

Brussels, June 2009

STATUS OF LECITHINS UNDER EC REGULATION 1907/2006 ON THE
REGISTRATION, EVALUATION, AUTHORISATION AND RESTRICTION OF
CHEMICALS ('REACH')

Annex IV of EC Regulation 1907/2006 (REACH) provides a list of substances that are exempt from Titles II, IV and VI because sufficient information is available to consider them to pose minimum risk to human health and to the environment because of their intrinsic properties (Article 2(7)(a)). These substances are not subject to registration under REACH.

In compliance with Article 138(4) or REACH, there was a requirement for the European Commission to review Annex IV by 1 June 2008 in order to determine whether the substances contained within the list do indeed meet the above criteria for continued exemption from registration, and to evaluate the potential for adding any further substances to the list.

In January 2008, as part of the Commission review of Annex IV, the EU Lecithin Manufacturers' Association (ELMA) submitted information on the human health and environmental properties of lecithins to support its continued listing in Annex IV, and as part of the submission, provided a more accurate description of what constitutes the complex group of substances that are referred to as "lecithins" in Annex IV of REACH and in the European Inventory of Existing Chemical Substances (EINECS) under EINECS Number 232-307-2 and CAS Number 8002-43-5.

In the ELMA submission, "lecithins" are defined as being: "usually prepared from oil-bearing seeds used for food, especially soybeans; may also be prepared from animal sources; a complex mixture of acetone-insoluble phosphatides, which consists chiefly of phosphatidyl-choline, phosphatidyl-ethanolamine, and phosphatidyl-inositol, combined with various amounts of other substances such as triglycerides, fatty acids, and carbohydrate."

In the ELMA document, it was also explained that it is possible to apply physical processing methods to lecithins prepared as above in order to obtain products with the functionality that is needed for different technical applications. Examples of the physical processing methods that may be applied include: removal of oil to produce de-oiled lecithins, or selection of certain lecithin fractions.

As a result of the review of Annex IV by the European Commission, amending Regulation EC 987/2008 was published on 9 October 2008, which contains a revised version of Annex IV, which it now replaces in the original text.

The revised version of Annex IV, contained within Regulation EC 987/2008, retains the listing for lecithins, which reference should be interpreted to mean the substances obtained from food sources, and with the compositional description as elucidated by ELMA, and as reproduced above. "Lecithins", that have not been chemically modified, meeting these compositional criteria, are deemed not to be subject to registration under REACH.