ROADMAP			
TITLE OF THE INITIATIVE	Defining criteria for identifying Endocrine Disruptors in the context of the implementation of the Plant Protection Product Regulation and Biocidal Products Regulation		
LEAD DG – RESPONSIBLE UNIT	DG ENV.A.3, DG SANCO.E.3	**DATE OF ROADMAP**	06/2014
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)

Chemicals with endocrine-disrupting properties ("endocrine disruptors" – **ED**) impact on the hormone system of animals and humans. Endocrine disruption is a relatively recent way of looking at the toxicity of chemicals. There is now scientific consensus in many areas, though diverging views exist on specific points within the scientific community and regulators worldwide.

There is general consensus on 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*.

Although provisions on ED are in force in some sectoral EU legislation, no formal criteria have been established, internationally or at the EU level, for identifying ED.

The placing on the market of plant protection products and biocidal products are regulated by two separate pieces of Union legislation namely the Plant Protection Product Regulation (EC) 1107/2009 (**PPPR**) and the Biocides Product Regulation (EU) 528/2012 (**BPR**). Under each instrument, the co-legislators have empowered the Commission to establish scientific criteria to identify substances with endocrine disrupting properties.

The BPR and the PPPR also set the regulatory consequences for substances considered as ED: Annex II, Section 3.6.5 of the PPPR and Article 5 of the BPR 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, Article 19(4) of the BPR 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.

(2)

The provisions in the PPPR and the BPR regarding EDs were adopted in the context of substantial scientific, policy and legislative activity within the EU and internationally during the past 15 years. The development of criteria that will be used to identify substances with endocrine disrupting properties under the Biocides Regulation and the Plant Protection Products Regulation is related to the general calls on the Commission to

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

- In 1999, the Commission 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 definition of horizontal criteria for identifying endocrine disruptors. The Commission is developing a Commission Staff Working Paper with the evaluation of the old 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

- The Commission also established in 2010 two Commission expert groups to provide open and transparent fora for the exchange information on various scientific and policy aspects related to ED. 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], which was published in March 2013.

Concerning EU legislation, apart from the PPPR and the BPR, specific provisions governing endocrine disruptors are included in several other pieces of the EU legislation that regulate the marketing and use of chemical substances. This applies, in particular, to the following:

- 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 addition, the Commission has to review the way ED are authorised under REACH.

- 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.*

- 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.*

However, there are differences in wording in relation to ED 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:

[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

Provisions in (related to)	Endocrine disrupting properties	Adverse effect	Strength of evidence for causal relationship
REACH	X	X[a]	"for which there is scientific evidence of probable"
Medical Devices Directive	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	-	-
Water Framework Directive	X	-	-
Cosmetics Regulation	X	-	-
PPP DR	X	-	-

a – an additional qualifier for the adverse/serious effect exists which leads to an equivalent level of concern to that of CMRs, PBT or vPvB

Moreover, the regulation of ED follows, in different pieces of legislation, different approaches:

Sector	Regulatory decision making taking into account
Plant protection products	Mainly Hazard with limited risk elements
Biocidal products	Hazard (general public uses) Risk / socio-economic considerations (approval)
Cosmetics	Hazard / risk (to be reviewed)
REACH	Hazard (for listing)/ /Risk / socio-economic considerations (to be reviewed)
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

Other sectorial legislation (e.g. on EU Occupational Safety and Health, on Pharmaceuticals and on Food Contact Materials) regulate ED together with other chemicals on a case by case basis, with no specific provisions related to ED.

Finally, the Classification, Labelling and Packaging Regulation transposes the UN Globally Harmonised System for Classification and Labelling into EU law. This enables the identification and categorisation of most known adverse effects relevant for human health and the environment. These include the main adverse human health effects expected to be caused by endocrine disruptors (i.e. reproductive toxicity and some cancers). 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.

(3)

Given the absence of criteria for identifying ED, no ex-post analysis of the existing policies has been carried out. However, impact assessments were carried out during the legislative process of the PPPR by different organisations (PSD, United Kingdom[3], KEMI, Sweden[4], and European Parliament[5]) aiming at determining which substances used as plant protection products have *endocrine disrupting properties which may cause adverse effects* and thereby would not be approved. These 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 contracted by the UK department for environment, food and rural affairs HSE[6]. The benefits of not approving these substances were not determined.

What are the main problems which this initiative will address?

The first problem addressed in this initiative is the absence of criteria for ED in the BPR and the PPPR, while ED are regulated in these pieces of legislation. These criteria have to be operational, i.e. they have to allow for science-based regulatory decision-making.

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

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

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

[6] 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

The second problem is that, since ED are referred to in numerous legislation, these criteria should be developed with the aim of enabling their "horizontal" application in the wider legislation covering the regulation of ED in different regulatory settings (see above).

Who will be affected by it?

The implementation of *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, and small and medium enterprises including farmers. International trade may also be affected.

Users like the general population, consumers, and workers exposed to ED will be affected directly or via the quality of the environment. There may also be indirect impacts for end consumers in terms of the availability of certain products or higher costs for products including agricultural commodities.

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 is a legal obligation for the Commission set out in the PPPR and in the BPR, 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.

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
- strengthening the functioning of the internal market

Specific objective for PPPR and BPR:

- providing for legal clarity, predictability and coherence in the identification of ED
- providing for scientific criteria that are operational in terms of regulatory decision-making,
- ensuring possibility to apply these criteria across all relevant Union legislation
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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**

Different options will be assessed. With regard to options 3 and 4 below, the assessment will also look at whether they can be implemented under existing regulations or whether legislative changes are needed.

Aspect I: EU criteria to identify EDs

Option 1: No policy change (baseline). No criteria are specified. The interim criteria set in the BPR and the PPPR could continue to apply.

Option 2: WHO/IPCS definition to identify endocrine disruptors (hazard identification).

Endocrine disruptors are identified 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 or mechanisms concerned (e.g. oestrogenic, androgenic, thyroid and/or steroidogenic axes).*

Option 3: WHO/IPCS definition to identify endocrine disruptors and introduction of additional categories based on the different strength of evidence for fulfilling the WHO/IPCS definition.

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 effects 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 or mechanisms concerned (e.g. oestrogenic, androgenic, thyroid and/or steroidogenic axes).*

Option 4: WHO/IPCS definition to identify endocrine disruptors and inclusion of potency as element of hazard characterization (hazard identification and characterisation).

Aspect II: Approaches to regulatory decision making

Option A: No policy change (Baseline). The provisions in the BPR and the PPPR on regulatory consequences are not changed.

Option B: Introduction of elements of further elements of risk assessment into sectorial legislation where management measures for placing substances on the market are mainly based on hazard identification. This introduction should be done where necessary and desired, to reduce potential socio-economic impacts (e.g. amending the PPPR to introduce measures similar to those in the BPR as regards the exemption of the ban for the cases where 'negligible risk' (Art 5(2) of the BPR), rather than of 'negligible exposure', can be demonstrated).

Option C: Introduction of further socio-economic considerations, including risk-benefit analysis, into sectorial legislation where necessary and desired, to allow the placing on the market of products in situations where an ED is essential to prevent adverse socio-economic impacts (e.g. amending the PPP Regulation to introduce measures similar to those in the Biocides Regulation as regards the exemption from the ban for cases where not approving the substance would have a disproportionate negative impact on society (Art 5.2. Regulation 528/2012)).

Proportionality Principle

Defining scientific criteria for the determination of endocrine disruptors 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?

Preliminary impact for the different options:

Aspect I - EU criteria to identify ED

Option 1: This option would run counter the requirements of the PPPR and the BPR. It would not address the second and third specific objective set out above.

Option 2: The different sectors may be affected in different ways, depending on the existing regulatory decision making processes. 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 mainly based on hazard identification (PPPR, BPR general public uses), the impact on number of identified substances is expected to be higher.

Option 3: The different sectors may be affected in different ways, depending on the existing regulatory decision making process. As in the Option 2, for sectors with decision making mainly 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 (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 may result 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.

Substances listed in Category 3 (endocrine active substances) may be stigmatised, 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: This option may result in fewer substances being identified than in option 2.

Aspect II - Approaches to regulatory decision making

Option A: The differences in regulatory approaches will persist – in particular between the PPPR and the BPR which could result in different regulatory decisions concerning the same ED.

Option B: Impacts on the availability of substances on the market are expected to be reduced with respect to Option A, because further elements of risk assessment will be introduced in legislation where the decision making is mainly based on hazard identification.

Option C: Impacts on the availability of substances on the market are expected to be reduced, because further socio-economic considerations will be introduced in legislation where desired and needed.

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) This initiative may be considered as simplification in the sense that it gives clarity on an important implementation aspect of the PPPR and the BPR.

(ii) and (iii) Administrative burden as defined in the Commission's impact assessment guidelines and impacts on relation with third countries (trade) may arise, depending on the chosen policy option.;

(iv) It is not expected that this initiative will need implementation arrangements;

(v) It is not expected that this initiative will produce transposition difficulties.

(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) There has been preliminary work carried out in 2013. The actual work starts in 2014.

(3) An IA Steering Group has been set up in 2013 in the context of the preliminary work. The group meets approx. every 3-6 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 assessment 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 linked with exposure to endocrine disruptors and associated costs to

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 2014, regarding the criteria, the options and the impacts (costs and benefits) of the options mentioned in Section D.

(3) Work on the studies is expected to be started in 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.

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.

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