Seveso Expert Group Document

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Directive 2012/18/EU (Seveso-III-Directive)

Questions & Answers – update for SEG-07

DRAFT

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1. INTRODUCTION

This document includes questions and answers (Q&A) concerning primarily technical issues, which arose in the implementation of Directive 2012/18/EC[1] (aka Seveso-III-Directive) and its predecessors.

The answers are the result of discussions between the European Commission services and the Seveso Expert Group (SEG)[2], and, prior to creation of the latter in 2011, in the Committee of Competent Authorities[3]. They aim at facilitating a harmonised implementation throughout the European Union. The answers cover only general aspects and do not deal with specific situations of individual Member States or economic operators. This document is solely a compilation of the relevant conclusions agreed at the various meetings.

The answers provided in this document do not represent an official position of the European Commission and cannot be invoked as such in the context of legal proceedings. Final judgements concerning the interpretation of the Directive can only be made by the European Court of Justice.

2. ANNEX I – DANGEROUS SUBSTANCES

2.1. Issues related to Annex I Part 1 – Categories of dangerous substances

2.1.1. Section P – Physical Hazards

Ref.	Issue
051	Question: Many people from the Seveso community are confused by ECHA's C&L inventory and their statements regarding whether a chemical is subject to Seveso or not. 1. What is the purpose of ECHA giving this Seveso-information at all, as it is in many cases confusing or even misleading? Furthermore, ECHA has no role in Seveso (as they also write in their Seveso-disclaimer), so on what grounds do they then give Seveso-information? 2. The problem is that ECHA's information on Seveso concerns only the harmonised (CLP Annex VI) classification of a chemical. However, harmonised classifications generally only apply to that particular hazard and many chemicals also have other hazards that should be classified for according to the normal self-

[1] Directive 2012/18/EU of the European Parliament and of the Council of 4 July 2012 on the control of major-accident hazards involving dangerous substances, amending and subsequently repealing Council Directive 96/82/EC, OJ L 197, 24.7.2012

[2] Commission Expert Group E02612 as included in the 'Register of Commission Expert Groups and Other Similar Entities' (http://ec.europa.eu/transparency/regexpert/index.cfm?do=groupDetail.groupDetail&groupID=2612)

[3] Committee of Competent Authorities established under the directive on the control of major-accident hazards involving dangerous substances (Seveso Directive 2012/18/EU) (aka CCA), Committee C14000 as included in the Comitology Register (http://ec.europa.eu/transparency/regcomitology/index.cfm)

	classification procedures stipulated in the CLP. Hence, the classification of a chemical from a supplier frequently involves more hazards than just the harmonised one. *The following example illustrates the problem:* *Formic acid has harmonised classification for skin corrosivity only, Skin Corrosive Cat. 1A (H314). For this aspect the C&L inventory provides the information that formic acid is not a Seveso substance, see https://echa.europa.eu/en/information-on-chemicals/cl-inventory-database/-/discli/details/49202.* *This would be correct if one would only look at the property "skin corrosivity". However, scrolling down the same page it becomes clear that several registrants have classified formic acid for "Acute Toxicity, inhalation, Cat. 3 (H331)". This is a hazard that would make formic acid a Seveso chemical (entry H2 of Seveso Annex I Part 1) with 50/200 ton thresholds.* *So if a company uses a supplier that classifies formic acid as Acutely toxic, inhalation, Cat. 3, the information in ECHA's C&L inventory is confusing if not misleading.* **Proposed answer:** The information sheet in ECHA's Classification and Labelling (C&L) inventory for the chemicals includes a section indicating whether the chemical is covered by the Seveso-III-Directive (SEVESO). This is part of a pilot project on including in the sheets information on other relevant legislation. The Seveso-related information included in the sheets reflects only legally binding harmonised classification. Therefore, as clearly visible on ECHA's website, the Seveso-related information has the same (light) blue colour as the harmonised C&L data, which aims precisely at preventing potential confusion. The "non-harmonised notified classification and labelling information" is of a different nature and is therefore presented on ECHA's website with a different colour (yellow-orange). Unlike the harmonised classification, this reflects self-classification by registrants (e.g. manufacturers, importers), which has not been formally verified. Whilst harmonised classification is legally-binding across the EU, self-classification does not bind other operators. However, Seveso Competent Authorities may use information on self-classification when making decisions on how operators should implement Seveso.

2.2. Issues related to Annex I Part 2 – Named dangerous substances

2.2.1. Questions on a specific named substance

Ref.	Issue
050	*Question:* For entry 45 in Seveso Annex I-Part 2: The named substance Dazomet (tetrahydro-3,5-dimethyl-1,3,5-thiadiazine-2-thione) includes a reference to note 21. That note reads:*"In cases where this dangerous substance falls within category P5a Flammable liquids or P5b Flammable liquids, then for the purposes*

of this Directive the lowest qualifying quantities shall apply".

The harmonised classification of Regulation (EC) No 1272/2008 on classification, labelling and packaging (CLP) however does not indicate that *'tetrahydro-3,5-dimethyl-1,3,5-thiadiazine-2-thione'* is a flammable liquid:. https://echa.europa.eu/information-on-chemicals/cl-inventory-database/-/discli/details/35952 . According to this information, the substance is a solid.

There do not appear to be any specific notes about concentrations in mixtures. Is the Note 21 a mistake for named substance number 45?

Proposed answer:

Tetrahydro-3,5-dimethyl-1,3,5-thiadiazine-2-thione (Dazomet) is a white crystalline substance that dissolves in water. The flashpoint[4] of the substance lies at 93ºC, the boiling point at 222,3 °C.

The guidance on the application of the CLP criteria for substances and mixtures, Version 5.0 of July 2017[5] includes the following general definition of a "Flammable liquid" in Annex I: 2.6.1.

> *"Flammable liquid means a liquid having a flash point of not more than 60 °C."*

The detailed CLP definitions and general considerations for the classification of flammable liquids (Annex I section 2.6.1) are as follows:

Annex I: *Table 2.6.1-*	
Label elements flammable liquids	
Category	*Criteria*
1	*Flash point < 23 °C and initial boiling point ≤ 35 °C*
2	*Flash point < 23 °C and initial boiling point > 35 °C*
3	*Flash point ≥ 23 °C and ≤ 60 °C1*

Considering that both the boiling and flash points of Dazomet are outside the boundaries of the categories mentioned above, it seems that the substance should not be classified as 'Flammable Liquid'. Consequently, also the reference to 'Note 21' from Annex I – part 2, entry 45 of the Seveso Directive does not apply to Tetrahydro-3,5-dimethyl-1,3,5-thiadiazine-2-thione (Dazomet).

[4] The flash point (of a volatile material) is the lowest temperature at which it can vaporize to form an ignitable mixture in air. https://pubchem.ncbi.nlm.nih.gov/compound/dazomet#section=Odor

[5] https://echa.europa.eu/documents/10162/13643/clp_guidance_draft_v5_part2_en.pdf

2.3. Issues related to the notes to Annex I

2.3.1. Note 21: Flammable liquids

050	*See question* on entry 45 Seveso Annex I-Part 2: The named substance Dazomet (tetrahydro-3,5-dimethyl-1,3,5-thiadiazine-2-thione) and its reference to note 21: *"In cases where this dangerous substance falls within category P5a Flammable liquids or P5b Flammable liquids, then for the purposes of this Directive the lowest qualifying quantities shall apply"*.