



Association des Amidonniers et Féculiers

PERMANENT EXEMPTION OBTAINED FOR “ALLERGEN LABELLING” OF WHEAT-BASED MALTODEXTRINS, GLUCOSE SYRUPS, DEXTROSE

We are pleased to announce that on the basis of EFSA opinions, on 28 November 2007 the Commission published with the enclosed [Directive 2007/68/EC](#), the list of food ingredients or substances permanently excluded from allergen labelling.

- **Wheat-based glucose syrups including dextrose, wheat-based maltodextrins and products thereof * are included in this list and therefore are permanently exempted from allergen labelling.**

The Commission's decision indicates that *“On the basis of the EFSA opinions and other available information, it can be concluded that certain ingredients or substances derived from those ingredients listed in Annex IIIa to Directive 2000/13/EC are not likely, under specific circumstances, to cause adverse reactions in susceptible individuals.”*

This reflects all the scientific work and commitments undertaken by the industry in this dossier consisting of :

- **Literature review;**
- **Code of Good Practice** on purification of wheat starch hydrolysates in which the industry commits to respect a maximum 20 ppm gluten/dry substance in the above-mentioned ingredients as a quality parameter;
- **Analytical studies** including characterization and quantification of (gluten) proteins in wheat starch hydrolysates;
- **Dietary exposure study;**
- **In vivo studies** on gluten intolerance and wheat allergy : “Evaluation of the safety of wheat starch hydrolysates (glucose syrup, dextrose and maltodextrins) in the context of coeliac disease” and “Risk of residual allergenicity and clinical reactivity of wheat glucose syrup and maltodextrins in wheat allergic patients.”;

- **Following the EFSA detailed evaluation, and based on [Directive 2007/68/EC](#), this means that the wheat origin of these ingredients does not have to be labelled on final consumer products.**

The Directive is applicable as from 26 November 2007.

* Such as polyols. For more information, please see <http://www.polyols-eu.org>



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Legislative background and history of Directive 2007/68/EC

Directive 2000/13/EC regarding the indication of the ingredients present in foodstuffs was amended by Directive 2003/89/EC which introduced the concept of “allergen labelling”.

According to this Directive, “cereals containing gluten and products thereof” must always be labelled with an indication of their botanical origin. However, products that are not likely to trigger adverse reactions, and for which the potential to trigger adverse reactions is under study, can be provisionally exempted from specific labelling on the basis of the evaluation of completed and on-going scientific studies notified to the Commission before 25 August 2004.

As announced in the AAC* communication in January 2004¹, the AAC notified to the Commission its on-going studies for wheat-based maltodextrins, glucose syrups and dextrose on 9 June 2004.

On 19 November 2004, the EFSA published its opinion on:

- Wheat-based maltodextrins,
- Wheat-based glucose syrups, including dextrose.

The EFSA opinions conclude that these wheat-based ingredients:

- “are unlikely to cause an adverse reaction in individuals with coeliac disease” and,
- “are not very likely to cause severe allergic reactions in the majority of cereal allergic individuals”².

On the basis of these EFSA opinions, on 22 March 2005 the Commission published with Directive 2005/26/EC, the list of food ingredients or substances provisionally excluded from allergen labelling. Wheat-based glucose syrups including dextrose, wheat-based maltodextrins and products thereof are included in this list and therefore were provisionally exempted from allergen labelling until 25 November 2007.

After having completed all its scientific studies, the AAC notified the final dossier to the Commission on 1 September 2006. On 6 June 2007, the EFSA issued its final opinion³ and confirmed that these wheat-based ingredients:

- are not very likely to trigger a severe allergic reaction in susceptible individuals.
- are unlikely to cause an adverse reaction in individuals with coeliac disease provided that the (provisional) value of gluten considered by Codex Alimentarius for foods rendered gluten-free is not exceeded.

On 28 November 2007, the Commission published the enclosed Directive 2007/68/EC, which lists food ingredients or substances permanently excluded from allergen labelling. Wheat-based maltodextrins, wheat-based glucose syrups, including dextrose and products thereof are included in this list. Additionally, glucose syrups based on barley are also included in this exemption.

Issued on 28 November 2007

Encl : Directive 2007/68/EC.

* For the sake of continuity and clarity, the notification files were finalised under the AAC heading. However, since 1 January 2006, AAC and the potato starch producers decided to create a new association that has the same objectives as the AAC but that also covers the interests of the potato starch industry. This new association is the AAF (Association des amidonniers et Féculiers - European Starch Industry Association). Therefore, all future contacts regarding this file have to be made with the AAF.

¹ http://www.aaf-eu.org/PDF/AAC_January_2004_-_Communication_on_allergen_labelling_of_wheat_starch_derivatives.pdf

² http://www.aaf-eu.org/pPDF/AAC_November_2004_-_Allergen_labelling_permanent_exemption.pdf

³ http://www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_1178623594476.htm