Amendments to the Appendix C

(26) in Appendix C, point (f) is replaced by the following:

'(f) substances, whether on their own, or in mixtures or in an article, in a concentration above 0,1 % weight by weight (w/w), and meeting the criteria laid down in Article 57 of Regulation (EC) No 1907/2006 and that were identified in accordance with Article 59(1) of that Regulation for a period of at least eighteen months, except if it is assessed and documented by the operators that no other suitable alternative substances or technologies are available on the market, and that they are used under controlled conditions[*1];

[*1] The Commission will review the exceptions from the prohibition from manufacturing, placing on the market or use of the substances referred to in point (f) once it will have published horizontal principles on essential use of chemicals.';

(27) in Appendix C, point (g) is deleted;

(28) in Appendix C, the following paragraph is added after point (f):

'In addition, the activity does not lead to the manufacture, presence in the final product or output, or placing on the market, of other substances, whether on their own, or in mixtures or in an article, in a concentration above 0,1 % weight by weight (w/w), that meet the criteria of Regulation (EC) No 1272/2008 for one of the hazard classes or hazard categories mentioned in Article 57 of Regulation (EC) No 1907/2006, except if it is assessed and documented by the operators that no other suitable alternative substances or technologies are available on the market, and that they are used under controlled conditions[*1].

[*1] The Commission will review the exceptions from the prohibition from manufacture, presence in the final product or output, or placing on the market of the substances referred to in this paragraph once it will have published horizontal principles on essential use of chemicals.'.

Focus on Appendix C f)bis (para 28 above)

Summary:

A strict interpretation of the Appendix C would lead to disqualifying from the EU Taxonomy a large number of industrial activities, including 'Manufacturing of aircraft', given that existing exemptions, authorisations and/or regulatory thresholds (granted in accordance with the EU legislative framework on chemicals) would not be considered. It is worth to be noted that, the use of substances (especially in the aviation sector) is highly regulated considering its specificities through the aviation safety regulation (and consequently the requirements are embedded in business operations).

This new provision could raise major concerns: (i) inconsistency with other pre-existing regulations (REACH, RoHS notably), (ii) creation of massive red tape, including through the supplier chain towards small and medium size companies, (iii) fulfilment of the requirements would not be technically feasible and (iv) significant legal uncertainty. For all these reasons, the Commission's upcoming FAQ should bring the necessary clarifications. This could be done through the following means.

Generally speaking, we recommend not to go beyond the existing regulatory obligations (including disclosure and assessment). Item f)bis should therefore be understood to apply only to substances which fall under one of the duties to communicate conditions under the current regulation requirements. In particular, the interpretation of appendix C should be focused on the fact that the **activity is carried out in alignment with existing Regulations listed in appendix C itself,** and therefore, taking into consideration all the authorisations, thresholds and additional provisions laid down in the listed legislations.

More specifically, following line-by-line the structure of paragraph 28, we set out below recommended interpretations to be incorporated in the upcoming FAQ.

It should however be stressed that, even with these recommendations, gathering the required data and assessing alignment would remain a very challenging task. This should be considered in the wider initiative of simplification and reduction of regulatory burden launched transversally at EU level.

- The provision *'in addition, the activity does not lead to the manufacture, presence in the final product or output, or placing on the market, of other substances, whether on their own, or in mixtures or in an article, in a concentration above 0,1 % weight by weight (w/w)"* should be interpreted as follows:
    - It should be limited to ***intentional*** manufacturing or addition of the substances concerned into the product AND
    - It should be limited to cases where this would lead to a known and significant environmental / health risk in line with its **end-use or end-user type**.
    - Alternatively, one could consider limiting the scope of substances concerned to those which would be considered as **material** for the activities within the meaning of CSRD.

- The provision *"that meet the criteria of Regulation (EC) No 1272/2008 for one of the hazard classes or hazard categories mentioned in Article 57 of Regulation (EC) No 1907/2006"* should be interpreted as follows:
    - It should be read as applying only to **substances with harmonised classification and with the currently existing hazard classes**.
    - Any upcoming hazard classes should **give right to a 5 year delayed application deadline** (avoid massive uncertainty in case of addition of classification).

- The provision *"except if it is assessed and documented by the operators that no other suitable alternative substances or technologies are available on the market"* should be interpreted as follows*:*
    - This should only require a **simple documentation by the operators** that no other suitable substance or technology is available on the market and in some cases AND/OR
    - A potential **waiver for safety or safety performance** (airworthiness) could be considered to be deemed sufficient to fulfil the criteria (as this would be of "*essential use*").

- The provision *"and that they are used under controlled conditions"* should be interpreted as follows:
    - **Compliance with current and existing legislation** on the EHS aspect is deemed appropriate to fulfil the requirement

- The provision "*The Commission will review the exceptions from the prohibition from manufacture, presence in the final product or output, or placing on the market of the substances referred to in this paragraph once it will have published horizontal principles on essential use of chemicals."* calls the following comments:

- This requires (i) a clear EU Commission **roadmap** (scope of review, why, which potential result, (ii) clarification of the meaning of the word **"*exception*"** (not part of the usual vocabulary of the chemical regulatory framework), (iii) key guidance **on the the notion of "essential use"** (meaning, assessment modalities, enforcement within the chemical regulatory framework in Reach and beyond?)

In due time, the review of the Taxonomy regulation could allow to review the content and application of the f) bis requirement.

The above elements are spelled out in more detail in Annex.

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Annex

Uncertainty and potential hurdle posed by the recital (28)

"Lead to the manufacture, presence in the final product or output, or placing on the market, of other substances"

- The favoured interpretation is the ***intentional*** manufacture, presence or placing on the market.
- The lack of intentionality opens the door to an almost infinite output of substances to be screened in the frame of the manufacturing process or final product that could be incidental to the manufacturing process itself.
- This also implies that by-products are being included due to the lack of intention at the manufacturing stage. These by-products could therefore provoke misalignment even in the case where they are not placed on the market or present in the final product

"that meet the criteria of Regulation (EC) No 1272/2008 for one of the hazard classes or hazard categories mentioned in Article 57 of Regulation (EC) No 1907/2006,"

- Lacks proportionality due to
    - the amount of existing chemicals that falls under this categories, not counting the future ones, including the several thousands forecasted to pertain the future categories such as PMTs or Endocrine Disruptors
    - Not required by regulatory framework today
    - Therefore companies have no legal obligation to declare and companies that have to make such disclosures no legal lever to obtain the data

- Data is not available for a vast majority of articles
    - as SVHC substances are not bound to be declared, even to ECHA according to notification exemption in article 3.3 if the producer or importer can exclude exposure to humans or the environment during normal or reasonably foreseeable conditions of use including disposal
    - Non SVHC are bound to be declared only through SDS e.g. for substances & mixtures, not for articles - with the exception of articles with substances or mixtures intended to be released under normal conditions of use
    - Substances, on its own or in mixtures, that are in articles with no intended release do no require SDS either
    - Companies that are integrators at the end of the supply chain will suffer more than anyone else in the supply chain due to the data gathering & check

- Technically infeasible in some case due to lack of existing methods or laboratory capacities for materials & articles that being processed further during the industrialisation process

- Extremely burdensome and in contradiction with the administrative burden reduction orientation from the EU

- Costly as it would require to multiply assessments on a rapid pace

- Presence of substance is not necessarily linked to EHS risk due to non exposure of the substance to environment or to humans be it industrial workers, professionals or general public

- Data disclosure within the supply chain could be overridden for Defence purpose or due to rules not applying in the EU such as Confidential Business Information (CBI) rule allowed in North America

- As a recall, article 118.2 states the limits for ECHA when it comes to disclosure.
    - "Disclosure of the following information shall normally be deemed to undermine the protection of the commercial interests of the concerned person:
        - (a) details of the full composition of a mixture ;
        - (b) without prejudice to Article 7(6) and Article 64(2), the precise use, function or application of a substance or mixture, including information about its precise use as an intermediate;
        - (c) the precise tonnage of the substance or mixture manufactured or placed on the market;
        - (d) links between a manufacturer or importer and his distributors or downstream users."

  We could argue that some of these elements, deemed as potentially undermining the protection of commercial interest of companies, shall not be made publicly available under other disclosure frameworks.

  Only exemption to this rule is to protect health, safety or environment under the conditions of article 118.3:
    - "Where urgent action is essential to protect human health, safety or the environment, such as emergency situations, the Agency may disclose the information referred to in this paragraph."

- This point will also create legal uncertainty and an unequal situation between actors in the market as there is no reference to the harmonised classification
    - Today, under the current regulatory framework, end users have to apply the harmonised classification ***if it does exist*** or the supplier classification with cases where the latter override the harmonised classification.
        - This could lead to disclosure discrepancies, for the same substance, between actors depending on their supplier

"The Commission will review the exceptions from the prohibition from manufacture, presence in the final product or output, or placing on the market of the substances referred to in this paragraph once it will have published horizontal principles on essential use of chemicals"

- Exception is not part of the currently used regulatory glossary therefore, the sentence is difficult to interpret or understand
- In the event that exception refers to exemption are we talking about:

- Exemption for the full text or partial exemption on the application of the text ? (out of scope substances or processes such as PPORD, etc.)
- Exemption from the Restriction process only ? (there are several thousands combination today of substances and exemptions of use/placing of the market under the Restriction list)
- If exception is meant to be the authorisation process, then this is not qualifying for an exemption as it is required to submit a dossier to obtain an authorisation of use

Bottom line - interpretation recommendations for the Appendix C f) bis (recital 28)

The requirement should interpreted as such:

- ***The point should be understood as applicable to substances which fall under one of the duties to communicate conditions under the current regulation requirements***

'In addition, the activity does not lead to the manufacture, presence in the final product or output, or placing on the market, of other substances, whether on their own, or in mixtures or in an article, in a concentration above 0,1 % weight by weight (w/w),

- ***Should be read as intentional manufacture or addition to the product of the below mentioned substances AND***
- ***Presence does not lead to a known and significant environmental / health risk in line with its end use or end-user type***

[this point is applicable today to SVHCs only with some exemptions anyway]

that meet the criteria of Regulation (EC) No 1272/2008 for one of the hazard classes or hazard categories mentioned in Article 57 of Regulation (EC) No 1907/2006,

- ***Should be read as only substances with harmonised classification and with the currently existing hazard classes are falling under the criterion.***
- ***Any upcoming hazard classes should give right to a delayed application deadline as it would create a medium term uncertainty based on the addition of classification in CLP/GHS foreseeable in the coming 5 years.***
    - ***In the event of a new classification being added to article 57, 5 additional years should be a minimum for assessment & evaluation for alignment with the criterion - based on the number of substances forecasted to be under these upcoming new hazard categories, this could be even more than 5***

[the lack of temporality makes the parameter a perpetual Damocles sword that will just create uncertainty and put companies under the threat of an almost overnight misalignment]

except if it is assessed and documented by the operators that no other suitable alternative substances or technologies are available on the market,

- ***Should be read as a simple documentation by the operators that no other suitable substance or technology is available on the market and in some cases AND/OR***

- ***A potential waiver for safety or safety performance (airworthiness) could be considered to with respect to the criteria***

[use of hazardous chemicals for the sake of product safety should allow alignment in the spirit of the essential use concept]

and that they are used under controlled conditions

- ***Should be read as compliance with current and existing legislation on the EHS aspect is deemed appropriate to fulfil the requirement***

[Current applicable EHS framework should be enough for alignment]

The Commission will review the exceptions from the prohibition from manufacture, presence in the final product or output, or placing on the market of the substances referred to in this paragraph once it will have published horizontal principles on essential use of chemicals.'.

- ***Should be a clear Roadmap from EU COM with necessary elements to understand what is being reviewed, on which purpose, when and what kind of potential output is expected from the exercise.***

- ***Clarification on what exception means as this is not part of the usual vocable used under the chemical regulatory framework***

- ***Last but not least, we are still missing the guidance on essential use and ultimately, what could mean and how it would be assessed and enforced within the chemical regulatory framework in Reach and beyond ?***

- ***Discrepancy between taxonomy requirements on disclosure on hazardous chemicals and current framework, even in the frame of the essential use***

- ***Essential use is revolving around Most Harmful Substances which are covering more hazards than Substances of Very High Concerns, therefore expanding the substance scope even further***

- ***Essential use will bring another layer of uncertainty due to the fact that, according to the Commission communication, its implementation will be on a case by case basis in each chemical regulation, therefore pushing even further the unpredictability of its effect on taxonomy alignment of companies***

“The overall aim of the essential use concept is to facilitate decision-making and increase regulatory efficiency to achieve a fast phase-out of the ***most harmful substances*** in nonessential uses while allowing uses still essential for society and continued availability of products serving human and animal health needs”

Most harmful chemical definition: *“Chemicals that cause cancers, gene mutations, affect the reproductive or the endocrine system, or are persistent and bioaccumulative, as well as chemicals affecting the immune, neurological or respiratory systems and chemicals toxic to a specific organ.*

Below are the cut-off values for disclosure according to the current regulatory framework:

- *Carcinogenicity Cat. 1A and 1B* ***=> 0.1% mandatory disclosure***
- *Germ cell mutagenicity Cat. 1A and 1B* ***=> 0.1% mandatory disclosure***
- *Reproductive/developmental toxicity Cat. 1A and 1B* ***=> 0.3% mandatory disclosure***
- *Endocrine disruption Cat. 1 (human health)* ***=> 0.1% mandatory disclosure in May 1st 2028 for mixtures***
- *Endocrine disruption Cat. 1 (environment) =* ***> 0.1% mandatory disclosure in May 1st 2028 for mixtures***
- *Respiratory sensitisation Cat. 1 =* ***> 0.1% mandatory disclosure***
- *Specific target organ toxicity – repeated exposure (STOT-RE) Cat. 1, including immunotoxicity and neurotoxicity =* ***> 1% mandatory disclosure***
- *Persistent, bioaccumulative and toxic/very persistent and very bioaccumulative (PBT/vPvB) =* ***> 0.1% mandatory disclosure***
- *Persistent, mobile and toxic/very persistent and mobile (PMT/vPvM)* ***> 0.1% mandatory disclosure***
- *Hazardous to the ozone layer Cat. 1* ***> 0.1% mandatory disclosure***