



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

A	Androgenic pathway
AC50	Half maximal active concentration
ACTIVE SUBSTANCE (AS)	In the context of the PPP and BP Regulations, a substance or a micro-organism that has an action on or against harmful organisms ^{1,2}
ADVERSE EFFECT	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 ³
ADVERSE OUTCOME PATHWAY (AOP)	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 ⁴
ANDROGEN	Androgens are steroidhormones that help to develop sex organs in men. They also contribute to sexual function in men and women ⁵
ANTISEPSIS	Preventing or stopping the growth of microorganisms
APICAL ENDPOINT	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 ⁴ 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

¹ 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

² 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

³ 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>.

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

⁵ 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) ⁵
APICAL TEST	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)
AUTOCHTHONOUS CASE	Case caused by a pathogen indigenous or endemic to a region
BENEFITS	The positive implications, direct and indirect, resulting from some action. This includes both financial and non-financial information ⁶
BIOCIDAL PRODUCT (BP)	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).
BP REGULATION	Biocidal Products Regulation
C1 (CARCINOGEN CATEGORY 1)	Known or presumed human carcinogen, according to Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures ⁷
C2 (CARCINOGEN CATEGORY 2)	Suspected human carcinogen, according to Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures ⁷
CAR	Competent Authority Report
CARCINOGEN	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 ⁷
CLP	Classification, Labelling and Packaging
CMR	Carcinogenic, Mutagenic, Reprotoxic

⁶ 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

⁷ 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.

CoRAP	Community Rolling Action Plan
COSTS	The negative implications, direct and indirect, resulting from some actions. Includes both financial and non-financial information ⁴
COST BENEFIT ANALYSIS (CBA)	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 ⁴
COST EFFECTIVENESS ANALYSIS (CEA)	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 ⁴
COST-OF-ILLNESS (COI)	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 ⁸
CUT-OFF CRITERIA	<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. 1107/2009² and <i>exclusion criteria</i> in Reg. 528/2012¹.</p> <p>In Reg. 1107/2009, <i>approval criteria</i> are:</p> <ul style="list-style-type: none"> - 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>); - based on a strong hazard component for other classes of substances (<i>carcinogens, toxic for reproduction, endocrine disruptors</i>). <p>In Reg. 528/2012, <i>exclusion criteria</i> are:</p> <ul style="list-style-type: none"> - 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; - based on a strong hazard component for the same classes of substances when used by professional users.
DAR	Draft Assessment Report
DG	Directorate General
DISCOUNT RATE	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

⁸ WHO. 2009. WHO guide to identifying the economic consequences of disease and injury. Geneva.

	to decrease over time ⁴
DISCOUNTING	A method used to convert future costs or benefits to present values using a discount rate ⁴
DOSE-RESPONSE CURVE	Graphical presentation of a dose-response relationship ¹⁰
DOSE-RESPONSE RELATIONSHIP	<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"¹⁰</p>
DOWNSTREAM USER	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 ⁴
E	Estrogenic pathway
EASIS	Endocrine Active Substances Information System
EATS	Estrogen, Androgen, Thyroid and Steroidogenesis
ECONOMIC IMPACTS	Costs and benefits to manufacturers, importers, downstream users, distributors, consumers and society as a whole ⁴
ECHA	European Chemicals Agency
EC50	Half maximal effective concentration
ED	Endocrine disruptor
EDSP	Endocrine Disruptor Screening Program
EFSA	European Food Safety Authority
ENDOCRINE / HORMONE SYSTEM	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. ⁹
ENDPOINT	<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 endpoints⁴</p>
ENVIRONMENT	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

⁹ Society of Endocrinology, UK. Retrieved from www.yourhormones.info

ESTROGEN	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 ⁵ .
EU	European Union
EXPOSURE	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 ¹⁰
FALSE POSITIVE	Test result that is incorrect because the test indicated a condition or finding that is not real ¹¹
FALSE NEGATIVE	Test result that is incorrect because the test failed to recognise an existing condition or finding ¹¹
FINANCIAL IMPACT	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 ⁴
FOOD SAFETY	Activities to protect the food supply from microbial, chemical, allergenic and physical hazards that may occur during all stages of food production and handling ¹²
FRICTION COST APPROACH	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) ⁴
FUNGICIDE	A substance used to kill fungi or eliminate/reduce unwanted effects of fungi
GENOTOXIC	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 ⁷
GENUS	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.
GD	Guidance Document
GOOD PLANT	A practice whereby the treatments with PPP applied to given plants

¹⁰ Risk assessment terminology: http://iupac.org/publications/ci/2001/march/risk_assessment.html

¹¹ Definitions taken from www.dictionary.com

¹² 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)

PROTECTION PRACTICE (GPPP)	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 ²
HAZARD	<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>
HAZARD ASSESSMENT	<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.¹⁰</p>
HAZARD CHARACTERISATION	<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 uncertainties¹⁰</p>
HAZARD IDENTIFICATION	<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.¹⁰</p>
HEALTH IMPACTS	Impacts on human health including morbidity and mortality effects.

	Covers health related welfare effects, lost production due to workers' sickness and health care costs ⁴
HEALTHY LIFE YEARS (HLY)	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 ²
HERBICIDE	A substance used to destroy or inhibit the growth of plants, especially weeds
HORMONE	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
HUMAN CAPITAL APPROACH	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 ⁴
IC50	Half maximal inhibitory concentration
IMPORT TOLERANCES	An MRL set for imported products to meet the needs of international trade where: <ul style="list-style-type: none"> - 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; or <ul style="list-style-type: none"> - 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 use¹³
INCIDENCE	The number of new cases of disease in a defined population over a specific time period ¹⁴
INSECTICIDE	A substance used to kill insects or eliminate/reduce unwanted effects of insects
INTACT ORGANISM	Not in vitro systems, or castrated or ovariectomised test animals ⁵
IN VITRO	In an artificial environment outside a living organism or body ¹⁴
IN VIVO	Within a living organism or body ¹⁴
IN VITRO ASSAY	Assay where whole live animals are not used. Systems used may include cell lines or subcellular preparations from untreated animals ⁵

¹³ 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

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

IN VIVO ASSAY	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 ⁵
IN SILICO METHODS	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 ⁵
JRC	Joint Research Centre
LIMIT OF DETERMINATION (LOD)	The lowest residue concentration which can be quantified and reported by routine monitoring with validated control methods ¹³
M1 (MUTAGEN CATEGORY 1)	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 ⁷
M2 (MUTAGEN CATEGORY 2)	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.
MAXIMUM RESIDUE LEVEL (MRL)	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 ¹³
MECHANISM OF ACTION	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 ⁴
(ENDOCRINE) MODALITY	A modality is an axis, pathway, signalling process or hormonal mechanism within the endocrine system ⁵
MODE OF ACTION (MOA)	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 ⁵
MOLECULAR INITIATING EVENT	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 outcome⁴</p>
MS	Member State
MULTI-CRITERIA ANALYSIS (MCA)	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 ⁴
MUTATION	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) ⁷
MUTAGEN	Agent (e.g. substance, radiation) giving rise to an increased occurrence of mutations in populations of cells and/or organisms. ⁷
NOAEL	No Observed Adverse Effect Level
NON APICAL ENDPOINT	<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 endpoint⁴</p>
OBESITY	The condition of severe overweight where a person has a body mass index (BMI) equal to or greater than 30 ¹⁵
OBESITY RATE	The proportion of the total population (or of a subgroup based on gender, age, etc.) with a BMI of 30 or above ²
OECD	Organisation for Economic Co-operation and Development
PATHOGENIC ORGANISM	Organism causing or capable of causing disease ¹⁴
PLANT PROTECTION PRODUCTS (PPP)	<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>
POTENCY	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
PPP REGULATION	Plant Protection Products Regulation
PRESENT VALUE	The future value of an impact expressed in present terms by

¹⁵ EUROSTAT: Health glossary, available on: http://ec.europa.eu/eurostat/statistics-explained/index.php/Category:Health_glossary

	means of discounting
PREVALENCE	The number of existing disease cases in a defined population during a specific period ¹⁴
PRICE ELASTICITY	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 a 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” ⁴
QUANTITATIVE STRUCTURE ACTIVITY RELATIONSHIP (QSAR)	(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 ⁵
TOXIC FOR REPRODUCTION (OR REPRODUCTIVE TOXICANT)	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 ⁷
R1 (TOXIC FOR REPRODUCTION CATEGORY 1)	Known or presumed human reproductive toxicant, according to Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures ⁷
R2 (TOXIC FOR REPRODUCTION CATEGORY 2)	Suspected human reproductive toxicant, according to Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures ⁷
REACH	Registration, Evaluation, Authorisation and Restriction of Chemicals
RESIDUES	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 ²
RISK	A function of the probability of an adverse health effect and the severity of that effect, consequential to a hazard ¹⁰ 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.
RISK ASSESSMENT	A scientifically based process consisting of four steps: hazard identification, hazard characterisation, exposure assessment and risk characterisation ¹⁰ , which calculates which and how bit the risk of adverse effects happening is after exposure to a certain hazard.

RISK MANAGEMENT	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 ¹⁰
S	Steroidogenesis pathway
SCCS	Scientific Committee on Consumer Safety
SENSITIVITY ANALYSIS	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 ⁴
SIN	Substitute It Now
SOCIAL COSTS	Denotes the opportunity cost to society and includes also external costs or externalities ⁴
STEROIDS	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 ¹⁶
STOT-RE	Specific Target Organ Toxicity - Repeated Exposure
SUBSTANCES	Chemical elements and their compounds, as they occur naturally or by manufacture, including any impurity inevitably resulting from the manufacturing process ²
SVHC	Substance of Very High Concern
SYSTEMATIC REVIEW	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.) http://www.cochranelibrary.com/about/about-cochrane-systematic-reviews.html
T	Thyroid pathway
TEDX	The Endocrine Disruptor eXchange
TOXCAST	Database of <i>in vitro</i> assay data from US Environmental Protection Agency (EPA)
TREATED ARTICLES	Any substance, mixture or article which has been treated with, or intentionally incorporates, one or more BP ¹
THYROID HORMONE	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 ⁵

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

UNCERTAINTY	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 ⁴
VECTOR	A vector is an organism, often an invertebrate arthropod, that transmits diseases (it transmits a pathogen from reservoir to host).
VULNERABLE GROUPS	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 ¹
WFD	Water Framework Directive
WHO	World Health Organization
WILLINGNESS TO PAY (WTP)	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 ³
WEIGHT-OF-EVIDENCE (Woe)	A process in which all of the evidence considered relevant to a decision is evaluated and weighted ⁵
WILDLIFE	Non-target species. This term does not cover wildlife intended to be controlled by the application of regulated products (i.e. target species) ⁵
VALIDATED ASSAY	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 ⁵

BIBLIOGRAPHY

- Acquavella J, Olsen G, Cole P, Ireland B, Kaneene J, Schuman S et al. 1998. Cancer among farmers: a meta-analysis. *Ann Epidemiol* 8:64–74
- Aise. Biocides 2015, 18th Annual Conference, Vienna, November 2015.
- Akobundu E, Jing J, Blatt L, et al. 2006. Cost-of-illness studies: a review of current methods. *Pharmacoeconomics*. 24(9):869-90.
- Alavanja MC, Sandler DP, McMaster SB, Zahm SH, McDonnell CJ, Lynch CF et al. 1996. Characteristics of pesticide use in a pesticide applicator cohort: the Agricultural Health Study. *Environ Health Perspect* 104: 362–369
- Allegranzi B, Pittet D. 2009. Role of hand hygiene in healthcare-associated infection prevention. *J Hosp Infect*. 73(4):305-15.
- Ament A., Evers S. 1993. Cost of illness studies in health care: a comparison of two cases. *Health Policy* 26: 29-42
- Anania, G. 2015. The role of trade policies, multinationals, shipping modes and product differentiation in global value chains for bananas. The case of Cameroon. International Conference of Agricultural Economists. Milan 29th May, 2015, published on the African Journal of Agricultural and Resource Economics 2015; 10(3): 174-191. Retrieved from: <http://ageconsearch.umn.edu/bitstream/211666/2/1%20Anania.pdf>
- Anses. 2014. Opinion of the French Agency for Food, Environmental and Occupational Health & Safety on the INSERM collective expert appraisal report “Pesticides. Health effects”. Request No. 2013-SA-0116. Retrieved from <https://www.anses.fr/en/system/files/PHYTO2013sa0116EN.pdf>
- Arcadia International. 2013. Ad-hoc study to support the initial establishment of the list of candidates for substitution as required in Article 80(7) of Regulation (EC) No 1107/2009. Framework Contract for evaluation and evaluation related services - Lot 3: Food Chain. Final Report, retrieved from: http://ec.europa.eu/food/plant/pesticides/approval_active_substances/docs/cfs_final_report_072013_en.pdf. Additional information available on: http://ec.europa.eu/food/plant/pesticides/approval_active_substances/index_en.htm
- Astrup, H., Barileb, F. A., Blaauboerc, B. J., Degend, G. H., Dekant, W., Dietrich, D., Domingog, J. L., Gorih G. B., Greim, H., Hengstlerd, J. G., Kacewj, S., Marquardtk, H., Pelkonenl, O., Savolainenm, K., and Vermeulenn, N. P. 2015. Principles of Pharmacology and Toxicology also Govern Effects of Chemicals on the Endocrine System. *Toxicol Sci*. Jul;146(1):11-5. Retrieved from: <http://www.ncbi.nlm.nih.gov/pubmed/26026993>
- Baldacchino F, Caputo B, Chandre F, Drago A, della Torre A, Montarsi F, et al. 2015. Control methods against invasive *Aedes* mosquitoes in Europe: a review. *Pest Manag Sci*. 71(11):1471-85.
- Bars, R. et al. 2012. Risk assessment of endocrine active chemicals: Identifying chemicals of regulatory concern. *Regulatory Toxicology and Pharmacology* 64 (1): 143-154. doi:10.1016/j.yrtph.2012.06.013
- Beausoleil et al. 2016. Review of non-monotonic dose-responses of substances for human risk assessment. EFSA supporting publication 2016:EN-1027. 290pp.
- Bellanger, M., Demeneix, B., Grandjean, P., Zoeller, R. T., & Trasande, L. 2015. Neurobehavioral Deficits, Diseases, and Associated Costs of Exposure to Endocrine-Disrupting Chemicals in the European Union. *The Journal of Clinical Endocrinology & Metabolism*. 100(4):1256-1266. DOI <http://dx.doi.org/10.1210/jc.2014-4324>
- Belli, N., et al. 2007. Effect of chemical treatments on ochratoxigenic fungi and common mycobiota of grapes. *Journal of Food Protection* 70: 157-163.
- Bellini R, Zeller H, Van Bortel W. 2014. A review of the vector management methods to prevent and control outbreaks of West Nile virus infection and the challenge for Europe. *Parasit Vectors*. 7:323.

- Bergman Å, Heindel J, Jobling S, Kidd KA, Zoeller RT, 2012. eds. State of the science of endocrine disrupting chemicals, Geneva: United Nations Environment Programme and the World Health Organization, 2013, retrieved from: http://unep.org/pdf/9789241505031_eng.pdf
- Bergman, Å., et al. 2015. Manufacturing doubt about endocrine disrupter science – A rebuttal of industry-sponsored critical comments on the UNEP/WHO report “State of the Science of Endocrine Disrupting Chemicals 2012”, *Regulatory Toxicology and Pharmacology* 73 (3) 1007-1017, ISSN 0273-2300. Doi: 10.1016/j.yrtph.2015.07.026.
- Bern, H et al. 1992. Statement from the work session on chemically-induced alterations in sexual development: the wildlife/human connection. pp 1-8 in *Chemically-Induced Alterations in Sexual and Functional Development: The Wildlife/Human Connection*. Eds. Colborn T. and Clement C., Princeton Scientific Publishing Co., NJ, U.S. Retrieved from: <http://www.ourstolenfuture.org/consensus/wingspread1.htm>
- Bernard H, Faber M, Wilking H, Haller S, Hohle M, Schielke A, et al. 2014. Large multistate outbreak of norovirus gastroenteritis associated with frozen strawberries, Germany, 2012. *Euro surveillance : bulletin European sur les maladies transmissibles = European communicable disease bulletin*. 19(8):20719.
- BfR. 2016. International Expert Meeting on Endocrine Disruptors (Berlin, April 2016). Available at: http://www.bfr.bund.de/en/international_expert_meeting_on_endocrine_disruptors-197246.html
- Blair A, Beane Freeman L. 2009. Epidemiologic studies of cancer in agricultural populations: observations and future directions. *J Agromed* 14:125–131
- Blair A, Dosemeci M, Heineman EF . 1993. Cancer and other causes of death among male and female farmers from twenty-three states. *Am J Ind Med* 23:729–742
- Boeing H, Dietrich T, Hoffmann K, Pischon T, Ferrari P, Lahmann PH et al. 2006. Intake of fruits and vegetables and risk of cancer of the upper aero-digestive tract: the prospective EPIC-study. *Cancer Causes and Control*. 17:957– 969.
- Bolt HM, Janning P, Michna H, Degen GH. 2001. Comparative assessment of endocrine modulators with oestrogenic activity: I. Definition of a hygiene-based margin of safety (HBMOS) for xeno-oestrogens against the background of European developments. *Archives of Toxicology*. 74: 649-662. Retrieved from: <http://www.ncbi.nlm.nih.gov/pubmed/11218041>
- Borgert, C. J., Baker, S. P., and Matthews, J. C. 2013. Potency matters: thresholds govern endocrine activity. *Regul. Toxicol. Pharmacol.*, 67, 83–88.
- Borgert, C.J., E.V. Sargent, G. Casella, D.R. Dietrich, L.S. McCarty, R.J. Golden. 2011. The human relevant potency threshold: Reducing uncertainty by human calibration of cumulative risk assessments, *Regulatory Toxicology and Pharmacology*. 62 (2): 313-328, doi.org/10.1016/j.yrtph.2011.10.012.
- Boyce JM. 2011. Measuring healthcare worker hand hygiene activity: current practices and emerging technologies. *Infect Control Hosp Epidemiol*. 32(10):1016-28.
- Bull FC, Armstrong TP, Dixon TD, Ham S, Neiman A, Pratt M. 2004. Physical inactivity. In: Ezzati M, Lopez A, Rodgers A, Murray CJL, eds. *Comparative quantification of health risks: global and regional burden of disease attributable to selected major risk factors*. Geneva, World Health Organization.
- BusinessWire. 2013. Research and Markets: Global Biocides Market 2013 Report. Retrieved from: <http://www.businesswire.com/news/home/20130709005713/en/Research-Markets-Global-Biocides-Market-2013-Report>
- Butland B., Jebb S., Kopelman P., et al. 2007. Foresight. Tackling obesity: future choices—project report, Government Office for Science, London. Retrieved from: https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/287937/07-1184x-tackling-obesity-future-choices-report.pdf.
- Carré, P., Pouzet, A. 2014. Rapeseed market, worldwide and in Europe. *Oilseeds & fats Crops and Lipids (OCL)* 21(1). DOI: 10.1051/ocl/2013054
- Cartier C., Warembourg C., Le Maner-Idrissi G., Lacroix A., Rouget F., Monfort C., Limon G., Durand G., Saint-Amour D., Cordier S., Chevrier C. 2015. Organophosphate Insecticide Metabolites in Prenatal and

- Childhood Urine Samples and Intelligence Scores at 6 Years of Age: Results from the Mother-Child PELAGIE Cohort (France). *Environ Health Perspect*. DOI: <http://dx.doi.org/10.1289/ehp.1409472>
- Cefic. 2009. Final Report of the High Level Group on Competitiveness of the European Chemicals Industry. Retrieved from: <http://www.cefic.org/Documents/PolicyCentre/HLG-Chemical-Final-report-2009.pdf>
- Cefic. 2016. Cefic-EBPF information for the socio-economic analysis part of the impact assessment on criteria to identify endocrine disruptors.
- Cefic. 2016. The European Chemical Industry Council. Facts and figures 2016. Retrieved on: <http://www.cefic.org/Facts-and-Figures/>
- Centers for Disease Control and Prevention. 2008. Guideline for disinfection and sterilization in healthcare facilities 2008. Retrieved from: http://www.cdc.gov/hicpac/pdf/guidelines/Disinfection_Nov_2008.pdf
- Champeil, A., J.F. Fourbet, T. Dore, L. Rossignol. 2004. Influence of cropping system on Fusarium head blight and mycotoxin levels in winter wheat. *Crop Protection* 23:531–537, p 531.
- Chen YC, Sheng WH, Wang JT, Chang SC, Lin HC, Tien KL, et al. 2011. Effectiveness and limitations of hand hygiene promotion on decreasing healthcare-associated infections. *PloS One*. 6(11):e27163.
- Clabaugh G., Ward M.M. 2008. Cost-of-illness studies in the United States: a systematic review of methodologies used for direct cost. *Value Health* 11(1):13-21. DOI <http://dx.doi.org/10.1111/j.1524-4733.2007.00210>
- Commission Directive 2011/71/EU of 26 July 2011 amending Directive 98/8/EC of the European Parliament and of the Council to include creosote as an active substance in Annex I thereto Text with EEA relevance. OJ L 195. 27 May 2011.
- Commission Regulation (EC) No 1881/2006 of 19 December 2006 setting maximum levels for certain contaminants in foodstuffs. Retrieved from: http://ec.europa.eu/food/safety/chemical_safety/contaminants/legislation/index_en.htm.
- Commission Regulation (EU) No 284/2013 of 1 March 2013 setting out the data requirements for plant protection products, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market Text with EEA relevance Communications 2013/C 95/01 and 2013/C 95/02, detailing the list of test methods and guidance documents for active substances and for PPP, respectively. OJ L 93. 3 April 2013.
- 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 of the European Parliament and of the Council concerning the placing of plant protection products on the market Text with EEA relevance. OJ L 93. 3 April 2013
- Cooper BS, Rice DP. 1976. The economic cost of illness revisited. *Soc Secur Bull* 39(2):21-36, who conclude that estimates based on the human capital approach, reformulated using a willingness-to-pay criterion, produce the only clear, consistent, and objective values.
- Council Directive 79/117/EEC of 21 December 1978 prohibiting the placing on the market and use of plant protection products containing certain active substances. OJ L 33, 8.2.1979, p. 36–40
- Council Regulation (EEC) No 2658/87 of 23 July 1987 on the tariff and statistical nomenclature and on the Common Customs Tariff. OJ L 256. 7 September 1987.
- Dancer S.J. 2014. Controlling hospital-acquired infection: focus on the role of the environment and new technologies for decontamination. *Clin Microbiol Rev*. Oct;27(4):665-90.
- Dettenkofer M, Wenzler S, Amthor S, Antes G, Motschall E, Daschner FD. 2004. Does disinfection of environmental surfaces influence nosocomial infection rates? A systematic review. *Am J Infect Control*. 32(2):84-9.
- Diamanti-Kandarakis E. et al. 2009. Endocrine-Disrupting Chemicals: An Endocrine Society Scientific Statement. *Endocrine Reviews* 30(4):293-342, doi:10.1210/er.2009-0002, available on: <https://www.endocrine.org/endocrine-press/scientific-statements>

- Directive 2000/60/EC of the European Parliament and of the Council of 23 October 2000 establishing a framework for Community action in the field of water policy (OJ L 327, 22.12.2000, p. 1).
- Directive 2002/32/EC of the European Parliament and of the Council of 7 May 2002 on undesirable substances in animal feed - Council statement. OJ L 140. 30 May 2002.
- Directive 2010/63/EU of the European Parliament and of the Council of 22 September 2010 on the protection of animals used for scientific purposes, OJ L 276, 20.10.2010
- Donaldson EF, Lindesmith LC, Lobue AD, Baric RS. 2010. Viral shape-shifting: norovirus evasion of the human immune system. *Nat Rev Microbiol.* 8(3):231-41. DOI: 10.1038/nrmicro2296.
- ECDC. 2016. Letter of 29 January 2016 to ECDC (Ares(2016)496069); ECDC provided its advice on 12th February 2016.
- ECDC. 2016. The European Surveillance System (TESSy) Data accessible at <http://ecdc.europa.eu/en/activities/surveillance/Pages/data-access.aspx>
- ECHA 2015. Guidance on the Biocidal Products Regulation. Volume IV Environment – Part B Risk Assessment (active substances) Retrieved on: http://echa.europa.eu/documents/10162/15623299/bpr_guidance_ra_vol_iv_part_b_en.pdf
- ECHA. 2011. Assessing the health and environmental impacts in the context of socio-economic analysis under REACH. Final Report- Part 1: Literature review and recommendations. Available at: http://echa.europa.eu/documents/10162/13580/reach_sea_part1_en.pdf.
- ECHA. 2011. Guidance on the preparation of socio-economic analysis as part of an application for authorisation. Helsinki. Retrieved from: http://echa.europa.eu/documents/10162/13637/sea_authorisation_en.pdf
- ECHA. 2012. RAC Opinion ECHA/RAC/CLH-O-0000002970-73-01/F, September 2012
- ECHA. 2016. Emission scenario documents. Retrieved from: <http://echa.europa.eu/fr/guidance-documents/guidance-on-biocides-legislation/emission-scenario-documents>
- ECHA. 2016. European Chemical Agency database on Biocidal Active Substances. Found on: <http://echa.europa.eu/web/guest/information-on-chemicals/biocidal-active-substances>
- ECHA. 2016. Guidance on biocides legislation, available on: <http://echa.europa.eu/guidance-documents/guidance-on-biocides-legislation>
- ECHA. 2016. Member State Committee (MSC) Opinions on Substances of Very High Concern (SVHC). Retrieved from: <http://echa.europa.eu/role-of-the-member-state-committee-in-the-authorisation-process/svhc-opinions-of-the-member-state-committee>
- ECHA. 2016. New web platform available on adverse effects of chemicals. http://echa.europa.eu/view-article/-/journal_content/title/new-web-platform-available-on-adverse-effects-of-chemicals
- ECHA. 2016. Willingness to pay to avoid certain health impacts. Retrieved from: <http://echa.europa.eu/support/socio-economic-analysis-in-reach/willingness-to-pay-to-avoid-certain-health-impacts>
- ECJ. 1972. Joined Cases C-21/72 & C-24/74, International Fruit Company, [1972] ECR I-1219.
- ECJ. 1992. Case C-286/90, Poulsen, [1992] ECR I-06019, para. 9
- ECJ. 1998. Case C-162/96, Racke, ECR [1998] I-3655, para 46.
- Ecorys. 2016. Background study for the assessment of the appropriateness and impact of the existing fee model for the Biocidal Products Regulation and its possible revision. Draft Final Report
- ECPA. 2016. Industry Statistics – ECPA Total. Retrieved on: <http://www.ecpa.eu/information-page/industry-statistics-ecpa-total>
- Edwards, S.G. 2009. Fusarium mycotoxin content of UK organic and conventional barley. *Food Additives and Contaminants* 26: 1185-1190.

- EEA. 2012. EEA Technical Report No 2/2012, The impacts of endocrine disrupters on wildlife, people and their environments – The Weybridge+15 (1996–2011) report. Retrieved on: <http://www.eea.europa.eu/publications/the-impacts-of-endocrine-disrupters>
- Efpia. 2016. European Federation of Pharmaceutical Industries and Associations. Industry & Economy. Retrieved on: <http://www.efpia.eu/topics/industry-economy>
- ENCA. 2013. Tight squeeze for SA citrus industry. Retrieved from: <https://www.enca.com/south-africa/tight-squeeze-sa-citrus-industry>
- Endocrine society. 2016. Website. Retrieved from: <https://www.endocrine.org/news-room/glossary>
- EPAA. 2016. European Partnership for Alternative Approaches to Animal Testing website. Retrieved from: http://ec.europa.eu/growth/sectors/chemicals/epaa/index_en.htm
- EPPO. 2015. PP 1/213 (4) Resistance risk analysis. Bulletin OEPP/EPPO Bulletin (2015) 45 (3), 371–387 ISSN 0250-8052. DOI: 10.1111/epp.12246.
- EPPO. 2015. PP 1/213 (4) Resistance risk analysis. Bulletin OEPP/EPPO Bulletin (2015) 45 (3), 371–387 ISSN 0250-8052. DOI: 10.1111/epp.12246.
- EPPO. 2016. EPPO activities on resistance to plant protection products. Retrieved from: <https://www.eppo.int/PPPRODUCTS/resistance/resistance.htm>
- EPPO. 2016. European and Mediterranean Plant Protection Organization (EPPO) Global Database, available on: <https://gd.eppo.int/>
- EU OSHA. 2016. Information about the European opinion polls on safety and health at work. Retrieved from: <https://osha.europa.eu/en/surveys-and-statistics-osh/european-opinion-polls-safety-and-health-work>
- European Centre for Disease Prevention and Control. 2013. Point prevalence survey of healthcare associated infections and antimicrobial use in European acute care hospitals. Stockholm: ECDC. Retrieved from: <http://ecdc.europa.eu/en/publications/Publications/healthcare-associated-infections-antimicrobial-use-PPS.pdf>
- European Centre for Disease Prevention and Control. 2013. Prevention of norovirus infection in schools and childcare facilities. Stockholm: ECDC. Retrieved from: <http://ecdc.europa.eu/en/publications/Publications/norovirus-prevention-infection-schools-childcare-facilities.pdf>
- European Commission. 1991. Guidance Document on the Assessment of the Relevance of Metabolites In Groundwater of Substances Regulated Under Council Directive 91/414/EEC. Retrieved on: http://ec.europa.eu/food/plant/pesticides/guidance_documents/docs/wrkd0c21_en.pdf
- European Commission. 1999. Communication from the Commission to the Council and the European Parliament - Community strategy for endocrine disruptors - A range of substances suspected of interfering with the hormone systems of humans and wildlife /* COM/99/0706 final */
- European Commission. 1999. European Commission's Scientific Committee for Toxicity, Ecotoxicity and the Environment (CSTEE) Opinion on Human and Wildlife Health Effects of Endocrine Disrupting Chemicals, with Emphasis on Wildlife and on Ecotoxicology Test Methods: March 1999. Available at: http://ec.europa.eu/health/ph_risk/committees/sct/documents/out37_en.pdf
- European Commission. 2000. Communication from the Commission on the precautionary principle /* COM/2000/0001 final */ Retrieved from: <http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A52000DC0001>
- European Commission. 2003. Commission Recommendation 2003/670/EC of 19 September 2003 concerning the European schedule of occupational diseases, OJ L 238, 25.9.2003, p.28
- European Commission. 2003. Report of experts participating in Task 3.2.10, Collection of occurrence data of Fusarium toxins in food and assessment of dietary intake by the population of EU Member States. Retrieved from: <http://ec.europa.eu/food/fs/scoop/task3210.pdf>
- European Commission. 2007. DG AGRI. Economic Impact of Unapproved GMOs on EU Feed Imports and Livestock Production. European Commission, DG AGRI Report.

- European Commission. 2009. Commission Staff Working Document SEC(2009)773, accompanying document to the Proposal for a Regulation of the European Parliament and of the Council concerning the placing on the market and use of biocidal products - Impact Assessment. Retrieved from: <http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52009SC0773&from=EN>
- European Commission. 2012. Interim Evaluation, Impact of the REACH regulation on the innovativeness of the EU chemical industry, Annexes, 2012 (Ares (2015)3396029).
- European Commission. 2013. Minutes of the expert meeting on endocrine disruptors. Retrieved from <http://sciences.blogs.liberation.fr/files/glover-u-s-perturbateurs-endocriniens.pdf>
- European Commission. 2014. 2014/227/EU: Commission Implementing Decision of 24 April 2014 on the non-approval of certain biocidal active substances pursuant to Regulation (EU) No 528/2012 of the European Parliament and of the Council Text with EEA relevance
- European Commission. 2014. Defining criteria for identifying Endocrine Disruptors in the context of the implementation of the PPP Regulation and BP Regulation. Retrieved from: http://ec.europa.eu/smart-regulation/impact/planned_ia/docs/2014_env_009_endocrine_disruptors_en.pdf
- European Commission. 2014. EIP-AGRI Focus Group Protein Crops: final report. <https://ec.europa.eu/eip/agriculture/en/content/eip-agri-focus-group-protein-crops-final-report>
- European Commission. 2014. Jean-Claude Juncker, Opening Statement in the European Parliament Plenary Session. A New Start for Europe: My Agenda for Jobs, Growth, Fairness and Democratic Change. Political Guidelines for the next European Commission. Strasbourg, 15 July 2014. Retrieved on: https://ec.europa.eu/priorities/sites/beta-political/files/juncker-political-guidelines_en.pdf
- European Commission. 2014. JRC. European Network of Cancer Registries Factsheet 2014. Retrieved from: <http://www.enr.eu/index.php/publications/factsheets>
- European Commission. 2014. Press release. Commission consults the public on criteria to identify Endocrine Disruptors. Retrieved from: http://europa.eu/rapid/press-release_IP-14-1057_en.htm
- European Commission. 2014. Report on the establishment of a European fund for minor uses in the field of plant protection products: http://ec.europa.eu/food/plant/pesticides/legislation/docs/com_2014_82_en.pdf.
- European Commission. 2014. Scientific Committee on Consumer Safety (SCCS) Memorandum on Endocrine Disruptors. 2014. SCCS/1544/14. Retrieved from: http://ec.europa.eu/health/scientific_committees/consumer_safety/docs/sccs_s_009.pdf
- European Commission. 2014. Statistics on agricultural markets 2014, DG AGRI. http://ec.europa.eu/agriculture/markets-and-prices/market-statistics/index_en.htm
- European Commission. 2014. The European Union explained. Agriculture - The EU's common agricultural policy (CAP): for our food, for our countryside, for our environment. Retrieved from: http://europa.eu/pol/pdf/flipbook/en/agriculture_en.pdf
- European Commission. 2015. Analysis of measures geared to the sustainable use of biocidal products, Final Report.
- European Commission. 2015. Conference "Endocrine disruptors: criteria for identification and related impacts". Retrieved from: http://ec.europa.eu/health/endocrine_disruptors/events/ev_20150416_en.htm
- European Commission. 2015. Endocrine Disruptors website. Stakeholders' dialogue on endocrine disruptors. Retrieved from: http://ec.europa.eu/health/endocrine_disruptors/stakeholders_dialogue/index_en.htm
- European Commission. 2015. EU Ecolabel Textile Products User Manual. Retrieved from: http://ec.europa.eu/environment/ecolabel/documents/User_manual_textile.pdf
- European Commission. 2015. Final report of an audit carried out in South Africa from 24 February to 06 March 2015. In order to evaluate the system of official controls and the certification of citrus fruit for export to the European Union. Retrieved from: http://ec.europa.eu/food/fvo/audit_reports/details.cfm?rep_id=3483
- European Commission. 2015. Import into the EU. DG Trade. <http://ec.europa.eu/trade/import-and-export-rules/import-into-eu/>

- European Commission. 2015. Public Consultation on defining criteria for identifying endocrine disruptors in the context of the implementation of the plant protection product regulation and the biocidal products regulation. Retrieved from: http://ec.europa.eu/dgs/health_food-safety/dgs_consultations/food/consultation_20150116_endocrine-disruptors_en.htm#CD and the database for received contributions is available at: <https://ec.europa.eu/eusurvey/publication/ED-consultation>
- European Commission. 2015. Selection of substances to be screened in the context of the impact assessment on criteria to identify endocrine disruptors. Retrieved from: http://ec.europa.eu/health/endocrine_disruptors/docs/impactassessment_chemicalsubstancesselection_en.pdf
- European Commission. 2016. Annex II: REFIT Initiatives. Annex to Commission Work Programme 2016; No time for business as usual. Retrieved from: http://ec.europa.eu/atwork/pdf/cwp_2016_annex_ii_en.pdf
- European Commission. 2016. Commission Work Programme 2016; No time for business as usual. Retrieved on: http://ec.europa.eu/atwork/pdf/cwp_2016_en.pdf
- European Commission. 2016. DG SANTE Website Directorate-General for Health and Food Safety: http://ec.europa.eu/food/safety/rasff/reports_publications/index_en.htm
- European Commission. 2016. EU Pesticide Database. Retrieved from: <http://ec.europa.eu/food/plant/pesticides/eu-pesticides-database/public/?event=homepage&language=EN>
- European Commission. 2016. EU position in world trade. <http://ec.europa.eu/trade/policy/eu-position-in-world-trade/>
- European Commission. 2016. Horizon 2020 Societal Challenge 1 call in the work programme 2016-2017 for a joint European programme on HBM (the European Human Biomonitoring Initiative – EHBMI).
- European Commission. 2016. JRC. Information Platform for Chemical Monitoring Data (IPChem). Retrieved from: <https://ipchem.jrc.ec.europa.eu/RDSIdiscovery/ipchem/index.html>
- European Council. 2000. Council conclusions (Environment) on endocrine disruptors. Brussels, 30 March 2000. Retrieved from: http://www.consilium.europa.eu/en/uedocs/cms_data/docs/pressdata/en/envir/07352.en0.html#_Toc480100459
- European Food Safety Authority 2015. The European Union, summary report on trends and sources of zoonoses, zoonotic agents and food-borne outbreaks in 2014. EFSA Journal [Internet]. 2015; 13(12):[191 p.]. Retrieved from: <http://ecdc.europa.eu/en/publications/Publications/zoonoses-trends-sources-EU-summary-report-2014.pdf>
- European Food Safety Authority, 2014. Modern methodologies and tools for human hazard assessment of chemicals. EFSA Journal 2014;12(4):3638, 87 pp. doi:10.2903/j.efsa.2014.3638
- European Food Safety Authority. 2010. Application of systematic review methodology to food and feed safety assessments to support decision making. EFSA Journal 8(6):1637. [90 pp.]. doi:10.2903/j.efsa.2010.1637
- European Food Safety Authority. 2010. EFSA Panel on Plant Protection Products and their Residues (PPR); Scientific Opinion on the development of specific protection goal options for environmental risk assessment of pesticides, in particular in relation to the revision of the Guidance Documents on Aquatic and Terrestrial Ecotoxicology (SANCO/3268/2001 and SANCO/10329/2002). EFSA Journal 2010;8(10):1821. [55 pp.]. doi:10.2903/j.efsa.2010.1821. Available online: www.efsa.europa.eu/efsajournal.htm
- European Food Safety Authority. 2010. EFSA scientific report of the Endocrine Active Substances Task Force. EFSA Journal 2010; 8(11):1932. [59 pp.]. doi:10.2903/j.efsa.2010.1932.
- European Food Safety Authority. 2011. Submission of scientific peer-reviewed open literature for the approval of pesticide active substances under Regulation (EC) No 1107/2009 (OJ L 309, 24.11.2009, p. 1-50). EFSA Journal 2011;9(2):2092. [49 pp.]. doi:10.2903/j.efsa.2011.2092.
- European Food Safety Authority. 2013. 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.
- European Food Safety Authority. 2013. Guidance on tiered risk assessment for plant protection products for aquatic organisms in edge-of-field surface waters. *EFSA Journal* 2013;11(7):3290, 268 pp. doi:10.2903/j.efsa.2013.3290.
- European Food Safety Authority. 2014. EFSA Guidance on Expert Knowledge Elicitation in Food and Feed Safety Risk Assessment. *EFSA Journal* 2014; 12(6):3734. DOI <http://dx.doi.org/10.2903/j.efsa.2014.3734>
- European Food Safety Authority. 2015. The 2013 European Union report on pesticide residues in food. *EFSA Journal* 2015;13(3):4038, 169 pp. doi:10.2903/j.efsa.2015.4038
- European Food Safety Authority. 2016. EFSA. Summary of the 2014 data collection on contaminant occurrence data. Published 21 January 2016. Retrieved from: <http://www.efsa.europa.eu/en/supporting/pub/954e>
- European Food Safety Authority. 2016. Pesticides: breakthrough on cumulative risk assessment. Retrieved from: <http://www.efsa.europa.eu/en/press/news/160127>
- European Parliament. 2009. Resolution on the Commission communication to the Council and the European Parliament on a Community strategy for endocrine disruptors - a range of substances suspected of interfering with the hormone systems of humans and wildlife (COM(1999) 706 - C5-0107/2000 - 2000/2071(COS)) OJ C 197 12 July 2001.
- European Parliament. 2012. Library briefing of the European Parliament 29/03/2012. Pesticide legislation in the EU. Towards sustainable use of plant protection products. Retrieved from: [http://www.europarl.europa.eu/RegData/bibliotheque/briefing/2012/120291/LDM_BRI\(2012\)120291_REVI_EN.pdf](http://www.europarl.europa.eu/RegData/bibliotheque/briefing/2012/120291/LDM_BRI(2012)120291_REVI_EN.pdf)
- European Parliament. 2013. Resolution of 14 March 2013 on the protection of public health from endocrine disruptors (2012/2066(INI))
- European Workshop. 1996. The Impact of Endocrine Disruptors on Human Health and Wildlife. Weybridge (UK), 2 to 4 December
- Eurostat. 2012. Statistics explained. Comparative price levels for food, beverages, and tobacco. Available on: http://ec.europa.eu/eurostat/statistics-explained/index.php/Comparative_price_levels_for_food,_beverages_and_tobacco
- Eurostat. 2013. Archive. Manufacture of chemicals and chemical product statistics. Retrieved on: http://ec.europa.eu/eurostat/statistics-explained/index.php/Archive:Manufacture_of_chemicals_and_chemical_products_statistics_-_NACE_Rev._2
- Eurostat. 2013. Statistics explained. Household consumption expenditure - background. Available on: http://ec.europa.eu/eurostat/statistics-explained/index.php/Household_consumption_expenditure_-_background
- Eurostat. 2015. News release 124/2015, 10 July 2015. Retrieved from: <http://ec.europa.eu/eurostat/documents/2995521/6903510/3-10072015-AP-EN.pdf/d2bfb01f-6ac5-4775-8a7e-7b104c1146d0>
- Eurostat. 2015. Statistics explained. Agricultural production – Crops. Retrieved from: http://ec.europa.eu/eurostat/statistics-explained/index.php/Agricultural_production_-_crops#Further_Eurostat_information
- Eurostat. 2015. Surgical operations and procedures statistics. Retrieved from: http://ec.europa.eu/eurostat/statistics-explained/index.php/Surgical_operations_and_procedures_statistics
- Eurostat. 2015. Agriculture, forestry and fishery statistics, 2014 edition. Retrieved from: <http://ec.europa.eu/eurostat/documents/3217494/6639628/KS-FK-14-001-EN-N.pdf/8d6e9dbe-de89-49f5-8182-f340a320c4bd>, (p 12)

- Eurostat. 2016. Health glossary, available on: http://ec.europa.eu/eurostat/statistics-explained/index.php/Category:Health_glossary
- Evidence-based Toxicology Collaboration. 2016. Website. Retrieved from: <http://www.ebtox.com/>
- FAO. 2012. FAO Guidelines on Prevention and Management of Pesticide Resistance. International Code of Conduct on the Distribution and Use of Pesticides. September 2012.
- FAO. 2013. Food and agriculture organization of the United Nations. The State of Food and Agriculture 2013. ISSN 0081-4539 Retrieved from: <http://www.fao.org/docrep/018/i3300e/i3300e.pdf>
- Fefac. 2015. Feed & food Statistical Yearbook 2014. European Feed Manufacturers Federation
- Filippo De Curtis, Vincenzo De Cicco, Miriam Haidukowski, Michelangelo Pascale, Stefania Somma, Antonio Moretti. 2011. Effects of agrochemical treatments on the occurrence of Fusarium ear rot and fumonisin contamination of maize in Southern Italy. *Field Crops Research* 123. 161–169, p 161.
- Food Standards Agency. 2012. FSA report from a preliminary study carried out by the FSA. R. Massey. 2012. "The likely effects of reduced pesticide usage on mycotoxin levels in food".
- Freedonia. 2016. World Agricultural Pesticides. Found on: <http://www.freedoniagroup.com/industry-study/2902/world-agricultural-pesticides.htm>
- Gamble CL, Ekwaru JP, ter Kuile FO. 2006. Insecticide-treated nets for preventing malaria in pregnancy. *Cochrane Database of Systematic Reviews*. (2):CD003755.
- Gerding DN, Muto CA, Owens RC, Jr. 2008. Measures to control and prevent *Clostridium difficile* infection. *Clin Infect Dis*. 46 Suppl 1:S43-9.
- Gerhard J. Nohynek, Christopher J. Borgert, Daniel Dietrich, Karl K. Rozman. 2013. Endocrine disruption: Fact or urban legend? *Toxicology Letters*. 23 (6): 295-305, ISSN 0378-4274. DOI: <http://dx.doi.org/10.1016/j.toxlet.2013.10.022>
- Gianess. L.P. and Puffer, C.A. 1992. Registration of minor pesticides: some observations and implications. In: *Inputs Situation and Outlook Report*, U.S. Dept. Agri. Econ. Res. Serv.: 52-60.
- Gibb et al. 2010. WHO estimates of the global and regional disease burden of four foodborne chemical toxins. *Food Research* 4: 1393.
- Glied S. 1996. Estimating the indirect cost of illness: an assessment of the forgone earnings approach. *Am J Public Health* 86 (12):1723-8.
- Gore A.C., Chappell V.A., Fenton S.E., Flaws J.A., Nadal A., Prins G.S., Toppari J., Zoeller R.T. 2015. EDC-2: The Endocrine Society's Second Scientific Statement on Endocrine-Disrupting Chemicals, *Endocr Rev*. 36(6):E1-E150. DOI: 10.1210/er.2015-1010
- Gore, A.C., et al. 2015. EDC-2: The Endocrine Society's Second Scientific Statement on Endocrine-Disrupting Chemicals. *Endocrine Reviews* 36 (6) doi.org/10.1210/er.2015-1010
- Gore, A.C., et al. 2015. Executive Summary to EDC-2: The Endocrine Society's Second Scientific Statement on Endocrine-Disrupting Chemicals. *Endocrine Reviews*, 36(6):593–602. doi: 10.1210/er.2015-1093
- Gorse GJ, Messner RL. 1991. Infection control practices in gastrointestinal endoscopy in the United States: a national survey. *Infect Control Hosp Epidemiol*. 12(5):289-96.
- Grand View Research. Biocides Market Analysis by product, by application and segment forecasts to 2022. Retrieved from: <http://www.grandviewresearch.com/industry-analysis/biocides-industry>
- Greenberg, D. et al. 2014. What Are the Challenges in Conducting Cost-of-Illness Studies? *Value in Health Regional Issues*. 4C:115-116. DOI <http://dx.doi.org/10.1016/j.vhri.2014.08.003>
- Greenland S., Robins J.M. 1988. Conceptual problems in the definition and interpretation of attributable fractions. *Am J Epidemiol*. 128(6):1185-97.
- Grundmann H, Barwolff S, Tami A, Behnke M, Schwab F, Geffers C, et al. 2005. How many infections are caused by patient-to-patient transmission in intensive care units? *Crit Care Med*. May;33(5):946-51.

- Gunstone, F. 2011. *Vegetable Oils in Food Technology: Composition, Properties and Uses*. 2nd Ed. Wiley Blackwell. ISBN 978-1-4443-3268-1
- Hauser, R., et al. 2015. Male reproductive disorders, diseases, and costs of exposure to endocrine-disrupting chemicals in the European Union. *The Journal of Clinical Endocrinology & Metabolism*.100(4):1267-1277. DOI <http://dx.doi.org/10.1210/jc.2014-4325>
- Headley, J.C. 1968. Productivity of agricultural pesticides. *Journal of Farm Economics* 50: 13-23.
- HEAL. 2014. Health costs in the European Union. How much is related EDCs? Edited by G. K. Jensen. Retrieved from: http://www.env-health.org/IMG/pdf/18062014_final_health_costs_in_the_european_union_how_much_is_realted_to_edcs.pdf
- HEAL. 2015. Towards Comprehensive Economic Valuation of Health Impacts from Endocrine Disrupting Chemicals. Retrieved from: http://env-health.org/IMG/pdf/2015.09.08_edcs_willingness_to_pay_heal_technical_briefing_final.pdf
- Hecker, M. and Henner, H. 2011. Endocrine disruptor screening: regulatory perspectives and needs. *Environmental Sciences Europe* 23:15. doi:10.1186/2190-4715-23-15
- Henseler, M., Piot-Lepetit, I., Ferrari, E., Gonzalez Mellado, A., Banse, M., Grethe, H., Parisi, C., Hélaïne, S. 2013. On the asynchronous approvals of GM crops: Potential market impacts of a trade disruption of EU soy imports. *Food Policy* 41: 166-176
- Higashihara N, et al. 2007. Subacute oral toxicity study of bisphenol F based on the draft protocol for the "Enhanced OECD Test Guideline no. 407". *Arch Toxicol*. Dec;81(12):825-32. Epub 2007 Jul 13. Retrieved from: <http://www.ncbi.nlm.nih.gov/pubmed/17628788>
- Hussein S. Hussein, Jeffrey M. Brasel. 2001. Toxicity, metabolism, and impact of mycotoxins on humans and animals. *Toxicology* 167, p 101.
- IFAH Europe. 2016. About the industry. Retrieved on: <http://www.ifaheurope.org/about/about-the-industry.html>
- IPCC. 2005. Intergovernmental Panel on Climate Change. Guidance notes for lead authors of the IPCC Fourth Assessment Report on addressing uncertainties. Retrieved from: <http://www.ipcc.ch/meetings/ar4-workshops-express-meetings/uncertainty-guidance-note.pdf>
- Jaime de Melo. 2015. "Bananas, the GATT, the WTO and US and EU domestic politics", *Journal of Economic Studies*, Vol. 42 Iss: 3, pp.377 - 399
- Jean Pierre Jouany. 2007. Methods for preventing, decontaminating and minimizing the toxicity of mycotoxins in feeds. *Animal Feed Science and Technology* 137: 342–362
- Jo C. 2014. Cost-of-illness studies: concepts, scopes, and methods. *Clin Mol Hepatol* 20(4):327-37. DOI <http://dx.doi.org/10.3350/cmh.2014.20.4.327>
- K.R.N. Reddy, N.I. Farhana, B. Salleh and C.A.F. Oliveira. 2010. Microbiological Control of Mycotoxins: Present Status and Future Concerns. in: A Mendez-Vilas (ed) *Current Research, technology and Education Topics in Applied Microbiology and Microbial Biotechnology*. FORMATEX 2010.
- Karolinska Institutet. 2016. EDC-MixRisk: safe chemicals for future generations. Information available on: <http://edcmixrisk.ki.se/aboutedcmixrisk/>
- Khanafer N, Voirin N, Barbut F, Kuijper E, Vanhems P. 2015. Hospital management of *Clostridium difficile* infection: a review of the literature. *J Hosp Infect*. 90(2):91-101.
- Koopmanschap M.A., Rutten F.F.H, van Ineveld B.M., et al. 1995. The friction cost method for measuring indirect costs of disease. *J Health Econ* 14(2):171-89. DOI [http://dx.doi.org/10.1016/0167-6296\(94\)00044-5](http://dx.doi.org/10.1016/0167-6296(94)00044-5)
- Koopmanschap M.A., Rutten FFH. 1996. A practical guide for calculating indirect costs of disease. *Pharmacoeconomics* 10 (5): 460-6.

- Kortenkamp, Martin, Faust, Evans, McKinlay, Orton, Rosivatz. 2011. State of the art assessment of endocrine disrupters. Final Report, Project Contract Number 070307/2009/550687/SER/D3. Retrieved from: http://ec.europa.eu/environment/chemicals/endocrine/pdf/sota_edc_final_report.pdf
- Kovaleva J, Peters FT, van der Mei HC, Degener JE. 2013. Transmission of infection by flexible gastrointestinal endoscopy and bronchoscopy. *Clin Microbiol Rev* 26 (2):231-54.
- Kroes, R., et al. 2004. Structure-based thresholds of toxicological concern (TTC): guidance for application to substances present at low levels in the diet. *Food and Chemical Toxicology* 42: 65–83. doi:10.1016/j.fct.2003.08.006
- Lacasse, K., Baumann, W. 2004. Textile chemicals, environmental data and facts. Springer, ISBN 978-3-642-62346-2. DOI 10.1007/978-3-642-18898-5
- Lamb et al. 2015. Comments on the opinions published by Bergman et al. (2015) on Critical comments on the WHO-UNEP state of the science of endocrine disrupting chemicals (Lamb et al. 2014). *Regulatory toxicology and pharmacology* 73(3): 754-757. doi:10.1016/j.yrtph.2015.10.029
- Lamb J.C. et al. 2014. Critical comments on the WHO-UNEP State of the Science of Endocrine Disrupting Chemicals – 2012. *Regulatory Toxicology and Pharmacology* 69 (1) 22-40. doi:10.1016/j.yrtph.2014.02.002
- Landefeld J.S., Seskin E.P. 1982. The economic value of life: linking theory to practice. *Am J Public Health* 72 (6): 555-66.
- Leaper DJ, Orr C, Maung Z, White A. 2001. *Inflammation and Infection: STEP 2000 Module II*. Royal College of Surgeons of England: Blackwell Science
- Legler, J., Fletcher, T., Govarts, E., Porta, M., Blumberg, B., Heindel, J. J., & Trasande, L. 2015. Obesity, diabetes, and associated costs of exposure to endocrine-disrupting chemicals in the European Union. *The Journal of Clinical Endocrinology & Metabolism* . 100(4):1278-1288. DOI <http://dx.doi.org/10.1210/jc.2014-4325>
- Lengeler C. 2004. Insecticide-treated bed nets and curtains for preventing malaria. *Cochrane Database of Systematic Reviews*.(2):CD000363.
- Levêque-Morlais, N., et al. 2015. The AGRiculture and CANcer (AGRICAN) cohort study: enrolment and causes of death for the 2005–2009 period. *International Archives of Occupational and Environmental Health*. 88 (1): 61-73. DOI 10.1007/s00420-014-0933-x
- Lippincott Williams & Wilkins. 2012. *Hospital epidemiology and infection control*. 4th ed.
- Lock K, Pomerleau J, Causer L, McKee M. 2004. Low fruit and vegetable consumption. In: Ezzati M, Lopez AD, Rodgers A, Murray CJL, eds. *Comparative quantification of health risks: global and regional burden of disease attributable to selected major risk factors*. Geneva, World Health Organization, 597–728.
- Lorenz R, Rhomberg, Julie E, Goodman. 2012. Low-dose effects and nonmonotonic dose–responses of endocrine disrupting chemicals: Has the case been made?, *Regulatory Toxicology and Pharmacology*. 64(1): 130-133. doi.org/10.1016/j.yrtph.2012.06.015
- Loutchanwoot, P., Srivilai, P., Jarry, H. 2013. Effects of the natural endocrine disruptor equol on the pituitary function in adult male rats. *Toxicology* Feb 8;304:69-75. doi: 10.1016/j.tox.2012.11.017.
- Lubulwa, A.S.G., Davis, J.S., 1994. Estimating the social costs of the impacts of fungi and aflatoxins in maize and peanuts. In: *Stored Product Protection: Proceedings of the 6th International Working Conference on Stored-product Protection*, Highley, E., Wright, E.J., Banks, H.J., Champ, B.R., Eds. CAB International, Zallingford, UK: pp 1017-1042.
- Mangram AJ, Horan TC, Pearson ML, Silver LC, Jarvis WR. 1999. Guideline for prevention of surgical site infection, 1999. *Hospital Infection Control Practices Advisory Committee. Infect Control Hosp Epidemiol*. 20(4):250-78; quiz 79-80.
- Marimuthu K, Pittet D, Harbarth S. 2014. The effect of improved hand hygiene on nosocomial MRSA control. *Antimicrob Resist Infect Control*. 3:34.

- Markets and markets. 2016. Biocides Market by Type – Global Trends and Forecasts to 2020. Retrieved from: <http://www.marketsandmarkets.com/PressReleases/biocides.asp>
- Mattke S, Balakrishnan A, Bergamo G, et al. 2007. A review of methods to measure health-related productivity loss. *Am J Manag Care* 13(4):211-7.
- Munn S., Goumenou M-P., 2013. Key scientific issues relevant to the identification and characterisation of endocrine disrupting substances - Report of the Endocrine Disrupters Expert Advisory Group. JRC-IHCP [29pp.] DOI: 10.2788/8659 (online). Retrieved from: <http://publications.jrc.ec.europa.eu/repository/bitstream/JRC79981/lbna25919enn.pdf>
- Munn S., Goumenou M-P. 2013. Thresholds for Endocrine Disrupters and Related Uncertainties Report of the Endocrine Disrupters Expert Advisory Group (ED EAG). JRC-IHCP DOI: 10.2788/8659
- National Edible Oil Distributor Association. 2015. Website: <http://www.neoda.org.uk/rapeseed-oil>
- National Research Council. 1987. Pesticide innovation and the economic effects of implementing the Delaney Clause (1987). Retrieved from: <http://www.ncbi.nlm.nih.gov/books/NBK218035/>
- Nguyen, D. M., & El-Serag, H. B. 2010. The Epidemiology of Obesity. *Gastroenterology Clinics of North America*, 39(1), 1–7. doi.org/10.1016/j.gtc.2009.12.014
- Nidumolu, R., Prahalad, C.K., and Rangaswami, M.R. 2009. Why sustainability is now the key driver of innovation. *Harvard Business Review*. September issue 2009. Retrieved from: <https://hbr.org/2009/09/why-sustainability-is-now-the-key-driver-of-innovation>
- Ntzani EE, Chondrogiorgi M, Ntritsos G, Evangelou E, Tzoulaki I, 2013. Literature review on epidemiological studies linking exposure to pesticides and health effects. EFSA supporting publication 2013:EN-497, 159 pp. http://www.efsa.europa.eu/sites/default/files/scientific_output/files/main_documents/497e.pdf
- OECD. 2012. Appendix 1. OECD Collection of Working Definitions 2012. Retrieved from: <http://www.oecd.org/chemicalsafety/testing/49963576.pdf>
- OECD. 2012. Guidance Document on Standardised Test Guidelines for Evaluating Chemicals for Endocrine Disruption, OECD Environmental Health and Safety Publications, Series on Testing and Assessment n°150, Organisation for Economic Cooperation and Development, Paris. Retrieved from: <http://www.oecd.org/officialdocuments/publicdisplaydocumentpdf/?cote=env/jm/mono%282012%2922&doclanguage=en>
- OECD. 2014. Health at a Glance: Europe 2014, OECD Publishing. doi 10.1787/23056088
- OECD. 2014. Obesity Update June 2014. Retrieved from <http://www.oecd.org/health/obesity-update.htm>
- OECD. 2016. Adverse outcome pathways, molecular screening and toxicogenomics. "What is an adverse outcome pathway". Retrieved from: <http://www.oecd.org/chemicalsafety/testing/adverse-outcome-pathways-molecular-screening-and-toxicogenomics.htm>
- OECD. 2016. Work Related to Endocrine Disrupters. Retrieved from: <http://www.oecd.org/env/ehs/testing/oecdworkrelatedtoendocrinedisrupters.htm>
- Ollinger, M. 1995. Innovation and regulation in the pesticide industry. CES 95-14.
- Olsson, I-M, et al. 2014 The cost of inaction - A Socioeconomic analysis of costs linked to effects of endocrine disrupting substances on male reproductive health, Copenhagen: Nordisk Ministerråd, retrieved from: <http://norden.diva-portal.org/smash/get/diva2:763442/FULLTEXT04.pdf>
- Otsuki, T, Wilson, J.S., Sewadeh, M. 2001. Saving two in a billion/ quantifying the trade effect of European Food Safety standards on African exports. *Food Policy* 26 (5): 495-514
- Patisaul, H. B., and Jefferson, W. 2010. The pros and cons of phytoestrogens. *Frontiers in Neuroendocrinology*, 31(4), 400–419. <http://doi.org/10.1016/j.yfrne.2010.03.003>
- Philips McDougal. 2010. The cost of new agrochemical product discovery, development and registration in 1995, 2000 and 2005-8. A consultancy study for Crop Life America and the European Crop Protection Agency.

- Phillips McDougall. 2010. Trends in crop protection R&D, Bratislava, Slovakia. Retrieved from: http://www.ecpa.eu/files/gavin/presentation_Matthew_Phillips.pdf.
- Phillips McDougall. 2013. R&D trends for chemical crop protection products and the position of the European market. A consultancy study undertaken for ECPA. Retrieved from: http://www.ecpa.eu/files/attachments/R_and_D_study_2013_v1.8_webVersion_Final.pdf
- Piersma, A.H., et al. 2011. Reproductive toxicants have a threshold of adversity. *Critical reviews in Toxicology* 41(6) 545-554. doi: 10.3109/10408444.2011.554794
- Pittet D, Hugonnet S, Harbarth S, Mourouga P, Sauvan V, Touveneau S, et al. 2000. Effectiveness of a hospital-wide programme to improve compliance with hand hygiene. *Infection Control Programme. Lancet.* 356 (9238): 1307-12.
- Pluess B, Tanser FC, Lengeler C, Sharp BL. 2010. Indoor residual spraying for preventing malaria. *Cochrane Database of Systematic Reviews.* (4):CD006657.
- Prentice, A. 2007. Are Defects in Energy Expenditure Involved in the Causation of Obesity? *Short Science Review. Foresight Tackling Obesity: Future Choices. Obesity Reviews,* 8(s1):89–91. Retrieved from: <http://onlinelibrary.wiley.com/doi/10.1111/j.1467-789X.2007.00325.x/epdf>
- Proposal for a Regulation of the European Parliament and of the Council on medical devices, and amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009. /* COM/2012/0542 final - 2012/0266 (COD) */
- Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC. OJ L 309.
- Regulation (EC) No 1223/2009 of the European Parliament and of the Council of 30 November 2009 on cosmetic products (OJ L 342, 22.12.2009, p. 59). Retrieved from: http://ec.europa.eu/health/endocrine_disruptors/docs/cosmetic_1223_2009_regulation_en.pdf
- 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. OJ L 353 31.12.2008, p. 1.
- Regulation (EC) No 1907/2006 of the European Parliament and of the Council 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. OJ L 396 30 December 2006.
- Regulation (EC) No 396/2005 of the European Parliament and of the Council on maximum residue levels of pesticides in or on food and feed of plant and animal origin and amending Council Directive 91/414/EEC OJ L 70, 16.3.2005, p. 1
- 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 Text with EEA relevance Regulations on Cosmetics (Regulation (EC) 1223/2009). OJ L 167 27 June 2012.
- Renehan AG, Tyson M, Egger M, Heller RF, Zwahlen M. 2008. Body-mass index and incidence of cancer: a systematic review and meta-analysis of prospective observational studies. *Lancet.* 371:569–578
- Rice D.P. 1967. Estimating the Cost of Illness. Washington, DC: US Department of Health, Education, and Welfare, Public Health Services, 1966. Rice D.P. Estimating the cost of illness. *Am J Public Health Nations Health* 57(3):424–40. DOI <http://dx.doi.org/10.2105/AJPH.57.3.424>
- Rice D.P. 1994. Cost-of-illness studies: fact or fiction? *Lancet* 344 (8936): 1519-20.
- Risk and Policy Analysts (RPA) et al. 2015. Study on the Calculation of the Benefits of Chemical Legislation on Human Health and the Environment, Final report for DG Environment, March 2016, Loddon, Norfolk, UK

- Rockhill B., Newman B., Weinberg C. 1998. Use and misuse of population attributable fractions. *Am J Public Health*. 88(1):15-9; Greenland S., Robins J.M. Conceptual problems in the definition and interpretation of attributable fractions. *Am J Epidemiol* 1988; 128(6):1185-97.
- Scarpino, V., A. Reyneri, M. Sulyok, R. Krska and M. Blandino. 2015. Effect of fungicide application to control Fusarium head blight and 20 Fusarium and Alternaria mycotoxins in winter wheat (*Triticum aestivum* L.). *World Mycotoxin Journal*. 8 (4): 499-510.
- Schembre DB. 2000. Infectious complications associated with gastrointestinal endoscopy. *Gastrointestinal Endoscopy Clinics of North America*. 10(2):215-32.
- Schultz A.B., Chen C.-Y., Edington D.W. 2009. The cost and impact of health conditions on presenteeism to employers: a review of the literature. *Pharmacoeconomics* 27(5):365-78. DOI <http://dx.doi.org/10.2165/00019053-200927050-00002>
- Schumpeter, J.A. 1961. *Theory of economic development*, New York, Oxford University Press.
- Senauer B., Gemma M. 2006. Reducing Obesity: What Americans Can Learn from the Japanese. *Choices Magazine*. Retrieved from: <http://www.choicesmagazine.org/2006-4/grabbag/2006-4-12.htm>
- Senauer B., Gemma M. 2006. Why Is the Obesity Rate So Low in Japan and High in the US?: Some Possible Economic Explanations. Gold Coast, Australia, 12–18 August. Retrieved from: <https://ideas.repec.org/p/ags/umrfwp/14321.html>
- Society of Endocrinology. 2016. Website Retrieved from www.yourhormones.info
- Sosić-Jurjević B, et al. 2010. Suppressive effects of genistein and daidzein on pituitary-thyroid axis in orchidectomized middle-aged rats. *Exp Biol Med* (Maywood). May;235(5):590-8. doi: 10.1258/ebm.2009.009279.
- Sroka S, Gastmeier P, Meyer E. 2010. Impact of alcohol hand-rub use on meticillin-resistant *Staphylococcus aureus*: an analysis of the literature. *J Hosp Infect*. 74(3):204-11.
- Stephenson G.R., Ferris I.G., Holland P.T., Nordberg M., 2006. Glossary of terms relating to pesticides (IUPAC Recommendations 2006), *Pure Appl. Chem.*, Vol. 78, No. 11, pp. 2075–2154. doi:10.1351/pac200678112075. Retrieved from: <http://www.iupac.org/publications/pac/2006/pdf/7811x2075.pdf>
- Swedish Chemical Agency. 2012. PM 2/12 Biocide treated articles - an Internet survey (2012). Retrieved from: <https://www.kemi.se/global/pm/2012/pm-2-12-biocide-treated-articles.pdf>
- Swedish Chemical Agency. 2014. Chemicals in textiles – Risks to human health and the environment. Report from a government assignment. Stockholm 2014. Retrieved from: <https://www.kemi.se/files/8040fb7a4f2547b7bad522c399c0b649/report6-14-chemicals-in-textiles.pdf>
- Swiss Federal Department of Home Affairs (FDHA). 2015. Federal Food Safety and Veterinary Office FSVO. Risk Assessment. Bisphenol F in mustard. Retrieved from: <http://www.efsa.europa.eu/sites/default/files/assets/af150611a-ax11.6.pdf>
- Tarricone R. 2006. Cost-of-illness analysis. What room in health economics? *Health Policy* 77(1):51-63. DOI <http://dx.doi.org/10.1016/j.healthpol.2005.07.016>
- Tavoschi L, Severi E, Niskanen T, Boelaert F, Rizzi V, Liebana E, et al. 2015. Food-borne diseases associated with frozen berries consumption: a historical perspective, European Union, 1983 to 2013. *Euro surveillance : bulletin European sur les maladies transmissibles = European communicable disease bulletin*. 20(29): 21193.
- TEEB. 2016. The economics of ecosystems and biodiversity website: <http://www.teebweb.org/>
- Teece, D.J., 1982. Towards an economic theory of the multiproduct firm. *Journal of Economic Behavior and Organisation* 3: 39-63.
- Testai, E., Galli, C.L., Dekant, W., Marinovich, M., Piersma, A.H., Sharpe, R.M., 2013. A plea for risk assessment of endocrine disrupting chemicals. *Toxicology*, <http://dx.doi.org/10.1016/j.tox.2013.07.018>

- Tinwell, H., S. Colombel, O. Blanck, R. Bars. 2013. The screening of everyday life chemicals in validated assays targeting the pituitary–gonadal axis. *Regulatory Toxicology and Pharmacology* 66 (2): 184-196 doi:10.1016/j.yrtph.2013.04.002
- Titley-O'Neal, C.P., Munkittrick, K.R., and MacDonald, B.A., 2011. The effects of organotin on female gastropods. *Journal of Environmental Monitoring*. 13: 2360-2388.DOI: 10.1039/C1EM10011D
- Trasande, L., et al. 2015. Estimating Burden and Disease Costs of Exposure to Endocrine-Disrupting Chemicals in the European Union, *Journal of Clinical Endocrinology and Metabolism* . 100(4):1245-1255. DOI <http://dx.doi.org/10.1210/jc.2014-4324>
- Trasande, L. 2014. Further limiting Bisphenol A in food uses could provide health and economic benefits. *Health Affairs*. 33(2):316-323. DOI <http://dx.doi.org/10.1377/hlthaff.2013.0686>
- United States Environmental Protection Agency. 2016. Endocrine Disruptor Screening Program (EDSP) Overview. Retrieved from:<http://www.epa.gov/endocrine-disruption/endocrine-disruptor-screening-program-edsp-overview>
- USDA 2015. USDA Citrus Semi-annual Report. Retrieved from: http://gain.fas.usda.gov/Recent%20GAIN%20Publications/Citrus%20Semi-annual_Pretoria_South%20Africa%20-%20Republic%20of_6-15-2015.pdf
- Uttendaele, M. 2014. Issues surrounding the European fresh produce trade: a global perspective. *Global Safety of Fresh Produce: A Handbook of Best Practice, innovative commercial solutions and case studies*. Ed. Hoorfar, J. Woodhead Publishing. Cambridge, UK.
- Van Den Berg B., Brouwer W.B.F, Koopmanschap M.A. 2004. Economic valuation of informal care: an overview of methods and applications. *Eur J Health Econ* 5(1):36-45. DOI <http://dx.doi.org/10.1007/s10198-003-0189-y>
- Vanova et al. 2008. The content of Fusarium mycotoxins, grain yield and quality of winter wheat cultivars under organic and conventional cropping systems. *Plant Soil Environ*. 54: 395-402.
- Vardon, P., McLaughlin, C, Nardinelli, C. 2003. Potential economic costs of mycotoxins in the United States. In: Council for Agricultural Science and Technology (CAST). *Mycotoxins: Risks in Plant, Animal, and Human Systems*, Task Force Report No. 139: Ames, IA, 2003.
- Visser, C.L.M., Schreuder, R., and Stoddard, F. 2014. The EU's dependency on soya bean import for the animal feed industry and potential for EU produced alternatives. *Oilseeds & fats Crops and Lipids (OCL)* 21(4). DOI: 10.1051/ocl/2014021
- Weber DJ, Anderson D, Rutala WA. 2013. The role of the surface environment in healthcare-associated infections. *Curr Opin Infect Dis*. 26(4):338-44.
- Weiser TG, Regenbogen SE, Thompson KD, Haynes AB, Lipsitz SR, Berry WR, et al. 2008. An estimation of the global volume of surgery: a modelling strategy based on available data. *Lancet*.372(9633): 139-44.
- WHO. 2009. Global Health Risks: mortality and burden of disease attributable to selected major risks. Retrieved from: http://www.who.int/healthinfo/global_burden_disease/GlobalHealthRisks_report_full.pdf
- WHO. 2009. WHO guide to identifying the economic consequences of disease and injury, Geneva
- WHO. 2009. WHO guidelines on hand hygiene in health care. Retrieved from: <http://www.who.int/gpsc/5may/tools/9789241597906/en/>
- WHO. 2012. State of the science of Endocrine Disrupting Chemicals 2012. Summary for Decision-Makers. Ed. Bergman Å., Heindel, J.J., Jobling S., Kidd, K.A., and Zoeller R.T. Retrieved from http://www.unep.org/pdf/WHO_HSE_PHE_IHE_2013.1_eng.pdf
- WHO. 2013. Country profiles on nutrition, physical activity and obesity in the 28 European Union Member States of the WHO European Region. Methodology and summary. Retrieved from <http://www.euro.who.int/en/health-topics/disease-prevention/nutrition/country-work/country-profiles-on-nutrition,-physical-activity-and-obesity-in-the-28-european-union-member-states-of-the-who-european-region.-methodology-and-summary>.

- WHO. 2014. Identification of risks from exposure to EDCs at the country level. Retrieved from: <http://www.euro.who.int/en/publications/abstracts/identification-of-risks-from-exposure-to-endocrine-disrupting-chemicals-at-the-country-level>
- WHO. 2014. Safe management of wastes from health-care activities 2014. Retrieved from: http://apps.who.int/iris/bitstream/10665/85349/1/9789241548564_eng.pdf?ua=1
- WHO. 2015. Identification of risks of EDCs: overview of existing practices and steps ahead. Report of a meeting in Bonn, Germany 7-8 July 2014
- WHO. 2015. World Health Organisation Regional Office for Europe. European health for all database (HFA-DB) Retrieved from: <http://data.euro.who.int/hfad/>
- WHO. 2016. WHO Pesticide Evaluation Scheme (WHOPES) Geneva [cited 2016 02 February]. Retrieved from: <http://www.who.int/whopes/en/>
- WHO/IPCS. 2002. Definition of an Endocrine Disruptor: an exogenous substance or mixture that alters function(s) of the endocrine system and consequently causes adverse health effects in an intact organism, or its progeny, or (sub)populations.
- WHO/IPCS. 2002. Global Assessment of the State-of-the-science of Endocrine Disruptors. World Health Organization/International Programme on Chemical Safety. WHO/PCS/EDC/02.2, 180 pp. Retrieved from: http://www.who.int/ipcs/publications/new_issues/endocrine_disruptors/en/
- WHO/IPCS. 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>.
- WHO/UNEP. 2015 Strategic Approach to International Chemicals Management (SAICM). International Conference on Chemicals Management fourth Session. SAICM/ICCM.4/9. Emerging policy issues and other issues of concern.
- Windler, L., Height, M., and Nowack, B. 2013. Comparative evaluation of antimicrobials for textile applications. *Environment International* 53: 62-73. <http://dx.doi.org/10.1016/j.envint.2012.12.010>
- World Bank. 2005. Food safety and Agricultural Health Standards. Challenges and Opportunities for Developing Country Exports. Report No. 31207 of the World Bank, Washington DC, USA. Retrieved from: http://siteresources.worldbank.org/INTRANETTRADE/Resources/Topics/Standards/standards_challenge_s_synthesisreport.pdf
- World Wildlife Fund. 2003. Innovation in the Chemicals Sector and the New European Chemicals Regulation, a WWF chemicals and health campaign report. Retrieved from: <http://www.wwf.org.uk/filelibrary/pdf/innovationreport.pdf>
- WTO. 2016. Summary reports of SPS Committee: https://www.wto.org/english/tratop_e/sps_e/sps_e.htm
- WTO. 2016. Summary reports of TBT Committee: https://www.wto.org/english/tratop_e/tbt_e/tbt_e.htm
- Wu, F. 2007. Measuring the economic impacts of Fusarium toxins in animal feeds. *Animal Feed Science and Technology* 137: 363-374.
- Xiong, B., and Beghin, J., 2014. Disentangling demand-enhancing and trade-cost effects of maximum residue regulations. *Economic Inquiry*. Vol. 52, No. 3, 1190–1203. doi:10.1111/ecin.12082
- Zinedine, A. et al. 2007. Review on the toxicity, occurrence, metabolism, detoxification, regulations and intake of zearalenone: an oestrogenic mycotoxin. *Food Chem Toxicol* 45(1): 1-18.
- Zoeller, R. T., Bergman, A., Becher, G., Bjerregaard, P., Bornman, R., Brandt, I., Iguchi, T., Jobling, S., Kidd, K. A., Kortenkamp, A., et al. 2014. A path forward in the debate over health impacts of endocrine disrupting chemicals. *Environ. Health*, 14, 118
- Zoller, O. et al. 2016. Natural occurrence of bisphenol F in mustard, *Food Additives & Contaminants: Part A*, 33:1, 137-146, DOI: 10.1080/19440049.2015.1110623