Harmonisation of product notification to Poisons Centres in EU Member States


Harmonisation of product notification

Based on article 45(4) of the CLP Regulation (EC) No 1272/2008, the European Commission (EC) tries to harmonise product notification by companies to Poisons Centres (PC) and Competent Authorities in EU Member States.

An important step towards harmonisation is finding consensus with stakeholders on product information requirements.

EAPCCT Guidelines 2013

The EAPCCT Working Group on Poisons Centres Activities / European Regulatory Issues (currently coordinated by John Thompson, NPIS unit Cardiff, UK) defined the product information requirements in 2010. Discussions of EAPCCT representatives with industry associations, Competent Authorities and the EC resulted in some modification of these requirements (EAPCCT Guidelines 2013).

CARACAL

The harmonisation project has been discussed by EC and Member States at the Competent Authorities on REACH and CLP (CARACAL) meetings of November 2013 and April 2014, respectively.

In the latest EC Working Paper on harmonisation of product notification (see overview below), there are some changes as compared to the ‘EAPCCT Guidelines 2013’.

Overview of product information requirements presented in the EC Working Paper Ca/06/2014 (discussed at CARACAL in April 2014)

<table>
<thead>
<tr>
<th>Concentration range of hazardous components in the mixture (%)</th>
<th>Maximum width of the concentration range</th>
</tr>
</thead>
<tbody>
<tr>
<td>&gt; 25 - ≤ 100</td>
<td>5 % units</td>
</tr>
<tr>
<td>&gt; 10 - ≤ 25</td>
<td>3 % units</td>
</tr>
<tr>
<td>&gt; 2 - ≤ 10</td>
<td>1 % units</td>
</tr>
<tr>
<td>&gt; 1 - ≤ 0.1</td>
<td>0.5 % units</td>
</tr>
<tr>
<td>&gt; 0.1 - ≤ 1</td>
<td>0.3 % units</td>
</tr>
<tr>
<td>≤ 0.1</td>
<td>0.05 % units</td>
</tr>
</tbody>
</table>

Example:

A substance in a mixture with a concentration of 26% falls in the category > 25 - ≤ 100 (with a 5% maximum bandwidth) and can be notified as: 21-26%, 22-27%, 23-28%, 24-29%, 25-30%, 26-31%. Also smaller ranges can be applied such as 25-27% etc.

For all other substances a similar approach with wider maximum bandwidths will be used.

Industrial mixtures, PPORD, R&D

Industry requested reduced notification requirements for mixtures that only have an industrial use. The substantial notification workload is seen as disproportional to the relatively low number of industrial exposures PCs have to deal with. As a compromise, the Safety Data Sheet is accepted, provided that detailed composition information is rapidly available 24h/7d. A study to evaluate the workability of this solution will be conducted.

Mixtures used for research and development (R&D) only and ‘product and process orientated research and development’ (PPORD) mixtures will be excluded from the notification obligation altogether.

Working Groups on specific topics

The EC will establish working groups with representatives of all stakeholders to develop:

- a standard electronic format notification
- a product category system

The submission of the notification should be provided electronically using a standard XML format (eXtensible Markup Language). In that way, all appointed bodies receiving the information will have the same exchangeable information available. The purpose of the categorisation system will be to allow PCs to statistically assess poison incidents across EU Member States in a harmonised way with the aim to identify risks and to propose measures for preventing exposures.

Next steps

The EAPCCT WG commented on and proposed adaptations to the product information requirements as presented in the EC Working Paper Ca/06/2014.

In a final step, the EC will develop a legislative proposal to add an Annex to the CLP Regulation describing EU harmonised product information requirements.

It is expected that the Annex will be implemented in the CLP Regulation in 2015. With a foreseen transitional period of two years, the harmonised notification in EU Member States can be achieved in 2017.