Position Paper



EXEMPTION OF VEGETABLE PROTEIN FLOURS, CONCENTRATES AND ISOLATES FROM REGISTRATION UNDER REACH

EUVEPRO¹ members have carried out an evaluation of the rationale for registering vegetable protein flours and concentrated vegetable protein products (comprising all vegetable protein concentrates and isolates) under EC Regulation 1807/2006 (REACH), and concluded that these products are exempted from registration according to the rationale provided below.

Composition and Production Process

Vegetable protein products referred to as "full fat flours" are obtained from beans, seeds or grains after de-hulling or de-husking and grinding. Whereas, for products described as "defatted flours" most of the vegetable oil is removed by solvent extraction. The remaining defatted flour is then comprised principally of vegetable protein, fibre and polysaccharides, together with some residual vegetable oil and other plant-derived minor components such as sucrose and other sugars which can be seen as impurities of this multicomponent polymeric substance.

Defatted vegetable protein flours can be further extracted to reduce the levels of fibre, polysaccharides and simple sugars to increase the protein content typically to >65% on a dry basis for products referred to as "concentrates" or to >90% for "isolated" proteins In this position paper, vegetable protein concentrates and isolates are referred to collectively as concentrated vegetable protein products.

In order to give them the functionality that is required for specific applications, all of these vegetable protein products may be subject to modification as a subsequent step after production.

Rationale for exemption from registration under REACH for full fat vegetable protein flours

Full fat vegetable protein flours being produced exclusively by mechanical means meet the exemption in annex V (8) for substances occurring in nature and are therefore exempted from registration. As stated above, after the full fat vegetable protein flours have been produced, they can be treated with chemicals or by other means to improve their functionality without losing the benefit of this exemption, as long as the treatment does not result in a chemical modification.

¹ European Vegetable Protein Federation (EUVEPRO); <u>www.euvepro.eu</u>



Rationale for exemption from registration under REACH for defatted vegetable protein flours and concentrated vegetable protein products

The proteins, polysaccharides and fibre present in defatted vegetable protein flours and concentrated protein products are natural polymers, which result from a polymerisation process that has taken place in nature. According to Article 2(9) of the REACH Regulation, any polymer meeting the definition of a polymer in Article 3(5) does not have to be registered.

Furthermore, under REACH as clarified in the ECHA FAQs on REACH by Industry², it is stated that "the monomer substance(s) or other substance(s) in the form of monomeric units and chemically bound substance(s) in natural polymers can, for practical reasons, be treated as non-isolated intermediates and do not have to be registered".

As appropriate for specialised uses, the vegetable proteins may be subject to subsequent treatments, which - when done with chemical reagents - may trigger a requirement to have these chemical reagents registered when they remain chemically bound to the polymeric substance beyond the 2% threshold set in article 6 (3) and they are used in more than 1 MT/year.

However, the vegetable protein products that have been modified by these subsequent treatments are not themselves subject to registration under REACH since they are still multi-component polymeric substances. The status of natural polymers that have been modified as a subsequent processing step is clarified in Question 6.3.11 of the ECHA FAQs on REACH by Industry³.

EUVEPRO

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² FAQs on REACH by Industry, Nov 2008, Version 2.3, Question 6.3.10

³ FAQs on REACH by Industry, Nov 2008, Version 2.3, Question 6.3.11