

EFFCA Statement on Cultures in Regulation (EC) No 1907/2006 on REACH

REACH is the EU chemical legislation. It stands for Registration, Evaluation and Authorisation of Chemicals. On 1 June 2007 the Regulation entered into force and replaced all existing EU chemical legislation. The regulation introduces a general obligation to register each substance manufactured or imported in the EU in quantities of one tonne or above per year.

The Regulation states that the registration provisions shall not apply in case a substance is either used in food or feeding stuffs in accordance with Regulation (EC) No 178/2002, or when a substance is covered by Annex V of REACH.

Annex V point 8 indicates that substances which occur in nature, if they are not chemically modified, are exempt from the obligation to register, as registration is deemed inappropriate or unnecessary for these substances. Live cultures fulfil these criteria; therefore they do not have to be registered under REACH.

Even though cultures are exempt from registration in all applications, the raw materials used to manufacture them are only exempt when specifically covered by annex IV or V of the Regulation, even when the final products are used solely for food or feed. However, this issue continues to be subject to on-going interpretation and discussion between industry and authorities.

Cultures are exempt from the registration, evaluation and authorisation provisions. Other provisions of REACH are still applicable, notably the duties to pass on information down the supply chain, classification and labelling obligations, and the restrictions procedure.

This statement represents EFFCA's understanding of the existing European regulations and EFSA scientific work. The present information is given without any liability on the part of EFFCA