**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[[1]](#footnote-1).

**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)[[2]](#footnote-2). Since no adequate testing and guidelines is defined for evaluation endocrine disrupting effects on non-target species, it is difficult to asses the impact at the moment. On top of this, there is an agreement in the Standing Committee on pesticides[[3]](#footnote-3) not to ban a pesticide solely for environmental reasons. In all current cases[[4]](#footnote-4) 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[[5]](#footnote-5) 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.

**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[[6]](#footnote-6).

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[[7]](#footnote-7), 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[[8]](#footnote-8). 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[[9]](#footnote-9). 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[[10]](#footnote-10), 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[[11]](#footnote-11). Despite this, the report shows that the impact is small, only 1% of the currently approved (around 500 in total) pesticides will be affected.

1. Swedish KEMI impact assessment, 2008[[12]](#footnote-12)

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[[13]](#footnote-13), Linuron, 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 had done so, a few additional endocrine disrupting pesticides might have been added to the list, such as Cypermethrin, Deltamethrin and Dimethoate[[14]](#footnote-14).

1. German BfR impact assessment, 2014[[15]](#footnote-15)

The German evaluation is, unlike the CRD/HSE one, not very thorough. BfR analysed classified pesticides (CLP regulation[[16]](#footnote-16)) 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 in 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[[17]](#footnote-17), overruling the endocrine criteria process[[18]](#footnote-18). 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 substancial 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 only for a “handful” of pesticides[[19]](#footnote-19). For this reason BfR in 2011 joined forces with the UK to include potency in the criteria[[20]](#footnote-20), 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[[21]](#footnote-21), 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 |  | +  |  |  |
|  |  |  |  |  |

1. 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[[22]](#footnote-22), 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.**

1. UK FERA report, 2013[[23]](#footnote-23)

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.

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[[24]](#footnote-24). 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[[25]](#footnote-25). 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[[26]](#footnote-26), overruling the endocrine criteria process[[27]](#footnote-27).

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 -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[[28]](#footnote-28).

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.

1. UK farmers and pesticide producers (Anderson report[[29]](#footnote-29))

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[[30]](#footnote-30), 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[[31]](#footnote-31)". 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[[32]](#footnote-32).

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.

1. ADAS report, made for pesticide industry umbrella organisation ECPA[[33]](#footnote-33).

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.

Pesticide industry group ECPA commissioned similar studies on azoles in Italy (consultancy Nomisma in 2011[[34]](#footnote-34)). 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.

1. ECPA policy paper on endocrine disrupting pesticides, version March 2013[[35]](#footnote-35).

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[[36]](#footnote-36).

1. The UK agriculture and horticulture development board, ADAS, 2014[[37]](#footnote-37)

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**.

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.

1. PAN Europe IMPACT ASSSESSMENT analysis, document with 4 Annexes, submitted to the public consultation of Commission, January 2015. [↑](#footnote-ref-1)
2. 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. [↑](#footnote-ref-2)
3. <http://ec.europa.eu/food/plant/standing_committees/sc_phytopharmaceuticals/index_en.htm> [↑](#footnote-ref-3)
4. see: [PAN report Resubmission](http://www.pan-europe.info/Resources/Reports/PAN%20Europe%20-%202012%20-%20Twisting%20and%20bending%20the%20rules.pdf) [↑](#footnote-ref-4)
5. 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) [↑](#footnote-ref-5)
6. 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](http://randd.defra.gov.uk/Document.aspx?Document=11345_PS2812finalreportfull.pdf) [↑](#footnote-ref-6)
7. [Commission roadmap endocrine disruption](http://www.google.nl/url?sa=t&rct=j&q=&esrc=s&source=web&cd=1&ved=0CCUQFjAA&url=http%3A%2F%2Fec.europa.eu%2Fsmart-regulation%2Fimpact%2Fplanned_ia%2Fdocs%2F2014_env_009_endocrine_disruptors_en.pdf&ei=vVagVMy7CNLfaoWAgeAF&usg=AFQjCNEDhbiBNs4jmA6Z4JYcCUYvkkfB2g&bvm=bv.82001339,d.d2s&cad=rja) [↑](#footnote-ref-7)
8. SANCO review report on Ioxynil, <http://ec.europa.eu/sanco_pesticides/public/?event=activesubstance.detail> [↑](#footnote-ref-8)
9. SANCO review report on Thiacloprid, <http://ec.europa.eu/sanco_pesticides/public/?event=activesubstance.detail> [↑](#footnote-ref-9)
10. 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**............... [↑](#footnote-ref-10)
11. EFSA opinion on endocrine disruption, March 2013, <http://www.efsa.europa.eu/en/efsajournal/pub/3132.htm> [↑](#footnote-ref-11)
12. Assessment made by Swedish national chemicals institute KEMI, [KEMI 23 incl ED pesticides](http://www.pan-europe.info/Campaigns/pesticides/documents/ed_pesticides/S%20KEMI%20impact%20cut-offs%20additional%202008_1.doc) [↑](#footnote-ref-12)
13. 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).

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., [↑](#footnote-ref-13)
14. See PAN Europe document IMPACT ASSESSMENT ANNEX Ib. [↑](#footnote-ref-14)
15. 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 [↑](#footnote-ref-15)
16. [C&L Inventory database - ECHA](http://echa.europa.eu/web/guest/information-on-chemicals/cl-inventory-database) [↑](#footnote-ref-16)
17. 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. [↑](#footnote-ref-17)
18. 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. [↑](#footnote-ref-18)
19. Arona-meeting, 26/27 June 2012 [↑](#footnote-ref-19)
20. JOINT DE – UK POSITION PAPER, REGULATORY DEFINITION OF AN ENDOCRINE DISRUPTER IN RELATION TO POTENTIAL THREAT TO HUMAN HEALTH, 16 May, 2011 [↑](#footnote-ref-20)
21. 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**............... [↑](#footnote-ref-21)
22. See PAN Europe IMPACT ASSESSMENT ANNEX Ia, submitted to the public consultation, January 2015. [↑](#footnote-ref-22)
23. Agronomic and economic impact assessment for possible human health and ecotoxicology criteria for endocrine disrupting substances

Report to Chemicals Regulation Directorate, FERA, June 2013 [↑](#footnote-ref-23)
24. See PAN Europe IMPACT ASSESSMENT ANNEX Ia and Ib, submitted to the public consultation, January 2015. [↑](#footnote-ref-24)
25. 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. [↑](#footnote-ref-25)
26. 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. [↑](#footnote-ref-26)
27. 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. [↑](#footnote-ref-27)
28. PAN Europe IMPACT ASSESSMENT ANNEX II, alternatives, submitted to the public consultation, January 2015. [↑](#footnote-ref-28)
29. <http://www.nfuonline.com/science-environment/pesticides/commission-endocrine-disruptor-consultation-we-need-you/> [↑](#footnote-ref-29)
30. 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 [↑](#footnote-ref-30)
31. [http://www.farmersguardian.com/arable-farming/growers-urged-to-respond-to-consultation-on-endocrine-disruption/68271.article#http://www.nfuonline.com/andersons-final-report/](http://www.farmersguardian.com/arable-farming/growers-urged-to-respond-to-consultation-on-endocrine-disruption/68271.article%23http%3A/www.nfuonline.com/andersons-final-report/) [↑](#footnote-ref-31)
32. Verena Seufert, Navin Ramankutty & Jonathan A. Foley, Comparing the yields of organic and conventional agriculture, 1 0 M AY 2 0 1 2 | V O L 4 8 5 | N AT U R E | 2 2 9 [↑](#footnote-ref-32)
33. 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 [↑](#footnote-ref-33)
34. <http://www.ecpa.eu/article/agriculture-today/assessment-economic-importance-azoles-european-agriculture-wheat-case-stud> [↑](#footnote-ref-34)
35. [ECPA PP/13/AP/22658 - Rev.1 - Punto Focal](http://www.google.nl/url?sa=t&rct=j&q=&esrc=s&source=web&cd=1&ved=0CCMQFjAA&url=http%3A%2F%2Fwww.puntofocal.gov.ar%2Fdoc%2Fpp13ap-22658r1.pdf&ei=Lv2iVPn6A4LxUJvPgaAL&v6u=https%3A%2F%2Fs-v6exp1-ds.metric.gstatic.com%2Fgen_204%3Fip%3D83.86.103.226%26ts%3D1419967790503023%26auth%3D3brhxwmnsidwosvpxrkppre2xl6rkehy%26rndm%3D0.7379202099118202&v6s=2&v6t=108652&usg=AFQjCNFpm3LvEYv8s-hxnpyAcipI_DCLLA&bvm=bv.82001339,d.d24&cad=rja) [↑](#footnote-ref-35)
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