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**The European Commission Proposals and  
Legal Requirements Concerning  
the Determination of Scientific Criteria  
to Identify Endocrine Disruptive Properties  
of Active Substances**

Julian Schenten and Martin Führ

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With the co-operation of *Vito Buonsante*

Legal opinion on behalf of



Darmstadt, June 2016

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## List of abbreviations

Art.	Article
BPR	Biocides Products Regulation
CLP	Regulation on Classification, Labelling and Packaging of Substances and Mixtures
COM	Communication (by the European Commission)
EAP	EU Environment Action Programme
EC	European Community
ECJ	European Court of Justice
ECLI	European Case Law Identifier
ED	Substance with endocrine disruptive properties
EFSA	European Food Safety Authority
EGC	General Court (of the European Union)
EU	European Union
GHS	Global Harmonised System of Classification and Labelling of Chemicals
IPCS	International Programme on Chemical Safety (of the WHO)
MRL	Maximum residue level
PPPR	Plant Protection Products Regulation
REACH	Regulation concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals
REFIT	Regulatory Fitness and Performance
SAICM	Strategic Approach to International Chemicals Management
SWD	Staff working document (by the European Commission)
TFEU	Treaty on the Functioning of the EU
WHO	World Health Organization

# 1

## Executive Summary

### Objectives and methods

This paper presents a legal assessment of two draft legislative acts addressing substances with endocrine disruptive properties (ED) published by the European Commission as of 15 June 2016:

- one introducing scientific criteria to identify endocrine disruptive properties of active substances to the Biocidal Product Regulation (BPR) and
- one introducing respective scientific criteria to the Plant Protection Product Regulation (PPPR) and additionally changing the approval mechanism for active substances with endocrine disruptive properties.

The Policy Options with respect to the scientific criteria subject to the European Commission Impact Assessment are analysed as well.

The assessment is based on legal criteria derived from the mandates confided by the BPR and the PPPR to the Commission to propose draft legislation. The legal criteria lead *inter alia* to the questions whether the draft legislation is limited to modifying non-essential elements of the basic legal acts and whether the draft legislation conforms to the normative objectives of that acts.

To this end, the legal requirements pursuant to the BPR and the PPPR as well as pursuant to the General Court judgment in Case T-521/14 with respect to the determination of scientific criteria to identify ED are analysed. The General Court stresses that criteria for the determination of endocrine disrupting properties have to be based strictly on scientific considerations.<sup>1</sup> Thus the consensus statement on the identification of ED agreed upon recently by international experts<sup>2</sup> has to be taken into account.

### Results

*Legal considerations to be taken into account by the European Commission when specifying scientific criteria for the identification of active substances with endocrine disruptive properties*

- The wording, the context and the purpose of the BPR and PPPR approval mechanisms for active substances shows that the scientific criteria to be

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<sup>1</sup> EGC, Judgment of 16 December 2015, Case T-521/14 (Sweden v Commission), ECLI:EU:T:2015:976, para. 71.

<sup>2</sup> "Scientific principles for the identification of endocrine disrupting chemicals – a consensus statement". Outcome of an international expert meeting organized by the German Federal Institute for Risk Assessment (BfR). April 2016, Solecki, Roland/ Kortenkamp, Andreas/ Bergman, Åke/ Chahoud, Ibrahim/ Degen, Gisela H/ Dietrich, Daniel/ Greim, Helmut/ Håkansson, Helen/ Hass, Ulla/ Husoy, Trine/ Jacobs, Miriam/ Jobling, Susan/ Mantovani, Alberto/ Marx-Stoelting, Philip/ Piersma, Aldert/ Slama, Remy/ Stahlmann, Ralf/ van den Berg, Martin/ Zoeller, R. Thomas/ Boobis, Alan R.

specified by the Commission must be based solely on hazard identification, thus excluding exposure-related considerations (section 3.3).

- The BPR provides the same approval mechanism for ED as for substances that meet the CMR classification criteria pursuant to the CLP Regulation. Likewise, the PPPR provides the same mechanism for ED as it does for carcinogens and reprotoxicants pursuant to CLP. From this systematic perspective it can be followed that in order to ensure a high level of protection the co-legislators of the BPR and the PPPR attribute to ED an equivalent level of concern as they attribute to CMR substances (section 3.4).
- The approval mechanisms for active substances set out in the BPR and the PPPR are applicable to substances known to have endocrine disruptive properties and also substances presumed to have such properties. This follows from the normative objectives of the BPR and the PPPR – *inter alia* ensuring a high level of protection while both regulations are “underpinned by the precautionary principle” – and also from a contextual assessment of the approval mechanisms which are expressly applicable to substances “known” to or “presumed” to have CMR properties pursuant to the CLP Regulation (section 3.5).
- Given the BPR and the PPPR are “underpinned by the precautionary principle”, the scientific criteria, too, need to reflect the precautionary principle (sections 3.1 and 4.1.3).

#### *Draft legislative acts specifying scientific criteria (section 4.2)*

The approval mechanisms set out in the BPR and the PPPR are applicable to substances with endocrine disrupting properties that “may cause” adverse effects. This wording refers to substances “known” to have endocrine disrupting properties as well as to substances which are “presumed” in this respect (see above).

The scientific criteria for the determination of endocrine disrupting properties as proposed by the Commission are limiting the scope of the approval mechanisms to substances “known” to have endocrine disruptive properties. As a consequence, the mechanisms do not apply to substances which are “presumed” to have such properties.

This is, however, not in line with the objectives and the systematic context of the BPR and the PPPR as basic legal acts. In addition, by limiting the material scope of the approval mechanisms the criteria exceed the objectives, content and scope of the powers mandated to the Commission by the basic acts. Moreover, by limiting the scope of the approval mechanisms the criteria affect essential elements of the basic acts.

Based on these findings the conclusion can be drawn that the Commission is not legally entitled to use its powers mandated by the BPR and the PPPR to implement the ED criteria as defined by the draft proposals as of June 15, 2016.

*Approval mechanism subject to the PPPR draft legislative act (section 4.3)*

In addition to introducing scientific criteria, the proposed Commission Regulation C(2016) 3751 alters the normative context steering the approval mechanism for active substances with endocrine disruptive properties as set out in Annex II PPPR. In particular, under existing law the approval ban of ED is subject to the condition that *exposure* of humans or non-target organisms is negligible. The draft, in contrast, introduces derogations on the grounds that *risk* is negligible. As a consequence, the exposure-based mechanism in existing law would be replaced by a mechanism based on specific risk assessment which would allow also 'non-negligible' exposure as long as a risk assessment concludes that the identified hazard of the substance in question is sufficiently low.

Refusing approval of ED unless exposure is negligible from a legal perspective has to be seen as an expression of the normative objectives pursuant to the PPPR. In Case T-521/14 the General Court ruled that in adopting the BPR the co-legislators already made a balance between the objective of improving the internal market and the objective of protecting human health, animal health and the environment. This balance must be respected by the Commission and cannot be undermined by issuing delegated acts specifying criteria for endocrine disruptive properties.

The mandates of the BPR and the PPPR to specify criteria are very similar. Hence, this ruling is also applicable with respect to the draft Commission Regulation to amend the PPPR. Basing a regulatory decision on the sole consideration of exposure on the one hand or basing it on risk considerations, thus reflecting hazard and exposure, on the other hand amounts to a change of the regulatory paradigm. Accordingly, the legislative history of the PPPR shows that the co-legislators clearly and deliberately rejected derogation based on specific risk assessment in terms of the draft, and only accepted the concept of 'negligible exposure'. The proposed changes are therefore not in agreement with aims of the basic legal act.

Annex II, Section 3.6.5 PPPR stipulates that the Commission shall present a draft of the measures concerning scientific criteria for the determination of ED properties to be adopted. By proposing amendments to the approval mechanism, the draft exceeds the objective, content and scope of the Commission's mandate in Annex II PPPR. Furthermore, Art. 78(1)(a) PPPR applies to "amendments to the Annexes, taking into account current scientific and technical knowledge". From a scientific point of view, substances with endo-



crine disruptive properties can be subjected to a risk assessment. However, whether to base derogations with respect to the approval ban on the concept of 'eligible exposure' or the concept of 'eligible risk' is a matter of risk management. Risk management, i.e. the reaction to a specific situation of concern is subject to a political decision, though, taking into account the societal perception of a specific risk. Hence, scientific knowledge alone cannot justify amendments of the approval mechanism set out in Annex II PPPR which is a function of risk management. As a consequence, by proposing changes to that mechanism the draft also exceeds the objective, content and scope of the legal basis chosen by the Commission Art. 78(1)(a) PPPR.

Finally, the draft has to be limited to modifying non-essential elements of the basic acts. As already established above, the co-legislators clearly and deliberately opted for a 'negligible exposure' derogation. Moreover, changes from 'negligible exposure' to 'negligible risk' would modify to a large extent the obligations and respective legal consequences imposed by the PPPR. Such changes would therefore alter essential elements of the basic act.

Based on these findings the conclusion can be drawn that the Commission would not be legally entitled to use the regulatory procedure with scrutiny as mandated by the PPPR to implement the draft criteria.

#### *Legal consequence*

The European Parliament and the Council are confided by the basic acts with certain procedural rights to object, based on the findings of the legal assessment, draft measures proposed by the European Commission. Alternatively, the ECJ may annul adopted legislative acts on the grounds of *inter alia* lack of competence (section 5).

#### *Policy Options subject to the Impact Assessment*

Policy Option 1 establishes the baseline scenario in which no policy changes occur. Option 1 therefore clearly breaches the legal obligation of the Commission imposed by the BPR and the PPPR to determine specific criteria for ED. Besides, in the absence of specific criteria provisional criteria would continue to apply. Unless evidence of the provisional criteria providing the same level of protection as do criteria specific to ED is established, Option 1 is not in line with the normative objectives of both the BPR and the PPPR (section 4.1.1).

In Policy Option 2 ED are defined largely in accordance with the respective WHO/ IPCS definition. Option 2 applies to "known" and to "presumed" ED. However, by not providing criteria to identify "presumed" ED as opposed to "known" ED Option 2 does not ensure identification of "presumed" ED. It is therefore not in line with the objectives of the basic acts (c.f. above). As a consequence, Option 2 would alter the material scope of the approval mechanisms set out in the BPR and the BPR. It would thus exceed the objectives,

content and scope of the legal mandates. Therefore the conclusion can be drawn that the Commission would not be legitimated to use its mandates provided for in the PPPR and BPR for implementing the legislative changes aimed at by Option 2 (section 4.1.2).

Option 3 is based on the WHO/ IPCS definition but introduces additional categories referring to the extent to which endocrine disruption mediated adverse effects of a substance can be substantiated by scientific evidence. Option 3 does ensure identification of substances only presumed to have endocrine properties that cause adverse effects. Furthermore, "endocrine active substances" are introduced for which available scientific evidence is particularly scarce. A structured identification of such substances supports the identification of future endocrine disruptive substances. This extension of the scientific criteria is thus in agreement with the precaution-oriented objectives of the basic acts. As a result, the Option 3 criteria are in line with the objectives of the basic legal acts. The identification of "endocrine active substances" under Option 3 would not trigger the exclusion criteria for the approval of active substances. Hence, it cannot be considered that introducing category III does exceed the Commission's mandates. For all these reasons, Option 3 would not affect essential elements of the basic acts. As a result, the conclusion can be drawn that the Commission would be legitimated to use its mandates provided for in the PPPR and BPR for implementing the legislative changes aimed at by Option 3. There are, however, some opportunities that should be considered to increase legal certainty of the criteria set out in Option 3 (section 4.1.3).

Option 4 applies the WHO/ IPCS definition but adds potency as a criterion to determine ED. According to the Commission, introduction of potency aims at prioritising substances of greater concern. It is thus to be expected that a potency cut-off criterion would narrow the scope of the scientific criteria significantly. In particular, the Option 4 criteria most likely would not apply to "presumed" ED. Hence, Option 4 is not in agreement with the normative objectives of the basic legal acts. Besides, it is questionable whether the Option 4 criteria are based on scientific considerations exclusively. In its Case T-521/14 judgment the General Court stressed that specifying the scientific criteria can only be done in an objective manner based on scientific information, regardless of any other considerations, in particular of economic considerations. According to the scientific consensus paper, however, potency is not relevant for the identification of ED. Besides, assessing the wording, context and purpose of Annex II PPPR and Art. 5(3) BPR shows that the criteria have to be based on hazard identification – excluding thus potency which is subject to hazard characterisation considerations. In addition, by not ensuring identification of presumed ED, the Option 4 criteria undermine the functionality of the approval mechanisms specified in the PPPR and the BPR. Hence, in sum, Option 4 would clearly overstep the objectives, content and scope of the powers

mandated to the Commission by the BPR and the PPPR. For similar reasons, Option 4 would alter essential elements of the basic acts. As a result, the conclusion can be drawn that the Commission would not be legitimated to use its mandates provided for in the PPPR and BPR for implementing the legislative changes aimed at by Option 4 (section 4.1.4).

## Background

Regulation (EU) No 528/2012 concerning biocidal products (BPR)<sup>3</sup> and Regulation (EC) No 1107/2009 concerning plant protection products (PPPR)<sup>4</sup> aim to harmonise market conditions for the named products while at the same time ensure a high level of protection of human and animal health and the environment. Both regulations specify approval mechanisms for active substances used in biocidal products or plant protection products respectively. Besides, both regulations provide for specific requirements for active substances with endocrine disruptive properties. To this end, the BPR obliged the European Commission to adopt no later than 13 December 2013 delegated acts specifying scientific criteria for the determination of endocrine disrupting properties. The PPPR obliged the European Commission to present a draft of the scientific criteria by the same date.

In 2014 the Commission initiated an Impact Assessment of various Policy Options with regard to the criteria and beyond.<sup>5</sup>

In July 2014 Sweden brought an action for failure to act against the Commission before the General Court (Case T-521/14). In its 16 December 2015 judgment the Court decided that the Commission has failed to fulfil its obligations under the BPR.<sup>6</sup>

On 15 June 2016 the Commission presented two draft legislative acts, one of which introduces scientific criteria to the BPR<sup>7</sup> and one of which introduces scientific criteria to the PPPR and additionally changes the approval mechanism for active substances with endocrine disruptive properties<sup>8</sup>.

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<sup>3</sup> Regulation (EU) No 528/2012 of 22 May 2012 concerning the making available on the market and use of biocidal products, 2012 OJ L 167/ 1.

<sup>4</sup> Regulation (EC) No 1107/2009 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, 2009 OJ L 309/ 1.

<sup>5</sup> European Commission, Roadmap. Defining criteria for identifying Endocrine Disruptors in the context of the implementation of the Plant Protection Product Regulation and Biocidal Products Regulation, 06/2014.

<sup>6</sup> EGC, Judgment of 16 December 2015, Case T-521/14 (Sweden v Commission), OJ C 48, 8.2.2016, p. 48.

<sup>7</sup> Draft Commission Delegated Regulation for setting out scientific criteria for the determination of endocrine-disrupting properties pursuant to the BPR, C(2016) 3752 projet, available at [http://ec.europa.eu/health/endocrine\\_disruptors/docs/2016\\_bpcriteria\\_en.pdf](http://ec.europa.eu/health/endocrine_disruptors/docs/2016_bpcriteria_en.pdf) (accessed on 16.6.2016).

<sup>8</sup> Draft Commission Regulation for setting out scientific criteria for the determination of endocrine disrupting properties and amending Annex II to the PPPR, C(2016) 3751 projet,

## 2

### Obligation of the Commission to determine scientific criteria

According to Art. 5(3) BPR, “[n]o later than 13 December 2013, the Commission shall adopt delegated acts in accordance with Article 83 [BPR] specifying scientific criteria for the determination of endocrine-disrupting properties”. Annex II, Section 3.6.5 PPPR obliges the Commission to present a draft of the scientific criteria by the same date. On 15 June 2016 the Commission has released draft legislative acts in this respect.

### 2.1

#### Ruling of the General Court

In July 2014 Sweden brought an action for failure to act before the General Court seeking a declaration that, by failing to adopt the acts provided for in the BPR, the Commission had infringed that regulation (Case T-521/14). In its 16 December 2015 judgment the General Court rules that

“the European Commission, by failing to adopt delegated acts to specify scientific criteria for the determination of endocrine-disrupting properties, has failed to fulfil its obligations under the first subparagraph of Article 5(3) [BPR]”.<sup>9</sup>

The Court holds that Art. 5(3) BPR clearly, precisely and unconditionally obliges the Commission to adopt such delegated acts.<sup>10</sup> The existence of scientific criticism regarding draft scientific criteria for the determination of endocrine-disrupting properties presented by the Commission in summer 2013 does not exonerate the Commission from its obligations set out in Article 5(3) BPR.<sup>11</sup>

With a view to its obligations under the BPR and other sectorial legislation, in 2014 the Commission started an Impact Assessment of several Policy Options concerning the scientific criteria for the determination of endocrine disrupting properties.<sup>12</sup> However, in its 16 December 2015 decision the General Court decides that there is no obligation in the BPR to perform an Impact Assessment with regard to the determination of scientific criteria, nor does the Impact Assessment exonerate the Commission from its obligations and timeframes set out in Article 5(3) BPR.<sup>13</sup>

Besides, the court rules that specifying scientific criteria for determining properties disrupting the endocrine system can only be done in an objective man-

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available at [http://ec.europa.eu/health/endocrine\\_disruptors/docs/2016\\_pppcriteria\\_en.pdf](http://ec.europa.eu/health/endocrine_disruptors/docs/2016_pppcriteria_en.pdf) (accessed on 16.6.2016).

<sup>9</sup> EGC, Judgment of 16 December 2015, Case T-521/14 (Sweden v Commission), OJ C 48, 8.2.2016, p. 48.

<sup>10</sup> EGC, Judgment in Case T-521/14 (fn. 1), para. 58.

<sup>11</sup> EGC, Judgment in Case T-521/14 (fn. 1), para. 73.

<sup>12</sup> European Commission, Roadmap (fn. 5).

<sup>13</sup> EGC, Judgment in Case T-521/14 (fn. 1), para. 74.

ner based on scientific information, regardless of any other considerations, in particular of economic considerations.<sup>14</sup> Rather, in adopting the BPR the legislator already made a balance between the objective of improving the internal market and the objective of protecting human health, animal health and the environment. This balance must be respected by the Commission and cannot be undermined.<sup>15</sup>

## 2.2

### Legal evaluation criteria applicable to the draft legislative acts

Art. 5(3) BPR stipulates that „the Commission shall adopt delegated acts in accordance with Article 83 specifying scientific criteria for the determination of endocrine-disrupting properties“. Such delegated acts concern non-essential elements of the BPR and are subject to the requirements of Art. 290 TFEU.<sup>16</sup>

Besides, Annex II, Section 3.6.5 PPPR stipulates that the Commission shall present a draft of the measures concerning scientific criteria for the determination of endocrine disrupting properties to be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 79(4) PPPR. According to Recital 9 of the draft issued by the Commission, in order “to reflect current scientific and technical knowledge in accordance with Article 78(1)(a) of Regulation (EC) No 1107/2009, points 3.6.5 and 3.8.2 of Annex II to Regulation (EC) No 1107/2009 should be amended.”<sup>17</sup> Article 78 PPPR applies to “measures designed to amend non-essential elements of this Regulation, inter alia, by supplementing it“. In addition, such measures “shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 79(4)“.<sup>18</sup> This procedure laid down in Art. 5a Council Decision 1999/468/EC<sup>19</sup> also reflects the normative content of Art. 290 TFEU.<sup>20</sup>

Consequently, delegated acts in terms of Art. 83 BPR as well as amendments and implementing measures in terms of Art. 78 PPPR are subject to the re-

<sup>14</sup> EGC, Judgment in Case T-521/14 (fn. 1), para. 71.

<sup>15</sup> EGC, Judgment in Case T-521/14 (fn. 1), para. 72; c.f. European Parliament resolution of 8 June 2016 on endocrine disruptors: state of play following the judgment of the General Court of the European Union of 16 December 2015 (2016/2747(RSP)), para J.

<sup>16</sup> C.f. Recital 72 BPR.

<sup>17</sup> Recital 9 of draft C(2016) 3751 projet.

<sup>18</sup> C.f. Recital 55 PPPR.

<sup>19</sup> Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission, 1999 OJ L 184/ 23, amended by Council Decision 2006/512/EC of 17 July 2006, 2006 OJ L 200/ 11, repealed by Regulation (EU) No 182/2011 of 16.2.2011, 2011OJ L 55/ 13. However, according to Art. 12 Regulation 182/2011 the “effects of Article 5a of Decision 1999/468/EC shall be maintained for the purposes of existing basic acts making reference thereto.”

<sup>20</sup> C.f. Recital 7a Council Decision 1999/468/EC.

quirements of Art. 290 TFEU.<sup>21</sup> Art. 290(1) TFEU provides that a “legislative act may delegate to the Commission the power to adopt non-legislative acts of general application to supplement or amend certain non-essential elements of the legislative act”. The provision continues that the “objectives, content, scope and duration of the delegation of power shall be explicitly defined in the legislative acts”.

Hence, as the (basic) legislative act presupposes the objectives of relevant delegated acts, such delegated acts may not pursue objectives not in line to those laid down the basic act.

Likewise, content and scope of the delegated act are determined by the basic act.

Guidance as to the determination whether legislative changes are essential or non-essential in relation to the basic act is given by a Legal Service opinion on the application of Article 290,<sup>22</sup> according to which the following aspects, in particular, need to be considered:

According to the Court of Justice, “the classification of ‘essential’ ‘must be reserved for provisions which are intended to give concrete shape to the fundamental guidelines of Community policy’. Accordingly, the modification of the material, geographical or temporal scope of a basic act constitutes an essential element of that act, which the legislature cannot in principle confer on the Commission under either Article 290 or Article 291 TFEU. No exception can be made unless the powers conferred on the Commission are so strictly circumscribed that its margin of discretion is either non-existent or extremely limited.

Likewise, the obligations imposed under an act and the consequences of any violation are essential elements which the basic act should define, at least with respect to their general nature.

When the Commission is granted the power to update the basic act, without any margin of discretion, in the light of scientific data which may become available over time, unless those scientific data are in themselves crucial to the choices made by the legislature in the basic act, it may be considered that such power does not affect the essential elements of the basic act.”<sup>23</sup>

As a result, for the evaluation of whether and to what extent the Commission is legally entitled to implement the requirements set out in the draft legislative

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<sup>21</sup> Likewise, the Policy Options subject to the Commission Impact Assessment were intended to be implemented by simplified legislative procedures, c.f. SWD(2016) 211 fin, 15.6.2016, p.16: “In this impact assessment the potential impacts of secondary legislation (implementing and delegated acts), required by Regulations (EC) No 1107/2009 and Regulation (EU) No 528/2012, are evaluated” (*footnotes omitted*). Therefore evaluation of these Options, too, is measured by the requirements pursuant to Art. 290 TFEU.

<sup>22</sup> Council of the EU, Opinion of the Legal Service, Application of Articles 290 (Delegated Acts) and 291 (Implementing Acts) TFEU, 8970/11, LIMITE, 11.4.2011.

<sup>23</sup> *Ibid*, para 7 et seq. (*emphasis added, footnotes omitted*).

acts of 15 June 2016<sup>24</sup> the following legal criteria has to be taken into account:

Proposed measures have to cumulatively be

- in line with the objectives of the basic act,
- in line with the objectives, content, scope and duration of the delegation of power explicitly defined in the basic act, i.e., Annex II, Sections 3.6.5 and 3.8.2 in conjunction with Art. 78(1)(a) PPPR and Art. 5(3) in conjunction with Art. 83 BPR, respectively, and
- limited to modifying non-essential elements of the basic act, whereas the respective evaluation is subject to an overall view of all relevant aspects (no violation of fundamental guidelines and obligations imposed, margins of discretion etc.).

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<sup>24</sup> As well as in the Impact Assessment Policy Options, c.f. fn. 21.

### 3

#### Legal requirements laid down in the BPR and the PPPR

This section establishes the normative objectives with respect to active substances with endocrine disruptive properties (ED) as well as their context in the BPR and the PPPR. Subsequently the legal requirements that scientific criteria to identify ED have to comply with are outlined.

#### 3.1

##### Purposes of the BPR and the PPPR

According to Art. 114(1) TFEU, a legal basis for both the BPR and the PPPR, Commission proposals with the aim of establishing or ensuring the functioning of the internal market “concerning health, safety, environmental protection and consumer protection, will take as a base a high level of protection taking account in particular of any new development based on scientific facts.”<sup>25</sup>

Accordingly, as stipulated by Art. 1(1) BPR, the purpose of this Regulation is “to improve the functioning of the internal market through the harmonisation of the rules on the making available on the market and the use of biocidal products, whilst ensuring a high level of protection of both human and animal health and the environment.” Similarly, the PPPR aims, pursuant to Art. 1(3) PPPR, “to ensure a high level of protection of both human and animal health and the environment and to improve the functioning of the internal market through the harmonisation of the rules on the placing on the market of plant protection products, while improving agricultural production.”

In both regulations particular attention shall be paid to the protection of vulnerable groups.<sup>26</sup> Besides, both regulations are “underpinned by the precautionary principle”,<sup>27</sup> a “fundamental principle of environmental protection”<sup>28</sup> referred to in Art. 191(2) TFEU on EU environmental policy. In this respect, Art. 1(4) PPPR also provides for a safeguard clause according to which

“Member States shall not be prevented from applying the precautionary principle where there is scientific uncertainty as to the risks with regard to human or animal health or the environment posed by the plant protection products to be authorised in their territory.”

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<sup>25</sup> Consolidated Version of the Treaty of the Functioning of the EU, 2012 OJ C 326/ 47.

<sup>26</sup> Recitals 8 and 24 PPPR, Art. 1(1), Recital 3 BPR.

<sup>27</sup> Art. 1(4) and Recital 8 PPPR, Art. 1(1) and Recital 3 BPR.

<sup>28</sup> ECJ, Opinion 2/00, ECLI:EU:C:2001:664, para. 29. For the normative content of this principle see already ECJ, Judgment of 5 May 1998, Case C-180/96, ECLI:EU:C:1998:192, para. 99 (UK and Northern Ireland v Commission): “Where there is uncertainty as to the existence or extent of risks to human health, the institutions may take protective measures without having to wait until the reality and seriousness of those risks become fully apparent.”



At the same time, EU policies call for addressing concerns over ED. This is *inter alia* reflected in the seventh general EU Environment Action Programme to 2020 (7<sup>th</sup> EAP)<sup>29</sup> which provides a contemporary interpretation of the environmental objectives laid down in EU treaty law.<sup>30</sup> There are uncertainties surrounding the human health and environmental implications of ED.<sup>31</sup> As a consequence, to address “concerns related to endocrine disruptors in all relevant Union legislation”, the Union will, in particular “develop harmonised hazard-based criteria for the identification of endocrine disruptors”.<sup>32</sup>

Furthermore, normative objectives of EU primary law and of the PPPR and the BPR have to be considered in their international law context.<sup>33</sup> In the 2002 Implementation Plan of the World Summit on Sustainable Development the United Nations declared to achieve “by 2020, that chemicals are used and produced in ways that lead to the minimization of significant adverse effects on human health and the environment”.<sup>34</sup> This goal was affirmed by the international community again at the ‘Rio+20’ World Summit in 2012<sup>35</sup> as well as in the 25 September 2015 ‘2030 Agenda’ Resolution.<sup>36</sup> In order to achieve this ambition, in 2006 under the title ‘Strategic Approach to International Chemicals Management’ (SAICM) an international policy agenda was adopted.<sup>37</sup> ED are among the SAICM ‘Emerging Policy Issues and Other Issues of Concern’, calling for appropriate action.<sup>38</sup> According to Recital 71 BPR the Regulation “should contribute to the fulfilment” of SAICM.

## 3.2

### Approval procedures for ED and further regulatory context

The BPR and the PPPR establish approval procedures for active substances, including those with endocrine disruptive properties, intended for use as or in

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<sup>29</sup> Annex to Decision No 1386/2013/EU, 2013 OJ L 354/ 171.

<sup>30</sup> Calliess, Christian, Art. 191 AEUV, in Calliess, Cristian/ Ruffert, Matthias 2011: EUV/AEUV, Das Verfassungsrecht der Europäischen Union mit Europäischer Grundrechtecharta, Munich, para. 8.

<sup>31</sup> Para. 50, 71(3) Annex to Decision No 1386/2013/EU.

<sup>32</sup> Para. 50 Annex to Decision No 1386/2013/EU.

<sup>33</sup> Recital 71 BPR; c.f. Art. 216(1) and (2) TFEU; Art. 3(5) Consolidated Version of the Treaty on European Union, 2012 OJ C 326/ 13.

<sup>34</sup> Para. 23 of Johannesburg Declaration on Sustainable Development and Plan of Implementation of the World Summit on Sustainable Development, 26 August - 4 September 2002, South Africa.

<sup>35</sup> Resolution ‘The Future we want’, UN Doc A/Conf.216/L.1 (2012), para. 213

<sup>36</sup> C.f. target 12.4 at UN General Assembly, Transforming our world: the 2030 Agenda for Sustainable Development, Resolution adopted by the General Assembly, 25.9.2015, A/70/L.1.

<sup>37</sup> See Dubai Declaration on International Chemicals Management.

<sup>38</sup> See Report of the International Conference on Chemicals Management on the work of its third session, SAICM/ICCM.3/24, Annex, Resolution III/2 F: Endocrine-disrupting chemicals; c.f.

[http://www.saicm.org/index.php?Option=com\\_content&view=article&id=523&Itemid=710](http://www.saicm.org/index.php?Option=com_content&view=article&id=523&Itemid=710) (accessed 31.5.2016).

biocidal products, or plant protection products respectively. Moreover, both regulations provide criteria that exclude active substance from approval unless certain exemptions apply.

However, as the overview will show, substances with endocrine disrupting properties are not *per se* excluded from approval. Rather, exclusion is finally only effective if, in the case of PPPR, exposure is not negligible, and, in the case of the BPR, risk is not negligible and other exemptions (e.g. socio-economic considerations) do not apply.

### 3.2.1

#### Biocides Products Regulation – BPR

Art. 5 BPR lists the properties of substances that “shall not” be approved as active substances. Art. 5(1)(d) BPR stipulates that active substances which are identified in accordance with Art. 57(f) and 59(1) of the REACH Regulation<sup>39</sup> as having endocrine disrupting properties or which are, based on BPR-specific criteria to be discussed below (c.f. section 4.1.1), “considered as having endocrine-disrupting properties that may cause adverse effects in humans” shall not be approved. Recital 12 BPR makes clear that, “[w]ith a view to achieving a high level of protection”, the exclusion criteria is linked to the “hazard profiles” of active substances.

However, based on *inter alia* risk-related considerations active substances fulfilling the exclusion criteria might still be approved if at least one of the following conditions set out in Art. 5(2) BPR are met:

- a) the risk to humans, animals or the environment from exposure to the active substance in a biocidal product is negligible,
- b) it is shown by evidence that the active substance is essential to prevent or control a serious danger to human health, animal health or the environment; or
- c) not approving the active substance would have a disproportionate negative impact on society when compared with the risk to human health, animal health or the environment.

An identical exclusion-derogation mechanism is provided for active substances classified in accordance with CLP<sup>40</sup> as, or which meet the criteria to be classified as, carcinogen category 1A or 1B, mutagen category 1A or 1B and toxic

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<sup>39</sup> Regulation (EC) No 1907/2006 of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC, 2006 OJ L 396/ 1.

<sup>40</sup> Regulation (EC) No 1272/2008 of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, 2008 OJ L 353/ 1.

for reproduction category 1A or 1B.<sup>41</sup> Active substances which meet the criteria for being PBT or vPvB according to Annex XIII REACH are subject to same mechanism as well.<sup>42</sup>

Furthermore, according to Art. 19(4)(d) BPR a “biocidal product shall not be authorised for making available on the market for use by the general public where it has endocrine-disrupting properties”.<sup>43</sup>

All these rules are complemented by information requirements for industry in the application procedure for approval of an active substance in Annex II BPR<sup>44</sup> as well as by common evaluation principles for competent authorities concerning biocidal products in Annex VI BPR.

### **3.2.2**

#### **Plant Protection Products Regulation – PPPR**

Active substances for use in plant protection products have to be approved in accordance with Art. 4 and Annex II PPPR. After Annex II, Section 3.6.5 PPPR an active substance is not eligible for approval if it is “considered to have endocrine disrupting properties that may cause adverse effect in humans”. Annex II, Section 3.8.2 PPPR excludes active substances from approval that are “considered to have endocrine disrupting properties that may cause adverse effects on non-target organisms”.

However, this exclusion may be subject to exposure-based exceptions. In view of Annex II, Section 3.6.5 PPPR an active substance considered to have endocrine disrupting properties that may cause adverse effect in humans might be approved if “the exposure of humans to that active substance [...] in a plant protection product, under realistic proposed conditions of use, is negligible”, while providing further criteria to render exposure negligible (c.f. section 4.3). Likewise, pursuant to Annex II, Section 3.8.2 PPPR substances considered to have endocrine disrupting properties that may cause adverse effects on non-target organisms might be approved if “the exposure of non-target organisms to that active substance in a plant protection product under realistic proposed conditions of use is negligible”.

An identical exclusion-derogation-mechanism applies to active substances that are or have to be classified in accordance with CLP as carcinogen category 1A or 1B or as toxic for reproduction category 1A or 1B.<sup>45</sup>

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<sup>41</sup> Art. 5(1)(a), (b) and (c) BPR.

<sup>42</sup> Art. 5(1)(e) BPR

<sup>43</sup> C.f. Recital 39 BPR.

<sup>44</sup> In particular Annex II, Sections 8.13.3 and 9.10 BPR.

<sup>45</sup> See Annex II, Sections 3.6.3 und 3.6.4 PPPR. In contrast, active substances that are or have to be classified as mutagen category 1A or 1B are banned without derogations, Annex II, Section 3.6.2 PPPR.

The exposure-based derogation provided for in the PPPR is an expression of the challenges to assess and control the risks posed by plant protection products. In the Communication accompanying the draft legislative acts of 15 June 2016 the Commission uses imagery from the animal kingdom to explain the difference between hazard, exposure and risk: “a lion is intrinsically a hazard, but a lion safely constrained in a zoo is not a risk, since there is no exposure.”<sup>46</sup> However, while a cage might be an effective management measure to control the risk posed by a lion, there is no ‘cage’ for containing the risks posed by plant protection products. Rather, such products are by design and function intended to be at least to some extent ‘openly’ applied to protect e.g. crops in the agricultural sector but also in forestry or in home gardens, thus potentially effecting the environment as well as humans and other organisms living therein.<sup>47</sup> Against this background, the co-legislators of the PPPR opted for an exposure-based derogation concept as means to ensure there is no risk.

Commission Regulation (EU) No 283/2013<sup>48</sup> sets out the data to be provided by the applicant for the approval of an active substance, including several endpoints with regard to endocrine disruptive properties.<sup>49</sup>

Derogating from Art. 4 PPPR, certain “basic substances” for which evaluations under EU legislation other than the PPPR provide evidence for safety may be approved subject to the requirements of Art. 23 PPPR. However, according to Art. 23(d) PPPR an active substance with the “inherent capacity to cause endocrine disrupting” may not be approved as basic substance.<sup>50</sup>

### 3.3

#### **Hazard identification as exclusive reference-point of the criteria**

The BPR and the PPPR mandate the commission to establish scientific criteria for the identification of endocrine disruptive properties of active substances (see section 2). There have been deliberations to add potency as a criterion to determine ED (section 4.1.4). Potency is related to a substance’s dose (concentration) – response function the identification of which is the second of four

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<sup>46</sup> COM(2016) 350 fin, 15.6.2016, p. 6.

<sup>47</sup> C.f. [http://ec.europa.eu/food/plant/pesticides/index\\_en.htm](http://ec.europa.eu/food/plant/pesticides/index_en.htm) (accessed 24.6.2016).

<sup>48</sup> Commission Regulation (EU) No 283/2013 of 1 March 2013 setting out the data requirements for active substances, in accordance with Regulation (EC) No 1107/2009, 2013 OJ L 93/ 1; c.f. Art. 8(4) PPPR.

<sup>49</sup> In particular Sections 5.8.3, 8.1.5, 8.2.2.2 and 8.2.3 Regulation 283/2013.

<sup>50</sup> C.f. Art. 4(7) PPPR concerning possible derogations from Art. 4(1) PPPR when on the basis of documented evidence included in the application an active substance is necessary to control a serious danger to plant health which cannot be contained by other available means.

steps in the internationally established<sup>51</sup> standard procedure for risk assessment:

1. hazard identification,
2. hazard characterisation (also: dose–response assessment),
3. exposure assessment, and
4. risk characterisation.<sup>52</sup>

However, as the present section will show, the scientific criteria for ED are to be based exclusively on hazard identification considerations (step 1 in risk assessment process).

Annex VI BPR defines hazard identification as the “identification of the adverse effects which a biocidal product has an inherent capacity to cause” and dose (concentration) — response (effect) assessment as the “estimate of the relationship between the dose, or level of exposure, of an active substance or substance of concern in a biocidal product and the incidence and severity of an effect”.<sup>53</sup> The human hazard identification procedure set out in Annex VI BPR shall address the properties and potential adverse effects of active substances present in a biocidal product including, among other endpoints, mutagenicity, carcinogenicity, reproductive toxicity as well as the disruption of the endocrine system.<sup>54</sup> Dose - response considerations belong to the second step in risk assessment.<sup>55</sup>

In Terms of Annex VI BPR the determination of an active substance as an ED is thus a hazard identification procedure and does not include a dose (concentration) — response (effect) assessment. This notion is also in line with the scientific consensus document.<sup>56</sup>

With respect to the approval procedure of active substances, Recital 12 BPR describes the goal and function of the exclusion criteria in Art. 5(1) BPR:

“With a view to achieving a high level of protection of human health, animal health and the environment, active substances with the worst hazard profiles should not be approved for use in biocidal products except in specific situations.”

To this end, Art. 5(1) BPR lists several active substances with an inherent capacity to cause adverse effects. With respect to active substances other than ED Art. 5(1) BPR particularly refers to hazard classifications consistent with the

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<sup>51</sup> WHO/ IPCS 2004. IPCS Harmonization Project – IPCS Risk Assessment Terminology, p. 14, see *ibid.* for definitions.

<sup>52</sup> C.f. v. Leeuwen, C.J. 2007: General Introduction, in: v. Leeuwen, C.J./ Vermeire, T. G. (eds.), Risk Assessment of Chemicals, 2. ed., Dordrecht., p. 16.

<sup>53</sup> Introducing remarks on “Terms and Definitions” in Annex VI BPR.

<sup>54</sup> Annex VI, Para. 25 in conjunction with Para. 22 and 23 BPR.

<sup>55</sup> Annex VI, Para. 26 et seq. BPR.

<sup>56</sup> Soleccki et al. (fn. 2), para 20.

CLP Regulation, namely CMR substances classified as carcinogen, mutagen or toxic for reproduction (each in categories 1A and 1B). According to CLP, dose or concentration is not relevant for these classifications.<sup>57</sup> Nor is dose or concentration relevant for the CLP classifications named by Art. 5(3) BPR that shall be applied to identify ED pending the adoption of specific ED criteria.<sup>58</sup>

Moreover, a contextual view of the entire regulatory mechanism as laid down in Art. 5 BPR shows that Para. 1 provides for exclusion criteria based on hazard identification while Para. 2 stipulates derogations from the exclusions in particular based on risk, thus also considering exposure and dose- or concentration-related information. Hence, in terms of the four steps in risk assessment, Art. 5(1) BPR is an operationalisation of hazard identification while the three other steps are taken account of in Art. 5(2) BPR.

Consequently, to make the scientific criteria fit for purpose with respect to the approval mechanism set out in Art. 5 and Annex VI BPR the criteria have to address the properties and potential adverse effects related to endocrine disruption and exclude dose - response considerations.

The same applies with a view to the structurally related mechanisms of the PPPR.

It follows that the criterion of potency cannot be part of the scientific ED criteria to be determined by the Commission. As put by the authors of the scientific consensus: "potency is not relevant for identification of a compound as an endocrine disrupter", but is an important factor for consideration during the characterisation of the hazards of ED<sup>59</sup> and thus to be considered at a later point in risk assessment.

Basing the scientific criteria solely on hazard identification and thus aligning the criteria with the – globally harmonised<sup>60</sup> – classification scheme according to CLP would moreover contribute to the coherence of chemicals legislation in the EU and beyond. It would therefore also contribute to the objectives of the ongoing Regulatory Fitness and Performance (REFIT) evaluation of the most relevant chemicals legislation, including CLP, BPR and PPPR, which strives to

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<sup>57</sup> See Sections 3.5.2, 3.6.2 and 3.7.2 of Annex 1 CLP. C.f. the general principles for classification Annex 1 CLP, in particular Section 1.1.1.5: "For the purpose of classification for health hazards (Part 3) route of exposure, mechanistic information and metabolism studies are pertinent to determining the relevance of an effect in humans. When such information, as far as there is reassurance about the robustness and quality of the data, raises doubt about relevance in humans, a lower classification may be warranted. When there is scientific evidence that the mechanism or mode of action is not relevant to humans, the substance or mixture should not be classified."

<sup>58</sup> See the references in fn. 57 for CLP-classification criteria as carcinogen category 2 and toxic for reproduction category 2.

<sup>59</sup> Solecki et al. (fn. 2), para 22.

<sup>60</sup> C.f. United Nations 2013: Globally Harmonised System of Classification and Labelling of Chemicals (GHS), 5. revised edition, New York, Geneva.

identify inconsistencies in various pieces of legislation in order to establish, if appropriate, regulatory coherence.<sup>61</sup>

Not least it should be noted that potency as a criterion in the identification of ED would in particular reduce economic burden on industry and authorities as it would clearly limit the number of substances subject to ED-specific requirements. However, as declared by the General Court, specifying scientific criteria for determining properties disrupting the endocrine system can only be done in an objective manner based on scientific information, regardless of any other considerations, in particular of economic considerations.<sup>62</sup>

### 3.4

#### Assumption of equivalent level of concern

Art. 5(1) BPR provides the same regulatory mechanism for ED (lit d.) as it does for certain CMR classified or classifiable according to CLP (lit. a) – c), see section 3.2.1). Likewise, Annex II PPPR provides the same mechanisms for ED as it does for certain carcinogens and reprotoxicants classified or classifiable according to CLP (section 3.2.2). From this systematic perspective it can be followed that in order to ensure a high level of protection the co-legislators attribute to ED an equivalent level of concern as they attribute to CMR substances.

This conclusion is further corroborated by the fact that the BPR excludes from approval both ED that are identified through the scientific criteria and also those determined in accordance with Art. 57(f) and 59(1) REACH on the identification of substances of very high concern. Substances that are identified on the legal basis of Art. 57(f) REACH are considered of equivalent level of concern compared to CMR substances.<sup>63</sup>

### 3.5

#### Relevance of “may cause” criterion for the level of scientific evidence

ED effects are a fairly new area of toxicology. This is the reason why in the first place the EU co-legislators were not able to include scientific criteria during the ordinary decision making processes. Against this background the question has to be answered which level of scientific evidence is required to

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<sup>61</sup> European Commission, Evaluation and Fitness Check Roadmap. Fitness check on the most relevant chemicals legislation (excluding REACH), as well as related aspects of legislation applied to downstream industries, 18.5.2016.

<sup>62</sup> EGC, Judgment in Case T-521/14 (fn. 1), para. 71.

<sup>63</sup> Art. 57(f) REACH refers to “substances — such as those having endocrine disrupting properties [...] — for which there is scientific evidence of probable serious effects to human health or the environment which give rise to an equivalent level of concern to those of other substances listed in points (a) to (e) [concerning inter alia CMR substances] and which are identified on a case-by-case basis in accordance with the procedure set out in Article 59”.

determine a substance as ED for the purpose of the legal instruments set out in the BPR and the PPPR.

The Art. 5(1)(d) BPR exclusion criteria for active substances are relevant for substances with “endocrine disrupting properties that may cause adverse effects in humans”. Annex II PPPR, too, refers to endocrine disrupting properties that may cause adverse effects but in this respect differentiates adverse effects in humans (Annex II, Section 3.6.5 PPPR) and adverse effects on non-target organisms (Annex II, Section 3.8.2 PPPR).

The regulations do not explain which conditions must be met by an ED to “may cause adverse effects”. It is not clear whether this wording applies only to those ED already “known” to cause adverse effects or if the “may cause” criterion also covers ED which, for the time being, are only “presumed” to cause adverse effects.

Thus the “may cause” wording has to be analysed, first, in the light of the normative objectives of the regulations which not only strive to ensure a high level of protection but are also underpinned by the precautionary principle. The precautionary principle recognizes the relevance of risk situations subject to scientific uncertainty (section 3.1) and thus also requires giving attention to, at the least,<sup>64</sup> ED only presumed to cause adverse effects.

Second, relevance of ED presumed to cause adverse effects also follows from a contextual interpretation of Art. 5 BPR and Annex II PPPR. As seen before, for the purpose of the approval mechanisms laid down in these provisions, active substances with ED properties and certain CMR substances are codified by the co-legislators as having an equivalent level of concern (section 3.4). In this respect, the mechanism set out in Annex II PPPR applies to active substances classified in accordance with CLP as, or which meet the criteria to be classified as, carcinogen category 1A or 1B or as toxic for reproduction category 1A or 1B. Substances with the same properties and additionally substances classified or classifiable as mutagen category 1A or 1B are subject to the procedure specified by Art. 5 BPR. Classifications in accordance with CLP may be subdivided into several categories, whereas

- category 1A addresses substances known to have the specific adverse effect and classification is largely based on human data and
- category 1B addresses substances presumed to have the specific adverse effect and classification is largely based on animal data.<sup>65</sup>

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<sup>64</sup> There are also notions of the precautionary principle which require attention to ED only suspected of causing adverse effects.

<sup>65</sup> See Annex I, Table 3.5.1, 3.6.1 and 3.7.1a CLP. Moreover, category 2 classifications may be distinguished which address substances suspected to have the specific inherent toxicity.



Hence, the mechanisms laid down in Art. 5 BPR and Annex II PPPR are applicable to CMR substances which are known and also to CMR substances which are presumed to have the specific adverse effect.

At the same time, for the purposes of Art. 5 BPR and Annex II PPPR CMR substances are attributed an equivalent level of concern as is attributed to ED. The approval procedures foreseen by the co-legislators are consequently addressing not only ED which are known but also ED which are presumed to cause adverse effects.

In order to determine the importance of only presumed ED with respect to the approval mechanism laid down in the BPR and the PPPR the relation of category 1A and category 1B CMR substances in terms of the number of substances classified accordingly has to be considered. In this respect, of all category 1 carcinogens listed on Annex VI CLP on harmonised classification and labelling of hazardous substances about 75 % are category 1B.<sup>66</sup> Likewise, about 75 % of all listed category 1 reprotoxicants belong to category 1B.<sup>67</sup> With respect to mutagenic substances all (100%) category 1 representatives listed on Annex VI belong to category 1B.<sup>68</sup> These numbers elucidate the importance the co-legislators ascribed to substances only presumed to have CMR properties. In most cases, based on the available scientific evidence it is not possible to assign category 1A classifications. As a consequence, to ensure a high level of protection the co-legislators opted to subject the quantitatively much more relevant category 1B classifications to the approval mechanisms of the BPR and PPPR. Likewise, there are assumedly only relatively few substances for which available scientific evidence allows identification as a “known” ED. As a consequence, given the rationale with respect to CMR, in order to make the BPR and PPPR approval mechanisms fit for their purposes they have to be applicable to “presumed” ED, too.<sup>69</sup>

As a result, the legal texts of the BPR and PPPR require identification of substances with endocrine properties known and presumed to cause adverse effects.

### **3.6** **Relevance of other ED categories**

According to Art.19(4)(d) BPR a biocidal product shall not be authorised for making available on the market for use by the general public where it has endocrine-disrupting properties – without mentioning that this product “may

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<sup>66</sup> Annex VI, Table 3.1 CLP.

<sup>67</sup> *Ibid.*

<sup>68</sup> *Ibid.*

<sup>69</sup> Third, relevance of ED presumed to cause adverse effects is also reflected by the data requirements for active substances in accordance with the PPPR which often refer to “potential” endocrine disruptors, c.f. 8.1.5, 8.2.2.2, 8.2.3 of Commission Regulation (EU) No 283/2013.

cause adverse effects". Similarly, according to Art. 23(d) PPPR active substances with the "inherent capacity to cause endocrine disrupting" are barred from the simplified approval procedure for basic substances, without reference made to any adverse effects.

Against this background the question arises, whether the different wordings of Art. 5(1)(d) BPR, Annex II PPPR, referring to the "may cause" criterion, on the one hand and Art. 19(4)(d) BPR, Art. 23(d) PPPR on the other indicate different requirements as to the knowledge of adverse effects caused by an ED:

- From the wording of Art. 19(4)(d) BPR, Art. 23(d) PPPR one could conclude that these provisions are applicable to so-called endocrine active substances, defined e.g. by EFSA as "any chemical that can interact directly or indirectly with the endocrine system, and subsequently result in an effect on the endocrine system, target organs and tissues", but without necessarily causing adverse effects.<sup>70</sup>
- However, these provisions could also be based on the rationale of the generic WHO/ IPCS definition for ED according to which "endocrine disruption" already implies to some extent adverse effects.<sup>71</sup> Hence, it is not clear whether the different wordings indicate different requirements.

As a result it has to be assumed that the legal requirements of Art. 19(4)(d) BPR, Art. 23(d) PPPR apply to known and presumed ED as do the requirements of Art. 5(1)(d) BPR, and of Annex II PPPR.

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<sup>70</sup> EFSA Scientific Committee, Scientific Opinion on the hazard assessment of endocrine disruptors, EFSA Journal 2013;11(3):3132, p. 11.

<sup>71</sup> C.f. WHO/ IPCS. 2002. Global assessment of the state-of-the-science of endocrine disruptors. WHO/PCS/EDC/02.2, [http://www.who.int/ipcs/publications/new\\_issues/endocrine\\_disruptors/en](http://www.who.int/ipcs/publications/new_issues/endocrine_disruptors/en) (accessed 16.6.2016).

## 4

### Legal assessment of the Commission documents

This section evaluates the European Commission draft legislative acts of 15 June 2016. In addition the Policy Options subject to the Impact Assessment are analysed. To this end, the legal evaluation criteria established in section 2.2 is applied while taking into account the legal requirements in section 3.

#### 4.1

##### Options subject to the Impact Assessment

The Policy Options considered by the Commission Impact Assessment address two different aspects of which aspect (I) "EU criteria to identify EDs"<sup>72</sup> is addressed by this section.<sup>73</sup>

##### 4.1.1

###### Policy Option 1: no legal changes

European Commission Policy Option 1 establishes the baseline scenario in which no policy changes occur. This means a continuation of the status quo without scientific criteria for endocrine disruptive properties being adopted. Accordingly, as regards Option 1 the legal evaluation criteria established in section 2.2 do not apply.

However, in view of the General Court ruling in Case T-521/14 not to adopt scientific criteria for the determination of ED would clearly infringe the obligations arising from the BPR. Besides, this ruling is also applicable to the similar obligations arising from the PPPR.

Moreover, pending the adoption of scientific criteria to determine endocrine disruptive properties of active substances Art. 5(3) BPR and Annex II, Section 3.6.5 PPPR stipulate that

- active substances that are classified in accordance with the CLP Regulation as, or meet the criteria to be classified as, carcinogen category 2 and toxic for reproduction category 2, shall be considered as having endocrine-disrupting properties; and
- substances such as those that are classified in accordance with the CLP Regulation as, or that meet the criteria to be classified as, toxic for repro-

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<sup>72</sup> C.f. European Commission, Roadmap (fn. 5), p. 4-6; SWD(2016) 211 fin, 15.6.2016, p. 19 ff.

<sup>73</sup> Aspect (II) Options addressed by the Impact Assessment do not relate directly to the criteria but to the approval mechanisms for active substances with endocrine disruptive properties, c.f. European Commission, Roadmap (fn. 5), p. 6. Section 4.3 assesses the respective amendments to the PPPR as proposed by the Commission.

duction category 2 and that have toxic effects on the endocrine organs, may be considered as having endocrine-disrupting properties.

In the absence of specific criteria the interim criteria would continue to apply. In this respect, however, the Court points out that from the provisional character of the interim criteria one can conclude that these are not considered to be able to ensure a sufficiently high level of protection to meet the objectives of Art. 5(3) BPR.<sup>74</sup> Moreover, there is no scientific justification for the interim criteria which considers certain carcinogens and reprotoxicants as having endocrine disrupting properties.<sup>75</sup>

As a result, Option 1 clearly breaches the legal obligation of the Commission imposed by the BPR and the PPPR to determine specific criteria for ED. Besides, unless evidence of the provisional criteria providing the same level of protection as do criteria specific to ED is established, Option 1 is not in line with the normative objectives of both the BPR and the PPPR.

#### **4.1.2**

##### **Policy Option 2: introduction of criteria for known and presumed ED**

In Option 2 endocrine disruptive substances are defined largely in accordance with the respective WHO/ IPCS definition<sup>76</sup> which is, according to the Commission, supported by a “general consensus”.<sup>77</sup> The criteria refer to active substances “known or presumed to have caused endocrine-mediated adverse effects” or “where there is evidence from experimental studies [...] to provide a strong presumption that the substance has the capacity to cause” these effects. Besides, Option 2 provides criteria for the determination of adverse effects and specifies the identification process.<sup>78</sup>

The Option 2 criteria link the determination of ED solely to hazard identification. Furthermore, according to the wording of point (a)(i) the criteria provide for the determination of active substances known and presumed to have caused the relevant adverse effects. However, the criteria do not specify the difference between these two categories. In particular, the criteria do not clearly stipulate that the requirements as to the establishment of scientific evi-

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<sup>74</sup> EGC, Judgment in Case T-521/14 (fn. 1), para. 77.

<sup>75</sup> Slama, Rémy/ Bourguignon, Jean-Pierre/ Demeneix, Barbara/ Ivell, Richard/ Panzica, Giancarlo/ Kortenkamp, Andreas/ Zoeller, Thomas. 2016. Scientific Issues Relevant to Setting Regulatory Criteria to Identify Endocrine Disrupting Substances in the European Union, *Environ Health Perspect*, DOI: 10.1289/EHP217, p. 6.

<sup>76</sup> C.f. WHO/ IPCS. 2002 (fn. 71) and, concerning the definition of adverse effects, WHO/ IPCS. 2009. Principles and methods for the risk assessment of chemicals in food. (Environmental Health Criteria). World Health Organisation. International Program on Chemical Safety, <http://www.who.int/foodsafety/publications/chemicalfood/en/> (accessed 16.6.2016).

<sup>77</sup> European Commission, Roadmap (fn. 5), p. 1; c.f. Solecki et al. (fn. 2), para 10.

<sup>78</sup> C.f. European Commission, Roadmap (fn. 5), p. 5 et seq.

dence have to be lower for presumed ED than the respective requirements with regard to known ED.

Given the wording and context of the provision, according to which known and presumed ED apparently are to be distinguished, and taking account of the objectives pursued by the BPR and the PPPR – *inter alia* ensuring a high level of protection while both regulations are “underpinned by the precautionary principle” –, addressees by the regulations in companies and authorities at least *should* apply the criteria in a way that reflects the differing requirements as to the establishment of scientific evidence. However, they are not obliged to do so. Thus, Option 2 does not ensure that presumed ED will indeed be identified.

Moreover, telling from the structure of the criteria there is a difference between, on the hand, known and presumed ED after point (a)(i) and, on the other, substances where experimental studies provide a strong presumption in this respect after point (a)(ii). However, the relation between ED that are presumed and those that are subject to a strong presumption based on experimental data is not clear, especially as there is no requirement which excludes experimental data from the determination of presumed ED. At the same time, according to point (b) experimental studies used to determine ED shall provide “clear evidence” in this respect whereas this requirement apparently applies to all types of ED referred to in points (a)(i) and (a)(ii). Hence, even with the inclusion of the “strong presumption” criterion it is not clear whether “presumed” ED in terms of the CLP category 1B indeed fall into the scope of Option 2.<sup>79</sup>

The approval mechanism provided for in Art. 5 BPR and Annex II PPPR addresses substances that “may cause” the relevant effects. This, as has been established in section 3.5, refers to known ED and also to presumed ED in terms of CLP category 1B. The Option 2 criteria do not ensure identification of presumed ED. As a consequence, they are not eligible for the mentioned regulatory mechanisms.

With respect to the legal evaluation (c.f. the evaluation criteria in section 2.2) of Option 2 the following aspects need to be taken into account:

First, the criteria have to be in line with the objectives of the basic legal acts. Option 2 does not ensure identification of active substances with endocrine properties only presumed to cause adverse effects. It is therefore not in line with the objectives of the basic acts which, as has been established in section 3.5, pursue regulation not only of known ED but also of presumed ED by the legal instruments specified in Art. 5 BPR and Annex II PPPR.

Besides, the criteria have to be in line particularly with the objectives, content and scope of the powers mandated to the Commission. Option 2 exclusively

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<sup>79</sup> Therefore Option 2 provides for limited legal certainty.

specifies criteria for the determination of ED. Moreover, these criteria are in all likelihood based on scientific considerations solely. In particular, they are based on hazard identification. Therefore, to this extent, Option 2 complies with the objectives, content and scope of the powers mandated to the Commission by the BPR and the PPPR. However, as has been established, Option 2 does not ensure identification of presumed ED. As a consequence, the Option 2 criteria undermine the functionality of the approval mechanisms set out in in the PPPR and the BPR. Hence, to that extent, the criteria clearly exceed the powers mandated to the Commission and are in sum not in line with the objectives, content and scope.

Finally, the criteria have to be limited to modifying non-essential elements of the basic acts. In this respect, the effects of the criteria on the legal instruments specified in Art. 5 BPR and Annex II PPPR are of particular importance. By not defining which lower strength of evidence standards apply to presumed ED as opposed to known ED the criteria risk limiting the scope of such instruments to known ED. This would constitute a modification of the material scope of the basic acts and thus alter the fundamental guidelines of the respective policies. At the same time, no limitations of the Commission's margin of discretion which could justify such modification are evident. These considerations strongly suggest that Option 2 affects essential elements of the basic acts.

The Commission would be legally entitled to initiate the legal changes specified by Policy Option 2 via the powers mandated to it by the PPPR and the BPR, if all three legal evaluation criteria established in section 2.2 would be fulfilled. However, Option 2 is not in line with the objectives of the basic acts and clearly exceeds objectives, content and scope of the mandates. Moreover, the analysis strongly suggests that Option 2 affects essential elements of the basic acts. Therefore the conclusion can be drawn that the Commission would not be legitimated to use its mandates provided for in the PPPR and BPR for implementing the legislative changes aimed at by Option 2.

### **4.1.3**

#### **Policy Option 3: introduction of ED categories**

Option 3 is based on the WHO/ IPCS definition but introduces additional categories referring to the extent to which endocrine disruption mediated adverse effects of a substance can be substantiated by scientific evidence:

- Category I: endocrine disruptors (known and presumed ED as specified in Option 2)
- Category II: suspected endocrine disruptors in respect of which there is some evidence for endocrine-mediated adverse effects, but where the evidence is not sufficiently strong to place the substance in category I

- Category III: endocrine active substances for which there is some in vitro or in vivo evidence indicating a potential for endocrine disruption mediated adverse effects in intact organisms and where the evidence is not sufficiently convincing to place the substance in category I or II.<sup>80</sup>

Option 3 links the determination of ED solely to hazard identification. The category I criteria to determine active substances with endocrine properties is identical to the criteria set out in Option 2. To that extent, the legal evaluation with respect to Option 2 is also applicable to Option 3. In particular, category I specified by Option 3 does not clearly stipulate that the requirements as to the establishment of scientific evidence have to be lower for presumed ED than the respective requirements with regard to known ED (section 4.1.2).

However, in contrast to Option 2, by introducing category II for “suspected endocrine disruptors” Option 3 does establish scientific criteria eligible to identify the type of ED which reflects the lower strength of evidence requirements relevant for category 1B classified or classifiable CMR substances.

The scientific criteria specified by category III refer to substances for which there is some in vitro or in vivo evidence indicating a potential for endocrine disruption mediated adverse effects. The strength of evidence required for these substances is thus similar to category 2 classified CMR substances.<sup>81</sup>

With respect to the legal evaluation (c.f. the evaluation criteria in section 2.2) of Option 3 the following aspects need to be taken into account.

First, the criteria have to be in line with the objectives of the basic legal acts. Option 3 does ensure identification of active substances with endocrine properties only presumed to cause adverse effects. It is therefore in line with the objectives of the basic acts which seek regulation of these substances by certain legal instruments. In Option 3 these substances are referred to as “suspected endocrine disruptors”. Furthermore, “endocrine active substances” are introduced as a third ED category. A structured identification of substances that meet the criteria set out in category III supports the identification of future endocrine disruptive substances. This extension of the scientific criteria is thus in agreement with the precaution-oriented objectives of the basic acts. As a result, the Option 3 criteria are in line with the objectives of the basic legal acts.

Besides, the criteria have to be in line particularly with the objectives, content and scope of the powers mandated to the Commission. Option 3 exclusively specifies criteria for the determination of ED. These criteria are in all likelihood based solely on scientific considerations. In particular, they are based on hazard identification. Therefore, to this extent, Option 3 complies with the objectives, content and scope of the powers mandated to the Commission by the

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<sup>80</sup> European Commission, Roadmap (fn. 5), p. 5.

<sup>81</sup> C.f. fn. 65.

BPR and the PPPR. The identification of ED under category III would not trigger the exclusion criteria for the approval of active substances. Hence, it cannot be considered that introducing category III does exceed the Commission's mandates.<sup>82</sup>

Finally, the criteria have to be limited to modifying non-essential elements of the basic acts. Based on the above findings Option 3 does not violate the fundamental guidelines set out in the BPR and the PPPR. It does furthermore not alter the existing obligations imposed by the basic legal acts. Hence, Option 3 would only affect non-essential elements of the basic acts.

As a result, the conclusion can be drawn that the Commission would be legitimated to use its mandates provided for in the PPPR and BPR for implementing the legislative changes aimed at by Option 3.

There are, however, some opportunities that should be considered to increase legal certainty of the criteria set out in Option 3. Category I does not provide different criteria for known and for presumed ED which could result in legal uncertainty. At the same time, category II on "suspected endocrine disrupters" does reflect the lower requirements as to the scientific evidence which is also subject to classifications in accordance with CLP of substances presumed to have CMR-properties (category 1B CMRs). It might thus be useful to rename Option 3 category II to "presumed" ED. Category I could meanwhile remain applicable only to known ED – equivalent to the respective category 1A CMR classifications. Moreover, denominating substances fulfilling the category III-criteria as 'endocrine active' could be misleading, since in the scientific literature this notion is often associated with substances that in some way interact with the endocrine system but without necessarily causing adverse effects.<sup>83</sup> Rather, the normative content of category III is very similar to the requirements regarding category 2 CMR classifications. Thus, one could rename category III to "suspected endocrine disrupters". Such category III substances would not be subject to the approval mechanisms pursuant to the PPPR and the BPR, though. Summed up it is suggested to reshuffle the Option 3 criteria as follows

- Category 1: known ED
- Category 2: presumed ED
- Category 3: suspected ED.

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<sup>82</sup> Indeed, only the introduction of criteria in terms of category III would allow Member States to consider precautionary measures with respect to endocrine active substances as mandated by the safeguard clause in Art. 1(4) PPPR.

<sup>83</sup> C.f., e.g., EFSA Scientific Committee (fn. 70), p. 11; Slama et al. (fn. 75), p. 9.



#### 4.1.4

##### Policy Option 4: introduction of potency as criterion

Option 4 applies the WHO/ IPCS definition but adds “potency as element of hazard characterization (hazard identification and characterisation)”.<sup>84</sup> According to the Impact Assessment documentation Option 4 aims “to identify, based on hazard elements and in the regulatory context of the PPP and BP Regulations, substances which meet the WHO/ IPCS definition and to prioritise the substances of greater concern”.<sup>85</sup> The roadmap does not elaborate on the relation between potency and the WHO/ IPCS definition, nor does it define the term. However, according to the scientific literature, potency is related to the dose (concentration) – response function of a substance.<sup>86</sup> The concept of potency therefore includes exposure-related considerations with regard to the dose or concentration necessary to induce certain effects, but without taking account of the actual exposure of humans, animals and the environment to the substance due to a specific application of the substance in e.g. products.<sup>87</sup>

With respect to the legal evaluation (c.f. the evaluation criteria in section 2.2) of Option 4 the following aspects need to be taken account of:

First, the criteria have to be in line with the objectives of the basic legal acts. According to the Commission, introduction of potency aims at prioritising ED of greater concern. It is thus to be expected that a potency cut-off criterion would narrow the scope of the scientific criteria significantly. In particular, the Option 4 criteria most likely would not apply to presumed ED. Hence, Option 4 is not in agreement with the normative objectives of the basic legal acts.

Besides, the criteria have to be in line particularly with the objectives, content and scope of the powers mandated to the Commission. Option 4 exclusively specifies criteria for the determination of ED and complies therefore with the content of the delegated powers mandated by the BPR and the PPPR. Insofar Option 4 complies with the objectives, content and scope of the powers mandated to the Commission by the BPR and the PPPR. However, it is questionable whether these criteria are based on scientific considerations exclusively. Annex II, Sections 3.6.5 and 3.8.2 PPPR as well as Art. 5(3) BPR oblige the Commission to specify scientific criteria for the identification of active substances with endocrine active properties. In its Case T-521/14 judgment the General Court stressed that specifying the scientific criteria can only be done in an objective manner based on scientific information, regardless of any other considerations, in particular of economic considerations. According to the scientific consensus paper, however, “potency is not relevant for identification of

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<sup>84</sup> European Commission, Roadmap (fn. 5), p. 6.

<sup>85</sup> SWD(2016) 211 fin, 15.6.2016, p. 22.

<sup>86</sup> EFSA Scientific Committee (fn. 70), p. 43; Slama et al (fn. 75), p. 10.

<sup>87</sup> Similar: COM(2016) 350 fin, 15.6.2016, p. 6.

a compound as an endocrine disrupter".<sup>88</sup> Besides, assessing the wording, context and purpose of Annex II PPPR and Art. 5(3) BPR shows that the criteria have to be based solely on hazard identification (section 3.3) – excluding thus potency considerations. Rather, where dose or concentration is to be considered in the identification of chemicals the BPR and the PPPR provide clear rules in this respect.<sup>89</sup> As a consequence, by introducing potency considerations to the criteria the Commission would overstep its mandated powers.<sup>90</sup> In addition, by not ensuring identification of presumed ED, the Option 4 criteria undermine the functionality of the instruments specified in Annex II PPPR and Art. 5 BPR. Hence, in sum, Option 4 clearly exceeds the objectives, content and scope of the powers mandated to the Commission by the BPR and the PPPR.

Finally, the criteria have to be limited to modifying non-essential elements of the basic acts. In this respect, the effects of the Option 4 criteria on the aforementioned approval procedures are of particular importance. By not ensuring identification of presumed ED Option 4 affects the material scope of the basic legal acts. At the same time, no limitations of the Commission's margin of discretion which could justify such modification are evident. These considerations thus show that Option 4 affects essential elements of the basic acts.

As a result, the criteria specified by Policy Option 4 do not conform to the objectives, content and scope of the powers mandated to the Commission by the BPR and the PPPR. In addition, the analysis shows that Option 4 affects essential elements of the basic acts. As a result, not all of the requirements of the legal evaluation criteria established in section 2.2 are fulfilled. Hence, the conclusion can be drawn that the Commission would not be legitimated to use its mandates provided for in the PPPR and BPR for implementing the legislative changes aimed at by Option 4.

## 4.2

### **Draft legislative acts specifying scientific criteria**

The Commission draft legislative acts of 15 June 2016 seek to introduce into the BPR and the PPPR a variation of the criteria specified by Policy Option 2 subject to the Impact Assessment.<sup>91</sup> The legal assessment of the draft criteria therefore takes into account the results to the assessment of Option 2 (sec-

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<sup>88</sup> Solecki et al. (fn. 2), para 22.

<sup>89</sup> This is e.g. the case for so-called "chemicals of concern" according to Art. 3(1)(f) BPR; see also Art. 3(4) PPPR.

<sup>90</sup> Limiting the determination of ED to questions of hazard identification would also contribute to regulatory coherence in terms of other pieces of chemical legislation and in particular with regard to the horizontal CLP Regulation.

<sup>91</sup> See C(2016) 3751 projet, Annex I, amendments to Annex II PPPR and C(2016) 3752 projet, Annex I, Section A.

tion 4.1.2). However, compared to the wording of Option 2, in particular, the scope of the draft criteria is explicitly narrowed to those ED “known to cause” adverse effects. In this respect, the Commission proposal is also not reflecting the WHO/ IPCS definition,<sup>92</sup> but it deviates from it.<sup>93</sup>

According to the draft criteria, an active substance shall be considered (PPPR), or identified (BPR) respectively, as having endocrine disrupting properties with respect to humans or non-target organisms if

- it “is known to cause an adverse effect” relevant for human health or non-target organisms,
- “it has an endocrine mode of action” and
- “the adverse effect relevant for [human health or non-target organisms] is a consequence of the endocrine mode of action”.

The criteria do therefore not provide for the identification of substances where there are some findings indicating ED properties but a final conclusion whether they are “known to cause” the respective effects cannot be drawn yet. In contrast to the original Option 2, the draft criteria do not even mention applicability to presumed ED.

With respect to judging on the link between adverse effect and mode of action the criteria stipulate that “the biological plausibility of the causal link between the adverse effect and the endocrine mode of action” shall be considered. The Commission opted for basing establishment of causality on the concept of biological plausibility because it acknowledges “that in practice, it will be very difficult to demonstrate ‘conclusive evidence’ of causality”.<sup>94</sup> However, the criteria do not explain what biological plausibility means as opposed to conclusive evidence. They do also not specify that establishment of conclusive evidence is not required to identify ED. As a consequence, the level of scientific evidence to determine ED required by the wording in the draft criteria is equivalent to the level of evidence subject to classifications of substances “known” to have CMR-properties in accordance with CLP (category 1A classification).

The BPR draft exclusively specifies criteria for the determination of ED. The PPPR draft, too, specifies criteria for the determination of ED. However, in addition, this latter draft adds amendments to the approval mechanism specified by Annex II PPPR. This draft therefore, as the analysis in section 4.3 will show, clearly exceeds the mandate for implementation measures provided by Art. 78(1)(a) in conjunction with Annex II, Sections 3.6.5 and 3.8.2 PPPR.

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<sup>92</sup> The WHO/ IPCS approach also defines “potential” ED, c.f. fn. 71.

<sup>93</sup> Notwithstanding the statement by the Commission to base the criteria to identify ED “on [the] WHO definitions” in Recital 2 of C(2016) 3751 projet and Recital 2 of C(2016) 3752 projet.

<sup>94</sup> COM(2016) 350 fin, 15.6.2016, p. 5.

However, the legal evaluation subject to the present section concentrates exclusively on the criteria for the determination of ED which are identical in both the BPR and the PPPR draft.

As to the legal evaluation (c.f. the evaluation criteria in section 2.2) of the draft criteria the following aspects need to be taken into account.

First, the criteria have to be in line with the objectives of the basic legal acts. The basic acts, as has been established in section 3.5, pursue regulation by the approval mechanisms specified by Art. 5 BPR and Annex II PPPR not only of "known" ED but also of "presumed" ED in terms of CLP category 1B classifications of CMR substances. However, the draft criteria require a level of scientific evidence equivalent to CLP category 1A classifications. They do therefore not ensure identification of active substances with endocrine properties only presumed to cause adverse effects. As a consequence, the criteria are not in line with the objectives and the systematic context of the basic acts. In this respect, the draft criteria are even more restrictive than those laid down in Option 2 subject to the Impact Assessment (section 4.1.2).

Besides, the draft criteria have to be in line particularly with the objectives, content and scope of the powers mandated to the Commission. The scientific criteria set out by the drafts are in all likelihood based on scientific considerations exclusively. In particular, they are based on hazard identification. Insofar, the criteria are in line with the objectives, content and scope of the powers mandated to the Commission. However, by not ensuring identification of presumed ED, the draft criteria undermine the functionality of the aforementioned approval mechanisms. Hence, to that extent, the criteria exceed the powers mandated to the Commission and are in sum not in line with the objectives, content and scope.

Finally, the draft criteria have to be limited to modifying non-essential elements of the basic acts. However, by not providing for the identification of presumed ED the criteria alter the material scope of the BPR and the PPPR and therefore affect the fundamental guidelines of the respective policies. At the same time, no limitations of the Commission's margin of discretion which could justify such modifications are evident. These considerations show that the criteria affect essential elements of the basic acts.

As a result, the draft criteria are not in line with the objectives and the systematic context of the BPR and the PPPR as basic legal acts. In addition, by limiting the material scope of the approval procedures the criteria clearly exceed the objectives, content and scope of the powers mandated to the Commission by the basic acts. Moreover, the analysis shows that the criteria affect essential elements of the basic acts. Hence, the draft does not comply with all three legal evaluation criteria established in section 2.2. Based on these findings the conclusion can be drawn that the Commission is not legally entitled

to use its powers mandated by the BPR and the PPPR to implement the draft criteria.

### 4.3

#### Approval mechanism subject to the PPPR draft legislative act

In addition to introducing scientific criteria, the Commission Regulation C(2016) 3751 proposal additionally alters the normative context steering the PPPR approval mechanism for active substances with endocrine disruptive properties as set out in Annex II PPPR. Annex II, Section 3.6.5 PPPR<sup>95</sup> *de lege lata* stipulates:

„An active substance, safener or synergist shall only be approved if, on the basis of the assessment of Community or internationally agreed test guidelines or other available data and information, including a review of the scientific literature, reviewed by the Authority, it is not considered to have endocrine disrupting properties that may cause adverse effect in humans, unless the exposure of humans to that active substance, safener or synergist in a plant protection product, under realistic proposed conditions of use, is negligible, that is, the product is used in closed systems or in other conditions excluding contact with humans and where residues of the active substance, safener or synergist concerned on food and feed do not exceed the default value set in accordance with point (b) of Article 18(1) of Regulation (EC) No 396/2005.“<sup>96</sup>

Annex II, Section 3.6.5.2 PPPR subject to the Commission proposal, in contrast, contains the following wording:

“An active substance, safener or synergist shall only be approved if, on the basis of the assessment of the available evidence carried out in accordance with the data requirements for the active substances, safeners or synergists and other available data and information, it is not identified as having endocrine disrupting properties with respect to humans according to the criteria specified in point 3.6.5.2, unless the risk to humans from exposure to that active substance, safener or synergist in a plant protection product, under realistic worst case proposed conditions of use, is negligible, in particular where the product is used in closed systems or in other conditions which aim at excluding contact with humans, and where maximum residue levels of the active substance, safener or synergist concerned in or on food and feed can, taking account of the latest opinion of the Authority with respect to that ac-

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<sup>95</sup> Annex II, Section 3.8.2 PPPR *de lege lata* contains very similar wording (compared to the cited provision aiming at the protection of human health) with regard to “endocrine disrupting properties that may cause adverse effects on non-target organisms”.

<sup>96</sup> *Emphasize added.*

tive substance, synergist, safener, be set in accordance with Regulation (EC) No 396/2005, which ensure a high level of consumer protection.”<sup>97</sup>

The proposed act then continues with the criteria to determine endocrine active substances (c.f. the analysis in section 4.2).<sup>98</sup>

Hence, the proposal changes the Annex II PPPR wording from “endocrine disrupting properties that may cause adverse effect” to “having endocrine disrupting properties”. This reflects the normative content of the criteria specified by the Commission which refer only to known endocrine disruptive substances.

In this context another aspect has to be taken into account: The derogation from the approval ban of ED *de lege lata* is subject to the condition that exposure of humans or non-target organisms is negligible. The draft, in contrast, introduces derogations on the grounds that risk is negligible. As a consequence, the exposure-based mechanism in existing law would be replaced by a mechanism based on specific risk assessment which would allow also “non-negligible” exposure as long as the risk assessment concludes that the identified hazard of the active substance in question is sufficiently low (c.f. section 3.2.2).<sup>99</sup>

Besides, Annex II as it stands specifies that exposure is negligible if the product “is used in closed systems or in other conditions excluding contact with humans”. The Commission proposal, in contrast, by using the wording “in particular” is open to further strategies to verify that risk is negligible. At the same time, the draft clarifies that the “other conditions” referred to must not have been proven to be actually adequate to exclude contact with humans but must merely aim at excluding such contact.

Finally, under existing law exposure can only be negligible when residues on food and feed do not exceed the default value of 0,01 mg/kg set in accordance with Regulation 396/2005.<sup>100</sup> According to the Commission draft, however, to establish that risk is negligible it has to be shown that maximum residue levels (MRL) can be set in accordance with Regulation 396/2005. The

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<sup>97</sup> *Emphasize added.*

<sup>98</sup> Likewise, the Commission proposal for amending Section 3.8.2 of the PPPR introduces a derogation from the approval ban for substances identified as having endocrine disrupting properties with respect to non-target organisms where “the risk from exposure of the non-target organisms to that active substance, safener or synergist in a plant protection product, under realistic worst case proposed conditions of use, is negligible”.

<sup>99</sup> See also section 3.3 according to which risk is determined in a process of risk characterisation, taking into account the specific hazard (of a substance) and exposure.

<sup>100</sup> Regulation (EC) No 396/2005 of 23 February 2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin and amending Council Directive 91/414/EEC, 2005 OJ L 70/ 1.

default value refers to the lowest possible<sup>101</sup> residue level; the MRL, in contrast, is based on a risk assessment.<sup>102</sup>

In Recital 9 of the draft the Commission justifies the amendments with its aim to reflect current scientific and technical knowledge. Given the context of Recitals 4 and 6, this justification refers to a statement in the 2013 Scientific Opinion of the EFSA Scientific Committee.<sup>103</sup> Based on that Opinion the Commission concludes that ED “may be assessed like most other substances of concern for human health and the environment, that is to say be subject to risk assessment and not only to hazard assessment”.<sup>104</sup>

However, the same Scientific Opinion clarifies that concepts such as “negligible level of exposure’, or ‘levels of concern’ are related to risk management and are therefore beyond the scope of this opinion.”<sup>105</sup> Moreover, it specifies that, “[w]hether hazard characterisation criteria alone, or risk assessment should be used for defining the level of concern for identified EDs for further regulatory measures is beyond the scope of this opinion and is a risk management decision”.<sup>106</sup>

Hence, from a scientific point of view “EDs can [...] 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”.<sup>107</sup> This does however not predetermine the risk management to be applied to ED. Rather, the “appropriate response in a given situation [of concern] is thus the result of a political decision, a function of the risk level that is ‘acceptable’ to the society on which the risk is imposed.”<sup>108</sup>

Against this background the legal evaluation (c.f. the evaluation criteria in section 2.2) of the proposed changes to the approval mechanism has to take into account the following aspects.

First, the proposed changes have to be in line with the objectives of the basic legal acts. The PPPR pursues to “ensure a high level of protection” and, to this end, is “underpinned by the precautionary principle”. Hence, all legal instruments, and risk management decisions linked to them, provided for in the regulation are shaped by these normative objectives. Refusing approval of active substances with endocrine disruptive properties unless exposure is negligible has to be seen as an expression of these normative objectives (c.f. section 3.2.2). In Case T-521/14 the General Court ruled that in adopting the BPR

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<sup>101</sup> EFSA, Reasoned opinion on the potential chronic and acute risk to consumers’ health arising from proposed temporary EU MRLs, 15.3.2007, p. 6.

<sup>102</sup> C.f. Art. 10(1) and Art. 14(2) Regulation 396/2005.

<sup>103</sup> EFSA Scientific Committee (fn. 70).

<sup>104</sup> Recital 6 of draft C(2016) 3751 projet; c.f. COM(2016) 350 fin, 15.6.2016, p. 8.

<sup>105</sup> EFSA Scientific Committee (fn. 70), p. 10.

<sup>106</sup> EFSA Scientific Committee (fn. 70), p. 43.

<sup>107</sup> EFSA Scientific Committee (fn. 70), p. 47 (*emphasize added*).

<sup>108</sup> COM(2000) 1 fin, 2.2.2000, p. 16, 13.

the co-legislators already made a balance between the objective of improving the internal market and the objective of protecting human health, animal health and the environment. This balance must be respected by the Commission and cannot be undermined when issuing delegated acts specifying ED criteria.<sup>109</sup> The mandates of the BPR and the PPPR to specify criteria are very similar. Hence, this ruling is also applicable with respect to the draft Commission Regulation to amend the PPPR. Basing a regulatory decision on the sole consideration of exposure on the one hand or basing it on risk considerations, thus reflecting hazard and exposure, on the other hand amounts to a change of the regulatory paradigm. Accordingly, the legislative history of the PPPR shows that the co-legislators clearly and deliberately rejected derogation based on specific risk assessment in terms of the draft, and only accepted the concept of 'negligible exposure'. The same applies to the further modifications provided for by the draft regulation (e.g., MRL shall replace default value). In other words, the normative requirements steering the approval mechanism laid down in the PPPR are an expression of the regulatory balance defined by the co-legislators in order to achieve the normative objectives of the PPPR. The proposed changes are therefore not in agreement with aims of the basic legal act.

Besides, the proposed changes have to be in line particularly with the objectives, content and scope of the powers mandated to the Commission.

- The draft Commission Regulation changes the Annex II PPPR wording from "endocrine disrupting properties that may cause adverse effect" to "having endocrine disrupting properties". This reflects the normative content of the criteria specified by the Commission. In this respect, reference can be made to the legal analysis in section 4.2 according to which, even in an isolated assessment of the specified criteria, these criteria clearly exceed the legal mandate of the Commission.
- The draft is based on the 2<sup>nd</sup> Para. of Annex II, Section 3.6.5 and on Art. 78(1)(a) PPPR. Annex II, Section 3.6.5 PPPR stipulates that the Commission shall present a draft of the measures concerning scientific criteria for the determination of ED properties to be adopted. By proposing additional amendments of the approval procedures for ED, the draft therefore to this extent clearly exceeds the objective, content and scope of the mandate in Annex II.
- Art. 78(1)(a) PPPR applies to "amendments to the Annexes, taking into account current scientific and technical knowledge". From a scientific point of view, ED can be subjected to a risk assessment. However, whether to base derogations with respect to the ED approval ban on the concept of 'eligible exposure' or the concept of 'eligible risk' is a matter of risk

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<sup>109</sup> EGC, Judgment in Case T-521/14 (fn. 1), para. 72; c.f. European Parliament resolution (fn. 15), para J.



management. Risk management, i.e. the reaction to a specific situation of concern is subject to a political decision, though, taking into account the societal perception of a specific risk. Hence, scientific knowledge alone cannot justify amendments of the approval mechanism set out in Annex II PPPR which is a function of risk management. As a consequence, by proposing changes to that mechanism for ED the draft clearly exceeds the objective, content and scope of the legal basis chosen by the Commission Art. 78(1)(a) PPPR.

As a result, the draft clearly exceeds the legal mandate confided to the Commission by the PPPR.

Finally, the draft has to be limited to modifying non-essential elements of the basic acts.

- To this end, first, the Commission's notion as to the concept of 'non-essential elements' is worth mentioning. According to the documentation of the Impact Assessment, the "Commission is empowered to amend non-essential elements of the Annexes in the [PPPR] taking into account current scientific and technological knowledge via Regulatory Procedure with Scrutiny [...]. This option [i.e. introduction of derogations based on specific risk assessment] is therefore feasible within the remit of the mandate of the Commission as it does not imply changes by ordinary legislative procedure to the basic act."<sup>110</sup> The Commission apparently takes the view that only the article text of the PPPR constitutes the basic legal act which reflects all essential elements of the regulation. Following this rationale, all provisions laid down in the PPPR annexes would constitute non-essential elements and amendments thereof would thus be subject to the simplified legislative procedures. This notion, however, is not in line with the legal criteria set out in section 2.2. Indeed, answering whether certain elements of a regulation are essential or non-essential requires an assessment of how these elements relate to the objectives and content of the basic act. In this respect it is not conclusive to base the answer solely on the fact that these elements are laid down in the article text or the annexes. As a consequence, from the location of the approval mechanism for active substances in the annexes the Commission may not conclude that these procedures are subject to the regulatory procedure with scrutiny referred to in Article 79(4) PPPR. Indeed, the approval mechanism laid down in Annex II PPPR could be a particularly obvious example for the legislator's opportunity to locate essential legal elements at a regulation's annexes. In Terms of the PPPR, active substance approval is one of the key regulatory elements, the importance of which is *inter alia* reflected by Recitals 9 et seq. PPPR, whereas their primary function is "to remove as far

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<sup>110</sup> SWD(2016) 211 fin, 15.6.2016, p. 24.

as possible obstacles to trade in plant protection products existing due to the different levels of protection in the Member States".<sup>111</sup>

- Proposed legislative changes can relate to essential elements when they violate the fundamental guidelines of a basic legal act. As already established above, the legislative history of the PPPR shows that the co-legislators clearly and deliberately rejected derogation based on specific risk assessment in terms of the draft, and only accepted the concept of 'negligible exposure'. The same applies to the further modifications provided for by the draft regulation (e.g., MRL shall replace default value). In this respect, even the Commission in a Communication accompanying the draft legislation admits that it is not for the draft to decide "how" to regulate ED as respective "regulatory consequences have already been set by the legislator in the [BPR and the PPPR]".<sup>112</sup> Changing the derogation provision from 'negligible exposure' to 'negligible risk' would thus modify the fundamental guidelines of the EU policies for plant protection products and therefore alter essential elements of the basic act.
- Changing the derogation provision from 'negligible exposure' to 'negligible risk' would modify to a large extent the obligations and respective legal consequences imposed by the PPPR which also indicates that the draft Commission Regulation alters essential elements of the basic act.
- In this context, it has also to be considered whether the powers conferred on the Commission are so strictly circumscribed that its margin of discretion is either non-existent or extremely limited. Annex II, Section 3.6.5 PPPR exclusively stipulates that the Commission shall present a draft of the measures concerning specific scientific criteria for the determination of endocrine disrupting properties to be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 79(4). The Commission is therefore to no extent required to introduce a draft modifying the approval procedure for ED. Nor is the Commission forced to do so by any general obligation provided for in the PPPR to update the regulation with respect to the current scientific state of knowledge. Rather, Art. 78(1)(a) PPPR provides a legal basis to amend the Annexes, taking into account current scientific and technical knowledge. Besides, the Commission justifies its draft with a need to reflect the current scientific and technical knowledge.<sup>113</sup> However, even if current scientific data were relevant for the determination of risk management procedures,<sup>114</sup> and even if the Commission were granted the power to update the approval procedure, without any margin of discretion, in the light of scientific data which

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<sup>111</sup> Recital 9 PPPR.

<sup>112</sup> COM(2016) 350 fin, 15.6.2016, p. 7.

<sup>113</sup> Recital 9 draft C(2016) 3751 projet.

<sup>114</sup> C.f. p. 37 explaining that this is not the case.

may become available over time, such power can affect the essential elements of the basic act, if those scientific data are in themselves crucial to the choices made by the legislature in the basic act.<sup>115</sup> Indeed, as the change from derogations based on 'negligible exposure' to 'negligible risk' marks a paradigm shift, the (arguably) scientific data referred to by the Commission are crucial to the choices made by the legislature in the basic act. As a consequence, the Commission is by no means circumscribed to propose the relevant changes of the approval procedures.

Hence, the amendments proposed by the draft Commission Regulation to the normative decisions by the co-legislators steering the approval mechanism for ED clearly exceed the objective, content and scope of the delegated powers mandated by the PPPR. Besides, the draft is not in line with the objectives of the basic act. Furthermore, the analysis shows that the criteria affect essential elements of the basic acts. Hence, the draft does not comply with all three legal evaluation criteria established in section 2.2. Based on these findings the conclusion can be drawn that the Commission would not be legally entitled to use the regulatory procedure with scrutiny as mandated by the PPPR to implement the draft criteria.

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<sup>115</sup> C.f. section 2.2.

## 5 Legal Consequences

The European Parliament and the Council are confided by the basic acts with certain procedural rights to object draft measures proposed by the European Commission.

Alternatively, the ECJ may annul adopted legislative acts on the grounds of *inter alia* lack of competence.

According to the findings of the legal assessment in section 4 the legal conditions for both legal consequences are fulfilled.

### 5.1 Procedural rights to the European Parliament and the Council

Annex II, Section 3.6.5 PPPR stipulates that the Commission shall present a draft of the measures concerning scientific criteria for the determination of endocrine disrupting properties to be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 79(4) PPPR.

The regulatory procedure with scrutiny is specified in Art. 5a Council Decision 1999/468/EC (c.f. section 2.2). According to Art. 5a(3)(b) of that Council Decision during the procedure “the European Parliament, acting by a majority of its component members, or the Council, acting by a qualified majority, may oppose the adoption of [a] draft by the Commission, justifying their opposition by indicating that the

- draft measures proposed by the Commission exceed the implementing powers provided for in the basic instrument or that the
- draft is not compatible with the aim or the content of the basic instrument or
- does not respect the principles of subsidiarity or proportionality”.

As consequence, provided the conditions with respect to the required majorities are fulfilled, both the Parliament and the Council are in their own rights legally entitled to reject the Commission Regulation C(2016) 3751 proposal on the grounds that the draft measures proposed concerning the determination of scientific criteria for ED and respective measures concerning the amendments to the approval procedures exceed the implementing powers provided for in the PPPR and are furthermore not compatible with the aim and the content of the basic instrument.

Under the same conditions the Parliament and the Council would be legally entitled to reject draft measures in terms of the Policy Options 2 and 4 subject to the Impact Assessment if proposed by the Commission in the regulatory procedure with scrutiny.

Art. 5(3) BPR stipulates that „the Commission shall adopt delegated acts in accordance with Article 83 specifying scientific criteria for the determination of endocrine-disrupting properties“. Such delegated acts are subject to the requirements of Art. 290 TFEU. According to Art. 290(2) TFEU legislative acts shall explicitly lay down the conditions to which the delegation is subject, e.g. whether “the European Parliament or the Council may decide to revoke the delegation“. Given a right to revoke is granted, the Parliament “shall act by a majority of its component members, and the Council by a qualified majority”.<sup>116</sup>

Accordingly, after Art. 83(5) BPR, a delegated act adopted pursuant to Art. 5(3) “shall enter into force only if no objection has been expressed either by the European Parliament or the Council within a period of two months of notification of that act to the European Parliament and the Council“. In a Communication on the implementation of Art. 290 TFEU the Commission defines “the general framework within which such delegations of power should operate”.<sup>117</sup> Pursuant to this framework,

a “delegated act that Parliament or the Council has opposed cannot enter into force. The Commission will then have the possibility of either adopting a new delegated act, amended where necessary to take account of the objections expressed, or presenting a legislative proposal under the terms of the Treaties, if the objections were based on its having overstepped the powers delegated to it.”<sup>118</sup>

Hence, provided the conditions with respect to the required majorities are fulfilled, the Parliament or the Council may object a delegated act proposed by the Commission. To this end, similar to the procedure with scrutiny, the two institutions might base their objections on the Commission having overstepped the powers delegated to it. As a result the conclusion can be drawn that the Parliament or the Council are legally entitled to object the Commission Delegated Regulation C(2016) 3752 proposal on the grounds that the draft measures proposed concerning the determination of scientific criteria for ED exceed the delegated powers provided for in the BPR.

Under the same conditions the Parliament and the Council would be legally entitled to reject Policy Options 2 and 4 subject to the Impact Assessment if proposed by the Commission as delegated act.

## 5.2

### Annulment by the European Court of Justice

Given the procedural rights confided to the Parliament and the Council would not suffice to reject the draft measures referred to in section 5.1, the Parlia-

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<sup>116</sup> Art. 290(2) TFEU.

<sup>117</sup> COM(2009) 673 fin, 9.12.2009, p. 2.

<sup>118</sup> COM(2009) 673 fin, 9.12.2009, p. 10.

ment, the Council as well as any Member State that might have been outvoted in the procedures may request the ECJ to review the legality of the then adopted legislative act(s). Pursuant to Art. 263(2) TFEU, the ECJ “shall for this purpose have jurisdiction in actions brought by a Member State, the European Parliament, the Council or the Commission on grounds of lack of competence, infringement of an essential procedural requirement, infringement of the Treaties or of any rule of law relating to their application, or misuse of powers”. As the draft measures referred to in section 5.1 exceed the mandates of the Commission provided for by the BPR and the PPPR, the ECJ can nullify the respective measures on the grounds of lack of competence.