
COMMITTEE OF EXPERTS ON THE TRANSPORT OF DANGEROUS GOODS AND ON THE GLOBALLY HARMONIZED SYSTEM OF CLASSIFICATION AND LABELLING OF CHEMICALS

Sub-Committee of Experts on the Globally
Harmonized System of Classification
and Labelling of Chemicals

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BUILDING BLOCK APPROACH: GUIDANCE AND IMPLEMENTATION

Guidance on the GHS building block approach

Transmitted by the Chair of the ad hoc Correspondence Group on the Building Block Approach

1. At the December 2005 meeting of the UN Sub-Committee of Experts for the Globally Harmonized System of Classification and Labelling of Chemicals, we agreed to establish a Correspondence Group to:
 - (i) examine whether hazard classes and hazard categories can be used as building blocks;
 - (ii) further analyze the use of hazard communication elements as building blocks, including transport exemptions;
 - (iii) consider the need for the development of guidance material.
2. The ad hoc Correspondence Group has exchanged emails on this subject since February 2006. See the Annex for a summary of the responses received.
3. Based on discussions at the ninth and tenth sessions of the UN Sub-Committee of Experts for the Globally Harmonized System of Classification and Labelling of Chemicals, the Correspondence Group considered two options.
 - 3.1 The status quo with no changes to Section 1.1.3: *Application of the GHS*, including Sub-section 1.1.3.1.5: *Building Block approach*.
 - 3.2 Insert a paragraph after 1.1.3.1.4 and immediately before Sub-section 1.1.3.1.5 that reads:

It is recognized that other principles or approaches may influence hazard communication decisions, for example precedence of hazards or risk based labelling. In the absence of these other approaches, the guidance provided in the building block approach would apply.
4. Most members preferred the status quo while some did not support either option. There was general agreement that guidance is desirable but it is clear from the responses that there are fundamental differences in the interpretation of the building block approach.
5. Without agreement on the fundamental interpretation of the building block approach, it appears to be impossible to develop guidance on this issue. Based on the responses received, and the UN SEGHS discussions, it would seem that the timing is not right to pursue development of guidance at this time. It is expected that as countries gain experience with implementation, a better understanding of the possible application of the building block approach will be achieved and the development of guidance on the building block approach will be possible at a later date.

Annex

Original email sent 13 February 2006

Correspondence Group on the Building Block Approach,

At the December 2005 meeting of the UN Sub-Committee of Experts for the Globally Harmonized System of Classification and Labelling of Chemicals, we agreed to establish a Correspondence Group to:

- (i) examine whether hazard classes and hazard categories can be used as building blocks;
- (ii) further analyze the use of hazard communication elements as building blocks, including transport exemptions;
- (iii) consider the need for the development of guidance material.

Based on the wide variety of conflicting positions that were taken at the December meeting, I am suggesting that there are two options.

1. The Status Quo with no changes to Section 1.1.3: *Application of the GHS*, including Sub-section 1.1.3.1.5: *Building Block approach*.
2. Insert a paragraph after 1.1.3.1.4 and immediately before Sub-section 1.1.3.1.5 that reads:

It is recognized that other principles or approaches may influence hazard communication decisions, for example precedence of hazards or risk based labelling. In the absence of these other approaches, the guidance provided in the building block approach would apply.

The existing text for the Building Block approach would then remain with no changes.

This option would not be part of the explanation of the building block approach but acknowledges that competent authorities may have different considerations that impact on hazard communications in their system/systems.

Note that the reference to risk based labelling is meant to include those sectors/target groups that may use a risk based approach - eg. pesticides.

I welcome comments on the above no later than Friday 24 February 2006.

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Responses Received (in order of receipt).

U.S.

I think we could live with either option, but at this point, the status quo is probably the best.... It does not appear to me that any kind of meaningful resolution of new language or guidance is possible given the polarized positions.

CEFIC

I have had a number of responses from Cefic members concerning the 2 options that you propose. I think that in their view there are two options available:

1. Leave the existing GHS text as it is;
2. Revise all of paragraph 1.1.3.1 and its sub-paragraphs to provide proper clarity

The second option in your paper was not considered to resolve the issue or to add clarity.

The consensus of their views was that if the GHS text relevant to the Building Block Approach is to be addressed, it should clearly define which elements of the GHS are Building Blocks as follows;

Building Blocks

Hazard Classes	Yes
Hazard Categories	Yes (subject to certain qualifications)
Label Elements	No (exception for Transport)
Safety Data Sheet	Yes

Furthermore sub-paragraphs 1.1.3.1.2 to 1.1.3.1.4 should provide greater clarity as to which Building Blocks are generally considered to be used by each of the use settings recognised in the GHS, this would need to be expanded to include emergency responders who would be expected to use safety data sheets, whereas they are generally not part of the transport system.

Some members also thought that for greater the opportunity should be taken to define all the elements of optionality in the GHS, i.e.:

Building Block Approach
Competent Authority Options/Discretions
Optional cut-offs for hazard communication for mixtures.

I think there is a general view amongst our members that this is a difficult and confusing area of the GHS, and it needs to be addressed.

Brazil

But in informal discussions our option is the number 1 (the status quo with no changes). Some suggested to have a guidance about BBA to clarify the issue and give examples how to apply.

Canada

Canada can live with either option.

IPPIC

IPPIC (International Paint and Printing Ink Council) represents an industry which places billions of mixtures on the world market, a large part of which are traded across borders.

IPPIC acknowledges your proposal. IPPIC believes that the main objective of the GHS must be to achieve the highest possible degree of harmonization of requirements for product labelling and safety data sheets. In supporting the GHS it is our industries vision that paint and printing ink products can be exported throughout the world under a single label and safety data sheet.

IPPIC believes any proposal that would lead to more "optionality" on the part of the enacting authorities would not be conducive to harmonization.

Therefore your proposal is viewed as insufficient to arrive at this objective.

Sweden

Option 1: We do not consider that this option is a possible way forward. We all agreed that further guidance or explanation of the Building Block Approach is needed and, as described in Kim's note, the correspondence group was established to clarify the three issues (i-iii), above. We should therefore try to do so.

Option 2: We find no justification for the suggested extra paragraph. Risk-based labelling in conjunction with GHS is handled in Annex 5 where it is outlined that such an approach has not been harmonised within GHS (A5.1.2).

The GHS defines four sectors: workers, consumers, emergency responders, and transport (see GHS section 1.4.3). Pesticides are not a sector that can be treated separately.

The global application of GHS should ideally be the same within each sector (Harmonised system for Classification and Labelling). However, it is not expected at this stage, that the application of GHS would be the same between sectors, because of different needs of the target groups/sectors.

Possible exceptions from the harmonisation could be specified in the GHS text as is already done for certain instances (e.g. Acute (*aquatic*) hazard categories 2 and 3, normally not used for package goods but for bulk transport (A9.2.1, GHS)).

The GHS allows additional, non-harmonised, labelling (risk-or hazard-based), e.g. for hazard communication of pesticides, to be regulated on a national basis. However, this should be in addition to the harmonised GHS requirements and not seen as an alternative option or something that can be used in precedence.

There is a need for a clear definition of what is meant by a "Building Block". The definition could be inserted as a footnote to 1.1.3.1.5.1. It is our understanding that a hazard class can be seen as a building block, but normally not a hazard category within a hazard class.

United Kingdom

We sense that your judgement is that there is presently little prospect of consensus on a substantive revision of the present text on the building block approach. If so, we can go along with your suggestion of keeping with the present text. However, as someone who is still relatively new to GHS I would add that the building block approach seems to be an area on which more work needs to be done in future to move towards greater clarity.

Your option 2 suggested an additional paragraph after 1.1.3.1.4. We found the draft paragraph a bit of a puzzle. The paragraph seems to imply that where the 'principles and approaches' of a competent authority provide for hazard communication as well as risk-based labelling for certain products such as pesticides, an

authority could develop its own hazard communication system instead of selecting building blocks from GHS. If so, this may not be an appropriate message. Furthermore, is reference to precedence of hazards very helpful here? At first sight it seems to add little to the first sentence in 1.1.3.1.5.1 which says that competent authorities are free to choose the building blocks they wish. However, it could also be argued that it is open to other interpretations.

Italy

My strong preference (taking care of the discussion that we had at the UNSCEGHS) is for leaving the Status Quo.

SDA

SDA members have considered the two options and support option 1.

Ireland

I am relatively new to the area of GHS but it would appear to me that the requirements presented for 'Option 2' for the most part already exists in the current GHS text under 1.1.3.1 so 'Option 2' is not really necessary and perhaps just confuses matters. Therefore we agree with Option 1.

However, I feel we really need to agree on the three issues as outlined in your original e-mail, without this implementing GHS is going to be very difficult.

The Irish CA responses to the three issues to be addressed are:

1. Hazard classes and hazard categories as building blocks.
 - Hazard classes are building blocks
 - Hazard categories are building blocks limited to the transport sector only.
2. Further analysis of hazard communication elements as a building block, including transport exemptions.
 - Hazard communication elements are building blocks, including labels and safety data sheets. The requirement for certain elements will be dependent upon the end user for example;
 - workplace (require all elements)
 - Emergency responders (require all elements)
 - Consumer (do not require safety data sheets)
 - Transport (do not require signal words, hazard statements, precautionary statements or safety data sheets).
3. Consider the need to develop guidance material

There is a need to develop guidance material. This can only be discussed in detail once agreement is reached in points 1 & 2 above.

Email sent March 1, 2006

Correspondence Group on the Building Block Approach,

Further to my email of 13 February 2006, 10 responses were received commenting on the options proposed. Attached please find a summary of the comments received.

Most of the respondents preferred the status quo while some did not support either option. There was general agreement that guidance is desirable but it is clear from the responses that there are fundamental differences in the interpretation of the building block approach. There were no suggestions as to how we could move forward to resolve the current impasse.

Without agreement on the fundamental interpretation of the building block approach, it would be impossible to develop guidance on this issue. Based on the responses received, and the UN SEGHS discussions, it would seem that the timing is not right to pursue development of guidance at this time. I expect that we need to gain experience with implementation to better understand the possible application of the building block approach and then revisit the development of guidance on this issue at a later date.

I welcome any views, in particular any suggestions of how to resolve the impasse, no later than 31 March 2006. In the absence of any further developments, I suggest that the above conclusion be brought forward to the UNSEGHS.

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Reponses Received (in order of receipt):

South Africa

As pointed out at the UNSCEGHS, strategies to implement GHS in a number of countries have identified much greater challenges than originally anticipated, particularly in the trade arena because the flexibility in the building block approach actually results in a non harmonized system in many ways.

Nevertheless, from the feedback I received, the members of our Chemical Industry Association are not in support of changing the text at this stage and are thus in favour of Option 1.

There is a strong feeling that urgent attention should be given to the development of guidance on the interpretation and application of the building block approach.

The first step to the development of such guidance is agreement on what elements of the GHS be seen as building blocks. From the discussions at the SCEGHS it seems that the following elements could be considered:

- hazards classes and hazard categories, and
- hazard communication (labels and SDSs).

If not all classes and categories are used as building blocks, the ones used must be as set out in the GHS with a clear indication which are applicable to the workplace, storage and the consumer (transport is already covered by the Model Regulations).

Furthermore, with the development of such guidance it should be taken into account that implementation of the building block approach would be at national level through national legislation. It is therefore important that the application of the building block approach does not lead to a lesser requirement than is currently the case in a country.

AISE

I think developing guidance on the building block approach is desirable *before* the implementation of the GHS. In general A.I.S.E supports the views expressed by Cefic.

France

First of all, it is to be reminded that even if the BBA allows different sectors to implement the GHS their own way, global harmonization in each sector should be sought.

As the BBA is at the basis of the implementation of the GHS, it appears necessary to provide guidance as soon as possible, and to anticipate possible difficulties in implementing.

About the options you submitted to the correspondence group: I think choosing between option 1 and option 2 is restrictive and it will not bring enough clarification. Option 1(status quo) cannot be considered as a way forward, as it was agreed at the UNSCEGHS in December that further guidance is needed on this point. Option 2 does not solve the matter either, and does not seem to clarify the situation in any way.

I think a way to develop guidance is to introduce in the body text a definition of what a BB is. Something that important cannot be addressed with a footnote. I got the feeling in December that a majority of participants agreed on the fact that a hazard class is a BB, and that a hazard category (with the restriction of taking a "continuum" of categories) within a hazard class is also a BB. Whether label elements and SDS are BBs remains to be discussed. I therefore think the correspondence group should focus on this aspect.

Anyway, it seems that the question of a risk based labelling has been addressed in December and that the conclusion was that it was already dealt with in other parts of the GHS. Therefore it should not be brought forward in the BBA topic.

I hope this will help and that the debate on such an important part will go on.

Our position which is, in brief:

- The need of complementary elements (in the text) with the aim of clarify some concepts like the BBA,
- The need of functional limits to ensure both the workability and the coherence of the couple GHS/BBA, and these in every level (intra/inter- sector; intra/inter- country).

I think our position could be assimilate to a mix taking into account the comments already sent by BBA group members. Details could be transmitted if necessary.

I hope that the BBA group could develop, a.s.a.p., a piece of text which will be better studied than a ½ option, and sufficiently specific to focus only BBA issues at this time.

Sweden

The Globally Harmonized System of Classification and Labelling of Chemicals (GHS) has been agreed at the UN level. The system was developed to protect human health and the environment from the harmful effects of hazardous chemicals but also to facilitate international trade. In GHS, a chemical or mixture is assigned to a hazard class depending on the nature of the hazard (i.e. effect) and a hazard category depending on the degree of hazard or, in some cases, the weight of evidence approach is used (e.g. for cancer, germ cell mutagenicity and reproductive toxicity).

GHS is currently in the process of being implemented worldwide. In order to ease implementation and incorporation of the various elements of the GHS in existing systems for classification and labelling of chemicals a building block approach (BBA) was adopted when the GHS was developed. However, recent

deliberations within the UN SCE GHS have made it clear that the meaning of the BBA is not evident. It is therefore obvious that a clearer definition of the building blocks referred to in section 1.1.3.1.5.3 is required. In addition, guidance on the use of the BBA is also urgently needed to facilitate implementation of the GHS.

Section 1.1.3.1.5.3 states: “*The harmonized elements of the GHS may thus be seen as a collection of building blocks from which to form a regulatory approach. While the full range is available to everyone, and should be used if a country or organization chooses to cover a certain effect [=hazard class] when it adopts the GHS, the full range does not have to be adopted*”.

The elements of the GHS are specified in 1.1.2.1: “*The GHS includes the following elements:*

- (a) *harmonized criteria for classifying substances and mixtures according to their health, environmental and physical hazards; and*
- (b) *harmonized hazard communication elements, including requirements for labelling and safety data sheets.*”

A substance or mixture is assigned a hazard class and a hazard category when the harmonized criteria for classification are met. The second sentence quoted from 1.1.3.1.5.3 above states that “*the full range ...[of the harmonized elements]... should be used if a country or organization chooses to cover a certain effect*”. Our interpretation is that if a hazard class (=effect) is chosen, then all hazard categories and hazard communication elements (=full range) should also be chosen.

There are two ways of adopting GHS where classification and labelling systems already exists: GHS can be adopted in full with additions as appropriate not to reduce protection of human health and the environment compared with existing systems currently in place or it can be adopted in parts in order to minimize changes to such systems (“customized GHS”).

The ultimate purpose of GHS is a globally harmonized system for classification and labelling of chemicals within and between the four sectors (“one substance – one global classification”). However, it is not expected at this stage that the implementation of GHS will be the same between sectors since there are different needs of the target groups/sectors, and other legal instruments may apply. Classification and labelling within the transport sector is determined by the UN Model Regulations which have a stronger legal status than GHS-based regulations that will be developed for the other three sectors (i.e. workers, consumers and emergency responders).

The global application of GHS should however be the same within each sector. Exceptions from global harmonisation should therefore be specified in the GHS text as is already done to a certain extent (e.g. Acute aquatic hazard categories 2 and 3, normally not used for package goods but for bulk transport, see A9.2.1).

GHS allows additional, non-harmonised, labelling (risk-/hazard-based) requirements, e.g. for hazard communication of pesticides, to be regulated on a national basis. However, this should be an addition to the harmonised GHS requirements and not seen as an alternative option or take precedence over BB.

Way forward

There is a need for a clear definition of a “Building Block” in GHS terminology. The definition could be inserted as a footnote to 1.1.3.1.5.1. The following proposal is based on the Irish CA response:

The building blocks of the GHS are the hazard classes, the hazard categories (limited to the transport sector only), and the hazard communication elements (label, signal words, hazard statements, precautionary statements and safety data sheets).

France

In addition to the 2 comments previously transmitted (comments which should be merged in the note of BBA group), France would like to precise its position on the BBA.

- As the interpretation of the BBA is a key-issue for the implementation of GHS, France considers necessary to insert in the text of the GHS a clear definition for BBs. In parallel, the BBA requires a guidance for its application. For example, this guidance could be another annex in the GHS. France would like that the discussion on the BBA, first developed in the BBA group, should be continued after the first progress report, which will be presented at the UNSEGHS meeting in July.
- For France, the BB definition must follow the following axes :
 - The hazard classes are BBs : each sector has the possibility not to apply some hazard classes as described in the GHS.
 - Within a hazard class, each category is a BB : for a hazard class, each sector/state has the possibility not to apply all categories. In order to preserve consistency and applicability of the BBA, some restrictions to this possibility must be set, as follow :
 - as cut offs: concentration limits should not be altered, hazard categories may not be re-combined,
 - To preserve harmonisation logics, only categories, which form a continuum should apply (see the scheme below),
 - In a concern of harmonisation between countries, and for the consistency of the system,, when a hazard class applies, at least category 1 should also apply.
 - Labelling elements, independent of the options written in the core text of the GHS, may not be detached from the chosen hazard classes and categories. In other words, labelling elements should not be considered as a BB as such. In the core text, the differences between « transport » and « labour, consumers » labelling are sufficiently clear for not defining a specific BB.
 - The use of an SDS is a BB, but not the content of an SDS. A sector has indeed the possibility not to use an SDS, but when used, its content should at least match that described in the GHS, in order to respond to the need of harmonised information communication on dangerous substances and mixtures.
- The interpretation of the BBA should enlighten countries and sectors about the implementation of the GHS harmonised criteria, and this interpretation should not take into account the other non-harmonised elements.

