



A Cefic Sector Group

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TO WHOM THIS MAY CONCERN

STATEMENT FROM APAG FATTY ACIDS PRODUCING COMPANIES

Concerns: COMMISSION REGULATION (EC) No 987/2008 of 8 October 2008, amending Regulation (EC) No 1907/2006 as regards Annex IV and V

The purpose of this statement is to clarify the position of fatty acids producers with regard to the updated version of Annex V to REACH and the relevant section of ECHA guidance document (Entry 9, P 29-32)

WORDING OF ANNEX V

The following substances obtained from natural sources, if they are not chemically modified, unless they meet the criteria for classification as dangerous according to Directive 67/548/EEC with the exception of those only classified as flammable [R10], as a skin irritant [R38] or as an eye irritant [R36] or unless they are persistent, bioaccumulative and toxic or very persistent and very bioaccumulative in accordance with the criteria set out in Annex XIII or unless they were identified in accordance with Article 59(1) at least two years previously as substances giving rise to an equivalent level of concern as set out in Article 57(f):

Vegetable fats, vegetable oils, vegetable waxes; animal fats, animal oils, animal waxes; fatty acids from C6 to C24 and their potassium, sodium, calcium and magnesium salts; glycerol.

ECHA GUIDANCE DOCUMENT TO ANNEX V

ECHA guidance document states:

In this exemption 'obtained from natural sources' means that the original source must be a natural material (plants or animals) and 'not chemically modified' means that the substances covered by this exemption, once obtained from a natural source, are not further chemically modified.

It goes on to say:

This exemption is not limited to 'naturally occurring substances' in the sense of the definition of Article 3(39). This means that the specified substances falling under this exemption can also be obtained through other processes than those described in Article 3(39)¹⁴.

¹⁴ The wording 'substances obtained from natural sources' is not identical with 'substances which occur in nature'. In particular, the term 'substances obtained from natural sources' is not restricted to the definition of Article 3(39).



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Taking into consideration:

- That ECHA guidance document is not legally binding.
- That ECHA guidance document does not specify the number of processes required to obtain fatty acids.
- That all substances which are in the closed list of Annex V , benefit from the exemption of registration – irrespective of the number of steps required to reach /manufacture those substances.
- Various discussions APAG and fatty acids producers have had with the Commission, ECHA and their respective national authorities.

APAG Fatty acids producing companies have concluded that **“ALL FATTY ACIDS FROM C6 to C24, IRRESPECTIVE OF THE WAY THEY ARE PRODUCED and PROVIDING THEY ARE FROM NATURAL SOURCES AND NOT CLASSIFIED¹ AND/OR NOT FURTHER CHEMICALLY MODIFIED ARE EXEMPT FROM REGISTRATION”**.

Consequently, fatty acids that, once obtained, do not undergo any further chemical process, are exempt from registration, providing that they meet the requirements of regulation 987/2008.

However, in order to secure a harmonised interpretation of the annex V, entry 9, Industry recommends to register hydrogenated fatty acids, irrespective of the way they are produced.

Yours sincerely,

Ch De Cooman
APAG Secretary General
On behalf of APAG Fatty Acids Producers

¹ according to Directive 67/548/EEC with the exception of those only classified as flammable [R10], as a skin irritant [R38] or as an eye irritant [R36] or unless they are persistent, bioaccumulative and toxic or very persistent and very bioaccumulative in accordance with the criteria set out in Annex XIII or unless they were identified in accordance with Article 59(1) at least two years previously as substances giving rise to an equivalent level of concern as set out in Article 57(f).