Association des Amidonniers et Féculiers

AAF STATEMENT ON REACH
REGISTRATION, EVALUATION, AUTHORISATION AND RESTRICTION OF CHEMICALS

AAF position on the status of starch and starch-derived products, proteins and protein-derived products and starch by-products in the context of REACH with regard to their use in applications other than food, feed and pharma[1].

1. Starch and starch-derived products

Native starch

Starch and pregelatinised starch are exempted from Registration under the REACH Regulation independently of the botanical origin.

Starch is listed on Annex IV of the Regulation that includes the products that are exempted from registration under the REACH Regulation on the basis that "sufficient information is known about these substances that they are considered to cause minimum risk because of their intrinsic properties" (Art. 2.7). This entry covers all botanical origins from which starch can be produced, including rice, barley, peas, etc. Reference to "corn, wheat and sorghum, and from roots and tubers such as potatoes and tapioca", is introduced in the text of the Regulation by the expression "such as" and it is therefore made as a way of example. Additionally, native and pre-gelatinised starch are regarded as one substance, irrespective of its botanical origin, when deciding that it is eligible to Annex IV.

Modified starches

Post-reacted or modified starches are exempted from registration when they meet the definition of "polymer" in Art. 3.5 of REACH.

Only the substances used for modification (= post-reactants) of the polymeric carbohydrate need to be registered according to Art. 6.3 of REACH when the polymer consists of 2 % weight by weight (w/w) or more of such substance in the form of chemically bound substance and the total quantity of that substance makes up 1 ton or more per year, per manufacture/import.

This is also confirmed by point 6.3.11 of the Frequently Asked Questions document published in November 2008 by the European Chemicals Agency[2].

Dextrin, maltodextrin, glucose and fructose

Dextrin, maltodextrin, glucose and fructose are exempted from Registration under the REACH Regulation independently of their botanical origin.

Dextrin, maltodextrin, glucose and fructose are listed in Annex IV of the Regulation, without specification of the botanical origin. Each entry covers all botanical origins from which they can be produced.

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[1] Applications in food, feed and pharmaceuticals are excluded from the scope of REACH by art. 2.5 of "Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemical substances (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC", OJ L 396, 30 December 2006, page 1.

[2] "Frequently Asked Questions on REACH by Industry", Version 2.3, Published on 6th November 2008.

Starch hydrolysed products

"Syrups, hydrolysed starch" and "Syrup, corn, dehydrated" should be regarded as exempted from Registration independently of the botanical origin.

The inclusion of "Syrups, hydrolysed starch" and "Syrup, corn, dehydrated" in Annex IV of the Regulation also covers all raw materials from which these products can be produced, despite the fact that the EINECS number that identifies them refers to "corn". "Syrups, hydrolysed starches" are the same whether they are made from corn starch, from wheat, potato, barley and rice starch or from another starch[3]. They only differ by the small fraction of impurities (starch lipids and starch proteins are degraded to nitrogen-containing compounds as peptides and lysophospholipids, minerals...) that do not have to be identified according to the section on well defined substances in the guidance document referenced above as these components are well below 1% and are not dangerous. Additionally, the EINECS classification of those products, limited to their corn derivation, is due to the fact that when the EINECS inventory was compiled, they were produced mainly by the maize starch industry. This no longer reflects current practices: due to the development of the new processes and to different economic reasons, the starch industry now uses several raw materials to produce those substances. Additionally, this interpretation is enhanced already by the German version of the EINECS list for syrups hydrolysed starch (EINECS 232-436-4) that refers to *cereal* starch (Getreidestärke), hence suggesting a much broader coverage than the English translation of the same EINECS list, which, as indicated above, simply refers to corn starch. The same applies for the dehydrated form of glucose syrup (CAS: 68131-37-3; EINECS: 268-616-4): the German translation of the relative EINECS list refers to *cereals* (Getreide), whereas the English one refers only to *corn*.

Despite the above, please be informed that the AAF is still in discussion with the European Commission and it is confident to obtain an explicit exemption for these products. In the meantime, as a precautionary measure, the AAF has recommended to its membership to pre-register "Starch hydrolysed products" deriving from botanical origins other than corn.

"Syrups, hydrolysed starch" that contain fructose

"Syrups, hydrolysed starch" that contain fructose should be regarded as exempted from Registration under Annex IV of REACH.

"Syrups, hydrolysed starch" and "fructose" are included in Annex IV of REACH. Fructose is currently produced from three sources:

- hydrolysis of sucrose, which yields glucose and fructose, followed by chromatographic separation of fructose,
- hydrolysis of inulin, which almost exclusive monomer is fructose,
- enzymatic conversion of the glucose present in "syrups, hydrolysed starch", which isomerises glucose into fructose, followed by separation of the fructose.

Therefore, the product obtained by blending "fructose" to "syrup, hydrolysed starch" (not isomerised) and the product obtained after isomerisation of "syrup, hydrolysed starch", have the same composition[4] and should be regarded as exempted from registration under REACH.

Despite the above, please be informed that the AAF is still in discussion with the European Commission and it is confident to obtain an explicit exemption for these products. In the meantime, as a precautionary measure, the AAF has recommended to its membership to pre-register "Syrups, hydrolysed starch" that contain fructose.

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[3] It is interesting to note that the food legislation does not distinguish between hydrolysed starches of different botanical origin. This appears in the definition of glucose syrups and glucose syrups, dehydrated in Directive (EC) 2001/111 on certain sugars and in the provisions on food labelling (Directive (EC) 2000/13, Art. 6.6 and annex).

[4] The definition, under EU law of "glucose syrups" does not differentiate for the presence of fructose, nor when the presence of fructose in glucose syrups derives by direct isomerisation or by adding fructose from other sources. Only as concerns labelling does EU law indicate that glucose syrups including more than 5% of fructose are to be labelled (among others) as "glucose-fructose syrups" (please refer to Art. 2.5 of Directive 2001/111/EC relating to certain sugars
intended for human consumption).

2. Proteins and protein-derived products

Polymeric proteins obtained from natural sources

Amino acid monomers of polymeric proteins and of chemically modified polymeric proteins obtained from natural sources are exempted from Registration[5].

Amino acid monomers of natural polymers obtained through a process covered by Art. 3.39 of REACH, and of the chemically modified natural polymers, are exempted from registration (ECHA Guidance for monomers and polymers). Recent guidance has been provided by the CASG on the Annexes of REACH that indicates that also in the case of polymers and of chemically modified polymers obtained from natural sources through processes that are not covered by Art. 3.39 of REACH, the monomers are exempted from registration since they are considered as 'non-isolated intermediates'. This guidance confirms that the obligation to register the monomers in polymers does not apply to the amino acid monomers of polymeric proteins and of chemically modified polymeric proteins, whether naturally occurring or obtained from natural sources.
Only the substances used for the modification of the polymeric protein that are chemically bound within the polymer need to be registered according to Art. 6.3 of REACH when the thresholds mentioned in this article are exceeded. Therefore, vegetable proteins and chemically modified vegetable proteins obtained from natural sources are exempted from the scope of REACH.

3. Starch by-products

Corn steep liquor, potato fibres, and concentrated potato juice

- Corn steep liquor (CSL) has been pre-registered.
- Potato fibres qualify for the exemption provisions for natural polymers as described under point 2 above for proteins made from natural sources.
- Concentrated potato juice complies with the exemption provided under REACH Annex V. .8. as a substance occuring in nature.

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[5] Points 7.6 and 7.7 of ECHA's Frequently Asked Questions, version 3.2, October 2010.