



## Press Release

Kaiseraugst, 7<sup>th</sup> June 2012

### DSM and Kemin comment on EFSA's opinion regarding a claim for lutein and eye health, and will seek further clarification

DSM Nutritional Products (DSM) and Kemin will seek further clarity regarding the opinion issued by EFSA on June 5, 2012 pertaining to lutein and maintenance of normal vision. The EFSA opinion was issued following submission of a comprehensive dossier by both companies substantiating a health claim in relation to lutein's antioxidant benefits for eye health. This is a claim originally submitted in the draft article 13 list in 2006 as authorized by France in 2004. However the newly issued opinion is again expressed as "insufficient". This is the second consecutive time that EFSA has drawn such a conclusion, which is unprecedented in the current claims initiative. In addition, the opinion relates to "maintenance of normal vision" which is seemingly different from the requested claim.

The EFSA opinion was issued in response to a dossier submitted by DSM and Kemin, in September 2011, seeking authorization for the following health claim: "Lutein, a constituent of the retina and the lens, contributes to protecting these tissues from oxidative damage". DSM and Kemin firmly believe there is a consistent body of evidence demonstrating lutein's antioxidant effect in in vitro and animal eye models. Studies on humans further report that lutein can protect the retina from additional oxidative damage caused by blue light. As recognized by the EFSA, "the protection of body cells and molecules (...) from photo-oxidative damage may be a beneficial physiological effect, assuming that any significant oxidative modification of the molecule is potentially harmful" (EFSA Journal 2011;9(12):2474). Thus lutein, acting as an antioxidant in the eye, may exert a protective effect against oxidative stress, which is beneficial to eye health.

The EFSA opinion is inconsistent with an earlier opinion issued by the French Food Safety Agency (AFSSA) in January 2004, which, after reviewing a dossier submitted by DSM and Kemin, determined that the two following claims were scientifically justified: "Lutein helps protect the retina and the lens from the oxidation" and "Lutein is one (of the) constituent(s) of the retina and the lens". It is further inconsistent with determinations of ANVISA (Brazilian Health Surveillance Agency) and the Natural Health Products Division of Health Canada, which have authorized antioxidant claims for lutein.

The June 5, 2012, opinion only addresses the proposed health claims that can be made on labeling of finished products but does not alter the ingredient's regulatory status. FloraGLO® Lutein retains its status as a lawful ingredient that may continue to be used by our customers in their food supplements and food. With this second consecutive inconclusive opinion it is unclear at this stage how the Commission will decide to proceed.

Consequently DSM and Kemin will continue to pursue long-term acceptance of eye health claims in the EU for products containing FloraGLO Lutein and will be actively reviewing additional, new health claim applications to ensure FloraGLO Lutein customers may continue to label their products with information about its important benefits for eye health.

For additional information on the recent EFSA opinion, visit <http://www.efsa.europa.eu/>.

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### **DSM - Bright Science. Brighter Living.™**

Royal DSM is a global science-based company active in health, nutrition and materials. By connecting its unique competences in Life Sciences and Materials Sciences DSM is driving economic prosperity, environmental progress and social advances to create sustainable value for all stakeholders. DSM delivers innovative solutions that nourish, protect and improve performance in global markets such as food and dietary supplements, personal care, feed, pharmaceuticals, medical devices, automotive, paints, electrical and electronics, life protection, alternative energy and bio-based materials. DSM's 22,000 employees deliver annual net sales of around €9 billion. The company is listed on NYSE Euronext. More information can be found at [www.dsm.com](http://www.dsm.com).

### **Kemin - Inspired Molecular Solutions™**

Kemin ([www.kemin.com](http://www.kemin.com)) provides "inspired molecular solutions" specifically developed to provide nutrition and health benefits for humans and animals. Committed to feed and food safety, Kemin maintains top-of-the-line manufacturing facilities where approximately 500 specialty ingredients are made for the global feed and food industries as well as the health, nutrition and beauty markets. A privately held, family-owned and operated company, Kemin has nearly 1,500 employees and operates in more than 90 countries with manufacturing facilities in Belgium, Brazil, China, India, Italy, Singapore, South Africa and the United States.

#### **For more information:**

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#### Forward-looking statements

This press release may contain forward-looking statements with respect to DSM's future (financial) performance and position. Such statements are based on current expectations, estimates and projections of DSM and information currently available to the company. DSM cautions readers that such statements involve certain risks and uncertainties that are difficult to predict and therefore it should be understood that many factors can cause actual performance and position to differ materially from these statements. DSM has no obligation to update the statements contained in this press release, unless required by law. The English language version of the press release is leading.