

REACH – Annex III

Introduction

Registrants of phase-in substances in the 1-10 tonnes per annum tonnage band may be able to benefit from reduced data requirements. If certain conditions are met, instead of a full Annex VII data set, a registrant has the option to provide only physicochemical data. This could reduce the cost required either to commission testing or for a letter of access, since there would be no need for data on human health or environmental endpoints.

This provision is outlined in Article 12(1)(a) & (b) and the criteria which substances must meet are found in Annex III of the REACH legal text.

To provide some encouragement to potential registrants to provide a full Annex VII data set, when a full data set is provided the registration fee can be waived as per Article 74(2).

Applying Article 12(1)

Article 12(1)(a) states that if a substance meets **either or both** of the Annex III criteria, then a full Annex VII data set is required. Article 12(1)(b) states that for substances meeting **neither** of the Annex III criteria, then only the physicochemical information in Annex VII needs to be provided.

The first criterion in Annex III is based on a prediction that a substance will have the type of hazards that could lead to it being a Substance of Very High Concern.

The second criterion has two parts and applies to substances that are predicted to have any type of human health or environmental hazard **and** will be used in a dispersive or diffuse way.

Annex III Criteria

- Criterion (a) considers substances which are predicted to meet the conditions for classification as a carcinogen, mutagen or reproductive toxicant (CMR) in category 1A or 1B; or substances which are predicted to be persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) as specified in Annex XIII;
- Criterion (b) is separated into two conditions; **both** of which must be fulfilled in order for it to apply. It considers:
 - (i) Substances with dispersive or diffuse use(s), especially when used in consumer mixtures or incorporated into consumer articles;
 - and**
 - (ii) Substances which are predicted to meet the conditions for classification for any human health or environmental hazard class as per Annex I of the CLP Regulation.

REACH – Annex III

'Dispersive or diffuse use' is further elaborated on in ECHA's document *Examples for application of the Annex III inventory*. In essence, any consumer use will be dispersive and/or diffuse. Many professional uses will also usually be dispersive and/or diffuse. (e.g., use by tradespeople, builders, etc). Uses in an industrial setting (e.g., in a factory) where there are systems in place to minimise release are unlikely to be dispersive or diffuse. Prediction of hazard classification can be through the application of (Quantitative) Structure-Activity Relationships [(Q)SARs] or other evidence.

ECHA's Annex III Inventory

ECHA have published a list of substances on their website under the heading 'Annex III Inventory'. If a substance appears on this list, then in ECHA's opinion it is **presumed** to meet the criterion b(ii), above; that is, it is predicted to be hazardous. The list does not take into account dispersive or diffuse use (this will depend on the particular supply chain). Therefore, the Annex III inventory is essentially a list of potentially hazardous substances. If a substance is on ECHA's Annex III Inventory, but it is not a CMR/PBT/vPvB and does not have dispersive or diffuse use, then it may still be eligible for reduced data requirements. ECHA's *Examples for application of the Annex III inventory* provide more information on how the inventory can be implemented, along with detailed scenarios for Annex III eligibility.

The flow diagram on the following page illustrates the eligibility for submitting a reduced data package.

Further information

For advice on the application of REACH obligations, you can contact the UK REACH Competent Authority's national helpdesk:

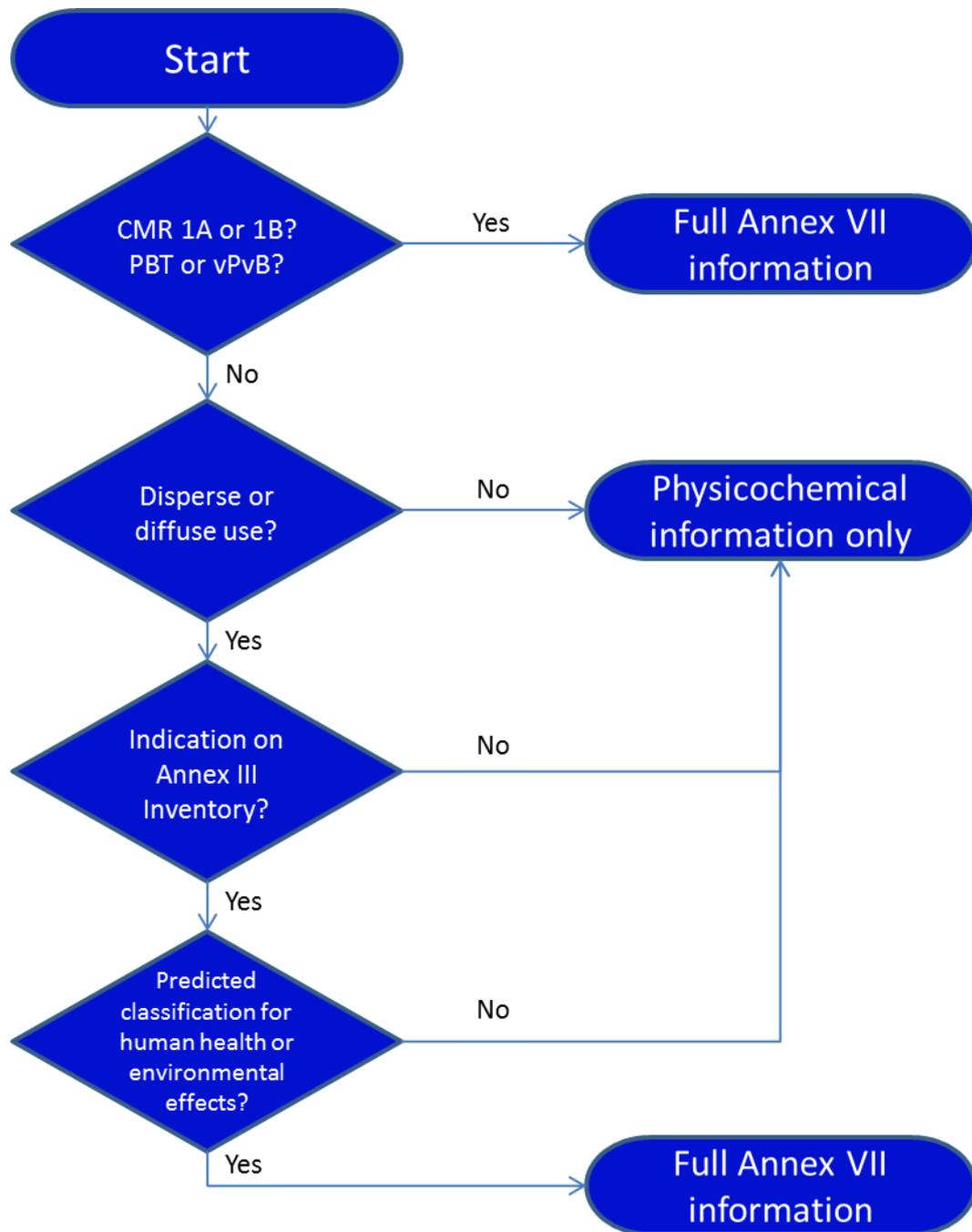
Email: UKREACHCA@hse.gov.uk

Website: www.hse.gov.uk/reach



REACH – Annex III

Flow diagram for the application of Annex III criteria for reduced data requirements for REACH registration at 1-10 tonnes per annum¹



¹ Adapted from ECHA's "Examples for application of the Annex III inventory" May 2016