



Council of the  
European Union

Brussels, 17 June 2016  
(OR. en)

10442/16  
ADD 16

ENV 440  
AGRI 357  
SAN 272  
MI 464  
CHIMIE 41  
IA 43

#### COVER NOTE

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From: Secretary-General of the European Commission,  
signed by Mr Jordi AYET PUIGARNAU, Director

date of receipt: 16 June 2016

To: Mr Jeppe TRANHOLM-MIKKELSEN, Secretary-General of the Council of  
the European Union

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No. Cion doc.: SWD(2016) 211 final - PART 16/16

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Subject: COMMISSION STAFF WORKING DOCUMENT  
IMPACT ASSESSMENT  
Defining criteria for identifying endocrine disruptors in the context of the  
implementation of the plant protection products regulation and biocidal  
products regulation  
Annex 16 out of 16  
*Accompanying the document*  
COMMUNICATION FROM THE COMMISSION TO THE EUROPEAN  
PARLIAMENT AND THE COUNCIL on endocrine disruptors and the draft  
Commission acts setting out scientific criteria for their determination in the  
context of the EU legislation on plant protection products and biocidal  
products

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Delegations will find attached document SWD(2016) 211 final - PART 16/16.

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Encl.: SWD(2016) 211 final - PART 16/16



Brussels, 15.6.2016  
SWD(2016) 211 final

PART 16/16

**COMMISSION STAFF WORKING DOCUMENT**

**IMPACT ASSESSMENT**

**Defining criteria for identifying endocrine disruptors in the context of the implementation of the plant protection products regulation and biocidal products regulation**

**Annex 16 out of 16**

*Accompanying the document*

**COMMUNICATION FROM THE COMMISSION TO THE EUROPEAN  
PARLIAMENT AND THE COUNCIL**

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

{COM(2016) 350 final}  
{SWD(2016) 212 final}

## ANNEX 16

### GLOSSARY AND BIBLIOGRAPHY

<b>A</b>	Androgenic pathway
<b>AC50</b>	Half maximal active concentration
<b>ACTIVE SUBSTANCE (AS)</b>	In the context of the PPP and BP Regulations, a substance or a micro-organism that has an action on or against harmful organisms <sup>1,2</sup>
<b>ADVERSE EFFECT</b>	A change in the morphology, physiology, growth, development, reproduction, or, life span of an organism, system, or (sub)population that results in an impairment of functional capacity, an impairment of the capacity to compensate for additional stress, or an increase in susceptibility to other influences <sup>3</sup>
<b>ADVERSE OUTCOME PATHWAY (AOP)</b>	A linear sequence of events from the exposure of an individual to a chemical substance through to an understanding of the adverse (toxic) effect at the individual level (for human health) or population level (for ecotoxicological endpoints). Representation of existing knowledge concerning the linkage between the molecular initiating event and an adverse outcome at the individual or population levels <sup>4</sup>
<b>ANDROGEN</b>	Androgens are steroidhormones that help to develop sex organs in men. They also contribute to sexual function in men and women <sup>5</sup>
<b>ANTISEPSIS</b>	Preventing or stopping the growth of microorganisms
<b>APICAL ENDPOINT</b>	Traditional, directly measured whole-organism experimental results of exposure in <i>in vivo</i> tests, generally death, reproductive failure, or developmental dysfunction. Observable effects of exposure to a toxic chemical in a test animal. An observable outcome in a whole organism, such as a clinical sign or pathologic state, that is indicative of a disease state that can result from exposure to a toxicant <sup>4</sup>  Results of an <i>in vivo</i> assay which describe a response by the organism as a whole, (e.g. fecundity or growth) which have

<sup>1</sup> Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products

<sup>2</sup> Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC

<sup>3</sup> WHO/IPCS (World Health Organization/International Programme on Chemical Safety), 2009. Principles and Methods for the Risk Assessment of Chemicals in Food. Environmental Health Criteria 240. 689 pp. Available from: <http://www.who.int/foodsafety/chem/principles/en/index1.html>.

<sup>4</sup> Appendix I. OECD Collection of Working Definitions 2012. Retrieved from: <http://www.oecd.org/chemicalsafety/testing/49963576.pdf>

<sup>5</sup> EFSA Scientific Committee; Scientific Opinion on the hazard assessment of endocrine disruptors: Scientific criteria for identification of endocrine disruptors and appropriateness of existing test methods for assessing effects mediated by these substances on human health and the environment. EFSA Journal 2013; 11(3):3132. [84 pp.] doi: 10.2903/j.efsa.2013.3132.

	possible implications for its biological fitness, rather than a response of the endocrine system alone (including physiological changes dependent on the endocrine system, such as Vitellogenin induction). Apical responses may or may not result from endocrine changes (e.g. fecundity may be affected both by some EDs and by some non-EDs) <sup>5</sup>
<b>APICAL TEST</b>	A test or assay aimed at detecting/measuring apical endpoints: generally in vivo testing describing a response by the organism as a whole (e.g. generally death, reproductive failure, or developmental dysfunction)
<b>AUTOCHTHONOUS CASE</b>	Case caused by a pathogen indigenous or endemic to a region
<b>BENEFITS</b>	The positive implications, direct and indirect, resulting from some action. This includes both financial and non-financial information <sup>6</sup>
<b>BIOCIDAL PRODUCT (BP)</b>	Biocidal products (BP) control unwanted organisms that are harmful to human or animal health, or that cause damage to human activities. BP include products such as insecticides, insect repellents, disinfectants, preservatives for materials and anti-fouling paints for the protection of ship hulls. BP are formulated products (e.g. liquid concentrates, wettable powder, granules) that contain at least one active substance that is responsible for the effect of the BP, which could be a chemical, a plant extract, a pheromone or a micro-organism (including viruses).
<b>BP REGULATION</b>	Biocidal Products Regulation
<b>C1 (CARCINOGEN CATEGORY 1)</b>	Known or presumed human carcinogen, according to Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures <sup>7</sup>
<b>C2 (CARCINOGEN CATEGORY 2)</b>	Suspected human carcinogen, according to Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures <sup>7</sup>
<b>CAR</b>	Competent Authority Report
<b>CARCINOGEN</b>	Substance or mixture of substances which induce cancer or increase its incidence. Substances which have induced benign and malignant tumours in well performed experimental studies on animals are considered also to be presumed or suspected human carcinogens unless there is strong evidence that the mechanism of tumour formation is not relevant for humans <sup>7</sup>
<b>CLP</b>	Classification, Labelling and Packaging
<b>CMR</b>	Carcinogenic, Mutagenic, Reprotoxic

<sup>6</sup> ECHA. Guidance on the preparation of socio-economic analysis as part of an application for authorisation. Helsinki: ECHA, 2011. Retrieved from:

[http://echa.europa.eu/documents/10162/13637/sea\\_authorisation\\_en.pdf](http://echa.europa.eu/documents/10162/13637/sea_authorisation_en.pdf)

<sup>7</sup> Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006.

<b>CoRAP</b>	Community Rolling Action Plan
<b>COSTS</b>	The negative implications, direct and indirect, resulting from some actions. Includes both financial and non-financial information <sup>4</sup>
<b>COST BENEFIT ANALYSIS (CBA)</b>	Analysis which quantifies, in monetary terms where possible, costs and benefits of a possible action, including items for which the market does not provide a satisfactory measure of economic value <sup>4</sup>
<b>COST EFFECTIVENESS ANALYSIS (CEA)</b>	Analysis widely used to determine the least cost means of achieving pre-set targets or goals (though it is not restricted to this use). CEA can be used to identify the least cost option among a set of alternative options that all achieve the targets. In more complicated cases, CEA can be used to identify combinations of measures that will achieve the specified target <sup>4</sup>
<b>COST-OF-ILLNESS (COI)</b>	Empirical approach to estimating the societal impact of disease and injury which combines 'direct costs' (medical care, travel costs, etc.) and 'indirect costs' (the value of lost production because of reduced working time) into an overall estimate of economic impact on society, often expressed as a percentage of current GDP <sup>8</sup>
<b>CUT-OFF CRITERIA</b>	<p>The term “<i>cut-off criteria</i>” is not used in the legislation. It is used in common language to refer to <i>approval criteria</i> in Reg. 1107/2009<sup>2</sup> and <i>exclusion criteria</i> in Reg. 528/2012<sup>1</sup>.</p> <p>In Reg. 1107/2009, <i>approval criteria</i> are:</p> <ul style="list-style-type: none"> <li>- purely based on hazard considerations for certain classes of substances (<i>mutagens, PBT = persistent, bioaccumulative and toxic, vPvB= very persistent and very bioaccumulative, POP= persistent organic pollutants</i>);</li> <li>- based on a strong hazard component for other classes of substances (<i>carcinogens, toxic for reproduction, endocrine disruptors</i>).</li> </ul> <p>In Reg. 528/2012, <i>exclusion criteria</i> are:</p> <ul style="list-style-type: none"> <li>- purely based on hazard considerations for certain classes of substances (<i>mutagens, PBT = persistent, bioaccumulative and toxic, vPvB= very persistent and very bioaccumulative, carcinogens, toxic for reproduction, endocrine disruptors</i>) when used by consumers;</li> <li>- based on a strong hazard component for the same classes of substances when used by professional users.</li> </ul>
<b>DAR</b>	Draft Assessment Report
<b>DG</b>	Directorate General
<b>DISCOUNT RATE</b>	Used to convert a future income (or expenditure) stream to its present value. It shows the annual percentage rate at which the present value of a future Euro, or other unit of account, is assumed

<sup>8</sup> WHO. 2009. WHO guide to identifying the economic consequences of disease and injury. Geneva.

	to decrease over time <sup>4</sup>
<b>DISCOUNTING</b>	A method used to convert future costs or benefits to present values using a discount rate <sup>4</sup>
<b>DOSE-RESPONSE CURVE</b>	Graphical presentation of a dose-response relationship <sup>10</sup>
<b>DOSE-RESPONSE RELATIONSHIP</b>	<p>Relation between the exposure to an agent and the change developed in a population in reaction to it.</p> <p><u>Note:</u> It may be expressed as the proportion of a population exposed to an agent that shows a specific reaction. It may also be used to signify the magnitude of an effect in one organism (or part of an organism); in that case, it is more specifically called "dose-effect relationship"<sup>10</sup></p>
<b>DOWNSTREAM USER</b>	Any natural or legal person established within the Community, other than the manufacturer or the importer, who uses a substance, either on its own or in a mixture, in the course of his industrial or professional activities. A distributor or a consumer is not a downstream user <sup>4</sup>
<b>E</b>	Estrogenic pathway
<b>EASIS</b>	Endocrine Active Substances Information System
<b>EATS</b>	Estrogen, Androgen, Thyroid and Steroidogenesis
<b>ECONOMIC IMPACTS</b>	Costs and benefits to manufacturers, importers, downstream users, distributors, consumers and society as a whole <sup>4</sup>
<b>ECHA</b>	European Chemicals Agency
<b>EC50</b>	Half maximal effective concentration
<b>ED</b>	Endocrine disruptor
<b>EDSP</b>	Endocrine Disruptor Screening Program
<b>EFSA</b>	European Food Safety Authority
<b>ENDOCRINE / HORMONE SYSTEM</b>	The endocrine system is the system in the body which produces hormones to provide an internal communication system between cells located in distant parts of the body. <sup>9</sup>
<b>ENDPOINT</b>	<p>The measurement of a biological effect.</p> <p>The recorded observation coming from an in chemico method, an in vitro assay or an in vivo assay.</p> <p>A large number of endpoints are used in regulatory assessments of chemicals. These include lethality, carcinogenicity, immunological responses, organ effects, developmental and reproductive effects, etc. In QSAR analysis, it is important to develop models for individual toxic endpoints<sup>4</sup></p>
<b>ENVIRONMENT</b>	Waters (including ground, surface, transitional, coastal and marine), sediment, soil, air, land, fauna and flora, and any interrelationship between them, and any relationship with other living organisms

<sup>9</sup> Society of Endocrinology, UK. Retrieved from [www.yourhormones.info](http://www.yourhormones.info)

<b>ESTROGEN</b>	Estrogens are a group of steroid compounds that are the primary female sex hormones. They promote the development of female secondary sex characteristics and control aspects of regulating the menstrual cycle <sup>5</sup> .
<b>EU</b>	European Union
<b>EXPOSURE</b>	Concentration, amount, or intensity of a particular agent that reaches an organism or population. It is usually expressed in as substance concentration, duration, frequency, and/or intensity <sup>10</sup>
<b>FALSE POSITIVE</b>	Test result that is incorrect because the test indicated a condition or finding that is not real <sup>11</sup>
<b>FALSE NEGATIVE</b>	Test result that is incorrect because the test failed to recognise an existing condition or finding <sup>11</sup>
<b>FINANCIAL IMPACT</b>	Costs and benefits incurred by identified actors in relevant supply chains. Financial costs will generally include taxes, subsidies, depreciation, capital charges and other transfer payments <sup>4</sup>
<b>FOOD SAFETY</b>	Activities to protect the food supply from microbial, chemical, allergenic and physical hazards that may occur during all stages of food production and handling <sup>12</sup>
<b>FRICTION COST APPROACH</b>	A refinement of the human capital approach that proposes to estimate the true level of foregone production by restricting itself to the short-term impact of illness at the level of the firm; it does this by counting only the production lost while a replacement worker is found (i.e. it depends on the time that organisations require to restore initial production levels) <sup>4</sup>
<b>FUNGICIDE</b>	A substance used to kill fungi or eliminate/reduce unwanted effects of fungi
<b>GENOTOXIC</b>	agent (e.g. substance, radiation) or processes which alter the structure, information content, or segregation of DNA, including those which cause DNA damage by interfering with normal replication processes, or which in a non-physiological manner (temporarily) alter its replication. Genotoxicity test results are usually taken as indicators for mutagenic effects <sup>7</sup>
<b>GENUS</b>	Genus is part of the biological classification of organisms in biology and of the scientific binomial nomenclature: the genus name forms the first part of the binomial species name. For instance the crop "maize" has the scientific name <i>Zea mays</i> , being "Zea" the genus and "mays" the species name within the genus.
<b>GD</b>	Guidance Document
<b>GOOD PLANT</b>	A practice whereby the treatments with PPP applied to given plants

<sup>10</sup> Risk assessment terminology: [http://iupac.org/publications/ci/2001/march/risk\\_assessment.html](http://iupac.org/publications/ci/2001/march/risk_assessment.html)

<sup>11</sup> Definitions taken from [www.dictionary.com](http://www.dictionary.com)

<sup>12</sup> Glossary of food safety related terms. Appendix A. Retrieved from: [http://www1.agric.gov.ab.ca/\\$Department/deptdocs.nsf/all/afs12301/\\$FILE/appendix\\_a\\_glossary.pdf](http://www1.agric.gov.ab.ca/$Department/deptdocs.nsf/all/afs12301/$FILE/appendix_a_glossary.pdf)

<b>PROTECTION PRACTICE (GPPP)</b>	or plant products, in conformity with the conditions of their authorised uses, are selected, dosed and timed to ensure acceptable efficacy with the minimum quantity necessary, taking due account of local conditions and of the possibilities for cultural and biological control <sup>2</sup>
<b>HAZARD</b>	<p>A biological, chemical or physical agent with the potential to cause an adverse health effect.</p> <p>Hazard is anything that can cause harm, whereas risk is the potential that a hazard will cause harm. In other words a hazard will not pose any risk unless exposure to that hazard is high enough so that it may cause harm. Risks associated with hazards can be zero, or at least greatly reduced, by reducing exposure. For instance, a knife – a hazardous object per se - would be banned completely if the decision is taken based on hazard, while it would be allowed for certain uses or restricted (e.g. not allowed for small children) if the decision is taken based on risk. Similarly, a substance (e.g. a drug or a pesticide active substance) is banned if the regulatory decision is based on its hazard, while it is allowed for certain uses, under certain (restricted) conditions and doses, if the decision is taken based on risk.</p>
<b>HAZARD ASSESSMENT</b>	<p>Process designed to determine factors contributing to the possible adverse effects of a substance to which a human population or an environmental compartment could be exposed. The process includes three steps: hazard identification, hazard characterisation, and hazard evaluation</p> <p><u>Note:</u> Factors may include mechanisms of toxicity, dose-effect and dose-response relationships, variations in target susceptibility, etc.<sup>10</sup></p>
<b>HAZARD CHARACTERISATION</b>	<p>The second step in the process of hazard assessment, consisting in the qualitative and, wherever possible, quantitative description of the nature of the hazard associated with a biological, chemical, or physical agent, based on one or more elements, such as mechanisms of action involved, biological extrapolation, dose-response and dose-effect relationships, and their respective uncertainties<sup>10</sup></p>
<b>HAZARD IDENTIFICATION</b>	<p>The first stage in hazard assessment, consisting of the determination of substances of concern, the adverse effects they may have inherently on target systems under certain conditions of exposure, taking into account toxicity data</p> <p><u>Note:</u> Definitions may vary in wording, depending on the context. Thus, here: [RISK ASSESSMENT] the first stage in risk assessment, consisting of the determination of particular hazards a given target system may be exposed to, including attendant toxicity data.<sup>10</sup></p>
<b>HEALTH IMPACTS</b>	Impacts on human health including morbidity and mortality effects.



	Covers health related welfare effects, lost production due to workers' sickness and health care costs <sup>4</sup>
<b>HEALTHY LIFE YEARS (HLY)</b>	Also called disability-free life expectancy (DFLE), is defined as the number of years that a person is expected to continue to live in a healthy condition <sup>2</sup>
<b>HERBICIDE</b>	A substance used to destroy or inhibit the growth of plants, especially weeds
<b>HORMONE</b>	Made by endocrine glands, hormones are chemical messengers that travel in the bloodstream to tissues or organs. They affect many processes, including growth, metabolism, sexual function, reproduction, and mood
<b>HUMAN CAPITAL APPROACH</b>	Measurement approach to estimate the value of production losses due to illness, disability or premature death, achieved by multiplying the total period of absence by the wage rate of the absent worker. This would be consistent with neo-classical theory where the firm employs labour to the point where the value of the marginal product of a worker is equated to the wage rate. The main limitation of the approach is that it (unrealistically) assumes the presence of full employment in the economy, and by focusing only on the productive capacity of individuals, ignores other benefits of improved health status <sup>4</sup>
<b>IC50</b>	Half maximal inhibitory concentration
<b>IMPORT TOLERANCES</b>	An MRL set for imported products to meet the needs of international trade where: <ul style="list-style-type: none"> <li>- the use of the active substance in a PPP on a given product is not authorised in the Community for reasons other than public health reasons for the specific product and specific use;</li> </ul> or <ul style="list-style-type: none"> <li>- a different level is appropriate because the existing Community MRL was set for reasons other than public health reasons for the specific product and specific use<sup>13</sup></li> </ul>
<b>INCIDENCE</b>	The number of new cases of disease in a defined population over a specific time period <sup>14</sup>
<b>INSECTICIDE</b>	A substance used to kill insects or eliminate/reduce unwanted effects of insects
<b>INTACT ORGANISM</b>	Not in vitro systems, or castrated or ovariectomised test animals <sup>5</sup>
<b>IN VITRO</b>	In an artificial environment outside a living organism or body <sup>14</sup>
<b>IN VIVO</b>	Within a living organism or body <sup>14</sup>
<b>IN VITRO ASSAY</b>	Assay where whole live animals are not used. Systems used may include cell lines or subcellular preparations from untreated animals <sup>5</sup>

<sup>13</sup> Regulation (EC) No 396/2005 of the European Parliament and of the Council 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

<sup>14</sup> Centers for Disease Control and Prevention (CDC). Retrieved from: <http://www.cdc.gov/>

<b>IN VIVO ASSAY</b>	Assay where a whole live animal is treated. This may be a mammalian assay where individual animals are treated or a wildlife assay where a population of animals is treated <sup>5</sup>
<b>IN SILICO METHODS</b>	The expression in silico is used to mean „performed on computer or via computer simulation“. The phrase was coined in 1989 as an analogy to the Latin phrases in vivo and in vitro which are commonly used in biology and refer to experiments done in living organisms and outside of living organisms, respectively <sup>5</sup>
<b>JRC</b>	Joint Research Centre
<b>LIMIT OF DETERMINATION (LOD)</b>	The lowest residue concentration which can be quantified and reported by routine monitoring with validated control methods <sup>13</sup>
<b>M1 (MUTAGEN CATEGORY 1)</b>	substances known to induce heritable mutations in the germ cells of humans, according to Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures <sup>7</sup>
<b>M2 (MUTAGEN CATEGORY 2)</b>	substances which cause concern for humans owing to the possibility that they may induce heritable mutations in the germ cells of humans, according to Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures.
<b>MAXIMUM RESIDUE LEVEL (MRL)</b>	The upper legal level of a concentration for a pesticide residue in or on food or feed set in accordance with Regulation (EC) No 396/2005, based on good agricultural practice and the lowest consumer exposure necessary to protect vulnerable consumers <sup>13</sup>
<b>MECHANISM OF ACTION</b>	Sequence of events leading from the absorption of an effective dose of a chemical to the production of a specific biological response in the target organ.  Understanding a chemical's mechanism requires appreciation of the causality and temporal relationships between the steps leading to a particular toxic endpoint, as well as the steps that lead to an effective dose of the chemical at the relevant biological target(s).  Mechanism of action for toxicity is the detailed molecular description of key events in the induction of cancer or other health endpoints. Mechanism of action represents a more detailed understanding and description of events than is meant by mode of action <sup>4</sup>
<b>(ENDOCRINE) MODALITY</b>	A modality is an axis, pathway, signalling process or hormonal mechanism within the endocrine system <sup>5</sup>
<b>MODE OF ACTION (MOA)</b>	A biologically plausible sequence of key events leading to an observed effect supported by robust experimental observations and mechanistic data. A mode of action describes key cytological and biochemical events – that is, those that are both measurable and necessary to the observed effect – in a logical framework <sup>5</sup>
<b>MOLECULAR INITIATING EVENT</b>	The initial point of chemical-biological interaction within the organism that starts the pathway.  Direct interaction of a chemical with specific biomolecules.

	<p>The molecular level, chemical-induced perturbation of a biological system.</p> <p>Chemical interaction at a molecular target leading to a particular adverse outcome<sup>4</sup></p>
<b>MS</b>	Member State
<b>MULTI-CRITERIA ANALYSIS (MCA)</b>	A computing technique which compares options and that involves assigning weights to criteria across the options will be compared, and then scoring options in terms of how well they perform against those weighted criteria. Weighted scores are then summed, and can then be used to rank options <sup>4</sup>
<b>MUTATION</b>	a permanent change in the amount or structure of the genetic material in a cell. The term ‘mutation’ applies both to heritable genetic changes that may be manifested at the phenotypic level and to the underlying DNA modifications when known (including specific base pair changes and chromosomal translocations) <sup>7</sup>
<b>MUTAGEN</b>	Agent (e.g. substance, radiation) giving rise to an increased occurrence of mutations in populations of cells and/or organisms. <sup>7</sup>
<b>NOAEL</b>	No Observed Adverse Effect Level
<b>NON APICAL ENDPOINT</b>	<p>Alternative, suborganism-level, in vitro responses, biomarkers, QSARs, genomics.</p> <p>Intermediate event or step at a level of biological organisation below that of the apical endpoint<sup>4</sup></p>
<b>OBESITY</b>	The condition of severe overweight where a person has a body mass index (BMI) equal to or greater than 30 <sup>15</sup>
<b>OBESITY RATE</b>	The proportion of the total population (or of a subgroup based on gender, age, etc.) with a BMI of 30 or above <sup>2</sup>
<b>OECD</b>	Organisation for Economic Co-operation and Development
<b>PATHOGENIC ORGANISM</b>	Organism causing or capable of causing disease <sup>14</sup>
<b>PLANT PROTECTION PRODUCTS (PPP)</b>	<p>Plant protection products (PPP) protect crops as well as desirable or useful plants. They are used in agriculture, forestry, horticulture, industrial areas (e.g. railways), amenity areas and in gardens.</p> <p>PPP are formulated products (e.g. liquid concentrates, wettable powder, granules) that contain at least one active substance that is responsible for the effect of the PPP, which could be a chemical, a plant extract, a pheromone or a micro-organism (including viruses).</p>
<b>POTENCY</b>	It's a measure of a substance's ability to produce an (adverse) effect. The higher the potency of a substance, the lower the dose sufficient to produce a certain adverse effect
<b>PPP REGULATION</b>	Plant Protection Products Regulation
<b>PRESENT VALUE</b>	The future value of an impact expressed in present terms by

<sup>15</sup> EUROSTAT: Health glossary, available on: [http://ec.europa.eu/eurostat/statistics-explained/index.php/Category:Health\\_glossary](http://ec.europa.eu/eurostat/statistics-explained/index.php/Category:Health_glossary)

	means of discounting
<b>PREVALENCE</b>	The number of existing disease cases in a defined population during a specific period <sup>14</sup>
<b>PRICE ELASTICITY</b>	A measure of the responsiveness of demand to a change in price. If demand changes proportionally more than the price has changed, the good is “price elastic”. An elasticity of 1 means that an 1% increase in price leads to a fall in demand of 1%. An elasticity of 0.5 means that a 1% change in the price leads to a fall in demand of 0.5%. If demand changes proportionally less than the price, it is “price inelastic” <sup>4</sup>
<b>QUANTITATIVE STRUCTURE ACTIVITY RELATIONSHIP (QSAR)</b>	(Q)SARs are methods for estimating properties of a chemical from its molecular structure and have the potential to provide information on hazards of chemicals, while reducing time, monetary cost and animal testing currently needed <sup>5</sup>
<b>TOXIC FOR REPRODUCTION (OR REPRODUCTIVE TOXICANT)</b>	Substance which induce reproductive toxicity or increase its incidence. Reproductive toxicity includes adverse effects on sexual function and fertility in adult males and females, as well as developmental toxicity in the offspring <sup>7</sup>
<b>R1 (TOXIC FOR REPRODUCTION CATEGORY 1)</b>	Known or presumed human reproductive toxicant, according to Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures <sup>7</sup>
<b>R2 (TOXIC FOR REPRODUCTION CATEGORY 2)</b>	Suspected human reproductive toxicant, according to Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures <sup>7</sup>
<b>REACH</b>	Registration, Evaluation, Authorisation and Restriction of Chemicals
<b>RESIDUES</b>	One or more substances present in or on plants or plant products, edible animal products, drinking water or elsewhere in the environment and resulting from the use of a PPP, including their metabolites, breakdown or reaction products <sup>2</sup>
<b>RISK</b>	A function of the probability of an adverse health effect and the severity of that effect, consequential to a hazard <sup>10</sup> Risk is the potential that a hazard will cause harm. Risks associated with hazards can be zero, or at least greatly reduced, by reducing exposure. For instance, a knife – a hazardous object per se - would be banned completely if the decision is taken based on hazard, while it would be allowed for certain uses or restricted (e.g. not allowed for small children) if the decision is taken based on risk. Similarly, a substance (e.g. a drug or a pesticide active substance) is banned if the regulatory decision is based on its hazard, while it is allowed for certain uses, under certain (restricted) conditions and doses, if the decision is taken based on risk.
<b>RISK ASSESSMENT</b>	A scientifically based process consisting of four steps: hazard identification, hazard characterisation, exposure assessment and risk characterisation <sup>10</sup> , which calculates which and how bit the risk of adverse effects happening is after exposure to a certain hazard.

<b>RISK MANAGEMENT</b>	The process, distinct from risk assessment, of weighing policy alternatives in consultation with interested parties, considering risk assessment and other legitimate factors, and, if need be, selecting appropriate prevention and control options <sup>10</sup>
<b>S</b>	Steroidogenesis pathway
<b>SCCS</b>	Scientific Committee on Consumer Safety
<b>SENSITIVITY ANALYSIS</b>	A “what-if” type of analysis to determine the sensitivity of the outcomes of an analysis to changes in parameters. If a small change in a parameter results in relatively large changes in the outcomes, the outcomes are said to be sensitive to that parameter <sup>4</sup>
<b>SIN</b>	Substitute It Now
<b>SOCIAL COSTS</b>	Denotes the opportunity cost to society and includes also external costs or externalities <sup>4</sup>
<b>STEROIDS</b>	Any of various molecules—including hormones—that contain a particular arrangement of carbon rings. Some common steroids include sex steroids, corticosteroids, anabolic steroids, and cholesterol <sup>16</sup>
<b>STOT-RE</b>	Specific Target Organ Toxicity - Repeated Exposure
<b>SUBSTANCES</b>	Chemical elements and their compounds, as they occur naturally or by manufacture, including any impurity inevitably resulting from the manufacturing process <sup>2</sup>
<b>SVHC</b>	Substance of Very High Concern
<b>SYSTEMATIC REVIEW</b>	A systematic review is a method to review scientific literature. It attempts to identify, appraise and synthesize all the empirical evidence that meets pre-specified eligibility criteria to answer a given research question. Researchers conducting systematic reviews use explicit methods aimed at minimizing bias, in order to produce more reliable findings that can be used to inform decision making. (See Section 1.2 in the Cochrane Handbook for Systematic Reviews of Interventions.) <a href="http://www.cochranelibrary.com/about/about-cochrane-systematic-reviews.html">http://www.cochranelibrary.com/about/about-cochrane-systematic-reviews.html</a>
<b>T</b>	Thyroid pathway
<b>TEDX</b>	The Endocrine Disruptor eXchange
<b>ToxCast</b>	Database of <i>in vitro</i> assay data from US Environmental Protection Agency (EPA)
<b>TREATED ARTICLES</b>	Any substance, mixture or article which has been treated with, or intentionally incorporates, one or more BP <sup>1</sup>
<b>THYROID HORMONE</b>	The thyroid gland makes T3 (triiodothyronine) and T4 (thyroxine), which together are considered thyroid hormone. T3 and T4 have identical effects on cells. Thyroid hormone affects heart rate, blood pressure, body temperature, and weight. T3 and T4 are stored as thyroglobulin, which can be converted back into T3 and T4 <sup>5</sup>

<sup>16</sup> Endocrine society website. Retrieved from: <https://www.endocrine.org/news-room/glossary>

<b>UNCERTAINTY</b>	This is a state characterising a situation where related parameters are not known or fixed or certain. It stems from a lack of information, scientific knowledge or ignorance and is a characteristic of all predictive assessments <sup>4</sup>
<b>VECTOR</b>	A vector is an organism, often an invertebrate arthropod, that transmits diseases (it transmits a pathogen from reservoir to host).
<b>VULNERABLE GROUPS</b>	Persons or group of population to be expected to be at higher risk and therefore need specific consideration when assessing the potential health effects of BP or PPP. These include pregnant and nursing women, the unborn, infants and children, the elderly and, when subject to high exposure to BP or PPP over the long term, workers and residents <sup>1</sup>
<b>WFD</b>	Water Framework Directive
<b>WHO</b>	World Health Organization
<b>WILLINGNESS TO PAY (WTP)</b>	Technique to elicit the value that individuals place on an economic resource or change in welfare by observing how much a person is willing to pay in order to obtain it. In the case of market transactions, WTP is observed directly and amounts to the price that is paid, while the valuation of non-market services and goods (such as the value of human life or the value of pain/suffering) might require the use of indirect measures, such as revealed choices or stated preferences <sup>3</sup>
<b>WEIGHT-OF-EVIDENCE (WOE)</b>	A process in which all of the evidence considered relevant to a decision is evaluated and weighted <sup>5</sup>
<b>WILDLIFE</b>	Non-target species. This term does not cover wildlife intended to be controlled by the application of regulated products (i.e. target species) <sup>5</sup>
<b>VALIDATED ASSAY</b>	A test method for which validation studies have been completed to determine the relevance (including accuracy) and reliability for a specific purpose. It is important to note that a validated test method may not have sufficient performance in terms of accuracy and reliability to be found acceptable for the proposed purpose <sup>5</sup>

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