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ENVIRONMENT DIRECTORATE-GENERAL  
Water, Chemicals & Biotechnology  
**Chemicals & Nanomaterials**

ENTERPRISE AND INDUSTRY DIRECTORATE-GENERAL  
Chemicals, Metals, Forest-based & Textile Industries  
**REACH**

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**4<sup>th</sup> Meeting of Competent Authorities  
for REACH and CLP (CARACAL)**

**2-3-4 February 2010**

**Centre A. Borschette, Rue Froissart, 36, BE-1040 Brussels, Belgium**

**Room 1 D**

***Concerns:* Status of Vegetable Oils Obtained from Genetically Modified  
Plants under REACH Regulation (EC) No. 1907/2006**

***Agenda Point:* 3.3**

***Action Requested:* The Competent Authorities and stakeholders are invited to  
take note of the document and provide their comments.**

***Disclaimer: Only the text of the Regulation is authentic and the Commission accepts no responsibility or liability whatsoever with regard to this paper.***

## **1. INTRODUCTION<sup>1</sup>**

Annex V of REACH contains a number of exemptions to the obligation to register and from the evaluation and downstream user provisions of REACH in accordance with Article 2(7)(b) of REACH. In particular Annex V point 9, contains the following exemption:

*9. 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.<sup>2</sup>*

Within the REACH Helpdesk Correspondents Network (REHCORN) the question arose with respect to the interpretation of the exemption under point 9 of Annex V to the REACH Regulation. In particular, the question at issue was whether the exemption for vegetable oils obtained from natural sources referred to in point 9 of Annex V covers vegetable oils obtained from genetically modified (GM) plants or whether vegetable oils obtained from GM plants should be treated differently from those obtained from non GM plants and therefore be subject to the registration requirements of REACH.

At the REHCORN meeting of 23/24 March 2009, the Commission services had replied to this question in the following way:

*“At the outset, it should be pointed out that the exemption No. 9 of the revised Annex V of REACH, is not limited to naturally occurring substances in the sense of the definition of Article 3(39) of REACH. This means that substances falling under this exemption can be obtained through other processes than those described in Article 3(39), including a chemical modification (e.g. ester hydrolysis to obtain fatty acids). The expression 'obtained from natural sources' means that the original source must be a natural material (e.g. plants or animals).*

*Additionally, Article 3(1) of REACH defines "substance" as "a chemical element and its compounds in the natural state or obtained by any manufacturing*

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<sup>1</sup> This document exclusively addresses the issue of oils that are derived from GMOs in the context of the exemption in Annex V.9 of REACH. It does not relate to any other substance derived from GMOs.

<sup>2</sup> Commission Regulation (EC) No 987/2008, OJ L 268, 8.10.2008, p.14

*process..." without specifying or limiting the character of the manufacturing itself or limiting number of individual steps within the manufacturing process till the substance is obtained. That would suggest that genetic modification could also be part of this process.*

*Furthermore, in relation to genetically modified organisms (GMOs), it should be recalled that their placing on the market (including food and feed products derived from GMOs) is in the first place governed by the EU GMO legislation (lex specialis). Current applications for authorisation concentrate on cultivation of GMOs, on genetically modified food and feed, and on food/feed products derived from GMOs, which are all covered by the GMO legislation. Concerning GMOs and products such as biofuels or fats derived from them for industrial uses, firstly the GMOs as such would need to be authorised according to the GMO legislation and secondly the products/substances would be eligible for exemption under point 9 of Annex V of REACH, so long as they comply with the other conditions of the exemption:*

- they are not chemically modified or*
- they do not meet the classification criteria (with the exception of those only classified as R10, R38 or R36) or*
- they do not meet the PBT criteria or*
- they do not meet the vPvB criteria or*
- they have not been identified as substances of equivalent concern in the candidate list".*

As a follow-up to this reply, several Competent Authorities for REACH gave their views on the question whether genetically modified organisms could be seen as natural sources for the purpose of point 9 of Annex V of REACH. This matter was further discussed among the relevant Commission services, including those responsible for genetically modified organisms, and at the 2<sup>nd</sup> and 3<sup>rd</sup> CARACAL meetings.

As the issue touches upon two areas of the EU legislation, it was decided that the Commission should seek the views of the competent authorities for REACH coordinated with the competent authorities responsible for GMO legislation, taking into account both the chemical and GMO legislation.

A joint letter to the competent authorities under REACH and under Directive 2001/18/EC, copied to the competent authorities under Regulation (EC) No 1829/2003, was prepared by the Commission and sent out on 7 December 2009 asking for coordinated views from each Member State by 15 January 2010. By the time of preparation of this document, the Commission received feedback from eighteen Member States and Norway. All the comments and views received have been made available on the CARACAL circa web-site.

## **2. ELEMENTS SUGGESTED FOR CONSIDERATION**

When seeking the joint views of Member States, the Commission suggested that in particular the following aspects should be taken into account:

- under the GMO legislative framework (Art. 4(4)/16(4) and 4(5)/16(4) of Regulation(EC) No 1829/2003 on GM food and feed) vegetable oils derived from GM plants for food and feed uses are covered by the GMO legislation (authorisation as well as labelling /traceability requirements); at the same time, substances used in food or feedingstuffs are excluded from several titles of REACH including the registration (Art. 2(5)(b) of REACH). The interpretation of the exemption listed in point 9 of Annex V of REACH therefore relates to vegetable oils for uses other than food and feed.
- under the Community legislation preceding REACH (i.e. Directive 67/548/EEC) the respective competent authorities concluded in 1997 that the oil extracted from a GM *Brassica napus* was not covered by EINECS entry 232-299-0 for rape oil ( CAS 8002-13-9) and therefore had to be notified as a new substance. This was recorded in the Manual of Decisions available at: [http://ecb.jrc.ec.europa.eu/DOCUMENTS/New-Chemicals/Manual\\_of\\_decisions.pdf](http://ecb.jrc.ec.europa.eu/DOCUMENTS/New-Chemicals/Manual_of_decisions.pdf). It should be noted that this relates to the question whether oil extracted from a plant is to be considered the same as an oil of a genetically modified variant of the same plant and not to the question whether a genetically modified organism can be considered as a natural source.
- In the draft guidance on Annex V<sup>3</sup> developed at the same time as the latest revision of Annex V<sup>4</sup>, the exemption “obtained from natural sources” is explained as meaning that the original source must be a natural material (plants or animals). In other words, the question whether genetically modified organisms are natural sources for the purpose of this entry depends on whether they are seen as natural material in this sense.
- Under Annex V point 9 of REACH only such oils are exempted that are not chemically modified and that do not meet the classification criteria (with the exception of those only classified as R10, R38 or R36) and/or PBT/vPvB criteria and that have not been identified as substances of equivalent concern in the candidate list. Therefore, if the genetic modification results in oils meeting those criteria, these oils are not exempted from registration.
- Consideration should also be given to the fact that under the REACH requirements, the registration dossiers are not to include risks specific to genetic modification and to the question whether in case of import, it would be possible to ascertain whether vegetable oil was extracted from GM plant or non GM plant.

### 3. SUMMARY OF THE COMMENTS RECEIVED AND THE COMMISSION FEEDBACK

The competent authorities have carefully considered the matter and, with the exception of three competent authorities, all provided general support to the Commission conclusion expressed in March 2009 that vegetable oils obtained from GM plants would be eligible for exemption under point 9 of Annex V of REACH, although as indicated below, several competent authorities qualified their support.

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<sup>3</sup> The text of the guidance has not yet been endorsed by the REACH Competent Authorities, its draft has been handed over to the European Chemicals Agency, where it is still under finalisation and should be discussed at this CARACAL meeting under Agenda point 6.5.

<sup>4</sup> The draft text prepared by the Commission services can be consulted on Europa website: <http://ec.europa.eu/environment/chemicals/reach/pdf/8%20Draft%20guidance%20V.pdf> and [http://ec.europa.eu/enterprise/sectors/chemicals/files/reach/com\\_rev\\_anx\\_v\\_guidance\\_090403\\_en.pdf](http://ec.europa.eu/enterprise/sectors/chemicals/files/reach/com_rev_anx_v_guidance_090403_en.pdf)

In their responses, the vast majority of the competent authorities have taken the line that, although the plant which is a source of the oils under discussion has been genetically modified, oils obtained from it can be considered as "obtained from natural sources" within the context of entry 9 of Annex V of REACH.

Several of the competent authorities indicated that the chemical identity/composition of the oil obtained from a GM plant should be the same as or not significantly different from the identity/composition of oil obtained from a non-GM plant in order to benefit from the Annex V.9 exemption. Furthermore, two competent authorities drew attention to the fact that although the equivalence/sameness of substance under REACH and under the GMO legislation can be seen as parallel concepts, they are not identical as the existing methods for substantial equivalence within the GMO context are simpler or still under development. On the other hand, impurities and traces are considered in less detail in the GMO risk assessment than in REACH. As a result, some substances considered "equivalent" under the GMO legislation may not fulfil the sameness criteria under REACH. The Commission services are of the view that the issue at stake is not whether the identity/composition of oils obtained from a GM plant is the same as the one obtained from a non GM plant but whether the GM plant is to be considered a natural source. The exemption in entry 9 of Annex V covers all vegetable oils as long as they are obtained from natural sources and fulfil all the criteria stipulated in that entry.

Although several competent authorities considered that oils with a different composition should be regarded differently from those with the same or non-significantly different composition, a large number of competent authorities pointed out that, given that in the majority of cases it was not practically possible to detect a difference in composition of oils coming from two different origins, nor to detect whether an oil was a mixture coming from GM and non-GM origin, the enforceability of the exemption in Annex V.9 would be at stake if the status of vegetable oils obtained from GM plants as compared to non-GM plants were different.

Following the assumptions above concerning the expression "obtained from natural sources", it can be concluded that the majority of Member States support the position that vegetable oils obtained from GM plants are to be covered by the exemption under point 9 of Annex V of REACH, provided that these oils also meet all other remaining conditions for the exemption :

- they are not chemically modified or
- they do not meet the classification criteria (with the exception of those only classified as R10, R38 or R36) or
- they do not meet the PBT criteria or
- they do not meet the vPvB criteria or
- they have not been identified as substances of equivalent concern in the candidate list.

One competent authority has furthermore submitted comments as to the understanding of the term "manufacturing" under REACH when connected to the particular case of oils obtained from plants. In its view, if plants are considered as a source for obtaining vegetable oils, then the manufacturing of oils begins with their extraction from this source (plants) and planting and growing of the plants should not be considered as a part

of the manufacturing under REACH. Given the overall analysis above, the Commission services concur with this view and, consequently, they would withdraw the second paragraph from their reply to REHCORN of March 2009.

Moreover, the Commission services would like to point out that the present document deals only with the specific question of vegetable oils obtained from GM plants within the context of exemption under point 9 of Annex V of REACH. The issues concerning substances identical to substances occurring in nature but obtained from GMOs as, for example, their metabolites, or the issue of compost from GMO plants that some competent authorities also referred to in their comments, go beyond the scope of this paper and the current discussion. This is true also of general discussion about the interpretation of Articles 3(39) and 3(40) of REACH. If needed, these issues might be examined separately.

Finally, some competent authorities pointed at lack of complementarity between the GMO legislation and REACH, in particular, between risk assessment for authorisation of technical plant oils extracted from GM plants under the GMO legislation and their placing on the market under REACH. In the view of the Commission services, these two systems should be complementary, while at the same time, should not overlap with each other. In this sense, the relationship and synergies between the GMO legislation and REACH could be assessed with the intention to avoid overlaps between the two legislations and, if required, be included as one element for the review that the Commission is tasked to do by 1 June 2012 under Article 138(6) of REACH.

#### **4. CONCLUSIONS**

The Commission believes that when considering the question whether the exemption for vegetable oils obtained from natural sources referred to in point 9 of Annex V covers vegetable oils obtained from GM plants or whether vegetable oils obtained from GM plants should be treated differently from those obtained from non GM plants and therefore be subject to the registration requirements of REACH, all the conditions comprised in the legal text of the exemption should be taken into account.

The legal text exempts specifically listed substances that were "obtained from natural sources" and at the same time fulfil a range of other additional conditions.

If a vegetable oil is obtained from a plant species that has been genetically modified, oils obtained from it can be considered as "obtained from natural sources" within the context of entry 9 of Annex V of REACH. Such vegetable oils obtained from GM plants are to be covered by the exemption under point 9 of Annex V of REACH provided that all other conditions for this specific exemption are met:

- they are not chemically modified or
- they do not meet the classification criteria (with the exception of those only classified as R10, R38 or R36) or
- they do not meet the PBT criteria or
- they do not meet the vPvB criteria or

- they have not been identified as substances of equivalent concern in the candidate list.

## **5. ACTION REQUESTED**

The Competent Authorities and stakeholders are invited to take note of the document and comment as appropriate. In particular, the CAs are invited to provide any comments on:

- the conclusions outlined in Section 4 above;
- whether a clarification of this issue should be included in the guidance on Annex V of REACH.