

Genetically Modified Organisms (GMOs) in Soybean Lecithin

Summary:

- The genetically modified Roundup Ready® soybean is approved and introduced on all important soybean markets
- A separation of natural and GM soybeans is not practiced on a large scale
- Lecithin derived from non-modified vegetable sources is not available in sufficient qualities and quantities
- Since 1997, traces of GMOs are detectable in crude soybean lecithin purchased for purification and use in PhosChol.
- **The purification process used in the production of PhosChol eliminates GMO residues. Consequently, no GMO traces have ever been detectable in purified fractions used in PhosChol.**

Background Situation

Today, the genetic modification of plants and crops is a legalized procedure all over the world. In 1999, seven genetically modified species were cultivated worldwide: soybeans, maize, rapeseed, cotton, potatoes, papaya and marrow. The area on which these species are commercially grown covered 39.9 million ha in 1999, representing an increase of 44% compared to the previous year.

The far most important GM plant with regard to cultivation area and quantities is soya. Three different varieties of GM soya are known today, developed by AgrEvo, DuPont and Monsanto, but only Monsanto obtained a license for the use of their GM soybeans within the EU.

Monsanto's GM soya was developed to reach a better tolerance for their herbicide Roundup® (glyphosinat) and, hence, a better crop yield. For this purpose, a gene of a natural soil bacterium (agrobacterium CP 4) is introduced into the plant which then produces a functional enzyme highly resistant against glyphosinat (CP 4 EPSP-Synthase).

The new GM soybean called Roundup Ready® soybean was approved by the US authorities (USDA, FDA and EPA) in 1994. Subsequently, the European commission permitted the import of this soybean in April 1996.

The Roundup Ready® (RuR) soybean was first sowed in the US in 1996 with a proportion of app. 2% related to the total US soybean seed. Since then, this proportion has grown dramatically. In 1999, more than 50% of the soybeans grown in the US, the far most important country of soybean cultivation, were genetically modified. In the meantime, even

countries like Brazil, who has long been considered as the last source for non-GM soya, have approved the RuR soybeans.

Even though attempts are made in this direction by some smaller industries, GM soya is neither marked nor separated from non-modified soya on the large scale during transport, storage and processing. There are two reasons for this fact:

- 1) No obligation exists from a legal point of view. The authorities agree on the point that with regard to product quality, human and ecological safety GM soybeans are not distinguishable from natural soybeans.
- 2) With the several million tons of soybeans shipped, stored and processed every year, a reliable and controllable separation is not feasible.

Crude Soybean Lecithin

With regard to its worldwide market share, soya is the main source for crude lecithin. There are few other vegetable sources for crude lecithin, such as sunflowers, rapeseed and lupines, but lecithin derived from those sources is either of insufficient product quality or only available at very low quantities not meeting industrial demand.

Commercial lecithin is obtained as a by-product of crude soya oil after an extraction and degumming process in the oilmills. Its proportion in the soybeans is app. 0.4 – 0.5 %. In the mid-nineties the European food industry processed app. 50.000 tons of crude lecithin yearly, corresponding to an amount of 10 million tons of soybeans.

With regard to the use of commercial soybean lecithin the following figures result: In order to obtain 300 tons of Purified Phospholipids yearly, one needs to purchase 3000 tons of crude lecithin.

These figures underline why it is impossible for any company processing crude lecithin on the large scale to guarantee that the lecithin used originates from non-modified sources only.

Due to its high nutritional value, low cost and good emulsifying capacity, crude soybean lecithin is widely utilised in the food and fodder industries, e.g. for the production of margarine or bread, cakes and pastries and for instantiating dairy products. Until today, there is no scientific evidence that food or food ingredients originating from genetically modified sources may cause any harm to human health or to the environment. Clinical evaluations have shown that, for example, the allergenic potential of genetically modified Roundup Ready[®] soybeans does not differ at all from the allergenic potential of non-modified soybeans.

Concerning the quality of commercial lecithin purchased for purification and use by Nutrasal, some facts need to be considered: It is the protein part of the Roundup Ready[®] soybeans which contains GMOs, the composition of the lipidic part (soya oil and soya lecithin) remains unchanged. In other words, the lipidic part of the Roundup Ready[®] soybean is chemically not distinguishable from the lipidic part of a natural soybean.

When the soybeans are processed in the oilmills, i.e. cracked and extracted with hexane, it is, however, possible that residues of soy protein find their way into the soya oil and, subsequently, into the crude lecithin.

Purified Lecithin Fractions

Crude soybean lecithin is the starting material which undergoes several purification steps (ethanolic extraction and one or more column chromatographies) to obtain fractions enriched in polyunsaturated phosphatidylcholine (PPC). These fractions have been used for decades in oral, parenteral and topical formulations.

Since 1997, when the first GM soybeans reached the market, PhosChol has been analyzed at regular intervals by an independent and certified laboratory (GeneScan GmbH, D – 79108 Freiburg) to see whether any GMO residues could possibly be detected in the lecithin fractions. Between 1997 and today, more than 80 analyses of different lots of crude lecithin and purified fractions derived from it have been conducted.

The method of analysis employed by GeneScan is the so-called polymerase chain reaction (PCR). Contrary to protein-based tests (ELISA tests), the PCR method analyses for transgene DNA. For this purpose, nanograms of DNA are extracted from the product sample, cleaned, treated with the reagents necessary and amplified over 50 cycles. Subsequently, the DNA is detected by means of its molecular weight as a specific spot in gel electrophoresis. The 50 cycle amplification ensures that even smallest amounts of transgene material are detectable. Due to its high sensitivity and accuracy the PCR analysis has become the method of choice for analytical laboratories.

As one could expect, GMO residues were detected in more than 50% of the lots of crude lecithin analyzed thus far. **However, no GMO traces have ever been detected in the final purified fractions used in the production of PhosChol**

We attribute these results to our fractionation process, where GMO traces present in the crude soybean lecithin are eliminated. This is supported by the fact that the examination results of purified fractions remain negative, even though the proportion of GM soybeans and, consequently, of lecithin containing GMO residues continuously rises.

Of course, testing results obtained until today do not relieve us of the responsibility to continue the regular control of the absence of GMOs in all of our Phospholipid fractions. Therefore, future tests will be regular and ongoing.

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