EUROPEAN COMMISSION
ENVIRONMENT DIRECTORATE-GENERAL
Green Economy
Chemicals

ENTERPRISE AND INDUSTRY DIRECTORATE-GENERAL
Resources Based, Manufacturing and Consumer Goods Industries
REACH
Chemicals Industry

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10-11 November 2014
CCAB, Brussels, Belgium

Concerns: **Q&As on the scope of certain authorisation exempting provisions**

Agenda Point: **Information point 12**

Action Requested: **The CARACAL are invited to take note of this document**

Q&A on exemptions from authorisation requirement[1]

- Article 2(5), subparagraphs (a) and (b), and Article 56 subparagraphs (4)((a), (b), and (c)) and (5)((a) and (b)) of REACH exempt from the authorisation requirement a number of uses in products (medicinal products, food or feedingstuffs, plant protection products, biocidal products, motor fuels, cosmetic products and food contact materials, respectively) within the scope of, or covered by, the sector-specific Union legislation specified in those provisions. Do these exemptions cover the incorporation of the Annex XIV substance into the product during the manufacturing process?

  Yes, these exemptions cover the incorporation of a substance into the product during the manufacturing process.

- Do these exemptions also cover the life-cycle steps (such as formulation) preceding the incorporation of the substance into the product in question?

  Yes, the uses of a substance upstream preceding an exempted end-use are also exempted but only in the volumes ending up in the exempted end-use.
  It should be noted that, with regard to uses in cosmetic products and in food contact materials, the exemption only applies when the intrinsic properties specified in Annex XIV for the substance in question concern hazards to human health.

- Article 56 (4)(d) of REACH contains an exemption from the authorisation requirement for the use as fuels in closed systems. Does this exemption also cover the life-cycle steps (such as formulation) preceding this end-use?

  Yes, the uses of a substance upstream, preceding "use as fuels in closed systems", are also exempted under the condition that the control of the risks – i.e., use in closed systems – is also pursued in the upstream life-cycle steps preceding the end-use as a fuel.

- Does an application for authorisation for the use of a substance in a medical device regulated by the sector-specific legislation referred to in Article 60(2) 2nd subparagraph of REACH have to be submitted for a substance for which Annex XIV specifies human health hazards only? Does this exemption cover the incorporation of the Annex XIV substance into the product during the manufacturing process? If so, are the life-cycle steps preceding the incorporation of the substance in the medical device subject to authorisation?

  Pursuant to Articles 60(2) and 62(6) of REACH, an application for authorisation is not required for a substance used in a medical device regulated under Directives 90/385/EEC, 93/42/EEC or 98/79/EC if that substance has been identified in Annex XIV for human health concerns only. Nor is an application required in such cases for the incorporation of the substance into the medical device during the manufacturing process or for the uses and corresponding volumes of that substance upstream preceding the end-use.

[1] ECHA will finalise the details of these Q&A for publication on its website.

- Article 56 (3) of REACH exempts from the authorisation requirement the use of a substance in scientific research and development (SRD). Does this exemption also cover the life-cycle steps (such as formulation) preceding the end-use in SRD?

  Yes, the uses of a substance upstream preceding an exempted end-use in SRD are also exempted in quantities of the substance ending up in the SRD use (under 1 t/y) subject to what is set out below.
  The definition of SRD in Article 3(23) requires any scientific experimentation, analysis or chemical research to be carried out "under controlled conditions" and "in a volume less than one tonne per year". Accordingly, the exemption in Article 56 (3) is delimited by a certain level of control of risks – i.e., use under controlled conditions and in a volume less than 1 tonne per year – which also apply to the upstream life-cycle stages preceding the end-use in SRD.

- Is the manufacture of a substance, whether for export or placing on the EU market, subject to the authorisation requirement?

  The manufacture of a substance is not subject to the authorisation requirement. After a substance has been manufactured it may have to be handled before it is exported or placed on the EU market. Operations which are necessary for the handling of a substance on its own in the manufacturing for export or placing on the EU market are considered to be part of the manufacturing stage (e.g. filling into appropriate containers, storage, addition of stabiliser, dilution to a safer concentration -if necessary for transport safety-), but not other uses such as the formulation of a mixture or incorporation of the substance into articles. The formulation of a mixture or incorporation of the substance into articles are considered "uses" within the meaning of Title VII of REACH and are subject to the authorisation requirement whether or not the mixture or articles will be exported or placed on the EU market.