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Review of consequences of legislative incoherence between CLPR & PPPR Regulations

Dear Mr Nunes De Almeida,
Dear Mr Pettinelli,

I write to draw your attention to a developing problem with classification of Plant Protection product substances where there are major ramifications for EU competitiveness and trading relations. The issue has been identified as part of the REFIT exercise, with the implications being incompatible with the principles of smart regulation.

The issue concerns the interaction of the Classification, Labelling and Packaging Regulation (CLPR; Regulation 1272/2008) and Plant Protection Products Regulation (PPPR; Regulation 1107/2009). A number of authorised PPPs are currently undergoing a review as part of the normal active substance renewal evaluation process (often referred to as AIR). As a part of that review, a decision on the classification of the substance is made. Unfortunately for PPP substances the consequences can be severe as the hazard classification may lead to the non-renewal of the PPP authorisation. The CLP Regulation was primarily designed to allow general chemicals to be classified for human health and environmental hazards with the information being communicated to downstream users via the SDS and the label. General chemicals of concern can be dealt with through REACH Authorisations and Restrictions where a detailed risk assessment is made and socio-economic factors may be considered whereas for PPP active substances the situation is different. Under the PPPR, a hazard classification can lead to a qualification of a substance as a cut-off substance, hence a risk assessment would not even be possible.

Classification does not consider the consequences for product authorisations, which should be a decisions for risk managers. Yet, risk managers are constrained by the hazard based classification 'cut-off criteria' in the PPP Regulation which dictates the non-approval of substances. The options and consequences that would normally be considered by the Committee for Socio-Economic Analysis (SEAC) for REACH chemicals does not apply therefore making risk management redundant. This is leading to scenarios where products that have a long history of safe use worldwide, run the risk of being removed from the EU market based on hazard and not risk.

As an example, one class of substances that are being impacted are the azole fungicides which are increasingly being allocated classification criteria that trigger the cut-off criteria in the PPPR. As the review of these substances continues a very high percentage of fungicides will be taken off the market, substantially increasing resistant strains of disease in EU agriculture. Azoles fungicides have been safely used worldwide, in some cases for over 30 years, and are vitally important in the control of diseases in important crops in the EU. If

this class of chemistry were to be lost to European farmers, the impact on yield and viability would be high. The classification process also has implications for biocidal products where similar authorisation restrictions are triggered, thus impacting a number of sectors such as wood and timber preservation that are vital for construction in Europe.

The Commission's REFIT study on risk management of chemicals¹ identified this regulatory incoherence problem and the problems arising due to unintended consequences. The situation runs a clear risk of regrettable substitutions "*...for example, the loss of certain active ingredients may lead to increased loading or application by farmers of other, less effective products, so as to retain crop quality and yields. Such behaviour can result in worse environmental and health impacts overall.*" (Section 3.2.7 of the study).

It should also be highlighted that trading partners worldwide would be deeply concerned if classified products could no longer be traded with the EU due to hazard based restrictions that diverge from standards agreed within the framework of the WTO's SPS agreement.

We welcome the REFIT study, which underlines the significant risks of the current legislation. We would urge you to review these issue with the REACH and PPP regulatory committees, to consider the unintended consequences and to promote a workable way forward which ensures that European farmers continue to have access to plant protection products that prevent fungal disease and disease resistance. Should this not be possible, the socio-economic, trade, environment and health costs for the EU could be severe.

We would very much welcome the opportunity to meet with you to discuss this further.

Yours sincerely



Euros Jones
Director Regulatory Affairs

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¹ http://rpald.co.uk/uploads/report_files/evaluation-report.pdf