduce the prion content. The rendered fats cleaned to a maximum of 0.15 percent of impurities are esterified, transesterified twice, washed three times, and then undergo distillation. Only pressure sterilized fats are used

Table 1. Results of the Prion Reduction Tests

Process Step	Reduction of Infectivity ID ₅₀ Results/Literature
Pressure Sterilization (133°C, 3 bar, 20 minutes)	Approx. 10 ³ -10 ⁵
Separation and Purification of the Fat (0.15% Impurities)	Approx. 10 ³
Esterification	> 10 ⁴
First Transesterification	> 10 ⁴
Second Transesterification	> 10 ⁴
Washing Steps	Each Washing Step 10 ¹ -10 ³
Distillation	10 ¹ (SSC assessment)

After the first bovine spongiform encephalopathy (BSE) case was discovered in Germany, it took the German government only five days to enact a law on a feed ban, the quickest law enactment ever. The German feed ban as of December 5, 2000, includes proteins and fats and is therefore stricter than the EU feed ban, which only refers to proteins (European Communities Council Decision 2000/766).

At the time of the German feed ban, Saria Bio-Industries, one of Europe's largest rendering companies, began setting up a plant that produced biodiesel exclusively from animal fats – the first one in Europe. In October 2001, biodiesel production started. The plant was designed by Biodiesel International,

the oleochemical industry. Category 3 fats can also be used in feed.

The ABPR did not have any influence on the German feed ban. Because the treatment conditions for oleochemical plants, which includes esterification and transesterification, were stricter than those used in the catalytic biodiesel process, Saria asked the commission for an evaluation of the biodiesel process as an alternative use. The application was submitted after nearly one year of experience and before the ABPR entered into force. The Scientific Steering Committee (SSC) published its opinion April 10-11, 2003, on only six methods for alternative uses, with the biodiesel process being one of them. The SSC stated that the process can be assumed to be safe for

(133 degrees Celsius, 20 minutes, 3 bar, 50 millimeter).

The risk reduction of pressure sterilization, fat purification, and distillation is assumed to be 10^3 - 10^5 , 10^3 , and 10. A risk reduction of 10^3 , for example, means the thousandfold diminution of infectious agents or infectivity, i.e., 20 of former 20,000 infectious doses, are left.

The study was performed by using scrapie-infected hamster brain. The scrapie strain 263 K represents the most investigated pathogenic prion strain and is used as a standard strain in research projects dealing with TSEs. Additionally, scrapie-infected hamster brain shows an unusually high concentration of pathogenic prions with more than one billion infectious doses (ID) per gram (10^9 ID₅₀/g). Esterification and both transesterification steps were conducted with the infectious hamster brain. The washing steps were tested with recombinant prions and non-infective pig brain homogenate. For every test, the infectious dose was added only once; samples, however, were taken after each step. The prions were extracted and analyzed by high sensitive western blotting. A risk reduction of at least 10^4 ID was analyzed for each chemical step and of 10 - 10^3 ID for every washing step. An overview of the results is shown in Table 1.

On the whole, Saria is getting a risk reduction of more than 10^{22} ID (i.e., 10 billion trillions) for its biodiesel and 10^{10} ID in minimum for the by-products. Furthermore, it must be mentioned that this risk assessment does not consider the BSE incidence at present. But taking the results together, a risk reduction of 10^{22} means that biodiesel would even then be safe enough if all positive BSE-cases ever found were “theoretically” processed in one batch. ❖