Briefing

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European Parliament

Setting criteria on endocrine disruptors

Follow-up to the General Court judgment

SUMMARY

Endocrine disruptors are substances that interfere with the functioning of hormones, with potentially harmful effects on health. A wide range of chemicals are suspected of being responsible for endocrine-disrupting activity. Defining scientific criteria for their identification is highly complex and has important repercussions for a wide range of stakeholders. There is a lack of consensus among both scientists and regulators.

Work on the issue has been conducted at EU and international level. The European Commission's delay in adopting scientific criteria has provoked strong reactions from various stakeholders.

The Commission is expected to come up with scientific criteria and to present the legal acts required before summer 2016.

In a judgment delivered on 16 December 2015, the General Court of the Court of Justice of the EU found that the Commission had breached European Union law by failing to act on endocrine disruptors. It concluded that the Commission did not comply with its clear obligation to specify scientific criteria for the identification of chemicals that have endocrine-disrupting properties by 13 December 2013. In addition, it stated that there was no requirement to carry out an impact assessment, which the Commission had suggested was necessary to evaluate the various possible options prior to taking its decision.

In this briefing:

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Author: Nicole Scholz

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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 act on endocrine disruptors. The ruling followed a case filed by Sweden against the Commission on 4 July 2014 for delays in establishing scientific criteria for the identification of chemicals that have endocrine-disrupting properties and, more specifically, for its failure to adopt delegated acts specifying such criteria by 13 December 2013.[1] It concluded that the Commission had not complied with its 'clear, precise and unconditional' obligation under the Biocidal Products Regulation (see box) by failing to adopt measures by the set deadline. In addition, the Court stated that there was no provision in the Regulation requiring an impact assessment, which the Commission had suggested was necessary to evaluate the various possible options prior to making its decision. The background to the General Court judgment and the issues surrounding the controversial endocrine disruptor dossier leading up to it are set out below.

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, and provide for the establishment of scientific criteria to identify endocrine disruptors by mid-December 2013, until which time the interim criteria set out in the PPPR and BPR apply. In the REACH Regulation (No 1907/2006) for the registration, evaluation, authorisation and restriction of chemicals, endocrine-disrupting chemicals (EDCs) are considered to be of similar regulatory concern as substances of very high concern, to be regulated on a case-by-case basis. Other pieces of EU legislation relevant to EDCs include the Water Framework Directive (2000/60/EC), Regulation 1272/2008 on the classification, labelling and packaging of substances and mixtures, the Toy Safety Directive (2009/48/EC) and the Cosmetics Regulation 1223/2009. European Commission Directive 2011/8/EU prohibits, on the basis of the precautionary principle, the production and sale of baby bottles containing bisphenol A (BPA) until further scientific data are available to clarify the toxicological relevance of some observed effects of this substance.

The challenge of identifying endocrine disruptors

Suspected health effects

Endocrine disruptors, or endocrine-disrupting chemicals (EDCs), are substances that interfere with the functioning of hormones and therefore may have harmful effects on human health.[2] A wide range of chemicals commonly used for a number of everyday products – such as electronics, plastics, pesticides, cosmetics, toys, food containers, antibacterials, etc. – are suspected of having the potential to be endocrine-disrupting under certain circumstances.[3] Some EDCs have been banned in fairly recent times but are still present in relatively large quantities in the environment. Others are naturally occurring substances and may enter the food chain.

The effects of EDCs are thought to depend on both the level and timing of exposure. EDCs are suspected of being capable of acting even at very low doses. Exposures are thought to have both immediate and more latent consequences, such as a heightened susceptibility to certain diseases and dysfunctions later in life. 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, behavioural and learning problems

(including attention-deficit hyperactivity disorder), infections, asthma, and perhaps obesity and diabetes. 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.

Uncertain science

There are still gaps in our understanding of endocrine disruptors, and experts disagree on a number of points. A long-running debate focuses on whether rules on EDCs should be based on hazard or risk assessment (see box). In addition, there is uncertainty over low-dose effects and whether a threshold ('potency-based cut-off') might be established, below which a substance can be considered safe. Proponents of the traditional approach to chemical risk assessment argue that 'the dose makes the poison': there is a linear relationship between dose and toxicity (the higher the dose, the higher the toxicity), and a safe level of exposure can be established. Opponents believe that this view should be transcended in the case of EDCs, for which 'the timing makes the poison'. They take the view that, according to recent scientific understanding, there may be no safe level, notably because exposure to EDCs is repeated and continuous, EDCs may accumulate over time in the human body (bioaccumulation), and exposures involve mixtures of compounds with possible synergistic activity (combination or cocktail effects).

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 humans are exposed to (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.

Elements of a working definition

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'.

It is a widely accepted definition and was used as a working definition in the 1999 Community strategy on endocrine disruptors. It also served as a basis for discussion in the Commission's Endocrine Disrupters Experts Advisory Group (ED EAG), which in 2013 published a report on key scientific issues with the aim of supporting the Commission's decisions on the establishment of criteria for identifying EDCs. The expert group supported a broad definition of 'endocrine system'. Traditionally, the endocrine system was identified with a group of glands producing and secreting hormones, such as the hypothalamus, the pituitary, the pineal, the thyroid, the parathyroids, the adrenals, the ovaries and testicles, and the pancreas. However, Kortenkamp et al. observed that 'the scientific advances in our understanding of receptor signalling and molecular biology are continuously blurring the borders between the nervous system, immune system and endocrine system. ... An implicit understanding of the endocrine system or endocrine signalling can therefore span from the classical definition of the endocrine system to one that encompasses any type of receptor-mediated signalling.'

Moreover, the expert group agreed that the elements required for the identification of an endocrine disrupter were: 'demonstration of an adverse effect for which there was convincing evidence of a biologically plausible causal link to an endocrine-disrupting mode of action and for which disruption of the endocrine system was not a secondary consequence of other non-endocrine-mediated systemic toxicity'. In the absence of appropriate data demonstrating non-relevance, data should be assumed to be relevant to humans. Factors such as potency, severity, irreversibility and lead toxicity[4] were considered to be part not of the identification but rather of the hazard characterisation of EDCs.[5]

The need for horizontal criteria

Defining which substances are to be considered to be endocrine disruptors has important implications for their regulation. Since horizontal scientific criteria for their identification are lacking, they are currently regulated according to varying approaches across different pieces of legislation.

The practical implementation of the criteria to be drawn up will have an impact on a wide range of stakeholders: on the one hand, the general population, in terms of the protection of human health from potentially harmful substances; and on the other, economic operators such as the chemical, electronic, consumer products, packaging, food and medical devices industries, including small and medium-sized enterprises and farmers. For businesses, the possibility of having chemicals banned on grounds of their suspected endocrine-disrupting properties is linked with concerns about the cost and availability of certain products, food safety and security, and ensuring competitiveness.

Science-based regulatory decision making – the EU as pioneer

In view of the complexity of defining formal scientific criteria for endocrine disruptors, the Commissioner for Health and Food Safety, Vytenis Andriukaitis, has stressed that 'setting these criteria is not merely a scientific question, but a scientific question in a regulatory context'. The decision to undertake an impact assessment was 'in no way influenced by external lobbying'. The Commissioner rejected some interpretations of the delay in bringing forward EDC criteria, qualifying them indirectly as 'conspiracy theories'. What was needed first of all was manageable regulatory criteria: 'We are ready to move forward ... to set a very good example for the wider world, because we are pioneers.'

The Commission has argued for the need for these criteria to be 'operational', that is, to allow for 'science-based regulatory decision making' (see box). It has also underlined that it requires input prior to legislating, owing to the complex issues involved and because diverging views still exist on many points.

The ongoing Commission impact assessment

The Commission decided in 2013 to undertake an impact assessment of the current interim criteria under discussion. Its rationale for the need to conduct an assessment: scientists are not unanimous on how scientific criteria should be defined and hold diverging views on how endocrine disruptors should be identified; and regulators worldwide have split opinions on how scientific criteria should be determined in a regulatory context, given the absence of legally binding criteria for identifying EDCs.

In preparation for the impact assessment, the Commission carried out a public consultation from 26 September 2014 to 16 January 2015, which received over 27 000 responses.[6] In March, April and May 2015, the Commission organised stakeholder roundtables, leading up to a high-level conference on 1 June 2015. On 6 November 2015, the Commission's Joint Research Centre (JRC) held a technical meeting to present

stakeholders with the methodology it had developed for evidence-screening of chemicals in the context of the 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: DG SANTE, June 2015.

The impact assessment comprises two studies: the first is an individual assessment of substances to determine which fall under which option for identifying EDCs. These substances (around 700) include most of those authorised under the PPPR and the BPR, as well as an additional group of chemicals falling under the REACH Regulation, the Cosmetics Regulation and the Water Framework Directive. They were selected using the methodology developed by the JRC and will be screened by an external contractor.[7] The second study, which will start once the screening is finalised, will assess potential (positive and negative) socio-economic impacts, such as those on health, the environment, agriculture and trade.

After the General Court judgment, the Commission said it would continue its work on the impact assessment, albeit at a quicker pace, and that decision-making concerning the criteria for identifying endocrine disruptors would follow thereafter. This decision has been met with criticism (see 'Stakeholder views').

Work on the issue conducted at EU and international levels

European Parliament

Based on the report by rapporteur Åsa Westlund (S&D, Sweden), Parliament adopted a resolution on the protection of public health from endocrine disruptors in March 2013. It called on the Commission to submit, as soon as possible, proposals for overarching criteria based on the WHO–IPCS definition of endocrine disruptors and for EU legislation to make clear what is regarded as a substance with endocrine-disrupting properties. According to the resolution, any possible combination effects should be taken into consideration, and – since current science does not provide a sufficient basis for setting a limit value below which adverse effects do not occur – endocrine disrupters should be regarded as 'non-threshold' substances.

On 20 January 2015, 11 MEPs sent a critical letter to Health Commissioner Vytenis Andriukaitis, urging him to work towards 'horizontal, science-based criteria fit for the various laws that address endocrine disruptors ... instead of developing criteria based on a sectorial view (pesticides and biocides) based on economic impact alone.'[8]

Responding to an oral question, Andriukaitis set out the Commission's response to the General Court judgment in a plenary debate on 2 February 2016. He stressed that the impact assessment was an 'essential tool' to guide future decisions, and dismissed the allegations of some Members that he represented the industry: the impact assessment was not about economic and social aspects but about scientific criteria and how to define, inter alia, potency, exposure and qualification.

European Commission and EU agencies

European Commission

The Commission has set up two expert groups on various scientific and policy aspects of endocrine disruptors. Both include representatives of industry associations, non-governmental organisations (NGOs), Commission staff, EU agencies and Member States. The **ad hoc group of Commission services, EU agencies and Member States** was established in 2010 for the Community strategy on endocrine disruptors under the Directorate-General for Environment (DG ENV) and focused on policy issues. The **Endocrine Disruptors Expert Advisory Group (ED EAG)**, organised by the JRC, was set up in November 2011 to reflect on scientific issues relevant to endocrine disruptors. The outcome of the latter group's meetings is summarised in two reports from 2013 (on key scientific issues and on thresholds for EDCs). In 2014, the group published a state-of-the-art review of alternative methods for regulatory toxicology. The **Scientific Committee on Consumer Safety** is an independent body that provides the Commission with policy advice on health and safety risks of non-food consumer products and services, and draws attention to emerging problems. In the framework of the Commission's public consultation, it published a memorandum on EDCs in 2014, supporting the conclusions of the European Food Safety Authority that EDCs can be treated like most other substances of concern for human health and the environment, that is, be subject to risk assessment and not only to hazard assessment.

EU agencies

The European Chemicals Agency (ECHA) coordinates and hosts an Endocrine Disruptor Expert Group, set up in February 2014. It provides non-binding scientific advice at the request of the EU Member States' competent authorities responsible for carrying out EDC assessments.

With regard to bisphenol A, a 2013 report of the European Environment Agency (EEA) cautioned that 'until final decisions are made, precautionary measures should be taken to lower human exposures to well below those that cause adverse effects in rodents and behavioural changes in humans in epidemiological studies'. This would mean terminating those uses of the substance that involve close contact with humans via food or the environment.

The European Food Safety Authority (EFSA) delivered a scientific opinion on the hazard assessment of endocrine disruptors in March 2013, in which it recommended a risk-based approach. In January 2015, EFSA published a re-evaluation of bisphenol A exposure. In parallel, as a result of a more refined risk-assessment method, it reduced the safe level ('tolerable daily intake' or TDI) of BPA from 50 to 4 micrograms per kilogram of body weight per day.

The European Medicines Agency (EMA) has issued a guideline on the phthalates most commonly used as excipients in human medicinal products authorised in the EU; it came into effect in June 2015.

Organisation for Economic Co-operation and Development

The Organisation for Economic Co-operation and Development (OECD) has worked for over 10 years on developing methods for screening and testing chemicals for endocrine disruption. In 2012, it published a 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. The paper describes a number of endocrine-signalling pathways that have been shown to be susceptible to endocrine disruption, and where the disruption could contribute to increasing the likelihood of some disorders in humans such as obesity, diabetes, reproductive dysfunction and neuro-behavioural abnormalities.

United Nations Environment Programme – World Health Organization

In 2012, a group of experts from the United Nations Environment Programme (UNEP) and the WHO published a report on the state of the science of endocrine-disrupting chemicals. The report pointed out that, because of the complexity of exposures and the emergence of diseases over a lifespan, it may never be possible to have absolute certainty that a specific exposure causes a specific disease or dysfunction. Furthermore, it cautioned that disease risk due to EDCs may be significantly under-estimated, concluding that 'EDCs have the capacity to interfere with tissue and organ development and function, and therefore they may alter susceptibility to different types of diseases throughout life'.

World Health Organization

In its 2012 report on endocrine disruptors and child health, the WHO summarised the current knowledge about the effects of EDC exposure on children, with the main focus on endocrine-related congenital disorders, thyroid hormone-related problems and puberty. It concluded that, despite ample evidence of endocrine disruption in wildlife, knowledge about the association of human disorders with exposure to EDCs was still limited.

Stakeholder views

Third countries: Argentina, Canada, United States

Argentina cautions that removing substances on the basis of hazard identification, as opposed to case-by-case risk assessment, could result in trade barriers. Canada warns that a decision based solely on hazard rather than risk analysis would have 'the potential to unnecessarily disrupt bilateral trade in agriculture and agri-food and feed products on which chemicals containing endocrine-disrupting properties are safely used'. The United States takes the view that implementing a system based solely on the hazardous properties of substances could have severe implications for EU imports of US agricultural goods: 'Creating technical regulations on the basis of hazard-based criteria are often (i) more trade restrictive than necessary because risk-based mitigation measures exist and because (ii) they do not fulfil a legitimate objective as they are not supported by scientific evidence.'

Scientists

A group of 73 scientists criticised the Commission's approach of developing horizontal criteria for defining whether a substance is an endocrine disruptor in an open letter of 18 June 2013 to the Commission (an initiative that was backed by a group of editors of journals of pharmacology and toxicology in an editorial published in parallel in several scientific journals). Referring to 'imminent decisions' and 'emerging policy' – most likely the leaked, unpublished Commission draft proposal for a recommendation – they were concerned that there was 'neither a scientific basis nor broad support by scientists

established in risk assessment' behind the approach. With regard to the issue of thresholds, they said: 'If the Commission will adopt a policy stating that it is impossible to define a safe limit or threshold' for a substance that classifies as an EDC, this would 'reverse current scientific and regulatory practices and, more importantly, ignore broadly developed and accepted scientific development and accepted knowledge regarding thresholds of adversity.' Regarding the issue of EDC identification, they added that, should the Commission propose 'that identification of an *in vitro* effect without a causal relationship to adversity in an intact organism may be sufficient to classify a substance as an "endocrine disruptor"', this 'would not only represent a rewriting of the rules and accepted practices of toxicology, ... but would also be contrary to all accumulated physiological understanding'.

The Endocrine Society argues that 'a growing body of epidemiological studies is revealing associations between EDC body burdens and a variety of diseases' and that therefore 'a precautionary approach is needed to limit EDC exposure'. More specifically, with regard to the mechanisms to consider when discussing dose-response characteristics of EDCs, it states: 'These fundamental endocrine principles demonstrate why it is impossible to define the "potency" of an EDC, why "thresholds" of action are not possible to identify, and why nonlinear dose-responses cannot be ignored despite some continued controversy on this point.'

NGOs

The Corporate Europe Observatory (CEO) denounces 'massive industry lobbying', referring to a documentary film (2014) by French journalist Stéphane Horel on 'how corporations and actors within the Commission are teaming up to demolish a major piece of public health legislation'.

The International Chemical Secretariat (ChemSec) calls for a balanced impact assessment. It is 'worried that the information spread by some industry parties is exaggerated' and sees a need to 'scrutinise the ... numbers presented by the pesticide industry associations and its allies and the lack of vision for solutions other than replacing one hazardous chemical with another'.

Pesticide Action Network Europe (PAN Europe) alleges that the Commission's DG for Health and Food safety (DG SANTE, formerly DG SANCO) 'secretly cooperated' with DG Enterprise to prevent DG Environment from moving forward with EDC regulation.

In a statement on the General Court judgment, ClientEarth claims that the process of assessing the economic impact 'is biased' and that 'it must stop immediately. ... The Commission needs to start protecting the public, not the chemicals industry.'

The European Consumer Organisation (BEUC) urges Health Commissioner Vytenis Andriukaitis to take immediate action to improve the protection of consumers against hormone-disrupting chemicals. It says it is disappointed that the Commission plans to continue with its impact assessment rather than swiftly adopt legal criteria, without which 'it is impossible to restrict or ban the most harmful' of these chemicals.

Industry

In a joint press release following an event held at the European Parliament, the Agri-food Chain Roundtable for Plant Protection, consisting of 19 EU associations, stressed that 'solutions are urgently needed to ensure the competitiveness of the entire agri-food chain and the supply of high quality products for European consumers'. In particular, it underlines that farmers lack available solutions due to problems with

mutual recognition, bringing new products to the market, and regulatory uncertainty (including as regards endocrine disruptors).

The European Chemical Industry Council (CEFIC) supports the Commission's move to define scientific criteria ('the sooner they are in place, the better'), arguing that they will make it easier to adopt regulatory measures and bring clarity and predictability to operators. It favours Option 4 of the roadmap, but with additional elements of hazard characterisation (namely severity of effect, (ir)reversibility of effect, potency and lead toxicity). In its submission to the public consultation, CEFIC insists that priority must be given to the task of 'effectively distinguishing between endocrine disruptors of regulatory concern and those substances that pose little or no concern for human health or the environment and that do not need to be regulated'. Commenting on the list of substances published by the Commission in December 2015, it underlines the need to avoid 'unfounded conclusions' concerning the nature of the selected substances so that 'beneficial substances' are not 'subject to stigmatisation and market pressure'.

A group of chemical and crop protection industries[9] commissioned a scientific review of the 2012 WHO–UNEP report, which found several 'shortcomings'. In a joint statement of February 2014, the industries signalled that the WHO–UNEP report 'should not be used as the basis for supporting chemicals policy on endocrine disruptors, as the report does not provide an objective assessment of the current state of the science on endocrine disruption'.

On a dedicated website, the European Crop Protection Association (ECPA) emphasises the importance of setting criteria to clearly distinguish endocrine disruptors from endocrine-active substances and that the 'focus is on identifying substances that are truly of concern'. It stresses that 'interaction with the hormonal system does not necessarily involve disruption'. At the Commission's June 2015 conference, pointing to the risk of hazard-based legislation, it said: 'Failure to consider exposure (dose) can result in focusing on substances of little/no regulatory concern.'

In its presentation at the June 2015 conference, Food Drink Europe asked whether the necessary level of food safety could be maintained if some of the EDC-containing biocides used in food processing (for cleaning, sanitation, disinfection and ensuring food safety and hygiene) were to be banned and whether comparable replacement substances were efficient.

Endocrine disruptor criteria expected by summer 2016

On 2 February 2016, Health Commissioner Vytenis Andriukaitis told Parliament that 'before summer' the Commission would come up with criteria that would be specified 'in an objective manner based on scientific evidence'. The Commission would present two pieces of legislation: an implementing regulation, under the Regulatory Procedure with Scrutiny,[10] containing the criteria that would be applied to the chemical substances falling under the Plant Protection Product Regulation, and a delegated act containing criteria applicable under the Biocidal Products Regulation.

Main references

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Endnotes

1 In an official statement, the Swedish Minister for the Environment, Lena Ek, expressed her concern that the Commission did not make a 'clear distinction between what science says about the intrinsic characteristics of these substances and the consequences of a substance being identified as an endocrine disruptor', while the Minister for EU Affairs, Birgitta Olsson, accused the Commission of having 'deliberately dragged its heels'.

2 This briefing will not deal with potential or identified impacts of EDCs on other animal species or the environment.

3 The substances under scrutiny include, for instance, bisphenol A (BPA), phthalates, polychlorinated biphenyls (PCBs), triclosan, parabens and DDT.

4 The report defines this as the effect that occurs at a lower dose than other toxic effects, that is, the most sensitive or dominant feature of the hazard profile of a substance.

5 According to IPCS risk assessment terminology, 'the qualitative and, wherever possible, quantitative description of the inherent property of an agent or situation having the potential to cause adverse effects'.

6 The findings, published in July 2015, show that Option 1 is not supported by the consultation, while many respondents backed the use of the WHO–IPCS 2002 definition as a starting point for defining an EDC.

7 In December 2015, the Commission published the list of substances selected for screening.

8 Michèle Rivasi (Greens/EFA, France), Christel Schaldemose (S&D, Denmark), Sirpa Pietikäinen (EPP, Finland), Dario Tamburrano (EFDD, Italy), Gerben-Jan Gerbrandy (ALDE, Netherlands), Margrete Auken (Greens/EFA, Denmark), Pavel Poc (S&D, Czech Republic), Nessa Childers (S&D, Ireland), Jytte Guteland (S&D, Sweden), Frédérique Ries (ALDE, Belgium), Younous Omarjee (GUE, France).

9 American Chemistry Council, Cefic, CropLife America, CropLife Canada, CropLife International, European Crop Protection Association.

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

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