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COMMUNICATION FROM THE COMMISSION TO THE EUROPEAN PARLIAMENT AND THE COUNCIL

on endocrine disruptors and the draft Commission acts setting out scientific criteria for their determination in the context of the EU legislation on plant protection products and biocidal products

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1. INTRODUCTION

Endocrine-disrupting chemical substances ("endocrine disruptors") are substances that alter the functions of the hormonal system and consequently cause adverse effects. As awareness of endocrine disruptors grew, so did public and political interest. The Commission responded with a "Strategy for endocrine disruptors" in 1999.[1] This set out a number of actions at EU level, with the short-term (research and international cooperation), mid-term (test methods) and long-term (regulatory) steps to take with the overall goal of minimising exposure.[2]

In the specific areas of biocides[3] and plant protection products[4] the legislation determines the regulatory consequences for endocrine disruptors. It also requires the Commission to determine how the criteria for endocrine disruptors should be defined, by drawing up acts "specifying scientific criteria for the determination of endocrine-disrupting properties".[5] Plant protection products protect plants against harmful organisms (examples are herbicides or insecticides used in agriculture). Biocides contain and control harmful organisms (examples are disinfectants used in hospitals).

The Commission has devoted particular attention to the task of developing criteria for these two areas. The result is reflected in two draft measures[6] which will now be the subject of the established procedures with (experts from) Member States and other EU institutions, before final adoption by the Commission. Though different procedures apply to the two measures, the Commission's examination of the issues has covered both areas and they will be taken forward in parallel.[7]

This Communication sets out the science-based decisions underlying the two draft measures, and is accompanied by an impact assessment which presents the state of the science regarding different criteria to identify endocrine disruptors. In addition, it provides information on the possible consequences.[8] The impact assessment is based on a preliminary screening of active substances approved for plant protection products and biocides for which information was available at EU level. It does not therefore constitute an evaluation of individual substances

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1 COM(1999)706 final, 17.12.1999.

2 This is one of the aspects covered in the 7th Environmental Action Programme (Decision No 1386/2013/EU of the European Parliament and of the Council of 20 November 2013 on a General Union Environment Action Programme to 2020 'Living well, within the limits of our planet', OJ L 354, 28.12.2013, p. 171).

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

4 Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market (OJ L 309, 24.11.2009, p. 1).

5 Article 5(3) of Regulation (EU) No 528/2012.

6 Draft Commission Delegated Regulation setting out scientific criteria for the determination of endocrine-disrupting properties pursuant to Regulation (EU) No 528/2012 and Draft Commission Regulation setting out specific scientific criteria for the determination of endocrine disrupting properties and amending Annex II to Regulation (EC) 1107/2009.

7 In the context of plant protection products, the draft text is voted in the Standing Committee (regulatory procedure with scrutiny). In the context of biocidal products, a draft delegated act is discussed in a group of experts of Member States. Both measures involve the Parliament and the Council, albeit in different procedural constellations (draft measure in regulatory procedure with scrutiny and adopted delegated act). In order to ensure coherence between the two acts, the Commission will present both texts simultaneously to the EU co-legislators for them to exercise their control functions.

8 SWD(2016) 211.

under the respective legislation (the Regulations covering plant protection products and biocidal products).[9]

This Communication sets out the issues on which the Commission has reached a conclusion and puts these in the broader context, while also stressing that parts of the debate are not directly relevant to the Commission's specific task of determining criteria to establish what is and what is not an endocrine disruptor (see Section 2). It sets out the implications of the setting of the criteria in the domains of plant protection products and biocides (section 3) and for other parts of the EU regulatory framework (Section 4) and recalls the other Commission actions on endocrine disruptors which are ongoing or pending (Section 5).

The Commission's conclusions build on work with Member States, input from EU regulatory agencies, independent scientific committees advising the Commission, the Commission's in-house scientific body (the Joint Research Centre[10]), and from multilateral and bilateral scientific and regulatory cooperation with third countries, as well as extensive contacts with stakeholders over the past 15 years.[11]

These discussions have shown the complexity of the topic: so too does the fact that no other country has so far adopted legally-binding scientific criteria to determine what is an endocrine disruptor. Against this background, the Commission conducted a thorough preparation of the measures, which it was unable to conclude in time to meet the legal deadline of December 2013. Following a ruling of the Court of Justice of the European Union (General Court) in December 2015,[12] the Commission reconfirmed its unequivocal commitment to the EU co-legislators to finalise its ongoing work, which by then was close to conclusion, and present the criteria before the summer 2016.

2. THE DEBATE ON CRITERIA FOR THE DETERMINATION OF ENDOCRINE DISRUPTORS AND THE COMMISSION'S CONCLUSIONS

There are a number of key scientific issues which have been the subject of debate and study and some – but not all – of these have a direct bearing on the draft measures on plant protection products and biocidal products. Several issues are also part of a more general debate about toxicology, rather than issues which concern endocrine disruptors alone.

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9 The analytical work in the impact assessment draws *inter alia* on a contracted study screening nearly all approved active substances for plant protection products (and the active substances for biocidal products for which information was available at EU level) to evaluate the impacts associated to options for criteria to identify endocrine disruptors under the Regulations on plant protection products and biocidal products. The screening was based on available evidence (no additional testing) and needed to be carried out in a limited time. The screening methodology was developed for the purpose of the screening exercise. The results of the screening therefore do not constitute evaluations of individual substances to be carried out under the respective legislations and in no way prejudge future decisions on active substances to be taken pursuant to these two Regulations.

10 The most important Joint Research Centre scientific and policy reports are the reports of the endocrine disrupters expert advisory group: "Key scientific issues relevant to the identification and characterisation of endocrine disrupting substances" (2013); and "Thresholds for endocrine disruptors and related uncertainties" (2013) (https://ec.europa.eu/jrc/en/publication/eur-scientific-and-technical-research-reports/thresholds-endocrine-disrupters-and-related-uncertainties; https://ec.europa.eu/jrc/en/publication/eur-scientific-and-technical-research-reports/key-scientific-issues-relevant-identification-and-characterisation-endocrine-disrupting).

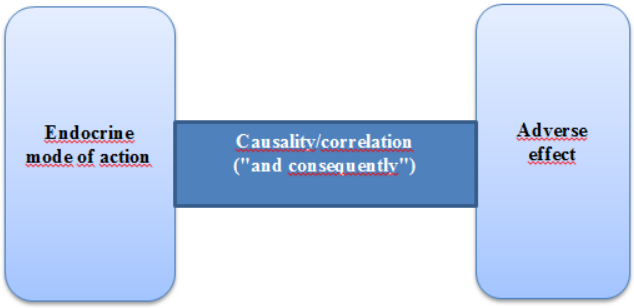
11 More information on the multitude of EU activities is available on the dedicated Commission web portal: http://ec.europa.eu/health/endocrine_disruptors/policy/index_en.htm.

12 Judgement in Case T-521/14, Sweden v Commission.

What is an endocrine disruptor?

In 2002, the International Programme on Chemical Safety, a joint programme of various UN Agencies, including the World Health Organisation, made an authoritative definition of an endocrine disruptor as *"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*".[13] The novelty in this definition was the introduction of a second element. The usual approach to defining the toxicity of chemical substances is "end points" – whether there is an adverse effect. The new, additional, element is the concept of "mode of action", the way in which a chemical substance has an impact (see Figure).

Figure



As well as the adverse effect, the draft scientific criteria now being presented aim to introduce in legal form this concept of the "endocrine mode of action" as one of the elements to consider when determining what is an endocrine disruptor for the two product areas concerned.

More specifically, the criteria set out that an endocrine mode of action is "*the inherent ability of a substance to interact or interfere with one or more components of an endocrine system*", without necessarily leading to an adverse effect. In line with the opinion of the European Food Safety Authority, they also clarify that an endocrine mode of action is not a (eco)toxicological hazard in itself.[14]

Currently, the discussion on the endocrine mode of action centres on the hormonal systems of oestrogen, androgen, thyroid, and steroidogenesis – as these are the only areas where standardised tests exist.[15] However, in order to be ready to adapt to future scientific developments, the draft measures are not limited to these hormonal systems.

Defining the "adverse effect"

One of the issues which the criteria needed to address is the definition of "adverse effect". The Commission will use the definition provided by the International Programme on Chemical Safety. This 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*

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[13] World Health Organisation International Program on Chemical Safety, Global assessment of the state-of-the-science of endocrine disruptors, 2002, WHO/PCS/EDC/02.2.

[14] European Food Safety Authority, Scientific criteria for identification of endocrine disruptors and appropriateness of existing test methods for assessing effects mediated by these substances on human health and the environment, 28.2.2013, EFSA Journal 2013;11(3):3132, p. 17 ("EFSA(2013)").

[15] See EFSA(2013), p. 29.

functional capacity, an impairment of the capacity to compensate for additional stress, or an increase in susceptibility to other influences."[16]

The challenge in practice lies in assessing the potential adversity of an effect at sub-organ level (molecular or cellular level). The conclusion of the European Food Safety Authority in 2013 was to make a distinction in terms of the degree of change observed: "*expert judgement will therefore be required to assess on a case-by-case basis the toxicological relevance of […] changes. In general, transient, inconsistent and minor fluctuations at the biochemical and molecular level may be considered adaptive (i.e. non-adverse), whilst sustained, consistent and permanent changes at the cell, organ- or organism-level, resulting in pathology or functional impairment in vivo, as well as altered timing of development, may be considered adverse*".[17] The Commission is following this approach.

The criteria also underline that endocrine-related adverse effects which are only indirectly triggered by a non-endocrine-related toxicity are not adverse effects that are relevant for the identification of a substance as an endocrine disruptor.[18] This clarification is necessary since, as the result of any generalized toxicity, there may be reactions of the endocrine system which would be the consequence rather than the cause of the specific adverse effect observed.

How to determine causality

The 2002 definition has at its heart the link between the mode of action and the adverse effect, (the phrase "and consequently" in the definition). The question remains about the extent to which this link should be clearly established – the degree to which a strict causality should be required. In 2013, the European Food Safety Authority concluded that there has to be *"a reasonable evidence base for a biologically plausible causal relationship between the [endocrine mode of action] and the adverse effects seen in intact organism studies*", i.e. a "reasonable evidence base" to determine causality. The alternative would have been a more rigid approach to causality (asking, for example, for "conclusive" evidence of the connection). The Commission considers that in practice, it will be very difficult to demonstrate "conclusive evidence" of causality. Therefore, the Commission intends to follow a concept of a reasonable evidence ("biological plausibility") to determine causality.

The relevance of "categories"

The debate on criteria to determine what is an endocrine disruptor has sometimes included the idea to establish a system of "categories" of endocrine disruptors. These "categories" refer to varying degrees of scientific evidence for the endocrine mode of action, the adverse effect, and the causality between the two (or indeed a combination of these elements).[19] Categories that have been put forward are, for example, "suspected endocrine disruptors", or substances that have only an endocrine mode of action (i.e. without scientific evidence of an adverse effect).

The Commission considers that establishing different categories of what *may be* an endocrine disruptor does not help to define what *is* an endocrine disruptor in the context of biocides and pesticides. Furthermore, such categorisation for pesticides and biocides would decrease legal

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16 World Health Organisation. International Program on Chemical Safety, Principles and methods for the risk assessment of chemicals in food. (Environmental Health Criteria), 2009.

17 EFSA(2013), p. 16.

18 Sometimes discussed as "specificity of the adverse effect".

19 Such categories are used in some areas of chemicals regulation. The issue is not to be confused with potency categories (see below).

certainty for regulators and stakeholders, without established benefits in terms of protection of health and the environment.[20]

The debate about a "safe threshold" for endocrine disruptors

The usual way of determining the safety of a chemical substance is based on a "safe threshold". The safe threshold gives the dosage below which no adverse effect is expected to occur.[21] Usually, once this level is established experimentally, a safety margin is added by reducing the value to a small proportion of it – for example, 1% of the threshold previously established. This concept is used by regulators worldwide,[22] but is nevertheless the subject of controversy in the area of endocrine disruptors – where there is a debate about whether a safe threshold can ever be established, or whether this can be left to case-by-case risk assessment. The Commission considers that answering the question of whether a threshold exists is neither necessary nor appropriate when defining scientific criteria for determining what is an endocrine disruptor.

The relevance of potency

The potency of a chemical substance describes its ability to produce an effect at a particular dose level.[23] In the EU general chemicals law used to classify chemical substances[24] – which is based on a global harmonised system – potency is used to determine which category of hazard a substance should fall into.[25] Consideration of potency is needed in risk assessment, and can also be useful for prioritising and screening substances.

However, to determine what is an endocrine disruptor, what matters is solely whether a chemical is an endocrine disruptor at all (i.e. the *identification* of the hazard, as opposed to its subsequent *characterisation*). The Commission has therefore concluded that, for the specific purpose of setting scientific criteria, it is not necessary to include considerations of how "potent" an endocrine disruptor is. Potency is a question to be asked only once it has been established that a substance is an endocrine disruptor at all. The impact assessment report accompanying this Communication addresses issues of potency, and identifies arguments in support of considering potency. However, the Commission follows the broad scientific consensus whereby potency should not be considered when identifying endocrine disruptors, but taken into account when evaluating the actual risk that endocrine disruptors may pose.

Regulation by "hazard" or "risk"

The regulation of chemical substances can be approached in two different ways: based on hazard or based on risk. A hazard-based approach regulates substances on the basis of their intrinsic properties, without taking account of the exposure to the substance. A risk-based

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[20] This does not preclude that categories are applied as a prioritisation tool, for example for additional research.

[21] With exceptions such as, for example, certain forms of mutagenicity and genotoxic carcinogenicity. With regard to these endpoints, current risk assessment practice applies a non-threshold approach, i.e. it is assumed that no amount of exposure is risk-free.

[22] EFSA have recalled that "*for most toxic processes, it is generally assumed that there is a threshold of exposure below which no biologically significant effect will be induced*" (EFSA(2013), p. 16).

[23] Sugar compared to sweeteners may serve as an illustration. Both have the intrinsic property of being sweet. However, the potency of most sweeteners is much higher than sugar, so that a lower dosage is needed to produce an effect.

[24] Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures (OJ L353, 31.12.2008, p. 1).

[25] For example, harmful/toxic/fatal contact with the skin.

approach factors in the exposure. A common analogy used is from the animal kingdom: a lion is intrinsically a hazard, but a lion safely constrained in a zoo is not a risk, since there is no exposure. In the area of chemical safety, there are several pieces of EU legislation that apply a hazard-based approach to toxicological safety, while others follow a risk-based approach.[26] [27]

The issue faced by the Commission in this exercise is to establish criteria to determine what is or is not an endocrine disruptor for the purposes of plant protection products and biocidal products – not to decide how to regulate these substances. The regulatory consequences have already been set by the legislator in the legislation on plant protection products (2009) and biocidal products (2012). Under this legislation, as a general rule, endocrine disruptors are banned on the basis of hazard[28], without undergoing a specific risk assessment on the basis of considerations of exposure (although in some cases derogations – either hazard, risk or considering socio-economic issues – may apply on a case by case basis, as stipulated by the legislation).

3. WHAT DO THE CRITERIA MEAN FOR THE REGULATORY AREAS OF BIOCIDES AND PLANT PROTECTION PRODUCTS?

The EU legislation for biocidal products and plant protection products provides that active substances which are endocrine disruptors shall not be approved, unless – in the case of plant protection products – there is negligible exposure or – in the case of biocides – a negligible risk. In principle, the question whether an active substance of a plant protection product or a biocide is an endocrine disruptor would be assessed each time it is subject to an approval procedure or a renewal procedure. In addition, all active substances used in plant protection products and biocidal products are only approved for a limited period of time, and their approvals are routinely reviewed.

Some of the adverse effects caused by endocrine disruptors (for instance effects on reproduction) have been assessed for many years which means that in practice many substances where evidence as endocrine disruptors is available have been already banned in the EU. The new criteria will however allow for a more accurate and up to date assessment.

In order to ensure quick action and that recent scientific developments will be taken into account, the more accurate scientific criteria will be applied immediately, except for cases where a draft Commission regulation has been voted on already but not adopted. In addition, in order to allow the assessment work to start, the Commission will today ask the European Food Safety Authority and the European Chemicals Agency to start looking at whether individual approved active substances, for which indications exist that they could meet the criteria to be identified as having endocrine disrupting properties, are endocrine disruptors according to the criteria in the draft texts presented today. This would help to ensure that these two regulatory Agencies would be ready to apply those criteria, in accordance with the applicable regulatory procedures, once the criteria enter into force.

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[26] The Commission is currently conducting a "fitness check", under the REFIT programme, to assess these aspects more in-depth (see http://ec.europa.eu/smart-regulation/roadmaps/docs/2015_grow_050_refit_chemicals_outside_reach_en.pdf).

[27] Generally, a risk-based approach allows consideration of proportionality when taking regulatory (i.e. risk-management) decisions.

[28] Endocrine disruptors may be approved with risk-mitigation measures if strict conditions are met.

Updating the grounds for possible derogation to current scientific and technical knowledge

Both the plant protection products legislation and the biocides legislation ban active substances having endocrine disrupting properties on the basis of hazard. However, some limited exceptions are permitted. The biocides legislation allows exceptions based on "negligible risk" and socio-economic considerations. The plant protection products legislation allows exceptions based on "negligible exposure" or, in certain situations and under strict conditions, a serious danger to plant health. In the context of endocrine disruptors, the European Food Safety Authority has supported the principle of a risk-based approach for plant protection products.[29] Scientific and technical knowledge has been evolving and suggests that endocrine disruptors in this area could be assessed based on risk, like most other substances. This is why the Commission, in line with the mandate given by the co-legislators[30], has concluded that the grounds for possible derogations for plant protection products should be updated so as to refer – in line with the biocides legislation – to "negligible risk", while fully maintaining the concept of a hazard-based ban of endocrine disruptors, thereby ensuring an equally high level of protection of health and the environment.

4. WHAT DO THE CRITERIA SET FOR BIOCIDES AND PLANT PROTECTION PRODUCTS MEAN FOR OTHER REGULATORY AREAS?

The scientific criteria to determine what is an endocrine disruptor are being set to fulfil legal obligations under the EU legislation for biocidal products and plant protection products. The criteria only apply in these two regulatory areas, and do not have a direct legal consequence for other areas of EU law. The goal is to provide criteria to the relevant EU bodies (European Chemicals Agency, European Food Safety Authority, Commission) and Member States.

As explained above, the criteria being put forward are fully in line with the definition of the World Health Organisation International Programme on Chemical Safety – which already exists and provides a common foundation for all areas of EU policy on chemical safety. The World Health Organisation definition is being applied already to identify endocrine disruptors in the context of other legislation and it can be expected that this will continue in the light of the adoption of the criteria by the Commission.

In any event, the EU regulatory framework is already working with the notion of "endocrine disruptors" (albeit without criteria set in EU legislation to define what is an endocrine disruptor). For example, the European Chemicals Agency has listed, in the "Candidate List of substances of very high concern for Authorisation", substances on the basis solely of their endocrine-disrupting properties.[31] The Scientific Committee on Consumer Safety has assessed the safety in relation to the endocrine-disrupting properties of various cosmetic ingredients.[32] And the Commission has listed endocrine disruptors in the context of the implementation of

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[29] EFSA(2013), p. 47: "*to inform on risk and level of concern for the purpose of risk management decisions* […] *risk assessment (taking into account hazard and exposure data/predictions) makes best use of available information. Endocrine disruptors can therefore be treated like most other substances of concern for human health and the environment, i.e. be subject to risk assessment and not only to hazard assessment*". This approach was supported by the Scientific Committee on Consumer Safety, an independent non-food scientific committee advising the Commission (Memorandum on Endocrine Disruptors, 16.12.2014. (SCCS/1544/14)).

[30] Article 78(1)(a) of Regulation (EC) No 1107/2009.

[31] http://echa.europa.eu/candidate-list-table.

[32] Examples are listed in SCCS/1554/14.

the EU water quality legislation[33] and restricted the placing on the market of endocrine disruptors in the context of REACH.[34] The difference with the two policy areas covered by the draft measures is that in these two policy areas there exists a legal obligation to define the criteria to determine what is an endocrine disruptor.

5. OTHER ACTIVITIES OF THE COMMISSION

Looking beyond the setting of scientific criteria to identify endocrine disruptors, the Commission will increase its efforts in the range of other activities ongoing in the three areas highlighted in the EU endocrine disruptors strategy, with a view to continue to minimise exposure to endocrine disruptors in line with the 7th Environmental Action Programme. These activities could be further enhanced by developing fora to deepen information exchange and develop consensus in both the scientific and regulatory communities, in line with the strategy.

Research

Since adoption of the EU endocrine disruptors strategy in 1999, the EU framework programmes for research have supported over 50 multinational collaborative research projects with over 150m EUR in funding. Horizon 2020 is supporting further research to advance knowledge and to provide solid scientific evidence for regulators and policy-makers in the area of toxicology. A key initiative will be the European Human Biomonitoring Initiative, which will be a European knowledge hub for the measurement of human exposure to chemical substances. The Joint Research Centre has also an important role to play, for example in the development of assessment methods and approaches and their translation into regulatory use.

With a view to the future, the Commission considers it important to ensure a good flow of information of comparable hazard data, biomonitoring data, and surveillance data between Member States and agencies. This would also contribute to addressing issues of combined exposure. [35] A web platform will be developed by the Commission, involving EU agencies and Member States, to serve as a hub to strengthen cooperation and the exchange of information.

International cooperation

The Commission is an active partner in the work at global level, in particular the Organisation for Economic Cooperation and Development (OECD), in addressing toxicological safety and in particular identifying endocrine-disrupting chemicals. Today, a number of tests for screening and testing endocrine activity of substances have been validated and approved as OECD test guidelines, but work is still ongoing. Additional comprehensive guidance has been prepared to help interpret the outcome of tests.

The Commission considers that it is critical to continue and strengthen this work, on the basis of priorities set jointly with Member States in the OECD framework by 2018, in order to have the necessary range of validated tests available, at the latest by 2025.

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[33] Annex I to Directive 2008/105/EC of the European Parliament and of the Council of 16 December 2008 on environmental quality standards in the field of water policy (OJ L 348, 24.12.2008, p. 84).

[34] Annex XVII to the Regulation (EC) No 1907/2006 of the European Parliament of the Council of 18 December 2016 concerning the Registration, Evaluation and Authorisation of chemicals (REACH) (OJ L 396, 30.12.2006, p. 1).

[35] I.e. combined exposure toxicity involving several substances, sometimes referred to as "cocktail effect".

The Commission is also in regular contact with competent authorities in third countries.

EU regulation

As noted above, EU regulatory agencies, independent scientific committees, the Commission and Member States already look at endocrine disruptors. This work is regulated through sectoral legislation in areas including the human health (including for consumers and workers), animal health, and the environment. Examples are the EU legislation on occupational safety and health (where the legislation on chemical agents at work[36] includes all chemical agents, including endocrine disruptors), food and feed safety (where toxicological risks, including those stemming from endocrine disruptors, are subject to comprehensive risk assessment), and consumer products (including for example cosmetics and toys), as well as environmental legislation.

However, clearly, a key challenge for regulators is the availability of good scientific data. Therefore, the Commission will take all necessary steps to ensure that data requirements as regards endocrine disruptors are reviewed – whether these data requirements are enshrined in EU legislation, guidelines of the Commission, or guidelines of regulatory agencies and independent scientific committees.

In addition, the Commission will act swiftly in order to further implement the legal obligations in the EU *acquis* in relation specifically to endocrine disruptors. In particular:

EU Cosmetics Regulation: According to the EU Cosmetics Regulation, the Commission has to "*review this Regulation with regard to substances with endocrine-disrupting properties*".[37] This review is overdue. A screening exercise of certain cosmetic ingredients that has been contracted by the Commission is close to completion. The Commission will present the review by the end of the year.

REACH: The authorisation of chemical substances under the REACH Regulation can follow two alternative pathways: Where a safe threshold can be established, the authorisation is granted on the basis of a controlled risk. Where no safe threshold can be established, an authorisation can only be granted "*if it is shown that socio-economic benefits outweigh the risk to human health or the environment arising from the use of the substance and if there are no suitable alternative substances or technologies*".[38] The Commission was tasked to "*carry out a review to assess whether or not, taking into account latest developments in scientific knowledge, to extend the scope of Article 60(3)* [authorisation on the basis of socioeconomic benefits instead of safe exposure]" to endocrine disruptors.[39] Following the presentation of scientific criteria today, this review can be finalised and the Commission will present it by the end of the year.

Water quality legislation: The regulatory framework for water quality refers in several instances explicitly to endocrine disruptors, for example as substances to be in particular considered as substances liable to cause pollution.[40] The Commission has to regularly review

[36] Council Directive 98/24/EC of 7 April 1998 on the protection of the health and safety of workers from the risks related to chemical agents at work (OJ L 131, 5.5.1998, p.11).

[37] Article 15(4) of Regulation (EC) No 1223/2009 of the European Parliament and of the Council of 30 November 2009 on cosmetic products (OJ L 342, 22.12.2009, p. 59).

[38] Article 60(4) of the REACH Regulation (EC) No 1907/2006.

[39] Article 138(7) of the REACH Regulation (EC) No 1907/2006.

[40] For example, Article 2(31) and Annex VIII, point 4 to Directive 2000/60/EC of the European Parliament and of the Council of 23 October 2000 establishing a framework for Community action in the field of water policy (OJ L 327, 22.12.2000, p. 1).

the list of priority (hazardous) substances[41] and substances to be listed in the "watch list",[42] as well as quality parameters for water intended for human consumption.[43] These reviews are ongoing in accordance with the applicable legislation.

6. CONCLUSION

The adoption of criteria to identify endocrine-disrupting substances will fulfil the legal obligations under the plant protection products and biocides legislation. Once adopted, the EU regulatory system will be the first regulatory system worldwide to define scientific criteria for endocrine disruptors in legislation.

The draft measures should now be looked at through the relevant procedures and be finalised quickly, to fulfil the legal requirement to have criteria in law: The Commission calls upon Member States and EU institutions involved in the further adoption process to work closely and constructively in order to swiftly adopt these texts.

As noted above, the Commission is also asking the relevant agencies to immediately start looking at individual substances, to accelerate the process once the criteria are in force.

The Commission, in close cooperation with EU regulatory agencies and independent scientific committees, as well as Member States and EU institutions, is committed to continuing to ensuring a high level of protection of health and the environment from toxicological risks, and believes that the two measures will represent an important step with respect to endocrine disruptors.

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41 Article 16(4) of Directive 2000/60/EC.

42 Article 8b(2) of Directive 2008/105/EC of the European Parliament and of the Council of 16 December 2008 on environmental quality standards in the field of water policy (OJ L 348, 24.12.2008, p. 84).

43 Article 11(1) of Council Directive 98/83/EC of 3 November 1998 on the quality of water intended for human consumption (OJ L 330, 5.12.1998, p. 32).