



Seminar on chemical substances self-classification issues in the context of the Seveso Directive

Vilnius, 23 October 2013

INTRODUCTION

The Seveso II Directive 96/82/EC and, as from 1 June 2015, the Seveso III Directive 2012/18/EU apply to establishments where 'dangerous substances' are present above certain thresholds, as identified in the respective Annexes of these Directives. These refer to substances and preparations / mixtures classified according to the Council Directive 67/548/EEC of 27 June 1967 on the classification, packaging and labelling of dangerous substances and Directive 1999/45/EC of the European Parliament and of the Council of 31 May 1999 on the classification, packaging and labelling of dangerous preparations and, accordingly, Regulation (EC) No 1272/2008 on the classification, labelling and packaging of substances and mixtures (CLP).

Manufacturers, importers and downstream users of substances and mixtures are obliged under Article 4 of the CLP Regulation to classify substances and mixtures before placing them on the market. Under CLP provisions, industry is obliged to ensure that if a substance is listed in Annex VI of the CLP Regulation, i. e. in the list of harmonised classifications, it must use that classification. However, for substances with incomplete harmonised classification, that is, in cases when only some hazard classes are harmonised e. g. carcinogenicity, manufacturers and importers must self-classify for the hazard classes that are not harmonised. The same self-classification approach applies to substances not listed in Annex VI.

As the scope of the Seveso Directive depends on the classification of the substances and mixtures present in a certain establishment, the process of self-classification may be an issue for a consistent approach to the application of the Seveso Directive across Member States.

In response to this issue, the Lithuanian competent authority for the Seveso Directive – the Fire and Rescue Department under the Ministry of the Interior – has the pleasure of hosting a Seminar on chemical substances self-classification issues in the context of the Seveso Directive on 23 October 2013 in Vilnius.

CONCEPT

The overall objective of the seminar is to share information and experiences on approaches used by Seveso competent authorities and industry with respect to the self-classification of dangerous substances, when applying the Seveso Directive to establishments where such substances are present.

The detailed objectives of the seminar are:

- Share experience of Seveso competent authorities in verification of Seveso establishments on the basis of the information on self-classification in the notification sent by the operator.
- Examine similarities and differences of approaches employed by Seveso competent authorities in complex cases for the application of the Seveso Directive in order to share

experience and identify practical means to ensure a homogeneous application of the Seveso Directive.

- Explore possible ways of communication between manufacturers, importers and downstream users of dangerous substances and Seveso competent authorities to facilitate data / information exchange to ensure timely and harmonized application of the Seveso Directive.

The topic of the seminar will be two-fold: the first part will consist of some introductory presentations to give an overview of the existing EU regulations and practical experience of Member States regarding self-classification; the second part will focus on defining possible pragmatic approaches for applying the Seveso Directive to establishments with respect to the self-classification of dangerous substances present.

PARTICIPANTS

The seminar will bring together representatives of Seveso competent authorities, industry as well as national and international organizations to share experience and discuss issues related to the application of the Seveso Directive to establishments with respect to the self-classification of dangerous substances present.

METHOD

All participants are expected to actively participate in the discussions to exchange experience and information.

Esteemed speakers and moderators are invited to encourage participants during the seminar, by presenting the experiences of their organisations. After the introductory presentations, a break out session will follow where participants will be divided into three working groups. It will be concluded by a plenary session presenting the results of the discussions on the following topics:

- Verification of Seveso establishments;
- Self-classification issues leading to uncertainties regarding the application of Seveso;
- Ways to establish good communication in the chain “Manufacturer, importer, downstream user – Seveso competent authority”.

Draft questions for the break out session aimed at encouraging discussions among participants have been prepared by **Audrius Ciuplys** and **Lina Buciene** from the Fire and Rescue Department, and **Olivia Walsh** from Irish Health and Safety Authority.

The registration to the working groups will be distributed to the participants by email after the registration deadline. We would kindly like to invite you to decide which working group you would like to participate in. However, we wish the working groups to be approximately equal in number of participants, therefore please consider an alternative working group which you would like to participate in case your chosen working group has reached its maximum number of participants. Participants will be assigned to the groups on a “first come, first served” basis. The participants will be informed of their group assignment prior to the meeting.

Each working group will focus on a specific topic, further described below.

1. Verification of Seveso establishments

Article 6 of the Seveso II Directive (Article 7 of the Seveso III Directive) requires the operator to send the competent authority a notification including information about the establishment and the types and quantities of dangerous substances present. The notification shall contain information sufficient to identify the dangerous substance or category of substance involved. There is no

requirement to send a substance's safety data sheet (SDS). Thus, the verification of a Seveso establishment depends in practice on the accuracy of information in the notification. A number of issues and questions may arise, related to the specificity / completeness and correctness of the information contained in the notification, which can impact on verification of whether the establishment is falling within the scope of the Seveso Directive or not.

The participants in this working group should be prepared to discuss this topic considering the following questions:

- a. How detailed should the information in the notification be to consider it as sufficient to identify the dangerous substances or category of substances involved?
- b. Which practical measures can be put in place by the competent authorities to achieve the required level of details?
- c. How can Member States ensure that the information in the notification is comprehensive and compliant with the information in the dangerous substances' Safety Data Sheets?
- d. How can Member States ensure that dangerous substances are classified correctly?
- e. How will the Seveso competent authorities control if the operators use a homogeneous classification of the same dangerous substance? Which practical measures could be put in place to achieve more consistency?

2. Self-classification issues leading to uncertainties regarding the application of Seveso

Recent work carried out by some responsible institutions found out that some Safety Data Sheets had incorrect data, leading to erroneous classification of dangerous substances. In other cases there is inconsistency because different suppliers may classify the same dangerous substance in a different way, e. g. on the basis of a different interpretation of information contained in the Safety Data Sheets.

When downstream users like Seveso operators become aware of new information on self-classification or when a change is introduced in a mixture, they must reconsider the classification of the substance or mixture. Since a downstream user relies on the classification from his supplier, self-classification can also be a particular problem for the operators of warehouses.

Changes to harmonized classifications are specific in terms of the classification changes and the time frames for their application. However, as self-classification is not as prescriptive, this may potentially lead to inconsistencies, for example between manufacturers, or within a supply chain, which accordingly may impact the application of the Seveso Directive

The participants in this working group should be prepared to discuss this topic considering the following questions:

- a. How should the competent authority proceed in cases where the information in the notification or SDS is insufficient or inadequate?
- b. How should the authorities deal with situations where different manufacturers, importers or downstream users self-classify a substance differently?
- c. How should the competent authorities deal with the complexity of the verification of dangerous substances inventory, and accordingly with the decisions on application of the Seveso Directive and on the tier of the establishment, in particular for what concerns Seveso warehouses?
- d. Given that there is variation in notified classifications of the same dangerous substances in the C&L inventory, how should the Seveso competent authorities deal with this in the interim?
- e. If a change in the additional self-classification determines the application of the Seveso Directive, how would the competent authorities define which dates could be considered

as a start for application of the new classification and, accordingly, of the requirements of the Seveso Directive?

3. Ways to Establish Good Communication in the Chain “Manufacturer, importer, downstream user – Seveso Competent Authority”

In the situation that not all operators are aware of their obligations with respect to the Seveso Directive, as well as CLP and REACH, communication is one of the tools to promote compliance. Effective communication in the chain “Manufacturer, importer, downstream user – Seveso competent authority” at all stages ensures that relevant and updated information is provided in a timely manner.

Seveso competent authorities and inspectors need a wide range of knowledge and skills. When it comes to the application of the Seveso Directive, inspectors must also be aware of CLP requirements, that apply to the classification of substances. This may require cooperation between various authorities, e. g. between the Seveso competent authorities, inspectors and authorities responsible for the implementation of the chemicals legislation (CLP&REACH).

The participants in this working group should be prepared to discuss the topic considering the following questions:

- a. What types of mechanisms and tools may be used by Seveso competent authorities to improve communication in the chain “Manufacturer, importer, downstream user – Seveso competent authority” to ensure a more consistent application of the Seveso Directive?
- b. Is there a need to involve competent REACH and CLP experts, incl. third-party, in the application of the Seveso Directive? If so, what arrangements might competent authorities put in place to achieve this?
- c. What could be the coordination challenges between REACH&CLP and Seveso competent authorities and the ways to overcome those?
- d. What competence (skills) should operators and Seveso inspectors have to be able to identify the correct classification of dangerous substances? What arrangements might competent authorities put in place to ensure continuous training of inspectors and, eventually, operators?

EXPECTED RESULTS

The aim of the discussion is to examine each of these topics, identifying the most important obstacles to consistent application of the Seveso Directive, and propose solutions, types of activities and tools that could be used to overcome them.