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[1] 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[2] 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[3] 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

[1] Åke Bergman, Jerrold J. Heindel, Susan Jobling, Karen A. Kidd, R. Thomas Zoeller, State of the Science of Endocrine Disrupting Chemicals 2012, WHO-UNEP.
[2] Environment and human health, Joint EEA-JRC report, EEA Report No 5/2013
[3] Commission roadmap endocrine disruption

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al. (2000)[4] 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[5] 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[6]. 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[7] 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.[8] 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

[4] 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
[5] 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
[6] 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.
[7] Health and Environment Alliance (HEAL). Health Costs in the European Union- How much is related to EDCs, June 2014
[8] 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.

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pass onto the next generations manifesting in diseases and disorders[9]. 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[10]. 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[11], 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'[12]. Law cannot be 'balanced' again since the balancing has already been done in co-decision in 2009.

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[9] 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

[10] EU Commission approves pesticides but has no health monitoring system in place to track health effects on humans and the environment

[11] 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.

[12] Commission roadmap endocrine disruption page 3, under 3).

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Further, Regulation 1107/2009 in Annex II, 3.6.5 provides for Commission to put forward scientific criteria[13] 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[14] in Annex III[15]. This means any impact

[13] 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).

[14] 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

[15] **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,

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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[16], ECPA[17]) and of UK[18] making economic assessments with the wrong baseline as if Directive 2009/128 doesn't exist.

UK[19] 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[20], UK farmers[21] and UK AHDB[22] 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.

— 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.

[16] http://www.agricentre.basf.co.uk/agroportal/uk/en/crops/agronomy_update_1/basf_news/future_without_triazoles/osr.html

[17] ECPA, POTENTIAL IMPACT OF CURRENT DRAFT PROPOSAL FOR ENDOCRINE DISRUPTION CRITERIA, March 2013

[18] 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

[19] 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

[20] ECPA PP/13/AP/22658 - Rev.1 - Punto Focal

[21] http://www.nfuonline.com/science-environment/pesticides/commission-endocrine-disruptor-consultation-we-need-you/

[22] 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 of 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 asses in general. The 2002-Agra Ceas study[23] concludes *that it is difficult to draw firm conclusions on profitability from the balance of the evidence, but*

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

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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[24] 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.

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

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