

ECPA's Position on the Classification of Plant Protection Products

(The Classification of Plant Protection Products under Regulations (EC) 1272/2008 and 1107/2009)

“ECPA believes that suppliers of plant protection products (PPP) are solely responsible for their CLP classification¹ and that pesticide registration authorities do not have the legal right to unilaterally amend that classification as part of the pesticide registration approval process.

Pesticide registration authorities remain responsible for the approval of the remainder of the plant protection product label.”

Introduction

Despite EU-wide classification rules, a plant protection product sold in different Member States may have different classifications². The main reasons for this disharmony are the lack of clarity in the classification and PPP Directives³ and differing interpretations of these Directives in national legislation.

The replacement of the Directives by direct acting, legally binding EU Regulations⁴ represents an opportunity to improve the labelling of Plant Protection Products by ensuring harmonization of their classification, regardless of the country of sales.

Legal position

The responsibility for classification of plant protection products is defined by the CLP Regulation. The PPP Regulation does not change this responsibility and it allows the supplier to decide the classification of plant protection products under article 31(2). Both Regulations are direct acting EU legislation that apply directly to companies. Case law has established that in the event of conflicts between national and EU legislation, EU legislation continues to be fully applicable, even to the extent of national legislation being overruled.

¹ This means formulated product, does not include the classification of pesticide active ingredients, “substances” in CLP terminology, which will usually be subject to the harmonized classification procedure described in article 37

² Source: ECPA unpublished survey of classification of plant protection products across different member states

³ Directives 67/548/EEC, 1999/45/EC and 91/414/EC

⁴ Regulation (EC) 1272/2008 (the CLP regulation) and Regulation (EC) 1107/2009 (the PPP regulation)

In legal terminology, CLP is known as “horizontal legislation” and the PPP Regulation is known as “vertical legislation”. Vertical legislation may override horizontal legislation provided that this is clearly stated. If the vertical legislation can be interpreted in different ways then it does not override the horizontal legislation. ECPA has received external legal advice that as the PPP regulation does not explicitly state that a registration authority is responsible for the classification or that they must approve a classification, then the responsibility for classification remains with the company.

This advice is in line with the intention of the legislator: during the drafting of the PPP regulation, the Internal Market Committee of the European Parliament stated that “the notifier should be responsible for the classification”⁵.

Additionally, in a recent legal case in France, the court ruled that suppliers of Plant Protection Products were responsible for the classification of their products and not the registration authority⁶.

Article 31(2) of the PPP Regulation and the CLP Regulation

Article 31(2) of Regulation 1107/2009 requires the national authorisation decision for a PPP to include a classification. Some Member States have interpreted this as mandating them with the responsibility of classification even though the same Article provides the facility for an authorisation holder to classify and update a label when changes are necessary.

Regulation 1272/2008, the CLP Regulation, is horizontal legislation which means it can be complemented by product-specific legislation, such as the PPP Regulation.

Recital 47 of the CLP Regulation emphasises that legislation specific to PPPs “shall remain fully applicable to any products within [its] scope”. For PPP legislation to differ from the general principle of the CLP Regulation then it should be explicit. As Article 31(2) does not expressly change the responsibility for classification, the principle of legal certainty requires that the supplier remains responsible for the classification of plant protection products.

In addition, Article 46 of the CLP regulation requires member states to appoint a competent authority who is responsible for enforcement of the CLP regulation. In many member states, the competent authority for CLP is not the pesticide registration authority. In these member states, the pesticide registration authority lacks the legal competence to enforce CLP.

Responsibility for the overall approval process, including specifying conditions of use, risk mitigation measures and the remainder of the pesticide label remains with the pesticide registration authority.

⁵ European Parliament report on the 1st reading on the proposal for a regulation of the European Parliament and of the Council concerning the placing of plant protection products on the market, amendment 24 concerning Article 35(2)

⁶ Conseil d'état, Nos 314744-314775-314807-314808 Decision of 26 May 2010

Supplier responsibility for classification will benefit both pesticide registration authorities and Crop Protection companies

For pesticide registration authorities, supplier responsibility for classification:

- Avoids the large resource requirement of a systematic label review and approval process solely due to the change in classification legislation.
- Is consistent with the current initiatives on better regulation and reduced administrative burden. It will reduce cost and resources of implementation for both authorities and industry.
- Avoids any potential legal liability for incorrect classifications.
- Harmonises classification rules and procedures for plant protection products with other sectors of the chemical industry.
- Is enforced via enforcement arrangements⁷, that are well established for the all chemical sectors, This means that the company will be responsible for any accident or mishap caused by incorrect classification.

For Crop Protection companies, supplier responsibility for classification:

- Facilitates efficient adaptation of current labels to CLP by enabling companies to schedule label change activities for CLP implementation at the same time as routine label changes. This avoids the significant, additional costs that would be caused by changing labels solely for the purposes of CLP implementation
- Allows companies to schedule label change activities evenly throughout the transition period and avoid concentration of the work into a short period of time
- Legal responsibility and liability for accurate classification and labelling remains with the Crop Protection company

For Crop Protection companies and pesticide registration authorities, supplier responsibility for classification:

- Avoids unfair competition caused by different classifications for the same product or formulation.
- Eliminates the danger of inadequate safety measures in case of accidents due to differing hazard classifications among Member States.
- Facilitates Crop Protection companies and the pesticide registration authorities working together to ensure a smooth transition to CLP and to avoid market distortion by, for example, agreeing common implementation dates for a specific market.
- Avoids the confusion caused by country specific classifications.
- Takes advantage of the company's in-depth understanding of the information on which to base the classification of his products, leading to improved quality of classifications and ensuring consistency across Europe.
- Provides a basis of a sustainable way of working for the future.

⁷ As required by article 46

Questions and Answers

- Q.** When reclassifying a product for CLP, do I need to notify my registration authority?
- A.** Although as the supplier you are responsible for reclassifying your product, we recommend that you inform your pesticide registration authority of the new classification as a courtesy. A well written safety data sheet contains all the information required for a competent person to understand how the classification was derived and ECPA recommends that the SDSs be the primary communication method on classification to registration authorities. We see no need for a complicated form.
- Q.** What happens if I need to change the classification of my product in the light of new data or Harmonised Classification?
- A.** Article 31(2) quite clearly states that an authorisation holder shall classify and update a label without delay following any change to the classification of the PPP in accordance with the CLP Regulation and immediately inform the competent authority.
- Q.** What happens if my pesticide registration authority does not agree with my classification?
- A.** In the first instance, we expect that you will discuss your differing views informally. As a result, you will either agree that you've made a mistake in your classification, and correct it, or your registration authority will understand the basis of your classification. If, after these discussions, your registration authority still does not agree with your classification and you do not agree with the pesticide registration authority's view, then you can continue to use your classification. The pesticide registration authority is free to initiate formal enforcement under their national enforcement provisions. If the pesticide registration authority is not the designated competent authority for CLP, they will have to pass the case to designated competent authority for CLP; they will not be able to take formal enforcement action themselves. The exact details of the enforcement procedure vary between countries; however the procedures commonly include a judicial review stage that allows you to appeal against the actions of the authority. This is the same procedure that is used to enforce CLP for all other chemical products.
- Q.** Article 31(2) of the PPP regulation states that the authorisation shall include the classification of the plant protection product. Does this mean that the registration authority has to approve the classification before they can issue an authorisation?
- A.** No. As detailed earlier, external legal advice that ECPA has received indicates that the responsibility for classification lies with the supplier and that the PPP regulation does not change this. Hopefully, during any informal discussions, the supplier and the registration authority will agree on the classification (see answer above). In the event that agreement cannot be reached, any classification contained in the authorisation document is advisory and the supplier is still required by the CLP regulation to use the classification that they believe is correct.
- Q.** Apart from the CLP information, may we change any other part of the label without approval from the pesticide registration authority?
- A.** No. The principles described in this paper apply to the CLP information only. All other changes to the label continue to require approval from the pesticide registration authority.