

## IMPACT ASSESSMENT ANNEX Ia

### The number of endocrine disrupting pesticides that may cause damage to human health and should be regulated (1107/2009, Annex II, 3.6.5<sup>1</sup>)

## Introduction

Although the pesticide regulation (Regulation 1007/2009) was put into force in 2011 and mandates to regulate the use of pesticides with endocrine disrupting properties, the criteria that define endocrine disrupting pesticides are still missing. In June 2014, the Commission published a Roadmap<sup>2</sup> that outlines the different options considered by the regulators for the definition, criteria and regulatory decision-making of endocrine disruptors. Most of the options considered fail to include all knowledge from the field of endocrine disruption research, as explained in PAN Europe's position paper on the roadmap<sup>3</sup>, and thus will inevitably jeopardize the effectiveness of the Pesticide regulation to protect human and the environment from exposure to chemicals that interfere with their hormonal system.

In the current report, PAN Europe has conducted a research to assess what will happen in the approval of pesticides, if the provisional criteria for endocrine disrupting pesticides are applied. As provided by Regulation 1007/2009, Art. 4, any assessment, leading to an approval of pesticides, needs to be done based on current scientific and technologic knowledge. And this is exactly what we've done, we have collected all available research, studies and reports, no matter from what source (independent literature or industry's dossiers), and developed a database with >800 documents that contains all current scientific knowledge on endocrine disrupting pesticides. Using this database we assessed the impact of the endocrine criteria on the approval of pesticides.

## Methodology

For the assessment of the pesticides we followed the Pesticide Regulation Annex II, 3.6.5 that identifies two elements: active substances used for pesticides should not be considered to have endocrine disrupting properties that may cause adverse effects<sup>1</sup>.

First, we composed a list of all pesticides, which have shown endocrine disrupting properties in scientific studies, mainly using in-vitro assays. We consulted the list of pesticides developed by Sweden<sup>4</sup>, as well as

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<sup>1</sup> 3.6.5. An active substance, safener or synergist shall only be approved if, on the basis of the assessment of Community or internationally agreed test guidelines or other available data and information, including a review of the scientific literature, reviewed by the Authority, it is not considered to have endocrine disrupting properties that may cause adverse effect in humans, unless the exposure of humans to that active substance, safener or synergist in a plant protection product, under realistic proposed conditions of use, is negligible, that is, the product is used in closed systems or in other conditions excluding contact with humans and where residues of the active substance, safener or synergist concerned on food and feed do not exceed the default value set in accordance with point (b) of Article 18(1) of Regulation (EC) No 396/2005.

By 14 December 2013, the Commission shall present to the Standing Committee on the Food Chain and Animal Health a draft of the measures concerning specific scientific criteria for the determination of endocrine disrupting properties to be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 79(4).

Pending the adoption of these criteria, substances that are or have to be classified, in accordance with the provisions of Regulation (EC) No 1272/2008, as carcinogenic category 2 and toxic for reproduction category 2, shall be considered to have endocrine disrupting properties.

In addition, substances such as those that are or have to be classified, in accordance with the provisions of Regulation (EC) No 1272/2008, as toxic for reproduction category 2 and which have toxic effects on the endocrine organs, may be considered to have such endocrine disrupting properties.

<sup>2</sup> [European Commission- Roadmap on Endocrine Disruptors](#)

<sup>3</sup> [PAN- Europe's position paper on Commission's EDCs-Roadmap](#)

<sup>4</sup> [KEMI 23 incl ED pesticides](#)

the review done by McKinlay et al. (2008)<sup>5</sup>. We also used the SANCO database on pesticides that provides good information on status of pesticides<sup>6</sup> and the CLP-website<sup>7</sup> to find out about the regulatory classifications of pesticides.

We also conducted a PUBMED<sup>8</sup> scientific literature search. It has to be noted that for many pesticides, especially the newer ones, hardly any studies can be found in independent literature, and the number of pesticides with endocrine disrupting properties is likely higher. This list of pesticides we composed, includes about 10% of the total number of pesticides approved in the EU and was used as a basis for further evaluation.

Next, for this list of pesticides we looked if they "may cause adverse effects" as indicated in the regulation (Reg. 1107/2009, Annex II, 3.6.5). We tried to identify studies, generally in-vivo mammalian studies and epidemiology studies, demonstrating adverse effects on the endocrine system. We used regulatory studies and independent studies. For the regulatory studies we analysed the Draft Assessment Reports (DAR) composed by the Rapporteur member state and the industrial applicant. Most DARs can be found on the EFSA webpage<sup>9</sup>, and for the older DARs we were obliged to do an official 'access to documents' request to DG SANCO. We also took advantage of an in-depth study done by UK-HSE/CRD<sup>10</sup> and again the work of Swedish KEMI<sup>11</sup>. We also included academic literature by searching PUBMED<sup>12</sup> and ScienceDirect<sup>13</sup> using as search terms the name of the "pesticide" + "endocrine" and examined the relevance of the study to our research. If we discovered specific research groups working on the pesticides, we searched on their name to get more information. When available, applications for pesticide renewal<sup>14</sup> and the subsequent RARs (Revised Assessment Reports<sup>15</sup>) were included in our evaluation. From the total literature collected, we tried to identify the adverse effects of the endocrine disrupting pesticides (ED pesticides).

We also looked at the interim-criteria, the temporary criteria that are being used in the absence of the adequate criteria. For the two sets of criteria (Reg. 1107/2009, Annex II, 3.6.5), we evaluated all collected literature to find out how many pesticides will likely qualify for being ED-pesticides based on the interim-criteria.

Last element of our evaluation is the criteria used for the regulatory process leading to approval or non-approval of a pesticide. Since the criteria are still under discussion, we analysed the different criteria separately to get the best picture of their impact on the approval of endocrine disrupting pesticides. These criteria are included options 1 - 4 and A - C of the roadmap published by the European Commission in June 2014<sup>16</sup>. This Annex, together with the other three annexes composed by PAN Europe, serve to answer the questions of the Public Consultation to Commission on the criteria for ED-pesticides, and will be referred to in the answers given by PAN Europe.

In order to assess the impact of the criteria options, here we analysed again the DARs and RARs<sup>17</sup>, looking for the evaluation remarks made by the Rapporteur member state. We also consulted the peer-reviews published by Food Authority EFSA<sup>18</sup> for regulatory assessments and the UK-CRD/HSE report<sup>19</sup>, especially

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5 R. McKinlay, J.A. Plant, J.N.B. Bell, N. Voulvoulis, Endocrine disrupting pesticides: Implications for risk assessment, *Environment International* 34 (2008) 168–183

6 [http://ec.europa.eu/sanco\\_pesticides/public/?event=homepage](http://ec.europa.eu/sanco_pesticides/public/?event=homepage)

7 <http://echa.europa.eu/web/guest/information-on-chemicals/cl-inventory-database>

8 <http://www.ncbi.nlm.nih.gov/pubmed>

9 EFSA DAR

10 UK CRD/HSE on endocrines

11 KEMI 23 incl ED pesticides

12 <http://www.ncbi.nlm.nih.gov/pubmed>

13 <http://www.sciencedirect.com/>

14 <http://registerofquestions.efsa.europa.eu/roqFrontend/?wicket:interface=:1:::>

15 EFSA DAR

16 European Commission- Roadmap on Endocrine Disruptors

17 EFSA DAR

18 <http://www.efsa.europa.eu/>, go to search site and include the name of the pesticide

19 UK CRD/HSE on endocrines

in relation to the use of the 'potency' criterion. The SANCO website was used to consult the SANCO 'review report'<sup>20</sup>, a report which is at the basis of the decisions made, and includes regulatory assessments of adverse effects. In some cases the regulatory decisions itself were consulted<sup>21</sup>.

All studies, reports, research are collected in a database. We are happy to send you a link to the database by Dropbox for personal use to check all documents used.

## Results

The summary outcome of our analysis can be found in the attached Annex Ib.

- Column A shows the 53 pesticides we analysed; please note this is about 10% of the currently in the EU approved 500 active substances of pesticides;
- Column B shows the pesticides with "endocrine disrupting properties", as required by the first part of the definition in Regulation 1107/2009, Annex II, 3.6.5. 50 pesticides with endocrine disrupting properties are presented in this column (the three remaining pesticides are classified R2+C2 and part of the interim-criteria);
- Column C gives a short description of the ED properties of these 50 pesticides; many are identified by McKinlay et al. (2008) and some by KEMI (2008). All studies are included in the PAN database, accessible on request;
- Column D shows the assessment of pesticides according to the so-called 'interim' criteria available in Regulation 1107/2009, Annex II, 3.6.5. According to the regulation, during the absence of specific criteria for endocrine disrupting chemicals, pesticides that fall under the interim criteria are considered endocrine disruptors. Five pesticides, Chlorotoluron, Dimoxystrobin, Epoxiconazole, Profoxydim and Tepraloxydim, all having the classification C2 + R2, "shall" be considered to have endocrine disrupting properties. These pesticides will not be subject to an assessment of the criteria, since they are 'interim' and criteria are not published yet. One could assume that they will not be re-approved in principle and we assumed this is the case. Column D shows another 8 pesticides (Abamectin, Amitrole, Ioxynil, Mancozeb, Maneb, Metconazole, Myclobutanil, Tebuconazole) that are part of the second 'interim' criterion R2 + toxic for the endocrine organ. The text here mentions that they "may" be considered to have endocrine disrupting properties, suggesting more room for manoeuvre for Commission. We assume these 8 will be subject to further hazard assessment by Commission, possibly with use of currently debated draft criteria;
- Column E shows all pesticides that fulfil the second part of the Regulation's (1107/2009) requirement "that may cause adverse effects" (ED pesticides), which should be regulated based on hazard assessment, not risk assessment. We identified 31 pesticides in total, some derived from the regulatory dossiers submitted in the past, some identified from independent literature we have collected, as well as the ones based on the interim criteria (only R2 + toxic effects on the endocrine organs; R2+C2 is considered a separate category without further assessment);
- Column F gives a short description of the type of adverse effects demonstrated in reports and studies;
- Column G includes only those ED pesticides identified from the regulatory dossiers, a total number of 20 pesticides. In the regulatory Commission procedure independent literature is not taken into account and approval decisions are based solely on studies submitted by the industrial applicant. Even though Regulation 1107/2009 includes an explicit article to take into account 'open peer-reviewed scientific literature'<sup>22</sup>, this provision is ignored at the implementation level<sup>23</sup>. This means that current knowledge for 11 pesticides (examples Chlorpyrifos, Chlorpyrifos-methyl,

<sup>20</sup> [http://ec.europa.eu/sanco\\_pesticides/public/?event=homepage](http://ec.europa.eu/sanco_pesticides/public/?event=homepage)

<sup>21</sup> [http://ec.europa.eu/sanco\\_pesticides/public/?event=homepage](http://ec.europa.eu/sanco_pesticides/public/?event=homepage)

<sup>22</sup> Art.8.5, Scientific peer-reviewed open literature, as determined by the Authority, on the active substance and its relevant metabolites dealing with side-effects on health, the environment and non-target species and published within the last 10 years before the date of submission of the dossier shall be added by the applicant to the dossier.

<sup>23</sup> [PAN E report Missed and Dismissed](#)

Cypermethrin, Deltamethrin, Dimethoate, Fipronil, Glyphosate, Lambda-cyhalothrin, Methomyl, Pyrimethanil, Triadimenol) will not be taken into account, will not lead to a changed regulatory decision, and will have no impact despite the valuable scientific knowledge they provide;

- In the next 4 Columns (H-K) we analysed the impact of the draft criteria on the 20 pesticides that presumably will be recognised by Commission as endocrine disruptors. The criteria are derived from the options considered in the 'Roadmap'<sup>24</sup> published by Commission in June 2014;
- In Column H, the criterion that can be applied by Commission is "human relevance". In the roadmap, under Option 2, the criteria are listed and "human relevance" is under 2 (d). This means, in plain terms, that an effect seen in the test animal is assumed not relevant for humans and can be dismissed. As we demonstrate, this criterion has been used many times by Commission in past regulatory decisions on these pesticides to dismiss adverse effects (indicated by a Y), in 7 out of the 20 cases;
- In Column I, the criterion that can be applied by Commission is "secondary effect"- a criterion, which can be found in the Roadmap under Option 2 (b). Regulators misinterpret this and consider that endocrine effects only count in the absence of other effects that are non-specific. This criterion has been used many times by Commission for the 20 pesticides we analysed, in 10 out of 20 decisions of pesticide approval;
- Column L, shows the assessment of applying criteria (used in Options 2, 3 and 4): adverse effects identified in regulatory dossiers (Column G) + criterion human relevance (Column H) + criterion secondary effects (Column I). When applying these criteria, only 7 pesticides (plus the pesticide Linuron for reproductive classification R1B<sup>25</sup>) would be regulated;
- Column J shows the results of including the criterion "potency" in the assessment. Potency is included in Option 4 of the roadmap. It means that any adverse effect observed in animal studies above a certain threshold exposure level is qualified irrelevant. Based on this criterion, for 13 out of the 20 pesticides, the endocrine disrupting effect observed would be qualified irrelevant. In these cases there is no impact from the endocrine effects on the regulatory decision because these effects will be dismissed;
- Column M shows what the combined impact of the criteria will be if -as suggested in Option 4 of the roadmap- the criterion "potency" is put on top of the criteria of option 2 of the roadmap. Now only 4 pesticides will remain to be regulated, Amitrole, Mancozeb and Maneb and Tralkoxydim. Linuron will be regulated anyway because of the reproductive classification R1B<sup>26</sup>;
- Column K shows the effect of including "further elements of risk assessment" (Roadmap, Regulatory Option B) into sectoral legislation. For pesticides, this would mean that regulation 1107/2009 will need to be revised from a hazard approach back to risk assessment. Using traditional risk assessment (current approach) no pesticide would be qualified as an endocrine disrupting pesticide since for all 20 pesticides Commission derived a 'safe level' of exposure. If this approach would be used, no matter with or without other criteria, no endocrine disrupting pesticide will be regulated as shown in Column N and the impact of the endocrine provisions in the Regulation (Annex II, 3.6.5) and the criteria would be zero.

<sup>24</sup> [Commission roadmap endocrine disruption](#)

<sup>25</sup> Regulation 1107/2009, Annex II, 3.6.4: An active substance, safener or synergist shall only be approved if, on the basis of assessment of reproductive toxicity testing carried out in accordance with the data requirements for the active substances, safeners or synergists and other available data and information, including a review of the scientific literature, reviewed by the Authority, it is not or has not to be classified, in accordance with the provisions of Regulation (EC) No 1272/2008, as toxic for reproduction category 1A or 1B, unless the exposure of humans to that active substance, safener or synergist in a plant protection product, under realistic proposed conditions of use, is negligible, that is, the product is used in closed systems or in other conditions excluding contact with humans and where residues of the active substance, safener or synergist concerned on food and feed do not exceed the default value set in accordance with point (b) of Article 18(1) of Regulation (EC) No 396/2005.

<sup>26</sup> 3.6.4. An active substance, safener or synergist shall only be approved if, on the basis of assessment of reproductive toxicity testing carried out in accordance with the data requirements for the active substances, safeners or synergists and other available data and information, including a review of the scientific literature, reviewed by the Authority, it is not or has not to be classified, in accordance with the provisions of Regulation (EC) No 1272/2008, as toxic for reproduction category 1A or 1B, unless the exposure of humans to that active substance, safener or synergist in a plant protection product, under realistic proposed conditions of use, is negligible, that is, the product is used in closed systems or in other conditions excluding contact with humans and where residues of the active substance, safener or synergist concerned on food and feed do not exceed the default value set in accordance with point (b) of Article 18(1) of Regulation (EC) No 396/2005.

## Conclusion

PAN Europe identified 5 pesticides that shall be regulated by the interim-criteria, and 31 that show adverse endocrine disrupting effects. These 31 should in principle all be regulated but due to Commission policy and to criteria this number will be lower. First of all, Commission policy does not take into account independent literature; this reduces the number to 20 ED-pesticides to be regulated. Commission proposes to use (draft) criteria developed by DG Environment in options 2/3 and 4 ('human relevance', 'secondary effects'). Use of these criteria reduces the number to only 7 ED-pesticides that will be regulated. Use of the 'potency' criterion (option 4) additionally reduces the number to 4 pesticides, and back introducing risk assessment (option B) will result in no pesticide at all regulated.

Now, it is shown that very little pesticides will be banned because of their endocrine disrupting properties, or even zero (option B, on further derogations), it is clear that regulatory option C makes no sense in the assessment of pesticides to protect public health.





PESTICIDES (INCLUDING CLP CLASSIFICATION)	REG. 1107/2009, ANNEX II, 3.6.5, PART 1, PESTICIDES WITH ED PROPERTIES.....	REASON FOR QUALIFYING FOR "PESTICIDE WITH ED PROPERTIES"	REG 1107/2009, INTERIM CRITERIA, ANNEX II, 3.6.5, R2+C2 or R2 + TOXIC TO ENDOCRINE ORGANS	REG 1107/2009, ANNEX II, 3.6.5, PART 2, -----THAT MAY CAUSE ADVERSE EFFECTS	ADVERSE ENDOCRINE EFFECTS OBSERVED IN THE REGULATORY DOSSIER OR IN INDEPENDENT LITERATURE	ED EFFECTS IDENTIFIED IN REGULATORY DOSSIER (EFSA/DAR/CRD/KEMI)	DISMISSAL CRITERION 1 LIKELY TO BE APPLIED? - HUMAN RELEVANCE COMMISSION ROADMAP JUNE 2014, UNDER OPTIONS 2&3 (d)	DISMISSAL CRITERION 2 LIKELY TO BE APPLIED? - SECONDARY EFFECT/NON-SPECIFIC. COMMISSION ROADMAP JUNE 2014, UNDER OPTION 2&3 (b)	DISMISSAL CRITERION 3 LIKELY TO BE APPLIED? - POTENCY (CRD PROPOSAL: LOAEL >10 mg/kg), ROADMAP, PART of OPTION 4	DISMISSAL CRITERION 4 LIKELY TO BE APPLIED? - SAFE THRESHOLDS FOR ENDOCRINE EFFECT, CRITERION INCLUDED IN ROADMAP, OPTION (B)	ED BASED ON DG ENV DRAFT CRITERIA, MARCH 2013 (Columns F+H+I)?	ED BASED ON DG ENV CRITERIA + POTENCY?	ED BASED ON DG ENV CRITERIA + POTENCY + THRESHOLDS/ RISK ASSESSMENT?
2,4-D	Y	Synergistic androgen effects when combined with testosterone		Y	Effect on thyroid wt and thyroid hormone (DAR); effect on serum hormone (inde lit)	Y		Y, fetotoxicity at maternally toxic doses (SANCO rr)	Y, LOAEL thyroid effect 75 mg/kg	Y, NOAEL for thyroid effects 5 mg/kg from industry studies	N	N	N
abamectin (R2) §	Y	Reduction of testosterone	Y, (R2 + toxic), expiry approval 30-04-2019	Y	There are a number of effects on lactation and oestrus and male reproductive function which could potentially be related to endocrine disruption (DAR/CRD); decreased sperm count and motility and increased seminiferous tubule damage; unknown mech. (inde lit).	Y	Y, findings in neonatal rats were attributed to a higher sensitivity related to a limited expression of P-glycoprotein, not relevant to humans (EFSA pr, 2008); Y, fetotoxicity seen in CF-1 mice not relevant acc. to EFSA	Y, while fetotoxicity was seen at lower dose, neuroxicity was chosen for deriving health standards		NOAEL 0,25 mg/kg for neurotoxicity; lower fetotoxicity/teratogenicity dismissed	N	N	N
amitrole (R2)	Y	Inhibits the production of thyroid hormones	Y (R2 + toxic), expiry approval 31-12-2015.	Y	Amitrole lowering T4-levels, 0,1 mg/kg; regulatory endocrine based on R2 and "toxic effects on endocrine organs"; EFSA proposes R1B based on malformations in rabbit.	Y	Y/N, thyroid cancer in rat not rel. for humans (SCP in 2001); but observed MOA is (EFSA, 2014);	N, developmental effects seen at doses of limited maternal toxicity		Y, relevant NOAEL for endocrine effects, thyroid tumours, is 0,5 mg/kg (EFSA pr , 2014)	Y	Y	N
bifenthrin (C2) §	Y	Interferes with the action of the female sex hormones, causing reductions in ovary weight and lack of oestrus. Decreases the level of thyroid hormones present in the		?	Range of in-vitro and fish studies with adverse effects on offspring (inde lit)	N				NOAEL 1,5 mg/kg reproduction			
bupirimate	Y	Effects on thyroid in vivo 2 year rat study		Y	Decreased bodyweight gain, increased relative kidney, liver and thyroid weight, increased incidence of thyroid follicular adenoma and fibroma in the skin (DAR, EFSA)	Y	Y, disturbance HPT-axis can lead to thyroid follicular cell tumours in rats, since humans are less sensitive to disturbance of the HPT-axis, this effect is not relevant. (DAR, 2007; EFSA 2010); Y, Skin fibroma's for females were considered irrelevant based on historical control data, even now they are just outside these HCD.		Y, LOAEL 156 mg/kg	Y, 15 mg/kg, weight changes liver, thyroid	N	N	N
captan (C2)	Y	Inhibits the action of estrogen			No tests for ED effects available; Captan part of US EST program, tier 1					NOAEL 10 mg/kg, embryo-foetal, maternal			
chlorothalonil (C2)	Y	Triggers the proliferation of androgen-sensitive cells.			Effects on amphibians, low dose, non-monotonic/ part of US testing program; effects in fish could be ED-mediated (DAR/CRD)	N	Due to anatomical difference, forestomach tumours are not considered relevant to human risk assessment (DAR/CRD)	Developmental effects: only at doses maternally toxic (DAR).					
chlorotoluron (C2, R2)	N		Y, expiry approval, 31-10-2017.		Applicant claims no ED effects in renewal request, 2013								
chlorpyrifos	Y	Anti-androgenic properties		Y	Independent studies observe adverse effects on thyroid and male reproductive system; regulatory studies from industry observe no endocrine effects; Evidence of effects on thyroid system at levels below those which inhibit cholinesterase (!),mouse, developm (De Angelis, 2009); EFSA pr 2014 expresses concerns on ED but waits for future studies at the next application	N		Y, increase embryofoeto-toxicity (Increased post-implantation loss at maternal toxic doses); Y, ED not lead toxicity		NOAEL 0,1 mg/kg plasma and RBC Che, CP-oxon, 0,01 mg/kg			N
chlorpyrifos-methyl	Y	Antagonises androgen activity		Y	Independent studies show effects on thyroid and sexual organs;	N							N
cypermethrin §	Y	Mimics the action of oestrogen. Metabolites also have oestrogenic effects.		Y	Six in-vivo mammalian studies avaialble showing reproductive effects and disruption of testicular devel. In offspring; NO reproductive effects observed in regulatory dossier (DAR 1999/CRD), even not in 3-gen (!)	N		Reduced litter size and pup weight at parental toxic doses (10 mg/kg)		NOAEL, 5 mg/kg rat, 2 yr reproduction			N
cyproconazole (R2) §	Y	Inhibits the enzyme aromatase, decreasing the production of oestrogens and increasing the available androgens.	? (no studies available)		Cyproconazole belongs to the triazole group of ergosterol-biosynthesis inhibitors, and thus might cause endocrine disrupting effects. However, the end points from a fish life cycle test and a short-term screening assay study were considered to be sufficient to address such concerns (EFSA, 2010)	N				NOAEL 2 mg/kg, liver effect male; litter loss female			
deltamethrin §	Y	Shows weak oestrogenic activity.		Y	Six in-vivo mammalian studies available showing reproductive effects and disruption of thyroid hormones and spermatogenesis; not taken into account in regulatory dossier; Bayer in renewal appll reviewed 6951 studies; none of them relevant!	N		Increased pup mortality and increased pup weight at parental toxic dose levels, 4,2 mg/kg		NOEAL 1 mg/kg, nervous system			N
dimethoate	Y	Disrupts the action of the thyroid hormones. Increases the blood concentration of insulin and decreases the blood concentration of lutenising hormone.		Y	Nine in vivo mammalian independent studies published showing damange testis and ovaries, disruption thyroid, and reproduction; not taken into account in regulatory dossier	N		Reproductive and developmental effects occurred at doses above that which caused toxicity (decreased brain AChE) in parental animals, therefore these effects are deemed to be secondary to parental toxicity and not due to endocrine effects		NOAEL 0,1 mg/kg, neurodevelopment			N
dimoxystrobin (R2, C2)	N		Y, expiry approval 31-01-2018		no ED-effects (DAR 2003/CRD)				LOAEL 20 mg/kg developmental; 20 mg/kg several types of cancer incl thyroid				

PESTICIDES (INCLUDING CLP CLASSIFICATION)	REG. 1107/2009, ANNEX II, 3.6.5, PART 1, PESTICIDES WITH ED PROPERTIES.....	REASON FOR QUALIFYING FOR "PESTICIDE WITH ED PROPERTIES"	REG 1107/2009, INTERIM CRITERIA, ANNEX II, 3.6.5, R2+C2 or R2 + TOXIC TO ENDOCRINE ORGANS	REG 1107/2009, ANNEX II, 3.6.5, PART 2, -----THAT MAY CAUSE ADVERSE EFFECTS	ADVERSE ENDOCRINE EFFECTS OBSERVED IN THE REGULATORY DOSSIER OR IN INDEPENDENT LITERATURE	ED EFFECTS IDENTIFIED IN REGULATORY DOSSIER (EFSA/DAR/CRD/KEMI)	DISMISSAL CRITERION 1 LIKELY TO BE APPLIED? - HUMAN RELEVANCE COMMISSION ROADMAP JUNE 2014, UNDER OPTIONS 2&3 (d)	DISMISSAL CRITERION 2 LIKELY TO BE APPLIED? - SECONDARY EFFECT/NON-SPECIFIC, COMMISSION ROADMAP JUNE 2014, UNDER OPTION 2&3 (b)	DISMISSAL CRITERION 3 LIKELY TO BE APPLIED? - POTENCY (CRD PROPOSAL: LOAEL >10 mg/kg), ROADMAP, PART of OPTION 4	DISMISSAL CRITERION 4 LIKELY TO BE APPLIED? - SAFE THRESHOLDS FOR ENDOCRINE EFFECT, CRITERION INCLUDED IN ROADMAP, OPTION (B)	ED BASED ON DG ENV DRAFT CRITERIA, MARCH 2013 (Columns F+H+I)?	ED BASED ON DG ENV CRITERIA + POTENCY?	ED BASED ON DG ENV CRITERIA + POTENCY + THRESHOLDS/ RISK ASSESSMENT?
diuron (C2) §	Y	Inhibits the action of androgens			No evidence for ED in regulatory studies (CRD); one in-vivo inde study demonstrates Diuron it is a multipotent carcinogen.								
epoxiconazole (C2, R2)	Y	Weak oestrogen inhibitor. Inhibits the enzyme aromatase, decreasing the production of oestrogens and increasing the available androgens; R2 & C2.	Y, expiry approval, 30-04-2019	Y	Mice: liver tumours (C2); rat ovary and adrenal gland tumours; reproductive and developmental effects (malformations): R2; 47 metabolites known; endocrine disruptor, inhibition of aromatase (EFSA pr)	Y	Y, a non-relevance of the tumours (liver neoplasia) seen in mice for human risk-assessment "could not be excluded" (EFSA pr)	Y, male and female gonads effects were identified as possible secondary targets of epoxiconazole toxicity (DAR 2005)	Y, LOAEL 23 mg/Kg, liver carcinomas	Y, 0,8 mg/kg mouse carcinogenicity	N	N	N
fenbuconazole (tbc R2)	Y	Inhibits the production of thyroid hormones	?, no studies available		Increased number of pups born dead, reduced litter size and decreased post-partum pup viability (EFSA pr 2010);in vitro studies show altered hormone level and gene expression	N							
fenoxycarb (tbc C2, tbc R2) §	Y	Interferes with the metabolism of testosterone	?, depending on classification decision		follicular hypertrophy in the thyroid in a 90-day study (CRD/DAR); ED-effects in fish, not observed in mammalian studies (EFSA 2010); a range of ED effects are observed in non-mammalian studies (inde lit)	N							
fipronil §	Y	Disrupts the production of thyroid hormones.		Y	Several in vitro and in vivo studies available of the ED effects of fipronil and its metabolite (inde lit)	N	The mechanism for induction of thyroid tumours was discussed by the experts and considered rat specific and not relevant to humans (EFSA pr 2005)			NOAEL 0,02 mg/kg, rat carcinogen study			N
flutriafol (R2), triazole	Y	Weak oestrogen inhibitor.	?, no studies available							NOAEL 1 mg/kg, reproduction and malformations offspring			
glyphosate	Y	Disrupts the action of aromatase preventing the production of oestrogens.		Y	No ED effects (DAR/CRD); several studies point at ED potential of glyphosate (inde lit);	N				NOAEL 30 mg/kg, liver			N
ioxynil (R2)	Y	Antagonises the action of thyroid hormones and the expression of the genes coding for their cellular receptors; R2 & tumous in ED organs: thyroid (rat), uterus (mouse).	Y, expiry approval 28-02-2015	Y	effects on the thyroid system incl overactivity of the thyroid gland, changes in thyroid hormone levels and the formation of thyroid tumours; also, a carcinogenic response was seen in the uterus (DAR/CRD); a series of non-mammalian studies demonstrates ED effects	Y	Y, mechan. studies suggest that Ioxynil induced thyroid carcinogenesis in rat is a species specific perturbation of thyroid hormone homeostasis (SANCO, 2004 rr)			Y, 0,5 mg.kg for thyroid tumours	N	N	N
iprodione (C2)	Y	Weakly promotes aromatase activity, increasing oestrogen production; weight changes, atrophy, hyperplasia in ED organs: adrenals, testes, ovary.		Y	Severe effects on the male reproductive system including tumours; these effects and those on the adrenals could be due to endocrine disruption (DAR/CRD). weight changes, atrophy, hyperplasia in ED organs: adrenals, testes, ovary (KEMI 2008). Affects steroidogenesis within the testis (inde lit).	Y		Y, effect on offspring (anogenital distance) at toxic maternal level	Y, LOAEL 15 mg/kg repro, adrenal	Y, NOAEL 6 mg/kg, tumours	N	N	N
lambda-cyhalothrin §	Y	Decreases the secretion of thyroid hormones.		Y	Based on in-vitro studies in inde lit L-cyhalothrin may affect endocrine function; the result of these studies cannot be disregarded in absence of testing according to guidelines (RAR 2013, RMS SE). Four in vivo mammalian independent studies published show effects on thyroid hormones, sperm , testis and immunity; not taken into account in regulatory dossier (other formulation; lack of detailed description).	N (Pending the adoption of specific scientific criteria to address Annex II, Point 3.6.5 of Regulation (EC) No. 1107/2009 the scientific determination of endocrine disrupting properties could not be finalised (EFSA pr 2014).	No evidence of a role for endocrine disruption in the mammary tumours found only in mice (CRD).			NOAEL 0,5 mg/kg, dog, CNS			N
linuron (R1B, C2)	Y	Competitively inhibits the binding of androgen to its receptor, inhibits androgen-inducing gene expression. Alters androgen-dependant ventral prostate gene expression; R1B, C2.	R1B, regular cut-off, 31-07-2016, only use allowed based on 'negligible use'	Y	Increases in testicular tumours and effects on male fertility, and decreases in thyroid tumours have been found in rats in standard toxicological studies in rodent species for linuron (DAR 2003/CRD).	Y	Y, changes in testosterone level in rat, DAR states that the effects of linuron are species specific (DAR 2003).	Y (for fetotoxicity); Y (also tumours at doses of general toxicity)		Y, a "no-effect" threshold was assumed (not studied) for tumours via HPT-axis, DAR 1996	Y (only escape is negligible use)	Y (only escape is negligible use)	Y (only escape is negligible use)
malathion	Y	Inhibits catecholamine secretion, binds to thyroid hormone receptors.			In vitro positive estrogenic activity dismissed because the activity of the test substance was less than 10% of the activity of 10–4 mM E2 (CRD); no mammalian ED effects observed (DAR/CRD); several studies show reproductive effects (inde lit)	N							
mancozeb (dithiocarbamate) R2- metabolite ETU	Y	Inhibits the production of thyroid hormones; carcinoma, adenoma in ED organ: thyroid.	Y, expiry approval 31-01-2018	Y	Thyroid adenomas and carcinomas, caused by metabolite ETU; pathology of the thyroid and on levels of thyroid hormones (DAR 2001/CRD); The overall body of toxicological data coming from a number of in vitro and in vivo assays indicates that there is no concern on genotoxicity, SANCO rr 2009).Eight (!) in-vivo inde studies available on thyroid, repro and cancer effects; 4 epidemiology studies available showing harm of Mancozeb in practice	Y	Generally (see red triangle), but not in this case because of ETU			Y, a no-effect level of 4.8 mg/kg was taken from the 2-year rat study (A further 2-year study gave no increased incidence of tumours and a NOAEL of 4 mg/kg bw/day based on ↓T4, DAR 2001)	Y	Y	N
maneb (dithiocarbamate) R2- metabolite ETU	Y	Inhibits the production of thyroid hormones; carcinoma, adenoma in ED organ: thyroid.	Y, expiry approval 31-01-2018	Y	Thyroid (inhibition of thyroid peroxidase by common metabolite ETU, hyperplasia/hypertrophy), liver (mice)	Y	Generally (see red triangle), but not in this case because of ETU			Y, a no-effect level of 5 mg/kg was taken from the 2-gen. rat study	Y	Y	N
metconazole (R2)	Y	Antiandrogen; weight changes of ED organs: adrenal, placenta	Y, expiry approcal 30-04-2018	Y	teratogenic potential in rabbits at doses producing no to severe maternal toxicity (EFSA pr 2006); weight changes of ED organs: adrenal, placenta (KEMI 2008)	Y		embryo- and foetotoxic at doses also producing maternal toxicity in rat developmental toxicity studies (EFSA pr 2006)	Y	NOAEL 24 mg/kg, maternal and foetotoxicity	Y	N	N
methiocarb	Y	Inhibits androgen activity whilst promoting oestrogen activity.			No ED effects (DAR 2004/CRD); part of US EDSP program	N							

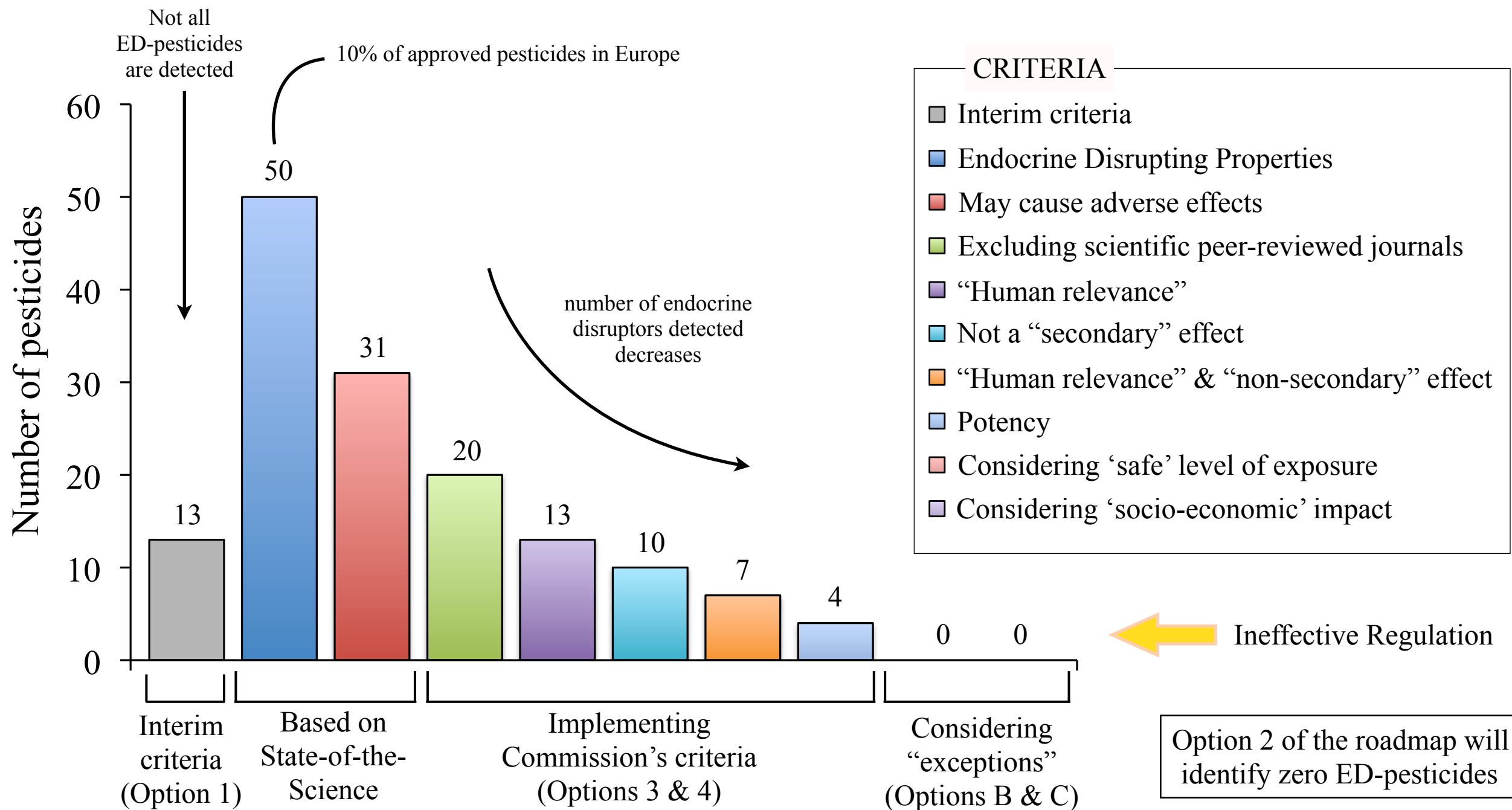


PESTICIDES (INCLUDING CLP CLASSIFICATION)	REG. 1107/2009, ANNEX II, 3.6.5, PART 1, PESTICIDES WITH ED PROPERTIES.....	REASON FOR QUALIFYING FOR "PESTICIDE WITH ED PROPERTIES"	REG 1107/2009, INTERIM CRITERIA, ANNEX II, 3.6.5, R2+C2 or R2 + TOXIC TO ENDOCRINE ORGANS	REG 1107/2009, ANNEX II, 3.6.5, PART 2, -----THAT MAY CAUSE ADVERSE EFFECTS	ADVERSE ENDOCRINE EFFECTS OBSERVED IN THE REGULATORY DOSSIER OR IN INDEPENDENT LITERATURE	ED EFFECTS IDENTIFIED IN REGULATORY DOSSIER (EFSA/DAR/CRD/KEMI)	DISMISSAL CRITERION 1 LIKELY TO BE APPLIED? - HUMAN RELEVANCE COMMISSION ROADMAP JUNE 2014, UNDER OPTIONS 2&3 (d)	DISMISSAL CRITERION 2 LIKELY TO BE APPLIED? - SECONDARY EFFECT/NON-SPECIFIC. COMMISSION ROADMAP JUNE 2014, UNDER OPTION 2&3 (b)	DISMISSAL CRITERION 3 LIKELY TO BE APPLIED? - POTENCY (CRD PROPOSAL: LOAEL >10 mg/kg), ROADMAP, PART of OPTION 4	DISMISSAL CRITERION 4 LIKELY TO BE APPLIED? - SAFE THRESHOLDS FOR ENDOCRINE EFFECT, CRITERION INCLUDED IN ROADMAP, OPTION (B)	ED BASED ON DG ENV DRAFT CRITERIA, MARCH 2013 (Columns F+H+I)?	ED BASED ON DG ENV CRITERIA + POTENCY?	ED BASED ON DG ENV CRITERIA + POTENCY + THRESHOLDS/ RISK ASSESSMENT?
methomyl	Y	Weakly promotes aromatase activity, increasing oestrogen production.		Y	No ED-effects in the regulatory dossier; in-vivo studies (inde lit) show hormone changes and damage to testis and spermatogenesis	N							N
metribuzin	Y	Causes hyperthyroidism, alters somatotrophin levels.		Y	Changes in thyroid hormones and follicular cell hyperplasia are indicative of endocrine disruption (DAR 2004/CRD); effects on thyroid hormones, LOAEL 15 mg/kg, in a U-shape dose-effect relationship (DAR 2004);	Y	Y, effects on thyroid hormone levels at 1,3 mg/kg considered non-adverse (rodent specific response to liver enzyme induction)		Y, LOAEL 15 mg/kg	Y, 2,2 mg/kg, two-gen rat; reproductive effects/mortality (DAR 2004)	N	N	N
myclobutanil (triazole) (R2)	Y	Weak oestrogen and androgen inhibitor. Binds to alpha oestrogen receptors and to androgen receptors. Inhibits the enzyme aromatase.	Y, approval expires 31-05-2021	Y	There is evidence of adverse effects on the male reproductive system (and the female reproductive system to a lesser extent) which could be due to endocrine disruption. The effects on thyroid and adrenal are equivocal as they were seen in the rat in the 90-day study but not in longer studies (DAR 2006/CRD). Three in vivo mammalian studies published show steroid disruption and decrease female	Y		Y, the endocrine effects observed in mammals were secondary effects as a consequence of direct toxic effects in the liver (EFSA pr 2010).	Y, LOAEL 80 mg/kg	NOAEL 2,5 mg/kg, liver	N	N	N
oxamyl	Y	Weak estrogen mimic			No information on ED-effects	N							
penconazole (R2)	Y	Weak oestrogen inhibitor. Inhibits the enzyme aromatase, decreasing the production of oestrogens and increasing the available androgens.	?, no studies available		Only additional studies in fish and birds required (EFSA 2006); penconazole trigger genes from the thyroid cancer pathway (inde lit)	N							
pirimicarb	Y	Antagonises cellular oestrogen receptors.			No ED effects in mammalain studies; for fish and birds effects could be ED-mediatedr (DAR 2003/CRD);	N	Relevance of lung tumours (mice) was questioned						
prochloraz (conazole)	Y	Antagonises the cellular androgen and oestrogen receptors, agonises the Ah receptor and inhibits aromatase activity, diminishes foetal steroidogenesis		Y	Effects on ovaries, prostate and thyroid could be due to endocrine disruption (DAR 2007, CRD); Specific in vivo tests for endocrine disruption suggest that endocrine disruption is having an effect on reproductive systems and thyroid hormones (case study OECD); ED-mechanism (oestrogen and androgen antagonism and disruption of steroidogenesis) in-vivo effects on the reproduction systems and the thyroid (effects on T4 and TSH) (inde lit);	Y	Differences in thyroid function between humans and rats may indicate that the effects on thyroid hormones are less relevant to humans. However, the relevance to humans of the repro effects cannot be excluded (CRD).	Y, adverse effects (offspring, reduced litter size; dead foetus) occurred at doses where there is generalised toxicity	Y, LOAEL 15 mg/kg	Y, 2,26 NOAEL for repro to also cover ED effects (EFSA pr 2011)	N	N	N
profoxydim (R2, C2)	N		Y, approval expires 31-07-2021				Carcinoma urinary bladder in both sexes and papilloma urinary bladder in females Mechanistic data showed non relevance to human risk assessment (SANCO rr)						
propamocarb	Y	Weakly promotes aromatase activity, increasing oestrogen production.			Some evidence of disruption of the male reproductive system (sperm concentration and count), but same findings not seen in previous 2-generation study (DAR 2004/CRD).								
propiconazole §	Y	Weak oestrogen inhibitor. Inhibits the enzyme aromatase, decreasing the production of oestrogens and increasing the available androgens.			The triazole antifungals myclobutanil, propiconazole and triadimefon cause varying degrees of hepatic toxicity and disrupt steroid hormone homeostasis in rodent in vivo models (inde lit)								
propyzamide (C2)	Y	Thyroid and testis tumours and ovarian hyperplasia in 2 year rat studies		Y	Effects potentially caused by disruption of endocrine systems were observed (thyroid and testicular tumours and ovarian hyperplasia); Evidence of endocrine disruption leading to formation of thyroid tumours (DAR 1998/CRD); Hormonal changes affecting the pituitary-testicular endocrine axis; thyroid follicle cell adenoma, benign Leydig cell tumours in rats and liver tumors in mice (SANCO rr)	Y	The thyroid tumours appear to be induced by increased catabolism of thyroid hormones due to increased liver enzyme activity (liver hypertrophy was observed) and this mechanism is considered not to be relevant to humans (due to quantitative differences between rats and humans in thyroid hormone homeostasis). However, the human relevance of the testis tumours and ovarian hyperplasia cannot be excluded..	Embryo: 31.6 mg/kg bw/day based on abortions and late resorptions at maternally toxic doses	Y, LOAEL 43 mg/kg 2 yr rat	Y, 2 mg/kg, mice, thyroid effects (DAR 2004)	Y	N	N
pyridate	Y	Binds to oestrogen and androgen receptors.			thyroid toxicity effects were observed in short-term, long-term and reproductive toxicity studies in rats (EFSA pr); RMS: no ED-related thyroid effects.EFSA: no conclusion			Embryotoxic only at maternal toxic doses.					
pyrimethanil	Y	Inhibits the production of thyroid hormones.		Y	thyroid effects and thyroid tumours at high doses (EFSA pr); thyroid inhibitor and thyroid tumours observed in inde lit	N							
pyriproxyfen (insect growth regulator)	Y	Estrogen mimic			a range of studies on non-mammalian organisms is available (inde lit)								
spiromefisen	Y	Evidence of disruption of the thyroid and its hormones and possible endocrine disruption of the female reproductive system.		Y	Evidence of disruption of the thyroid and its hormones and possible endocrine disruption of the female reproductive system (oestrus cycle and ovaries), DAR 2008/CRD;	Y		Y, Reduced oestrous cycling frequency, increased number of ovarian primordial follicles (both considered related to strong general systemic toxicity), EFSA 2007	Y, LOAEL 15 mg/kg	Y, 6 mg/kg, rat 2 year, thyroid and female reproductive system, DAR 2004	N	N	N



PESTICIDES (INCLUDING CLP CLASSIFICATION)	REG. 1107/2009, ANNEX II, 3.6.5, PART 1, PESTICIDES WITH ED PROPERTIES.....	REASON FOR QUALIFYING FOR "PESTICIDE WITH ED PROPERTIES"	REG 1107/2009, INTERIM CRITERIA, ANNEX II, 3.6.5, R2+C2 or R2 + TOXIC TO ENDOCRINE ORGANS	REG 1107/2009, ANNEX II, 3.6.5, PART 2, -----THAT MAY CAUSE ADVERSE EFFECTS	ADVERSE ENDOCRINE EFFECTS OBSERVED IN THE REGULATORY DOSSIER OR IN INDEPENDENT LITERATURE	ED EFFECTS IDENTIFIED IN REGULATORY DOSSIER (EFSA/DAR/CRD/KEMI)	DISMISSAL CRITERION 1 LIKELY TO BE APPLIED? - HUMAN RELEVANCE COMMISSION ROADMAP JUNE 2014, UNDER OPTIONS 2&3 (d)	DISMISSAL CRITERION 2 LIKELY TO BE APPLIED? - SECONDARY EFFECT/NON-SPECIFIC. COMMISSION ROADMAP JUNE 2014, UNDER OPTION 2&3 (b)	DISMISSAL CRITERION 3 LIKELY TO BE APPLIED? - POTENCY (CRD PROPOSAL: LOAEL >10 mg/kg). ROADMAP, PART of OPTION 4	DISMISSAL CRITERION 4 LIKELY TO BE APPLIED? - SAFE THRESHOLDS FOR ENDOCRINE EFFECT, CRITERION INCLUDED IN ROADMAP, OPTION (B)	ED BASED ON DG ENV DRAFT CRITERIA, MARCH 2013 (Columns F+H+I)?	ED BASED ON DG ENV CRITERIA + POTENCY?	ED BASED ON DG ENV CRITERIA + POTENCY + THRESHOLDS/ RISK ASSESSMENT?
tebuconazole (triazole) - R2 §	Y	Inhibits the enzyme aromatase, decreasing the production of oestrogens and increasing the available androgens; hypertrophy ED organ: adrenal.	Y, approval expires 31-08-2019	Y	Hypertrophy ED organ: adrenal (KEMI 2008); Tebuconazole induced adverse effects on reproductive development in the offspring after exposure in utero, i.e. virilised the female offspring, and caused feminizing effects in male offspring; 1,2,4-triazole metabolite more toxic/fertility/testis spermatogenesis (DAR 2008); Adverse reproductive effects could be related to endocrine disruption(CRD); Several in vivo inde studies show effects on thyroid and sexuality; mixture effects, even synergistic.	Y	Y, the liver tumours in mouse studies were considered not relevant for humans (EFSA pr); Y, the thyroid tumours observed in male rats were not considered relevant for humans (DAR, 2008)	Y/N depending on rat study at maternal toxic dose or lower (DAR, 2008)	Y, LOAEL 30 mg/kg rat, foetal (DAR, 2008)	Y, NOAEL 3 mg/kg, (DAR, 2008)	N	N	N
tepraloxydim (R2, C2)	Y	Effects on the weight of thyroid gland may be indicative of endocrine disruption (DAR 1999/CRD).	Y, approval expires 31-07-2017		Effects on the weight of thyroid gland may be indicative of endocrine disruption (CRD);			Thyroid effects and fetotoxicity at higher dose than adenomas and carcinomas	LOAEL for carcinomas and adenomas 30 mg/kg	NOEL 5 mg/kg (for adenomas and carcinomas)			
thiacloprid (neonicotinoid) C2, tbc R2 §	Y	adenoma in ED organs: in thyroid, uterus, ovary	?, if classified R2, approval expires 30-04-2017	Y	Adverse effects raising a concern for endocrine disruption (thyroid, ovarian and uterine tumours, effects on reproduction) are observed in multiple studies (DAR 2001/CRD); Adenoma in ED organs: in thyroid, uterus, ovary (KEMI, 2008); Thyroid adenomas in male rats. Uterine adeno carcinomas in rats. Ovarian luteomas in mice. Fetotoxicity (SANCO rr).	Y		Y, the mechanistic data indicate that hepatic enzyme induction is the primary cause of the thyroid, uterine and ovarian changes (SANCO rr)	N, LOAEL 2,5 mg/kg	NOAEL 1 mg/kg, SANCO review report	N	N	N
thiophanate-methyl (metabolite is spindle poison carbendazim) (M2)	Y	Effects on thyroid hormones and thyroid pathology in vivo rat 2 year study		Y	Thyroid (rat: follicular hypertrophy, hyperplasia, tumours), liver (mouse: tumours), anaemia (rat); genotoxic with a threshold (SANCO rr);	Y		Slight skeletal variation at maternal toxic doses in rabbits	Y, LOAEL 60 mg/kg	Y, 8,8 mg/kg, 2 year rat, thyroid (DAR 2003)	Y	N	N
tralkoxydim (tbc C2)	Y	C2 + R2 (KEMI) + regulatory evidence		Y	Increased incidence of Leydig cell hyperplasia, increased incidence of burden on tumours in male rats, tumours in ovarian, possibly by ED mechanism (DAR, 2005); Induction of metabolising enzymes and hormonal changes in the pituitary-thyroid-axis (rat) (SANCO rr)	Y	Discussion on non-relevance of Leydig cell tumours, and on use of "historical control data" for ovarian tumours by applicant to dismiss these effects (DAR, 2005)		LOAEL 5 mg/kg	Y, NOEL of 0,5 mg/kg for the range of effects seen	Y	Y	N
tolclofos-methyl	Y	Antagonises cellular oestrogen receptors											
triadimenol (tbc R2), triazole	Y	Oestrogen mimic, also inhibits the enzyme aromatase, decreasing the production of oestrogens and increasing the available androgens	?	Y	ED effects not studied (SANCO rr); studies in inde lit available showing ED effects	N							
TOTAL 53 pesticides analysed	50 pesticides with ED properties		13 pesticides could be part of the 1107/2009 interim criteria; 5 are clearly ED (R2+C2); the rest uncertain	31 ED pesticides may cause adverse effects		20 ED pesticides may cause adverse effects according to the regulatory dossier					Only 7 ED pesticides (plus Linuron, being R1B) of the 20 in the regulatory dossier will be qualified as an endocrine if the DG ENV draft criteria are applied	Only 4 ED pesticides (plus Linuron being R1B) will be qualified as an endocrine if on top of the criteria also potency is used	NO ED pesticide will be qualified as an endocrine if risk assessment is used with safe thresholds as foreseen in the ED roadmap; one pesticide will be subject to banning because of being R1B.

# Assessment of ED-Pesticides



Summary diagram: Assessment of pesticides for endocrine disrupting properties by PAN Europe. The Commission is considering different options to define endocrine disrupting chemicals (EDs) for regulatory purposes (provided in the Roadmap). The Regulation requires the ban of pesticides with endocrine disrupting properties that may cause adverse effects. PAN Europe has carried out an assessment of pesticides for endocrine disrupting properties based on the regulation requirements (PPPR 1107/2009) and compared it to the assessment of using the criteria proposed by the Commission in the different options of the Roadmap. The full analysis is provided in Annexes 1&2.

**Summary table:** Assessment of pesticides for endocrine disrupting properties performed by PAN Europe based on the State-of-the-Science on endocrine disruptors and the regulation requirements (PPPR 1107/2009) and by using the criteria proposed by the Commission in the different options of the Roadmap. The full analysis is provided in Annexes 1&2. Option 2 will fail to capture any ED-pesticides and is not included.

[illegible]

## **IMPACT ASSESSMENT, ANNEX II**

### **Alternatives in agriculture for endocrine disrupting pesticides.**

## **Introduction**

This Annex shows the results of the investigation undertaken by PAN Europe on the alternatives available in agriculture for endocrine disrupting pesticides- the ones under debate in recent years. In 2013, UK Health and Safety Executive HSE published a report on the costs of the potential ban of pesticides<sup>1</sup> and evaluated the pesticides previously listed by CRD/HSE as being potentially banned in the EU<sup>2</sup>. Many subsequent reports, such as the ones from the pesticide umbrella organisation ECPA<sup>3</sup> and UK-farmers organisations<sup>4</sup>, used the data collected by CRD/HSE and others in a more or less repeated message. Pesticide producer BASF and another farmer organisation, ELO, focussed on azoles in cereals<sup>5</sup>. From this collection of pesticides that the UK, industry and farmers expect most problems for, we took the most debated 13 pesticide-pest combinations to look into alternatives and the seriousness of the expected problems and claimed costs. We also included a pesticide which is part of the endocrine interim criteria, and a pesticide qualified endocrine disruptor based on independent literature.

## **Methodology**

PAN Europe first collected all the available alternatives for the 13 pest-pesticide combinations from public available sources in the different EU countries<sup>6</sup>. We looked at available synthetic alternatives, at non-chemical alternatives, and especially at the 'Integrated pest management' (IPM) system as described in EU Directive 2009/128, Annex III, a system all farmers in the EU have to apply from January 1, 2014 onwards. The draft collection was then sent to a panel of independent experts for peer-review. The experts are actively working as specialists in biological control, integrated pest management and sustainable use of pesticides; they can be consulted for the IA on request<sup>7</sup>.

<sup>1</sup> Agronomic and economic impact assessment for possible human health and ecotoxicology criteria for endocrine disrupting substances, Report to Chemicals Regulation Directorate, June 2013,

<http://www.pesticides.gov.uk/guidance/industries/pesticides/News/Collected-Updates/Information-Updates-2014/January/Regulation+ EC No 1107 2009-progress on endocrine disrupters and candidates for+substitution>

<sup>2</sup> Extended impact assessment study of the human health and environmental criteria for endocrine disrupting substances proposed by HSE, CRD, January 2013, <http://www.pesticides.gov.uk/guidance/industries/pesticides/News/Collected-Updates/Information-Updates-2014/January/Regulation+ EC No 1107 2009-progress on endocrine disrupters and candidates for+substitution>

<sup>3</sup> [ECPA lobby paper on endocrines](#), March 2013

<sup>4</sup> <http://www.fwi.co.uk/news/eu-pesticide-review-could-cost-uk-industry-905m.htm>, December 2014

<sup>5</sup> [BASF ELO on azoles](#), 2012.

<sup>6</sup> It concerns the following website with information on alternatives: Swiss, IOBC, <http://www.iobc-wprs.org/pub/index.html>, UK HGCA, <http://www.hgca.com/>, DE, Julius-Kühn Institut, <http://www.jki.bund.de/en/startseite/home.html>, FR, Arvalis, <http://www.arvalis-infos.fr/index.html>, DK, DAAS, Aarhus, <http://www.vfl.dk/system/404.htm#.VJh7IcgU>, NL, "Groen Kennisnet", <http://www.groenkennisnet.nl/plant/Pages/default.aspx>, NL, "Kenniscentrum Wageningen", <http://www.kennisakker.nl/kenniscentrum/kenniscentrum>,

<sup>7</sup> Please send a message to [hans@pan-europe.info](mailto:hans@pan-europe.info)



## Results

Overall, the experts consulted by PAN Europe disagreed that the ban of the indicated pesticides will result in substantial yield losses, taking into account the availability of synthetic alternatives in every case. In some difficult cases, such as Septoria in cereals, a lot of attention and knowledge is needed but still available alternatives are sufficient to control the pest.

The list of alternatives for the 13 pest-crop combinations is given below in Table 1.

Table 1. Alternatives for 13 pest-crop combinations.

Pesticide	Main plant pest use	Claimed costs by industry in case of banning (UK Fera, BASF)	Synthetic alternatives	Non-chemical alternatives/IPM, resistant varieties, rotation, biological control, etc.
Azoles (epoxiconazole, cyproconazole, etc.). <b>Eight azoles are banned in DK(**); Four in FR (***)</b>	Septoria tritici in cereals	4,6 billion for Europe assumed, yield loss, from net exporter to net importer (UK); resistance problems due to massive use of chemicals	SDHI pesticides: Boscalid, Isopyrazam, Bixafen, Fluxapyroxad Cyprodinil and Strobilurimn such as Azoxystrobin	Bacterial seed treatment (e.g., Cerall from Bioagri); less vulnerable varieties towards Septoria (Bristol, Robigus, Fortissimo, Tabasco, Lincoln, Tulsa, Carenius), avoid early planting
Azoles, Difenoconazole, Flusilazole, Prothioconazole	Phoma stem canker in winter oil seed rape	Many millions, assumed reduction yield 9,8% (UK); the Agri Chamber in Schleswig-Holstein has shown that there is rarely a benefit of spraying; in fact azoles are misused for stem growth reduction.	Fludioxonil, metalaxyl, thiram, penthiopyrad, picoxystrobin	Resistant varieties (Escort, Twister), crop rotation, cultural control measures (burning stubble), bacterial seed treatment
Myclobutanil (azole)	Grape, powdery mildew	Not considered an endocrine by UK	trifloxystrobin, azoxystrobin, spiroxamine	Ampelomyces quisqualis (parasitic fungus), Aureobasidium pullulans, a yeast, sulphur, resistant varieties, low spraying frequency to prevent resistance, spray forecast model
Mancozeb	Downy mildew in Brassica/Grapevine/Lettuce	No yield reduction but other costs assumed by UK Fera	Mandipropamid (Brassica), Copper, Metalaxyl, Cymoxanil (Grapevine)	Resistant varieties (Brassica); Sulphur, Potassium bicarbonate, cropping density (Lettuce), field location (lettuce), many biologicals in development
Mancozeb	Late blight in potatoes	Not mentioned as increasing costs by UK Fera; resistance problems due to massive use of chemicals.	Cyazofamid, fluazinam (preventive), cymoxanil, dimethomorph, ametoctradin, fluopicolide, propamocarb, fenamidone, potassium phosphite.	Resistant varieties (Carolus, Bionica, Sarpo Mira, Vitabella), planting distance, early harvesting,
Ioxynil	Broad-leaved herbs in onions and leeks	Assumed 20-40% yield reduction (UK)	Bromoxynil (leek), Pyridate, Pendimethalin, Oxyfluorfen, Fluzifop-P-butyl, Clethodim	Use 'false' seed bed, soil solarisation, mechanical weeding; pyro-weeding
Thiacloprid	Oil seed rape/ pollen beetle - seed coating	No yield reduction; other pesticides are more expensive (UK); (this claim is questionable, pyrethroids are cheaper)	Indoxacarb Pymetrozine	Beetle resistant to pyrethroid insecticides, monitoring for thresholds necessary (*), use of kaolin, of entomopathogenic fungi, parasitic wasps in- and off-filed (parasitisation up to 80% if no pesticides are used).

Pesticide	Main plant pest use	Claimed costs by industry in case of banning (UK Fera, BASF)	Synthetic alternatives	Non-chemical alternatives/IPM, resistant varieties, rotation, biological control, etc.
Thiacloprid	Aphids in strawberries	No yield reduction (UK); Thiacloprid kills many beneficial mites and repels beneficial wasps.	Pirimicarb, Pymetrozine,	Various types of biological control, wasps in greenhouses (aphidius ervi), parasitic flies, lacewings and ladybirds. Entomopathogenic fungus and also physical killers like soaps, polysaccharides, pyrethrin
Pyrethroids (cypermethrin, deltamethrin, L-cyhalothrin)	Aphids in grain (transmitting virus)	No yield reduction, higher price of synthetic alternatives (UK); much resistance against pyrethroids	Pirimicarb, Pymetrozine, Flonicamid, Rynaxypyr	Use is not needed; if left untreated, natural enemies will develop and balance the pest (virus concerns exaggerated); avoid early sowing to escape main aphid migration period, natural pyrethrin
Amitrole (part of endocrine interim criteria)	Non-selective herbicide in orchards	Not ranked as an EDC (UK)	Chlorotoluron (dismissed because it's a C2R2), Clopyralid, glyphosate (dismissed because it's a EDC)	Mechanical weeding, covered soil; pyro-weeding
Abamectin (Vertimec)	Tarsonemid control (mite) in strawberries	Impact expected but unknown (UK); other synthetic are more effective	Cyromazin, Spinosad, Bifenazate, Hexythiazox, Spiromesifen	Heat treatment of plants, Biological control with a range of Amblyseius spp. (predatory mites) and Hymenopteran parasites with very good results
Chlorpyrifos	Apple blossom weevil	Significant yield losses for some apple varieties (UK)	Thiacloprid (dismissed because it's a EDC), Spinosad	Earwigs, Quassia extract, pheromones
Dimethoate (endocrine as determined by independent literature)	Aphids in (seed) potatoes	Not considered an EDC (UK)	Pymetrozin, Flonicamid, Pirimicarb,	Encouraging predators and parasitoids like wasps, ladybirds; paraffin oils

(\*) Monitoring for thresholds (for all pest organisms) is a prerequisite for IPM and organic production. This can be done by pheromone traps, colour traps, direct observation (counting), presence of diseases, forecast models, etc. Should be compulsory in all countries and crops to prevent/reduce resistances of many pest organism.

(\*\*) bromuconazole, cyproconazole, fluquinconazole, flusilazole, flutriafol, ipconazole, prochloraz, tetraconazole

(\*\*\*) bromuconazole, fluquinconazole, fuberidazole, ipconazole.

All experts stress the need to move to another system, the integrated crop management, to prevent further resistance against current pesticides used, to make better use of available predators, and to reduce the amount of toxic agrochemicals that is released into the environment causing environmental pollution and degradation of ecosystems. The pesticide groups of Azoles and Pyrethroids are almost at the end of their life-stage. Resistance of pests is at such a level that the use of pesticides- in higher doses and in mixtures (pesticide cocktails)- has become futile.

It is important to note that the resistance to pests is the result of the current system: too high pesticide spraying frequency, too narrow crop rotation and vulnerable crop varieties. This system encourages resistance and creates a continuous loop where stronger and higher pesticide quantities are necessary. To escape from this loop we need to move towards sustainable agricultural practices.

The system of IPM is the most developed for changing current practices and it is not only an option but a legal requirement. IPM is much more knowledge-based (such as monitoring & need to know the lifecycle of pests, thresholds & timing of intervention, use of mechanical weeding etc) and therefore extension services should be used to stimulate and encourage farmers. A EU-wide program should be adopted and proper incentives (such as CAP) should be used.

An element of the current system is the lack of innovation. Substituting one synthetic chemical by another is no real innovation but just the continuation of 'calendar' spraying. IPM on the other hand is very innovative, working with predators, ecosystems, sounds, heat, etc and a range of other non-chemical based options to control pests. Choosing for IPM means profit and jobs for many SMEs in Europe to provide for extension services. Food quality will increase and this will give Europe a competitive advantage on the market. The environment will improve and this will protect biodiversity and species extinction and will also have a positive socioeconomic impact as it will stimulate tourism in agricultural areas. Undoubtedly, the application of IPM is beneficial for all sectors.

## Conclusion

The conclusion drawn by PAN Europe is that the ban of a number of harmful pesticides with endocrine disrupting properties from the market not only is favourable but also feasible. There are a range of alternatives available, even synthetic alternatives that there will be hardly any substantial yield loss. Certainly not the huge yield-losses claimed by UK and industry, who ignore the implementation of IPM by member states. Many alternatives are readily available and additional alternatives can be introduced with the use of proper extension services.





## **IMPACT ASSESSMENT ANNEX III**

### **Evaluation of currently published reports on the potential impact of EU endocrine disrupting pesticide policy.**

## **Introduction**

Several reports have been published to claim huge costs and negative effects of the implementation of the EU endocrine disrupting (ED) pesticide policy. UK national institutes and pesticide industry have been at the forefront of making huge claims of damage. UK likely because of their opposition against the 'hazard' approach in Regulation 1107/2009 from the start (UK voted against the endocrine hazard approach) and their constant lobby work at all levels in the EU to return to traditional risk assessment evaluation of pesticides. Pesticide industry, such as the umbrella organisation ECPA but also multinationals like BASF and Syngenta, used assessments of the estimated yield losses by farmers to protect their trade in pesticides. US Croplife and British farmers were amongst the forces helping UK and pesticide industry in their missions. German health institute BfR, which has a fixed political line to defend as well, also published an impact assessment, cooperating on certain points with the UK. As far as we know there is as yet no independent assessment of the impact of the Endocrine Disrupting Chemicals (EDCs)- policy. PAN Europe therefore developed its own in-depth assessment<sup>1</sup>.

## **Methodology**

In the next paragraphs we discuss the most relevant reports published so far and assess their quality and flaws; from this analysis we get to a set of final conclusions on the state-of-the-knowledge of the impact of the ED-pesticide policy. We only discuss human health effects- the effects for which the criteria for endocrines will be developed for. The endocrine disruption effects on non-target organisms in the environment need to be taken into account as well in pesticide decision-making, but here the Regulation doesn't refer to the criteria (Regulation 1107/2009 Annex II, 3.8.2)<sup>2</sup>. Since no adequate testing and guidelines is defined for evaluation endocrine disrupting effects on non-target species, it is difficult to assess the impact at the moment. On top of this, there is an agreement in the Standing Committee on pesticides<sup>3</sup> not to ban a pesticide solely for environmental reasons. In all current cases<sup>4</sup> of decision-taking by Commission (non-specified!) 'mitigation measures' have to make sure that the high risks observed will be reduced in practice. While a monitoring of the many hundreds cases of 'mitigation measures' is lacking, it is unsure if the 'mitigation measures' are effective or imposed at all in EU member states. From the decision to ban Aldicarb<sup>5</sup> because of the risks to birds in 2003, up till now, 12 years later, no single pesticide has been banned for environmental reasons and we assume this will also occur with endocrine disruptors. Regulation 1107/2009, Annex II, 3.8.2 will therefore have no impact on market access of pesticides in practice.

<sup>1</sup> PAN Europe IMPACT ASSESSMENT analysis, document with 4 Annexes, submitted to the public consultation of Commission, January 2015.

<sup>2</sup> Regulation 1107/2009, Annex II, 3.8.2. An active substance, safener or synergist shall only be approved if, on the basis of the assessment of Community or internationally agreed test guidelines, it is not considered to have endocrine disrupting properties that may cause adverse effects on non-target organisms unless the exposure of non-target organisms to that active substance in a plant protection product under realistic proposed conditions of use is negligible.

<sup>3</sup> [http://ec.europa.eu/food/plant/standing\\_committees/sc\\_phytopharmaceuticals/index\\_en.htm](http://ec.europa.eu/food/plant/standing_committees/sc_phytopharmaceuticals/index_en.htm)

<sup>4</sup> see: [PAN report Resubmission](#)

<sup>5</sup> COUNCIL DECISION of 18 March 2003 concerning the non-inclusion of aldicarb in Annex I to Council Directive 91/414/EEC and the withdrawal of authorisations for plant protection products containing this active substance (2003/199/EC)





## Results

### Part A. the number of pesticides affected by the ED-pesticide policy.

#### 1. UK (HSE/CRD) on the identification of the pesticides subject to the EU endocrine policy<sup>6</sup>.

The report analyses about 100 pesticides for endocrine disrupting adverse effects and concludes that (only) 5 pesticides are "more likely to pose a risk" for human health, the names of these pesticides are Abamectin, Thiacloprid, Ioxynil, Linuron and Mancozeb. The report is the outcome of a thorough exercise based on regulatory documents and a limited number of academic studies.

The biggest flaw of the report is that it focuses mainly on one specific criterion, "potency", the criterion included questionably in Option 4 of the roadmap to define EDCs<sup>7</sup>, while not fully assessing other criteria. For instance UK includes Ioxynil as "more likely to pose a risk", while Commission assumes that the thyroid tumours caused by Ioxynil are rat-specific and have no human relevance<sup>8</sup>. For Thiacloprid the same story; here Commission assumes that 'hepatic enzyme induction' is the primary cause of thyroid, uterine and ovarian changes caused by Thiacloprid<sup>9</sup>. So while the report is detailed, the focus on "potency" makes it less accurate on other topics and criteria for endocrines. For a good understanding it is necessary to underline that "potency" has no scientific basis and it was developed in the regulatory arena to dismiss certain adverse effects of chemicals in order to allow their use. It is an arbitrarily chosen cut-off level for exposure in animal testing studies and totally irrelevant to EDCs that may cause adverse effects at very low levels comparable to the ones of the endogenous hormones. Since the pesticide Regulation needs to be science-based<sup>10</sup>, there seems to be no place for potency in any regulatory assessment.

The report has to serve the advocacy work of UK to bring on board the "potency" criterion and is therefore more political than scientific. This is reinforced by the fact that the "Client manager" of the report Ms. Brescia has several other "hats". She served in the JRC-expert group on endocrine disruption (organised by DG Environment) where she defended the UK position against the hazard approach, explaining that the UK-proposal to include "potency" is a way to re-introduce risk assessment (Arona-meeting, 26/27 June 2012). She was also part of the EFSA expert panel of "independent experts" on endocrine disruption<sup>11</sup>. Despite this, the report shows that the impact is small, only 1% of the currently approved (around 500 in total) pesticides will be affected.

#### 2. Swedish KEMI impact assessment, 2008<sup>12</sup>

Sweden analysed the available regulatory dossiers for endocrine disrupting effects of pesticides. They identified 4 pesticides as endocrine disruptors using the interim-criteria of Regulation 1107/2009<sup>13</sup>, Linuron,

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<sup>6</sup> Extended impact assessment study of the human health and environmental criteria for endocrine disrupting substances proposed by HSE, CRD, 2013, [UK CRD/HSE on endocrines](#)

<sup>7</sup> [Commission roadmap endocrine disruption](#)

<sup>8</sup> SANCO review report on Ioxynil, [http://ec.europa.eu/sanco\\_pesticides/public/?event=activesubstance.detail](http://ec.europa.eu/sanco_pesticides/public/?event=activesubstance.detail)

<sup>9</sup> SANCO review report on Thiacloprid, [http://ec.europa.eu/sanco\\_pesticides/public/?event=activesubstance.detail](http://ec.europa.eu/sanco_pesticides/public/?event=activesubstance.detail)

<sup>10</sup> Regulation 1107/2009, Art.4: An active substance shall be approved in accordance with Annex II if it may be expected, **in the light of current scientific and technical knowledge**.....

<sup>11</sup> EFSA opinion on endocrine disruption, March 2013, <http://www.efsa.europa.eu/en/efsajournal/pub/3132.htm>

<sup>12</sup> Assessment made by Swedish national chemicals institute KEMI, [KEMI 23 incl ED pesticides](#)

<sup>13</sup> Regulation 1107/2009, Annex II 3.6.5. An active substance, safener or synergist shall only be approved if, on the basis of the assessment of Community or internationally agreed test guidelines or other available data and information, including a review of the scientific literature, reviewed by the Authority, it is not considered to have endocrine disrupting properties that may cause adverse effect in humans, unless the exposure of humans to that active substance, safener or synergist in a plant protection product, under realistic proposed conditions of use, is negligible, that is, the product is used in closed systems or in other conditions excluding contact with humans and where residues of the active substance, safener or synergist concerned on food and feed do not exceed the default value set in accordance with point (b) of Article 18(1) of Regulation (EC) No 396/2005.

By 14 December 2013, the Commission shall present to the Standing Committee on the Food Chain and Animal Health a draft of the measures concerning specific scientific criteria for the determination of endocrine disrupting properties to be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 79(4).



Tralkoxydim, Tepraloxydim, Epoxiconazole (Molinate and Flusilazole are not approved anymore). They also identified 8 pesticides further with endocrine disrupting adverse effects, Amitrole, Ioxynil, Mancozeb, Maneb, Metconazole, Iprodione, Tebuconazole and Thiacloprid. Sweden did not apply any of the endocrine criteria; they were not yet proposed at that time.

The work of Sweden is thorough and of good quality. The only flaw in the study is that open peer-reviewed scientific literature is not taken into account. If Sweden would have done so, a few additional endocrine disrupting pesticides might have been added to the list, such as Cypermethrin, Deltamethrin and Dimethoate<sup>14</sup>.

### 3. German BfR impact assessment, 2014<sup>15</sup>

The German evaluation is, unlike the CRD/HSE one, not very thorough. BfR analysed classified pesticides (CLP regulation<sup>16</sup>) and added a random sample from the available pesticides, admitting a bias in the selection method. They then evaluated the -around 40- pesticides obtained based on evidence from the regulatory dossier as well as academic studies.

BfR analyses three options, option 1 hazard + human relevance (but not whether endocrine disruption is considered a secondary effect- an element that the commission is using to dismiss endocrine disrupting effects in the presence of other toxic effects), option 2 hazard + potency, and option 3 interim + human relevance (?). Unfortunately these options are not readily comparable to the options from the roadmap. Nevertheless, we have attempted to analyse their outcome. Table 6 in the BfR-report presents the outcome.

Hazard + human relevance resulted in 14 ED-pesticides (mixed up with interim criteria substances); hazard + potency in 5 ED-pesticides, Amitrole, Epoxiconazole, Ioxynil, Linuron, and Metconazole, and 3 questionable Mancozeb, Fenpropimorph and Tebuconazole, while option 3 -unsurprisingly, because of the selection- shared all 16 under interim criteria. As mentioned before, adding Linuron to this list is irrelevant - this is a clear flaw in the study- because it will be regulated already as a Reprotoxin 1B<sup>17</sup>, overruling the endocrine criteria process<sup>18</sup>. Further “sloppy” mistakes were made by including banned pesticides (flusilazole, molinate).

The German study, unfortunately, doesn't offer much knowledge on the impact of the ED-pesticide policy. We do not understand why BfR didn't look at the several lists of suspected pesticides (EU-list, TEDX-list, McKinlay-list) and analysed an apparently non-random sample. Remarkably the substances mentioned in the outcome show a substantial overlap with the analysis of Sweden, UK and PAN Europe.

This German report, although it has been published as a scientific article, must be considered being part of the German advocacy work against the regulation of EDC pesticides. BfR has repeatedly explained that their “political bosses” wouldn't allow a loss of many pesticides and that they were allowed to support the ban

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Pending the adoption of these criteria, substances that are or have to be classified, in accordance with the provisions of Regulation (EC) No 1272/2008, as carcinogenic category 2 and toxic for reproduction category 2, shall be considered to have endocrine disrupting properties.,

<sup>14</sup> See PAN Europe document IMPACT ASSESSMENT ANNEX Ib.

<sup>15</sup> P. Marx-Stoelting, L. Niemann, V. Ritz, B. Ulbrich, A. Gall, K.I. Hirsch-Ernst, R. Pfeil, R. Solecki, Assessment of three approaches for regulatory decision making on pesticides with endocrine disrupting properties, Regulatory Toxicology and Pharmacology xxx (2014) xxx-xxx

<sup>16</sup> [C&L Inventory database - ECHA](#)

<sup>17</sup> Regulation 1107/2009, Annex II, 3.6.4. An active substance, safener or synergist shall only be approved if, on the basis of assessment of reproductive toxicity testing carried out in accordance with the data requirements for the active substances, safeners or synergists and other available data and information, including a review of the scientific literature, reviewed by the Authority, it is not or has not to be classified, in accordance with the provisions of Regulation (EC) No 1272/2008, as toxic for reproduction category 1A or 1B, unless the exposure of humans to that active substance, safener or synergist in a plant protection product, under realistic proposed conditions of use, is negligible, that is, the product is used in closed systems or in other conditions excluding contact with humans and where residues of the active substance, safener or synergist concerned on food and feed do not exceed the default value set in accordance with point (b) of Article 18(1) of Regulation (EC) No 396/2005.

<sup>18</sup> Regulation 1107/2009, art. 4.1 : The assessment of the active substance shall first establish whether the approval criteria set out in points 3.6.2 to 3.6.4 and 3.7 of Annex II are satisfied. If these criteria are satisfied the assessment shall continue to establish whether the other approval criteria set out in points 2 and 3 of Annex II are satisfied.



only for a “handful” of pesticides<sup>19</sup>. For this reason BfR in 2011 joined forces with the UK to include potency in the criteria<sup>20</sup>, while BfR experts were vocal in the JRC expert group and were included as an 'independent' expert in the EFSA panel on endocrines. ‘Potency’ has no scientific basis and it used in the regulatory arena to dismiss certain adverse effects of chemicals for political reasons. It is an arbitrarily chosen cut-off level for exposure in animal testing studies. Since the pesticide Regulation needs to be science-based<sup>21</sup>, there seems to be no place for potency in any regulatory assessment.

Summary Table, pesticides confirmed as a human health ED-pesticide based on a hazard approach and draft DG Environment criteria in different reports

Name pesticide	Sweden KEMI	UK CRD/HSE	PAN Europe	Germany BfR
Amitrole	+		+	+
Ioxynil	+	+		+
Mancozeb	+	+	+	+
Maneb	+		+	+
Metconazole	+		+	+
Tebuconazole	+	+		+
Iprodione	+	+		
Thiacloprid	+	+		
Abamectin		+		

#### 4. PAN Europe evaluation of the reports

The conclusion on the impact of the pesticide endocrine policy is that the number of pesticides affected is limited, if the draft criteria would be applied, 5 - 8 pesticides likely would be affected. With the criterion potency added, the number is lower, 4 (PAN Europe) - 5 (CRD/HSE).

This number is separate from the numbers affected by the interim criteria. UK CRD/HSE and KEMI didn't look at the interim criteria, while German BfR confusingly mixed up the pesticides evaluated with the interim criteria with the ones subject to the full criteria to be published after the public consultation (both analysed interim criteria pesticides for interim and full criteria). The impact of the interim criteria is difficult to assess<sup>22</sup>, given the text of the Regulation ("shall" and "may"), the lack of experience and guidelines, but interim-criteria nevertheless are currently implemented rules and no part of the endocrine criteria-setting policy.

### **Part B. the analysis of the costs of the pesticide endocrine policy.**

#### 5. UK FERA report, 2013<sup>23</sup>

The FERA report uses the outcome of the UK CRD/HSE report for calculating yield losses. It is a detailed report on assumed yield losses but with major flaws.

<sup>19</sup> Arona-meeting, 26/27 June 2012

<sup>20</sup> JOINT DE – UK POSITION PAPER, REGULATORY DEFINITION OF AN ENDOCRINE DISRUPTER IN RELATION TO POTENTIAL THREAT TO HUMAN HEALTH, 16 May, 2011

<sup>21</sup> Regulation 1107/2009, Art.4: An active substance shall be approved in accordance with Annex II if it may be expected, **in the light of current scientific and technical knowledge**.....

<sup>22</sup> See PAN Europe IMPACT ASSESSMENT ANNEX Ia, submitted to the public consultation, January 2015.

<sup>23</sup> Agronomic and economic impact assessment for possible human health and ecotoxicology criteria for endocrine disrupting substances Report to Chemicals Regulation Directorate, FERA, June 2013



First of all, from the four types of impact calculated, only the first one (Impact 1: Loss of active substances more likely to pose a risk in Group 1) is relevant. Impact 2, banning all pesticides including the ones “less likely” to pose a risk, has no relevance at all since there is no basis, considering the options in the roadmap, to classify all of them as EDCs. If “human relevance”, “secondary effect”, and “potency” are used, none of these pesticides would be affected by the pesticide endocrine policy<sup>24</sup>. This approach cannot even serve a ‘worst case’ scenario and is outside the scope of the roadmap.

The Impact 3 and 4 calculations can hardly be considered valid. As the UK CRD/HSE report explains, the pesticides in this group are ASSUMED to have mechanistic data showing they are ED-pesticides<sup>25</sup>. This is just a speculation without any scientific basis and shouldn’t form part of this report. While the CRD/HSE report concludes that there is lack of information on Chlorpyrifos, the FERA-report concludes that the ban on Chlorpyrifos/Thiacloprid will result in a 225.000 £ loss, yearly, in the UK. This is a massive flaw in the FERA-report. Impact 4 of the FERA-report shows the same speculation and non science-based assumptions and should be disregarded.

Returning to the impact 1 calculation (Impact 1: Loss of actives more likely to pose a risk in Group 1), FERA calculates 158.000 £ yield loss, yearly, in the UK from the 5 pesticides indicated. Here, the costs of the ban on Linuron are misleadingly included, while it is well-known that Linuron will not be assessed for the endocrine disruption criteria. As mentioned before, there is no point, and a clear flaw in the study, adding Linuron to this list because it will be regulated already as a Reprotoxin 1B<sup>26</sup>, overruling the endocrine criteria process<sup>27</sup>.

This claim by FERA is the most misleading one, since Linuron accounts for 75% of the costs calculated by FERA, meaning the claim is 41.000 and not 158.000 £. It is a shame that this wrong amount is broadcasted widely in the public arena, encouraging industry and farmers organisations to use wrong data in their advocacy work.

Please also note that FERA concludes correctly that the replacing of Mancozeb will have no costs impact. In agreement with the PAN Europe study, many good alternatives for pest prevention and control for this active pesticide substance are available in the market (PAN Europe, Impact Assessment Annex II).

A last element is the lack of transparency on the assessment of yield losses and costs- the 41.000 £ for the UK. The FERA report mentions that all chemicals and non-chemical alternatives are taken into account -

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<sup>24</sup> See PAN Europe IMPACT ASSESSMENT ANNEX Ia and Ib, submitted to the public consultation, January 2015.

<sup>25</sup> UK CRD/HSE report 2013, page 28:

The 26 pesticides were assumed to have mechanistic data showing them to be EDs.

The toxicity apical data were re-assessed and a LOAEL relevant to endocrine-related adverse effects determined – more than one LOAEL may be derived based on different regulatory tests (e.g. 90-days, 2-years and reproduction).

Where there was no relevant LOAEL based on endocrine-related adverse effects in standard toxicity tests, a LOAEL (or LOEL) from an endocrine activity/disruption in vivo screening assay was used in the assessment.

The LOAEL values and the severity of the effects at the LOAELs were compared to the STOT-RE Cat 1 guidance values and the substances ranked as EDs more or less likely to pose a risk. For the overall conclusion for each substance, the lowest LOAEL identifying the highest level of concern was used.

<sup>26</sup> Regulation 1107/2009, Annex II, 3.6.4. An active substance, safener or synergist shall only be approved if, on the basis of assessment of reproductive toxicity testing carried out in accordance with the data requirements for the active substances, safeners or synergists and other available data and information, including a review of the scientific literature, reviewed by the Authority, it is not or has not to be classified, in accordance with the provisions of Regulation (EC) No 1272/2008, as toxic for reproduction category 1A or 1B, unless the exposure of humans to that active substance, safener or synergist in a plant protection product, under realistic proposed conditions of use, is negligible, that is, the product is used in closed systems or in other conditions excluding contact with humans and where residues of the active substance, safener or synergist concerned on food and feed do not exceed the default value set in accordance with point (b) of Article 18(1) of Regulation (EC) No 396/2005.

<sup>27</sup> Regulation 1107/2009, art. 4.1 : The assessment of the active substance shall first establish whether the approval criteria set out in points 3.6.2 to 3.6.4 and 3.7 of Annex II are satisfied. If these criteria are satisfied the assessment shall continue to establish whether the other approval criteria set out in points 2 and 3 of Annex II are satisfied.





which is a good point- but we fail to see how this is done. It is done by “expert judgement” which we agree is difficult to validate but still more transparency is needed. A case study would have been informative in order to understand how this is done. Now the only thing we see is an estimate by an (unknown) expert. While we know that yield can vary a lot over seasons, it is uncertain if a worst-case assumption is made in a specific bad weather year. For instance, it isn’t very reassuring to read that for the yield losses, the industry was allowed to comment on the work of FERA (page 2 of the report). We feel a more independent approach would have been appropriate. This is also illustrated by the contrasting views expressed by the group of experts consulted by PAN Europe who could identify many chemical and non-chemical alternatives for the FERA-pesticides and generally were of the opinion that yield losses would not be substantial<sup>28</sup>.

As a conclusion, the FERA impact assessment is far from convincing and proves little, if any, substantial yield loss and costs from the potential ban of ED-pesticides.

#### 6. UK farmers and pesticide producers (Anderson report<sup>29</sup>)

This lobby report prepared by consultancy Anderson for UK farmers Union and pesticide producers is an example of shameless exaggeration and scaremongering. Any pesticide detected in any report, no matter the relevance, is included in this report. It is very strange to see substances included from the CRD 2008-report<sup>30</sup>, which was made at the time when different regulatory proposals from Commission, Parliament and Council were still at the table before the final negotiations. The magazine “Farmers Guardian” communicates on the basis of this report that “87 out of around 250 approved pesticides in the UK could be lost to the farming industry as a result of EU policies and their implementation in the UK, while the wider food supply chain could see economic losses of up to £2.5bn per year<sup>31</sup>”. In the report, in reality, it is assumed that 40 pesticides will be banned because of the endocrine criteria, but -as demonstrated in part A of this document- this number will likely be 5 to 8, and therefore the claims made by Anderson are groundless and misleading. The calculation of yield losses is very intransparent and it looks like chemical and non-chemical alternatives are not even taken into account. Assumed yield losses are between 4 - 50%, which is hard to believe because even a total conversion to organic (no synthetic pesticides at all) would not lead to this level of yield losses<sup>32</sup>.

In conclusion the Anderson report is based on many wrong assumptions and flaws and doesn't contribute to more knowledge on the impact of pesticide endocrine policy.

#### 7. ADAS report, made for pesticide industry umbrella organisation ECPA<sup>33</sup>

The ADAS report on the impact of a ban of all azoles is an interesting report that provides information on the use of azoles in different crops in Europe. For the current impact assessment of the criteria for ED-pesticides, however, the report has no relevance. As demonstrated by the currently available impact assessments (paragraph 4, above), only two azoles, metconazole and tebuconazole, will likely be affected by the EDCs policy, and potentially epoxiconazole based on the interim criteria. This means that many azole pesticides will remain available on the market and therefore, the exercise done by ADAS lacks any reality value. It would have been better if ADAS had looked to the ban of just the three mentioned azole pesticides. Also the fact that Denmark has 8 azoles less on the market than the UK would be an interesting research topic on the impacts.

<sup>28</sup> PAN Europe IMPACT ASSESSMENT ANNEX II, alternatives, submitted to the public consultation, January 2015.

<sup>29</sup> <http://www.nfuonline.com/science-environment/pesticides/commission-endocrine-disruptor-consultation-we-need-you/>

<sup>30</sup> Assessment of the impact on crop protection in the UK of the ‘cut-off criteria’ and substitution provisions in the proposed Regulation of the European Parliament and of the Council concerning the placing of plant protection products in the market. This assessment has been prepared as a supplement to the regulatory impact assessment for this proposal, May 2008

<sup>31</sup> <http://www.farmersguardian.com/arable-farming/growers-urged-to-respond-to-consultation-on-endocrine-disruption/68271.article#http://www.nfuonline.com/andersons-final-report/>

<sup>32</sup> Verena Seufert, Navin Ramankutty & Jonathan A. Foley, Comparing the yields of organic and conventional agriculture, 10 MAY 2012 | VOL 485 | NATURE | 229

<sup>33</sup> Evaluation of the benefits provided by the azole class of compounds in wheat, and the effect of losing all azoles on wheat and potato production in Denmark, France and the UK. Report 1 – Impact of the loss of all azoles, ADAS, 2011

Pesticide industry group ECPA commissioned similar studies on azoles in Italy (consultancy Nomisma in 2011<sup>34</sup>). As with the ADAS-report, the Nomisma-report doesn't add any knowledge to the impact assessment for endocrine disrupting pesticides in relation to the roadmap.

Also, pesticide multinational BASF together with landowner organisation ELO published brochures and flyers on the need to keep the azoles on the market; however, for the impact assessment they do not add any relevant data.

#### 8. ECPA policy paper on endocrine disrupting pesticides, version March 2013<sup>35</sup>.

ECPA used this document to lobby different Commission services. Their claim was to include the criterion "potency" and to start an impact assessment. ECPA refers to a PSD/HSE assessment from 2009 to state that 37 pesticides will be affected by the EDCs-policy, adding that "the number of substances likely to be affected is greater than the 37 active substances that were initially identified by PSD/CRD". ECPA now focuses on the market value of these pesticides and calculates 3-4 billion Euros market value that would be lost, and to make it extra scary, it states that this accounts for 80% of the fungicide market.

This document is not based on a serious assessment of the pesticide EDCs-policy in relation to the roadmap. In reality, in agreement with the more recent 2013-report of UK CRD/HSE 5 - 8 pesticides will be affected by the endocrine policy and not "more than 37". The entire analysis made by ECPA is misleading.

It is also questionable to look at market value for the pesticides banned. Pesticides will be replaced by other pesticides, methods and practices, and this will also generate market value. The data put forward by ECPA are thus flawed since the alternatives are not even calculated. This is without considering the question if market value is a good parameter for the impact assessment at all. External costs of pesticides are conveniently forgotten by ECPA as well as the need to move to more sustainable practices<sup>36</sup>.

#### 9. The UK agriculture and horticulture development board, ADAS, 2014<sup>37</sup>

This AHDB-report, again drafted by ADAS has many similarities with previous reports, especially on clearly wrong assumptions and flaws. This time a ban of 17 - 66 pesticides (different scenario's) is assumed, acknowledging that "the categorisation was based on WRC (2013) and information provided by ECPA". The analysis is done in vain because no solid analysis shows that 51 pesticides will be banned because of the endocrine policy, best estimates are between 5 and 8. The report with these exaggerated claims and costs will likely serve lobby purposes and add confusion to media, farmers and politicians.

This study has no relevance for the impact assessment.

## Conclusions

Unfortunately, most reports are not based on a realistic number of pesticides likely banned for endocrine reasons. This counts for the report of the UK farmers (ADAS), ECPA (Nomisma, ADAS) and AHDB (ADAS); **they add no knowledge for the impact assessment and can be disregarded.**

<sup>34</sup> <http://www.ecpa.eu/article/agriculture-today/assessment-economic-importance-azoles-european-agriculture-wheat-case-stud>

<sup>35</sup> [ECPA PP/13/AP/22658 - Rev.1 - Punto Focal](#)

<sup>36</sup> Directive for a sustainable use of pesticides, 2009.

<sup>37</sup> Endocrine disruptors – collation impacts across all sectors to give clear messages on impacts of changing availability on farmers and production Sarah Wynn, ADAS UK Ltd, December 2014

The only report with some value is the UK-FERA report from 2013, and especially the calculations referred to as "impact 1". From these calculations, the pesticide Linuron has to be removed and for the remaining 4 the impact could be assessed. Substituting Mancozeb has no impact and -in this exercise- the impact of the remaining three should have received a closer examination. A "valid" impact assessment should be carried out by completely independent experts and in a transparent way. Are chemical alternatives available? What happened in EU member states where the pesticide was banned, now or in the past? Are non-chemical alternatives available including system changes like rotation and more resistant crop varieties? How can potential yield losses be estimated in a transparent way?

For now we maintain that the costs for farmers (as one element of the impact assessment) are low in case of substitution, if any.



## IMPACT ASSESSMENT, ANNEX IV

### PAN Europe's views on the Impact Assessment (IA) regarding the criteria for endocrine disruptive pesticides

## Introduction

There is a scientific consensus now<sup>1</sup> that endocrine disrupting chemicals (EDCs) cause damage to health and the environment. A large group of actively publishing endocrinologists put it this way:

*“We are starting to understand that a large number of non-communicable diseases have their origin during development and that environmental factors interact with our genetic background to increase susceptibility to a variety of diseases and disorders. It is also clear that one of the important environmental risk factors for endocrine disease is exposure to EDCs during development. It is also clear from human studies that we are exposed to perhaps hundreds of environmental chemicals at any one time. It is now virtually impossible to examine an unexposed population around the globe. Trends indicate an increasing burden of certain endocrine diseases across the globe in which EDCs are likely playing an important role, and future generations may also be affected.”*

A recent EEA-JRC report<sup>2</sup> confirms the views of WHO-UNEP. While the exact contribution of endocrine disrupting chemicals to health and the environment is difficult to assess, EEA states a precautionary principle approach is needed to prevent further widespread harm to society.

Such a precautionary principle approach is agreed and adopted by EU Commission, Council and Parliament in pesticide Regulation 1107/2009 and waits to be implemented. However, in 2013 the European Commission suddenly decided to undertake an impact assessment on the implementation and this decision unfortunately not only delays prevention of harm to humans and ecosystems but it also creates a changed playing field.

### PAN Europe's views.

While it is not entirely clear what impacts the Commission's impact assessment will look at, the language used at page 3 of the 'roadmap' from June 2014<sup>3</sup> looks like only the monetary values of risks and benefits of options will be weighed. We do not favour a risk/benefit analysis based on monetary values. Our views on the future impact assessment are:

#### **1. The process of reducing life, health, and the natural world to monetary values is inherently flawed.**

Several studies have been published on the (monetary) impact of the pesticide endocrine policy for farmers and industry. This already creates a lot of debate because the “expert judgement” on yield losses of crops done by experts connected to the commercially interested parties is far from independent. On the other hand, very few studies have been published on the (monetary) benefits of phasing out harmful pesticides. Pretty et

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<sup>1</sup> Åke Bergman, Jerrold J. Heindel, Susan Jobling, Karen A. Kidd, R. Thomas Zoeller, State of the Science of Endocrine Disrupting Chemicals 2012, WHO-UNEP.

<sup>2</sup> Environment and human health, Joint EEA-JRC report, EEA Report No 5/2013

<sup>3</sup> [Commission roadmap endocrine disruption](#)



al. (2000)<sup>4</sup> were one of the first that tried to calculate the external costs of current industrial agriculture and estimated that society in the US pays 208 pounds per hectare as a minimum. The potentially huge costs of pesticides contributing to the fast rising non-communicable diseases (cancers, metabolic diseases, cognitive disorders etc) were still not included in his study. In a subsequent study from 2005<sup>5</sup> the authors calculated around 150 pounds costs for the UK consumers per year of external costs.

Nordic co-operation recently published a report called “The cost of inaction” in an attempt to expose the socio-economic costs related to the effects of EDCs, some of them pesticides, just on male reproductive health. The report concludes that in the best-case scenario the total cost of illness related to negative effects on human male reproduction due to exposure to EDCs in the Nordic countries (Denmark, Finland, Iceland, Norway and Sweden) is 3.6 million EUR a year and in the worst-case scenario 40 EUR million<sup>6</sup>. If we extrapolate these numbers to the EU-28 the cost would amount between 59 million -1.2 billion per year! The Nordic co-operation only focused on the costs from male reproductive disorders but if we consider most endocrine-related diseases the costs are much higher. In an attempt to estimate the overall health costs in Europe of most known endocrine-related diseases (human infertility, cryptorchidism, hypospadias, breast cancer, prostate cancer, ADHD, autism, overweight, obesity and diabetes) HEAL<sup>7</sup> concluded that approximately 36 billion EUR are due to exposure to EDCs. To date, no impact assessment provided by the industry has presented the “expenses” that Europe will save from health costs if it eliminates the use of EDCs, especially in pesticides that we eat from residues left in our food. Although obtaining a specific value for the health costs due to pesticide exposure is challenging, neglecting that these costs even exist is unacceptable, dangerous and against human rights.

A 1992-study of Pimentel et al.<sup>8</sup> is one of the very few that considered health costs of the use of pesticides, acute poisoning, treatment in hospitals and lost work-days. Yearly health costs were estimated to be 787 million dollars per year for the US. Additionally the authors assumed 1% of all cancers to be pesticide-related and calculated another 707 million dollar cost per year. These studies illustrate that it is notoriously difficult the estimate costs and for many aspects it will be hardly, if ever, possible to make reliable estimates.

Due to the massive differences in resources of those defending private vs. public interests there is a lack of good studies on the external costs of pesticide use and the main reason behind these differences is that a monetary calculation is inherently flawed. Efforts to value life illustrate the basic problems. Cost-benefit analysis involves the creation of artificial markets for things - like good health, long life, and clean air - that are not bought and sold. It might be possible for instance to estimate (by interview) the amount of money people are willing to pay to avoid the risk to pesticide poisoning but it will not be possible to put an amount of life itself; life is not for sale. Cost-benefit analysis also ignores the fact that citizens are concerned about risks to their families and others as well as themselves, ignores the fact that market decisions are generally very different from political decisions, and ignores the incomparability of many different types of risks to human life. The kind of problems which arise in attempting to define the value of human life in monetary terms also arise from evaluating the benefits of protecting human health and the environment in general. Many animals, plants and ecosystems are close to become extinct, mainly due to the use of pesticide and the industrial type of agriculture. Getting extinct is an irreversible act- they will not be available anymore for future generations upon which, it is impossible to put a monetary value.

An important element is that cost-benefit analysis generally discounts future harm. Several pesticides, including endocrine disrupting pesticides, have shown to be capable of affecting DNA and the mutations

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<sup>4</sup> J.N. Pretty, C. Brett, D. Gee, R.E. Hine, C.F. Mason, J.I.L. Morison, H. Raven, M.D. Rayment, G. van der Bijl, An assessment of the total external costs of UK agriculture, *Agricultural Systems* 65 (2000) 113-136

<sup>5</sup> J.N. Pretty, A.S. Ball, T. Lang, J.I.L. Morison, Farm costs and food miles: An assessment of the full cost of the UK weekly food basket, *Food Policy* 30 (2005) 1-19

<sup>6</sup> Ing-Marie Olsson m.fl. [The cost of Inaction. A Socioeconomic analysis of costs linked to effects of endocrine disrupting substances on male reproductive health](#), 2014 TemaNord.

<sup>7</sup> [Health and Environment Alliance \(HEAL\). Health Costs in the European Union- How much is related to EDCs, June 2014](#)

<sup>8</sup> Pimentel, D., Acquay H., Biltonen, M., Rice, P., Silva, M., Nelson, J., Lipner, V., Giordane, S., Horowitz, A., D'Amore, M. 'Environmental and Economic Costs of Pesticide Use', *Bioscience*, 1992, No 42:10, pp. 750-760.

pass onto the next generations manifesting in diseases and disorders<sup>9</sup>. How will the effects on future generations be compared to the effects on present generations? And what is the cost of the diseases that we will prevent in the future if we eliminate the use of harmful pesticides?

Further, cost-benefit analysis is a simplified model based on a limited understanding of natural processes that ignores the impact that species extinction and contamination due to pesticide use may have on ecosystems' equilibrium and environmental health. How many species have they already become extinct due to the use of pesticide and what is their impact on other ecosystems? What is the cost of ecosystems degradation?

Cost-benefit analysis also ignores the question of who suffers as a result of pesticide pollution and, therefore, threatens to reinforce existing patterns of economic and social inequality. Will the health effects on residents be taken serious this time in the impact analysis- an aspect which has been ignored by regulators and dominating parties for decades?

Cost-benefit analysis is not objective, it rests on a series of assumptions and judgments that cannot remotely be described as objective.

## **2. Impossible to connect risk to harm in current practice of pesticide use.**

In the regulatory arena there are often big technical discussions between EU member states and the Commission on the outcome of a single animal test study that shows harm of the exposure to one single pesticide. To find a relation between the use of a pesticide in practice and public health is an illusion. Hundreds of pesticides are sprayed on hundreds of crops (and many thousands of other chemicals are present in consumer products), exposing directly (spray-drift of residents) or indirectly (food, water, air) millions of people by a mere cocktail of chemicals, every day. Daily practice of pesticide use, thus, is a highly uncontrolled 'experiment' while the monitoring of their effects is lacking<sup>10</sup>. This is the worst 'experiment' you can imagine, which makes an impact assessment impossible. Only in very special cases (workers disease in industry production facilities; special crop in remote area with one dominant pesticide) one might be able to find relations but very few of these 'epidemiology studies' have been published on pesticides. Also, the level of contribution of endocrine damage by pesticides and other chemicals will never be clear.

## **3. Health impact is the only relevant topic.**

Regulation 1107/2009 is primarily a health regulation. It aims to protect people and the environment<sup>11</sup>, and "not have any harmful effect on human health". A true precautionary principle regulation of no harmful effect. Harmful effects simply are not allowed in placing pesticides on the market. Costs for farmers or the pesticide industry therefore cannot be a reason to allow harmful effects, which seems to be suggested implicitly by the 'roadmap'<sup>12</sup>. Law cannot be 'balanced' again since the balancing has already been done in co-decision in 2009.

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<sup>9</sup> Schug, T.T.m Janesick, A., Blumberg, B., Heindel J.J. Endocrine disrupting chemicals and disease susceptibility, J Steroid Biochem Mol Biol (2011) 127:204-215

<sup>10</sup> EU Commission approves pesticides but has no health monitoring system in place to track health effects on humans and the environment

<sup>11</sup> Regulation 1107/2009, Art.4.2: The residues of the plant protection products, consequent on application consistent with good plant protection practice and having regard to realistic conditions of use, shall meet the following requirements:

(a) they shall not have any harmful effects on human health, including that of vulnerable groups, or animal health, taking into account known cumulative and synergistic effects where the scientific methods accepted by the Authority to assess such effects are available, or on groundwater;

(b) they shall not have any unacceptable effect on the environment.

For residues which are of toxicological, ecotoxicological, environmental or drinking water relevance, there shall be methods in general use for measuring them. Analytical standards shall be commonly available.

<sup>12</sup> [Commission roadmap endocrine disruption](#) page 3, under 3).

Further, Regulation 1107/2009 in Annex II, 3.6.5 provides for Commission to put forward scientific criteria<sup>13</sup> for endocrine disrupting pesticides and propose measures concerning these scientific criteria to the Standing Committee. This means that science-based criteria need to be developed and not a decision based on cost-benefit analysis. Cost-benefit has no place in current legislation. Our view is that for all options 1- 4 and A – C provided in the roadmap, the health impact should be considered as the leading element of assessment, and the best option should be selected based on the optimal chance to prevent harm to people and the environment and implement art.4 of the Regulation.

#### **4. The total impact should be considered, including all hidden or external impacts.**

We feel the Commission should take its natural impartial role and make sure that all impacts of the use of pesticides will be considered, especially the impacts on those interested parties who's voice is not heard very loudly in Brussels arena: the public and the environment. The impact of health damage to people by residues of pesticides in food, including the daily mix of pesticides consumed, the impact of air pollution of pesticides for residents, the impact of the contamination of rivers and lakes, of ground- and drinking water by pesticides, the impact on biodiversity, the impact on birds, bees, mammals, the extinction of natural plants in agricultural areas, the damage to soil biodiversity by narrow crop rotations, the depletion of soil organic matter by industrial-type agriculture, the reduction of soil fertility and the gradual environmental degradation. All these elements need to be included to get a real picture.

Our view is that for the impact assessment on endocrines -at least- the following topics need to be assessed:

- damage to health, employees, bystanders, consumers through food (especially the daily mix of pesticides), air pollution for residents, the cumulative effects with other chemicals and the prolonged -lifelong/chronic- exposure.
- loss of eco-services (soil biodiversity due to monocultures, beneficial organisms, nesting for birds and other organisms, feed for bees, birds, etc.)
- damage to environment & biodiversity (decrease of bird populations, bees, mammals, aquatic organisms, plants, ecosystems, etc.)
- greenhouse gas pollution (high use of nitrogen promotes the loss of organic matter and the use of machinery in intensive agriculture releases carbon dioxide into the atmosphere)
- loss of soil fertility & organic matter by industrial farming methods.
- Contamination of lakes and rivers, the impact on ecosystems as well as on pristine environments in proximity to agricultural lands
- Health costs of diseases developed due to pesticide exposure
- Costs of producing stronger pesticides due to the gradual resistance of pests and the costs of disposal of the non-effective pesticides
- Environmental contamination from pesticides' manufacture itself, toxic effluents in rivers, greenhouse emissions and toxic solid waste.

#### **5. The correct baseline should be chosen for assessing the impact in the food chain.**

From January 2014 on EU farmers have to do their crop protection according to the principles of Integrated Pest management (IPM) as defined by Directive 2009/128<sup>14</sup> in Annex III<sup>15</sup>. This means any impact

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<sup>13</sup> Regulation 1107/2009, Annex II, 3.6.5: By 14 December 2013, the Commission shall present to the Standing Committee on the Food Chain and Animal Health a draft of the measures concerning specific scientific criteria for the determination of endocrine disrupting properties to be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 79(4).

<sup>14</sup> DIRECTIVE 2009/128/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 21 October 2009, establishing a framework for Community action to achieve the sustainable use of pesticides

<sup>15</sup> **General principles of integrated pest management**

1. The prevention and/or suppression of harmful organisms should be achieved or supported among other options especially by:  
— crop rotation,

assessment for the future implementation of criteria for endocrine disruption should consider these IPM principles as the baseline. This is the legal baseline in Europe since January 2014 and it would be unjustified to use current dominant industrial-type agriculture with a crop-protection regime almost entirely based on the use of synthetic pesticides as the baseline. Synthetics are only allowed as a 'last resort' in IPM and not as the basis. We've seen already position papers of pesticide companies (BASF<sup>16</sup>, ECPA<sup>17</sup>) and of UK<sup>18</sup> making economic assessments with the wrong baseline as if Directive 2009/128 doesn't exist.

UK<sup>19</sup> and pesticide industry have been greatly exaggerating the impact of pesticide policy in the past and estimated that 15% of all pesticides would be banned or restricted as a result of Regulation 1107/2009 and 20-30% of yield loss is expected in cereals. In reality, almost no pesticide has been banned since 2009 and on the contrary, the number of pesticides approved has increased 100%, from 250 pesticides to the 500 currently used, while there is no sign of yield loss in cereals. This apparently has served the industry's lobby agenda, and the current reports such as the one from ECPA<sup>20</sup>, UK farmers<sup>21</sup> and UK AHDB<sup>22</sup> also neglect the implementation of IPM. The major flaw in their calculation is that the baseline used is wrong. The systems used in industry/UK calculations are not based on IPM at all but on intensive spraying regimes of industrial agriculture. This means these crop protection systems generally do not make use of crop rotation, do not use resistant crop varieties, do not use wide planting distances, do not use a balanced fertilisation, do not use beneficial organisms or biological control. Any natural element is ignored. They use an extreme vulnerable system and by suggesting the need of a synthetic equivalent to the pesticide expected to be banned by the EDC-criteria, they insist to maintain the vulnerable system and to disregard the Directive on IPM. We feel it is unjustified to disregard democratically accepted policy rules and to act in disagreement with legal requirements.

Let's illustrate our point of view on the need of the proper baseline with examples.

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— use of adequate cultivation techniques (e.g. stale seedbed technique, sowing dates and densities, under-sowing, conservation tillage, pruning and direct sowing),

— use, where appropriate, of resistant/tolerant cultivars and standard/certified seed and planting material,

— use of balanced fertilisation, liming and irrigation/drainage practices,

— preventing the spreading of harmful organisms by hygiene measures (e.g. by regular cleansing of machinery and equipment),

— protection and enhancement of important beneficial organisms, e.g. by adequate plant protection measures or the utilisation of ecological infrastructures inside and outside production sites.

2. Harmful organisms must be monitored by adequate methods and tools, where available. Such adequate tools should include observations in the field as well as scientifically sound warning, forecasting and early diagnosis systems, where feasible, as well as the use of advice from professionally qualified advisors.

3. Based on the results of the monitoring the professional user has to decide whether and when to apply plant protection measures. Robust and scientifically sound threshold values are essential components for decision making. For harmful organisms threshold levels defined for the region, specific areas, crops and particular climatic conditions must be taken into account before treatments, where feasible.

4. Sustainable biological, physical and other non-chemical methods must be preferred to chemical methods if they provide satisfactory pest control.

5. The pesticides applied shall be as specific as possible for the target and shall have the least side effects on human health, non-target organisms and the environment.

6. The professional user should keep the use of pesticides and other forms of intervention to levels that are necessary, e.g. by reduced doses, reduced application frequency or partial applications, considering that the level of risk in vegetation is acceptable and they do not increase the risk for development of resistance in populations of harmful organisms.

7. Where the risk of resistance against a plant protection measure is known and where the level of harmful organisms requires repeated application of pesticides to the crops, available anti-resistance strategies should be applied to maintain the effectiveness of the products. This may include the use of multiple pesticides with different modes of action.

8. Based on the records on the use of pesticides and on the monitoring of harmful organisms the professional user should check the success of the applied plant protection measures.

<sup>16</sup>[http://www.agricentre.basf.co.uk/agroportal/uk/en/crops/agronomy\\_update\\_1/basf\\_news/future\\_without\\_triazoles/osr.html](http://www.agricentre.basf.co.uk/agroportal/uk/en/crops/agronomy_update_1/basf_news/future_without_triazoles/osr.html)

<sup>17</sup> ECPA, POTENTIAL IMPACT OF CURRENT DRAFT PROPOSAL FOR ENDOCRINE DISRUPTION CRITERIA, March 2013

<sup>18</sup> UK Fera, Agronomic and economic impact assessment for possible human health and ecotoxicology criteria for endocrine disrupting substances, Report to Chemicals Regulation Directorate, June 2013

<sup>19</sup> UK PSD, Assessment of the impact on crop protection in the UK of the 'cut-off criteria' and substitution provisions in the proposed Regulation of the European Parliament and of the Council concerning the placing of plant protection products in the market, May 2008

<sup>20</sup> [ECPA PP/13/AP/22658 - Rev.1 - Punto Focal](#)

<sup>21</sup> <http://www.nfuonline.com/science-environment/pesticides/commission-endocrine-disruptor-consultation-we-need-you/>

<sup>22</sup> Endocrine disruptors – collation impacts across all sectors to give clear messages on impacts of changing availability on farmers and production Sarah Wynn, ADAS UK Ltd, December 2014

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For instance, on the potential ban of mancozeb in Brassica, an impact assessment should start by collecting all IPM-methods and practices in Brassica to avoid the disease Downy Mildew, and -first of all- by considering if mancozeb is necessary in the IPM-system at all. First of all, for the Downy Mildew problems in Brassica the use of resistant varieties is a solution and a basic requirement in IPM. Next, cultural control measures and biological pesticides need to be considered. This whole set of IPM-measures should be the baseline of any calculation. Using the vulnerable varieties in many current crops as ECPA and UK-institutes promote is not only unjustified but also the CAUSE of current problems. Using vulnerable varieties with a mix of pesticides increases the resistance of the fungi and is a dead-end street. This is the pesticide treadmill, requiring all the time new synthetics, making the problem even worse. IPM-system for combating fungi is the only viable system for a sustainable future. Thereafter, in the IPM-system for Brassica/Downy mildew, it needs to be considered if the IPM-measures are sufficient to ensure a good yield, and if necessary (as a last resort) synthetics could be applied in a low frequency. As it can be seen for Mancozeb/Brassica several synthetics are available and this answers already the question on the impact (zero impact on yield).

A similar exercise as done below should be performed for every substance/crop combination to identify the IPM-baseline before starting an assessment of the impact. Many IPM-measures are available and are not more expensive. Additional IPM-measures, not in wide use yet, should be considered, especially when the costs are (slightly) higher

Pesticide	Plant disease	Claimed costs by industry in case of banning	Synthetic alternatives	Non-chemical alternatives/IPM, resistant varieties, rotation, biological control, etc.
Mancozeb	Downy mildew in Brassica/Grapevine/Lettuce	No yield reduction but other costs assumed by UK Fera	Mandipropamid (Brassica), Copper, Metalaxyl, Cymoxanil (Grapevine)	Resistant varieties (Brassica); Sulphur, Potassium bicarbonate, cropping density (Lettuce), field location (lettuce), many biologicals in development

We propose for the impact assessment to do some case-studies and assess:

1. For the crop of choice, to write down the system of IPM-methods and practices for crop growing according to Directive 2009/128;
2. Indicate which IPM-methods and practices are available without any additional costs for the farmer that should be used in all cases;
3. Indicate which IPM-methods and practices are available with extra costs that could contribute to the crop protection of the pest assessed, partly or fully;
4. Indicate -in a given IPM-system- if an(other) synthetic pesticide is needed (as the last resource, when no IPM-methods and practices are available) and -if so- under what conditions or restrictions
5. Calculate the extra costs (if any) of option 4.

The economy of IPM-based agriculture is difficult to assess in general. The 2002-Agra Ceas study<sup>23</sup> concludes *that it is difficult to draw firm conclusions on profitability from the balance of the evidence, but*

<sup>23</sup> Agra CEAS Consulting, INTEGRATED CROP MANAGEMENT SYSTEMS in the EU, Amended Final Report for European Commission DG Environment, 2002.



*the case study evidence at least suggests that it is possible to achieve similar levels of profitability using ICM Integrated crop Management (similar to IPM) techniques as a result of lower yields and hence revenue being balanced out by reductions in production costs. A more recent study by Jacquet<sup>24</sup> shows that in France the use of pesticide can be reduced by 30% without impact on farm revenues.*

Implementing IPM on farm level will have negligible impacts on crop yield if it is done gradually and innovation is focussed on developing IPM more. If the food chain can be involved, the less polluted product of farmers could be better marketed and lead to a higher profit. Big gains are made for society by the reduced external costs, health and the environment. This also counts for generating a new impulse for innovative companies introducing IPM on a wide scale. A positive result is also a higher quality food in Europe, with a potential competitive trade advantage. The entire operation of banning of endocrine disruptors, combined with IPM, has many positive economic impacts for society as a whole.

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24 Florence Jacquet, Jean-Pierre Butault, Laurence Guichard, An economic analysis of the possibility of reducing pesticides in French field crops, Ecological Economics xxx (2011) xxx–xxx

