

**FEDIOL - IMACE STATEMENT ON THE ALLERGEN
LABELLING OF FULLY REFINED SOYBEAN OIL AND
FULLY REFINED PEANUT OIL**

1. NOTIFICATION FOR TEMPORARY LABELLING EXEMPTION

- FEDIOL and IMACE have submitted to the EU Commission joint notifications for the exemption of fully refined soybean and fully refined peanut oil from mandatory labelling.
- According to the scientific literature and specifically designed studies, full refining of vegetable oil results in the almost complete removal of the proteins. Consequently, the indication of, for instance, the soybean origin of fully refined soybean oil would unnecessarily limit the range of foods that are today available for consumers allergic to soy.
- The soybean oil submission
 - Covers neutralised (alkali refined), bleached and deodorised soybean oil, as well as hydrogenated and interesterified fats.
 - Develops the arguments for non-allergenicity i.e. review of the scientific literature and particularly the results of the clinical study of the US Nebraska University of 2004.
 - Describes the ongoing studies regarding additional protein characterisation of soybean oils.
- The peanut oil submission
 - Covers neutralised (alkali refined), bleached and deodorised peanut oil, as well as hydrogenated fats and interesterified fats.
 - Develops the arguments for non-allergenicity i.e. review the scientific literature and particularly the results of the clinical study of the UK Southampton University Hospital of 1997.
 - Describes the ongoing studies to demonstrate protein concentration and characterisation of various refined peanut oils sold in European markets and link them to the oils used in the Southampton study.

2. BACKGROUND

- Foodstuffs need to be labelled according to the requirements of EU Directive 2000/13/EC, as amended by EU Directive 2003/89/EC. The 2003 amendment does not allow any labelling exemptions for the ingredients, specified in Annex IIIa of the Directive, known to trigger allergies or intolerances. The presence of these ingredients must always be indicated. The list contains "soybeans/peanuts and products thereof" thereby also covering "fully refined soybean oil and fully refined peanut oil".
- However, Directive 2003/89/EC establishes a strict procedure allowing for a temporary labelling exemption of Annex IIIa ingredients or substances for which it has been scientifically established that they are not likely, under specific circumstances, to trigger adverse reactions.

3. TIME TABLE

- Entry into force

25.11.2003	Directive 2003/89 is published in EC Official Journal L 308 of 25.11.03, p.15
25.11.2004	Implementation by Member States

25.11.2005 Prohibition to sell products that are not in compliance with the new rules.
Products that have been labelled or put on the market prior to 25.11.2005 may be sold until depletion of stock.

- Temporary labelling exemption

25.08.2004 Latest date for notifications to be received by the EU Commission

25.11.2004 Publication of list of derived products that are provisionally exempted from allergen labelling required by Directive 2003/89/EC. **Publication has not yet occurred as all EFSA opinions are not yet available.**

The expected timeframe for the official publication of the list is now March 2005.

25.11.2007 Substances for which no final studies have been delivered will be re-included in Annex IIIa i.e. mandatory allergen labelling.

- FEDIOL /IMACE submissions

FEDIOL and IMACE submitted the soybean oil notification on 07.07.2004 and the peanut oil notification on 23.08.2004.

- EFSA opinions

- The EFSA opinion¹ for N/RBD peanut oil was published on November 19. The general conclusion from the panel is as follows:

"The panel considers that it is possible that this product could cause allergic reactions in peanut allergic individuals".

- The EFSA opinion² for N/RBD soybean oil was published on December 21. The general conclusion from the panel is as follows:

"The Panel considers that it is not very likely that N/RBD soybean oils will cause a severe allergic reaction in the majority of soybean allergic individuals."

4. OTHER SOYBEAN AND PEANUT DERIVED INGREDIENTS OR SUBSTANCES

- Other derived soybean/peanut products i.e. lecithin, tocopherols, sterols, physically refined and fractionated oils/fats are not covered by the eventual exemption of fully refined soybean oil and fully refined peanut oil.
- Additionally, in a letter to the Federation of EU Food Additives and Food Enzyme Producers (ELC), the EU Commission confirmed that additives derived from ingredients, that receive a temporary labelling exemption, will be excluded from the allergen list. For example, mono- and diglycerides derived from fully refined soybean oil will be excluded from the allergen list if fully refined soybean oil receives eventual labelling exemption.

¹ http://www.efsa.eu.int/science/nda/nda_opinions/688/nda_opinion17_ej133_refpeaoil_en1.pdf

² http://www.efsa.eu.int/science/nda/nda_opinions/753/01.opiniononfullyrefinedsoybeanoil1.pdf