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CONTRIBUTION

From:	General Secretariat of the Council
To:	Delegations
N° prev. doc.:	ST 16273/22 + ADD 1
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Subject:	Commission Delegated Regulation (EU) .../... of 19.12.2022 amending Regulation (EC) No 1272/2008 as regards hazard classes and criteria for the classification, labelling and packaging of substances and mixtures - Statement by Finland on the delegated act

Delegations will find in the Annex the statement by Finland on the above delegated act, which is integral part of the revision of Regulation (EC) No 1272/2008 (the CLP Regulation).

Finland will present these comments at the Working Party Meeting for Technical Harmonisation (Dangerous Substances - Chemicals) on 22 February 2023.



**MINISTRY OF
SOCIAL AFFAIRS AND HEALTH**
Finland



Ympäristöministeriö
Miljöministeriet
Ministry of the Environment



Helsinki 24.1.2023

Ref.: Commission Delegated Regulation (EU) .../... of 19.12.2022 amending Regulation (EC) No 1272/2008 as regards hazard classes and criteria for the classification, labelling and packaging of substances and mixtures - C(2022) 9383 final (ST 16273/22 + ADD 1)

Dear Colleagues,

First, Finland would like to wish all the best for Sweden for their Presidency. We also wish to thank the Commission for the proposal and the informative presentation in the meeting last week. Although this was not expressed in the meeting, also Finland would like to make a scrutiny reservation regarding the proposal.

Due to the very challenging schedule, we will not be making any detailed comments on the proposal at this stage, but will present those in the meeting to be held on February 22nd. However, we wish to voice once again our concerns regarding the way the Commission is using a Delegated Act to introduce, in our view, new essential elements to CLP since this is relevant also regarding amendments proposed to especially articles 36, 37 and 53 in the proposal presented to the Council Working Group.

Furthermore, in page 15 in section 5 "Other elements" under "Procedure for adoption" the Commission describes the adoption of the new hazard classes in the CLP Regulation as non-essential elements, and mentions the Commission initiative at the GHS Sub-Committee regarding these new hazard classes (ST/SG/AC.10/C.4/2022/18). However, the text (in page 15) discusses only hazard classes and fails to give the updated picture of the discussion, which took place at the 43rd Session of the GHS Sub-Committee. According to the official report (ST/SG/AC.10/C.4/86) of the GHS December meeting (<https://unece.org/transport/documents/2022/12/reports/report-sub-committee-experts-globally-harmonized-system>):

On document ST/SG/AC.10/C.4/2022/18, some delegations were of the opinion that the current state of science on test guidelines and test methods, available data and lack of consensus on how to address substances with the properties listed in the proposal from the European Union, did not justify the development of new hazard classes and/or additional labelling provisions in the GHS. They considered that the hazardous characteristics targeted by the proposal were (or could be) covered by existing hazard classes in the GHS and challenged their characterization as intrinsic hazards. They pointed out that additional information on these properties could be included in the Safety Data Sheet, instead of introducing additional label elements as they felt this would not necessarily result in increased safety. It was mentioned that consensus should be achieved first at international level on how to address these properties before considering starting the work at the Sub-

Committee. Concerns were also voiced regarding the additional challenge that the results of this work could represent for countries in earlier stages of implementation of the GHS as regards availability of resources and knowledge to ensure effective application at national level. They concluded that the options and considerations outlined in informal documents INF.33 and INF.38, as well as others mentioned during the discussion (e.g.: consider using Annex 11 of the GHS to address the topic) should be taken into account before taking a decision on a possible way forward.

52. Many delegations supported addressing endocrine disruptors for human health and endocrine disruptors for the environment; as well as persistent, bioaccumulative, toxic (PBT); very persistent, very bioaccumulative (vPvB); persistent, mobile, toxic (PMT); and very persistent, very mobile (vPvM) substances in the GHS. In particular, one delegation welcomed the ambitious agenda towards a higher level of protection of human health and environment and development of safer alternatives. Several other delegations considered that the approach proposed in informal document INF.39 providing more structure to the scope of the work and outlining a stepwise approach to maintaining consistency with existing hazards and hazard classes addressed in the GHS, would allow the Sub-Committee to take into account all the issues and concerns raised. In particular, it would allow involvement of experts from all disciplines; the possibility to receive feedback from all stakeholders (including industry representatives and OECD and non-OECD members, among others); and consideration of the best available scientific knowledge and data, while offering the possibility to explore other options.

53. Having heard the opinions of all those who requested the floor, the Sub-Committee welcomed the proposal from the European Union to lead an informal working group on the basis of the terms of reference and workplan contained in informal document INF.39, and decided to include a new item on its programme of work for 2023-2024. It was noted, however, that it would not be appropriate to refer to “unaddressed hazards”. Following a proposal by the expert from the United Kingdom, the Sub-Committee agreed to rename the item to read “potential hazard issues and their presentation in the GHS”. Noting in addition that the scope of the work of the informal working group addressed several endpoints, the Sub-Committee suggested that the work could be shared by other experts as co-leaders responsible for a particular endpoint, on the understanding that this would be done in coordination with the representative of the European Union as the main lead of the work of the informal working group and the overall supervision of the Sub-Committee. Interested experts were invited to contact the representative of the European Union.

In our view, the above-mentioned discussion shows that in the GHS Sub-Committee there are differing views on the proposed new hazard classes, and that the work at the GHS Sub-Committee might lead to a different result compared with the EU proposal for the CLP Regulation. This also points to the argument that hazard classes are an essential element of the CLP Regulation, and it is a political choice from the Commission to add these in the CLP Regulation without first agreeing on them at the GHS level.