Briefing

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European Parliament

Commission proposals on identifying endocrine disruptors

SUMMARY

Endocrine disruptors are substances that interfere with the functioning of hormones, with potentially harmful effects on health. Defining scientific criteria for their identification is highly complex and has important repercussions. There are gaps in scientific understanding as well as diverging regulatory views.

The European Commission's delay in adopting scientific criteria has provoked strong reactions. In a judgment delivered on 16 December 2015, the General Court of the Court of Justice of the European Union found that the Commission had breached EU law by failing to act on endocrine disruptors.

The Commission has now proposed the long-awaited criteria, and has presented the draft legal acts required for their implementation. However, stakeholders on all sides of the debate are critical of the proposal. Members of the European Parliament are divided on the issue.

The proposed delegated act and implementing act will now have to be approved, according to procedures subject to scrutiny in Parliament and Council.

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In this briefing:

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Introduction

On 15 June 2016, the European Commission presented the long-awaited proposal on scientific criteria for the identification of endocrine disruptors. The Commissioner for Health and Food Safety, Vytenis Andriukaitis, thereby followed up on his promise to come up with such criteria 'before summer'.

The package includes a communication, an impact assessment, and two draft legal acts: an implementing act applying to the chemical substances falling under the Plant Protection Regulation; and a delegated act applicable to the Biocidal Products Regulation.

Legislative framework

The Plant Protection Products Regulation (No 1107/2009 – PPPR) and the Biocidal Products Regulation (No 528/2012 – BPR) ban substances with endocrine-disrupting properties as a general rule on the basis of hazard. Both define 'substance of concern' as any substance having an 'inherent capacity to cause an adverse effect', although some limited exceptions are permitted. The Regulations provide for the establishment of scientific criteria to identify endocrine disruptors by mid-December 2013, when the interim criteria set out in the PPPR and BPR apply.

Background: identifying endocrine disruptors

Suspected health effects and gaps in understanding

Endocrine disruptors, or endocrine-disrupting chemicals (EDCs), are substances that interfere with the hormonal function and therefore may have harmful effects on human health.[1] A wide range of chemicals, commonly used for a number of everyday products, are suspected of having a potential for endocrine disruption under certain circumstances. The effects of EDCs are thought to depend on both the level and timing of exposure. EDCs are suspected of being capable of action even at very low doses. Exposure is thought to have both immediate and latent consequences. The most sensitive window of exposure to EDCs appears to be during critical periods of development (for instance, foetal development and puberty). Limited human evidence supports the idea that exposure during these periods may play a role in the increased incidence of reproductive diseases, endocrine-related cancers and behavioural and learning problems. However, for many of these, evidence is weak and it is very difficult to carry out meaningful experimental or epidemiological studies and prove cause and effect in humans. There are still gaps in our scientific understanding of endocrine disruptors. In addition, regulators are divided on whether rules on EDCs should be based on hazard or risk assessment (see box).

Hazard vs risk

A hazard is a potential threat to health because of the properties of a substance, such as its capacity to cause a certain disease. A hazard assessment looks at the *possibility* of adverse effects.

The risk that a substance could cause a negative effect depends on a combination of hazard and exposure, namely on the amount of substance to which humans are exposed (the level of exposure), the duration of exposure, and when exposure occurs (as a foetus, child, or adult). A risk assessment considers the *likelihood* of adverse effects.

Within the EU, some Member States support a hazard-based approach and others a risk-based approach.

The need for operational criteria

According to the definition of the International Programme on Chemical Safety (IPCS) of the World Health Organization (WHO) (also known as 'WHO–IPCS'), an endocrine

disruptor is an 'exogenous substance or mixture that alters function(s) of the endocrine system and consequently causes adverse health effects in an intact organism, or its progeny, or (sub)populations'. Defining which substances are to be considered EDCs has important implications for their regulation. The Commission had argued for the need for these criteria to be 'operational'; that is, to allow for 'science-based regulatory decision making'. It had also underlined that it required input prior to legislating, owing to the complex issues involved and because diverging views remain, and decided in 2013 to undertake an impact assessment. The impact assessment is based on a June 2014 roadmap that outlines four different options with regard to setting EU criteria for identifying endocrine disruptors and three for regulatory decision-making.

European Commission roadmap defining criteria for identifying endocrine disruptors

Criteria for identifying endocrine disruptors

Option 1: No criteria are specified; the PPPR and BPR interim criteria continue to apply

Option 2: WHO–IPCS definition to identify EDCs (hazard-based)

Option 3: WHO–IPCS definition to identify EDCs, plus introduction of additional categories based on the different strengths of evidence (namely 'suspected endocrine disruptors' and 'endocrine-active substances')

Option 4: WHO–IPCS definition to identify EDCs, plus inclusion of potency as element of hazard

Criteria for regulatory decision-making

Option A: No policy change (baseline)

Option B: Introduction of further elements of risk assessment into sectoral legislation

Option C: Introduction of further socio-economic considerations into sectoral legislation

Source: European Commission, DG SANTE, June 2015.

General Court judgment

In a judgment delivered on 16 December 2015 (case T-521/14), the General Court of the Court of Justice of the European Union (EU) found that the European Commission had breached EU law by failing to adopt criteria for the identification of endocrine disruptors by 13 December 2013. (For more detail on the judgment, see the previous version of this briefing, published in April 2016.)

European Parliament resolution

In its recent resolution of 8 June 2016, Parliament called on the Commission to deliver without delay on its obligation and 'to adopt immediately hazard-based scientific criteria for the determination of endocrine-disrupting properties'.

In its resolution of 14 March 2013, Parliament called on the Commission to submit, as soon as possible, proposals for overarching criteria based on the WHO–IPCS definition of EDCs, and for EU legislation to make clear what substances are regarded to have endocrine-disrupting properties, with different categories based on the strength of evidence. The resolution also asked for possible combination effects to be taken into consideration.

The Commission proposal

Proposed definition and criteria

The definition put forward is based on the WHO–IPCS definition (Option 2 of the June 2014 roadmap). As laid out in the communication, a substance (or mixture) is considered an endocrine disruptor if:

- it is known to cause an adverse effect on human health;
- it has an endocrine mode of action; and
- the adverse effect relevant for human health is a consequence of the endocrine mode of action (that is, if there is a causal link between adverse effect and mode of action).

The scientific criteria aim to introduce this concept of 'endocrine mode of action' in legal form. According to the Commission, the criteria are scientific (that is, based on science, not on socio-economic considerations); their purpose is to *define* endocrine disruptors; they will only apply to plant protection products and biocidal products;[2] and they are proposed to protect both human health and the environment.

The communication also highlights issues that are part of a more general debate around endocrine disruptors and toxicology, and it clarifies a number of terms and concepts:

Endocrine mode of action is defined as 'the inherent ability of a substance to interact or interfere with one or more components of an endocrine system'.[3] **Adverse effect** is a 'change in the morphology, physiology, growth, development, reproduction or life span of an organism, system, or (sub)population that results in an impairment of functional capacity, an impairment of the capacity to compensate for additional stress, or an increase in susceptibility to other influences'.[4]

With regard to the causal link between adverse effect and mode of action, the Commission acknowledges that it will, in practice, be very difficult to demonstrate 'conclusive evidence' of **causality**. It therefore proposes to follow the approach of 'biological plausibility', or reasonable evidence. According to the Commission, establishing **categories that take varying degrees of scientific evidence into account**[5] (such as 'known', 'presumed' or 'suspected' endocrine disruptors), does not help to define what an endocrine disruptor actually *is* in the context of plant protection products and biocidal products, but only what it *may be*. Concerning **safe thresholds** (whether there is a dosage below which no adverse effect is expected to occur), the Commission finds that it is 'neither necessary nor appropriate' to address this question in the context of setting identification criteria. As for **potency** (the ability of a chemical substance to produce an effect at a particular dose), the Commission states that it will follow the 'broad scientific consensus' according to which potency should not be considered *when identifying* EDCs, but taken into account *when evaluating the actual risk* they may pose (see box).

In addition, the Commission specifies[6] how the identification of an EDC should be carried out, namely: based on all available relevant scientific evidence; using a weight-of-evidence approach (that is, a process in which all of the evidence considered relevant

Expert consensus fed into the criteria

A meeting of 23 international experts, hosted by the German Federal Institute for Risk Assessment (BfR) on 11–12 April 2016, attended by representatives from the European Commission and the European Food Safety Authority (EFSA), adopted a consensus statement on principles for the identification of endocrine disruptors.

The scientists recognised, among other things, that the identification of endocrine-disrupting substances is a hazard identification procedure and has to rely on weight-of-evidence evaluations of both adversity and mode of action together.

According to the statement, which is based on WHO–ICPS terminology for the four steps in risk assessment, potency is an important factor to be taken into account during the *characterisation of hazards* of endocrine disruptors, but it is not relevant for the *identification* of a compound, such as an EDC.

The Commission took this scientific consensus into consideration when drawing up the criteria.

to a decision is evaluated and weighted); and applying a systematic review methodology.

Impact assessment

An impact assessment (IA) accompanies the communication,[7] which – according to Commissioner Vytenis Andriukaitis – was important to allow the College to take a properly informed decision.

The IA followed a two-step procedure. The **first step** was a screening of 'nearly all approved' active substances used in plant protection products, and of those substances used in biocidal products for which information was available. According to the Commission, the screening resulted in an estimate of how many and which substances used in the PPPR and BPR may be identified as EDCs under Options 1 to 4, but it did not constitute an evaluation of individual substances to be carried out under the respective legislation. In the **second step**, building on the results of the screening, and complemented by additional information, the impacts in different policy areas were assessed.

According to the IA, Option 2 in combination with Option B of the roadmap (the option chosen by the Commission, namely: the WHO–ICPRS definition, with an adjustment of the PPPR derogations in the light of current scientific knowledge), is expected to reach the widest consensus amongst scientists, Member States and stakeholders.

The Commission indicates, in the IA executive summary, that all options offer the same high level of protection of human health and environment under the current PPPR and BPR. As for the impact on businesses, the decreased availability of plant protection products or biocidal products was assumed to negatively affect SMEs, given that farmers are mainly SMEs and that the biocidal products industry is mainly represented by SMEs.

Proposed legislative changes

While active substances with endocrine-disrupting properties under the PPPR and the BPR are banned on the basis of hazard, some derogations may apply – on grounds such as 'negligible exposure' (in the PPPR) or 'negligible risk' (in the BPR). The Commission proposes to update the grounds for possible derogations under the PPPR by changing the wording – in line with the BPR – to 'negligible risk'. According to the Commission, current scientific knowledge suggests that 'endocrine disruptors in this area could be assessed based on risk, like most other substances', while 'fully maintaining the hazard-based ban of endocrine disruptors, thereby ensuring an equally high level of protection of health and the environment'.

Environment ministers call for more protective criteria

In a joint letter to Commissioner Vytenis Andriukaitis and European Commission President Jean-Claude Juncker, three Environment Ministers – Ségolène Royal (France), Esben Lunde Larsen (Denmark) and Karolina Skog (Sweden) – expressed their concern about the proposed criteria.

In particular, they draw attention to the fact that only substances *known* to cause an adverse effect can be identified as endocrine disruptors, and argue for the need to apply the precautionary principle. Moreover, they state that the draft modification of the PPPR does not fulfil 'the need to ensure the highest level of human health protection', inviting the Commissioner to amend the proposal 'in a more protecting way'.

Stakeholder views

European Parliament

Members of the European Parliament are divided on the issue. Among the concerns raised in an exchange of views with Commissioner Vytenis Andriukaitis in the Committee on the Environment, Public Health and Food Safety (ENVI) on 16 June 2016 were, notably:

- the restrictive definition of what constitutes an EDC;
- the introduction of wider exemptions;
- the fact that the system of derogations does not take the cocktail effect into account;
- the absence of categories for different degrees of scientific evidence;
- the fact that the proposed criteria apply to biocidal products and plant protections products only;
- the fact that the criteria have to rely on 'biological plausibility' rather than conclusive evidence;
- that risk assessment should be an integral part of the legislation, and derogations should be exceptions; and
- the question as to whether the changes of wording, interpreted as a shift from a hazard-based to a risk-based approach, were in line with the Commission's legal mandate.

Scientists

According to the Endocrine Society, which called for Option 3 of the roadmap, the Commission's criteria are 'too strict to effectively protect the public from endocrine-disrupting chemicals'. They would result in very few EDCs being identified and regulated: 'The European Commission has set the bar so high that it will be challenging for chemicals to meet the standard, even when there is scientific evidence of harm.'

NGOs

EDC-Free Europe, a coalition of 65 public interest groups, condemns the proposal. The coalition and its campaign partners, which include, among others, the International Chemical Secretariat (ChemSec), CHEMTrust, Corporate Europe Observatory (CEO) Health and Environment Alliance (HEAL), Health Care Without Harm (HCWH) and Pesticides Action Network (PAN Europe), put forward two main arguments. Firstly, the Commission proposes to identify EDCs only if they are proven to cause adverse effects. According to the coalition, this high level of proof is incoherent with the usual approach taken in the EU – for identifying carcinogens, for example – and since the proposal will have far-reaching implications for all EU chemical laws, it should ensure coherence and to protect humans and wildlife. Secondly, the coalition argues that the proposed amendment to widen an existing exemption in the PPPR for chemicals already identified as EDCs (by changing 'negligible *exposure*' to 'negligible *risk*') would mean 'continued uncontrolled exposure to these chemicals of high concern'. In addition, the coalition considers the move to be potentially illegal, as it would alter the legislative act as adopted by the co-legislators.

The European Consumer Organisation (BEUC) is of the opinion that an EU definition of endocrine disruptors 'needs to identify all chemicals that may disrupt the hormonal system', and that it is necessary to distinguish between 'known', 'presumed' and 'suspected' EDCs. According to BEUC, the proposed criteria demand an 'onerous level of proof' for a substance to be defined as an EDC, and the proposal will not effectively protect consumers as only a few substances would be defined and regulated as EDCs.

Industry

The pesticides, chemicals and plastics industries – which include the European Chemical Industry Council (Cefic), the European Crop Protection Agency (ECPA) and PlasticsEurope – set out their views in a joint statement. The industries are 'disappointed' that they still lack the scientific criteria that would allow differentiation

between a substance of regulatory concern and a substance of no or low concern. They consider 'regulating by derogation' as unacceptable, since this does not provide certainty and predictability for product development and innovation. They argue that the WHO–IPCS definition alone is unsuitable and that using this definition will identify many substances that pose no risk to human health or the environment as EDCs. According to the industries, potency must be taken into account.

The Association of European farmers and agri-cooperatives Copa & Cogeca urged Member States 'to ensure all decisions on criteria to identify endocrine disruptors and authorisation of them are based on science, using a risk-based approach', not the 'hazard-based approach proposed by the Commission'. They are concerned that putting more restrictions on plant protection products and their availability may put European farmers at a competitive disadvantage.

Next steps

The European Commission has requested the European Food Safety Authority (EFSA) and the European Chemicals Agency (ESA) to investigate whether individual substances that are already approved can be identified as endocrine disruptors according to the proposed criteria.

The delegated act, with criteria applicable under the BPR, will be discussed by a group of Member States' experts prior to adoption by the Commission.

The implementing act, applicable to plant protection products under the PPPR, will be discussed and then voted by the Standing Committee (regulatory procedure with scrutiny).[8]

Both texts will be presented simultaneously to Parliament and Council for exercise of their control function as co-legislators, which allows for the possibility of blocking the texts.[9]

Main references

Detailed review paper on the state of the science on novel *in vitro* and *in vivo* screening and testing methods and endpoints for evaluating endocrine disruptors, OECD, 2012.

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Slama Rémy et al., Scientific Issues Relevant to Setting Regulatory Criteria to Identify Endocrine Disrupting Substances in the European Union, Environmental Health Perspectives, 2016.

Endnotes

1 This briefing does not address potential or identified impacts of EDCs on other animal species or the environment.

2 As stated in the communication, the Commission will 'act swiftly' to further implement the legal obligations specifically in relation to EDCs. In particular, it intends to present reviews of the EU Cosmetics Regulation and REACH by the end of 2016; the reviews of water quality legislation are ongoing.

3 European Food Safety Authority (EFSA), 2013.

4 WHO International Programme on Chemical Safety (WHO–IPCS), 2002.

5 Such categories are used, for instance, with regard to carcinogens and reproductive toxicants in the 2008 Regulation on classification, labelling and packaging of substances and mixtures (CLP Regulation), see Annex I tables 3.6.1 and 3.7.1(a).

6 In the two draft legal acts.

7 As laid out in the previous version of this briefing, stakeholders, including Members of the European Parliament, criticised the Commission for its decision to carry out an impact assessment, thus delaying the adoption of criteria, with the Court stating in its judgment that there was no provision requiring an impact assessment.

8 For an explanation of the procedures, see the Commission's comitology website.

9 See also Parliament's Rules of Procedure (Rule 105 on delegated acts and Rule 106 on implementing acts).

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