

ANNEX 4

CONSUMER PRODUCT LABELLING BASED ON THE LIKELIHOOD OF INJURY

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A4.1 Introduction

A4.1.1 The Globally Harmonized System of Classification and Labelling of Chemicals is based on an assessment of the intrinsic hazardous properties of the chemicals involved. However, it has been recognized that some systems provide information about chronic health hazards in consumer products only after considering additional data regarding potential exposures to consumers under normal conditions of use or foreseeable misuse. These systems thus provide information based on an assessment of risk, or the likelihood of injury occurring from exposure to these products. Where this exposure assessment and determination of likelihood of injury reveal that the potential for harm to occur as a result of the expected exposures is insignificant, chronic health hazards may not be included on the product label for consumer use. This type of system was recognized in a paper clarifying the scope of the GHS work in 1998¹:

“The application of the components of the system may vary by type of product or stage of the life cycle. Once a chemical is classified, the likelihood of adverse effects may be considered in deciding what informational or other steps should be taken for a given product or use setting”.

A4.1.2 The work on the GHS has not addressed harmonisation of this type of approach. Therefore, specific procedures to apply this approach would have to be developed and applied by the competent authority. However, in recognition that it is an approach that has been used, and will continue to be used in the future, this annex is being provided to give additional guidance on how such an approach may work in practice.

A4.1.3 Exposure assessments for some consumer products are used to determine what information is included on a label in this type of approach. Regulators and manufacturers obtain exposure data or generate hypothetical exposure data based on customary use or foreseeable misuse. These assumptions are then used to determine whether a chronic health hazard is included on a consumer product label, and what precautions are to be followed, under a risk-based approach. These decisions are thus made on the basis of considerations regarding the likelihood of harm occurring in the consumer exposure situations that have been identified.

A4.1.4 Consumer product labels in some systems are based on a combination of hazard and risk. However, acute and physical hazards may be indicated on the label, while chronic health effects labelling based on risk is not indicated. This may be due in part to the expectation that exposures to some consumer products are of short duration, and thus may not be sufficient to lead to the development of chronic health effects as a result of those exposures. These expectations may not be accurate where consumer products are used in a workplace, e.g. paints or adhesives used by construction workers on a regular basis

A4.1.5 While intrinsic hazards of a chemical can be determined for all sectors, information about exposure, and thus risk, varies significantly among the sectors covered by the GHS. The vehicle by which this information is then transmitted to the user also varies. In some cases, particularly in the consumer setting, the label is the sole source of information, while in others, especially the workplace, it is one piece of a comprehensive system, supplemented by SDSs and worker training. In transport, a label transmits the primary information, but additional information is provided by the transport documentation.

¹ IOMC Description and Further Clarification of the Anticipated Application of the Globally Harmonized System (GHS), IFCS/ISG3/98.32B.

A4.2 General principles

A4.2.1 While the specific risk assessment approach has not been addressed or harmonized in the GHS, certain general principles are as follows:

- (a) *All chemicals should be classified based on GHS classification criteria*

The first step in the process of classifying hazards and communicating information should always be classification of intrinsic hazards based on the GHS criteria for substances and mixtures;

- (b) *Risk-based labelling can only be applied by the competent authorities to the chronic health hazards of chemicals in the consumer product setting. All acute health, environmental and physical hazards should be labelled based on intrinsic hazards*

The hazard classification should lead directly to labelling of acute health effects, environmental and physical hazards. The labelling approach that involves a risk assessment should only be applied to chronic health hazards, e.g. carcinogenicity, reproductive toxicity, or target organ systemic toxicity based on repeated exposure. The only chemicals it may be applied to are those in the consumer product setting where consumer exposures are generally limited in quantity and duration;

- (c) *Estimates of possible exposures and risks to consumers should be based on conservative, protective assumptions to minimise the possibility of underestimating exposure or risk*

Exposure assessments or estimates should be based on data and/or conservative assumptions.

Assessment of the risk and the approach to extrapolating animal data to humans should also involve a conservative margin of safety through establishment of uncertainty factors.

A4.2.2 *An example of risk-based labelling used in the United States Consumer Product Safety Commission*

A4.2.2.1 In general, consumers rely on product labels for information about the effects of a chemical product. Whereas other sectors have additional sources of information (e.g. safety data sheets, transport documents) to expand upon or refine product information and relate risk to the hazard information provided, the consumer sector generally does not.

A4.2.2.2 As noted above, the general rule for the GHS is that the label information will be based on intrinsic properties (hazards) of the chemical in all sectors. The rationale for hazard based labelling in the GHS has been described earlier in this document, and may be applied to consumer products as well as products in other sectors.

A4.2.2.3 In particular, the principle of the user's "right-to-know" about the intrinsic hazards of the chemical is important and widely supported by many stakeholders. Hazard information is an incentive to choose less hazardous chemicals for use. It may not be possible to accurately predict the exposures when the products are used, and consumer protective measures are less certain than those in other more structured sectors.

A4.2.2.4 On the other hand some research has indicated²⁻⁷ that a consumer's attention can be diverted by too much information on a label regarding all potential hazards. It appears there is some evidence that warnings focused on specific hazards that are likely to cause injury enhance consumer protection.

A4.2.2.5 To ensure that consumers have the information needed to take appropriate protective measures, a risk-based labelling approach examines likely or possible exposures and communicates information related to the actual risks of exposure. Consumer exposures from use, foreseeable use and accidents can be estimated since products are designed for specific use(s).

A4.2.2.6 The following process has not been harmonized in the GHS. It is consistent with US Consumer Product Safety Commission Guidelines⁸ and with other national and international guidelines on conducting risk assessments⁹⁻¹¹. A substance or product under evaluation for chronic hazard labelling for consumer use in the US must satisfy a two-part test. First, it must present one of the chronic hazards covered, i.e. be classified as a chronic hazard based on specific criteria. Second, a risk assessment must be carried out to establish whether it has the potential to cause substantial illness or injury during or as a result of "reasonably foreseeable handling or use or from ingestion by children". If the result of the risk assessment indicates the risk is very low, the substance or product need not be labelled for chronic hazard. In other words, whether a given substance is labelled for a chronic effect depends not only on whether it is hazardous, but also on exposure and risk.

A4.2.2.7 The extent of the exposure assessment would depend on the hazard. For example, for non-cancer chronic endpoints, an "acceptable daily intake" (ADI) would be calculated from the "no observed adverse effect level" (NOAEL). For a conservative estimate of exposure, one can assume that the consumer will use the entire consumer product in a day and/or assume that all of the hazardous substance/mixture that the consumer is exposed to will be absorbed. If the resulting exposure is lower than the "acceptable daily intake" no hazard communication would be required. If the exposure level is higher than the ADI, then a more refined quantitative assessment could be performed before making a final labelling decision. If refined data are not available, or a refined analysis is not done, the hazard would be communicated on the label.

A4.2.2.8 For carcinogens, a unit risk from exposure to the carcinogen would be calculated based on linear extrapolation with the multistage model as a default model. Life time exposures can be calculated either by assuming worst case scenarios (such as all of the substance in a product is reaching the target tissue at each use, exposure is daily/weekly/monthly), or by determining actual exposures during use, or some combination of these approaches.

A4.2.2.9 The competent authority will need to establish what level of risk is acceptable to implement such an approach to consumer product labelling for chronic effects. For example, CPSC recommends labelling for a cancer hazard if the lifetime excess risk exceeds one-in-a-million from exposure during "reasonably foreseeable handling and use."

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