MINISTERIO DE SANIDAD, SERVICIOS SOCIALES E IGUALDAD

MINISTERIO DE AGRICULTURA, PESCA, ALIMENTACIÓN Y MEDIO AMBIENTE

SPANISH COMMENTS [(1)] IN RELATION TO THE NEW DRAFT TO THE COMMISSION DELEGATED REGULATION SETTING OUT SCIENTIFIC CRITERIA FOR THE DETERMINATION OF ENDOCRINE-DISRUPTING PROPERTIES PURSUANT TO REGULATION (EU) Nº528/2012

This document includes the comments related to the draft Commission Delegated Regulation setting out scientific criteria for the determination of endocrine-disrupting properties following Regulation (EU) Nº 528/2012, which was presented in the 67th meeting of CA for Biocides.

Overall, we appreciate the Commission's efforts to respond to the comments of most Member States, including Spain, by extending the concept of endocrine disruptor not only to those known, but also to criteria for the determination of endocrine properties.

However, we do not believe that these or other relevant issues will be resolved unless the content of the new regulation makes it possible to apply the criteria and their harmonized and realistic interpretation throughout the European territory in the evaluation of biocides which can be endocrine disruptors

From our point of view, the following issues remain unresolved:

1. In regards to the problem of categorization, it seems that the Commission firmly maintains the criterion of not distinguishing between categories of disrupters, but rather only determining whether or not the biocide substances are.

This makes risk characterization impossible and greatly hampers decision making, facilitating the use of arbitrary criteria. An example illustrating this fact is that of bisphenol-A (BF-A), currently considered an endocrine disruptor. It is now replaced by other chemical compounds of similar structure, such as BF-S and BF-F. At the moment, there is evidence that BF-S has properties similar to BF-A, but they do not exist for BF-F. In a proposed system with two categories (DE or non-DE), it would take years to prove that BF-S has the same properties as BF-A

2. The current risk assessment methodology for biocidal products is based on the determination of an AOEL / PNEC value, which is contrasted with the exposure values to which the user / environment will be exposed. However, endocrine disruptors in many cases have no threshold, and there is no possibility of establishing an AOEL / PNEC. Contact with any amount of substance, however small it may be, is dangerous. In this case, only a negligible exposure (practically zero), may be acceptable.

So far, the approach adopted has allowed not to approve substances that meet the interim criteria for ED, ie carcinogenic cat. 2 and toxic for reproduction cat. 2.

By eliminating the interim criteria and having to demonstrate endocrine mode of action (which is not always easy), it allows us to suspect that some substances, especially those with no threshold, will be approved without the competent authority being able to do nothing about it.

(1) Comments from Spanish CA for Biocides Regulation: Dirección General de Salud Pública, Calidad e Innovación del Ministerio de Sanidad, Servicios Sociales e Igualdad and Dirección General de Calidad y Evaluación Ambiental y Medio Natural del Ministerio de Agricultura, Pesca, Alimentación y Medio Ambiente

3.- We have some concerns regarding the way in which the condition of endocrine disruptor is determined, and that we understand that it must necessarily be developed through a guide, which should be finalized at the time of application of the regulation.

What exactly is an endocrine mode of action? Does an endocrine mode of action include indirectly produced endocrine system alterations, for example through changes in the microbiota or alterations of the immune system linked to a high risk of metabolic pathology?

How is plausibility demonstrated in the link between mode of action and adverse effect? It is not currently known how obesity causes insulin resistance and type 2 diabetes. Different hypotheses are debated but it is unclear. However, the scientific community has no doubt that obesity can trigger type 2 diabetes

The answers to these questions should be included in the guide that must necessarily be available on the date of application of the regulation.

4.- Finally, to say that the Commission should ensure, through a recital, its commitment to the precautionary principle.

SPECIFIC COMMENTS

In CONCLUSION, our proposal, which incorporates some of the elements that were present in our original opinion, and some additional, is the following

1. - Make express reference to the precautionary principle in the recitals

2. - The date of application of the Regulation must be conditional on the operational availability of the guide, where the uncertainties arising from the application of the harmonized criteria are solved, like for instance, what exactly is the mode of action endocrine and how the plausibility of the link is demonstrated.

3.- Identification of the substance with endocrine disrupting properties should be based on all relevant scientific data. In any case, the aspects related to the weight of the evidence can be developed in the guide.

4.- **Annex, Section A (1) (a):**

The word *"shows"* is not the most appropriate. It could be replaced by *"There is evidence that may cause*" or support Sweden's proposal "*It is known or presumed to cause"…*

Section A (1) (b):

On the endocrine mode of action, scientists disagree. An endocrine disrupter may have several different modes of action (alteration of the microbiota and immune system may lead to alterations in the endocrine system).

Section A (2)

We consider that all relevant scientific data should be taken into account. Perhaps this section could be simplified if part of the text goes to a guide.

Section B (1)

In the first paragraph, we propose to delete the phrase ….. *"at the (sub)population level"*

Section B (1) (a):

The word "*shows"* is not the most appropriate. It could be replaced by *"There is evidence that may cause*" or support Sweden's proposal "*It is known or presumed to cause"…*

Section B (1) (b):

On the endocrine mode of action, scientists disagree. An endocrine disrupter may have several different modes of action (alteration of the microbiota and immune system may lead to alterations in the endocrine system).

Section B (2)

We consider that all relevant scientific data should be taken into account. Perhaps this section could be simplified if part of the text goes to a guide.

ADDITIONAL COMMENTS

In order to give greater consistency in the approach to chemicals across relevant regulations, we consider that **"SCIENTIFIC CRITERIA FOR THE DETERMINATION OF THE ENDOCRINE DISRUPTING PROPERTIES" must** also be covered by the REACH Regulation, according to article 138.7, as well as in other affected sectoral regulations.

On the other hand, a review clause at 5 years would be welcome

Madrid, 30th November de 2016