

Comments on the guidance on the identification of endocrine disruptors for pesticides and biocides (public consultation)

Within the constitutional system of the EU, only the EU co-legislators and the Member States have the power to decide which level of chemical risk is acceptable. When the EU co-legislators decided to ban the use of endocrine disruptors (EDCs) in pesticides and biocides, they decided that the risk of using EDCs in pesticides or biocides is, with a few strictly delimited exceptions, unacceptable.

The co-legislators have set a level, or 'standard' of environmental and health protection which is now binding. It has to be upheld, including by the EU institutions and the Member States in charge of implementing the regulations

When proposing the first version of the EDC criteria in the context of the Pesticides Regulation,¹ the Commission did not respect this obligation when it tried to reduce the scope of the ban. The European Parliament sanctioned this attempt by vetoing the proposal. When adopting this guidance, EFSA and ECHA have to respect the same limits to their discretion. The current version of the guidance however exceeds these limits. In addition, EFSA and ECHA need to be aware of the risk of litigation that they might incentivise if they create expectations for the industry that are in contradiction with the Pesticides or Biocides Regulations.²

This contribution to the public consultation first reminds ECHA and EFSA of the limit of their mandate and then makes recommendations **so that**:

- The guidance does not violate the standard of protection set by the European Parliament and the Council in the Pesticides and Biocides Regulations;
- The guidance does not exceed the boundaries of the Pesticides and Biocides Regulations and of the mandate given to ECHA and EFSA,
- The guidance does not exclude any "relevant available scientific evidence" in contradiction with the criteria.

1 Reminder: the limits of EFSA and ECHA's legal mandate

EU law sets strict limits to the power of EU Agencies. They cannot be delegated discretionary powers and their decisions have to rigorously abide by the limits of their mandate³.

¹ Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC (OJ L 309, 24.11.2009, p. 1–50)

² Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products (OJ L 167, 27.6.2012, p. 1–123).

³ See CJEU, Case 9/56 and 10/56, Meroni & Co., Industrie Metallurgiche s.p.a. v High Authority, 1957-1958 ECR 133 and CJEU, Case 98/80, Giuseppe Romano v Institut national d'assurance maladie-invalidité, 1981 ECR 1259, para 20 as refined by CJEU, Case C-270/12, United Kingdom of Great Britain and Northern Ireland v Council of European Union and European Parliament, ECLI:EU:C:2014:18.

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The Commission gave to ECHA and EFSA a narrow mandate, limited to providing scientific and technical assistance⁴. Their role is limited to provide support to 'scientific hazard identification'.⁵ They did not receive regulatory power and their decisions therefore cannot, in any way, modify the effect of the Pesticides and Biocides Regulations as intended by the co-legislators.

In addition, and whatever their mandate, Agencies, like the Commission, can never encroach upon the essential elements of a legislative act when exercising their delegated power. In a legislative act setting a standard of environmental or health protection, the level of protection is an essential element of the act because it is the very core of the decision to regulate a dangerous activity⁶. The Court confirmed that the EDC ban is a core element of the legislation⁷. It requires, in the words of the Court, a “political choice” “falling within the responsibilities of the European legislature, in that it requires the conflicting interests at issue to be weighed up on the basis of a number of assessments”.⁸

The consequence of this strict legal framework is that ECHA or EFSA, as the Commission, cannot temper in any way with the co-legislator decision to protect health and the environment by banning substances which are considered as having endocrine disrupting properties that may cause adverse effect in humans or the environment.

2 Where the guidance slips and fails

2.1 The guidance illegally lowers the level of protection set by the co-legislators and the precautionary principle

There are more than one acceptable scientific methods which can be used to identify which substances are endocrine disruptors. The method promoted by the guidance is not ineluctable. Its selection is the result of ECHA and EFSA's discretion, exercised when they decided to promote one method rather than another. Importantly however, when ECHA and EFSA exercise their decision, they have to comply with the Pesticides and Biocide regulations. Therefore, they have to make sure that the method they select is the most apt to fully achieve the objective set by the co-legislators.

In other words, they have to make sure to select the method which is, when applied, **the most able to identify all the endocrine disruptors that may have adverse effect in human and the environment**. The co-legislators' intention to ban the use of all endocrine disruptors that

⁴ See the mandate received from the Commission per the letter sent by Mr Prats Monne to Mr Url and Mr Dancet on the 17th of October 2016, Ref. Ares(2016)5971523-17/10/2016 as well as the limitation to the role of the Agencies as set by the legal basis used to give them the mandate- Article 31 of Regulation (EC) No 178/2002 (for EFSA) and Article 76 (1) (d) of Regulation (EU) No 528/2012 (for ECHA).

⁵ Ibid.

⁶ Judgment of the Court of 5 September 2012, European Parliament v Council of the European Union, Case C-355/10, ECLI:EU:C:2012:516, para. 71-75 and 79.

⁷ Judgment of the General Court of 16 December 2015, Kingdom of Sweden v European Commission, Case T-521/14, ECLI:EU:T:2015:976.

⁸ Judgment of the Court of 5 September 2012, European Parliament v Council of the European Union, Case C-355/10, ECLI:EU:C:2012:516, para.76.

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may have adverse effects in pesticides and biocides, as shown by the pre-defined system of ban and exemptions organised by the regulations⁹.

In any scientific assessment of the hazard of a substance, there is a risk to obtain 'false positive' (a substance is falsely identified as hazardous) or 'false negative' (a substance is falsely identified as safe). Avoiding false positives requires having rigorous scientific method able to provide sufficient evidence. Avoiding false negatives requires to not ask for a 'devil's proof', aka **a level of evidence impossible or excessively difficult to obtain under current scientific knowledge.**

The choice of where the reasonable level of evidence stands, between those two extremes, does not lie with ECHA and EFSA. It has already made by the EU member states when they integrated the precautionary principle in the EU Treaties¹⁰ and re-stated by the EU co-legislators in the Pesticides and Biocides Regulations. The precautionary principle enacts in law the idea that decision makers can act to prevent a hazardous activity even if some information on the hazard is still missing, when there are preliminary objective scientific indications of reasonable grounds for concern¹¹. A comprehensive scientific assessment is needed, based on the most reliable scientific data and most recent results of research, but a likelihood of harm is enough to justify regulatory action when scientific uncertainties remain on the existence or extent of the hazard.¹²

Replaced in the context of the EDC criteria under the Pesticides and Biocides Regulations, this means that **ECHA and EFSA have an obligation to select the method which limits the most the risk of false negatives.** In other words, the guidance shall not make the identification of EDC impossible or excessively difficult by choosing as 'harmonised' method a method requiring an excessive level of evidence.

This is however what the draft guidance does, as shown by the contributions to the public consultation submitted, for example, by PAN Europe, HEAL and ChemTrust. When choosing which method is the most suitable to identify EDCs, ECHA and EFSA have used their discretion to select a method which undermines the objective set by the pesticide and biocide regulation, **by making it impossible or excessively difficult to achieve it.**

This is in particular the case of the **requirement to demonstrate a detailed understanding of the mode of action linking the endocrine activity with the adverse effects.** The co-legislators decided that substances with endocrine related adversity shall not be used in pesticides or biocides. The Pesticides and Biocides Regulations also accept the potential uncertainties remaining on the assessment of endocrine disruptors by adding to the criteria the concept of biological plausibility: "endocrine mode of action shall be established based on biological plausibility, which shall be determined in the light of current scientific knowledge"¹³.

⁹ Article 1 of Biocides Regulation, Article 1 of Pesticides Regulation.

¹⁰ Article 191 of the Treaty on the Functioning of the EU (TFEU).

¹¹ See the Communication on the Precautionary Principle (COM(2000)1final) at 9-10 and see also, as the Court stated 'where there is uncertainty as to the existence or extent of risks to the health of consumers, the institutions may take protective measures without having to wait until the reality and the seriousness of those risks become fully apparent' CJEU in Case C-77/99 Gowan ECLI:EU:C:2010:803, para 73.

¹² See ECJ in the Gowan Case, Ibid, para 75-78.

¹³ Commission Delegated Regulation (EU) 2017/2100 of 4 September 2017 setting out scientific criteria for the determination of endocrine-disrupting properties pursuant to Regulation (EU) No 528/2012 of the European Parliament and Council (OJ L 301, 17.11.2017, p. 1-5), Annex, Section A (2)(c).

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Establishing the key event(s) leading the mode of action can be impossible in the current state of knowledge on endocrine disruptors, can be excessively long or difficult - this is the case even for EDCs that the decision-makers have already decided to restrict or ban, such as BPA. As a result, by making this requirement a pre-condition to identify a substance as EDC, even when there is sufficient information on endocrine related adversity, equals to lowering the level of protection set by the legislator by drastically limiting the number of substances with endocrine related adversity which will be, in practice, banned from use in pesticide and biocide. It is an excessive requirement which goes beyond what is needed to establish that an endocrine activity is biologically plausible, in light of the level of protection set by the co-legislator, the precautionary principle and the current state of research on endocrine disruptors.

By requiring a detailed identification of the mode of action, ECHA and EFSA have amended, in practice, the level of protection set by the legislator and hence exceeded their mandate. In order to comply with the limits set to their power by EU law, ECHA and EFSA need to change the requirement for an overly detailed knowledge of the Mode of Action and key events as explained by PAN, ChemTrust and HEAL in their contribution to the public consultation.

Recommendations 1: amend all language which communicate the idea that a full identification of the Mode of Action is required, and clarify that what is required is evidence showing biological plausibility, in particular in chapter 3.5 p 30

2.2 The scope of the guidance illegally extends beyond the Pesticides and Biocides Regulations

Line 192 of the guidance states that "the principles outlined in this draft guidance document may be useful and applicable for the determination of endocrine disrupting properties on any substance, provided that the criteria set for the determination of endocrine disrupting properties under the respective framework applicable to the substance do not differ substantially from those set in the Commission delegated Regulation (EU) 2017/2100". This line raises two main issues.

First, the mandate given to ECHA and EFSA to adopt guidance to identify EDC is strictly limited to the scope of the Pesticides and Biocides Regulations. While it would have been more efficient and coherent for the Commission to propose identification criteria applicable to all sectors,¹⁴ it is not what it did. By extending the scope of the guidance to, potentially, other regulations, ECHA and EFSA illegally exceed the limits of their mandate.

Second, the language of the provision is confusing as the criteria adopted under the Pesticides and Biocides Regulations were adopted to fit the specific context of the pesticides and biocides sectors, and after the consultation of stakeholders active only in that field. It may not be suitable for other sectors, which might raise specific issues (e.g. exposure to vulnerable groups). The guidance itself has been adopted in consideration of this specific context and should therefore

¹⁴ See <https://www.documents.clientearth.org/wp-content/uploads/library/2017-02-14-the-criteria-to-identify-endocrine-disruptors-implications-beyond-pesticides-and-biocide-disrupted-criteria-coll-en.pdf>

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clearly state it. This does not exclude decision-makers to get inspiration from the guidance while adapting it for other regulations when the need arises.

Recommendation 2: line 192 should be deleted.

2.3 The guidance has to clearly open the door to "all available relevant scientific data"

The Regulation setting the EDC criteria states that "all available relevant scientific data" shall be taken into account in the identification of which substance are EDCs.¹⁵ This wording clearly shows the intention to include the widest scientific data available. This has two implications for the guidance.

- **The guidance cannot limit the scope of the scientific data to be taken into account**

The guidance aims at recommending the use of specific methods in order to harmonise the approach adopted by the main actors within the EU, but **the mandate given to ECHA and EFSA does not grant them the power to amend this provision by limiting the scope of scientific data which may be taken into account.**

The guidance is not legally binding. The mandate given to ECHA and EFSA does not grant them the power to adopt regulatory binding decisions. However, it does give to the industry indications on what decision-makers may expect and require, and in that sense, it may create "legitimate expectations". This creates a risk of litigation and a delay in the proper identification of EDCs.

When deciding on the wording and content of the guidance therefore ECHA and EFSA need to take into account its potential legal effect and anticipate any "legitimate expectation" the industry might rely on to refuse providing additional information or taking into account certain evidence.

Recommendations 3: This means that every time that the guidance describes the scientific data to be taken into account, it should to explicitly state, that "data other than [the one collected using the methods described by the guidance] may be required from the industry by public authorities when relevant and should be taken into account when available". In particular concerning:

- **Section 3.1 line 350, section 2 lines 205-206**, in particular to avoid distinction such as **section 3.1 lines 371-376** regarding the limitation to "EATS modalities" as opposed to any "ED modalities" (see PAN Europe comments);

¹⁵ Commission Delegated Regulation (EU) 2017/2100 of 4 September 2017 setting out scientific criteria for the determination of endocrine-disrupting properties pursuant to Regulation (EU) No 528/2012 of the European Parliament and Council (OJ L 301, 17.11.2017, p. 1–5), Annex, Section A (2)(a).

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- **Section 2 lines 229-231:** knowledge on invertebrates shall be taken into account if available and can be required by public authorities if relevant.

- **The guidance should refer explicitly to new knowledge and novel test methods**

The guidance acknowledges the lack of data or test methods on several occasions, but does not anticipate the ineluctable development of new data and novel test methods. In order to avoid any doubt and thus future resistance and litigation from industry, and ensure that the guidance stands the test of time, the guidance should be explicit on this issue.

Recommendations 4: The Guidance should specify that:

- "all available relevant scientific data" includes data produced using tests methods or using knowledge available at the time the dossier is submitted, even if these methods and knowledge were not available when the guidance was adopted
- The decision makers have to take into account new knowledge when available, and require novel test methods to be used when relevant.