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<Commission>{ENVI}Committee on the Environment, Public Health and Food Safety</Commission>

<RefProc>2022/0432</RefProc><RefTypeProc>(COD)</RefTypeProc>

<Date>{16/05/2023}16.5.2023</Date>

<TypeAM>AMENDMENTS</TypeAM>

<RangeAM>296 - 329</RangeAM>

<TitreType>Draft report</TitreType>

<Rapporteur>Maria Spyraki</Rapporteur>

<DocRefPE>(PE745.493v01-00)</DocRefPE>

<Titre>proposal for a regulation of the European Parliament and of the Council amending Regulation (EC) No 1272/2008 of the European Parliament and of the Council on classification, labelling and packaging of substances and mixtures</Titre>

<DocAmend>Proposal for a regulation</DocAmend>

<DocRef>(COM(2022)0748 – C9‑0433/2022 – 2022/0432(COD))</DocRef>

AM\_Com\_LegReport

<RepeatBlock-Amend><Amend>Amendment <NumAm>296</NumAm>

<RepeatBlock-By><Members>Jutta Paulus</Members>

</RepeatBlock-By>

<DocAmend>Proposal for a regulation</DocAmend>

<Article>Annex I – paragraph 1 – point 1</Article>

<DocAmend2>Regulation (EC) No 1272/2008</DocAmend2>

<Article2>Annex I – Part 1 – point 1.1.1.3</Article2>

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| Text proposed by the Commission | Amendment |
| 1.1.1.3. A weight of evidence determination means that all available information bearing on the determination of hazard is considered together, such as the results of suitable in vitro tests, relevant animal data, human experience such as occupational data and data from accident databases, epidemiological and clinical studies and well-documented case reports and observations. For substances, information from the application of the category approach (grouping, read-across) ***and*** (Q)SAR results are also considered. The quality and consistency of the data shall be given appropriate weight. Information on substances related to the substance being classified shall be considered, as appropriate. Information on substances or mixtures related to the mixture being classified shall be considered in accordance with Article 9(4). Information on the site of action and the mechanism or mode of action study results shall also be considered. Both positive and negative results shall be assembled together in a single weight of evidence determination.; | 1.1.1.3. A weight of evidence determination means that all available information bearing on the determination of hazard is considered together, such as the results of suitable in vitro tests***, results of adequate non-mammalian embryo models such as aquatic eleutheroembryos as well as invertebrate species***, relevant animal data, human experience such as occupational data and data from accident databases, epidemiological and clinical studies and well-documented case reports and observations. For substances, information from the application of the category approach (grouping, read-across)***,*** (Q)SAR***, and omics'*** results are also considered. The quality and consistency of the data shall be given appropriate weight. Information on substances related to the substance being classified shall be considered, as appropriate. Information on substances or mixtures related to the mixture being classified shall be considered in accordance with Article 9(4). Information on the site of action and the mechanism or mode of action study results shall also be considered. Both positive and negative results shall be assembled together in a single weight of evidence determination; |

Or. <Original>{EN}en</Original>

<TitreJust>Justification</TitreJust>

Testing for endocrine properties will create the need of additional testing. It is therefore important that alternative methods such as the use of non-mammalian embryo models or of using invertebrate species as well as omics are used where adequate.

</Amend>

<Amend>Amendment <NumAm>297</NumAm>

<RepeatBlock-By><Members>Pietro Fiocchi</Members>

</RepeatBlock-By>

<DocAmend>Proposal for a regulation</DocAmend>

<Article>Annex I – paragraph 1 – point 2</Article>

<DocAmend2>Regulation (EC) No 1272/2008</DocAmend2>

<Article2>Annex I – part 1 – section 1.2.1.4</Article2>

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| Text proposed by the Commission | Amendment |
| The dimensions of the label and of each pictogram***, and the font size of letters*** shall be as follows: | The dimensions of the label and of each pictogram shall be as follows: |
|  | *(This amendment applies throughout the text. Adopting it will necessitate corresponding changes throughout.)* |

Or. <Original>{EN}en</Original>

(Annex I, 1.2.1.4)

<TitreJust>Justification</TitreJust>

As noted in the ECHA Guidance on labelling and packaging in accordance with Regulation (EC) No 1272/2008 Version 4.2 March 2021 – “Readability is determined by the combination of font size, letter spacing, spacing between lines, stroke width, type colour, typeface, width-height ratio of the letters, the surface of the material and significant contrast between the print and the background. ”Overly prescriptive additional requirements regarding font size, distance between two lines and background colour are not justified and severely limit the flexibility of suppliers It is sufficient if the label or fold-out label is easily readable and clearly stand out from the background. In fact, the additional requirements would hinder the free movement of products in the Single Market, which in turn would entail an adjustment of logistics.

</Amend>

<Amend>Amendment <NumAm>298</NumAm>

<RepeatBlock-By><Members>Pietro Fiocchi</Members>

</RepeatBlock-By>

<DocAmend>Proposal for a regulation</DocAmend>

<Article>Annex I – paragraph 1 – point 2</Article>

<DocAmend2>Regulation (EC) No 1272/2008</DocAmend2>

<Article2>Annex I – part 1 – section 1.2.1.4. – Table 1.3 – title</Article2>

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| Text proposed by the Commission | Amendment |
| Minimum dimensions of labels***,*** pictograms ***and font size*** | Minimum dimensions of labels ***and*** pictograms |
|  | *(This amendment applies throughout the text. Adopting it will necessitate corresponding changes throughout.)* |

Or. <Original>{EN}en</Original>

(Annex I, 1.2.1.4)

<TitreJust>Justification</TitreJust>

As noted in the ECHA Guidance on labelling and packaging in accordance with Regulation (EC) No 1272/2008 Version 4.2 March 2021 – “Readability is determined by the combination of font size, letter spacing, spacing between lines, stroke width, type colour, typeface, width-height ratio of the letters, the surface of the material and significant contrast between the print and the background.”

</Amend>

<Amend>Amendment <NumAm>299</NumAm>

<RepeatBlock-By><Members>Pietro Fiocchi</Members>

</RepeatBlock-By>

<DocAmend>Proposal for a regulation</DocAmend>

<Article>Annex I – Paragraph 1 – point 2</Article>

<DocAmend2>Regulation (EU) No 1272/2008</DocAmend2>

<Article2>Annex I – Part 1 – Section 1.2.1.4. – Table 1.3</Article2>

*Text proposed by the Commission*

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| Capacity of the package  | Dimensions of the label (in millimetres) for the information required by Article 17 | Dimensions of each pictogram (in millimetres) | ***Minimum font-size*** |
| Not exceeding 3 litres:  | If possible, at least 52x74 | Not smaller than 10x10If possible, at least 16x16 | ***8pt*** |
| Greater than 3 litres but not exceeding 50 litres:  | At least 74x105 | At least 23x23 | ***12pt*** |
| Greater than 50 litres but not exceeding 500 litres:  | At least 105x148 | At least 32x32 | ***16pt*** |
| Greater than 500 litres: | At least 148x210 | At least 46x46 | ***20pt’;*** |

*Amendment*

|  |  |  |  |
| --- | --- | --- | --- |
| Capacity of the package  | Dimensions of the label (in millimetres) for the information required by Article 17 | Dimensions of each pictogram (in millimetres) |  |
| Not exceeding 3 litres:  | If possible, at least 52x74 | Not smaller than 10x10If possible, at least 16x16 |  |
| Greater than 3 litres but not exceeding 50 litres:  | At least 74x105 | At least 23x23 |  |
| Greater than 50 litres but not exceeding 500 litres:  | At least 105x148 | At least 32x32 |  |
| Greater than 500 litres: | At least 148x210 | At least 46x46 |  |

Or. <Original>{EN}en</Original>

<TitreJust>Justification</TitreJust>

 As noted in the ECHA Guidance on labelling and packaging in accordance with Regulation (EC) No 1272/2008 Version 4.2 March 2021 – “Readability is determined by the combination of font size, letter spacing, spacing between lines, stroke width, type colour, typeface, width-height ratio of the letters, the surface of the material and significant contrast between the print and the background.” Overly prescriptive additional requirements regarding font size, distance between two lines and background colour are not justified and severely limit the flexibility of suppliers It is sufficient if the label or foldout label is easily readable and clearly stand out from the background. In fact, the additional requirements would hinder the free movement of products in the Single Market, which in turn would entail an adjustment of logistics.

</Amend>

<Amend>Amendment <NumAm>300</NumAm>

<RepeatBlock-By><Members>Danilo Oscar Lancini, Maria Veronica Rossi, Aurélia Beigneux, Elisabetta De Blasis, Rosanna Conte</Members>

</RepeatBlock-By>

<DocAmend>Proposal for a regulation</DocAmend>

<Article>Annex I – Paragraph 1 – point 2</Article>

<DocAmend2>Regulation (EU) No 1272/2008</DocAmend2>

<Article2>Annex I – Part 1 – Section 1.2.1.4. – Table 1.3</Article2>

*Text proposed by the Commission*

|  |  |  |  |
| --- | --- | --- | --- |
| Capacity of the package  | Dimensions of the label (in millimetres) for the information required by Article 17 | Dimensions of each pictogram (in millimetres) | ***Minimum font-size*** |
| Not exceeding 3 litres:  | If possible, at least 52x74 | Not smaller than 10x10If possible, at least 16x16 | ***8pt*** |
| Greater than 3 litres but not exceeding 50 litres:  | At least 74x105 | At least 23x23 | ***12pt*** |
| Greater than 50 litres but not exceeding 500 litres:  | At least 105x148 | At least 32x32 | ***16pt*** |
| Greater than 500 litres: | At least 148x210 | At least 46x46 | ***20pt’;*** |

*Amendment*

|  |  |  |  |
| --- | --- | --- | --- |
| Capacity of the package  | Dimensions of the label (in millimetres) for the information required by Article 17 | Dimensions of each pictogram (in millimetres) |  |
| Not exceeding 3 litres:  | If possible, at least 52x74 | Not smaller than 10x10If possible, at least 16x16 |  |
| Greater than 3 litres but not exceeding 50 litres:  | At least 74x105 | At least 23x23 |  |
| Greater than 50 litres but not exceeding 500 litres:  | At least 105x148 | At least 32x32 |  |
| Greater than 500 litres: | At least 148x210 | At least 46x46 |  |

Or. <Original>{EN}en</Original>

</Amend>

<Amend>Amendment <NumAm>301</NumAm>

<RepeatBlock-By><Members>Danilo Oscar Lancini, Silvia Sardone, Matteo Adinolfi, Rosanna Conte, Gianantonio Da Re, Gianna Gancia, Maria Veronica Rossi, Aurélia Beigneux, Elisabetta De Blasis</Members>

</RepeatBlock-By>

<DocAmend>Proposal for a regulation</DocAmend>

<Article>Annex I – paragraph 1 – point 3</Article>

<DocAmend2>Regulation (EU) No 1272/2008</DocAmend2>

<Article2>Annex I – Part 1 – Section 1.2.1.5</Article2>

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|  |
| Text proposed by the Commission | Amendment |
| ***1.2.1.5. The text on the label shall have the following characteristics:*** | ***deleted*** |
| ***(a) the background of the label shall be white;*** |  |
| ***(b) the distance between two lines shall be equal or above 120 % of the font size;*** |  |
| ***(c) a single font shall be used that is easily legible and without serifs;*** |  |
| ***(d) the letter spacing shall be appropriate for the selected font to be comfortably legible.*** |  |
| ***For the labelling of inner packaging where the contents do not exceed 10 ml, the font size may be smaller than indicated in Table 1.3, as long as it remains legible for a person with average eyesight, where itis deemed important to place the most critical hazard statement and where the outer packaging meets the requirements of Article 17.*** |  |
|  | *(This amendment applies throughout the text. Adopting it will necessitate corresponding changes throughout.)* |

Or. <Original>{EN}en</Original>

</Amend>

<Amend>Amendment <NumAm>302</NumAm>

<RepeatBlock-By><Members>Pietro Fiocchi</Members>

</RepeatBlock-By>

<DocAmend>Proposal for a regulation</DocAmend>

<Article>Annex I – paragraph 1 – point 3</Article>

<DocAmend2>Regulation (EC) No 1272/2008</DocAmend2>

<Article2>Annex I – Part 1 – point 2– Section 1.2.1.5</Article2>

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|  |
| Text proposed by the Commission | Amendment |
| ***1.2.1.5. The text on the label shall have the following characteristics:*** | ***deleted*** |
| ***(a) the background of the label shall be white;*** |  |
| ***(b) the distance between two lines shall be equal or above 120 % of the font size;*** |  |
| ***(c) a single font shall be used that is easily legible and without serifs;*** |  |
| ***(d) the letter spacing shall be appropriate for the selected font to be comfortably legible.*** |  |
| ***For the labelling of inner packaging where the contents do not exceed 10 ml, the font size may be smaller than indicated in Table 1.3, as long as it remains legible for a person with average eyesight, where itis deemed important to place the most critical hazard statement and where the outer packaging meets the requirements of Article 17.*** |  |
|  | *(This amendment applies throughout the text. Adopting it will necessitate corresponding changes throughout.)* |

Or. <Original>{EN}en</Original>

<TitreJust>Justification</TitreJust>

It is not appropriate to establish strict rules for the format of labels, as the current provisions reported in the article 31(3) of the CLP Regulation and the relative Annex I - part I – point 2- section 1.2.1.4 – table 1.3 –are sufficient to guarantee the correct legibility and flexibility of the text elements in the label. In order to improve the formatting of labels, more label examples could be added in the Guidance on Labelling and Packaging, as suggested in the recital 11.

</Amend>

<Amend>Amendment <NumAm>303</NumAm>

<RepeatBlock-By><Members>Pietro Fiocchi</Members>

</RepeatBlock-By>

<DocAmend>Proposal for a regulation</DocAmend>

<Article>Annex I – paragraph 1 – point 3</Article>

<DocAmend2>Regulation (EC) No 1272/2008</DocAmend2>

<Article2>Annex I – Part 1 – Section 1.2.1.5</Article2>

|  |
| --- |
|  |
| Text proposed by the Commission | Amendment |
| ***The text on the label shall have the following characteristics:*** | ***deleted*** |
| ***(a) the background of the label shall be white;*** |  |
| ***(b) the distance between two lines shall be equal or above 120 % of the font size;*** |  |
| ***(c) a single font shall be used that is easily legible and without serifs;*** |  |
| ***(d) the letter spacing shall be appropriate for the selected font to be comfortably legible.*** |  |
|  | *(This amendment applies throughout the text. Adopting it will necessitate corresponding changes throughout.)* |

Or. <Original>{EN}en</Original>

<TitreJust>Justification</TitreJust>

As noted in the ECHA Guidance on labelling and packaging in accordance with Regulation (EC) No 1272/2008 Version 4.2 March 2021 – “Readability is determined by the combination of font size, letter spacing, spacing between lines, stroke width, type colour, typeface, width-height ratio of the letters, the surface of the material and significant contrast between the print and the background.”Overly prescriptive additional requirements regarding font size, distance between two lines and background colour are not justified and severely limit the flexibility of suppliers. It is sufficient if the label or fold-out label is easily readable and clearly stand out from the background. In fact, the additional requirements would hinder the free movement of products in the Single Market, which in turn would entail an adjustment of logistics.

</Amend>

<Amend>Amendment <NumAm>304</NumAm>

<RepeatBlock-By><Members>João Albuquerque, Sara Cerdas</Members>

</RepeatBlock-By>

<DocAmend>Proposal for a regulation</DocAmend>

<Article>Annex I – paragraph 1 – point 3</Article>

<DocAmend2>Regulation (EC) No 1272/2008</DocAmend2>

<Article2>Annex I – Part 1 – Section 1.2.1.5. – point a a (new)</Article2>

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|  |
| Text proposed by the Commission | Amendment |
|  | ***(aa) there is a significant contrast between the print and the background;*** |

Or. <Original>{EN}en</Original>

</Amend>

<Amend>Amendment <NumAm>305</NumAm>

<RepeatBlock-By><Members>João Albuquerque, Sara Cerdas</Members>

</RepeatBlock-By>

<DocAmend>Proposal for a regulation</DocAmend>

<Article>Annex I – paragraph 1 – point 3</Article>

<DocAmend2>Regulation (EC) No 1272/2008</DocAmend2>

<Article2>Annex I – Part 1 – Section 1.2.1.5. – point d a (new)</Article2>

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| Text proposed by the Commission | Amendment |
|  | ***(da) the label elements provided in accordance with Articles 18, 20 and 21 shall be emphasised through a typeset that clearly distinguishes it from the rest of the text for example by means of the colour or style.*** |

Or. <Original>{EN}en</Original>

</Amend>

<Amend>Amendment <NumAm>306</NumAm>

<RepeatBlock-By><Members>Pietro Fiocchi</Members>

</RepeatBlock-By>

<DocAmend>Proposal for a regulation</DocAmend>

<Article>Annex I – paragraph 1 – point 3</Article>

<DocAmend2>Regulation (EC) No 1272/2008</DocAmend2>

<Article2>Annex I – Part 1 – Section 1.2.1.5 – paragraph 2</Article2>

|  |
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|  |
| Text proposed by the Commission | Amendment |
| ***For the labelling of inner packaging where the contents do not exceed 10 ml, the font size may be smaller than indicated in Table 1.3, as long as it remains legible for a person with average eyesight, where itis deemed important to place the most critical hazard statement and where the outer packaging meets the requirements of Article 17.*** | ***deleted*** |
|  | *(This amendment applies throughout the text. Adopting it will necessitate corresponding changes throughout.)* |

Or. <Original>{EN}en</Original>

<TitreJust>Justification</TitreJust>

As noted in the ECHA Guidance on labelling and packaging in accordance with Regulation (EC) No 1272/2008 Version 4.2 March 2021 – “Readability is determined by the combination of font size, letter spacing, spacing between lines, stroke width, type colour, typeface, width-height ratio of the letters, the surface of the material and significant contrast between the print and the background. ”Overly prescriptive additional requirements regarding font size, distance between two lines and background colour are not justified and severely limit the flexibility of suppliers. It is sufficient if the label or fold-out label is easily readable and clearly stand out from the background. In fact, the additional requirements would hinder the free movement of products in the Single Market, which in turn would entail an adjustment of logistics.

</Amend>

<Amend>Amendment <NumAm>307</NumAm>

<RepeatBlock-By><Members>Nicola Procaccini, Pietro Fiocchi</Members>

</RepeatBlock-By>

<DocAmend>Proposal for a regulation</DocAmend>

<Article>Annex I – paragraph 1 – point 4 a (new)</Article>

<DocAmend2>Regulation (EC) No 1272/2008</DocAmend2>

<Article2>Annex I – Part 1 – Section 1.3.7 a (new)</Article2>

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| Text proposed by the Commission | Amendment |
|  | ***(4a) In Part 1 of Annex I, the following Section 1.3.7.a is added:*** |
|  | ***1.3.7.a Mixtures designed to be inhaled via electronic cigarettes and contained in refill containers*** |
|  | ***The labelling elements referred to in Article 17(1) shall only be provided on the outer packaging of disposable electronic cigarettes and single use cartridges. The elements referred to in Article 17(1) (d) to (g) shall only apply if the mixture contained is classified as having respiratory sensitisation and/or acute inhalation toxicity properties. This applies accordingly to the application of Articles 48 and 48a.*** |
|  | ***For refill containers, the label elements in accordance with the first subparagraph of Article 17(2) shall be provided in accordance with sections 1.5.1 and 1.5.1.2 of Annex I. A tie-on tag shall not be used.*** |

Or. <Original>{EN}en</Original>

</Amend>

<Amend>Amendment <NumAm>308</NumAm>

<RepeatBlock-By><Members>Pietro Fiocchi</Members>

</RepeatBlock-By>

<DocAmend>Proposal for a regulation</DocAmend>

<Article>Annex I – paragraph 1 – point 4 a (new)</Article>

<DocAmend2>Regulation (EC) No 1272/2008</DocAmend2>

<Article2>Annex I – Part 1 – Section 1.3.7. a (new)</Article2>

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|  |
| Text proposed by the Commission | Amendment |
|  | ***(4a) In Point 1 of Annex I, the following Section 1.3.7.a is added:*** |
|  | ***1.3.7.a By derogation from Article 5(3), hydrocarbon substances with more than one constituent, impurity or additive, can be classified using all available reliable whole substance or constituent data in a weight of evidence approach according to Regulation (EC) No 1907/2006 (Annex XI section 1.5 Grouping of substances and read-across approach).*** |

Or. <Original>{EN}en</Original>

</Amend>

<Amend>Amendment <NumAm>309</NumAm>

<RepeatBlock-By><Members>Martin Hojsík, Billy Kelleher, María Soraya Rodríguez Ramos, Michal Wiezik, Susana Solís Pérez</Members>

</RepeatBlock-By>

<DocAmend>Proposal for a regulation</DocAmend>

<Article>Annex I – paragraph 1 – point 9</Article>

<DocAmend2>Regulation (EC) No 1272/2008</DocAmend2>

<Article2>Annex I – Part 1 – Section 1.5.2.4.1. – point b – point iv a (new)</Article2>

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|  |
| Text proposed by the Commission | Amendment |
|  | ***(iva) Serious eye damage/irritation, category 1;*** |

Or. <Original>{EN}en</Original>

<TitreJust>Justification</TitreJust>

This addition improves minimum consumers safety protection level, which should be ensured regardless of the packaging volume.

</Amend>

<Amend>Amendment <NumAm>310</NumAm>

<RepeatBlock-By><Members>Martin Hojsík, Billy Kelleher, María Soraya Rodríguez Ramos, Michal Wiezik, Susana Solís Pérez</Members>

</RepeatBlock-By>

<DocAmend>Proposal for a regulation</DocAmend>

<Article>Annex I – paragraph 1 – point 9</Article>

<DocAmend2>Regulation (EC) No 1272/2008</DocAmend2>

<Article2>Annex I – Part 1 – Section 1.5.2.4.1 – point b – point v a (new)</Article2>

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|  |
| Text proposed by the Commission | Amendment |
|  | ***(va) Skin sensitisation, category 1 (sub-categories 1A and 1B);*** |

Or. <Original>{EN}en</Original>

<TitreJust>Justification</TitreJust>

This addition improves minimum consumers safety protection level, which should be ensured regardless of the packaging volume.

</Amend>

<Amend>Amendment <NumAm>311</NumAm>

<RepeatBlock-By><Members>Martin Hojsík, Billy Kelleher, María Soraya Rodríguez Ramos, Michal Wiezik, Susana Solís Pérez</Members>

</RepeatBlock-By>

<DocAmend>Proposal for a regulation</DocAmend>

<Article>Annex II – paragraph 1 – point -1 (new)</Article>

<DocAmend2>Regulation (EC) No 1272/2008</DocAmend2>

<Article2>Annex II – Part 3 – Section 3.1.1.1</Article2>

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|  |
| Present text | Amendment |
|  | ***-1. In in Part 3 of Annex II, point*** 3.1.1.1. ***is amended as following:*** |
| 3.1.1.1.Packaging of whatever capacity containing a substance or mixture supplied to the general public and classified for acute toxicity, categories 1 to 3, STOT — single exposure category 1, STOT — repeated exposure category 1, or skin corrosion category 1 shall be fitted with child-resistant fastenings. | ‘***3.1.1.1.*** Packaging of whatever capacity containing a substance or mixture supplied to the general public and classified for acute toxicity, categories 1 to 3, STOT — single exposure category 1, STOT — repeated exposure category 1, or skin corrosion category 1***, or serious eye damage category 1*** shall be fitted with child-resistant fastenings.’ |

Or. <Original>{EN}en</Original>

<TitreJust>Justification</TitreJust>

This addition is necessary to improve the protection of children´s health.

</Amend>

<Amend>Amendment <NumAm>312</NumAm>

<RepeatBlock-By><Members>João Albuquerque, Sara Cerdas</Members>

</RepeatBlock-By>

<DocAmend>Proposal for a regulation</DocAmend>

<Article>Annex II – paragraph 1 – point -1 (new)</Article>

<DocAmend2>Regulation (EC) No 1272/2008</DocAmend2>

<Article2>Annex II – part 3 – section 3.1.1.1</Article2>

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|  |
| Present text | Amendment |
|  | ***(-1) In in Part 3 of Annex II, section 3.1.1.1 is replaced by the following:*** |
| Packaging of whatever capacity containing a substance or mixture supplied to the general public and classified for acute toxicity, categories 1 to 3, STOT — single exposure category 1, STOT — repeated exposure category 1, or skin corrosion category 1 shall be fitted with child-resistant fastenings | ‘Packaging of whatever capacity containing a substance or mixture supplied to the general public and classified for acute toxicity, categories 1 to 3, STOT — single exposure category 1, STOT — repeated exposure category 1, or skin corrosion category 1***, or serious eye damage category 1*** shall be fitted with child-resistant fastenings***.’*** |

Or. <Original>{EN}en</Original>

</Amend>

<Amend>Amendment <NumAm>313</NumAm>

<RepeatBlock-By><Members>Martin Hojsík, Billy Kelleher, María Soraya Rodríguez Ramos, Michal Wiezik, Susana Solís Pérez</Members>

</RepeatBlock-By>

<DocAmend>Proposal for a regulation</DocAmend>

<Article>Annex II – paragraph 1 – point -1 a (new)</Article>

<DocAmend2>Regulation (EC) No 1272/2008</DocAmend2>

<Article2>Annex II – Part 3 – section 3.2.1.</Article2>

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|  |
| Present text | Amendment |
|  | ***-1a. In in Part 3 of Annex II, section 3.2.1. is replaced by the following:*** |
| 3.2.1. Packaging to be fitted with a tactile warning | ‘3.2.1. Packaging to be fitted with a tactile warning |
| Where substances or mixtures are supplied to the general public and classified for acute toxicity, skin ***corrosion***, germ cell mutagenicity category 2, carcinogenicity category 2, reproductive toxicity category 2, respiratory ***sensitisation, or Stot***, categories 1 ***and*** 2, aspiration hazard, ***or*** flammable gases, liquids ***and solids in*** categories 1 ***and 2***, the packaging of whatever capacity, shall be fitted with a tactile warning of danger. | Where substances or mixtures are supplied to the general public and classified for acute toxicity, skin ***corrosion/skin irritation, serious eye damage/eye irritation, endocrine disruption for human health category 2, endocrine disruption for the environment category 2***, germ cell mutagenicity category 2, carcinogenicity category 2, reproductive toxicity category 2, respiratory ***or skin sensitization***, ***STOT*** categories 1 ***or*** 2, aspiration hazard, flammable gases, ***flammable*** liquids categories 1 ***or 2, or flammable solids***, the packaging of whatever capacity, shall be fitted with a tactile warning of danger.’ |

Or. <Original>{EN}en</Original>

<TitreJust>Justification</TitreJust>

Tactile warnings should be updated, in line with other articles, in order to ensure sufficient level of protection of health of people with handicap.

</Amend>

<Amend>Amendment <NumAm>314</NumAm>

<RepeatBlock-By><Members>João Albuquerque, Sara Cerdas</Members>

</RepeatBlock-By>

<DocAmend>Proposal for a regulation</DocAmend>

<Article>Annex II – paragraph 1 – point -1 a (new)</Article>

<DocAmend2>Regulation (EC) No 1272/2008</DocAmend2>

<Article2>Annex II – part 3 – section 3.2.1.1</Article2>

|  |
| --- |
|  |
| Present text | Amendment |
|  | ***(-1a) In in Part 3 of Annex II, section 3.2.1.1 is replaced by the following:*** |
| Where substances or mixtures are supplied to the general public and classified for acute toxicity, skin ***corrosion***, germ cell mutagenicity category 2, carcinogenicity category 2, reproductive toxicity category 2, respiratory ***sensitisation***, STOT categories 1 or 2, aspiration hazard, flammable gases, flammable liquids categories 1 or 2, or flammable solids, the packaging of whatever capacity, shall be fitted with a tactile warning of danger. | ‘Where substances or mixtures are supplied to the general public and classified for acute toxicity, skin ***corrosion/skin irritation, serious eye damage/eye irritation***, germ cell mutagenicity category 2, carcinogenicity category 2, reproductive toxicity category 2, ***endocrine disruption for human health category 2, endocrine disruption for the environment category 2,*** respiratory ***or skin sensitization***, STOT categories 1 or 2, aspiration hazard, flammable gases, flammable liquids categories 1 or 2, or flammable solids, the packaging of whatever capacity, shall be fitted with a tactile warning of danger.’ |

Or. <Original>{EN}en</Original>

</Amend>

<Amend>Amendment <NumAm>315</NumAm>

<RepeatBlock-By><Members>Martin Hojsík, Billy Kelleher, María Soraya Rodríguez Ramos, Michal Wiezik, Susana Solís Pérez</Members>

</RepeatBlock-By>

<DocAmend>Proposal for a regulation</DocAmend>

<Article>Annex II – paragraph 1 – point 1</Article>

<DocAmend2>Regulation (EC) No 1272/2008</DocAmend2>

<Article2>Annex II – Part 3 – section 3.4. – point b</Article2>

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|  |
| Text proposed by the Commission | Amendment |
| (b) a label is firmly affixed on a visible place of the refill station and with a font size that is easily legible and without serifs; | (b) a label is firmly affixed on a visible place of the refill station and with a font size that is easily legible and without serifs ***and is provided free of charge by suppliers***; |

Or. <Original>{EN}en</Original>

<TitreJust>Justification</TitreJust>

Suppliers should provide self-adhesive stickers or tie-on tags to ensure easy access to information by consumers.

</Amend>

<Amend>Amendment <NumAm>316</NumAm>

<RepeatBlock-By><Members>João Albuquerque, Sara Cerdas</Members>

</RepeatBlock-By>

<DocAmend>Proposal for a regulation</DocAmend>

<Article>Annex II – paragraph 1 – point 1</Article>

<DocAmend2>Regulation (EC) No 1272/2008</DocAmend2>

<Article2>Annex II – Part 3 – Section 3.4 – point b</Article2>

|  |
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|  |
| Text proposed by the Commission | Amendment |
| (b) a label is firmly affixed on a visible place of the refill station and ***with a font size that is easily legible and without serifs***; | (b) a label is firmly affixed on a visible place of the refill station and ***fulfils the requirements in Article 31***; |

Or. <Original>{EN}en</Original>

</Amend>

<Amend>Amendment <NumAm>317</NumAm>

<RepeatBlock-By><Members>João Albuquerque, Sara Cerdas</Members>

</RepeatBlock-By>

<DocAmend>Proposal for a regulation</DocAmend>

<Article>Annex II – paragraph 1 – point 1</Article>

<DocAmend2>Regulation (EC) No 1272/2008</DocAmend2>

<Article2>Annex II – Part 3 – Section 3.4 – point b a (new)</Article2>

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|  |
| Text proposed by the Commission | Amendment |
|  | ***(ba) a label that fulfils the requirements in Article 31 is available at the refill station, free-of-charge for consumers in a self-adhesive sticker form to be affixed on the container used by the consumer. Where refill stations provide several substances or mixtures, labels should easily and clearly identify which substance or mixture provided at the refill station they correspond to.*** |

Or. <Original>{EN}en</Original>

</Amend>

<Amend>Amendment <NumAm>318</NumAm>

<RepeatBlock-By><Members>Pietro Fiocchi</Members>

</RepeatBlock-By>

<DocAmend>Proposal for a regulation</DocAmend>

<Article>Annex II – paragraph 1 – point 1</Article>

<DocAmend2>Regulation (EC) No 1272/2008</DocAmend2>

<Article2>Annex II – Part 3 – Section 3.4 – point e</Article2>

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|  |
| Text proposed by the Commission | Amendment |
| (e) overfilling packaging is ***technically*** prevented; | (e) overfilling packaging is ***prevented by technical or organisational means (f) filling a substance or mixture into unsuitable packaging is*** prevented ***by technical or organisational means***; |
|  | *(This amendment applies throughout the text. Adopting it will necessitate corresponding changes throughout.)* |

Or. <Original>{EN}en</Original>

<TitreJust>Justification</TitreJust>

This is a developing area and economic operators, most notably SMEs, must be allowed to innovate, to utilise different systems, and to continue to promote, use and adapt existing systems.

</Amend>

<Amend>Amendment <NumAm>319</NumAm>

<RepeatBlock-By><Members>Pietro Fiocchi</Members>

</RepeatBlock-By>

<DocAmend>Proposal for a regulation</DocAmend>

<Article>Annex II – paragraph 1 – point 1</Article>

<DocAmend2>Regulation (EC) No 1272/2008</DocAmend2>

<Article2>Annex II – Part 3 – Section 3.4 – point ii</Article2>

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|  |
| Text proposed by the Commission | Amendment |
| (ii) Specific target organ toxicity – Single exposure, categories 1***, 2 and 3***; | (ii) Specific target organ toxicity – Single exposure, categories 1 ***and 2***; |
|  | *(This amendment applies throughout the text. Adopting it will necessitate corresponding changes throughout.)* |

Or. <Original>{EN}en</Original>

<TitreJust>Justification</TitreJust>

Including Category 3 is not proportionate as it covers minor reversible effects and does not represent a significant hazard.

</Amend>

<Amend>Amendment <NumAm>320</NumAm>

<RepeatBlock-By><Members>Martin Hojsík, Billy Kelleher, María Soraya Rodríguez Ramos, Michal Wiezik, Susana Solís Pérez</Members>

</RepeatBlock-By>

<DocAmend>Proposal for a regulation</DocAmend>

<Article>Annex II – paragraph 1 – point 1</Article>

<DocAmend2>Regulation (EC) No 1272/2008</DocAmend2>

<Article2>Annex II – Part 3 – Section 3.4. – point iv a (new)</Article2>

|  |
| --- |
|  |
| Text proposed by the Commission | Amendment |
|  | ***(iva) Serious eye damage/irritation, category 1;*** |

Or. <Original>{EN}en</Original>

<TitreJust>Justification</TitreJust>

This addition improves minimum consumers safety level, which should be ensured regardless of packaging means.

</Amend>

<Amend>Amendment <NumAm>321</NumAm>

<RepeatBlock-By><Members>João Albuquerque, Sara Cerdas</Members>

</RepeatBlock-By>

<DocAmend>Proposal for a regulation</DocAmend>

<Article>Annex II – paragraph 1 – point 1</Article>

<DocAmend2>Regulation (EC) No 1272/2008</DocAmend2>

<Article2>Annex II – Part 3 – Section 3.4 – point iv a (new)</Article2>

|  |
| --- |
|  |
| Text proposed by the Commission | Amendment |
|  | ***(iva) Serious eye damage/irritation category 1;*** |

Or. <Original>{EN}en</Original>

</Amend>

<Amend>Amendment <NumAm>322</NumAm>

<RepeatBlock-By><Members>Martin Hojsík, Billy Kelleher, María Soraya Rodríguez Ramos, Michal Wiezik, Susana Solís Pérez</Members>

</RepeatBlock-By>

<DocAmend>Proposal for a regulation</DocAmend>

<Article>Annex II – paragraph 1 – point 1</Article>

<DocAmend2>Regulation (EC) No 1272/2008</DocAmend2>

<Article2>Annex II – Part 3 – Section 3.4. – point v a (new)</Article2>

|  |
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|  |
| Text proposed by the Commission | Amendment |
|  | ***(va) Skin sensitisation, category 1 (sub-categories 1A and 1B);*** |

Or. <Original>{EN}en</Original>

<TitreJust>Justification</TitreJust>

This addition improves minimum consumers safety level, which should be ensured regardless of packaging means.

</Amend>

<Amend>Amendment <NumAm>323</NumAm>

<RepeatBlock-By><Members>João Albuquerque, Sara Cerdas</Members>

</RepeatBlock-By>

<DocAmend>Proposal for a regulation</DocAmend>

<Article>Annex II – paragraph 1 – point 1</Article>

<DocAmend2>Regulation (EC) No 1272/2008</DocAmend2>

<Article2>Annex II – Part 3 – Section 3.4 – point v a (new)</Article2>

|  |
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|  |
| Text proposed by the Commission | Amendment |
|  | ***(va) Skin sensitisation category 1 (sub-categories 1A, 1B);*** |

Or. <Original>{EN}en</Original>

</Amend>

<Amend>Amendment <NumAm>324</NumAm>

<RepeatBlock-By><Members>Pietro Fiocchi</Members>

</RepeatBlock-By>

<DocAmend>Proposal for a regulation</DocAmend>

<Article>Annex II – paragraph 1 – point 2</Article>

<DocAmend2>Regulation (EC) No 1272/2008</DocAmend2>

<Article2>Annex II – Part 5 – paragraph 2</Article2>

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|  |
| Text proposed by the Commission | Amendment |
| For a substance or a mixture supplied at a ***filling*** station and directly pumped into a receptacle ***that forms an integral part of a vehicle and from where the substance or mixture is normally not intended to be removed, the*** label elements ***referred to in Article 17*** shall be provided on the respective pump.; | ‘For a substance or a mixture supplied at a ***fuel service*** station and directly pumped into a receptacle***, the following*** label elements shall be provided on ***or next to*** the respective pump***:*** |
|  | ***Product identifier for the substance or trade name or designation of the mixture***; |
|  | ***Hazard pictogram;*** |
|  | ***Hazard and precautionary statements;*** |
|  | ***Signal word.*** |
|  | ***Fuel service stations shall not be considered as refill stations in the sense of Annex II part 3.4.’*** |
|  | *(This amendment applies throughout the text. Adopting it will necessitate corresponding changes throughout.)* |

Or. <Original>{EN}en</Original>

<TitreJust>Justification</TitreJust>

We propose to use ‘fuel service station’ and add a sentence to make a clear distinction between the requirements under Annex II Part 5 for fuels and other bulk products sold at fuel service stations and the requirements for refill stations in Annex II Part 3.4 (new).The proposed modifications will allow to continue the bulk sales of fuels to fill cannisters or other larger containers, as e.g. used by farmers.

</Amend>

<Amend>Amendment <NumAm>325</NumAm>

<RepeatBlock-By><Members>Anna Zalewska</Members>

</RepeatBlock-By>

<DocAmend>Proposal for a regulation</DocAmend>

<Article>Annex II a (new)</Article>

<DocAmend2>Regulation (EC) No 1272/208</DocAmend2>

<Article2>Annex VI – Part 2</Article2>

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|  |
| Present text | Amendment |
|  | ***In Annex VI, Part 2 is replaced by the following:*** |
| 2. PART 2: DOSSIERS FOR HARMONISED CLASSIFICATION AND LABELLING | ‘2. PART 2: DOSSIERS FOR HARMONISED CLASSIFICATION AND LABELLING |
| This Part lays down general principles for preparing dossiers to propose and justify harmonised classification and labelling. The relevant parts of sections 1, 2 and 3 of Annex I to Regulation (EC) ***No 1907/2006*** shall be used for the methodology and format of any dossier. For all dossiers any relevant information from registration dossiers shall be considered and other available information may be used. For hazard information which has not been previously submitted to the Agency, a robust study summary shall be included in the dossier. A dossier for harmonised classification and labelling shall contain the following: | This Part lays down general principles for preparing dossiers to propose and justify harmonised classification and labelling. The relevant parts of sections 1, 2 and 3 of Annex I to Regulation (EC) ***No 1907/2006*** shall be used for the methodology and format of any dossier. For all dossiers any relevant information from registration dossiers shall be considered and other available information may be used. For hazard information which has not been previously submitted to the Agency, a robust study summary shall be included in the dossier. A dossier for harmonised classification and labelling shall contain the following: |
| —***ProposalThe*** proposal shall include the identity of the substance or substances concerned and the harmonised classification and labelling proposed. | — ***Proposal The*** proposal shall include the identity of the substance or substances concerned and the harmonised classification and labelling proposed. |
| —Justification for the proposed harmonised classification and ***labellingA*** comparison of the available information with the criteria contained in Parts 2 to 5, taking into account the general principles in Part 1, of Annex I to this Regulation shall be completed and documented in the format set out in Part B of the Chemical Safety Report in Annex I to Regulation (EC) ***No 1907/2006.*** | — Justification for the proposed harmonised classification and ***labelling A*** comparison of the available information with the criteria contained in Parts 2 to 5, taking into account the general principles in Part 1, of Annex I to this Regulation shall be completed and documented in the format set out in Part B of the Chemical Safety Report in Annex I to Regulation (EC) ***No 1907/2006.*** |
| ***—***Justification for other effects at Community ***levelFor*** other effects than carcinogenity, mutagenicity, reprotoxicity and respiratory sensitisation a justification shall be provided that there is a need for action demonstrated at Community level. This does not apply for an active substance in the meaning of Directive 91/414/EEC or Directive 98/8/EC. | ***— Justification for the proposed grouping of substances to harmonized classification and labelling Where a harmonised classification and labelling proposal is made for group(s) of substances, the dossier shall include scientific justification (based on assessment of available data on physico-chemical, ecotoxicological and toxicological properties as specified in REACH Annex XI (1.5)) using a weight of evidence approach, for the grouping of substances and for applying a similar classification.*** |
|  | ***—*** Justification for other effects at Community ***level For*** other effects than carcinogenity, mutagenicity, reprotoxicity and respiratory sensitisation a justification shall be provided that there is a need for action demonstrated at Community level. This does not apply for an active substance in the meaning of Directive 91/414/EEC or Directive 98/8/EC.***’.*** |

Or. <Original>{EN}en</Original>

</Amend>

<Amend>Amendment <NumAm>326</NumAm>

<RepeatBlock-By><Members>João Albuquerque, Sara Cerdas</Members>

</RepeatBlock-By>

<DocAmend>Proposal for a regulation</DocAmend>

<Article>Annex II a (new)</Article>

<DocAmend2>Regulation (EC) No 1272/2008</DocAmend2>

<Article2>Annex VI – Part 2</Article2>

|  |
| --- |
|  |
| Present text | Amendment |
|  | ***In Annex VI, part 2 is replaced by the following:*** |
| PART 2: DOSSIERS FOR HARMONISED CLASSIFICATION AND LABELLING | ‘PART 2: DOSSIERS FOR HARMONISED CLASSIFICATION AND LABELLING |
| This Part lays down general principles for preparing dossiers to propose and justify harmonised classification and labelling. | This Part lays down general principles for preparing dossiers to propose and justify harmonised classification and labelling. |
| The relevant parts of sections 1, 2 and 3 of Annex I to Regulation (EC) No 1907/2006 shall be used for the methodology and format of any dossier. | The relevant parts of sections 1, 2 and 3 of Annex I to Regulation (EC) No 1907/2006 shall be used for the methodology and format of any dossier. |
| For all dossiers any relevant information from registration dossiers shall be considered and other available information may be used. For hazard information which has not been previously submitted to the Agency, a robust study summary shall be included in the dossier. | For all dossiers any relevant information from registration dossiers shall be considered and other available information may be used. For hazard information which has not been previously submitted to the Agency, a robust study summary shall be included in the dossier. |
| A dossier for harmonised classification and labelling shall contain the following: | A dossier for harmonised classification and labelling shall contain the following: |
|  | —***Proposal*** |
| — ***ProposalThe*** proposal shall include the identity of the substance or substances concerned and the harmonised classification and labelling proposed. | ***The*** proposal shall include the identity of the substance or substances concerned and the harmonised classification and labelling proposed. |
| — Justification for the proposed harmonised classification and labelling | — Justification for the proposed harmonised classification and labelling |
| A comparison of the available information with the criteria contained in Parts 2 to 5, taking into account the general principles in Part 1, of Annex I to this Regulation shall be completed and documented in the format set out in Part B of the Chemical Safety Report in Annex I to Regulation (EC) No 1907/2006. | A comparison of the available information with the criteria contained in Parts 2 to 5, taking into account the general principles in Part 1, of Annex I to this Regulation shall be completed and documented in the format set out in Part B of the Chemical Safety Report in Annex I to Regulation (EC) No 1907/2006. |
| — Justification for other effects at Community level | — Justification for other effects at Community level |
| For other effects than carcinogenity, mutagenicity, reprotoxicity and respiratory sensitisation a justification shall be provided that there is a need for action demonstrated at Community level. This does not apply for an active substance in the meaning of ***Directive 91/414/EEC or Directive 98/8/EC***. | ***For other effects than carcinogenity, mutagenicity, reprotoxicity, endocrine disruption for human health and the environment, persistent bioaccumulative and toxic (PBT), very persistent, very bioaccumulative (vPvB), persistent, mobile and toxic (PMT), very persistent, very mobile (vPvM),*** and respiratory sensitisation a justification shall be provided that there is a need for action demonstrated at Community level. This does not apply for an active substance in the meaning of ***Regulation (EU) No 1107/2009 or Regulation (EU) No 528/2012***.’ |

Or. <Original>{EN}en</Original>

</Amend>

<Amend>Amendment <NumAm>327</NumAm>

<RepeatBlock-By><Members>Martin Hojsík, Billy Kelleher, María Soraya Rodríguez Ramos, Michal Wiezik, Susana Solís Pérez</Members>

</RepeatBlock-By>

<DocAmend>Proposal for a regulation</DocAmend>

<Article>Annex II a (new)</Article>

<DocAmend2>Regulation (EC) No 1272/2008</DocAmend2>

<Article2>Annex VI – Part 2</Article2>

|  |
| --- |
|  |
| Present text | Amendment |
|  | ***Annex VI Part 2 is replaced by the following:*** |
| 2. PART 2: DOSSIERS FOR HARMONISED CLASSIFICATION AND LABELLING | ‘2. PART 2: DOSSIERS FOR HARMONISED CLASSIFICATION AND LABELLING |
| This Part lays down general principles for preparing dossiers to propose and justify harmonised classification and labelling. | This Part lays down general principles for preparing dossiers to propose and justify harmonised classification and labelling. |
| The relevant parts of sections 1, 2 and 3 of Annex I to Regulation (EC) No 1907/2006 shall be used for the methodology and format of any dossier. | The relevant parts of sections 1, 2 and 3 of Annex I to Regulation (EC) No 1907/2006 shall be used for the methodology and format of any dossier. |
| For all dossiers any relevant information from registration dossiers shall be considered and other available information may be used. For hazard information which has not been previously submitted to the Agency, a robust study summary shall be included in the dossier. | For all dossiers any relevant information from registration dossiers shall be considered and other available information may be used. For hazard information which has not been previously submitted to the Agency, a robust study summary shall be included in the dossier. |
| A dossier for harmonised classification and labelling shall contain the following: | A dossier for harmonised classification and labelling shall contain the following: |
| —Proposal | —Proposal |
| The proposal shall include the identity of the substance or substances concerned and the harmonised classification and labelling proposed. | The proposal shall include the identity of the substance or substances concerned and the harmonised classification and labelling proposed. |
| —Justification for the proposed harmonised classification and labelling | —Justification for the proposed harmonised classification and labelling |
| A comparison of the available information with the criteria contained in Parts 2 to 5, taking into account the general principles in Part 1, of Annex I to this Regulation shall be completed and documented in the format set out in Part B of the Chemical Safety Report in Annex I to Regulation (EC) No 1907/2006. | A comparison of the available information with the criteria contained in Parts 2 to 5, taking into account the general principles in Part 1, of Annex I to this Regulation shall be completed and documented in the format set out in Part B of the Chemical Safety Report in Annex I to Regulation (EC) No 1907/2006. |
| —Justification for other effects at Community level | ***For dossier for harmonised classification and labelling of groups of substances, justification for the grouping.*** |
| For other effects than carcinogenity, mutagenicity, reprotoxicity and respiratory sensitisation a justification shall be provided that there is a need for action demonstrated at Community level. This does not apply for an active substance in the meaning of Directive 91/414/EEC or Directive 98/8/EC. | —Justification for other effects at Community level |
|  | ***For other effects than carcinogenity, mutagenicity, reprotoxicity and respiratory sensitisation a justification shall be provided that there is a need for action demonstrated at Community level. This does not apply for an active substance in the meaning of Directive 91/414/EEC or Directive 98/8/EC.’*** |

Or. <Original>{EN}en</Original>

</Amend>

<Amend>Amendment <NumAm>328</NumAm>

<RepeatBlock-By><Members>Alexander Bernhuber</Members>

</RepeatBlock-By>

<DocAmend>Proposal for a regulation</DocAmend>

<Article>Annex III – paragraph 1 a (new)</Article>

<DocAmend2>Regulation (EC) No 1272/2008</DocAmend2>

<Article2>Annex VIII – Part A – section 2.2 a</Article2>

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|  |
| Present text | Amendment |
|  | ***In Annex VIII, in part A, section 2.2a is replaced by the following:*** |
| In the case of bespoke paints, submitters may, without prejudice to Article 25(8), opt not to submit information and not to create a Unique Formula Identifier in accordance with this Annex. | ‘In the case of bespoke paints ***or on-site formulated mixtures***, submitters may, without prejudice to Article 25(8), opt not to submit information and not to create a Unique Formula Identifier in accordance with this Annex.’ |

Or. <Original>{EN}en</Original>

</Amend>

<Amend>Amendment <NumAm>329</NumAm>

<RepeatBlock-By><Members>Alexander Bernhuber</Members>

</RepeatBlock-By>

<DocAmend>Proposal for a regulation</DocAmend>

<Article>Annex III – paragraph 1 </Article>

<DocAmend2>Regulation (EC) No 1272/2008</DocAmend2>

<Article2>Annex VIII - Part A, section 2.4 – subparagraph 1 – point 6 a (new)</Article2>

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|  |
| Present text | Amendment |
|  | ***In Annex VIII, in part A, Section 2.4, the following point 6a is added:*** |
|  | ‘***6a. ‘on-site formulated mixture’ means a mixture that is formulated in a volume less than 10 ml on a tailor-made basis for an individual consumer or professional user at the point of supply.’*** |

Or. <Original>{EN}en</Original>

</Amend></RepeatBlock-Amend>