European Commission

ROADMAP			
TITLE OF THE INITIATIVE	Defining criteria for identifying Endocrine Disruptors in European legislation and their implementation in legislation concerning certain chemicals *This initiative replaces parts of the initiative*: The development of a definition and criteria for identifying Endocrine Disruptors		
LEAD DG – RESPONSIBLE UNIT	DG ENV.A.3, DG SANCO.E.3	DATE OF ROADMAP	15/01/2014

This indicative roadmap is provided for information purposes only and is subject to change. It does not prejudge the final decision of the Commission on whether this initiative will be pursued or on its final content and structure.

A. Context and problem definition

(1) What is the political context of the initiative?
(2) How does it relate to past and possible future initiatives, and to other EU policies?
(3) What ex-post analysis of existing policy has been carried out? What results are relevant for this initiative?

(1) The Political Context

The past 15 years have seen a considerable number of scientific, policy and legislative activities in the area of endocrine disruptors, both at EU and at international level, as summarized below.

Science

Endocrine disruptors (ED) are substances which interfere with the hormonal (or endocrine) system. More precisely, they are defined by WHO/IPCS(2002) as *an exogenous substance or mixture that alters function(s) of the endocrine system and consequently causes adverse health effects in an intact organism, or its progeny, or (sub)populations*. Those substances are thought to be linked the growing number of hormonal problems observed in the human population and wildlife (such as e.g. reduced semen quality in men, female precocious puberty, hormonal cancers, obesity, feminisation of aquatic species). Endocrine disruption is not an end-point but a mode of action.

~~The concerns about potential risks of endocrine disrupting chemicals on human health and the environment have been growing over the last 25 years. There is now scientific consensus in many areas, though diverging views exist on specific points within the scientific community.~~

~~There is general consensus to use, for regulatory purposes, the WHO/IPCS (2002) definition of an Endocrine Disruptor. It is defined as *an exogenous substance or mixture that alters function(s) of the endocrine system and consequently causes adverse health effects in an intact organism, or its progeny, or (sub)populations*.~~

~~Already in 1999 it was shown that endocrine disruptors caused population level changes in animal wildlife species and the evidence has increased since then. There is mounting evidence from animal experiments and there are now some epidemiological studies showing that human exposure to endocrine disrupting chemicals during foetal development and puberty may play a role in the increased incidences of certain endocrine related diseases in these studies. The extent of the role of exposure to EDs on the increasing incidence of these diseases as compared to other factors (e.g. genetics, life style, nutrition, and other environmental factors) is not established. The issue of relevance of non monotonic dose responses for risk assessment and the issue of whether or not it is possible to determine a safe threshold of exposure to endocrine disruptors are currently subject to scientific debate.~~

~~Science is progressing rapidly and has identified different endocrine routes (axes). Validated test methods currently exist for the detection of substances that act through the oestrogenic, androgenic, thyroid and steroidogenic axes in mammals and fish, with fewer tests available for birds and amphibians. The evidence, scientific understanding and consensus about other endocrine axes are continuously evolving, but validated test methods for detecting effects of substances on these additional axes do not exist yet~~

A number of scientific opinions, commissioned studies, reports of European agencies and reports from international organisations addressing the state of the art regarding endocrine disruptors and focusing on specific aspects were published.

EU-Policy

Comment [g1]: (From ENTR A5/IA unit): this policy initiative is likely to have an impact on business competitiveness, in particular for cost and international competitiveness of economic operators producing and marketing chemical substances as well as those producing medical devices or dealing with water pollutants falling within the scope of the Water Framework Directive We would propose the inclusion of a short analysis on sectoral competitiveness based on the approach described in the competitiveness proofing Competitivness proofing operational guidance (http://ec europa eu/smart-regulation/impact/key_docs/docs/sec_2012_0091_en pdf) The methodology stated in this document should be followed This Guidance provides a methodology to allow the evaluation of the possible sectorial impacts of the regulatory measures considering three key areas:
* Cost competitiveness
* Ability to innovate
* and international competitiveness
We would like also that the requirement for competitiveness proofing is included in the ToR of the IA studies
Similarly as many SMEs are involved in the sector of biocides DG ENTR requires an SME test to be carried out according to the following guidance:
http://ec europa eu/smart-regulation/impact/key_docs/docs/meg_guidelines pdf
Please also note that we have competitiveness helpdesk so colleagues ...

Comment [g2]: This is not exactly correct as the document suggests changes to the legislations which are not an automatic consequences of defining criteria
Therefore, the title would need to be updated, see suggestions

Comment [g3]: This section would need to be shortened and more focussed otherwise we are losing the line when reading
Elements of the strategy should be removed as they are not appropriate here
Please see insertion coming from agreed LTT/briefing between Env and Entr that may be useful as a summary

Comment [L4]: There is general consensus that the WHO/IPCS definition can be used as a common and accepted definition of an endocrine disruptor (i e to ensure use of common terminology) but there has been **no** consensus that the definition can/should be used for regulatory purposes!

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Comment [g5]: This is not specific to ED Either it is clarified (by adding that it is general to all chemicals) and then the issue of low doses is also be added or it is removed (if we consider the section focussed on ED)

Comment [g6]: This section could be deleted as the summary above could be sufficient

Comment [g7]: This is not relevant here given that we focus only on criteria and changing legislations

Calls on the Commission to establish horizontal hazard-based scientific criteria to identify endocrine disruptors were adopted by both the Council and the European Parliament, in the form of Council conclusions and an own initiative report, respectively (please add links). Recently, through the agreement in ordinary procedure on the 7th Environmental Action Programme, this action was reconfirmed by both co-legislators (add link).

Additionnally, specific pieces of legislation (the PPPR and the BPR, see section "regulatory context" for more details) require the Commission to establish scientific criteria for the determination of endocrine disrupting properties of certain chemicals, therefore work on the definition of criteria for identifying endocrine disruptors started.

Finally, the Commission established in 2010 two Commission expert groups to provide open and transparent fora for information exchange on endocrine disruptors and to get orientation on various scientific and policy aspects related to this topic. The "Ad hoc group of Commission Services, EU Agencies and Member States", consisting of policy experts, focussed on policy issues. The other group, called "the Endocrine Disruptors Expert Advisory Group", was set up to provide detailed reflections on scientific issues relevant to endocrine disruptors, not specific to any regulatory framework, including advice/orientation on scientific criteria for the identification of endocrine disrupting substances. Both groups included representatives of industry associations, non-governmental organisations, Commission Services, European Agencies and Member States. The outcome of "the Endocrine Disruptors Expert Advisory Group" meetings is summarised in the "JRC Report on key scientific issues relevant to the identification of endocrine disrupting substances"[1]. Further, the Commission mandated EFSA to deliver a "Scientific Opinion on the hazard assessment of endocrine disruptors"[2]. Both scientific reports were published in March 2013.

Regulatory context

Specific provisions governing endocrine disruptors are already included in several pieces of the EU legislation that regulate the authorisation of substances and in some cases further action at sectorial level is required. This applies in particular to the Plant Protection Products Regulation (PPPR)[3], the Biocidal Products Regulation (BPR)[4], the Chemicals Regulation REACH (REACH)[5], and the Cosmetics Regulation (CR)[6]. Similar provisions were also introduced into the Commission Proposal for a Regulation on Medical Devices (MDR)[7]. Further, the Water Framework Directive (WFD)[8] lists substances with endocrine disrupting properties among the main pollutants that should be particularly addressed by Member States in relation to the quality of surface and

Comment [L8]: Although DG ENTR is fully supporting the idea, it is fair to remind that the EP actually asked to *"base the criteria … on a comprehensive hazard assessment* [which] *should then be utilized in the risk assessment and risk management procedures as prescribed in various relevant legislation"*

Comment [g9]: Please add links

Comment [g10]: To what 'this' relates? If it relates to the new strategy, I do not believe we cannot make this link as there is no new strategy
As for the time being we have to work under the old strategy, see suggested changes

Deleted: In 1999, the EU adopted a Strategy on Endocrine Disruptors. A review of the 1999 Strategy and the development of a new Strategy taking into account the newest scientific knowledge was set out in Commission Working Program 2012 and is on-going. One key element of this on-going work is the

Comment [g11]: The IA will show (or not) that the criteria have to be horizontal

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Comment [g12]: It has to be reminded that the trigger is the fact that PPPR and BPR are requiring criteria to be established I understand that this is described in the section regulatory context but a sentence should be added to make the link as this is not logic otherwise

Comment [g13]: This should be removed as there is no new strategy yet

Deleted: The initiative presented in this roadmap is part of this new Strategy.

[1] Report of the Endocrine Disrupters Expert Advisory Group: "Key scientific issues relevant to the identification and characterisation of endocrine disrupting substances" http://ihcp.jrc.ec.europa.eu/our_activities/food-cons-prod/endocrine_disrupters/jrc-report-scientific-issues-identification- endocrine-disrupting-substances

[2] EFSA 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 http://www.efsa.europa.eu/en/efsajournal/pub/3132.htm

[3] Regulation (EC) N 1107/2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2009:309:0001:0050:EN:PDF

[4] Regulation (EU) N 528/2012 concerning the making available on the market and use of biocidal products http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2012:167:0001:0123:EN:PDF

[5] Regulation (EC) N 1907/2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32006R1907:EN:NOT

[6] Regulation (EC) N 1223/2009 of the European Parliament and of the Council of 30 November 2009 on cosmetic products http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2009:342:0059:0209:en:PDF

[7] 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 http://ec.europa.eu/health/medical-devices/files/revision_docs/proposal_2012_542_en.pdf

[8] 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. http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32000L0060:EN:NOT

ground water. Finally, the Regulation on data requirements for active substances under Plant Protection Product Regulation (PPP DR)[9] sets data requirements for substances considered to be potential endocrine disruptors.

In more detail:

- There are legal requirements to specify *scientific criteria for the determination of endocrine disrupting properties* for both Plant Protection Products and Biocidal Products.

  There was a common agreement during the co-decision procedure of the Plant Protection Products Regulation and the Biocidal Products Regulation that scientific criteria for the determination of endocrine disrupting properties could not be developed and included before adoption. It was therefore agreed that such criteria be developed by the Commission and included in the Plant Protection Products Regulation through a Regulatory Procedure with Scrutiny and included in the Biocidal Products Regulation through a delegated act.

  Interim criteria were defined both in the Plant Protection Products Regulation and the Biocidal Products Regulation and are applicable as from....

  The Plant Protection Products Regulation (in Annex II, Section 3.6.5 of Regulation (EC) 1107/2009) and the Biocidal Products Regulation (in Article 5 of Regulation (EU) 528/2012) stipulate that substances having *endocrine disrupting properties which may cause adverse effects* will not be approved for the respective use, unless:

  - For a Plant Protection Product:
    - the exposure is negligible or
    - the substance is necessary to control a serious danger to plant health which cannot be contained by other available means including non-chemical method (this provision can only be applied for a maximum period of 5 years);
  - For a Biocidal Product:
    - the risks are negligible, in particular where the product is used in closed systems or under other conditions which aim at excluding contact with humans and release into the environment, or
    - the substance is essential to prevent or control serious dangers to human health, animal health or the environment or
    - not approving the substance would have disproportionate negative impacts on society when compared with the risks.

  Further, the Biocidal Products Regulation (in Article 19(4) of Regulation (EU) 528/2012) stipulates that substances having *endocrine disrupting properties* (i.e. *not* specifying 'which may cause adverse effects') will not be approved for use by the general public.

- Substances having *endocrine disrupting properties for which there is scientific evidence of probable serious effects to human health or the environment which give rise to an equivalent level of concern to substances identified as carcinogens, mutagens, toxic for reproduction, persistent, bioaccumulative and toxic (PBT) or very persistent and very bioaccumulative (vPvB)* may be subject to the REACH authorisation process. In accordance with Article 138(7) of the REACH Regulation, the Commission has to review the way endocrine disrupting substances are authorised under REACH. Furthermore, the restriction process under REACH can be initiated at any time for EDs that would pose an unacceptable risk to the human health or the environment, in order to impose conditions on the manufacture, use and/or placing on the market on such substances.
- For Cosmetics, a review of the regulation with regard to substances *with endocrine-disrupting properties* is requested, once agreed criteria are available or at the latest on 11 January 2015.
- For Medical Devices, the proposal requires that they *shall be designed and manufactured in such a way as to reduce as far as possible the risks posed by substances that may leach or leak from the device. Special attention shall be given to carcinogenic, mutagenic or toxic to reproduction and to substances having endocrine disrupting properties for which there is scientific evidence of probable serious effects to human health and which are identified as substances of very high concern in accordance with REACH. Moreover, some devices (or their parts) shall be labelled when they contain certain phthalates.*

Comment [g14]: Please specify the date

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[9] Regulation (EU) No 283/2013 setting out the data requirements for active substances under Plant Protection Product Regulation http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2013:093:0001:0084:EN:PDF

- In the Water Framework Directive substances *which have been proved to possess properties which may affect steroidogenic, thyroid, reproduction or other endocrine-related functions* in or via the aquatic environment are listed as main pollutants.
- The regulation on data requirements for plant protection product regulation defines data requirements for *potential endocrine disruptors.*

Other sectorial legislation (e.g. on EU Occupational Safety and Health, on Pharmaceuticals and on Food Contact Materials) regulate endocrine disruptors together with other chemicals on a case by case basis, with no specific provision introduced for those substances, using the risk assessment approach defined in the respective legislation.

(2) Relation to Other Initiatives

The Commission is developing a Commission Staff Working Paper with the evaluation of the current Community strategy on endocrine disruptors and a Communication to the European Parliament, the Council and the European Economic and Social Committee on the new European Union Strategy for Endocrine Disruptors replacing the Community Strategy for Endocrine Disruptors from 1999

(3) Existing Assessments

No ex-post analysis of the existing policies has been carried out. However, three impact assessments were carried out during the co-decision process for the adoption of the Plant Protection Products Regulation by different organisations (PSD, United Kingdom[10], KEMI, Sweden[11], and the European Parliament[12]) aiming at determining which active substances used in plant protection products have *endocrine disrupting properties which may cause adverse effects* and thereby would not be approved. These three assessments were based on preliminary and not yet agreed criteria to identify endocrine disruptors. The implied costs and benefits of such action were not assessed.

Recently a fourth such assessment, including the economic costs due to the agronomic consequences of not approving substances fulfilling criteria was published by the UK HSE[13]. The benefits of not approving these substances were not determined.

Assessments on the agronomic and trade consequences of not approving substances fulfilling criteria have also been undertaken by industry, mainly for Plant Protection Products.

What are the main problems which this initiative will address?

This initiative will address the following problem: Endocrine disruptors are not consistently regulated across the EU legislation due to the lack of identification criteria.

Add first a section on the fact that there is no criteria and why it is so difficult to identify them. See below a few lines taken from previous agreed Env/Entr LTT, as an example:

One current challenge is that there are no systematic criteria to identify EDs and that their identification is made case by case, using a weight of evidence (= reviewing the whole amount of scientific evidence) approach. In that context, identification criteria would greatly simplify the assessment by public

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Comment [g15]: Given the current state of play internally and developments, there may be a need to update or delete the section

Comment [B16]: There's no reason to mention the CLP Regulation in particular here Might be more logical to refer to REACH and the SVHC Roadmap implementation for EDs

Deleted: With the adoption in 2008 of the Classification, Labelling and Packaging (CLP) Regulation, the UN Globally Harmonised System for Classification and Labelling was introduced into the EU, transposing the internationally agreed system for identifying and categorising most known adverse effects relevant for human health and the environment. These include already the main adverse human health effects expected to be caused by endocrine disruptors (i.e. reproductive toxicity and some cancers).

Deleted: Under the CLP Regulation, the relevance to humans of adverse effects observed in animal studies is based on the mode of action of the substance, but without explicitly considering specifically endocrine disruption

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Comment [L17]: This relates to the existing ECPA and CPA reports which should be referenced

[10] http://www.pesticides.gov.uk/Resources/CRD/Migrated-Resources/Documents/R/Revised_Impact_Report_1_Dec_2008(final).pdf

[11] http://www.kemi.se/Documents/Bekampningsmedel/Docs_eng/SE_positionpapper_annenII_sep08.pdf]

[12] http://www.europarl.europa.eu/RegData/etudes/etudes/join/2008/408559/IPOL-JOIN_ET(2008)408559_EN.pdf

[13] Extended impact assessment study of the human health and environmental criteria for endocrine disrupting substances proposed by HSE, CRD.
http://randd.defra.gov.uk/Default.aspx?Menu=Menu&Module=More&Location=None&Completed=0&ProjectID=18083

The Food and Environment Research Agency (2013). Agronomic and Economic Impact Assessment for Possible Human Health and Eco-toxicological Criteria for Endocrine Disrupting Substances.
http://randd.defra.gov.uk/Document.aspx?Document=11346_PS2818finalreportfull.pdf

authorities or industry

Specific risk-management provisions for substances having endocrine disrupting properties already exist in four pieces of legislation (WFD, REACH, PPPR and BPR), were recently proposed in a Commission proposal for MDR, and might further be proposed as a result of the required review of the CR as regards endocrine disruptors. However, due to the fact that here are no formal criteria for identification of endocrine disruptors and the provisions differ between the sectorial legislations, it leads to the possible diverging outcome as regards identification of substances having endocrine disrupting properties among the pieces of legislation, creating uncertainties to economic operators.

In some of these sectorial legislations (plant protection products and biocides), interim criteria to identify endocrine disruptors are defined and applicable. However, the same legislations state that these interim criteria should be replaced by end of 2013. As regards the other pieces of legislation, no such interim criteria have been foreseen.

Drivers:

Three main drivers for the above mentioned problem were identified and are explained below.

1. **Lack of scientific criteria for identification of substances having endocrine disrupting properties**

Although specific risk management provisions on endocrine disruptors are in force in some sectorial legislation, there are no formal criteria established, internationally or at the EU level, for identification of substances having endocrine disrupting properties. The need for such criteria has been recognised by the co-legislators in the adoption of PPPR and BPR, which specifically require the Commission to develop scientific criteria for determination of endocrine disrupting properties and set provisional criteria to be applied till the adoption of scientific criteria for determination of endocrine disrupting properties. The need for such criteria exists also under other legislation. Furthermore, given the multiple uses a substance can have, therefore being subjects to several EU legislations, horizontal criteria for identification of EDs are needed to enable a harmonised approach to the identification of EDs across legislation.

Without horizontal criteria, there is a risk that a substance would be identified as an endocrine disruptor under one piece of legislation and not under another one, leading to inconsistency and incoherent regulatory actions. Each sectorial legislation would continue to act independently contributing to a possibly inconsistent approach with regards to the identification of endocrine disruptors in the EU acquis, thereby creating uncertainty and reducing predictability for economic operators, users, Member States and third countries.

2. **Differences in wordings as regards "endocrine disrupting properties" within and among the legislation**

There is a difference in wording as regards "endocrine disrupting properties" among and within EU legislation. All provisions refer to endocrine disrupting properties, some provisions make also a reference to adverse effects and describe causal relation between the endocrine disrupting properties and adverse effect and some provisions provide additional qualifier for the adverse effect. The language of the existing provisions can be summarised as follows:

Provisions in (related to)	Endocrine disrupting properties	Adverse effect	Strength of evidence for causal relationship
REACH (authorisation)	X	X[a]	"for which there is scientific evidence of probable"
MDD	X	X[a]	"for which there is scientific evidence of probable"
PPPR (approval)	X	X	"that may cause"
BPR (approval)	X	X	"that may cause"
BPR (consumer ban)	X	-	-
WFD	X	-	-
CR	X	-	-
PPP DR	X	-	-

a – there is an additional qualifier for the adverse effect: serious effect which gives rise to an equivalent level of concern to that of CMRs, PBT or vPvB

This different wording as regards "endocrine disrupting properties" within and among the legislation may lead to

Comment [L18]: Please ensure that all these abbreviations are explained in the final roadmap

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Comment [g19]: Or negative effects?

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Comment [g20]: The problem is the lack of criteria (we proceed via WoE now although since Dec 2013, PPPR and BPR are supposed to follow interim criteria) The IA will show the need for harmonization

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different interpretation as regards the evidence required for a substance to be identified as falling within the scope of the legal provisions. In order to avoid inconsistency, the differences in wording need to be addressed when implementing the criteria in each individual piece of sectorial legislation

3. Differences in the regulatory decision making as regards substances having "endocrine disrupting properties" among the provisions of sectorial legislation

Substances with endocrine disrupting properties may be used for different purposes (e.g. as plant protection products, biocidal products, cosmetics, industrial chemicals, medical devices). They are regulated in independent sectorial legislations with different approaches regarding the regulatory decision making (i.e. taking into account hazard, risk, or socio-economic considerations) as summarized below.

Sector	Regulatory decision making taking into account
Plant protection products	Hazard
Biocidal products	Hazard (general public uses) Risk / socio-economic considerations (approval)
Cosmetics	Hazard / risk (to be reviewed)
REACH	1) authorisation: Hazard (for listing) subject to the concept of equivalent concern to CMR/PBTvPvB/ /Risk / socio-economic considerations (to be reviewed) 2) restriction: Risk / socio-economic considerations
Medical devices	Risk / socio-economic considerations (proposal currently in co-decision)
Water framework directive	No decision making directly applicable to authorisation of products; the provisions are risk based

When implementing the criteria in the sectorial legislation, the differences in the regulatory decision making among the provision should be considered as they may influence the impacts of the criteria on the society.

Who will be affected by it?

The implementation of horizontal *scientific criteria for the determination of endocrine disrupting properties* into the various pieces of sectorial legislation will affect economic operators, users, Member States and third countries.

This includes operators marketing chemical substances (plant protection products, biocides, cosmetics and industrial chemicals), laboratories performing animal testing, researchers, small and medium enterprises including farmers, and operators emitting water pollutants falling within the scope of the water framework directive. Also economic operators applying the legislation on medical devices will be affected. Harmonized criteria across the EU and across various sectors will furthermore affect Member States and the internal market. International trade may also be affected.

Users like general population, consumers, and workers exposed to such substances will be affected directly or via the quality of the environment.

In more detail:

Consumers and environment may benefit from the reduced exposure to endocrine disruptors resulting from the new criteria and their implementation into the sectorial legislation. The change regarding the number of available substances for a diversity of products (e.g. valid alternatives to plant protection products identified as endocrine disruptors), may impact availability of products and/or prices, depending on the availability of alternatives.

Users (e.g. SMEs including farmers) may benefit from the reduced occupational exposure to endocrine disruptors resulting from the new criteria and their implementation into the sectorial legislation. The availability of products for their activities could be affected, if such substances are taken from the market (e.g. Regulation (EC) No 1107/2009 currently foresees hazard based decision making with very limited derogations).

Economic operators producing and marketing chemical substances (e.g. biocides, plant protection products, cosmetics, industrial chemicals), producing medical devices or dealing with water pollutants falling within the scope of the Water Framework Directive may be affected because some chemicals may be subject to ban, conditions on the manufacture, use or placing on the market or emission reductions.

Animals: there may be as a consequence an increase in the request for animal testing and thus in the number of animals needed, with all related consequences

Member States and internal market: the implementation of harmonized criteria across the EU and across the various sectors may prevent inconsistent national measures and enable an efficient single market.

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Comment [g21]: What is meant? That legislative changes should be proposed? Is it part of this IA? What is thought to solve this problem should be clarified (either here or later on)

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Comment [g22]: Animal testing and animal welfare should not be forgotten There will be an increase in testing so we might be criticized for this increase in the use of animals (see all the battle when Reach was set up)

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Comment [L23]: The impact assessment related to consumers & environment, and users focuses only on the presumed benefits of reducing the exposure to substances regarded as EDs The text is not considering the potential risks to consumers & environment if these substances are being removed from the market (e g from risks no longer being managed such as mycotoxins, or inherent risks resulting from the alternatives being used in the place of the substances removed from the market?) This is normally done for Biocides but not for PPP

Comment [L24]: Europe 2020, EU competitiveness and innovation are policies that an IA report shall normally also be assessing in order to ensure the coherence of the options with other overarching EU policy objectives

Comment [g25]: I would see "emissions reduction" as encompassed in the "conditions on the manufacture" instead

R&D institutes: the criteria may stimulate the need for more research

International trade under the WTO-SPS agreements and international relations. The ban of certain substances and products in the EU may affect international trade. In particular, maximum residue levels (MRLs) of plant protection products identified as endocrine disruptors will likely be set at the default value of 0.01 mg/kg for all products including imported products and this may impact international trade.

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Comment [L26]: This statement here on page 6 is inconsistent with the following statement on page 15: "The sectorial legislation (BPR, PPPR, REACH, WFD, CR, MDR) is conform with WTO rules " The PPPR will not conform with WTO rules if barriers to trade are created by the ED cut-off criteria and if MRLs are set at the default value of 0 01 mg/kg although the EU has obligations under WTO to follow a risk assessment procedure for the setting of MRLs

Is EU action justified on grounds of subsidiarity? Why can Member States not achieve the objectives of the proposed action sufficiently by themselves? Can the EU achieve the objectives better?

The Initiative addresses legal requirements set out in the Plant Protection Product Regulation and in the Biocidal Products Regulation, which were both adopted through the ordinary legislative procedure. The objectives can therefore not be met through Member State action. EU Action is therefore justified.

In addition, from the human health and environmental point of view, exposure to endocrine disruptors does not adhere to specific borders. Therefore, action at the level of the Union is desired.

Defining horizontal scientific criteria for the determination of endocrine disrupting properties is considered a crucial step to achieve harmonization across the EU on this topic as well as a high level of protection of human health and the environment.

B. Objectives of the initiative

What are the main policy objectives?

General objective within the Treaty:

- ensuring a high level of protection to human health and the environment
- strengthen the functioning of the internal market through harmonisation in the identification of ED

This initiative will address:

Specific objective :

- Provide for legal clarity, predictability and coherence in the identification of endocrine disruptors.

Operational objective:

- Establish horizontal scientific criteria for the identification of endocrine disruptors
- Implement the criteria in the sectorial legislation.
- Proceed to regulatory changes to EU chemicals legislation managing the risks arising from such substances

Comment [g27]: Is it really appropriate as it is not foresee in this IA (unless I missed it) to amend legislations specifically to insert the criteria?

Comment [g28]: This aspect should be added as "2 IA in 1" are proposed to be run in this document, if it is decided to continue as proposed
See suggestions to match with what is proposed in the roadmap later on

Do the objectives imply developing EU policy in new areas?

No.

C. Options

(1) What are the policy options (including exemptions/adapted regimes e.g. for SMEs) being considered?
(2) What legislative or 'soft law' instruments could be considered?
(3) How do the options respect the proportionality principle?

(1) **The Policy Options**

The options presented in this section were developed considering two aspects:

a) the EU horizontal criteria for identifying endocrine disruptors

b) the regulatory decision making for authorisation of substances in the EU sectorial legislation

Both aspects can have different alternatives. The combination of alternatives for the two aspects will result in an option. For clarity, below the alternatives for the two aspects are explained. Further down the options derived are

presented.

Aspect I: EU horizontal criteria to identify endocrine disruptors: A total of 6 different ways to set EU horizontal criteria to identify endocrine disruptors have been considered as potential alternatives:

1) **No policy change (baseline).** No horizontal criteria are specified. Interim criteria for Plant Protection Product and Biocide sectors are in place. REACH and WFD will continue identifying EDs based on the WHO/IPCS definition, but without having specified criteria for their identification. The Regulation on Medical Devices is in ordinary legislative procedure and will likely include specific provisions on endocrine disruptors, but no criteria for their identification. A review of Cosmetic Regulation is foreseen by January 2015.

2) **Criteria based on hazard identification only.** Endocrine disruptors are identified horizontally as:

   a) *Substances which are:*
      i) *known or presumed to have caused endocrine-mediated adverse effects in humans or population-relevant endocrine-mediated adverse effects in animal species living in the environment or*
      ii) *where there is evidence from experimental studies (in vivo), possibly supported with other information (e.g,(Q)SAR, analogue and category approaches) to provide a strong presumption that the substance has the capacity to cause endocrine-mediated adverse effects in humans or population-relevant endocrine-mediated adverse effects on animal species living in the environment;*
   b) *the experimental studies used to determine if a substance is an endocrine disruptor shall provide clear evidence of endocrine-mediated adverse effects in the absence of other toxic effects, or if occurring together with other toxic effects, the endocrine-mediated adverse effects should not be a non-specific secondary consequence of other toxic effects;*
   c) *An adverse effects is a change in the morphology, physiology, growth, development, reproduction, or, life span of an organism, system, or (sub)population that results in an impairment of functional capacity, an impairment of the capacity to compensate for additional stress, or an increase in susceptibility to other influences, as stated in (WHO/IPCS (2009)*
   d) *where there is (e.g. mechanistic) information demonstrating that the effects are clearly not relevant for humans and not relevant at population level to animal species living in the environment, then the substance should not be considered an endocrine disruptor;*
   e) *The identification shall follow a step by step procedure as follows:*
      i) *gather all available data;*
      ii) *assess the data quality, reliability, reproducibility and consistency;*
      iii) *consider adversity and mode of action together in a weight of evidence approach based on expert judgement*
      iv) *evaluate whether endocrine disruption is due to a specific endocrine-mediated mode of action and not to a non-specific secondary consequences of other toxic effects;*
      v) *evaluate human and wildlife relevance;*
      vi) *final (eco)toxicological evaluation indicating, where possible, whether the adverse effect is in relation to human health or environment (vertebrates and/or invertebrate populations), and where possible which are the axes concerned (e.g. oestrogenic, androgenic, thyroid and/or steroidogenic axes).*

3) **Criteria based on hazard identification and inclusion of potency** as element of hazard characterization (hazard identification and characterisation).

   Endocrine disruptors are identified as in 2), considering additionally potency in such way that endocrine mediated adverse effects in experimental animals are taken into account only if observed at concentrations

Deleted: There is a risk that a substance would be identified as an endocrine disruptor under one piece of legislation and not under another one, leading to inconsistency between pieces of legislation and inconsistent risk management measures. This would create uncertainty and reduce predictability for economic operators, users, Member States and third countries

Comment [g29]: There is no consensus to recognize that the WHO definition means hazard identification only Please correct

Deleted: WHO/IPCS definition to identify endocrine disruptors (hazard identification)

Deleted: WHO/IPCS definition to identify endocrine disruptors

Comment [g30]: To be clarified – will it encompass other elements of hazard characterisation (ie a full hazard assessment)? Or is it limited to potency?

From reading the other options, it seems that you limit "the determination of endocrine disrupting properties" to hazard identification or hazard identification + potency and do not consider hazard assessment as a valid option This is regrettable

On a general note, it's regrettable that potency without cut off has not been considered

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at or below 10 mg/kg body weight per day. The value 10 mg/kg body weight per day is consistent with the STOT-RE hazard classes in CLP Regulation and GHS[14].

4) **Criteria based on hazard identification and introduction of additional categories based on the strength of evidence** for fulfilling the WHO/IPCS definition. It is left to each sectorial legislation to include and define the regulatory consequences for categories.

Category I: endocrine disruptors (as defined in 2a-2d)

Category II: suspected endocrine disruptors

a) *substances where there is some evidence for endocrine-mediated adverse effects from humans, animal species living in the environment or from experimental studies, but where the evidence is not sufficiently strong to place the substance in Category I. If, for example, limitations in the study (or studies) make the quality of evidence less convincing, Category II could be more appropriate.*

b) *Endocrine-mediated adverse effects should be observed in the absence of other toxic effects, or if occurring together with other toxic effects, the endocrine-mediated adverse should not be a non-specific secondary consequence of other toxic effects;*

c) *the points c) and d) for Category I remaining valid as well.*

Category III: endocrine active substances

a) *Substances for which there is some in vitro or in vivo evidence indicating a potential for endocrine disruption mediated adverse effects in intact organisms and where the evidence is not sufficiently convincing to place the substance in category I or II.*

The allocation to categories shall follow a step by step procedure as follows:

i) *gather all available data;*

ii) *assess the data quality, reliability, reproducibility and consistency;*

iii) *consider adversity and mode of action together in a weight of evidence approach based on expert judgement*

iv) *evaluate whether endocrine disruption is due to a specific endocrine-mediated mode of action and not to a non-specific secondary consequences of other toxic effects;*

v) *evaluate human and wildlife relevance;*

vi) *final (eco)toxicological evaluation and decision on categorisation indicating, where possible, for Categories I and II whether the adverse effect is in relation to human health or environment (vertebrates and/or invertebrate populations), and where possible which are the axes concerned (e.g. oestrogenic, androgenic, thyroid and/or steroidogenic axes).*

5) **criteria based on hazard identification and including potency** (combination of 3 and 4).

Categories of endocrine disruptors are defined as in 4), considering additionally potency in such way that endocrine mediated adverse effects in experimental animals are taken into account only if observed at concentrations at or below 10 mg/kg body weight per day.

6) **Specify EU-horizontal scientific criteria once these are defined by international fora** (e.g. at the Codex Alimentarius, UN-GHS, or in other international fora). **DISCARDED.**

Research and debate on endocrine disruptors is increasingly growing in the international arena but no discussion on international criteria to identify such substances has yet started.

This possibility is not considered realistic since there are significant differences in regulatory approaches concerning endocrine disruptors in the different regions, which represent a significant obstacle for finding consensus at wider international level. Moreover, EU-horizontal criteria do not need to be agreed at

[14] GHS – Globally Harmonised System of Classification and Labelling of Chemicals

Deleted: WHO/IPCS definition to identify endocrine disruptors

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Comment [g31]: We understand from the meeting that this is the result of a compromise between Env and Sanco but we regret that there is not an option proposing 2categories, per EFSA recommendation: ED and endocrine active substances

Deleted: WHO/IPCS definition to identify endocrine disruptors and introduction of additional categories based on the strength of evidence for fulfilling the WHO/ PCS definition and inclusion of potency as element of hazard characterization

Comment [g32]: To be removed to be in line with the wording of 3)

Deleted: It is left up to each sectorial legislation to include categories and define the regulatory consequences for categories.

international level to be applicable across the whole European Union.

Aspect II: Approaches to regulatory decision making (RDM)

A total of 3 different ways as regards regulatory decision making have been identified as potential alternatives:

A. **No policy change (Baseline).** No provisions are changed.

B. **Policy change: introduction of elements of risk assessment into sectorial legislation** which imposes management measures for placing substances on the market on the basis of hazard identification, where necessary and desired, to reduce potential socio-economic impacts (e.g. amending the PPP Regulation to introduce measures similar to those in the Biocides Regulation as regards the exemption of the ban for the cases where 'negligible risk' (Art 5.2. Regulation 528/2012), rather than of 'negligible exposure', can be demonstrated).

C. **Policy change: introduction of socio-economic considerations into sectorial legislation** which imposes management measures for placing substances on the market on the basis of hazard identification, where necessary and desired, to reduce potential socio-economic impacts (e.g. amending the PPP Regulation to introduce measures similar to those in the Biocides Regulation as regards the exemption of the ban for the cases where the substance is essential to prevent a serious danger or not approving the substance would have a disproportionate negative impact on society (Art 5.2. Regulation 528/2012)).

Policy Options:

The options presented in this section were developed considering the two aspects explained above, i.e. the EU horizontal criteria for identifying endocrine disruptors and the approaches to regulatory decision making for authorisation of substances in the EU sectorial legislation. The options are derived from the combination of alternatives for the two aspects. They are presented in this section and summarized in the table below

For all options, an alignment regarding how endocrine disruptors are referred to in the sectorial legislations will be needed.

SUMMARY TABLE:

ASPECT I: Approaches for criteria to identify endocrine disruptors	ASPECT II: Approaches to regulatory decision making (RDM)		
	A. No policy change	B. Policy change: Introduction of elements of risk assessment where necessary to reduce potential impact	C. Policy change: Introduction of socio-economic considerations where necessary to reduce potential impact
1. No policy change	OPTION 1.A (BASELINE)	Not applicable[15]	
2. hazard identification	OPTION 2.A	OPTION 2.B	OPTION 2.C
3. hazard identification + inclusion of potency)	~~OPTION 3.A~~	Similar to 2B and 2C, respectively[16]	
4. hazard identification + introduction of categories	~~OPTION 4.A~~	~~OPTION 4.B~~	~~OPTION 4.C~~
5. hazard identification + introduction of categories + inclusion of potency	OPTION 5.A	Similar to 4B and 4C, respectively[17]	

[15] **Not applicable** because Option 1.A is the baseline and some EU legislations requests the definition of new criteria for identifying ED.

[16] **Discarded** because the introduction of a decision making based on risk assessment or Socio Economic Analysis may already include hazard characterization in the decision making process, making these options similar to 2B and 2C, respectively.

[17] **Discarded** because the introduction of a decision making based on risk assessment or Socio Economic Analysis may already include hazard characterization in the decision making process, making these options similar to 4B and 4C, respectively.

Comment [g33]: This should not be discarded as this is a real option (even if we know in advance it would take time) It could be said that EU would start the discussions etc

Comment [g34]: This aspect should be reflected in all the sections above(problem definition etc)

Comment [L35]: There is a lack of a "real" risk assessment option in the IA The only consideration of risk assessment is within a derogation Within the IA there should be an option E "Policy change: introduction of risk assessment into sectorial legislation" As the impact assessment includes options which need changes to legal texts (options B and C), there is no reason not to include a real risk assessment option, i e an option assuming removal of the hazard based cut-offs and managing endocrine related concerns completely via risk assessment This would assess the pre Reg 1107/2009 situation and also compare with the global situation

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6. Specify EU-horizontal scientific criteria once these are defined by international fora	OPTION 6.A **Discarded**[18]	**Not applicable**[19]

DESCRIPTION OF THE OPTIONS:

Option 1.A: No policy change (BASELINE)

5) **No horizontal criteria** are specified. Interim criteria for Plant Protection Product and Biocide sectors are in place. REACH and WFD will continue identifying EDs based on the WHO/IPCS definition, but without having specified criteria for their identification. The Regulation on Medical Devices is in co-decision and it will likely include specific provisions on endocrine disruptors, but no criteria for their identification. A review of the Cosmetic Regulation is foreseen by January 2015.

Approaches to regulatory decision making (RDM): No policy change. The **current provisions in the sectorial legislation remain unchanged.**

Option 2.A:

EU horizontal criteria to identify endocrine disruptors: Endocrine disruptors are identified horizontally based on hazard identification). See more details under Aspect I.2.

Approaches to regulatory decision making (RDM): No policy change. The **current provisions in the sectorial legislation remain unchanged**

Option 2.B:

EU horizontal criteria to identify endocrine disruptors: Endocrine disruptors are identified horizontally based on hazard identification. See more details under Aspect I.2.

Approaches to regulatory decision making (RDM): **ntroduction of elements of risk assessment into sectorial legislation** which imposes management measures for placing substances on the market on the basis of hazard identification, where necessary and desired, to reduce potential socio-economic impacts (e.g. amending the PPP Regulation to introduce measures similar to those in the Biocides Regulation as regards the exemption of the ban for the cases where 'negligible risk' (Art 5.2. Regulation 528/2012), rather than of 'negligible exposure', can be demonstrated).

Option 2.C:

EU horizontal criteria to identify endocrine disruptors: Endocrine disruptors are identified horizontally based on hazard identification. See more details under Aspect I.2.

Approaches to regulatory decision making (RDM): **introduction of socio-economic considerations into sectorial legislation** which imposes management measures for placing substances on the market on the basis of hazard identification, where necessary and desired, to reduce potential socio-economic impacts (e.g. amending the PPP Regulation to introduce measures similar to those in the Biocides Regulation as regards the exemption of the ban for the cases where the substance is essential to prevent a serious danger or not approving the substance would have a disproportionate negative impact on society (Art 5.2. Regulation 528/2012)).

Option 3.A:

EU horizontal criteria to identify endocrine disruptors: Endocrine disruptors are identified horizontally based on hazard identification and **potency** in such way that endocrine mediated adverse effects in experimental animals are taken into account only if observed at concentrations at or below 10 mg/kg body weight per day (hazard identification and characterisation). See more details under Aspect I.3.

Approaches to regulatory decision making (RDM): No policy change. The **current provisions in the sectorial legislation remain unchanged.**

Options 3.B and 3C: Similar to 2.B and 2.C, respectively

These Options would add to Option 3.A, the introduction of elements of risk assessment (Option 3B) socio-economic considerations (Option 3C) into sectorial legislation, where necessary and desired, in order to reduce potential socio-economic impacts.

[18] **Discarded** because not considered realis ic. There are significant differences in regulatory approaches in the different regions, which represent a significant obstacle for finding consensus at wider international level. Moreover, EU-horizontal criteria do not need to be agreed at international level to be applicable across the whole European Union.

[19] **Not applicable** because Option 6.A is discarded.

Comment [g36]: See above, this should remain

Deleted: EU horizontal criteria to identify endocrine disruptors:

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Comment [L37]: See remark above suggesting an option representing the pre-PPPR situation with a full risk assessment approach

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Comment [L38]: Options 2B and 2C are similar to 3B and 3C but it should be underlined that the first two do not include potency; the same applies for option 4B/4C compared with 5B/5C By discarding them we have to realise that we exclude those options which include potency in the criteria plus negligible exposure and socio-economic considerations (=exemptions existing for Biocides) Also as mentioned above neither is there a pure risk assessment option

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These Options are however not further investigated because the introduction of a decision making based on risk assessment and/ or socio-economic considerations may already include hazard characterisation in the decision making process. In summary, Options 2B and 2C are similar to 3B and 3C, respectively.

Option 4.A

EU horizontal criteria to identify endocrine disruptors: Endocrine disruptors are identified horizontally based on hazard identification and **additional categories based on the strength of evidence** for fulfilling the WHO/IPCS definition are introduced as described above in Aspect I.4. It is left up to each sectorial legislation to include and define the regulatory consequences for categories.
Approaches to regulatory decision making (RDM): No policy change. The **current provisions in the sectorial legislation remain unchanged.**

Option 4.B:

EU horizontal criteria to identify endocrine disruptors: Endocrine disruptors are identified horizontally based on hazard identification and **additional categories based on the strength of evidence** for fulfilling the WHO/IPCS definition are introduced as described above in Aspect I.4.
Approaches to regulatory decision making (RDM): **introduction of elements of risk assessment into sectorial legislation** which imposes management measures for placing substances on the market on the basis of hazard identification, where necessary and desired, to reduce potential socio-economic impacts (e.g. amending the PPP Regulation to introduce measures similar to those in the Biocides Regulation as regards the exemption of the ban for the cases where 'neglig ble risk' (Art 5.2. Regulation 528/2012), rather than of 'negligible exposure', can be demonstrated).

Option 4.C:

EU horizontal criteria to identify endocrine disruptors: Endocrine disruptors are identified horizontally based on hazard identification and **additional categories based on the strength of evidence** for fulfilling the WHO/IPCS definition are introduced as described above in Aspect I.4.
Approaches to regulatory decision making (RDM): **introduction of socio-economic considerations into sectorial legislation** where necessary and desired, to reduce potential socio-economic impacts (e.g. amending the PPP Regulation to introduce measures similar to those in the Biocides Regulation as regards the exemption of the ban for the cases where the substance is essential to prevent a serious danger or not approving the substance would have a disproportionate negative impact on society (Art 5.2. Regulation 528/2012)).

Option 5.A:

EU horizontal criteria to identify endocrine disruptors: Endocrine disruptors are identified horizontally based on hazard identification and including potency, **additional categories based on the strength of evidence** for fulfilling the WHO/IPCS definition are introduced **and** considering additionally **potency** in such way that endocrine mediated adverse effects in experimental animals are taken into account only if observed at concentrations at or below 10 mg/kg body weight per day. See more details under Aspect I.5. It is left up to each sectorial legislation to include and define the regulatory consequences for categories.
Approaches to regulatory decision making (RDM): No policy change. The **current provisions in the sectorial legislation remain unchanged.**

Options 5.B and 5C: SIMILAR TO 4.B AND 4.C, RESPECTIVELY

These Options would add to Option 5.A, the introduction of elements of risk assessment (Option 5B) socio-economic considerations (Option 5C) into sectorial legislation, where necessary and desired, in order to reduce potential socio-economic impacts.
These Options are however not further investigated, because the introduction of a decision making based on risk assessment and/ or socio-economic considerations may already include hazard characterisation in the decision making process. In summary, Options 4B and 4C are similar to 5B and 5C, respectively.

Option 6.A: Specify EU horizontal criteria once defined in international fora. DISCARDED

Research and debate on endocrine disruptors is increasingly growing in the international arena, but no discussion on international criteria to identify such substances has yet started.

This option is not considered realistic since there are significant differences in regulatory approaches concerning endocrine disruptors in the different regions, which represent a significant obstacle for finding consensus at wider international level. Moreover, EU-horizontal criteria do not need to be agreed at international level to be applicable across the whole European Union.

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Comment [L39]: See remark above suggesting an option representing the pre-PPPR situation with a full risk assessment approach

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Comment [g40]: See comments above, this should be left

(2) **Legislative or 'Soft Law' Options**

There are three possibilities as how to define and implement horizontal criteria which will be considered in the impact assessment:

1. The criteria and categories are specified in the form of a Commission recommendation;
2. The criteria and categories are specified in the form of a Commission communication
3. The criteria and categories are defined and set in a Regulation

The feas bility and appropriateness of each of these possibilities depends on the final option chosen. Options 2.A, 3.A, 4.A and 5.A can be achieved by all three possibilities, however the horizontal nature of the criteria would be best ensured via a Regulation. Options 2.B, 2.C, 4.B and 4.C can be achieved only via a Regulation as modification of the provisions in (some) sectorial legislation would be necessary.

Currently the legal requirements set out in the Plant Protection Product and the Biocidal Product Regulations regarding the definition of criteria for identifying endocrine disruptors specify the legislative procedures to apply, which are:

- For the Plant Protection Products Regulation: Regulatory Procedure with Scrutiny;
- For the Biocidal Products Regulation: Delegated Act.

Soft law options such as for instance self-regulatory approach are not considered optimal, as it cannot be ensured that horizontal criteria are being set and adhered to, which is not an advisable solution as explained in Section A of the problem definition. Those options will not be investigated further in the frame of this IA

Comment [g41]: This to make clear that soft law will not be subject to the IA as such (if I have understood well)

(3) **Proportionality Principle**

Defining horizontal scientific criteria for the determination of endocrine disruptors and the alignment of the sectorial legislation with the criteria is the only way to ensure a harmonised and coherent approach when dealing with endocrine disruptors and to achieve legal coherence and certainty, regulatory consistence and predictability to all players.

The considered options do not go beyond what is necessary to achieve the objectives satisfactorily. The scope of their action is limited to those aspects that Member States cannot achieve satisfactorily on their own and where action at Union level is preferred.

D. Initial assessment of impacts

What are the benefits and costs of each of the policy options?

General Considerations on impacts on authorisations of products / legislation:

Setting horizontal criteria for identification of endocrine disruptors is expected to affect several sectorial pieces of EU legislation to a variable extent depending on the current provisions as regards regulatory decision making provided for in the respective legislation (see problem definition and table below). As a consequence, socio-economic impacts may vary among sectors.

Legislation containing provisions on ED	Expected impact on the availability of substances on the market
Plant Protection Products Regulation Biocidal Products Regulation (general public uses)	Higher impact (decision-making based on hazard identification)

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Biocidal Products Regulation (approvals) REACH Cosmetic Products (to be reviewed) Medical Devices (proposal currently in co-decision) Water Framework Directive	Lower impact (decision making based on risk assessment and/or socio-economic considerations)

Preliminary impact for the different options:

Option 1.A: No policy change (BASELINE): No EU horizontal criteria to identify endocrine disruptors are specified and the current provisions in the sectorial legislation regarding regulatory decision making remain unchanged.

Although the administrative burden is low, the confidence in the measures taken may be low because the interim criteria were set by the legislator as temporary measures.

Further, this option does not foresee extending horizontal criteria to other relevant legislation. This option is thus not achieving consistency across the EU sectorial legislations on chemicals, providing instability for the economic operators, in particular in the cases where the same chemical substance falls under different legislations and where there might be risk that a substance would be identified as an endocrine disruptor under one piece of legislation and not under another one, leading to inconsistency between pieces of legislation and inconsistent risk management measures.

Option 2.A: Endocrine disruptors are identified horizontally based on **hazard identification** and the current provisions in the sectorial legislation regarding regulatory decision making remain unchanged.

This Option defines science-based horizontal criteria. The criteria used will identify substances fulfilling the WHO/IPCS definition as endocrine disruptors for the sectorial legislation mentioned before (PPPR, BPR, REACH, CR, MDR, WFD).

The different sectors may be affected in different ways, depending on the respective current regulatory decision making process in place. For sectors that foresee decision making based on risk or on socio-economic considerations (BPR, REACH, MDR, WFD), the impact on number of identified substances may be less significant. For sectors with decision making based on hazard identification (PPPR, BPR general public uses), the impact on number of identified substances is expected to be higher.

Option 2.B: Endocrine disruptors are **identified as in Option 2.A and elements of risk assessment** may be introduced into sectorial legislation.

This Option defines science-based horizontal criteria and introduces the possibility to amend some sectorial legislation by introducing elements of risk assessment in the decision making process. Impacts on the availability of substances on the market are expected to be reduced with respect to Option 2.A, because the regulatory decision making will be based on risk assessment and not on hazard identification.

Option 2.C: Endocrine disruptors are **identified as in Option 2.A and socio-economic considerations** may be introduced into sectorial legislation.

This option defines science-based horizontal criteria and introduces the possibility to amend some sectorial legislation by introducing socio-economic considerations in the decision making process. Impacts on the availability of substances on the market are expected to be reduced with respect to Options 2.A and 2.B, because the regulatory decision making will consider also socio-economic considerations. In those legislative pieces in which elements of socio-economic assessment will be newly introduced, the level of protection might be different compared to the application of the current rules.

Option 3.A: Endocrine disruptors are identified as in **Option 2.A considering additionally potency (hazard identification and characterisation)**. The current provisions in the sectorial legislation regarding regulatory decision making remain unchanged.

This option defines science based horizontal criteria as in option 2.A and adds the hazard characterisation

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Comment [L42]: See remark above suggesting an option representing the pre-PPPR situation with a full risk assessment approach

Comment [g43]: This is a purely hypothetical claim as you have no idea where the level of protection actually is today as practically no decisions have been taken, and/or EDs have been banned anyway due to reprotoxic or other effects Also to note: if a ban is motivated by hazard identification only, even though a risk assessment would show that there is actually no risk (due to low exposures), the level of protection is not at all higher as continued use of the substance would also not cause a risk

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Comment [g44]: In our view, hazard assessment is out (not only hazard identification) Risk assessment starts with considerations of real life exposure

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consideration of a potency cut off. This option may result in fewer substances being identified by the criteria than in options 2.A, 2.B. and 2.C. across all relevant legislation using the criteria. The inclusion of this parameter represents a pragmatic approach to identify only the most potent substances. An issue that may need to be reconciled is the consideration of risk management in certain pieces of legislation (e.g. BPR, REACH) in substance identification as an ED and in risk management.

Option 4.A: Endocrine disruptors are identified as in **Option 2.A** and **additional categories based on the strength of evidence** for fulfilling the WHO/IPCS definition are introduced. The current provisions in the sectorial legislation regarding regulatory decision making remain unchanged.

This Option defines science-based horizontal criteria. The criteria used will identify substances fulfilling the WHO/IPCS definition as endocrine disruptors for the sectorial legislation mentioned before (PPPR, BPR, REACH, CR, MDR, WFD).

The different sectors will be affected in different ways, depending on the respective current regulatory decision making process in place. As in the Option 2.A, for sectors with decision making based on hazard identification (PPPR, BPR general public uses), the impact on number of identified substances are expected to be higher as compared to the sectors with decision making based on risk or on socioeconomic considerations (BPR, REACH, MDR, WFD).

The number of substances identified as EDs in Category 1 is expected to be lower as compared to the option 2.A (option without categories): experience with the categorisation of CMRs has shown that the existence of categories better facilitates the work of assessors who have to judge the varying strength of evidence when making their decisions, by mitigating the pressure to make yes/no decisions. In turn this results in less substances being identified in the higher category (Cat 1). The categories would allow for differentiated regulatory action and categories 2 and 3 would provide early warning and trigger for industry to verify the safety of their products. On the other hand, it will create stigmatisation due to the black-listing effects of substances in cat 2 and 3 . Furthermore, this will create uncertainties on the market as regulatory consequences attached to cat II and II might not be clear and totally different from one piece of legislation to the others.

Substances listed in Categories 2 and 3 (endocrine active substances) may be stigmatized, although they do not comply with the WHO/IPCS definition of endocrine disruptor. In addition, because of the ban on animal tests for substances exclusively used in cosmetic products, this would result in a permanent listing under Category 3 for those substances.

Option 4.B: Endocrine disruptors are identified as in **Option 2.A** and **additional categories based on the strength of evidence** for fulfilling the WHO/IPCS definition are introduced. **Elements of risk assessment** may be introduced into sectorial legislation.

This Option defines science-based horizontal criteria and introduces the possibility to amend some sectorial legislation by introducing elements of risk assessment in the decision making process. Impacts on the availability of substances on the market are expected to be reduced with respect to Option 4.A, because the regulatory decision making will be based on risk assessment and not only on hazard identification.

The number of substances identified as EDs in Category 1 is expected to be lower as compared to option 2.B (option without categories): experience with the categorisation of CMRs has shown that the existence of categories better facilitates the work of assessors who have to judge the varying strength of evidence when making their decisions, by mitigating the pressure to make yes/no decisions. In turn this results in less substances being identified in the higher category (Cat 1). The categories would allow for differentiated regulatory action and categories 2 and 3 would provide early warning and trigger for industry to verify the safety of their products. On the other hand, it will create stigmatisation due to the black-listing effects of substances in cat 2 and 3 . Furthermore, this will create uncertainties on the market as regulatory consequences attached to cat II and II might not be clear and totally different from one piece of legislation to the others.

Substances listed in Categories 2 and 3 (endocrine active substances) may be stigmatized, although they do not comply with the WHO/IPCS definition of endocrine disruptor. In addition, because of the ban on animal tests for substances exclusively used in cosmetic products, this would result in a permanent listing under Category 3 for those substances.

Option 4.C: Endocrine disruptors are identified as in **Option 2.A** and **additional categories based on the strength of evidence** for fulfilling the WHO/IPCS definition are introduced. **Socio-economic considerations** may be introduced into sectorial legislation.

This option defines science-based horizontal criteria and introduces the possibility to amend some sectorial legislation by introducing socio-economic considerations in the decision making process. Impacts on the availability of substances on the market are expected to be reduced with respect to Options 4.A and 4.B, because the regulatory decision making will consider also socio-economic considerations. In those legislative pieces in which elements of socio-economic assessment will be newly introduced, the level of protection might

Comment [g45]: Not only to consumers but within the whole industry (down stream users), which will have the biggest impacts

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Comment [L46]: See remark above suggesting an option representing the pre-PPPR situation with a full risk assessment approach

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be different compared to the application of the current rules

The number of substances identified as EDs is expected to be lower as compared to option 2B (option without categories): experience with the categorisation of CMRs has shown that the existence of categories better facilitates the work of assessors who have to judge the varying strength of evidence when making their decisions, by mitigating the pressure to make yes/no decisions. In turn this results in less substances being identified in the higher category (Cat 1). The categories would allow for differentiated regulatory action and categories 2 and 3 would provide early warning and trigger for industry to verify the safety of their products. On the other hand, it will create stigmatisation due to the black-listing effects of substances in cat 2 and 3 . Furthermore, this will create uncertainties on the market as regulatory consequences attached to cat II and II might not be clear and totally different from one piece of legislation to the others

Substances listed in Categories 2 and 3 (endocrine active substances) may be, although they do not comply with the WHO/IPCS definition of endocrine disruptor. In addition, because of the ban on animal tests for substances exclusively used in cosmetic products, this would result in a permanent listing under Category 3 for those substances.

Option 5.A: Endocrine disruptors are identified as in **Option 2.A, additional categories based on the strength of evidence** for fulfilling the WHO/IPCS definition are introduced **considering additionally potency (hazard identification and characterisation)**. The current provisions in the sectorial legislation regarding regulatory decision making remain unchanged.

This option defines science-based horizontal criteria and adds the risk management consideration of a potency cut off as in Option 3.A. This option may result in fewer substances being identified by the criteria than in options 4.A, 4.B. and 4.C. across all relevant legislation using the criteria. The inclusion of this parameter represents a pragmatic approach to identify only the most potent substances. An issue that may need to be reconciled is the consideration of risk management in certain pieces of legislation (e.g. BPR, REACH authorisation) in substance identification as an ED and in risk management.

The number of substances identified as EDs in Category 1 is expected to be lower as compared to option 3.A (option without categories): experience with the categorisation of CMRs has shown that the existence of categories better facilitates the work of assessors who have to judge the varying strength of evidence when making their decisions, by mitigating the pressure to make yes/no decisions. In turn this results in less substances being identified in the higher category (Cat 1). The categories would allow for differentiated regulatory action and categories 2 and 3 would provide early warning and trigger for industry to verify the safety of their products. On the other hand, it will create stigmatisation due to the black-listing effects of substances in cat 2 and 3 . Furthermore, this will create uncertainties on the market as regulatory consequences attached to cat II and II might not be clear and totally different from one piece of legislation to the others

Substances listed in Categories 2 and 3 (endocrine active substances) may be stigmatized in communication to consumers, although they do not comply with the WHO/IPCS definition of endocrine disruptor. In addition, because of the ban on animal tests for substances exclusively used in cosmetic products, this would result in a permanent listing under Category 3 for those substances.

The category system (adjusted for categorisation also according to potency) allows for maintaining the information that a substance is a low potent endocrine disruptor.

Could any or all of the options have significant impacts on (i) simplification, (ii) administrative burden and (iii) on relations with other countries, (iv) implementation arrangements? And (v) could any be difficult to transpose for certain Member States?
(i) All options with exception of the baseline (Option 1.A) aim at establishing horizontal criteria applicable across all relevant legislation and is expected to simplify the implementation of the legislation as well as to avoiding re-examining at a later stage possible harmonization of dysharmonized criteria and their impacts on current legislation. (ii) It is expected that this initiative will create administrative burdens as considerable work will follow for authorities and economic operators it. (iii) The sectorial legislation (BPR, PPPR, REACH, WFD, CR, MDR) is conform with WTO rules. The number of substances identified by the options may have corresponding impact on trade. For example, in the PPPR, as no other country has developed criteria for identifying endocrine disruptors, we may expect restrictions as regards the maximum residue levels of some products placed on the EU market by third countries (maximum residue levels (MRLs) of plant protection products identified as endocrine disruptors will likely be set at the default value of 0.01 mg/kg for imported products). (iv) it is expected that this initiative will need implementation arrangements; (v) it is not expected that this initiative will produce transposition difficulties.

Comment [g47]: Same comment as in g27

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Deleted: stigmatized in communication to consumers

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Comment [g48]: This is incorrect as we will have several legislative actions to undertake following this (legal instrument to communicate, acts under BPR and PPPR etc)

Deleted: is not expected that this initiative will significantly a priori alter the administrative burden;

Comment [g49]: This is not really correct we 'll have to implement the "criteria"

Deleted: not

(1) Will an IA be carried out for this initiative and/or possible follow-up initiatives? (2) When will the IA work start? (3) When will you set up the IA Steering Group and how often will it meet? (4) What DGs will be invited?
(1) Yes (2) January 2014 (3) An IA Steering Group is foreseen. It will be set up and meet for the first time in January 2014 and then approximately every three months (4) ENV, ENTR, SANCO, RTD, JRC, AGRI, MARE, TRADE, EMPL, COMP, CLIMA, CNECT, SG, LS
(1) Is any option likely to have impacts on the EU budget above € 5m? (2) If so, will this IA serve also as an ex-ante evaluation, as required by the Financial Regulation? If not, provide information about the timing of the ex-ante evaluation.
(1) No. (2) Not relevant.

E. Evidence base, planning of further work and consultation
(1) What information and data are already available? Will existing IA and evaluation work be used? (2) What further information needs to be gathered, how will this be done (e.g. internally or by an external contractor), and by when? (3) What is the timing for the procurement process & the contract for any external contracts that you are planning (e.g. for analytical studies, information gathering, etc.)? (4) Is any particular communication or information activity foreseen? If so, what, and by when?
(1) The existing databases with hazard and risk assessment information from e.g. ECHA, EFSA and European Commission (e.g. JRC, SANCO) are intended to be used as a basis for the Impact Assessment. The existing impact assessments performed by some Member States and by the EP may be also used as information for the formal IA (see Section A). (2) Information on disease incidences associated with the exposure to endocrine disruptors and associated costs to the society should be collected. One or more contracts to support the Impact Assessment are expected, using internal resources or the framework contracts established by DG ENV and DG SANCO. Moreover, further information will be gathered through a public consultation, expected to start in first quarter 2014, regarding the criteria, the options and the impacts (costs and benefits) of the options mentioned in Section D. The IA is expected to be carried out in three main steps as mentioned in Section D: I. For each sectorial EU legislation concerned by EDs, an estimation of the number of substances potentially flagged as endocrine disruptors under the different alternatives for defining horizontal criteria (Aspect I), via e.g. a identification on the basis of the ECHA, EFSA and/or Commission (JRC, SANCO) databases of the main families of substances potentially affected (toxicological expertise needed); II. For the Plant Protection Products, Biocides, REACH and Cosmetics sectors, where possible and necessary, a detailed identification of the substances affected by the different options (toxicological expertise needed); III. For the Plant Protection Products and Biocides sectors, as well as other chemicals related legislation, where possible and necessary, a socio-economic assessment of the different options (socio-economic expertise needed). (3) The studies are expected to be started in early 2014. (4) None currently.
Which stakeholders & experts have been or will be consulted, how, and at what stage?
Member State experts, industry representatives, NGOs and social partners participated in the Ad-hoc policy group and expert group established in 2010 by the Commission to discuss developments on endocrine disruptors. Several meetings were held between November 2010 and May 2013. In addition, the Commission hosted a major EU conference in Brussels in June 2012. JRC experts have been consulted and involved in the process.

Comment [g50]: Do we have such clear data? For the time being, as the causes are multifactorial, it's more than difficult to relate one type of cancer etc to a specific ED

Comment [B51]: Why not for the others?

Comment [g52]: Per discussion at the meeting, I understand it will be a lighter SEA so perhaps good to be mentioned here if needed Just to indicate to STKH that it will be conducted in any case but in a different way

In August 2012, the Commission (DG SANCO) mandated EFSA to issue a scientific opinion on the hazard assessment of endocrine disruptors, which was published on March 2013.

One or more contracts to support the Impact Assessment with the necessary toxicological and socio-economic expertise are foreseen.

A public consultation will be held, expected to start in first quarter 2014, to collect views of all interested parties.