

Legal obligation to notify to the European Chemicals Agency (ECHA) an information on classification and labelling

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In the REGULATION (EC) No 1272/2008 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006, in the article I Purpose and scope the following provisions are included:

1. The purpose of this Regulation is to ensure a high level of protection of human health and the environment as well as the free movement of substances, mixtures and articles as referred to in Article 4(8) by:

- a) harmonising the criteria for classification of substances and mixtures, and the rules on labelling and packaging for hazardous substances and mixtures
- b) providing an obligation for:
 - (i) manufacturers, importers and downstream users to classify substances and mixtures placed on the market;
 - (ii) suppliers to label and package substances and mixtures placed on the market
 - (iii) manufacturers, producers of articles and importers to classify those substances not placed on the market that are subject to registration or notification under Regulation (EC) No 1907/2006 [REACH – authors' footnote]
- c) providing an obligation for manufacturers and importers of substances to notify the Agency of such classifications and label elements if these have not been submitted to the Agency as part of a registration under Regulation (EC) No 1907/2006 [REACH – authors' footnote]
- d) establishing a list of substances with their harmonised classifications and labelling elements at Community level in Part 3 of Annex VI
- e) establishing a classification and labelling inventory of substances, which is made up of all notifications, submissions and harmonised classifications and labelling elements referred to in points (c) and (d).

In accordance with provision of the article 39 Scope, producers and importers of:

- a) substances subject to registration in accordance with Regulation (EC) No 1907/2006 [REACH – authors' footnote]
- b) substances within the scope of Article I which meet the criteria for classification as hazardous and are placed on the market either on their own or in a mixture above the concentration limits specified in this Regulation or Directive 1999/45/EC, where relevant, which results in the classification of the mixture as hazardous have the following obligations mentioned in the article 40 Obligation to notify the Agency:
 1. Any manufacturer or importer, or group of manufacturers or importers (hereinafter referred to as 'the notifier(s)'), who places on the market a substance referred to in Article 39, shall notify to the Agency the following information in order for it to be included in the inventory referred to in Article 42:
 - a) the identity of the notifier(s) responsible for placing the substance or substances on the market as specified in section I of Annex VI

to Regulation (EC) No 1907/2006 [REACH – authors' footnote]

2. The information listed in paragraph 1 shall be updated and notified to the Agency by the notifier(s) concerned when, pursuant to the review in Article 15(1), a decision to change the classification and labelling of the substance has been taken.
3. Substances placed on the market on or after 1 December 2010 shall be notified in accordance with paragraph 1 within one month after their placing on the market.

4. However, substances placed on the market before 1 December 2010 may be notified in accordance with paragraph 1 before that date.

The information referred to in (a) to (f) shall not be notified, if it has been submitted to the Agency as part of a registration pursuant to Regulation (EC) No 1907/2006 [REACH – authors' footnote], or if it has already been notified by that notifier.

Attention!!!

The only representatives may submit information required for notification to the inventory, as a part of REACH registration dossier. However, they are not authorised to notify to the inventory in the name of the producer from outside of the EU. In case when companies from the countries beyond the EU do not want, in order to maintain confidentiality, to disclose composition of their substances or mixtures to the EU importers, they may appoint one of the importers to notify in the name of other importers (notification in the name of group of importers). In this case only selected importer will receive confidential information required for notification. Such importer can be also the only representative, who was appointed to the purpose of REACH registration: only representative may become an importer through the sample receiving of relevant substances or mixtures. Such procedure makes him responsible for import, including the substance or mixture safe handling.

The notifier shall submit this information in the format specified pursuant to Article 111 of Regulation (EC) No 1907/2006 [REACH – authors' footnote].

2. The information listed in paragraph 1 shall be updated and notified to the Agency by the notifier(s) concerned when, pursuant to the review in Article 15(1), a decision to change the classification and labelling of the substance has been taken.
3. Substances placed on the market on or after 1 December 2010 shall be notified in accordance with paragraph 1 within one month after their placing on the market.

However, substances placed on the market before 1 December 2010 may be notified in accordance with paragraph 1 before that date.

According to the provisions of article 42, paragraph 1 of the CLP regulation – information included in the inventory corresponding to the information mentioned in the article 119, paragraph 1 of the regulation (EC) No 1907/2006 (REACH), is publicly available. Agency makes available other information on each substance inserted to the inventory to those notifiers and registrants, who have been submitted information on this substance according to article 29, paragraph 1 of the regulation (EC) No 1907/2006 (REACH). Moreover, subject to article 118 of this regulation, ECHA makes such information available to other third parties.

In CLP regulation in further part of the article 42 there are the following provisions in the relevant paragraphs:

2. The Agency shall update the inventory when it receives updated information in accordance with Article 40(2) or Article 41.
3. In addition to the information referred to in paragraph 1, the Agency shall, where applicable, include the following information in each entry:
 - a) whether, in respect of the entry, there is harmonized classification and labelling at Community level by inclusion in Part 3 of Annex VI
 - b) whether, in respect of the entry, it is a joint entry between registrants of the same substance as referred to in Article 11(1) of Regulation (EC) No 1907/2006
 - c) whether it is an agreed entry of two or more notifiers or registrants in accordance with Article 41
 - d) whether the entry differs from another entry on the inventory for the same substance.

The information referred to in (a) shall be updated where a decision is taken in accordance with Article 37(5).

Legal obligation to notify to the European Chemicals Agency (ECHA) an information on classification and labelling is independent on tonnage of produced or imported substance.

We would like also to pay particular attention for the fact that mentioned above legal obligation may refer to such substances like:

- Waste (including waste polymers), which have lost the waste status being further economically utilized and in this purpose transferred to other entrepreneurs, i.e. placed on the market
- Selected polymers.

We should remember that although wastes are generally completely exempted from the obligations resulted from REACH obligation and polymers are exempted from registration and evaluation according to the provisions of this regulation, nevertheless if the conditions mentioned above are met and such substances present relevant health or environmental hazard – there exists legal obligation to notify an information on classification and labelling.

Notification, an information on classification and labelling is free of charge.

It is worth emphasizing that the provisions of CLP and REACH regulations interpenetrate each other, particularly in the range of notification on substance classification and labelling. Evolving in detail the provisions of section 2.1-2.3.4 of annex VI to the REACH regulation, it should be once again highlighted that producers or importers who will have an obligation to notify information on substance classification and labelling will have to submit to the ECHA the following information:

- a) the identity of the notifier as specified in section 1 of Annex VI to Regulation (EC) No 1907/2006 (REACH)
- b) the identity of the substances as specified in section 2.1 to 2.3.4 to Annex VI to Regulation (EC) No 1907/2006 (REACH)

Name or other identifier of each substance:

 - ✓ Name(s) in the IUPAC nomenclature or other international chemical name(s)
 - ✓ Other names (usual name, trade name, abbreviation)
 - ✓ EINECS or ELINCS number (if available and appropriate)
 - ✓ CAS name and CAS number (if available)
 - ✓ Other identity code (if available)

Information related to molecular and structural formula of each substance:

 - ✓ Molecular and structural formula (including Smiles notation, if available)
 - ✓ Information on optical activity and typical ratio of (stereo) isomers (if applicable and appropriate)
 - ✓ Molecular weight or molecular weight range

Composition of each substance:

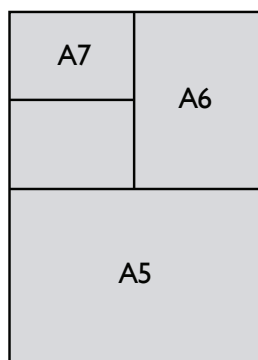
 - ✓ Degree of purity (%)
 - ✓ Nature of impurities, including isomers and by-products
 - ✓ Percentage of (significant) main impurities
 - ✓ Nature and order of magnitude (... ppm, ... %) of any additives (e.g. stabilising agents or inhibitors)
- c) Substance classification
- d) Justification of the classification
- e) specific concentration limits or M-factors, where applicable
- f) the label elements specified in points (d), (e) and (f) of Article 17(1) for the substance or substances together with any supplemental hazard statements for the substance, determined in accordance with Article 25(1).

On the basis of received information the Agency will establish and maintain a classification and labelling inventory in the form of a database available on the ECHA website. In this inventory among other things the following information about substances will be included:

- Name of the substance in the IUPAC nomenclature
- Name of the substance consistent with the EINECS inventory, if such exists
- Classification and labelling of the substance.

English translation by the Author

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