



PAN Europe Conference
Our Disrupted Food, EDCs in pesticides residues.
30th of September 2013, European Parliament, Brussels.



Hosted by MEP Arsenis

Children and unborn should not be exposed to pesticide residues in everyday food which could damage their hormonal system. To identify the harmful residues all pesticides need to be tested for their endocrine activity.

The “horizontal” EU criteria for endocrine disrupting chemicals (EDCs), that should have been ready by the end of 2013, have been delayed as an additional step to the process has been imposed. In fact, during the summer, the Secretary General demanded an Impact Assessment. Since the requirement concerning the deadline of December 2013 was mainly for Pesticides and Biocides; the Impact Assessment will be most probably done on these two products groups as a priority.

Despite the delay, the criteria will still be subsequently adapted for the different vertical topics, such as pesticides. This second part will be decided upon by the Standing Committees of national representatives in closed-door meetings and result in implementation rules. During this conference PAN-Europe wanted to debate the relevance of the possible criteria for pesticides for the implementation rules in the SANCO Standing Committee as well as discuss the next necessary steps, such as testing of pesticides for EDC activity. The current data requirements are not developed for EDCs and the question is what should be done to implement rules on testing. The background is the legal text on EDCs, saying a ban is necessary for “pesticides with endocrine disrupting properties that may cause adverse effects” (Regulation 1107/2009).

Therefore we developed three main topics. A scientist worked on each of them, proposing an answer during the conference.

- ***In the light of the Pesticides Legislation, how effective are the current EDC criteria?*** Can the possible elements of the criteria - human relevance, secondary effects, specificity, potency- be misused in final decision-taking, given the tradition of using these elements in the classical risk assessment of pesticides.
Prof. Vyvyan Howard, Nano Systems Biology, Centre for Molecular Bioscience, University of Ulster, Ireland
- ***Current Data Requirement for Pesticides to identify Endocrines Disrupting Chemicals.*** Are they adequate to identify/capture endocrine disrupting chemicals in pesticides?
Dr. Fiorella Belpoggi, Director and Chief of Pathology of the Cesare Maltoni Cancer Research Centre of the Ramazzini Institute, Italy.
- ***Which tests are needed to effectively identify pesticides with endocrine disrupting properties?*** Start with a screening programme? What next?
Prof. Barbara Demeneix, Director CNRS Unit “Evolution of Endocrine Regulations”; Head of Department “Regulation Development and Molecular Diversity, Natural History Museum, Paris. France.

In the light of the Pesticides Legislation, how effective are the current EDC criteria?

Prof Howard started reminding about the regulation:

- “...pesticides with endocrine disrupting properties that may cause adverse effects cannot be approved...”
- Article 4 of the Regulation obliges DG SANCO to evaluate pesticides “*in the light of current scientific and technological knowledge*”

Furthermore, Prof. Howard rightly stressed that the most worrying effects of endocrine disrupting chemicals are those which happened during pregnancy and fetal development. EDC effects on the unborn cannot be reversed afterwards. Moreover they have been observed during animal tests at very low doses, sometimes 1000x lower than the regulatory standards (Bisphenol A and breast cancer scientific studies).

The main problem of the current regulatory approach is that they focus on the adult -ignoring therefore effects on the unborn- and focus on one chemical at a time -ignoring the cocktail of chemicals everyone is exposed to through everyday consumption of several products, food and many others-. Additionally the pesticide testing protocol - data requirements-, does not include effective tests to highlight low dose endocrine disruption. Therefore, with the current data requirements, the dossiers given to regulators will not show accurately most of the endocrine disrupting effects. Prof Howard stated that given all these uncertainties and likely serious effects, the precautionary principle should be used, as the pesticide Regulation provides for. Therefore any undermining of the pesticide Regulation by old protocols and unjustified criteria should be prevented.

Prof. Howard concluded underlining that “the mandatory tests published in the revised data requirements of DG SANCO do not contain any tests for endocrine disruption.” Prof. Howard urged the EU regulators “to require all 400 pesticides currently on the market to be subjected to endocrine disruption testing, based on current scientific knowledge.” Finally, Prof. Howard reminded, that DG SANCO, responsible for the regulation, should return to the original text of the Regulation, allowing them to demand adequate information and therefore protect European citizens’ health.

Current Data Requirement for Pesticides to identify Endocrines Disrupting Chemicals.

Dr. Belpoggi is the director of the **Cesare Maltoni Cancer Research**, part of one of the most experienced cancer research institutes in the world, the Ramazzini Institute (RI). During her presentation, she reported the WHO statement that the internationally agreed and validated test methods capture only a limited range of the known spectrum of endocrine disrupting effects and are inadequate to detect endocrine disrupting effects that are linked to many human diseases. This increases the likelihood of harmful effects in humans and wildlife being overlooked.

Further testing will be needed to identify biologically significant effects including low dose effects, effects from early life-stage exposures, non-monotonic dose response curves, impact of chemical mixtures, or behavioural and cognitive effects that are often missed with traditional toxicity testing. Such testing will likely require both animal testing and use of alternative methods. Sprague Dawley (SD) rat models, which are already in use for carcinogenicity bioassays and for the Endocrine Disruptor Screening Program (EDSP) of the

EPA, seem to be particularly appropriate. In this strain of rats, during carcinogenicity bioassays on suspected EDCs, pilot groups for studying also EDC effects should be planned; this would save animals, time and money and give new important information. For instance, concerning the endocrine disrupting fungicide Mancozeb, the observed increase of thyroid cancer was clearly related to treatment after 2 years, which is about two-thirds of a rat's natural life span, representing the equivalent for humans the age of 60-65. However OECD guidelines do not require testing of pesticides and other chemicals of more than 2 years, when animals are sacrificed, ignoring a very important factor in cancerogenesis: latency-time of the different tumours.

An on-going experiment performed by the RI in collaboration with the USA-Mount Sinai School of Medicine, on SD rats, demonstrated that the endocrine system presents specific highly vulnerable periods in particular prenatal, neonatal, pre-pubertal Windows of Susceptibility (WOS) and therefore exposure during these periods poses higher risks than in adulthood.

To conclude, Dr Belpoggi declared that “some pesticides or their metabolites have demonstrated endocrine disrupting properties and that the studies on EDCs effects cannot be performed with conventional protocols.” She also wanted to underline that nowadays OECD or EFSA guidelines do not establish criteria for studying EDCs and therefore actions are needed. Therefore, the Collegium Ramazzini has just finalized a specific statement on this issue. Finally, Dr. Belpoggi stated that EU regulators should urgently integrate the testing requirements for pesticides and improve the nowadays outdated, conventional tests with some more sensitive ones, which already exist and have proved their efficiency.

Which tests are needed to effectively identify pesticides with endocrine disrupting properties?

Prof Demeneix started by saying that the current testing requirements for pesticides will not detect certain effects on the fetus, notably on the development of the reproductive axis and on thyroid hormone signalling, vital for normal brain development in unborn babies and children. She underlined that we may observe already visible negative health effects in society. For instance, a 30-fold increase in autism has occurred since 1980; also other neurodevelopmental disorders such as Attention Deficit/Hyperactivity Disorders (ADHD) are increasing.

A scientific opinion published by EFSA in 2013 showed that over 103 pesticides out of 287 screened affected the thyroid gland or thyroid hormone signalling. As the thyroid has an important role in the brain development it is possible that some of the autism and ADHD increases are due to endocrine disruptor effects on thyroid signalling and brain development.

Prof Demeneix presented some screening tests for pesticides, which are easy to put in practice, quite quick, and only require a moderate budget allowing rapid screening to identify the most harmful chemicals. Screening costs are a fraction of the health of illness potentially linked to endocrine disruption. For instance, just in the UK, the annual cost of autism has been estimated to be over £25 billion (Knapp et al, 2009).

In addition, since the thyroid is highly conserved in evolution, amphibian embryos are ideal for screening and can predict effects on thyroid signalling in humans. Like fish embryos, amphibian embryos are transparent and can be used for rapid fluorescent-based screening, usually in 3 days time. She underlined that these kinds of in vitro tests give many of the advantages of in vivo ones. Many laboratories in Europe are developing these tests.

In addition to the tests on the thyroid system, tests on fish and amphibian embryos have been developed to screen for chemicals affecting the reproductive system (estrogens/androgens).

Therefore Prof. Demeneix calls on EU regulators to urgently declare as compulsory these screening tests mandatory for pesticide producers application dossiers.

FOR MORE DETAILS, PLEASE REFER TO THE PRESENTATIONS.

Discussion.

The discussion, chaired by MEP Kriton Arsenis, started with three statements of PAN-Europe, **addressed to EU regulators, mainly of course DG SANCO which is responsible for the pesticides regulations.**

Our 3 statements were the following:

- 1. Stop embracing “loophole” criteria for EDCs such as potency and human relevance and return to the text of the Regulation. SANCO should also include strict criteria in the coming impact assessment to calculate the benefits for European Citizens.**
- 2. Revise the current outdated testing protocols for pesticides because they do not identify EDCs and do not show adverse effects for the unborn.**
- 3. Additionally, as a matter of urgency, require industry to conduct EDCs screening tests for all pesticides.**

Since pesticide regulation is under DG SANCO's responsibility, absence of a DG SANCO representative to our conference was deeply regretted, especially as they had given a positive answer to MEP Arsenis' official invitation, saying they were ready to answer to questions during the discussion. Of course PAN Europe acknowledges that some unforeseen circumstance might have prevented the invited Head of Unit to come. Nevertheless we would have very much appreciated if DG SANCO had sent a representative among the several persons working on pesticides in their DG.

We thank DG Envi Policy Officer Peter Korytar for attending and for accepting to answer to several regulatory linked answers during the discussion. Mr Korytar mentioned the commitment of the European Commission to work on EDCs since 1998 with survey, communications, and presentations as well as the work on the criteria of the criteria. For the moment, DG Envi is waiting for the roadmap of the impact assessment, which will be the next policy step.

Besides the discussion on EDC regulation and the need for testing, another parallel one, on the need to employ pesticides to ensure the food production necessary to feed the population of the whole world, was promoted by a remark from the representative of the Permanent Representation of Ireland to the EU. PAN Europe believes it was outside the scope of the discussion and this would need a separate conference as well as a specific report. Nevertheless, we would like to remind here that alternatives to pesticides exist, such as agro-ecological methods supported by Olivier De Schutter UN Special Rapporteur on the right to

food, and would permit to ensure food for everybody; not forgetting that some habit changes, like eating less meat, are also needed.

The main discussion focussed on the use of the precautionary principle in EU regulations, the need to raise awareness among citizens as well as the protocols used for testing, with several questions to our scientists. It is interesting to note that only the representatives from industry questioned the need for additional testing, admitting nevertheless that we need to find a compromise. The speakers answered by saying that if there is no in-utero-exposure, we are not reproducing the real human condition and therefore we do not study the most sensitive period of life. In fact, the regulatory tests cover only the adult period, ignoring prenatal and neonatal windows of susceptibility; only strong toxic acute and chronic effects –cancer- emerge with the present guidelines.

Therefore PAN Europe believes that a long road is still ahead of scientists, EU regulators and NGOs to reach an effective regulation to protect European consumers' health from EDCs. Only a change in the information required from the industries based on appropriate tests will enable this essential goal to be reached. We hope that this conference as well as PAN Europe claims will help the regulators to choose an adequate path to EDC Free Food.