

CSR sections 9 & 10 – Explanation on the modified format.

1. Background

Formats for section 9 and 10 of the CSR are provided on the ECHA website. These formats are not mandatory.

In order to improve the user friendliness of the CSR, the lay-out of data in these formats differ from the CSR format as set out in Section 7 of Annex 1 of REACH. It is important to note, however, that this change in lay-out does not modify the information requirements as put forward by the legal text. This document briefly describes the modified format and its benefits.

According to the Annex 1 CSR format, the conditions of use (exposure scenario), the related release and exposure estimates and the corresponding risk characterisation are scattered over various subsections in the CSR. In order to understand the assessment for one use, the reader of the CSR has to scroll up and down the document.

In order to overcome this problem, the format provided by ECHA pursuant to Article 111 of REACH includes the risk characterisation together with the exposure estimates per exposure scenario. The information elements and their relationship to each other will however be maintained as laid down in Annex 1 of REACH.

2. Proposed Format Changes

The high level chapter structure is modified:

- In section 9, the exposure scenario information (title, operational conditions and risk management measures) for each contributing scenario is followed immediately by the corresponding exposure estimates and risk characterisation

Advantage: all relevant information for a given contributing scenario is presented in one place. The current difficulties in searching through the document are eliminated.

The section is now renamed: 9. EXPOSURE ASSESSMENT (and related risk characterisation)

- In section 10, only the risk characterisation for the overall exposure remains (current 10.x). The risk characterisation for individual exposure scenarios (including the risk combined for the different routes dermal/inhalation/oral) is presented in Section 9 together with the exposure estimates. The current sub-differentiation in section 10 (human health, environment, worker, consumer, humans via the environment) is maintained but integrated in the structure of the exposure assessment in section 9.

Advantage: The length of the document is greatly reduced (avoiding duplicating titles and labels).

The section is now renamed: 10. RISK CHARACTERISATION RELATED TO COMBINED EXPOSURE