34th Meeting of Competent Authorities for REACH and CLP (CARACAL)
Open Session

Concerns: Health and environmental classification of aerosols
Agenda Point: CLP 6
Action Requested: For endorsement in writing.

Written comments by 8 May 2020 can be sent to:
GROW-CARACAL@ec.europa.eu,
ENV-CARACAL@ec.europa.eu,
1. **CONCLUSION FOR ENDORSEMENT**

**Regardless of the classification principle applied**, aerosols should be classified for health and environmental effects as follows depending on the case:

a) If the propellant or other gas is *not* released upon spraying it should not be taken into account for classification of the aerosols. However, if the propellant or other gas itself is classified as hazardous for health or the environment, that classification should be reflected in the label of the aerosol.

b) If the propellant or other gas *is* released upon spraying, but is separated from the other constituents of the mixture by the expected time of impact with the sprayed surface, it should also not be taken into account for classification of the mixture from which it is separated. However, if the propellant or other gas itself is classified as hazardous for health or the environment, that classification should be reflected in the label of the aerosol.

c) By contrast, if the propellant or other gas is partially or fully released upon spraying, and is not separated from the other constituents of the mixture by the expected time of impact with the sprayed surface, the released part of the gas should be taken into account for classification.

COM would like to ask CARACAL to endorse this conclusion. COM will subsequently contact ECHA in order to amend FAQ 1456. COM will also ask ECHA to adapt the Guidance on the Application of the CLP Criteria with regard to this topic, to reflect the amendments of the aerosol classification brought about by the 12th ATP and this endorsed conclusion.

2. **BACKGROUND AND REASONING**

The reasoning and background expressed in previous CARACAL meetings are repeated in the Annex for the reader’s convenience as well as the previous summaries of and responses to comments. References to the term “propellant” should be read as references to the concept of “propellant or other gas” throughout the text.

Below is a summary of the reasoning:

2.1. **Classification of aerosols by bridging principles**

Section 1.1.3.7 of Annex I to the CLP Regulation regulates how an aerosol form of a mixture shall be classified for health effects other than CMR in case bridging principles are applied, *i.e.* in case the aerosol form has *not* been tested but the non-aerosolised form *has* been tested (*c.f.* section 1.1.3 of Annex I). It (as amended through the 12th ATP) states that in such cases, the aerosol form shall be classified in the same hazard categories as the tested non-aerosolised form, provided that the added propellant does not affect the hazardous properties of the mixture upon spraying.

COM understands that “non-aerosolised” form excludes the propellant, and that the “aerosol form” simply means the form that must be classified, uses those concepts within those meanings throughout this note.

Section 1.1.3.7 of Annex I leaves the following questions open:
1) How shall an aerosol form of a mixture be classified in cases where the bridging principles are not applied?
2) When does an added propellant affect the hazardous properties of the mixture upon spraying?

2.2. Classification of aerosol forms by principles other than bridging

In a number of cases, the bridging principles in section 1.1.3.7 of Annex I cannot be directly applied in classifying an aerosol form of a mixture for health or environmental effects. This concerns first of all CMR classification, which is excluded from section 1.1.3.7 of Annex I, and which pursuant to Article 6(3) in the first place shall be based on the substances in the mixture. Second, it concerns classification for health effects other than CMR in cases where the mixture itself has been tested, which is excluded from the entire section 1.1.3 of Annex I, and which pursuant to Article 6(2) shall be based on the information available for the mixture itself. Third, it concerns all environmental effects, which are all excluded from section 1.1.3.7 of Annex I, and which pursuant to Articles 6(2) and 6(4) shall be based either on the information available for the mixture itself or on the substances in the mixture, as the case may be.

In all three cases, the question arises to what extent information relating to the non-aerosolised form (either to the substances contained in the non-aerosolised mixture, or to the non-aerosolised mixture itself) should form the basis for classifying the aerosol form.

It follows from the second subparagraph of Article 6(1) of CLP that mixtures shall be classified based on information related to the form in which they are placed on the market and, where relevant, can reasonably be expected to be used. For the purpose of defining the form in which aerosols are placed on the market and used, COM suggests that the bridging principles in section 1.1.3.7 of Annex I should be guiding also in the three cases referred to above. That is because it would not be justifiable to classify different forms of a mixture depending on the different classification principles applied. In other words, regardless of the classification principle applied, for health and environmental effects aerosols should be classified as the non-aerosolised form if the propellant does not affect the hazardous properties of the mixture upon spraying.

2.3. Propellant affecting the hazardous properties of the mixture

Regarding the question when an added propellant affects the hazardous properties of the mixture upon spraying, according to definition of aerosols under section 2.3. of Annex I to the CLP Regulation and based on the comments received after CARACAL-29, COM understands that gases are used either in compressed, liquefied or dissolved form. It is mentioned in the comments that compressed gases remain in the container/aerosol can. A first conclusion of COM is that to the extent the propellant is a gas (compressed, liquefied or dissolved) which remains in the receptacle, it does not affect the hazardous properties of the mixture upon spraying. Consequently, any propellant remaining in the receptacle should not be taken into account for the classification of an aerosol. However, as the propellant remains in the aerosol containers, in order to ensure adequate risk management measures at the waste stage, in particular in case of recycling, the classification for human health and the environment of the propellant should be reflected in the label of the aerosol containers. Second, COM understands based on the comments that liquefied gases can act as either solvents or propellants.

A solvent is released together with the active ingredients and stays in the same droplet/aerosol
state as the active ingredients (this would be similar to the concept of “non-dissociated” used in the previous conclusions). The solvent should thus be taken into account for classification.

By contrast, a propellant which is released as well from the receptacle will typically evaporate upon release, i.e. it does not stay in the same physical state, but is separated (“dissociates”) from the mixture. Thus, the propellant should not be taken into account for classification of the mixture which is separated from the propellant. In other words, the mixture separated from the propellant should be classified taking into account its own intrinsic hazardousness, or – depending on the classification method used – the hazardousness of its constituent substances in their concentration in the mixture separated from the propellant.

On the other hand, a propellant released from the receptacle and separated from the mixture will actually be released in its own right. Where both the mixture and the propellant are released and separated from each other, it is in fact not one mixture that is placed on the market and used, but two. Therefore, in such a situation, should the propellant as such be classified for health or environmental hazards, that classification would have to be labelled on the aerosol together with the labelling elements of the mixture from which it is separated upon spraying.

As suggested by the industry, the principle can be extended to other gases in an aerosol.

A remaining question is the timing of the gas’ separation from the mixture, or the meaning of “upon spraying” in section 1.1.3.7 of Annex I to the CLP Regulation. COM suggests that it means at the expected time of impact with the sprayed surface. The exact share of a gas which is released from a receptacle and non-separated from the mixture at the expected time of impact with the sprayed surface will inevitably be a case by case assessment.

3. **RESPONSE TO COMMENTS RECEIVED AFTER CARACAL-29**

<table>
<thead>
<tr>
<th>MS/Observer</th>
<th>Comments</th>
<th>COM response</th>
</tr>
</thead>
</table>
| DE          | - Overall support of the conclusions;  
- Strong support for the conclusion “Propellant is released together with the mixture upon spraying and the propellant is dissociated from the mixture upon use -> Propellant NOT to be taken into account”. This would be the most abundant situation concerning aerosol spray cans. It reflects that via spraying, mixture constituents are applied in much higher concentrations compared to their initial concentration when contained together with the propellant in the aerosol dispenser;  
- Drafting suggestions and proposal to split previous conclusion (i) into two parts:  
(ii) a. Propellant is released during use and does not dissociate: Propellant to be taken into account for classification if the propellant stays in the same droplet/aerosol composition as the other constituents of the released mixture upon or after use.  
(ii) b. Propellant is released during use and does dissociate: Propellant not to be taken into account for classification, if it undergoes a... | - COM thanks for support;  
- The conclusion was further developed in order to take into account the situation where the gas (propellant in compressed gases or propellant/solvent in liquefied gases) is bound to the active ingredients of the mixture and stays in the same composition as the other constituents. Gist of DE reasoning was taken-up in the proposed conclusions.  
- COM believes that (i)(b) is not needed;  
- On Guidance: Please see proposal above. |
<table>
<thead>
<tr>
<th><strong>Phase Transfer</strong></th>
<th><strong>Question whether it is necessary to include this topic in the Guidance on the Application of the CLP Criteria.</strong></th>
</tr>
</thead>
</table>
| **IE**            | - Overall support of the conclusions;  
|                   | - Specify that these conclusions refer to classification for health and environmental effects only;  
|                   | - Suggestion to add the wording “whereby the propellant is not taken into account for classification” for conclusion (i);  
|                   | - Support conclusion (ii) and amendment of FAQ 1456.                                                 |
| **UK**            | - The proposed way forward is overly simplistic and does not take into account the many but related variables/unknowns in the different scenarios where the propellant may or may not be released;  
|                   | - Considerations to what extent should the propellant evaporate before it is considered to be ‘dissociated’ from the mixture and therefore not included in the classification;  
|                   | - Agreed definition of the aerosolised and non-aerosolised form;  
|                   | - Question whether consideration should be given to revising the guidance on the application of the classification criteria. |
| **FEA – Comments** | - Concerns about former conclusion (i) and the term “dissociated”;  
| of 5 April 2019   | - Misunderstanding of the roles of liquefied gases used in aerosols;  
| and 19 March 2019 | - Liquefied gases are always mixed with the active substances upon use;  
|                   | - COM interpretation is exposure based given that the use phase is considered;  
|                   | - Proposal to use the word “gas” rather than “propellant”;  
|                   | - Suggestion to always take the gas into account when classifying if released during use, independently whether the gas is bound to the rest of the mixture;  
|                   | - Description in Appendix how aerosol dispensers function and main distinction between active ingredients, solvents, propellant gas;  
|                   | - Liquefied gases consist of solvents and propellant gas whereas compressed gases only consists of propellant gas;  
|                   | - Comparison of formulations for spray dispensers: If the propellant were to be excluded |
| **N/A**           | - COM thanks for support;  
|                   | - Reference to applicability made at the beginning of the conclusions and in the title of the paper. |
| **COM thanks for** | - COM thanks FEA for the comments and the useful information;  
| **comments and the useful** | - COM interpretation is based on Article 6(1) of CLP and not exposure based;  
| **information;**   | - Word “gas” rather than “propellant” is used;  
| **COM interpretation is** | - Aim is to classify mixture when used and if the gas is not separated from the other constituents of the mixture by the expected time of impact with the sprayed surface, the mixture would be under classified;  
| **based on Article 6(1)** | - New conclusions are based on the distinction between compressed and liquefied gases;  
| **of CLP and not**   | - With current conclusions the propellant of the liquefied gas should not be taken into account if it evaporates/is separated from the other constituents of the mixture. |
from the calculation for classification, the liquefied gas would be over-classified. mixture by the expected time of impact with the sprayed surface. The solvent (if released during use and not separated from the other constituents) should be taken into account.

| **DUCC** | Supports FEA comments. | COM takes note. |
Annex

CONCLUSIONS PRESENTED AT CARACAL-29

Regardless of the principle used for the health and environmental classification of aerosols, aerosols should be classified as follows depending on the case:

(i) **Propellant is released during use:** Propellant to be taken into account for classification, unless the propellant is dissociated from the mixture upon use.

(ii) **Propellant is not released during use:** Propellant not to be taken into account for classification.

COMPOSITION ON THE CLASSIFICATION OF AEROSOL MIXTURES FOR HEALTH AND ENVIRONMENTAL HAZARDS UNDER CLP IN THE CASE WHERE BRIDGING PRINCIPLES ARE NOT USED

COM maintains its position expressed in CA/53/2018. Below, the reasoning presented during CARACAL-27 and CARACAL-28 is repeated for the reader’s convenience.

The remaining question would be how aerosol mixtures should be classified when using the methods other than bridging principles, *i.e.* when the aerosol is classified based on available data on the mixture itself or on the additivity formula. This question concerns both (i) classification for CMR endpoints and (ii) classification for other endpoints.

As regards (i) classification for CMR endpoints, the general applicable classification method are the additivity rules given that the method to use available test data on the mixture itself is excluded for CMR endpoints by virtue of Article 6(3) of the CLP stating that the economic operators “shall only use the relevant available information […] for the substances in the mixture”. However, test data on the mixture itself may be used in the case of Article (6)3 para. 2, *i.e.* where the available test data on the mixture itself demonstrate CMR effects which have not been identified from the information on the individual substances.

For other endpoints the tiered approach applies, *i.e.* the identification, examination and evaluation of mixtures shall follow the three applicable methods: classification based on relevant information on the mixture itself (it remains to be determined whether testing is in that case done on the aerosolised or the non-aerosolised form; this is dependent on the scenario as explained below), application of bridging principles, application of additivity rules.

**Health and environmental classification of aerosol mixtures in case the bridging principles are not used**

It follows from the second subparagraph of Article 6(1) of CLP that mixtures shall be classified based on information related to the form in which they are placed on the market and, where relevant, can reasonably be expected to be used. In the case of aerosols, it can be argued that in some cases, the form in which the mixture is placed on the market – *i.e.* the aerosolised form – is different from the form in which it is used – *i.e.* the non-aerosolised form. The question therefore occurs which of the two forms should be reflected in the classification and communicated on the label of the aerosol for both cases when the aerosol is
classified based on available data on the mixture itself or on the additivity formula.

The Commission services’ conclusion is that the bridging principles should be guiding in this respect also for the other classification methods: also in these cases, the aerosol should be classified as the non-aerosolised form if the propellant does not affect the hazardous properties of the mixture upon spraying. This will typically be the case if the propellant is not released together with the mixture upon spraying. Such mixtures are placed on the market in the aerosolised form, but can reasonably be expected to be used in the non-aerosolised form. Pursuant to the second subparagraph of Article 6(1) of CLP, and in analogy with the bridging principles, the classification should reflect the form in which they can reasonably be expected to be used.

By contrast, the aerosol should not be classified as the non-aerosolised form when the propellant does affect the hazardous properties of the mixture upon spraying, e.g. because the propellant is released together with the mixture upon spraying and the propellant is associated to the mixture upon use – in short, one mixture only is released. Such an aerosol should also be classified in the form in which the entire mixture can reasonably be expected to be used, i.e. in the form which comes out upon spraying and in the case the propellant and the mixture are not dissociated from each other.

Conversely, if the mixture and the propellant were dissociated from each other, two mixtures and not one mixture would be released upon use and thus there would be no dilution effect affecting the hazardous properties of the mixture. If the propellant and the mixture were dissociated from each other upon use, one would fall back in scenario 1, in which the propellant does not affect the hazardous properties upon use and thus it should not be taken into account in the classification.

**BACKGROUND**

Industry representatives expressed their concerns about the publication of the ECHA FAQ 1456 entitled "When deciding on the classification of aerosol mixtures concerning
health and environmental effects, does the propellant have to be excluded”

1. FAQ 1456 states that when applying the calculation method the propellant has to be excluded, because otherwise this would result in a dilution effect, which would in particular not be line with the general approach taken in CLP concerning CMR substances.

According to industry representatives, the exclusion of the propellant for the hazard-based classification under CLP is not a minor issue and should be discussed at CARACAL level. The matter was brought up at the CASG-ATP meeting on 11-12 October 2017, at the CARACAL meetings held on 15-16 November 2017, 7-8 March 2018, 12 June 2018 and 21-22 November 2018. At CARACAL 27 in June COM presented paper Doc. CA/53/2018, explaining that while there is a link with the bridging principle on aerosols (in both GHS and CLP), COM is of the view that the issue goes beyond the correct interpretation of the application of bridging principles in the case of aerosols. Thus, an approach for the classification of aerosols using the calculation method was also presented. Point 3 of Doc. CA/53/2018 was divided into two scenarios:

1) Bridging principles for aerosol classification and the CLP alignment to GHS;
2) Aerosol classification where the bridging principles are not used.

Under Scenario 1) a draft text was proposed for point 1.1.3.7 of Annex I to CLP, based on the discussions on the related text at GHS level. The proposed text was taken up in the 12th

---

1 Answer to FAQ 1456: Yes, the propellant has to be excluded, provided that it does not affect the hazardous properties of the aerosol mixture and there is scientific evidence available that shows the aerosolised form is not more hazardous than the non-aerosolised form.

The aerosol bridging principle, set out in Annex 1.1.3.7, requires the aerosol form of a mixture to be classified in the same hazard category as the non-aerosol form of a tested mixture. The bridging principle does not apply to the CMR hazard classes.

However, a similar approach should generally be used where methods, other than bridging principles, are applied for the classification of mixtures, especially for mixtures containing CMR substances. Where the calculation method includes the propellant, this results in a dilution effect of CMR substances, which is not in line with the general approach taken in CLP concerning CMR substances in mixtures. Further, this would not reflect the actual hazards of the mixture, as it is placed on the market, since the propellant normally evaporates.

It is therefore recommended to exclude the propellant for the identification of health and environmental hazards of aerosols provided that it does not affect the hazardous properties of the aerosol.

In practice, this means that, for example, when considering the classification of an aerosol, where the non-aerosolised form of a mixture contains 1.2 % of a carcinogen (Carc. cat. 2), this should be included in the classification of the aerosol regardless of the amount of propellant added. So, where a mixture consists of 33 % propellant and 67 % non-aerosolised form, which nominally would bring down the concentration of the carcinogen to 0.8 %, the mixture would still be classified.

2 The bridging principle for aerosols provided for in 1.1.3.7 of Annex I of CLP cannot be applied to CMR substances (see Article 6(3) of CLP), thus for mixtures containing CMR substances the calculation rules would be applicable in all cases where no information based on the aerosolised mixture itself is available.

3 https://circabc.europa.eu/ui/group/8a073cb6-03cb-4665-a866-4a17b17a6f60/library/32c81b1b-cb15-4200-a64c-2e92571de39f/details

4 “1.1.3.7. Aerosols: In the case of the classification of mixtures covered by sections 3.1, 3.2, 3.3, 3.4, 3.8 and 3.9, an aerosol form of a mixture shall be classified in the same hazard category as the tested non-aerosolised form of the mixture, provided that the added propellant does not affect the hazardous properties of the mixture upon spraying”.
ATP to CLP, which received a favourable vote at the REACH Committee meeting of 28-29 September 2018.

Scenario 2) was further presented and discussed at CARACAL 28 and COM presented its conclusions in CA/121/2018. Further comments were raised by MSs during the meeting and received after CARACAL 28.

A summary of and a response to comments is provided in Annex.
## SUMMARY OF AND RESPONSE TO COMMENTS RECEIVED

### SUMMARY OF AND RESPONSE TO COMMENTS RECEIVED AFTER CARACAL 27 ON DOC CA/53/2018

<table>
<thead>
<tr>
<th>MS/Observer</th>
<th>Comments on 1) Bridging principles for aerosol classification and the CLP alignment to GHS 2) Aerosol classification where the bridging principles are not used</th>
<th>COM response</th>
</tr>
</thead>
<tbody>
<tr>
<td>DK</td>
<td>1) Support for the wording.</td>
<td>COM thanks for the comments.</td>
</tr>
<tr>
<td></td>
<td>2) Support for the COM’s interpretation. By this interpretation the propellants are taken into account only when they are “released during use or otherwise affecting the hazardous properties of the mixture upon use”. If this interpretation is generally supported a new FAQ should be elaborated or the guidance updated to ensure common understanding.</td>
<td>COM takes note of the support and agrees that a new FAQ should be elaborated if its interpretation is endorsed.</td>
</tr>
<tr>
<td>DE</td>
<td>1) Support for the wording.</td>
<td>COM thanks for the comments.</td>
</tr>
<tr>
<td></td>
<td>2) The wording in document CA/53/2018 “where the propellant is not released together with the mixture upon spraying” would not be appropriate for DE’s understanding, because especially cases where the propellant is released together with the mixture upon spraying give rise to many questions and uncertainties. In their opinion also in these cases the propellant should not be used as diluting factor for the health hazardous properties of the mixture, especially not in case of CMR substances. Thus also in using the calculation method the propellant should usually not be included in determining the classification of a mixture.</td>
<td>COM thanks DE for the comments. Concrete examples of such cases where the release of the propellant leads to more uncertainties would be very welcomed. COM’s interpretation does not necessarily imply a potential ‘downgrading’ of classification in case the propellant is taken into account. When the propellant is released, it is to be assessed for each case what the impact is on the classification of the mixture in its totality.</td>
</tr>
<tr>
<td>NO</td>
<td>1) Support.</td>
<td>COM thanks for the comments.</td>
</tr>
<tr>
<td></td>
<td>2) Support.</td>
<td>COM thanks for the comments.</td>
</tr>
<tr>
<td>DUCC</td>
<td>1) Support.</td>
<td>COM thanks for the comments.</td>
</tr>
<tr>
<td></td>
<td>2) Supports position of FEA.</td>
<td>Please see below.</td>
</tr>
<tr>
<td>FEA</td>
<td>1) FEA fully supports the full alignment on the text of the UN GHS as proposed.</td>
<td>COM thanks for the comments.</td>
</tr>
<tr>
<td></td>
<td>2) FEA agrees only partially with the COM interpretation.</td>
<td>COM takes note of FEA’s comments. Further explanation of COM’s position on the inclusion of the propellant for classification is given in section 3 below.</td>
</tr>
<tr>
<td></td>
<td><strong>FEA agrees that:</strong></td>
<td>- the liquefied gas should be included in the</td>
</tr>
</tbody>
</table>
calculation when it is expelled and excluded when it is not expelled;

**FEA does not agree that:**

- the rule applied to the bridging principles should be extended to the application of the calculation method, i.e. that in case the propellant affects the hazardous properties of a mixture upon spraying/use, it should always be taken into account, regardless whether the propellant is released or not during use. As proposed by COM, the propellant can only be taken into account in the calculation (and thus a less severe classification might be applied) in case the propellant does not affect the hazardous properties of a mixture upon spraying/use.

**FEA is of opinion** that the concept of the bridging principle should not be extended to the already conservative calculation method. When the aerosol is classified based on available test data for the full mixture i.e. in the formulation as it exists in the aerosol dispenser, then the gas has been tested with the rest of the formulation and is *de facto* included.

It should be noted that in general - for classification based on test data - for CMR endpoints, test data on the mixture itself are not allowed for classification purposes according to CLP Art. 6(3) (contrary to what seems to be suggested in FEA’s comment). Instead, test data on the individual substances contained in the mixture shall be used.

As explained in section 3 below, when using test data, classification is to be done based on the aerosolised or the non-aerosolised form, depending on the scenario (propellant release or not). But in any event, regardless of the mixture used as a basis for classification (aerosolised or non-aerosolised), for CMR endpoints, only test data on the individual substances in that mixture can be used while for other endpoints data on the entire mixture (aerosolised or not) are allowed.

---

**SUMMARY OF AND RESPONSE TO COMMENTS AFTER CARACAL 28 ON DOC. CA/121/2018**

<table>
<thead>
<tr>
<th>SUMMARY OF COMMENTS</th>
<th>COMMISSION’S COMMENTS</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>It should be noted that in general - for classification based on test data - for CMR endpoints, test data on the mixture itself are not allowed for classification purposes according to CLP Art. 6(3) (contrary to what seems to be suggested in FEA’s comment). Instead, test data on the individual substances contained in the mixture shall be used. As explained in section 3 below, when using test data, classification is to be done based on the aerosolised or the non-aerosolised form, depending on the scenario (propellant release or not). But in any event, regardless of the mixture used as a basis for classification (aerosolised or non-aerosolised), for CMR endpoints, only test data on the individual substances in that mixture can be used while for other endpoints data on the entire mixture (aerosolised or not) are allowed.</td>
</tr>
</tbody>
</table>
IE

- IE appreciates this paper from the Commission on the classification of aerosols and generally agrees with the Commission.

- Overall, IE can support the paper but it will need to clarify the classification and labelling obligations when the mixture and the propellant are in separate compartments within a single aerosol package. IE has some concerns regarding the use of the aerosol bridging principle to determine how to classify an aerosol using the additivity approach. CLP uses a tiered approach, so if there is information on the mixture itself (i.e. it is tested), then the aerosol bridging principle can be used. However, where the mixture is not tested, the next step is to use the additivity approach. In doing so, the user needs to revert to Article 6(1) which refers to “the forms and physical states” and “reasonably be expected to be used”.

- As the expertise for physical hazards lies with the United Nations Sub Committee of Experts for the Transport of Dangerous Goods (UNSCETDG), we also suggest that this is also discussed with DG MOVE colleagues, who can, in turn bring it to the UNSCETDG for their attention.

On the different conclusions presented in the Caracal paper:

- (1) Propellant is released during use. Propellant to be taken into account for classification: IE agrees with this, as the propellant, in this case, is part of the mixture. Therefore, when using the additivity approach, the propellant is included in the overall calculation. Notwithstanding the provisions of the Aerosol Dispensers Directive, we understand that any aerosolised mixture would, in addition to any health or environmental hazards, be classified as category 3 aerosol (H229), in accordance with Section 2.3 (Aerosols) of CLP.

- (2) Propellant is not released during use but affects the hazardous properties of the mixture upon use. Propellant to be taken into account for classification: While IE sees merit in the Commission proposal, we are not sure if the paper gives sufficient clarity on the final classification of the product. As the propellant and the mixture are (or appear to be) in separate containers within the aerosol packaging it still needs to be classified and labelled separately such as in the example of a coaxial cartridge containing two separate mixtures within one packaging.

- (3) Propellant is not released during use and does not in any other manner affect the hazardous properties of the mixture upon use. Propellant is not taken into account for classification: IE considers that greater clarification on what is meant by the phrase ‘any other manner’ would be useful here. While there may be a case where the propellant is not released and doesn’t affect the overall hazardous properties

COM

- COM thanks IE for the input;

- In COM’s view separate classification and labelling for both the propellant and the mixtures is too complicated. Consumers might be confused about seeing labelling for two mixtures on the package and industry would have the double burden;

- The tiered approach of CLP should also be used in the case of classification of aerosol mixtures. However, for CMR endpoints, the only applicable classification method are the additivity rules, because Article 6(3) of CLP provides that the relevant information in paragraph (1) shall only be used for the substances (and not the mixture) in the mixture.

- We would not involve our colleagues in DG MOVE, since this is a pure issue on CLP and COM believes that it can be dealt with by this expert group.

- (1) Please see new COM conclusion that makes two differentiations of point (1) taking into account other MS’s comments. Indeed, Section 2.3 (Aerosols) would continue to apply.

- (2) Please see new COM conclusion in which point (2) is deleted. COM believes that separate classification and labelling for both the propellant and the mixtures is too complicated. Consumers might be confused about seeing labelling for two mixtures on the package and industry would have the double burden. As far as we know, this would not solve the problem for those cases in which the propellant and the mixture are not contained in different departments.

- In revised point (3) the sentence “in any other manner affect the hazardous properties of the mixture upon use” is deleted. Section 2.3 of Annex I to CLP on Aerosols continues to apply.
of the product, given that all aerosols under pressure need to be classified with at least category 3 (H229). IE questions a conclusion stating that the propellant is not taken into account for classification. In any case, the propellant will need to be taken into account for the purpose of complying with the Aerosol Dispensers Directive.

| NL | NL agrees with the Commissions proposed approach. |
|    | COM thanks NL for the support. |
| SK | SK competent authority agrees with COM’s interpretation of principle for the classification of aerosols, when aerosols should be classified as follows depending on the case: |
|    | 1) Propellant is released during use: Propellant to be taken into account for classification. |
|    | 2) Propellant is not released during use but affects the hazardous properties of the mixture upon use: Propellant to be taken into account for classification. |
|    | 3) Propellant is not released during use and does not in any other manner affect the hazardous properties of the mixture upon use: Propellant not to be taken into account for classification |
|    | COM thanks SK for the support and hopes that SK can also agree with the new proposed solution. |
| DE | Comments received on 10 January 2019 |
|    | DE considers that the Commission basically proposes to use the aerosol specific bridging principle in section 1.1.3.7 of Annex I CLP also as guidance in cases, where the application of the bridging principles is not foreseen (e.g. for carcinogenic properties). DE fully agrees to this position. |
|    | However, DE cannot support the conclusions drawn in paragraphs (i) to (iii) on the last page of the mentioned document. DE outlined in its previous comment, that for CMR properties the application of the concentration limits leads to a less severe classification, in case the propellant is included in the calculation. The level of protection for mixtures in aerosolised form would thus be considerably lower than for liquid mixtures which are not sprayed. From a human health perspective, this does not seem to be justified, as sprayed aerosols would at least be considered for the same hazard category as the same mixture in non-aerosolised form (being applied without spraying). |
|    | The discussion during the last meetings indicated, that the topic is quite complex. There were considerable concerns expressed by the aerosol associations, fundamentally challenging our position and the already published FAQ on ECHAs website. Also other member states expressed difficulties to find an appropriate solution. Therefore DE would like to propose a more in depth discussion within CARACAL or e.g. its subgroup on ATPs. According to DE, it would be necessary to find a common |
|    | COM thanks DE for the support. |
|    | COM understands DE’s concerns and hopes that the new proposed solution, which tries to address this issue, can be acceptable. |
Comments received on 14 March 2019:

- DE would like to highlight again, that for CMR properties the application of the concentration limits lead to a less severe classification, in case the propellant is included in the calculation. The level of protection for mixtures in aerosolised form would thus be considerably lower than for liquid mixtures, which are not sprayed. This can hardly be justified.

- DE supports the comments submitted by FR as follow up of the 28th CARACAL and relate directly to the items (i)-(iii) provided in document CA/121/2018, section 3.1:
  - Item "(i) Propellant is released during use: Propellant to be taken into account for classification."
  DE also asks the question what happens when the aerosol is released. The aerosol will consist of two different physical forms with different ingredients. The propellant will be transferred to the gas phase and stay there because of rapid evaporation. In addition there will be droplets which contain the remaining active and concentrated mixture. For the intended use only the droplets are needed which are finely dispersed by the spraying procedure for better application. DE is of the view that thus classification should reflect the properties of these droplets as accurate as possible.
  - Item "(ii) Propellant is not released during use but affects the hazardous properties of the mixture upon use: Propellant to be taken into account for classification."
  Also DE agrees that there are no examples for this situation.
  - Item "(iii) Propellant is not released during use and does not in any other manner affect the hazardous properties of the mixture upon use: Propellant not to be taken into account for classification."
  DE supports the FR comment that the hazards of propellant and mixture should both be assessed separately and hazard information should be provided in a similar manner as for two-component-systems described in the ECHA guidance document on labelling and packaging.

- COM understands DE’s concerns and hopes that the new proposed solution, which tries to address this issue, can be acceptable.

- On Item (i): COM welcomes the FR and now also DE suggestion and has tried to take this proposed solution up in the revised formulation of conclusion (1).

- On Item (ii): Conclusion (ii) has been deleted.

- On Item (iii): COM is of the view that taking into account the propellant would create a dilution effect in case of environmental/health hazard classification of aerosols. Thus, also in case of accidents, if the propellant were not taken into account in the classification, the latter would be more severe.

FR

- FR agrees with the Commission that Article 6(1) of CLP can be applied for the specific case of aerosols.
- FR considers that there is no need to distinguish CMR from other hazards.
- (i) Propellant is released during use: Propellant to be

- COM thanks FR for the support.
taken into account for classification. According to FR, the question is not “is the propellant released?” but “if the propellant is released, does it stay mixed with the aerosol?”. If upon released the propellant and the aerosol are dissociated, the classification should be based on the propellant in its pure form and on the mixture without the propellant as users will be exposed to the two different phases. This point is of particular interest for irritant, corrosive or sensitising mixture where the substance concentration on the site of contact directly drives the effect.

- (ii) Propellant is not released during use but affects the hazardous properties of the mixture upon use: Propellant to be taken into account for classification. FR did not identified examples for this case.

- (iii) Propellant is not released during use and does not in any other manner affect the hazardous properties of the mixture upon use: Propellant not to be taken into account for classification. According to FR, as exposure can occur in case of accident (eg breach in the can etc…), even if it is not released during a normal use, the hazard of the propellant should be assessed as it is done for two components products.

| FEA | Concerning the classification under the bridging principles (point 1.1.3.7 of Annex I to CLP), FEA supported the new text proposed in the 12th ATP to CLP1, which received a favourable vote at the REACH Committee meeting of 28-29 September 2018.

FEA also supports in principle the conclusion laid down in doc. CA/121/2018 but is not aware of any cases where option (ii)2 will apply. FEA therefore suggests streamlining the conclusion to avoid any ambiguity and possible new divergent interpretations by amending the general conclusion to read (additions are **bold underlined**, deletions are **stricken through**):

In conclusion regardless of the principle used for the health and environmental classification of aerosols, aerosols should be classified as follows depending on the case:

(i) **The** (propellant) **gas** is released during use: (Propellant) **gas** to be taken into account for classification.

(ii) (ii) Propellant is not released during use but affects the hazardous properties of the mixture upon use: Propellant to be taken into account for classification: (iii)

(iii) **The** (propellant) **gas** is not released during use and does not in any other manner affect the hazardous properties of the mixture upon use: (Propellant) **gas** not to be taken into account for classification.

| COM | and has tried to take this proposed solution up in the revised formulation of conclusion (1).

- Conclusion (ii) has been deleted.

- COM is of the view that taking into account the propellant would create a dilution effect in case of environmental/health classification. Thus, also in case of accidents, if the propellant were not taken into account in the classification, the latter would be more severe.

| FEA | COM thanks FEA for the support.

- Option (ii) is deleted.

- COM thanks FEA for including the specification that this interpretation applies to the health and environmental classification of aerosols.

- COM will take-up the formal suggestions in bold.

- In option (iii) the suggested deletion is taken-up.
| **DUCC** | **FAQ 1456 should then be amended accordingly.** | **DUCC confirmed its support for the comments submitted by its member organisation FEA (European Aerosols Federation) on 11 January 2019.** | **COM notes this support.** |