EUROPEAN COMMISSION
ENVIRONMENT DIRECTORATE-GENERAL
Circular Economy and Green Growth
Sustainable Chemicals

DIRECTORATE-GENERAL INTERNAL MARKET, INDUSTRY, ENTREPRENEURSHIP AND SMES
Consumer, Environmental and Health Technologies
REACH
Chemicals

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Open Session

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Room: SICCO MANSHOLT (MANS)
Building CHARLEMAGNE
Rue de la Loi 170, Brussels, 1049

Concerns: **Implementation of Annex VIII – Actors in the supply chain**

Agenda Point: **5**

Actions Requested: **- For endorsement**

- Written comments can be sent to:

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1. CONCLUSIONS

In the view of the Commission services, re-branders and re-labellers who solely affix their own brand, or adapt corporate colours or identifiers on the label to a mixture or adapt the label in other manners, should be considered as distributors and not downstream users under the CLP and REACH Regulations. In consequence, such re-branders and re-labellers are not duty-holders pursuant to Art. 45 of CLP (hereinafter "**Art. 45**") and do not have any direct obligations based on that Article. Should a re-brander or re-labeller, or any other distributor, place on the market a mixture for which no notification has been made by that actor in the supply chain pursuant to Art. 45, he or she could therefore *not* be held responsible for breach of that Article read in isolation.

However, **all distributors, including re-branders and re-labellers**, have to comply with Art. 4(10) of CLP (hereinafter "**Art. 4(10)**"), which prohibits the placement of **a mixture on the market unless it is compliant with CLP.** In the view of the Commission services, that compliance requirement includes compliance with Art. 45, which provides that a national appointed body shall have at its disposal emergency health information for mixtures supplied in its Member State. A distributor placing on the market a mixture, which would jeopardise an appointed body's access to that information, would therefore run the risk to be in breach of Art 4(10).

In other words, although a distributor has no direct notification obligation under Art 45, he/she also has no right to either distribute a mixture in a different Member State than the one he purchased it from, or distribute it with a different product identifier than that of his/her supplier, without previously making sure that the relevant appointed body has access to the relevant emergency health information. That is because both those actions could have the result that (alleged) previous compliance with Art. 45 – based on a notification made by an importer or downstream user to the appointed body of the Member State where *the importer or downstream user* placed the mixture on the market, and with the product identifier used by *the importer or downstream user* – would suddenly turn to incompliance because of the distributor's own placing on the market. In such a case, the distributor would have placed the mixture on the market in breach of Art. 4(10), and penalties could be imposed on him by virtue of that Article.

CARACAL members and observers are invited to endorse this conclusion.

In case of endorsement of the proposed approach, the Guidance on the implementation of Annex VIII will be adapted accordingly.

2. JUSTIFICATION FOR THE CONCLUSION

While COM's position regarding the qualification of re branders and re-labellers has not changed, in view of the strong need expressed by MSs to curb the information loss, COM proposes to follow the

second alternative approach presented at the last CARACAL meeting in paper CA/120/2018[1] with some further refinements taking on board Member States' comments.

COM's proposed approach primarily hinges upon Art. 4(10), requiring substances and mixtures placed on the market to comply with CLP[2], thus putting the obligation on *all types of actors* to ensure that the chemicals they place on the market fulfil CLP requirements.

For some of the requirements under CLP, distributors may rely on the information provided to them by their suppliers. For example, Art. 4(5) states that distributors may use the classification for a substance or mixture derived by an actor in the supply chain[3]. This is justified, as it can be reasonably assumed that the upstream actor or supplier has fulfilled its obligations and the classification indicated on the label is the correct one. As by definition a distributor cannot change the composition of the chemical he places on the market (otherwise he would be a downstream user), the classification will also not change.

By contrast, in the case of information provision for the purposes of Art. 45, the distributor himself may make specific changes to a distributed mixture so that it will be no longer compliant with CLP, although by definition these changes do not concern the composition of the mixture. For example, when the distributor changes the product or brand name of the mixture, a change of the product identifier within the meaning of Annex VIII Part B Section 4.1 is brought about and this information will not be available in the supplier's original notification. Thus, there is an obligation to continue providing valid information, which can only be achieved by means of a submission update, in line with Annex VIII Part B Section 4.1 of CLP, otherwise the mixture will not comply with Art. 45. A similar and comparable lack of information will occur where the distributor himself supplies the mixture in another Member State, different from the one where he bought it from his/her supplier. In both examples, because the distributor himself/herself takes an action, which can cause non-compliance with Art. 45, it can be argued that Art. 4(10) imposes on him/her a direct obligation to prevent the potential non-compliance before placing the mixture on the market.

On the other hand, the requirement for distributors to ensure that the products they place on the market are compliant with CLP does not lead to the obligation for them to submit a new notification under Art. 45. Indeed, Art. 45 puts the notification obligation on importers and downstream users only. Art. 45 also provides that the appointed bodies in the Member States must have the information from importers and downstream users at their disposal. This information includes "the chemical composition of mixtures placed on the market and classified as hazardous on the basis of their health

[1] https://circabc.europa.eu/ui/group/8a073cb6-03cb-4665-a866-4a17b17a6f60/library/8fe98887-7308-43df-a96b-c0303d46d3a7/details

[2] Art. 4(10): "Substances and mixtures shall not be placed on the market unless they comply with this Regulation".

[3] Art. 4(5): "In fulfilling their responsibilities under paragraph 4, distributors may use the classification for a substance or mixture derived in accordance with Title II by an actor in the supply chain".

and physical effects". So even if the distributor has no direct notification obligation in Art. 45, he/she must take notice, before placing a mixture on the market, of the of importers' and downstream users' obligation to provide the information on the mixtures placed on the market to the appointed bodies, whatever the brand or the Member State. Thus, the distributor should not rely solely on the importer or downstream user for compliance with Art. 45 in the context of his/her own placing on the market, and should therefore not presume that his/her own placing on the market is compliant with Art 4(10). Hence, **the missing information has to be made available to the appointed bodies one way or the other, whether directly by the distributor or via the downstream user,** in order for the distributor to fully comply with the CLP Regulation.

COM's proposed approach is also further reinforced by the cooperation obligation provided for by Art 4(9) of the CLP Regulation.[4] In line with this provision, the distributor is obliged to cooperate with the upstream duty holders: this can be achieved through upstream communication by the distributor to their supplier concerning all relevant information about the distribution step. In this manner, the upstream duty holders will receive the relevant information and be in a position to supplement their submission. Alternatively, if the distributor does not want to disclose this information to the upstream duty holder, then the former should be obliged to submit the notification on their own and on behalf of the upstream duty holder.

The advantage of COM's proposed approach is the fairer distribution of responsibilities between the upstream supplier (downstream user(s)) and the distributor. Also, enforcement will be more practicable: downstream users are to demonstrate that they acted diligently, *i.e.* in case of receipt of information from distributors this information has to be taken up in the notification because of their direct obligations under Art. 45. In cases where the duty holders, *i.e.* the importers or downstream users, did not provide such information to the distributor, the distributor is prevented from placing on the market the incompliant mixture by virtue of Art. 4(10), unless the distributor himself/herself provides the required information directly to the appointed body.

For actors in the supply chain other than importers or downstream users, orders or penalties, depending on the applicable laws in the Member States, can be imposed by virtue of Article 4(10).

[4] Art. 4(9): "Suppliers in a supply chain shall cooperate to meet the requirements for classification, labelling and packaging in this Regulation".

3. BACKGROUND

According to Art. 45 legal obligations regarding information submission to appointed bodies are imposed on importers and downstream users. Concerns were raised by Member States and Poison Centres regarding the potential loss of information in cases where a distributor purchases a product in Member State A and places it on the market in Member State B. Given the fact that distributors do not have a direct notification obligation under Art. 45 or Annex VIII, no submission would be done in MS B and information would therefore not be available in that MS in case of an emergency. Moreover, if a mixture was placed on the market under a different brand name in the same MS, the mixture could only be identified via the UFI and not via the brand name.

A discussion on the status of re-branders and re-labellers under Annex VIII to CLP was held at the 26th, 27th and 28th CARACAL meeting of respectively March, June and November 2018 as well as during the CASG-ATP meeting in October.

An overview of and a response to the comments received after the 28th CARACAL meeting is given in Annex.

Annex

	SUMMARY OF COMMENTS	COMMISSION'S COMMENTS
Support for alternative approach proposed by COM	• **SK**: SK welcomes the proposed alternative approach, which hinges upon Art. 4(10). This establishes an obligation for all types of actors to ensure that these chemicals comply with the requirements of CLP.	• COM thanks for the support.
	• **IE-NPIC**: The IE-NPIC welcomes the alternative approach. It makes it clear that distributors, including re-branders, have a responsibility to ensure that the products they place on the market have been notified to the relevant appointed body.	• COM thanks for the support.
	• **DE**: DE supports the statements regarding Art. 4(10) (see point 1 below). However, the question of whether the re-branders/re-labellers are obligated to submit information in accordance with Art. 45 has to be considered separately (see point 2 below).	• COM thanks DE for the support on the alternative approach.
	• **1)** If an actor in the supply chain changes the product name or brand name of a mixture, a product identifier within the meaning of Annex VIII Part B section 4.1 is changed. Thus, there is an obligation in accordance with Annex VIII Part B section 4.1 to provide a submission update. If the mixture is placed on the market without a submission update, it will not comply with the requirements of Art. 45 in conjunction with Annex VIII, as no valid information has been submitted for the changed mixture. Under Art. 4(10), the mixture may not be placed on the market by any actors as it does not comply with the provisions of Art. 45 in conjunction with Annex VIII. It is therefore in the interest of every actor in the supply chain wishing to place the mixture on the market that a correct submission for the mixture is provided. This applies irrespective of who is obligated to submit information under Art. 45. Art. 4(10) CLP ensures that a mixture may only be placed on the market if it fulfils all requirements of the CLP Regulation.	• COM agrees with DE's interpretation and has fine-tuned its alternative reading based on the comments received.
	• **2)** The question as to who specifically is obligated to submit information under Art. 45 has to be considered separately. It is conceivable for a third party to submit information on behalf of the duty holder under Art. 45. However, only the duty holder can be penalised for neglecting to submit information in accordance with Art. 45 and Annex VIII. Only the duty holder may be ordered by the responsible enforcement authority to submit information. For other actors in the supply chain not obligated to submit information under Art. 45, orders or penalties can only relate to the fact that mixtures which do not comply with Art. 45 may not be placed on the market. Therefore, the solution	• COM agrees with DE that penalties can be imposed only on the duty holders under Art. 45. However, penalties by virtue of Art. 4(10) can be imposed on any other actors. COM paper has been fine-tuned based on this argumentation.

	presented in relation to Art. 4(10) should not be viewed as an "alternative approach", but rather as a supplementary provision which applies in all cases. • In any case, DE maintains the opinion that actors who place a mixture from a third party on the market under their own brand or trade name meet the definition of "downstream user" within the meaning of Art. 2(19) CLP.	• COM takes note of this reading and refers to its previous position papers outlining COM's different opinion.
	• **NL**: NL agrees with the Commission's proposed approach	• COM thanks for the support.
	• **IT**: IT welcomes COM's efforts to find a solution by adopting an alternative approach using Art. 4(10). An amendment of Art. 45 should be the real solution anyway. • IT deems that Art. 4(10) recalls a shared responsibility of the distribution level to ensure that the products placed on the market are compliant with the notification duty. This interpretation appears to be in line with the DPD on which Art. 45 was based, foreseeing the duty to notify for "the manufacturers or persons responsible for marketing". Such a wording helped to ensure that PCs will have all the information they need. • A huge awareness raising for companies of the distribution chain could offer a support to by-pass the critical issue of loss of knowledge. The re-labeller/re-brander should have the possibility to add the new name which he has chosen for the product and there would be possible ways to implement this: 1) The distributor himself could act on the original notification filling a dedicated field by specific IT procedure; 2) The distributor could update the duty-holder (formulator/importer) who will then in turn update his own notification; 3) The distributor could create a "sub-notification" linked to the original notification by the original UFI. This could be done without knowing the composition of the mixture. • The enforceability of the indirect duty of the re-brander/re-labeller is problematic from a legal point of view, anyway an effort to find a solution could be investigated at national level by adopting (if it has not been there yet) a specific sanction for a non-compliant mixture by virtue of Art. 4(10).	• COM thanks IT for the support on the alternative approach. COM will investigate whether an amendment of Art. 45 could be envisaged in the future under a new Commission. • COM agrees that awareness raising among distributors will be necessary. The possible ways of implementation outlined under 1) and 2) correspond more or less with the solutions outlined by COM in point 2: Upstream communication by the distributor to his supplier or submission by the distributor himself. • COM takes note of the comment and indeed, such ways of imposing sanctions at national level could be explored, if not already done.
	• **DUCC**: DUCC refers that its previous position dated 7 November 2018 (available on CIRCABC), remains valid: "Any decision or clarification on this point will undoubtedly introduce additional responsibilities for many economic operators (some of whom will be SMEs), but in the meantime there is a lack of legal clarity".	• COM takes note of this comment; the alternative approach of COM was introduced in order to provide more legal clarity.

Rebranders = Downstream-users	• **BE**: BE interprets re-branders as downstream users in its current legislation since more than 2 years. Until now BE did not receive any argument that legally contradicts BE's interpretation. BE will therefore still consider that a re-brander is a DU in the sense of the CLP with all the related obligations coming with this status.	• COM takes note of the BE comments and statements.
	• **IE**: Overall IE sees merit in the approach outlined in CA/120/2018, which relies upon article 4(10). It may ensure compliance where a distributer breaks the link between the original supplier (by either changing the product name or supplier details on the label, or marketing it in another Member State/changing the language) in that he should assume the obligation to notify to the relevant poison centre(s). This alternative approach appears to be more in line with Article 17 of Directive 1999/45/EC, on which Article 45 CLP was based, which placed the duty to notify on "the manufacturers or persons responsible for marketing".	• COM thanks for the support.
	• However, IE does have some remaining concerns with the approach. The end outcome or options for the distributor is still the same here as it was with the previous option – the obligation to provide information to the appointed bodies can be achieved either by the distributor providing the information upstream to his supplier for inclusion in the supplier's notification, or if he does not want to disclose the information to his supplier, then he does the notification himself. The main difference between this current approach and the previous one is that it does not rely on contractual arrangements being in place, which certainly would have been problematic.	• COM takes note of this comment and reaffirms that by adopting the alternative approach, the obligations of the distributors are not based on contractual arrangements but all actors are bound by Art. 4(10) to be compliant with the CLP.
	• IE has concerns on the enforceability of this Art. 4(10). IE sees the obligation on the distributor as an indirect one, which may be problematic from an enforcement point of view. It is not clear on whom the enforcement action would be taken: The downstream user (under Art. 45) or the distributor (under Art. 4(10))?	• COM is of the view that enforcement actions can be taken respectively on the downstream users by virtue of Art. 45 and on the distributors directly by virtue of Art. 4(10).
	• A second concern is the fact that there will be instances whereby the distributor will not have the full compositional details of the original mixture, which will be problematic, if he chooses to do his own notification. We note that Article 4(5) of CLP enables distributers to use the classification of a mixture derived by another actor in the supply chain. It therefore may follow that this classification information is used for notification of the same mixture. Therefore, where a distributor notifies a product from another supplier, IE considers that the optimal solution is that the UFI of the original mixture is included in his notification. This would ensure that the toxicological and compositional information, related to the UFI, for that mixture, remains consistent.	• COM agrees with this statement. The distributor will be obliged to use the UFI of the downstream users in order to be compliant with Art. 4(10).

	• IE notes the intention that the guidance on the implementation on Annex VIII will be updated if the proposed approach is agreed. IE questions whether also a change of the legal text, perhaps to Annex VIII, is required.	• A change of Annex VIII would not resolve the problem given that the basic text in Art. 45 limits the notification obligations to downstream users and importers. COM will investigate whether an amendment of Art. 45 could be envisaged in the future under a new Commission.
	• **FR (Summary):** FR competent authorities consider that, as soon as a company changes the label, the brand or the package of the hazardous mixture it places on the market, the company should be considered as a downstream user and not as a distributor given that a distributor only stores and places the mixture on the market based on the packaging from the producer/importer. • FR considers that the alternative approach of COM is not binding enough: Art. 4(10) merely states that substances and mixtures shall only be placed on the market if they comply with CLP Regulation. Conversely, Art. 45 is clear and accurate: only importers and downstream users shall notify information relating to emergency health response to appointed bodies. Art. 2 of CLP provides precise definitions of importers, distributors and downstream users: distributors cannot be considered as downstream users. Art. 4(10) does not allow a broad interpretation of Article 45 by adding distributors, and thus relabellers, rebranders and repackagers as notifiers. • In FR, a system for notifying the composition of hazardous chemicals exists for thirty years: The FR authorities consider that a chemical mixture is characterised by its composition, labelling and packaging. In practice, it is up to the company mentioned on the mixture label to declare the composition of the mixtures it places on the market.	• COM takes note of FR position. • COM is of the view that Art. 45 and Art. 4(10) are not mutually exclusive but should rather be read in conjunction. It is true that Art. 4(10) does not extend the obligations in Art. 45 to the other actors. Art. 4(10) rather provides certain compliance obligations in addition for the other actors. • COM takes note of FR statement.
Amendment of Art. 45 is necessary	• **FI**: FI supports the view of the Commission that re-branders are distributors. However, FI does not see how importers and downstream users can be held legally responsible for collecting information from downstream actors in the supply chain. If a re-brander does not want to disclose his information upstream and wants to submit a notification himself, importers or DU cannot be held liable for the content of the notification given that they have no true possibility to control whether the submitted information is correct. Hence, FI cannot support the alternative solution presented by COM to use Article 4(10). • FI would like to support the SE CA's proposal (CA/MS/85/2018) that a reasonable solution would be to amend Art. 45 by including re-branders and to specify that they are duty holders. This would also mean that a definition of re-brander should be	• COM takes note of FI position. • After a new COM is appointed, COM might investigate whether an amendment of Art. 45 could be envisaged.

	included in Article 2.	
	• **SE:** **Art. 4(10)** COM has presented a solution based on Art. 4(10), where the importer or downstream user would still be the main responsible for information provision to the appointed bodies. In addition, there would also be an (indirect) obligation for distributors to provide that information. SE shares the opinion that it must be clear legally how this could work: SE believes that this would for example require additional amendments of Annex VIII. However, SE is doubtful whether it is possible to use Art. 4 (10) for this purpose. Art. 4 is about general classification, labelling and packaging requirements, *i.e.* requirements for the nature of the products themselves. Obligations to notify to the appointed bodies cannot be considered as a requirement for the products themselves.	• COM takes note of SE statement. A change of Annex VIII would not resolve the problem given that the basic text in Art. 45 limits the notification obligations to downstream users and importers. After a new COM is appointed, COM might investigate whether an amendment of Art. 45 could be envisaged.