[X1ANNEX XII

GENERAL PROVISIONS FOR DOWNSTREAM USERS TO ASSESS SUBSTANCES AND PREPARE CHEMICAL SAFETY REPORTS

Editorial Information

X1 Substituted by Corrigendum to Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC (Official Journal of the European Union L 396 of 30 December 2006).

[F1INTRODUCTION

The purpose of this Annex is to set out how downstream users are to assess and document that the risks arising from the substance(s) they use are adequately controlled during their use for a use not covered by the Safety Data Sheet supplied to them and that other users further down the supply chain can adequately control the risks. The assessment shall cover the life-cycle of the substance, from its receipt by the downstream user, for his own uses and for his identified uses further down the supply chain. The assessment shall consider the use of the substance on its own, in a mixture or in an article.

The assessment shall address all nanoforms that are covered by the registration. Justifications and conclusions drawn from the assessment shall be relevant to the nanoforms, from their receipt by the downstream user, for his own uses and for his identified uses further down the supply chain.

In carrying out the chemical safety assessment and producing the Chemical Safety Report, the downstream user shall take account of information received from the supplier of the chemical in accordance with Article 31 and 32 of this Regulation.

When nanoforms of the substance are covered by his own use or his identified uses down the supply chain, an appropriate metric for the assessment and presentation of the results in steps 1- 6 of the chemical safety assessment under 0.6.1 and 0.6.2 shall be considered, with the justification included in the chemical safety report and summarised in the safety data sheet. A multiple metric presentation is preferable, ensuring availability of mass metric information.

Where available and appropriate, an assessment carried out under **[**F2other**]** legislation, (e.g. risk assessments completed under Regulation (EEC) No 793/93) shall be taken into account in the chemical safety assessment and be reflected in the Chemical Safety Report. Deviations from such assessments shall be justified. Assessments carried out under other international and national programmes may also be taken into account.

Textual Amendments

F2 Word in Annex 12 substituted (31.12.2020) by virtue of The REACH etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/758), reg. 1(1), **Sch. 3 para. 9**; 2020 c. 1, Sch. 5 para. 1(1)

The process which the downstream user goes through in carrying out the chemical safety assessment and in producing his Chemical Safety Report, involves three steps:**]**

STEP 1: DEVELOPMENT OF EXPOSURE SCENARIO(S)

The downstream user shall develop exposure scenarios for uses not covered in a Safety Data Sheet supplied to him in accordance with Section 5 of Annex I.
STEP 2: IF NECESSARY, A REFINEMENT OF THE HAZARD ASSESSMENT BY THE SUPPLIER

If the downstream user considers the hazard and PBT assessments reported in the Safety Data Sheet supplied to him to be appropriate, then no further hazard assessment or PBT and vPvB assessment is necessary. In this case he shall use the relevant information reported by the supplier for the risk characterisation. This shall be stated in the Chemical Safety Report.

[[F3]When nanoforms of the substance are covered by his own use or his identified uses down the supply chain, the assessment shall cover the hazard, PBT and vPvB assessment of nanoforms(s) as used.**]**

Textual Amendments

F3 Inserted by Commission Regulation (EU) 2018/1881 of 3 December 2018 amending Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) as regards Annexes I, III,VI, VII, VIII, IX, X, XI, and XII to address nanoforms of substances (Text with EEA relevance).

If the downstream user considers the assessments reported in the Safety Data Sheet supplied to him to be inappropriate, then he shall carry out the relevant assessments in accordance with Sections 1 to 4 of Annex I as appropriate to him.

[[F1]In those cases where the downstream user considers that information, in addition to that provided by the supplier, is necessary for producing his Chemical Safety Report, the downstream user shall gather this information. Where this information can only be obtained by testing on vertebrate animals, he shall submit a proposal for a testing strategy to the Agency in accordance with Article 38. He shall explain why he considers that additional information is necessary. While waiting for results of further testing, he shall record in his chemical safety report the risk management measures intended to manage the risks being explored that he has put in place. The above record taking shall address all nanoforms that are covered by his own uses or his identified uses down the supply chain. Such information shall be relevant to the nanoforms.**]**

On completion of any additional testing, the downstream user shall revise the Chemical Safety Report, and his Safety Data Sheet if he is required to prepare one, as appropriate.
STEP 3: RISK CHARACTERISATION

A risk characterisation shall be carried out for each new exposure scenario as prescribed in Section 6 of Annex I. The risk characterisation shall be presented under the relevant heading of the Chemical Safety Report and summarised in the Safety Data Sheet under the relevant heading(s).

When generating an exposure scenario it will be necessary to make initial assumptions about the operating conditions and risk managements measures. If the initial assumptions lead to a risk characterisation indicating inadequate protection of human health and the environment, then it shall be necessary to carry out an iterative process with amendment of one or a number of factors until adequate control can be demonstrated. This may require the generation of additional hazard or exposure information or appropriate alteration of the process, operating conditions or risk management measures. Therefore, iterations may be made between on the one hand developing and revising an (initial) exposure scenario, which includes developing and implementing risk management measures, and on the other hand generating further information

to produce the definitive exposure scenario. The purpose of generating further information is to establish a more precise risk characterisation, based on a refined hazard assessment and/or exposure assessment.

The downstream user shall produce a Chemical Safety Report detailing his chemical safety assessment using Part B, Sections 9 and 10, of the format set out in Section 7 of Annex I and the other sections of this format, if appropriate.

Part A of the Chemical Safety Report shall include a declaration that the risk management measures outlined in the relevant exposure scenarios are implemented by the downstream user for his own uses and that the risk management measures outlined in the exposure scenarios for the identified uses are communicated down the supply chain.**]**

Status:
Point in time view as at 31/12/2020.

Changes to legislation:
There are currently no known outstanding effects for the Regulation (EC) No 1907/2006 of the European Parliament and of the Council, INTRODUCTION .