Poison centres:

A ‘how to’ guide for Annex VIII compliance

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Authors: Dr Charlotte Blackburn and Dr Rebecca Pickering

Introduction

Article 45 of CLP (Regulation (EC) No 1272/2008) put in place the requirement for Member States to set up appointed bodies who will receive information on the composition of hazardous mixtures placed on the market.

At present, the exact requirements for each Member State are stipulated in national regulations and the information required to be notified varies considerably. In some Member States submission of a Safety Data Sheet (SDS) suffices, whilst other Member States have much stricter and more intensive requirements, which inevitably places a high level of administrative burden on industry.

Article 45 also included the requirement to review the possibility of harmonising the information that was submitted to the appointed receiving bodies. Following this review, Regulation (EU) 2017/542 was adopted, which adds an additional Annex (VIII) to CLP. The first amendment to Annex VIII, Delegated Regulation (EU) 2020/11, was published in January 2020, postponing the first compliance date by one year and bringing in other smaller changes. The second amendment to Annex VIII of the Classification, Labelling and Packaging (CLP) Regulation, which entered into force on Nov. 14, 2020, addresses the concerns raised regarding workability, as well as the labelling of bespoke or custom paints.

This guide will take you through some of the key requirements of Annex VIII and help identify the steps you need to take to achieve compliance.

Am I obliged to submit a Poison Centre Notification?

The obligation to submit a Poison Centre Notification (PCN) is dependent on your role in the supply chain and the products in your portfolio. The first step is to determine whether you are a duty holder. This will need to be determined on a case-by-case basis as your role may vary from product to product.

In the context of Article 45 and Annex VIII, duty holders, or "submitters", are importers and downstream users that place hazardous mixtures on the market. Hazardous mixtures are those mixtures that (a) fall into the scope of CLP and (b) have a physical or health hazard classification. There are some exceptions, including mixtures that are for scientific research and development or product and process-oriented research and development; and mixtures that are classified only as gases under pressure and/or explosives.

Therefore, if some of your products are substances, or mixtures that are classified for environmental hazards only, or mixtures that are not classified as hazardous in accordance with CLP, then these are exempt from the notification requirements of Annex VIII. In addition, mixtures that are only subject to supplemental labelling requirements – EUH208, for example – are not themselves classified as hazardous under CLP and are therefore not required to be notified.

For each product in your portfolio which you are obliged to notify, information must be submitted to each Member State in which you place the product on the market. The information must also be submitted in the language(s) required by the Member State; some Member States will allow English whereas others will allow only an official language (or multiple official languages).

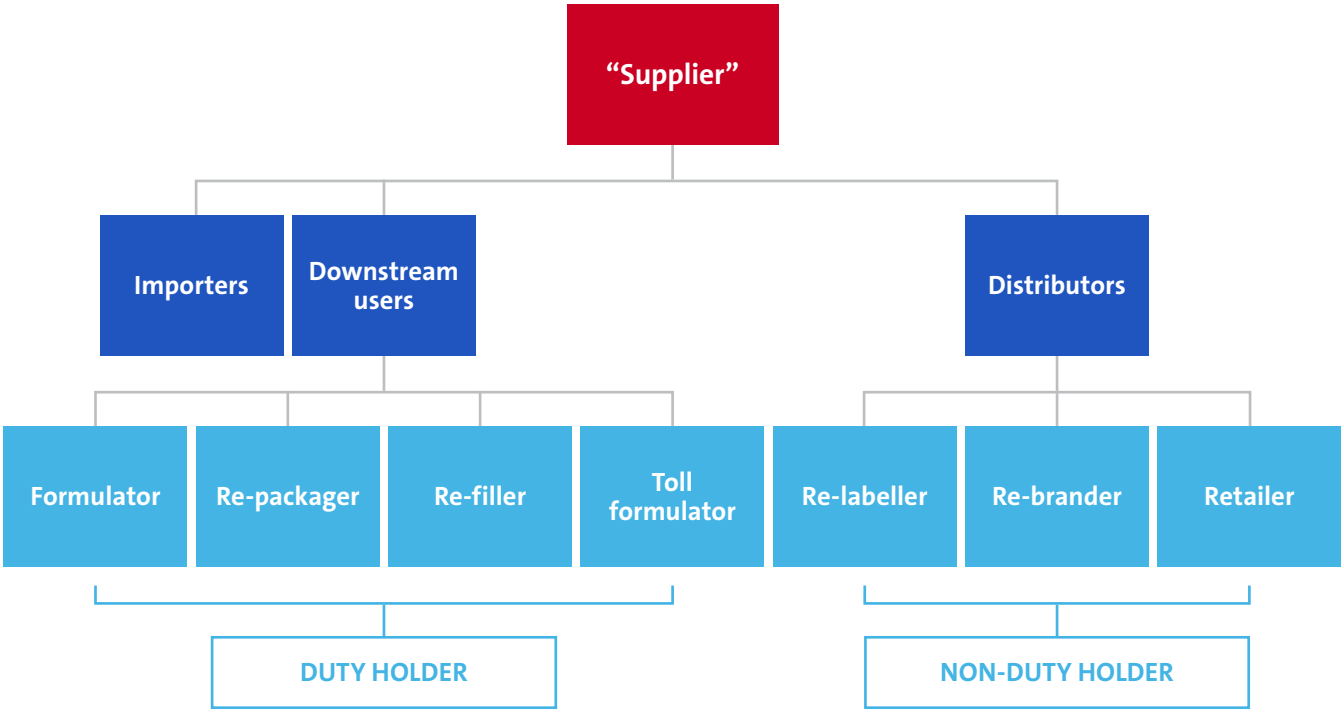

Figure 1. The roles of duty-holders and non-duty holders

Whilst distributors are not considered duty holders, they do need to comply with Article 4(10) of CLP, which stipulates that any substance or mixture that is placed on the market must comply with the CLP regulation. As such, if a distributor knowingly places on the market a mixture that has not been notified to the relevant appointed bodies in accordance with Annex VIII, they would be in breach of Article 4(10).

Distributors must therefore make sure that the appointed body in each Member State in which they are placing the product on the market has received a submission that covers their product (i.e., trade name and/or UFI). This will require communication upstream to the supplier to make them aware of the distribution step including (a) in which Member States they intend to place the product on the market and (b) the product identifiers (trade name, UFI) if they differ from the supplier's. If the distributor chooses not to disclose this information to their supplier, then they would need to submit their own notification, to ensure compliance of the product.

Are there any cases where I may need to submit a PCN as a non-duty holder?

There might be. For example, as a re-brander you have to ensure that your product is covered by your supplier's submission. However, if you do not want to make your supplier aware of this re-brand, for them to include it in their own submission, then you would need to submit the notification yourself.

Where individual products do not fall into the scope of PCN requirements, and you are therefore not considered a duty-holder, it is also possible to make a voluntary notification.

You may want to do this for several reasons; for example, if your non-hazardous mixture ends up in a further mixture downstream (mixture in mixture, or MIM) in one of your customer's products and you do not want to disclose the composition. A further scenario may be that you are placing a product on the market that is not classified as hazardous in accordance with CLP but may be harmful to certain groups of people. In these cases, if a call was made to a poison centre, the availability of information would facilitate an effective response.

When do I need to submit the information?

Article 45 of CLP is not new and there has always been the requirement to submit information to poison centres according to national regulation before a product is placed on the market.

There are however deadlines in place for making a submission in the new harmonised format (PCN) as laid out in Annex VIII CLP. So, if you have determined that you are a duty holder under Annex VIII for a product, the next step is to identify when the PCN is required to be submitted by.

There are three key deadlines, and which one of these you are required to meet depends on the end use-type of the product. In the context of Annex VIII, there are three use-types for mixtures: "mixture for consumer use", "mixture for professional use" and "mixture for industrial use".

Figure 2. Submission deadlines

** The deadline for mixtures placed on the market for consumer use was originally Jan 1, 2020, however an amendment to the regulation postponed this first compliance deadline to Jan 1, 2021 which brings it in line with the deadline for professional use mixtures. A number of workability issues relating to Annex VIII requirements have been raised, such as dealing with the impact of multiple suppliers of technically equivalent raw materials. The deferral of the first deadline by one year should allow time for necessary solutions to be developed and any resulting changes to the new rules made.*

You will need to identify the final use of the product before it reaches its end-of-life stage. It may be that you only sell your product directly to professional users, but if they further distribute the product and it ends up on the consumer market, then you will need to meet the 'mixture for consumer use' deadline.

The same will apply if a mixture you sell to industry eventually becomes integrated into a final mixture that is intended for use by consumers. It is therefore important that you understand the full supply chain and efforts should be made to talk to your customers downstream. If you already have a product on the market and have notified Member States in accordance with current national legislation, then you have until January 1, 2025 to comply with Annex VIII (unless the product changes). After January 1, 2025, every mixture placed on the market that falls into the scope of CLP and has a physical or health hazard must have a PCN submitted that complies with the requirements of Annex VIII.

What happens if my product changes?

If you plan to take advantage of the transitional period, but certain product information (e.g., mixture composition, mixture classification, toxicological properties or product identifiers) changes between the applicable submission deadline and January 1, 2025, then you will be required to make a notification that complies with the requirements of Annex VIII.

Can I submit the PCN before the first deadline?

The current national systems will remain in place until the first deadline and it will be at the discretion of each Member State to accept submissions in the new harmonised format before this time. Currently, only some Member States have confirmed that they are already connected to the ECHA submission system and ready to accept notifications. For all other Member States, duty holders must continue to notify their mixtures according to the requirements of national legislation until further notice (this will be at the latest until December 31, 2020 for mixtures placed on the market for consumer and professional use).

What sort of information do I need to submit?

The implementation of Annex VIII means that there will only be one set of information to gather for each product across all Member States, with the exception of the specific language requirements.

The new harmonised information requirements broadly encompass four key areas: details of the submitter; information on the mixture; Unique Formula Identifier (UFI); and product details.

Much of the data that is required is the same as that used to classify your product according to CLP and to create a compliant EU SDS. However, there are details that are specific to Annex VIII that you will need to gather that form part of the notification, and you might need to talk to your suppliers to achieve the full information requirements.

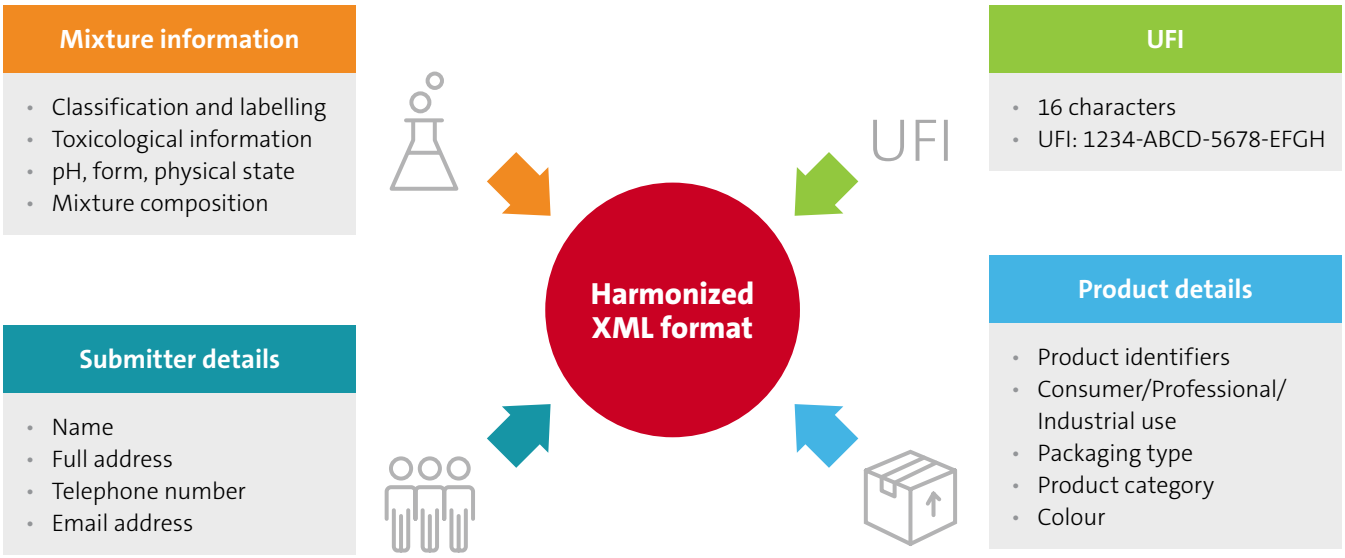

Figure 3. Harmonised information requirements.

What is a UFI and how do I generate one?

A Unique Formula Identifier, or UFI, is a 16-digit alphanumeric code that forms part of the Annex VIII requirements, and allows unambiguous identification of a particular product, enabling poison centres to quickly determine the mixture involved in case of a poisoning incident.

A UFI is typically generated using a formulation number and a VAT number which, using a particular algorithm, will ensure that there is no duplication across companies. Companies are responsible for generating their own UFIs, and this can be done now, free-of-charge, using the tool provided by ECHA or through a third-party software provider. ECHA's UFI Generator can be found here. Management of the UFI generation process is very important. As a company, you will need to know which UFI corresponds to which mixture, which VAT number was used, and the internal formulation number used to generate the UFI. Tracking this information internally means that the same UFI is never used for mixtures of different compositions.

When it comes to using the generated UFIs, it is important to note that a single UFI can only ever represent one mixture composition. However, it is possible for a single mixture composition to have multiple UFIs (for marketing or confidentiality reasons, for example). In this case, all of the UFIs that are assigned to a particular mixture can be included in one submission or a submission for each UFI can be made.

The UFI that you generate for a particular mixture composition is considered supplemental information under CLP and shall be printed on or affixed to the product label; the alphanumeric code itself must be preceded by the acronym "UFI" followed by a colon ("UFI:"). For practical reasons, you may opt to print or affix the UFI on the inner packaging as long as it is clearly visible and located by the other labelling information. It is not necessary to include the UFI on each layer of packaging, which is in derogation from Article 33 of CLP. If it is impossible to include the UFI on the inner packaging due to its shape or size, the UFI can be printed or affixed on the outer packaging, located with the other label elements.

The only exemptions from the UFI labelling requirements are for industrial use only products or unpackaged products. In the case of mixtures supplied for use at industrial sites, the UFI may instead be included in the SDS; for unpackaged products, the UFI can be included in the SDS or in the copy of the label elements that accompanies the product, in accordance with Article 29(3) of CLP.

For those products where the UFI has to appear on the label or packaging, CARACAL has endorsed that there is no default requirement to place the UFI on the SDS. You can include the UFI on the SDS voluntarily, but it is worth considering that if you have to submit a revised PCN you would have to update the UFI on the SDS and re-issue the SDS. Note: If you are already complying with current Member State poison centre notification requirements, for each applicable product and market, and are taking advantage of the transitional period, then you do not have to generate a UFI or put it on the label/packaging at the moment. However, once you submit a PCN in compliance with Annex VIII then you will be required to do so.

Will I be able to find all of the information that I need on the SDS for the product?

Some of the information can be sourced from the SDS; for example, the classification of the mixture and the label elements (Section 2 of the SDS) and the toxicological information (Section 11 of the SDS). However, the harmonised format requires the full product formulation and this level of compositional breakdown is typically not declared on the SDS. There are also certain pieces of information that are required under Annex VIII, such as the packaging details and use type(s), that won't be included on the SDS.

Annex VIII also introduces the concept of a harmonised European product categorisation system (EuPCS) which is used to describe the intended use of a mixture and forms part of the Annex VIII information requirements. From the list of product categories, you will need to assign the one which best defines the main intended use of the product (for example 'Mixtures for further formulation' or 'Hand dishwashing detergents') based on the user next in the supply chain.

You should make sure that you are communicating within your supply chain to obtain the full information requirements; for example, the end-use type of your mixture, whether any re-branding or re-labelling activities are being carried out, and in which countries your product is placed on the market (by a distributor, for example).

How much information do I need on the formulation?

Ideally, you will be able to indicate the full breakdown of the components that make up your mixture, whether these components are substances, or mixtures that you have incorporated into your product (a mixture in mixture, or MIM). Above certain thresholds (dependent on the classification), both hazardous and non-hazardous mixture components have to be declared in the submission.

Along with the component identifier and hazard classification, the exact concentration or concentration range must also be given for each of the identified components. The allowable concentration ranges (specified in Annex VIII) depend on the classification of the components and differ to the concentration ranges permissible in Section 3 of the SDS.

My mixture is made up of other mixtures, and I don't know their full compositions – how do I deal with this?

Mixtures are often made up of other mixtures which you may have bought in from suppliers; in the context of Annex VIII, these are referred to as mixtures in mixtures, or MIMs. Ideally, your supplier will be able to provide you with the full composition of the MIM that you use in your product, and if this is the case then you should declare the breakdown of the substances in your PCN submission.

However, it may be that your supplier does not provide you with the full formulation, and you only have the information from the SDS that they provided to you. In this case, you will need to identify the MIM by its product identifier and its UFI - but you will need to make sure that the relevant appointed body has already received the information on the MIM. If some of the MIM components are known from the SDS, then these should also be given in your submission. If your supplier changes the UFI of a MIM or you change supplier, then you will need to update your PCN accordingly.

If your supplier does not have a UFI for the MIM (if the MIM is non-hazardous, for example) or the relevant appointed body has not received the information on the MIM, then the MIM shall be identified by means of its product identifier (trade name or designation of the mixture), together with its concentration and the compositional information contained in the SDS and any other known components, along with the name, email address and telephone number of the MIM supplier.

Are generic product identifiers allowed?

Generic product identifiers can be used to identify one or more components of a mixture if they fall into one of the following classes and are used exclusively for these purposes: perfumes and colouring agents. However, this is subject to certain criteria; the generic product identifier can only be used if the relevant components are not classified for any health hazards and are in the mixture in a sum total concentration not exceeding 5% for perfumes or 25% for colouring agents. Due to the non-hazardous requirement for a generic product identifier, many perfumes will not be covered by a generic product identifier and all individual substances in the component will, therefore, need to be listed.

I have multiple suppliers of very similar (but not exactly the same) components — how do I use the Interchangeable Component Group (ICG)?

The use of ICGs will provide a general solution for several sectors to help overcome situations where different but toxicologically similar components are used interchangeably in the formulation of mixtures. As long as there are no changes in classification, hazard or emergency health response, when using this option, the submitter can provide the concentration for the group instead of each component.

What if my product is a paint?

Another workability solution included in the second amendment to Annex VIII concerned bespoke or custom paints, which are paints made for an individual consumer or professional user at the point of sale by tinting or colour mixing. Due to the very high number of possible colours and associated poison centre notifications, the amendment provides suppliers of such mixtures the option to opt out of submitting information and creating a unique formula identifier (UFI) in accordance with Annex VIII. However, each of the mixtures contained in the bespoke paint must still be notified and have their own UFIs.

Does the standard formulas solution apply to my industry?

The concept of defined standard formulas for cement, gypsum binders and ready-mixed concrete has been introduced to help overcome difficulties in knowing the exact composition of mixtures at any given time and the variations in concentration range exceeding those declared under Annex VIII.

Mixtures conforming to one of these standard formulas do not need to comply with the standard requirements regarding the information on composition. To use this solution, the submitter must ensure that the final composition includes all the components listed in the standard formula, plus others in addition to them. The submitter cannot select and include only certain components from the standard formula.

For similar reasons as those described for the cement, gypsum and ready-mixed concrete sectors, it will be possible to submit the identity and concentration of the mixture's components listed in the EU Safety Data Sheet for certain defined fuels along with other known information on the products' chemical composition.

Can I include multiple products in the same PCN?

Each notification that is made must correspond to one formulation. However, if multiple products have the same formulation then it is possible to submit the details of individual products within the same notification; for example, a product may be sold under two trade names, but as long as the PCN includes all of the trade names and their corresponding UFIs, then the submission will cover both products.

There is also the possibility to perform a group submission such that, subject to strict criteria, information on multiple mixtures that have limited differences can be provided in the same submission. In these cases, where the criteria are met, one UFI can be used to cover all of the mixtures in the group or each mixture can have its own UFI.

How will I prepare and submit the required information?

A number of tools have been made available by ECHA which will enable all of the required information to be prepared in the correct format and submitted. The required information will have to be submitted electronically in the mandatory XML-based format (available on the ECHA Poison Centres website here).

A PCN portal has been developed by ECHA which will enable PCN submissions, dispatching of submissions and central storage of submissions. Member States do have the option to opt-out and develop their own submission systems, so submitters will need to make sure they are aware of the submission instructions in each country that they place their products on the market.

Will there be a fee to submit the notifications?

The tools provided by ECHA can be used free of charge, however, it is at the discretion of each Member State as to whether a fee is payable in order to be able to make the submission to their appointed body. At present, the majority of Member States have said that there will be no fees involved, while a small number are considering or will be levying fees.

Can my non-EU supplier submit information on my behalf?

As duty holders, EU importers have the responsibility to submit a PCN for the products that they import. In order to submit the PCN, they will need to gather the information required under Annex VIII, which includes the full formulation, and ideally, they will be provided with this level of information by their non-EU supplier. However, the non-EU supplier may wish to retain their confidential business information (CBI) and not disclose the full formulation. In this case, there is a workaround that has been highlighted in ECHA guidance.

If the non-EU supplier has a legal entity based in the EU (or a contractual agreement with an EU-based legal entity), they can generate a UFI for the mixture and perform a voluntary PCN submission (in all relevant Member States). The non-EU supplier should inform the EU-importer of the UFI and confirm a submission has been done. The EU-importer can then make their own submission, referencing the UFI of their non-EU supplier's mixture. The EU importer and the non-EU supplier are strongly recommended to enter into a contractual agreement to cover the details of the submission approach.

What steps should I take now?

The first deadline is less than one year away and there is a lot that you can be doing now to prepare.

Know your obligations	Are you a duty holder (remember this answer may be different for different products)? Are you an importer or downstream user of mixtures classified for physical and health hazards? Will you need/want to perform any voluntary submissions?
Know your portfolio	Which products need to be notified? Which countries are you placing the products on the market?
Understand your supply chain	Does your product end up in a 'final mixture' intended for consumer, professional and/or industrial use? What markets are your customers selling into? Are your customers re-branding the product?
Generate your UFIs	Will you undertake a "mixture-centric" or "product-centric" approach? Will each product or SKU have a separate UFI, even if they have the same formulation? Will each re-brand have a separate UFI? How will you ensure that the UFIs you generate are unique?
Collect your data	Have you gathered all the required information for the PCN? Do you need to talk to your suppliers and customers to get all the information?
Prepare your submission	How are you going to prepare your XML file?
Keep the information up to date	How will you continuously monitor your portfolio and supply chain in order to submit revised PCNs if necessary?

UL Solutions can help. Our world-class team of **global regulatory specialists** and our **expert software tools** can assist you in meeting your obligations and avoiding the financial and legal costs of non-compliance.

For further information about Poison Centres and the upcoming Annex VIII deadlines, visit UL.com/services/poison-centres.

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