

Streamlining EU Chemical Legislation for Competitiveness of European Agriculture and Better Regulation

Towards a definition of Negligible Exposure and Endocrine Disruptors

Introduction

The new European Commission has set its political priorities in jobs, growth and competitiveness, and has identified better regulation as one of its main drivers to achieve these. Indeed, *how* regulation is drafted has a direct impact on innovation and competitiveness and the Commission has taken this into consideration and given it top priority. Not by chance, First Vice President of the Commission has been entrusted to ensure Better Regulation, and Second Vice President is responsible for steering the EU towards competitiveness, both with overarching responsibilities over the other Commissioners. Moreover, the creation of DG Grow shows the prioritization of growth in this Commission.

After six months since the new Cabinet was appointed, the challenge has now moved towards how to implement these priorities in specific sectors, regulations and actions, while keeping Europe's unique safety, quality and health standards. The agrochemical sector provides several opportunities for the Commission to implement its new political approach, and streamline regulations to boost competitiveness of European Agriculture, in line with the recent move of biocides from DG ENVI to DG SANTE, under the same DG as pesticides.

(Agro) Chemical legislation: need for a coherent approach

Agrochemicals are essential tools to ensure the competitiveness of European farmers, and thus, of European Agriculture. From pesticides to fertilizers, they constitute farming high-end inputs which require permanent investments to achieve innovation and increase productivity and competitiveness. Health and safety aspects derived from these products also need to be addressed, reason why their placing in the market tends to be highly regulated.

The necessity to strictly regulate these products is not incompatible with policy coherence and better regulation. Combining the highest safety standards for consumers with innovation and rapid access to the market to boost competitiveness should be possible, and actually a policy objective of its own. However, current agrochemical legislation (composed of several regulations) is incoherent, contradictory in some cases, obsolete in others, and from the shared experience between Member States and business is acting as a breaker for innovation and competitiveness of EU Agriculture.

For instance, basic concepts such as the approach to risk (hazard vs risk management) or to the concept of Negligible Exposure are divergent in "brother" legislations such as those for plant protection products (PPP) and biocides; impact of CLP provisions regarding reclassification of substances is generating unexpected (and unmanageable) consequences on the market; and while some of the chemical legislations foresee socioeconomic derogations for their provisions (REACH, Biocides), others don't (PPP).

This situation results in an incoherent patchwork of chemical legislations which is hindering investments and innovation, development of new tools for farmers, and acting as a barrier for the competitiveness of EU Agriculture.

Two immediate opportunities preceding Regulatory Reviews: Negligible Exposure and Endocrine Disruptors

While the review of these legislations under this legislature will still take some time according to the usual review periods (+/- every ten years), the Commission is currently facing two major policy debates that can have a significant impact in the sector (positive or negative, depending on how they are politically managed) and which constitute a unique opportunity to take a first step in streamlining of chemical legislation: the definition of Negligible Exposure under PPP legislation, and the cross-sectorial definition of Endocrine Disruptors.

Defining Endocrine Disruptors

The definition of Endocrine Disruptors has been a major political debate in Brussels and Member States for far too long. Being cross-sectorial (it touches on PPP, Biocides, REACH, cosmetic legislations, among others) the implications of one definition and the methodology to determine whether a substance is a disruptor of the endocrine system or not, vary substantially from one sector to another. For instance, the initial proposal of the Commission would have had a tremendous negative impact on Agriculture, with about 37 active substances used in plant protection products and biocides removed (market value of €3-4 billion and about 10% of the approved actives on the market representing 35-45% of formulated plant protection products use); and a yield impact on crops such as wheat, potatoes, oilseed rape and vines close to 10-20% loss.

While the initial intention of the Commission was a “one-suits-all approach”, the lack of consensus between DGs and Member States forced a more comprehensive approach that should eventually lead to a Policy on Endocrine Disruptors on the basis of an “ED Roadmap” recently published. This is in itself a step forward, as it would streamline legislations if the process is well managed. However, given the considerable delay of the Commission to come up with the definitive ED criteria (especially in the PPP legislation), in the short term this situation is creating considerable legal incertitude, incoherent evaluations of products and substances, and can lead to serious damages to companies and legal liability for the Commission for these.

ED Roadmap, Interim Criteria and Better Regulation

The ED Roadmap, as published by the European Commission, identifies various options to conclude on definitive criteria. One of these options considers the inclusion of elements of risk assessment (potency, reversibility-severity of the effects) and socio-economic considerations. The Commission is therefore putting forward options that consider a risk-management approach (present in REACH and Biocide legislations) as opposed to current hazard approach dominant in PPP legislation. In other words, DG SANTE, is seriously considering options which could lead to totally different conclusions than when an evaluation is made under the current “interim criteria” included in the PPP Legislation.

While the ED Roadmap is being implemented, several substances need to be evaluated under current PPP and Biocide Legislations, although it is uncertain whether they should be assessed under “old ED criteria” or under “new criteria”. This legal uncertainty makes sufficiently clear that it would be disproportionate and discriminatory to conclude on the ED profile of a substance at the present time knowing perfectly that definitive criteria will be adopted shortly and could lead to a conclusion in the totally opposite direction of the interim criteria and potentially favourable to a given substance. This is even more true since, as per provision 3.6.5 of the Regulation 1107/2009 on PPP, the European Commission was legally required to propose the definitive criteria by 14 December 2013.

As a result, any rushed decision would not only infringe with the reinforced Better Regulation policy of the new European Commission but would lead to a serious and irreparable commercial loss on the side of companies, a loss that could have been prevented under good management and legal procedures.

How to politically manage this situation under the better regulation approach and competitiveness priorities, while ensuring fair treatment of those companies currently facing decisions based on ED interim criteria, should be a topic of discussions at the top level of the European Commission as it may jeopardize all efforts of the Commission in this important dossier.

Negligible Exposure Guidance Document: a first step towards streamlining legislations

When Directive 91/414 on PPP was revised, leading to current regulation 1107/2009, it was clear that the political intention was to move towards a more hazard based procedure with a view to achieve a predictable process for all parties and to achieve a higher level of human and environment protection. The exclusion criteria were therefore adopted and defined under article 4.

This being, the legislator also agreed that, in a series of circumstances, active substances should be included into the Regulation and approved for use in products and these were defined in and Annex II, where a reference to negligible exposure is made.

It is clear from the intention of the legislator that these derogations are not purely hazard-based cut-offs and that there is a reference to the concept of exposure, i.e. a risk assessment is required. The obvious interpretation resulting from the adoption of these derogations is that these are of a general nature and that any substance meeting the definition of negligible exposure can be included in Regulation 1107/2009, irrespective of its classification, the latter becoming even irrelevant.

Since the adoption of the regulation in 2009, no definition has been agreed on how to determine Negligible Exposure, and no Guidance Document (GD) has so far being formally adopted by the Commission. During the past months, a Working Group chaired by the Commission and composed of several Member States has advanced in these definitions and has produced a draft GD which now needs to be politically discussed between Member States and shared with Stakeholders in the advisory procedure.

This draft GD clearly brings the PPP Regulation closer to the biocides one (which is more risk-management oriented, with 3 possible derogations) through an interpretation of "negligible exposure" in line with the "negligible risk" of the biocides legislation. This approach would streamline both legislations in this area and would avoid the paradox situation in which a same substance could be authorised for a similar use as biocidal product but not as a plant protection one.

The more political elements are currently being discussed at the Standing Committee on Plants, Animals, Food and Feed. Where to set the threshold of "negligible exposure" (10% of the AOEL or lower) or whether to include Personal Protective Equipment in the measurement of the exposure are among the "open items" for discussion. On the basis of these political negotiations, the objectives of streamlining legislations to boost competitiveness of the sector would be met or not (as for instance, a very low threshold would mean in practice a cut-off, for instance).

Managing cases while no GD is adopted

It is yet uncertain when the GD will be formally adopted, a situation which, after six (!) years since the adoption of the PPP Regulation, is creating serious legal incertitude to companies and may generate considerable commercial losses to many of them. In fact, with the first substances falling under the cut-

off criteria currently being evaluated, companies have submitted dossiers proving negligible exposure and a safe use, yet no “official criteria” has been set to decide whether this is the case or not.

In this scenario, it is politically very sensitive to determine under which parameters the Commission could decide whether or not negligible exposure is proven on a given dossier. It seems clear that if a substance is not approved by denying Negligible Exposure derogation the Commission could be legally liable if by the final criteria included under the Guidance Document that same substance could have been placed in the market.

In this context, it is fundamental to ensure that any decision on transitional cases is done under the principles of better regulation and is in line with the Commission and Member States efforts of streamlining biocides and pesticide regulations in what concerns to negligible exposure and negligible risk.

Conclusion: towards a comprehensive streamlining of chemical legislation?

With growing global pressure for competitiveness and a need to foster growth to ensure the sustainability of Europe’s unique welfare standards, the focus of the Commission in jobs, competitiveness and better regulation is necessarily the right approach.

Agriculture plays a unique role in the socio-economic landscape of Europe and should be a priority sector for the Commission when implementing its new strategic regulatory approach. In the specific area of agrochemicals, the Commission faces an opportunity in the debates on Endocrine Disruptors and Negligible Exposure to start streamlining legislation as a mechanism to improve competitiveness of the sector. This strategic alignment should precede forthcoming regulatory reviews in any of the chemical regulations, and will certainly facilitate further streamlining when these reviews take place.

However, these efforts must be considered as the first steps of a much longer and complex path if Europe wants to boost the competitiveness of its agriculture to create jobs and foster growth on the long term. A much wider political and strategic approach to the agrochemical sector in particular, and to the entire agricultural value chain in general, needs to be developed by the EU Institutions and its Member States, in partnership with business, academia and other stakeholders, to move towards an ecosystem that facilitates innovation oriented to competitiveness that ensures the sustainability of European agriculture as a pillar of Europe’s socioeconomic model. Agricultural productivity in Europe needs to be improved with better regulation, which is a key objective of the PPP regulation.