

European UFI/PCN Notification

a non-EU supplier perspective

Recently, new rules have come into effect for placing hazardous mixtures on the EU* market. The product label needs to be updated to include the Unique Formula Identifier (UFI). The Poison Center Notifications (PCN) have to be done using the newly implemented PCN portal based on the harmonized content and format described in ANNEX VIII of the CLP regulation

This factsheet explains the responsibilities and implications of, and complications for non-EU suppliers with an EU legal entity, or EU distributors of products from outside the EU. It also offers a solution for products sold on the market directly by non-EU suppliers without an EU legal entity or distributor.

*CLP (+ Annex VIII) is applicable to the EEA: EU + Iceland, Liechtenstein and Norway.

Responsibilities

According to Annex VIII of CLP, the non-EU supplier is never the duty holder for the PCN notification in the EU.



Import into EU:

The importer is the official EU duty holder, but still needs information from the non-EU supplier to comply with CLP Annex VIII.

Export to EU:

The non-EU supplier needs a contract with a legal entity in the EU. The EU legal entity in this case becomes the official duty holder, but still needs information from the non-EU supplier to comply with CLP Annex VIII.

Implications

A non-EU supplier has no responsibilities regarding a PCN notification for the EU. However, the EU duty holder receiving/distributing/selling products still needs information only the non-EU producer/supplier can provide, e.g. about the composition of the product.

As non-EU producer/supplier, this is usually not information you like to share with costumers of even distributors. On the other hand, you do need to provide certain information to avoid making your product **unmarketable** in the EU.

Providing information in an initial PCN notification is not a possibility, because only EU-based entities have access to the PCN portal.

The **solution** in this case is providing a **voluntary PCN notification via a trusted third party** in the EU, like the SDS factory. The SDS factory has no function in the supply chain and can notify products under secrecy to the PCN portal as a voluntary initial submission. The EU customer/distributor can then link their submission to this voluntary initial submission.

Benefits

- ❖ The EU duty holder does not get access to the information in the initial submission.
- ❖ The composition is undisclosed in the supply chain and only shared under secrecy with the competent authorities.
- ❖ Linking a submission does create the possibility for Poison Centers to find the required information in the initial submission in case of an emergency.
- ❖ **Products can continue being marketed/sold in the EU.**

Would you like more information on UFI/PCN or third-party submissions? Do not hesitate to contact us!