Endocrine Disruptors and Impact on Health

WORKSHOP

EN 2012
Abstract

This report summarises the presentations and discussions at the Workshop on Endocrine Disruptors and Health, held at the European Parliament in Brussels, on Tuesday 18 September 2012. The aim of the workshop was to better understand the impacts of endocrine disruptors on health and to provide input into the ongoing policy discussions at EU-level. The workshop was hosted and chaired by MEP Åsa Westlund (S&D, SE), Rapporteur for the Parliament’s own initiative report on the “Protection of public health from endocrine disruptors”.
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**CONTRIBUTING EXPERTS**
Gustaaf Borchardt, Director "Water, Marine Environment & Chemicals", European Commission, DG Environment
Tapani Piha, Head of Unit SANCO D3 Risk Assessment, European Commission, DG SANCO
Jacqueline McGlade, Director, European Environment Agency
Peter Korytar, Policy Officer "Chemicals in particular Biocides, Endocrine Disruptors and Mixture Toxicity", European Commission, DG Environment
Jim Bridges, Prof. of Toxicology and Environmental Health, Dean for International Strategy at Univ. of Surrey, chairman of SCENIHR
Andreas Kortenkamp, Prof. for Human Toxicology at Institute for the Environment, Brunel University, London
Alberto Mantovani, National Health Institute of Health (ISS), Italy
Peter Smith, Executive Director of the Programme Product Stewardship, CEFIC
Yannick Vicaire, Chemical policy Officer at Réseau Environment Santé (RES)

**SUMMARY PREPARED BY**
Ms Monica Guarinoni
Ms Katalin Császár
Mr Alan Strutt
Milieu Ltd.
Brussels, Belgium

**RESPONSIBLE ADMINISTRATORS**
Dr Marcelo SOSA IUDICISSA
Dr Purificación TEJEDOR DEL REAL
Policy Department Economic and Scientific Policy
European Parliament
B-1047 Brussels
E-mail: Poldep-Economy-Science@europarl.europa.eu

**ABOUT THE EDITOR**
To contact the Policy Department or to subscribe to its monthly newsletter please write to: Poldep-Economy-Science@europarl.europa.eu

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<th>Description</th>
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<tr>
<td><strong>BPA</strong></td>
<td>Bisphenol A</td>
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<td><strong>CMR</strong></td>
<td>Carcinogen Mutagenic Reprotoxic</td>
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<td><strong>DG ENVIRONMENT</strong></td>
<td>Directorate General for Environment</td>
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<td><strong>DG SANCO</strong></td>
<td>Directorate General for Health and Consumers</td>
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<td><strong>EC</strong></td>
<td>European Commission</td>
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<td><strong>ECHA</strong></td>
<td>European Chemicals Agency</td>
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<tr>
<td><strong>ED</strong></td>
<td>Endocrine Disrupting</td>
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<td><strong>EDC</strong></td>
<td>Endocrine Disrupting Chemical</td>
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<td><strong>EEA</strong></td>
<td>European Environment Agency</td>
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<td><strong>EFSA</strong></td>
<td>European Food Safety Authority</td>
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<td><strong>EMA</strong></td>
<td>European Medicines Agency</td>
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<td><strong>ENVI</strong></td>
<td>Committee on Environment, Public Health and Food Safety</td>
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<td><strong>EP</strong></td>
<td>European Parliament</td>
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<tr>
<td><strong>REACH</strong></td>
<td>Registration, Evaluation, Authorisation and Restriction of Chemicals</td>
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<td><strong>OECD</strong></td>
<td>Organization for Economic Co-operation and Development</td>
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<td><strong>PPP</strong></td>
<td>Plant Protection Products</td>
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<tr>
<td><strong>PBT</strong></td>
<td>Persistent Bioaccumulative Toxic</td>
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<tr>
<td><strong>PAH</strong></td>
<td>Polycyclic Aromatic Hydrocarbons</td>
</tr>
<tr>
<td><strong>vPvB</strong></td>
<td>very Persistent very Bioaccumulative</td>
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<tr>
<td><strong>WHO</strong></td>
<td>World Health Organization</td>
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EXECUTIVE SUMMARY

On 18 September 2012, the Committee on Environment, Public Health and Food Safety (ENVI) of the European Parliament organised a workshop on “Endocrine Disruptors and Impact on Health”, which was hosted by MEP Åsa Westlund (S&D, SE), Rapporteur for the Parliament’s own initiative report on “Protection of public health from endocrine disruptors”. The aim of the workshop was to increase understanding and awareness of the health impacts of endocrine disrupting chemicals (EDCs) and to provide input into the on-going policy discussions at EU level.

In her opening statement, Ms Westlund (MEP) pointed out that the issue of EDCs is a crucial subject considering the potential implications for public health, but also a very technical one. Hence, the workshop represented a good opportunity to get a better understanding from experts on the latest scientific information.

The first panel consisted of six speakers who provided presentations on the EU policy framework regarding EDCs, as well as on the latest research on the health impact of EDCs.

Mr Gustaaf Borchardt, Director of "Water, Marine Environment & Chemicals" within the European Commission, DG Environment, began the proceedings by presenting the "Commission Strategy on Endocrine Disruptors". He noted that the Strategy was adopted back in 1999 and highlighted its main achievements, which include the identification of the problems related to EDCs and the fact that EDCs are taken into consideration in EU legislation on chemicals, pesticides and biocides. In view of the revision of the strategy, which is due next year, he acknowledged that gaps in science still exist. However, he pointed out that current evidence is sufficient to justify immediate action.

The need to take political action on the basis of existing evidence on EDCs was further emphasised by Mr Tapani Piha, Head of the Risk Assessment Unit within DG Health and Consumers. He stressed that EDCs constitute a cross-cutting public health issue, which policy-makers need to manage according to the best scientific knowledge and by adopting a holistic approach.

Prof Jacqueline McGlade, Director of the European Environment Agency, presented a recent report (the so-called “Weybridge+15” report) shedding light on the impacts of EDCs on wildlife, people and their environments. The report highlights the increased rates of hormone-related diseases both in humans and in wildlife. Although drawing a link between human endocrine disorders and EDCs remains difficult, Ms McGlade stressed that the precautionary principle must be applied when regulating. The main challenges for legislators are to act responsibly in the absence of conclusive proof, to adequately define EDCs and to create policy that is sensitive to the unique time scales, doses and periods of vulnerability along which these chemicals act.

As indicated by Mr Peter Korytar, Policy Officer in the Unit "Chemicals in particular Biocides, Endocrine Disruptors and Mixture Toxicity" in DG Environment, the European Commission has to develop criteria for the identification of EDCs in pesticides and biocides legislation by 2013. In this respect, it is important to develop horizontal criteria that could be applicable to all relevant legislation.
Some of the challenges in assessing the risks from EDCs were further addressed by Prof Jim BRIDGES, chairman of SCENIHR (DG SANCO Scientific Committee). In particular, he highlighted the need to review current toxicity testing protocols and develop guidelines for good scientific practice, as well as to ensure a regular review of progress and priorities on EDCs.

Finally, Prof Andreas Kortenkamp from the Institute for the Environment at the Brunel University (London) presented a brief summary of the current understanding of the effects of EDCs on human health. He highlighted the increasing trends in developing hormonal cancers, genital malformations in boys, male and female reproductive problems, as well as obesity and type 2 diabetes. Although the causes are not completely known, laboratory studies point to the sensitivity of the endocrine systems especially at critical windows of development in the womb. Prof. Kortenkamp concluded the first part of the workshop by calling for more adequate testing of EDCs in the EU.

The second part of the workshop brought into the debate the view of some stakeholders, namely a national health institute, industry and NGOs.

Prof. Alberto Mantovani from the Italian National Health Institute put forward recommendations on the need to better collect and integrate the existing data on environment, health and food at national and international level, as a way to carry out more efficient analyses.

Mr Peter Smith, Executive Director of the Programme Product Stewardship of the European Chemical Industry Council (CEFIC), introduced the industry’s point of view in the discussion. He mentioned that appropriate scientific evidence is essential for industry to change its practices and highlighted the need for a science-based approach in the identification of the health hazards of chemicals, as well as in risk assessment and risk management.

In the last presentation, Mr Yannick Vicaire from the French NGO Réseau Environment Santé (RES) urged the European Parliament to promote a quick reduction of exposure and ultimate phase out of EDCs, referring to the effects of these chemicals on human health as a real epidemic.

In her concluding remarks, MEP Ms Westlund thanked all the experts for their important input into the upcoming debates on the Parliament’s own initiative report on EDCs, both in the Environment, Public Health and Food Safety Committee and in plenary.
1. LEGAL AND POLICY BACKGROUND

Endocrine disrupting chemicals (EDCs) encompass a variety of chemical classes, including drugs, pesticides and compounds used in the plastics industry and in consumer products, as well as industrial pollutants. These substances are known or suspected to interfere with the endocrine system in animals and in humans, even at low level of exposure. Health effects attributed to EDCs include a range of reproductive problems and certain types of cancer (e.g. breast and prostate cancers). In addition, EDCs may contribute to the development of type II diabetes and obesity as well as to certain neurological conditions and to the disruption of the immune system.

Back in 1996, the European Commission sponsored an international meeting to address the potential impacts of endocrine disruptors on the health of humans and wildlife and to establish an agreed integrated plan for future research and monitoring activities in this field ("The Weybridge Report"). As new evidence was obtained associating adverse health effects with EDCs, the European Commission established a legislative-based strategy for this category of chemicals, known as the 'Community strategy for endocrine disruptors'.

The EDC strategy outlined short, medium and long-term actions to be undertaken in order to address the potential impacts of EDCs on health and the environment. In particular, short-term actions included the establishment of a list of priority substances on the basis of the current scientific data available and with the purpose of further evaluating the role of such substances in endocrine disruption. The medium-term actions of the Commission's strategy focused on the development of practical and experimental activities needed to test the suspected EDCs. The test development process is directed by the Organization for Economic Co-operation and Development (OECD) through a framework that is intended both for new and existing substances, with the Commission channelling input from Member States. The long-term actions concerned the updating, amending or adapting of the related legislative framework. In this respect, numerous initiatives have been taken in the past 13 years as a result of which various pieces of legislation now address chemicals with the potential for endocrine disruption. Of particular relevance is the Commission's Regulation concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (the REACH Regulation). Other legislation on testing, assessment, use and disposal of specific substances such as pesticides, biocides and cosmetics has also been adopted.

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A large number of chemical substances have been placed on the market in Europe for many years without sufficient information on the hazards they may pose on human health and the environment. The REACH Regulation entered into force on 1 June 2007 with the purpose of improving the protection of human health and the environment against hazardous chemicals while enhancing the competitiveness of the EU chemicals industry. In the context of REACH, manufacturers and importers are now required to collect information on the properties of chemicals and to register the information in a central database managed by the European Chemicals Agency (ECHA) in Helsinki. The Regulation also introduces the progressive substitution of the most dangerous chemicals when suitable alternatives exist. An authorisation is required for the use and placing on the market of chemicals of very high concern, including substances which are Carcinogenic, Mutagenic and Reprotoxic (CMR category 1 and 2), Persistent Bioaccumulative Toxic (PBT) and very Persistent very Bioaccumulative (vPvBs), as well as chemicals that are identified from scientific evidence as causing probable serious effects to humans or the environment, such as EDCs. REACH indicates that the Commission shall develop guidance to clarify the criteria for the detection of EDCs in close co-operation with industry, Member States and other relevant stakeholders. By 1 June 2013, the Commission has to review whether or not substances that have endocrine disrupting properties should still be authorised if a suitable safer alternative exists.

Similarly to REACH, the 2009 Regulation on the marketing of Plant Protection Products (the PPP Regulation) defines rules for the authorisation of pesticides to make sure that human health and the environment are adequately protected. In particular, the Regulation establishes that a substance cannot be approved if it is a CMR (1A or 1B), PBT, vBvB or if it is considered to have endocrine disrupting properties. Under the PPP Regulation, the Commission shall present a draft of the measures concerning specific scientific criteria for the determination of ED properties by December 2013.

The recently adopted Biocides Regulation simplifies and streamlines the requirements for approving biocides, by providing for the EU-level authorisation of certain biocidal products and by improving the functioning of national authorisation processes and mutual recognition. The Regulation also indicates specific criteria for the non-approval of biocides, and exclusion criteria include endocrine-disrupting properties that may cause adverse effects in humans. As for the PPP Regulation, scientific criteria for the determination of endocrine-disrupting properties shall be specified by the Commission by December 2013.

Another piece of legislation that looks at the assessment and testing of specific chemicals is the Cosmetic Products Regulation. Amongst others, it stipulates that the Commission shall carry out a review of endocrine-disrupting substances when Community or internationally agreed criteria for identifying the ED properties are available, or at the latest by early 2015.

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Next year will therefore be a key moment for EU policy related to EDCs. The 1999 Commission strategy will be revised with the aim of proposing science-based criteria, which could then be used in all relevant legislation. As mentioned above, in 2013, the Commission is also expected to review the authorisation of endocrine disruptors under the REACH Regulation, as well as to propose criteria for the identification of substances with endocrine disrupting properties under the pesticides and biocides legislation.

The Workshop was therefore very timely against this background and would provide input into the on-going policy discussions. Presentations touched upon the science-based criteria for the identification of EDCs, as well as the wider policy implications for the EU regulatory framework.
2. PROCEEDINGS OF THE WORKSHOP

2.1 Science-Based Criteria for Regulating Endocrine Disrupters (EDCs)

2.1.1 Welcome and opening - MEP Åsa Westlund, Rapporteur for the Parliament’s own initiative report on “Protection of public health from endocrine disruptors”

In her introductory speech, Ms Westlund (MEP) welcomed and thanked the participating experts. The main findings of the workshop will be fed into the development of the European Parliament’s own initiative report on the ‘Protection of public health from endocrine disruptors’, for which Ms Westlund is a Rapporteur and will contribute to the revision of other related files coming up later in 2012.

The report will be presented before the Environment, Public Health and Food Safety (ENVI) Committee within a month and decided upon after Christmas 2012 in plenary. The issue of EDCs is a crucial subject considering their risks for public health, but also a very technical one. Ms Westlund expressed the hope that the workshop could help to better understand the different aspects of EDCs, in particular how EDCs should be defined, discovered and regulated taking into account public health implications but also other considerations such as the economic costs and animal testing. She then gave the floor to the first speaker.

2.1.2 Commission Strategy on EDCs – Mr Gustaaf Borchardt (European Commission)

Mr Gustaaf Borchardt: Director of "Water, Marine Environment & Chemicals", European Commission Directorate General for the Environment (DG ENV)

Mr Borchardt congratulated Ms Westlund for the organisation of the workshop. He said that it came at a very crucial time for the European Commission, which is currently working on the revision of the strategy on EDCs. Mr Borchardt stressed that in a conference organised by the European Commission in June on "Endocrine Disruptors: Current challenges in science and policy",12 Commissioners and Presidency Ministers called for rapid action on this subject since plenty of evidence and science already exist and policy-makers have already waited too long to take action.

Mr Borchardt provided a background on the past EU initiatives on the subject. In particular, he mentioned the Community Strategy on EDCs that the EU launched in 1999 upon an initiative of the European Parliament.13 After thirteen years, it is now time to reflect on the effectiveness of the strategy and the next steps.

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The strategy identified problems, policies and eleven actions on EDCs, which have been assessed through regular progress reports since 1999. The main achievements of the strategy can be seen in the different pieces of legislation which have come into force or have recently been adopted, namely the Regulation on the Evaluation, Authorisation and Restriction of Chemicals (REACH), the Regulation on the placing of Plant Protection Products on the market and the Regulation on Biocides. Eleven test methods have also been developed or modified under the auspices of the Organization for Economic Cooperation and Development (OECD) to detect endocrine disrupting properties. Eighty related research projects are being funded through the Research Framework Programme, and a priority list has been established for further testing. The strategy on EDCs has therefore been a very useful and important tool to make progress. The next phase is to develop criteria for the identification of EDCs in the legislation on plant protection products and biocides by the end of 2013.

In conclusion to his presentation, Mr Borchardt stressed that the June conference created a very good momentum and emphasised that, despite some knowledge gaps, there is already an overwhelming amount of information showing that the tipping point on EDCs has been reached and it is now high time to take action.

2.1.3 Health and Consumers science and regulation perspective – Mr Tapani Piha (European Commission)

Mr Tapani Piha: Head of the Risk Assessment Unit, European Commission DG Health and Consumers (DG SANCO)

Speaking on behalf of the Director General of DG SANCO, Mr Piha started his presentation by underlining that there has been growing scientific knowledge on the health impacts of EDCs on humans and wildlife over the past four years. The European Commission strategy on EDCs, as outlined by the previous speaker, has allowed the EU to accomplish a lot. However, plenty of unknown elements still exist and there is an urgent need to develop criteria and methodologies for the identification of EDCs.

DG SANCO is responsible for several pieces of legislation related to EDCs, in particular for the Regulation on Plant Protection Products and the Directive on Cosmetics. Both need to incorporate criteria for the identification of EDCs. In particular, the PPP Regulation foresees the incorporation of criteria in the approval process by December 2013, whereas a review of the Cosmetics Directive is due when European Union-wide or international criteria become available, or at the latest by 2015. DG SANCO considers EDCs as a cross-cutting public health issue. Hence, EDCs have to be tackled in a holistic manner and by using science-based policy-making. In particular, the EU agencies the European Food Safety Authority (EFSA) and the European Medicines Agency (EMA), as well as the EU scientific committees, have a key role to play in providing solid scientific advice on implementing legislation.

Mr Piha concluded his presentation by highlighting challenges and issues that require additional research. In particular, “as we look deeper and deeper into the subject of EDCs, there are areas that go beyond the traditional thinking on toxicology, such as low-dose exposure and non-monotonic dose-response relationship” said Mr Piha. The challenge will be to understand and integrate these important scientific elements into the regulatory context. Mr Piha finally mentioned that some stakeholders are calling for precautionary measures, whereas others are asking for a more science-based approach. In DG SANCO, science is considered as the best guide to provide the highest possible level of health protection.

Prof. Jacqueline McGlade: Director of the European Environment Agency

In her presentation, Prof. McGlade introduced the main findings of a recent report published by the European Environment Agency (EEA) on “The impacts of endocrine disrupters on wildlife, people and their environments” (the Weybridge+15 report).\textsuperscript{14} Even to a non-specialist eye, the report shows that EDCs have become a very high priority because of their potential health impacts and that there is a collection of chemicals requiring attention.

The report focuses on male and female end-points by looking at the scientific evidence accumulated over the 15 years since the first Weybridge report. The evidence points to increasing rates of hormone-related disease, such as falling semen quality, early onset of puberty, and increased incidence of cancer and metabolic disease. The signal has been coming in from the natural environment for quite some time, with plenty of evidence on endocrine disruption in wildlife (e.g. in many freshwater and marine water fish species) including the catastrophic decline and even local extinction of many mollusc populations.

After a review of the current evidence, Prof. McGlade stressed that humans are exposed to an increasing amount of EDCs from an early age and even in the womb. Exposure routes through the water and food chains are often still unclear. However, a lot of chemicals (e.g. by-products from the paper industry, run-off from steroids in cattle feed and oestrogen from the contraceptive pill) pass through sewage into water and find their way into the water cycle. In this respect, the water, brewing and beverage industry is looking at the operational aspects of removing these chemicals from water and progressing ideas in this area, although the initial cost estimates are alarmingly high.

The report highlights that linking EDCs to human disease remains difficult because of the ‘time lag problem’, i.e. the time it takes for the effects to manifest after exposure at different stages in life. Another issue is that there are critical periods of vulnerability (e.g. in foetal life) that are not the same as for other contaminants. Also, the report points to the lack of reference materials and of a wider range of biomarkers.

Prof. McGlade concluded her presentation by stressing that a precautionary approach is still needed when talking about EDCs. Regulating EDCs remains complex. The core discussion should focus on finding an agreed definition of EDCs, recognising the “cocktail” effect of different chemicals mixed together, investing in more sophisticated testing system, and acknowledging that, unlike with traditional contaminants, low-dose exposure may not have a simple linear response.

2.1.5 Envisaged criteria for endocrine disruptors – Mr Peter Korytar (European Commission)

Mr Peter Korytar: Policy Officer, Unit "Chemicals, Biocides, and Nanomaterials", European Commission Directorate General for the Environment (DG ENV)

In his presentation, Mr Korytar focused on the work of the European Commission related to the development of criteria for the identification of EDCs, as required by the Regulations on PPP and on Biocides.

In particular, Mr Korytar described the conclusions of a report commissioned by the European Commission in 2009 to look at the state of the art in the assessment of EDCs. The aims of the report were: 1) to carry out a review of the evidence collected since 2002 (i.e. year of publication of the WHO global assessment on EDCs); 2) to analyse approaches for the identification of criteria in EU Member States or other countries; and 3) to draw conclusions and provide input for the review of the Commission’s EDC strategy as well for criteria identification.

The report identified the two following critical areas:

- Definition of EDCs, with general acceptance of the definition for endocrine disrupting chemicals developed by the WHO International Programme on Chemical Safety.
- Definition of endocrine system, low-dose effects, non-monotonic dose-response relationship.

The report also proposes four stages in the identification process: identification of mode of action, whether it is relevant, toxicological evaluation and final decision.

After the publication of the report, the Commission organised a conference (as explained by Mr Borchardt) and set up an ad hoc working group on EDCs including members from other Commission services, relevant EU agencies (ECHA, EMA, EEA, EFSA), Member State authorities, industry associations and NGOs. The working group aims to be a platform bringing science and policy together to exchange information, discuss horizontal aspects and provide input for future policy in this area. An expert subgroup was also established to address more technical issues related to risk assessment. Main findings of discussions at the expert subgroup level are fed into the work of the ad hoc group and therefore provide input to frame the European Commission’s policy.

Mr Korytar mentioned that discussions at the first three meetings of the expert subgroup followed the structure of the report and focused on the ED definition (agreeing to use the WHO/ICSD definition as a starting point), the ED system, adversity and mode of action, cause-response relationship and hazard characterisation.
2.1.6 Challenges in assessing the risks from potential endocrine disruptors – Prof. Jim Bridges (UK)

Prof. Jim Bridges: BSc, PhD, DSc, Hon DSc, Professor of Toxicology and Environmental Health and Dean for International Strategy at the University of Surrey, Guilford

Before starting his presentation, Prof. Bridges mentioned that the SCENHIR Committee has not addressed EDCs yet. Therefore, he would present personal views informed by his recent work as well as by discussions in a recent conference in Berlin on EDCs and low doses.¹⁸

First of all, Prof. Bridges noted that many hormones regulate body functions. However, most of the work done so far has focused on just three hormones. The hormonal system is not only influenced by chemical exposure but also by numerous external stimuli. Levels of hormones fluctuate over time and the extent of these changes is normally regulated by the body through homeostatic (control) mechanisms. Adverse effects may occur if exposure to an external stimulus is very strong and the duration prolonged. If the body is unable to remedy the adverse effects, then illness can arise. Therefore, we have to distinguish between normal effects, adverse effects and adverse effects that are detrimental to human health.

Prof. Bridges then highlighted three possible impacts in test systems on hormone effects due to a chemical: no identified impact (which could also be due to the fact that current testing procedures might not be refined enough to detect some impacts), changes with no adverse consequences and relevant adverse effects for which it is important to identify the exposure range. In particular, if changes in the hormonal levels are prolonged and exceed normal limits, adverse effects may occur. Interpretation of an adverse effect implies knowing if the hormonal effect found in test systems is relevant for human health; and if so, whether it is likely to occur at the levels to which humans may be exposed. If both conditions are met, the risks to human health need to be assessed.

Summarising very succinctly the current evidence on EDCs, Prof. Bridges noted that, while using cell preparations, many chemicals have been shown to change hormone levels. However, laboratory studies on animals exposed to chemicals identified as EDCs typically do not show an increased incidence of chronic adverse effects that can be attributed reliably to hormonal changes. Therefore, the primary causes of increased occurrence of hormone-related diseases are uncertain.

The question of whether EDCs are causing an increase in the development of some human diseases remains very challenging for epidemiology. On the one hand, humans are exposed to thousands of chemicals. On the other hand, there are a number of causative and exacerbating factors for hormone-related diseases and it is difficult to single-out the role of EDCs in disease causation.

Prof. Bridges put forward some recommendations on priorities for progress, namely to find a common understanding on the definition of EDCs; to establish and maintain a properly validated database on EDCs that is widely accessible; to review current toxicity testing protocols to identify whether some adaptations would be useful in identifying and characterising those EDCs that are most likely to impact adversely on human health; to develop guidelines for good scientific practice (data generation and data reporting); and to ensure a regular review of progress and priorities on EDCs.

To conclude, Prof. Bridges left the audience with the following open question: “Do we need, in the EU, a transparent framework to aid decision making on particular risks (such as exposure to EDCs) in the context of other risks to human health (and to the environment) from chemicals and other stressors?”.

2.1.7 Endocrine disruption and human health – a role for chemical exposure? – Prof. Andreas Kortenkamp (UK)

Prof. Kortenkamp: Professor for human toxicology at the Institute for the Environment, Brunel University

In his presentation, Prof. Kortenkamp provided an overview of the current understanding of the linkages between EDCs and human health. He started off by showing a heat map of testicular cancer in Scandinavia from the early 1970s to 2003. The evolution of the disease demonstrates a massive increase in the development of testicular cancer over a relatively short time span. Similar trends can be observed with other hormone-related illnesses with levels of incidence increasing in all countries, particularly for hormonal cancers, genital malformations, male and female reproduction, as well as obesity and type-2 diabetes.

Although the causes for these trends are still widely unknown, it is clear that such a rapid increase in the endocrine disease burden cannot be due to genetic causes. On the contrary, when looking at people moving to different countries, environmental factors, including chemical exposure, prevail in the causation of illnesses. Laboratory studies carried out during the past twenty years with animals have shown the exquisite sensitivity of the endocrine system. For example, a genetic male would be demascunilised if the sex hormone does not kick-in in a specific window of foetal life. This means that some chemicals may interfere with the ‘programming’ function of hormones already in the womb. This also means that there are critical windows of exposure in foetal life with effects that become manifest only later in life, when the damage is done and irreversible. However, because the damage becomes apparent only at a later stage, it remains very difficult to link the effects back to the time of exposure.

Regarding the evidence linking EDCs with hormone-related disorders, Prof. Kortenkamp explained that human studies exist showing associations with the oestrogen DES (1 study), PBDEs (3 studies), trans-chlordane, other Persistent Organic Pollutants (POPs) (4 studies), phthalates (4 studies), paracetamol and other analgesics (4 studies). Other studies express uncertainties about the role of other POPs, whereas there are huge knowledge gaps about widely used chemicals, such as phthalates and other phenolic compounds. However, what comes through with all studies is that many chemicals in current use have not yet been studied for their effects on the endocrine system and the effects of combined exposure are very difficult to capture in epidemiological studies. Prof. Kortenkamp said that a quote from Linda Birnbaum, Director of the U.S. National Institute for Environmental Health Studies (NIEHS), very well encapsulates the current challenges for epidemiology: “Are we assessing the effects of the wrong chemicals at the wrong time, in the wrong tissues, ignoring mixture effects?”

Experimental studies have shown that 8% of all chemicals, i.e. 2000 chemicals in current commercial use, interfere with male sex hormones. However, huge problems exist with testing procedures to detect endocrine disrupting properties. Current testing requirements in the EU do not include testing for ED effects. The OECD conceptual framework provides some guidance, but in most cases scientific tools have not yet been translated into useful pathways. Prof. Kortenkamp argued that an agreement on the definition for EDCs exists. However, problems remain on the methods that could be used to identify such chemicals.
Against the background of all these uncertainties, Prof. Kortenkamp stressed that the Member States’ current proposals on this subject are not sufficiently protective and are not addressing the issue on the basis of the latest evidence. Commercial implications are considered, but knowledge gaps are disregarded. He concluded by warning that, if these proposals were adopted, many EDCs would remain unregulated, undermining the objectives of the EU legislation including those of REACH.

2.1.8 First Rounds of Questions and Answers

After the first part of the workshops, Ms Westlund opened the floor for questions.

The first question was asked by a representative of the chemical company BASF to Prof. Kortenkamp on whether evidence exists that hormones can change DNA-level and hence cause cancer. Prof. Kortenkamp replied that there is very little evidence in this respect. However, he explained that this is not the mechanism which drives the effects of EDCs. Chemicals interfering with the programming phase in foetal life are what may cause problems later in life. The BASF representative then called for more cautious assumptions when linking EDCs with cancer.

The second question was posed by Mr PORI who asked Prof. Kortenkamp whether the technologies on sequencing and other available tools are sufficient to discover early disruption of the hormone system or if new tools have to be developed. In Prof. Kortenkamp’s view, many tools are already available to identify EDCs, e.g. the OECD instruments. However, the existing tools capture only a small part of what is happening with the endocrine system, which is very complex. Of the about 50 hormones we are aware of, only three hormones are currently tested. This shows that there is a need to develop new tools and refine current ones. Prof. BRIDGES added that quite a few tools have already been developed. However, he highlighted a need for continuous monitoring of these tools in the future.

The third question posed by MEP Linda McAvan (S&D, UK) concerned whether there is a consensus in the scientific community on EDCs as a health problem, as well as on the need to protect foetuses. She argued that increased rates of hormone-related diseases may also be due to improved diagnostic tools. Prof. Kortenkamp explained that there is consensus on the fact that hormone-related disease trends are real and give rise to concerns. The debate in the scientific community is rather on what might be causing these trends. For a summary of the scientific consensus, he pointed to the Weybridge+15 report of the EEA and the European Commission report on the state of the art mentioned during the workshop. He added that an upcoming UNEP/WHO report will also provide a good summary of the scientific evidence and where the consensus is. Prof. BRIDGES highlighted the large knowledge gaps particularly on mixture effects of chemicals, which makes risk assessment of EDCs more difficult. He called for potency ranking and also pointed out the potential ED properties of some natural substances (e.g. soya bean proteins).

A representative from the NGO Health and Environment Alliance asked Prof. McGlade to further explain her statement that we need to act on additional exposure. Prof. McGlade explained that multiple exposure in the food chain has not even been taken into account yet. For example, even natural substances that are coming into the market and are apparently harmless could increase the concentration of EDCs in the food chain. Therefore, there is a potentially enormous agenda on human health considering this additional exposure.
MEP Krista Klass and Ms McAvan came back to the issue of water pollution and asked Prof. McGlade whether EDCs can be, in principle, removed from water. Prof. McGlade explained that the concerns on concentration of EDCs in water came initially from the brewing industry, which is currently working with the water industry to increase dilution so that the concentration of chemicals is reduced. The analysis of contamination levels, as well as of the level of investment needed by industry is very much linked also to other related EP debates. Hence, Prof. McGlade promised to provide updated evidence and figures on the subject.

Ms Klass also asked Prof. Kortenkamp to explain what his definition of endocrine disruptor is. Prof. Kortenkamp explained that the methods to identify EDCs exist and are not controversial. An ED is a substance that blocks the androgen receptor thus interfering with the programming effect of the hormones, especially in foetal life. In this respect, he concluded by calling for more protective measures for women of reproductive age.

A representative from the NGO Women in Europe for a Common Future wondered why a lot more is known on the health effects of EDCs on male rather than on female reproduction. She also expressed concerns that women of reproductive age are not adequately protected. Prof. Kortenkamp explained that the female reproductive system is much more complex than the male one and therefore less knowledge is available. He emphasised that more than 140,000 chemicals have been registered with the European Chemicals Agency (ECHA) under REACH. This number was rather unexpected and might well mean that the number of substances with endocrine disrupting effects is also larger than originally thought. Prof. Kortenkamp added that hazard-based cut-off criteria have been introduced in the Regulation on PPP. Preparing the hazard profile to identify these chemicals without risk assessment will now be an important but challenging task for scientists. However, this does not mean that all pesticides will be banned as a result of the Regulation. Finally, he mentioned that science has already made good progress on the anticipation of mixture effects.

The last question by Ms Westlund on where EDCs can be found in everyday life remained unanswered due to lack of time.
2.2 Exposure to EDCs: Effects on Human Health

2.2.1 Vision from a public health centre – Prof. Alberto Mantovani (IT)

Prof. Alberto Mantovani: Professor, Food and Veterinary Toxicology, Department of Veterinary Public Health and Food Safety, National Health Institute (ISS)

The aim of Prof. Mantovani’s presentation was to provide an example of how a national public health institute in Mediterranean Europe is tackling the issue of endocrine disruption. The Italian National Health Institute focuses on how to use scientific knowledge to improve public health standards (including on food safety), as well as to disseminate and organise information through databases and disease registries. The Institute’s actions undertaken on ED are related to information gathering, preparation of databases, biomonitoring, and tackling knowledge gaps.

In the late 1990s, there was a widespread recognition in Italy that a problem of EDCs existed and therefore coordination efforts were needed. An open call for projects by the Italian Health Ministry included for the first time a mention of EDCs. Thanks to this call, the Institute was able to start a pilot project, which produced a website and a database targeted at scientists and stakeholders working in health, environment and food safety to stimulate action and networking on EDCs. The database is rather unique in that it includes interactions between EDCs and natural diet components. A broader database on Italian research on the subject is also included in the project.

In 2008, the Institute identified a gap in biomonitoring on EDCs, which led to a specific pilot project (the PREVIENI project)\(^\text{19}\) funded by the Environment Ministry and carried out in collaboration with WWF. The project integrated analytical chemistry (exposure), toxicology (biomarkers of effective dose) and human medicine in environmental biota and humans. The focus was on those EDCs still not included in official controls, such as bisphenol A (BPA). The project concluded that possible concerns exist on these substances and that human exposure is higher in large metropolitan areas.

Prof. Mantovani concluded his presentation by highlighting that research on EDCs could support the updating of toxicological risk assessment. Also, he recommended a better integration of health, environment and food data, as well as greater support for public awareness and risk communication.

\(^{19}\) PREVIENI project website: [http://www.iss.it/prvn/?lang=2](http://www.iss.it/prvn/?lang=2)
2.2.2 Example of industry best practice in reduction/substitution of the usage of EDCs – Mr Peter Smith (CEFIC)

Mr Peter Smith: Executive Director of the Programme Product Stewardship of the European Chemical Industry Council (CEFIC)

Mr Smith introduced his presentation by explaining that the European Chemical Industry Council (CEFIC) is the biggest representative of the chemical industry with 29,000 companies in Europe, 1.2 million people involved and 100 researchers including some that focus on endocrine disruption. When addressing endocrine disruptors, Mr Smith advocated for a three-stage process: the first dealing with hazard understanding, the second with risk assessment and the third with risk management.

Regarding hazard understanding, the WHO definition points to the adverse effects that a substance can cause on the endocrine system. In Mr Smith’s view, it is essential to look at the criteria that establish such adverse effects and to define how much evidence is needed to confirm that a substance complies with the ED definition. Also, industry looks to expert agencies such as EFSA and ECHA to provide independent assessments of specific substances (or mixtures) and establish if the ED definition applies or not.

The second step is risk assessment. It provides an evaluation of the likelihood that the potential harm will actually occur by introducing exposure to the substance into the equation. Therefore, risk assessment goes beyond identifying a hazard. If a substance is harmful but isolated or controlled, it should not pose problem.

Risk management is actually the final step in the process and details what measures need to be taken to safely manage a hazardous substance so that it does not present harm to either humans or the environment. Such measures can take various forms: protective clothing, rigorous containment, thresholds with sufficient safety margin to ensure that the actual exposure level is well below the level at which no adverse effect is seen, and reduction/substitution of a substance. Regulatory controls also contribute to the final risk management measures. In particular, for ED, existing legislation (e.g. REACH) maintains a proportionate regulatory response to the risk.

When talking about best practices for reduction and substitution, Mr Smith pointed out that reduction/substitution tends to feature when improving product performance (innovation) and, in this context, it follows a period of research/discovery for improved substances. Occasionally, reduction/substitution can be driven by safety concerns if it has been established that there is an adverse effect and that no other risk management measures are appropriate. In other words, reduction/substitution is based on new knowledge and appropriate scientific evidence.

In his concluding remarks, Mr Smith highlighted the need for a science-based approach to determine substances of regulatory concern. He also called for the establishment of clear criteria for each stage in the evaluation of ED, as well as for the development and validation of robust test methods. Finally, he mentioned the need for continued collaboration with all stakeholders to establish a common understanding of ED, their impact on human health and environmental safety leading to the use of appropriate risk management measures.
2.2.3 French NGO with successful results of awareness campaign – Mr Yannick Vicaire (FR)

Mr Yannick Vicaire: Chemicals Policy Officer, Réseau Environnement Santé (RES)

In his presentation, Mr Vicaire highlighted the lessons learnt from his French NGO, which has been successfully campaigning on EDCs at the national and European level over the past few years. Réseau Environnement Santé (RES) was created in 2009 to follow-up on national implementation of the REACH Regulation, as well as the WHO Health and Environment Plan. It brings together environmental groups, health professionals, patients’ associations and scientists to focus on the state of scientific evidence on environment and health and promote policy change.

EDCs are one of the main activity areas of the association. For long a concern of RES members, Mr Vicaire stressed that enough evidence now exists to prove that EDCs are causing real epidemics that our society needs to stop. In particular, he referred to damage to reproductive health, hormonal cancers, metabolic diseases and neurodevelopmental disorders as the main health effects of EDCs.

By disseminating scientific information, the NGO managed to raise awareness of the public and politicians, and to obtain a unanimous ban on BPA baby bottles, as well as linings and food containers. Convincing the French agencies to adopt a new paradigm took longer considering that EDCs brought about a revolution in toxicology. Mr Vicaire highlighted that the French government also drew lessons from past health scandals, such as the delayed ban on asbestos that caused a high disease toll. Also, he stressed that the media and the public in France are increasingly aware of the health impacts of endocrine disruption, with health insurers also getting mobilised.

In his final remarks, Mr Vicaire underlined that Member State initiatives can help generate EU-wide action and spearhead a paradigm shift, as well as speed up the process in the adoption of more protective policies. The European Parliament has a very important role to play and the own-initiative report on EDCs is an opportunity to inform the upcoming action of the European Commission. In particular, Mr Vicaire called for a clear, hazard-based definition of EDCs allowing preventive and precautionary action. He also stressed that EDCs should get equal treatment to PBT/vPvB (substitution) under REACH and that these substances should be taken out of the market even before the deadline. Finally, he mentioned that new evidence on mixtures and low-dose exposure requires a precautionary strategy.

Mr Vicaire concluded by saying that the implications of endocrine disruption are wide. Immediate policy action is needed because the health of this and future generations is at stake.
2.2.4 Second Round of Questions and Answers

Before opening the floor for the second round of questions and answers, Ms Westlund tried to summarise her understanding of where EDCs can be found. She mentioned that EDCs exist almost everywhere (on the floor, in cosmetic and electronic products, in dust etc.), and most people are not aware of all the uses of these chemicals in our society.

Ms Corinne LePage (MEP) from the Group of the Alliance of Liberals and Democrats for Europe (ALDE) then took the floor as the shadow rapporteur on the Parliament's own initiative report on EDCs. Ms LePage's first question was addressed to Prof. Kortenkamp and concerned the protection of vulnerable populations, in particular the concrete actions that can already be put in place to protect this group while waiting for better scientific knowledge and criteria definition on EDCs. The second question was addressed to Mr Smith focusing on how thresholds should be determined for cocktail effects and in the context of low-dose exposure.

In his answer, Prof. Kortenkamp pointed to a recent brochure prepared by the Danish Government to inform women of reproductive age on what they can do through individual avoidance action, i.e. what chemical substances they can avoid. Prof. Kortenkamp highlighted that this type of initiative is a step in the right direction. However, through individual action there is only a limited amount of chemicals that can be avoided. He explained that everyone is exposed to chemicals through the air they breathe, the food they eat, etc. in a way that not much can be controlled individually. Political action is therefore necessary. Better information campaigns as well as improved labelling legislation are important to inform the public. However, according to Prof. Kortenkamp improved chemicals regulation is the most effective way to address the issue. In addition, he mentioned that the EU policy on phthalates, including a ban of certain phthalates in toys and other children’s products is a step forward. Nevertheless, evidence shows that a lot of the damage is already done in the womb; hence pregnant women should be protected at least at the same level as children. To conclude, Prof. Kortenkamp highlighted that more global and thought-through policy actions are needed.

Mr Smith addressed the question on the mixture effects by explaining that industry is looking, first and foremost, for a sound understanding of ED materials and criteria to manage them. He highlighted that industry has started to investigate the issue of mixture through a research programme, but right now this is a step beyond what they can reasonably tackle. The concept of threshold goes back to the discussion on low-dose exposure. Mr Smith re-emphasised that risk management is about establishing safety thresholds below which there are no adverse effects. The importance of thresholds is to understand if exposure to certain materials has an adverse effect or not, on a case by case basis.

Disappointment for Mr Smith’s presentation was expressed by Mr Vicaire. The NGO representative stressed that he was expecting more on best practices from industry on substitution/reduction. For example, on cosmetics, some companies (L’Oreal, Yves Rocher) have taken some hazardous substances out of their cosmetic products. Examples of early substitution from early warnings exist and should be highlighted. Mr Smith explained that the reason for not providing more details on substitution is that he viewed such practice as only one of the possible risk management tools, and not necessarily the most appropriate. He mentioned that only once in his career he could see new data on the dose-effect relationship of a chemical justifying substitution. Prof McGlade took the floor later on to underline that most of the products actually end up in the environment. Hence, looking for substitution should be a priority for producers.
In response to the chair’s question on where EDCs can be found, Dr. Mantovani highlighted that although we do not know enough about these chemicals, surely we know more than what we think we know. He stressed that there is a general weakness in exploiting and integrating the data (including on emerging contaminants) that are collected in national and international programmes and through research projects.

A representative from Chemical Watch addressed a further question to Mr Smith on what level of science industry accepts to adopt a science-based approach. She mentioned that experts were currently discussing EDCs in Nairobi, at the meeting of the Strategic Approach to International Chemicals Management (SAICM), and she was wondering whether SAICM is a process that industry supports. Mr Smith addressed this question by saying that the presence of industry at the workshop showed that the sector is indeed interested in the science and new evidence on EDCs.

The spokesperson of the BPA coalition representing Europe-based manufacturers and users of bisphenol A, took the floor to mention that a lot of documentation on BPA and its uses can be found on the coalition’s website. A comment was also made from a representative of a large chemical company to point out that a review of epidemiological studies on EDCs shows that the quality of these studies is generally very poor. The Commission was therefore urged to look at the quality of research before taking decisions.

2.2.5 Conclusions: MEP Åsa Westlund

In her concluding remarks, Ms Westlund thanked all the experts for their important input into the upcoming debates on the Parliament’s own initiative report on “Protection of public health from endocrine disruptors”, both in the ENVI Committee and in plenary.

20 BPA Coalition website: www.bpacoalition.org.
ANNEX 1: PROGRAMME

WORKSHOP
Endocrine Disruptors and Impact on Health

Tuesday, 18 September 2012 from 12:30 to 15:00
European Parliament, Room Altiero Spinelli A5E-2, Brussels

Organised by the Policy Department A-Economy & Science
for the Committee on the Environment, Public Health and Food Safety (ENVI)

AGENDA

Welcome and opening by Chair Åsa Westlund, MEP, Rapporteur.

Part 1: Science Based Criteria for Regulating Endocrine Disrupters (EDCs)

12.30
Gustaf Borchardt, Director "Water, Marine Environment & Chemicals", European Commission DG Environment,
‘Commission Strategy on Endocrine Disruptors’

12.40
Tapani Piha, Head of Unit SANCO D3 Risk assessment (incl. Health Technologies),
European Commission, DG SANCO

12.50
Jacqueline McGlade, Director, European Environment Agency,

13.00
Peter Korytar, Policy Officer "Chemicals in particular Biocides, Endocrine Disruptors and Mixture Toxicity", European Commission DG Environment,
‘Envisaged criteria for endocrine disruptors’
13.10
Jim Bridges, Univ. of Surrey, chairman of SCENIHR (European Commission Scientific Committee),
‘Challenges in assessing the risks from potential endocrine disruptors’.

13.20
Andreas Kortenkamp, Institute for the Environment, Brunel University, London.
‘Endocrine disruption and human health-a role for chemical exposures?’

13.30
Q&A, Open discussion.

Part 2: Exposure to EDCs: Effects on Human Health

14.00
Alberto Mantovani, National Health Institute of Health (ISS), Italy-
‘Vision from a public health centre’.

14.10
Peter Smith, Executive Director of the Programme Product Stewardship, CEFIC-
‘Example of industry best practice in reduction/substitution of the usage of EDCs’.

14.20
Yannick Vicaire, Réseau Environment Santé (RES)-
‘French NGO with successful results of awareness campaigns’.

14.30
Q&A, Open discussion with Shadow rapporteurs.

14.55
Final remarks Åsa Westlund, Rapporteur.

15.00
End
ANNEX 2: SHORT BIOGRAPHIES OF EXPERTS

Professor Jim Bridges
Professor Bridges spent most of his academic career at the University of Surrey where, at various times he held posts of: founding Director of the Robens Institute of Industrial and Environmental Health and Safety, founding Head of the European Institute of Health and Medical Sciences and Dean of Science.

He has published nearly 400 scientific papers and reviews particularly in the areas of toxicology, environmental and public health risk assessment.

From 1997-2004 he was the chair of the newly established EU Independent Scientific Advisory Committee on Toxicity, Ecotoxicity and the Environment (CSTEE) and from 2004 onwards has served as the chair of the EU Independent Scientific Committee on Emerging and Newly Identified Health Issues (SCENHIR).

Professor Bridges has throughout his career been very active in the development of education programmes in toxicology and environmental health. He also played a leading role in the establishment of both the British Toxicology Society and EUROTOX.

Professor Andreas Kortenkamp
Mr Kortenkamp is professor for human toxicology at the Institute for the Environment, Brunel University. His research interests are in exploring environmental pollutants and their effects on diseases. He is particularly interested in dealing with the effects of multi-component mixtures of chemicals that can disrupt hormone action. Professor Kortenkamp has served on the US National Research Council Panel on cumulative risk assessment for phthalates, and is currently a member of the US Consumer Health Advisory Panel on the assessment of phthalates. He has produced the State of the Art Report on Mixture Toxicology and the State of the Art Report on Endocrine Disrupters for the European Commission, DG Environment. Recently, he has been called on to the World Health Organisation panel for updating the Global Assessment of Endocrine Disrupters. He also serves on a EFSA working group on mixtures of pesticides. He earned his Ph.D. from Bremen University, Germany, and in 2001 started his academic career at the School of Pharmacy, University of London. In July 2011 he joined Brunel University, West London.

Professor Alberto Mantovani
Prof Mantovani was born in Bologna, February 22, 1956. He graduated in Veterinary Medicine (University of Bologna) in 1979 and received his Master of Science in Veterinary Public Health (University of Edinburgh) in 1982. Since 1985 he has been working in the field of toxicology at the Italian National Health Institute (ISS), developing his expertise on reproductive and developmental toxicology and, since 1999, the risk assessment of endocrine disrupters ED. (see the ED area in the ED website http://www.iss.it/inte ISS). He currently leads the unit of Food and Veterinary Toxicology, Dept of Veterinary Public Health and Food Safety (ISS).
Between 2000-2003, he was coordinating the Italian pilot national project on ED funded by the Ministry of Health, and the PREVENT project. Then, between 2008-2011 he was responsible for the coordination of a pilot national action on ED biomonitoring in biota and humans funded by Ministry of Environment (http://www.iss.it/prvn). The Unit led by Prof. Mantovani has also contributed, and is contributing to several EU projects on ED (CASCADE, ReProTect, AQUAMAX, TDS-Exposure).

Since 2011 Prof Mantovani has been a member of the Italian Committee for Food Safety (Ministry of Health). Since 2003 he has also been a member of the Scientific Panel on Additives and Products or Substances Used in Animal Feed (FEEDAP) of the European Food Safety Authority (EFSA), and since 2009 he has been the FEEDAP vice-chair. Since 2003 he has contributed as an expert to other EFSA activities (opinions on organotins, bisphenol A, non-animal testing, thresholds of Toxicological Concern). Finally, since July 2012 he has member of the EFSA PPR Panel, dealing with risk assessment of pesticides.

**Mr Peter Smith**

Mr Peter Smith completed his academic studies at the Universities of London (Imperial College) and Sheffield, graduating with a Ph.D. in Physical Organic Chemistry in 1985.

Upon graduation, Peter began his career in the consumer goods industry working in the Research & Development Department at Procter & Gamble. During his 27 years’ experience at P&G, Peter has worked in a wide range of product categories (ranging from toothpaste to laundry detergents to Cosmetics and, most recently, Pet Food).

He has extensive experience across the different R&D disciplines and has worked in the UK, Italy, and Belgium. He is married and has two school-aged children.

Peter Smith joined CEFIC in January 2012 as Director Executive of Product Stewardship Programme.

**Mr Yannick Vicaire**

Mr Vicaire is an environmentalist, graduated in technical chemistry, environmental and waste management at the engineering school of INSA Lyon.

His work experience includes:

- 2 years in the R&D department of Veolia-Onyx group (industrial waste);
- 8 years in the Toxics campaign of various offices of Greenpeace (France, Czech Republic and Greenpeace International): main dossiers included REACH regulation, WEEE/RoHS Directives, Basel Convention, Cosmetics and Environmental Liability Directives;
- 2 years as a freelance consultant for different NGOs including CCFD (Comité Catholique contre la Faim et pour le Développement), Friends of the Earth Europe and Greenpeace International;
- As of 2010, Chemicals policy officer for Réseau Environnement Santé (RES).

Yannick Vicaire is currently a member of the Executive Committee of HEAL (Health and Environment Alliance) and also sits in the boards of Greenpeace Czech Republic and French organisation CNIID (Centre National d’Information Indépendante sur les Déchets).
ANNEX 3: PRESENTATIONS
Presentation by Gustaaf Borchardt

Community strategy for endocrine disruptors

Workshop on endocrine disruptors and impact on health
18 September 2012, European Parliament

Gustaf Borchardt
European Commission, DG Environment

Community Strategy for Endocrine Disruptors

COMMISSION OF THE EUROPEAN COMMUNITIES

Brussels, 17.12.1999
COM(1999) 706 final

COMMUNICATION FROM THE COMMISSION
TO THE COUNCIL AND THE EUROPEAN PARLIAMENT

Community Strategy for Endocrine Disruptors
a range of substances suspected of interfering with the hormone systems of humans and wildlife
Community Strategy for Endocrine Disruptors

Objectives of the paper were:

- To identify problem of endocrine disruption, its causes and consequences
- To identify appropriate policy action on the basis of the precautionary principle in order to respond quickly and effectively to the problem, thereby alleviating public concern

11 actions identified:

- 7 short-term actions
- 3 medium-term actions
- 1 long-term action

Main achievements

- Endocrine specific provisions in REACH, Plant protection product and Biocidal regulations
- 11 OECD test methods for identification of EDs developed
- Research and development in this field supported by over 120 millions of euro
- Priority list of substances for further testing of their role in endocrine disruption established
Current focus

- Development of horizontal criteria for identification of endocrine disruptors
  - Required by regulations on plant protection products and biocidal products by December 2013
  - Need for horizontal criteria across legislations
- Review and possible revision of the strategy
  - Need to review whether strategy is fit for purpose
- REACH review as regards endocrine disruptors
  - Required to review the way how endocrine disruptors can be authorised

EU conference on endocrine disruptors

Objective:
- To hold dialogue between the stakeholders to provide a basis for deciding on the appropriate response to the challenge of EDs

3 main sessions:
- State of the science on EDs
- Identification of EDs
- Policy objectives for EDs

Participants
- Over 300 participants including policy makers and experts from EU Member States and outside the EU, academic scientists, industry groups, trade organisations and NGO’s.
Thank you for your attention

Prof. Jacqueline McGlade
Executive Director, EEA

Endocrine disruption - a new type of disease

Today’s human systems are being affected by increased rates of hormone disruption related diseases
Epidemiology & disease characteristics

- **♂** end-points - falling semen quality, cryptorchidism, testicular cancer
- **♀** end-points – breast cancer, polycystic ovarian syndrome, endometriosis,
- non-reproductive – thyroid function & cancer, neurodevelopment, adrenal, obesity and metabolic syndrome and pancreatic cancer
- early onset of puberty
- ......

Endocrine disease also affects wildlife

- Many freshwater and marine fish are now found with intersex characteristics
- Declines in biodiversity
- Catastrophic loss of invertebrate species
Exposure to EDCs in water

By-products from the paper industry, run-off from steroids in cattle feed into rivers & lakes
Oestrogen from the contraceptive pill via the sewage systems

Can we link EDCs to human diseases?

Linking EDCs to human illness is difficult because of:
• time lag problem
• critical periods of vulnerability
• lack of biological reference materials and life-term studies
• lack of biomarkers e.g. non-serum thyroid markers

We need to adopt the precautionary principle to avoid additional exposure
How easy will it be to regulate EDCs?

- There is no agreed definition of what constitutes an EDC and how to measure and assess risk
- When mixed together, EDCs can act differently to the sum of their parts
- Unlike traditional contaminants, decreased exposure may, perversely, increase risk. This makes concepts of ‘safe doses’ highly complex
- Natural substitutes will increasingly become part of the mix e.g. algal mycosporine amino acids as sunscreens

Conclusions

- Need to narrow down the definition of EDCs binding to hormone receptors or interacting with receptor signal transduction
- Identify and validate two-tier testing system (screening and positives)
- Adapt current toxicological hazard identification and subsequent risk assessment to specific characteristics of the endocrine system that will work for natural as well as synthetic EDCs
- Abandon the low dose discussion. Analyse endocrine responses based on endocrinological approaches and methodology
Thank you!

Jacqueline McGlade
jacqueline.mcglae@eea.europa.eu

European Environment Agency
Workshop on Endocrine Disruptors and Impact on Health

Presentation by Peter Korytar

Envisaged criteria for endocrine disruptors

Workshop on endocrine disruptors and impact on health
18 September 2012, European Parliament

Peter Korytár
European Commission, DG Environment

Legal requirement

Regulation 1107/2009 on Plant Protection Products

  a draft of the measures concerning specific scientific
  criteria for the determination of endocrine disrupting
  properties .......

Regulation 528/2012 on Biocidal Products

- No later than 13 December 2013, the Commission shall
  adopt .......... scientific criteria for the determination of
  endocrine disrupting properties
Need for ED criteria

*Horizontal criteria applicable to all relevant legislation are needed*

*Criteria needed for both*
- Human health
- Environment

Scientific review

*Contract 'State of the art of the assessment of EDs'*

*Tasks*
- Task 1: Analyse scientific literature and outcomes of EU funded research projects on EDs
- Task 2: Analyse approaches to assess EDs in EU countries and competing economies
- Task 3: Draw conclusions and answer policy relevant questions

*Report highlights critical issues and provides recommendations as regards the criteria*
- Definition of EDs, of endocrine system, of adverse effects, low dose and non-monotonic dose response curves, etc
- Stage 1: consideration of the quality of ED-related effects - adversity and mode of action
- Stage 2: Evaluating human and wildlife relevance
- Stage 3: Toxicological evaluation (potency, specificity, severity)
- Stage 4: Final decision, classification and categorisation
Ad-hoc group on EDs

Composition
- Commission services, EU Agencies, Member States’ Authorities, Industry Associations and NGOs

Purpose
- Information exchange on endocrine disruptors
- Bringing science on endocrine disruptors and chemical’s policy together
- Discussing horizontal aspects of regulation on endocrine disruptors
- Providing orientation to the Commission on development and implementation of EU policy in this field

Expert sub-group on EDs

Composition
- Commission services, EU Agencies, experts with experience in risk assessment from Member States, Industry Associations and NGOs

Purpose
- Exchange of information on detailed technical and scientific issues on endocrine disruptors
- Support the ad-hoc group in technical and scientific issues

Input from
- EFSA’s scientific committee
- SANCO’s non-food scientific committees
Process

Commission ← Ad hoc group ← Expert sub-group ← Scientific Committees

Policy related considerations for the criteria
Technical and scientific elements of the criteria

Expert sub-group on EDs

Meetings
- November 2011, April and June 2012
- Next meeting planned for early November 2012

Examples of discussion topics
- ED definition - WHO/IPCS definition
- Endocrine system - broad range of views
- Adversity and mode of action; casual relation between the two
- Hazard characterisation (specificity, potency, …)
Thanks for your attention
Workshop on Endocrine Disruptors and Impact on Health

Presentation by Jim Bridges

CHALLENGES IN ASSESSING THE RISK FROM POTENTIAL ENDOCRINE DISRUPTORS (ED’s)

Prof Jim Bridges
Chair, Scientific Committee on Emerging and Newly Identified Health Risks and Emeritus Professor of Toxicology and Environmental Health

Hormones and human health

- Many hormones regulate body functions
- Levels of hormones are continually changing in response to numerous external stimuli
- An external stimulus may increase or decrease the levels/activity of an individual hormone
- The extent of these changes is normally limited by homeostatic (control) mechanisms
- Adverse effect may occur if exposure to an external stimulus (e.g., a natural or synthetic chemical) is very potent (strong) and the duration prolonged
- If the body is unable to remedy the adverse effects, ill health can arise.
**Possible impacts in test systems on hormone levels/effects due to a chemical**

i) No impact

ii) Changes occur but no adverse consequences → identify exposure range

   (*physiological*)

iii) Relevant adverse effects → identify exposure range (i.e., potency)

   (*toxic*)

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**Assessing the significance of hormone level changes**

i) Unlikely to be a risk to human health

   The changes in the level of the hormone(s) are short-lived and/or are within the normal limits of fluctuations over time (termed modulation) in humans

ii) Potentially an adverse effect

   The changes are prolonged and outside the normal limits of hormone level fluctuations
**Interpretation of an adverse effect found in test systems**

Is the hormonal effect(s) found relevant for human health?

↓

↓

NO

↓

YES

Is it likely to occur at the levels to which humans may be exposed?

↓

↓

NO

↓

YES

risks to human health needs to be assessed

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**SUMMARY OF CURRENT UNDERSTANDING OF STUDIES ON ED’s**

a) Using cell preparations many chemicals have been shown to change hormone levels and/or their effects. These have been termed ED’s

b) In laboratory studies animals, exposed to chemicals identified as ED’s, typically does not show an increased incidence of chronic adverse effects that can be attributed reliably to hormonal changes

c) There is an increase occurrence of some human diseases that could be mediated by a hormonal mechanism. The primary causes are uncertain.
Are endocrine disruptors causing an increase in some human diseases?

A very challenging question for epidemiology because:

i) For those diseases studied in detail it is evident that there are a number of causative and exacerbating factors.

ii) Humans are exposed to many thousands of chemicals everyday. For those shown to be ED’s it is very difficult to identify at present their contribution to these diseases at current levels of exposure.

Proposed priorities for progress

i) Establish and maintain a properly validated data base on ED’s that is widely accessible.

ii) Review current toxicity testing protocols to identify whether some adaptations would be useful in identifying and characterising those ED’s that are most likely to impact adversely on human health.

iii) Develop guidelines for good scientific practice (data generation and data reporting) to be adopted by individuals requesting research funding

iv) Ensure a regular review of progress and priorities on ED’s
A question

Do we need, in the EU, a transparent framework to aid decision making on particular risks (such as ED’s exposure) in the context of other risks to human health (and to the environment) from chemicals and other stressors?
Endocrine disruption and human health – a role for chemical exposures?

Professor Andreas Kortenkamp
Institute for the Environment
Brunel University London

18 September, European Parliament, Brussels
Endocrine disease burden as high as never before

- **Hormonal cancers** – breast, prostate, testis
- **Genital malformations** in boys (testis non-descent, penile malformations)
- **Male and female reproduction**
- **Obesity** and type 2 diabetes
The causes?

- ...not completely known

- but laboratory studies show the **exquisite sensitivity** of the endocrine systems

The action of...

...the male sex hormone in the womb makes a man!
Critical windows – irreversible effects

Critical window of causation in foetal life

Effect later in life

Time

Tissue level

Male reproductive disorders

- Human health studies: Associations with
  - DES (1 study), PBDEs (3 studies)
  - Trans-chlordane, other POPs (4 studies)
  - Phthalates (4 studies)
  - Paracetamol and other analgesics (4 studies)

- Not sure about:
  - Other POPs (PCBs, DDT/DDE, HCB, HCH)

- Huge knowledge gaps with widely used chemicals
  - Phthalates
  - Other phenolic compounds
Challenges for epidemiology

“Are we assessing the effects of the wrong chemicals at the wrong time, in the wrong tissues, ignoring mixture effects?”

*Linda Birnbaum*

*Director, NIEHS*

Experimental studies

• 8% of all chemicals interfere with male sex hormones

• = 2000 chemicals
Testing for endocrine disruption is inadequate in the EU

Current testing requirements
OECD Conceptual Framework
guidance is not yet drafted or
those included in the Detailed
Review Paper

Other receptors /pathways

Member State proposals are not sufficiently protective

• UK – Germany proposals target only the most potent substances
• Consideration for commercial implications…
• …but disregard for knowledge gaps and uncertainty
• Many known endocrine disrupters will remain unregulated
Thank you
Endocrine Disrupters: the standpoint of a Public Health Institute

Alberto Mantovani
Director of Food and Veterinary Toxicology Unit
Dept. of Food Safety and Veterinary Public Health
Istituto Superiore di Sanità

A public Health Institution: The Instituto Superiore di Sanità (ISS) Italian National Health Institute

The scientific body of the Health Ministry and the Italian National Health System

Aims: science for public health targets
• to facilitate translation of scientific knowledge into public health practice
• to contribute to up-to-date standards in public health activities (e.g. patents, validation of methods and guidelines)

Last, but not least, to build up databases, registries, training/communication activities
Endocrine disrupters (ED) and public health let’s focus on:

Information - Dissemination
Databases
Field research: real-life biomonitoring
Tackling “hot issues”: Innovative methods/guidelines

ED at the ISS: the flow begins

Late ‘90s. Growing interest on health and environmental implications of ED stimulates both research and policy makers attention also in Italy. But a co-ordination effort is needed.

1999: yearly call of the Ministry of Health for research projects, open to national and regional institutions.
ED included as priority topics for the first time.
The ISS wins the call.

2000-3. National pilot project on ED.
Main topics: reproductive development (toxicological studies), biomonitoring (internal exposure; biomarkers of thyroid effects)
**Information and dissemination**

The ED thematic area of the ISS website: a deliverable of the National pilot project

- full English version
- Updated weekly

http://www.iss.it/inte

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**The ED website: an overview**

**Main target:** scientists, health operators (stimulate action and networking)

**Main sections** (a comprehensive view on ED):

- Emerging topics (ED and obesity, bisphenol A..)
- Risk mitigation (how to reduce risk in foods, environment and exposed organisms)
  - Children (vulnerable subpopulation),
  - Feeds (carry-over along food chain),
    - the database EDID
  - the database on Italian
  - ED research
EDID the first database on interactions between ED and natural diet components

**Aim:** to support whole food safety assessment; can nutrients mitigate ED effects?
Can ED act as anti-nutritional factors?
(e.g., iodine and thyroid-acting ED)

**EDID**
EDC Diet Interactions Database

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The database on Italian research on ED

**three sections:**
- cell/molecular biology,
- toxicology/exposure (environment, food)
- epidemiology/biomonitoring (human/biota)

**2008:** Census of Italian research on ED with the support of university consortium INBB.

**2009:** Results presented during national ED workshop at ISS.

**Strengths:** ecotoxicology, analytical chemistry

**Weaknesses:** in vivo toxicology, epidemiology/biomonitoring
Real-life biomonitoring: the PREVIENI (PREVENT) project

http://www.iss.it/prvn
Full English version

The PREVIENI Project

(2008-11) funded by the Environment Ministry
A pilot biomonitoring project integrating analytical chemistry (exposure), toxicology (biomarkers of effective dose), human medicine
In biota and humans (Environment is Health)
Response to: the need for integrated biomonitoring data in Italy (stop wasting money on simple measures !)
to the signals flagged by WWF through DETOX campaign (WWF is PREVIENI’s stakeholder)
The PREVIENI Project

- Focus on ED **not included** in official control programs (BPA, PFOS/PFOA, DEHP, PBDE, as well as PAHs)
- Comparison between two comparable biota (from two WWF-managed areas) with different expected contamination
- Human populations from different areas: ED and fertility, ED and mother-child transfer
- Question: *is there ground for concern?*

Results presented December 2011 and submitted for publication, but already:

- possible concerns for PAHs and PBDE (biota), BPA and PFOS (humans)
- higher human exposure in large metropolitan community
- biota seems to find balance mechanisms

PREVIENI website will continue:  
the project entrained interactions with  
people and communities:  
public-targeted risk communication  
documents on the website  
(and they will increase)
Useful research to support risk analysis

- Novel tests to identify ED effects in overlooked targets: the prostate (Lorenzetti et al., Reprod Toxicol 2010)
- Tackling the “cocktail” effect: grouping PCB on the basis of common mechanisms (Tait et al., Reprod Toxicol, 2011)
- Biomonitoring inorganic arsenic (a ED-like trace element) in a highly polluted, crisis area of Italy (Cubadda et al., 2012)
- A ISS European patent: BEST, a multiprobe bio/sensor platform for early identification at-line of food chain contaminations (Authors: Frazzoli et al.)

Research on ED could support the updating of toxicological risk assessment

What could be done more?

- Nothing original: recommendations pointed out by documents on ED issued by Italian Government committees (with ISS support):

Priorities and objectives for the evaluation and management of the risk to human health and quality of the environment from exposure to endocrine disruptors

www.iss.it/binary/inte/cont/IE_Environment_and_Health.pdf
An integrated national action on ED is still lacking: what priorities?

- the assessment (including cost-effectiveness) and transfer of innovative methods to Environment-Food-Health surveillance carried out at regional level
- the integration of different data collections (biota, water, farm animals, feed, food..) to pinpoint potential critical areas
- and, most important, data collection on human health: birth defect registries (reproductive tract anomalies), precocious puberty, endometriosis, cancer registries (testicular cancer)

BUT.........

What could be done more?

✓ ...Lot of data do exist, their analytical quality is acceptable... but *they might be collected, analysed and exploited* more effectively

✓ More research into *risk mitigation*, including substitution of hazardous chemicals with effective alternatives

✓ risk communication to support public awareness and empowerment (informed behaviors do mitigate risk !): mind that communicate in a correct and understandable way is not so easy!
Presentation by Peter Smith

Endocrine Disruptors and Impact on Health
European Parliament Workshop, 18 September 2012

A three change process

- Hazard Understanding
- Risk Assessment
- Risk Management
Addressing Endocrine Disruptors
Step 1: Hazard

- World Health Organisation (WHO) definition
  « Substances or mixtures that alters functions of the endocrine system and consequently causes adverse effects in the intact organisation, on its progeny, or (sub) populations. »
- Criteria are needed to establish how much evidence of an adverse effect and causation is required to confirm that a substance complies with the ED definition.
- There is some expert judgement required. And hence we look to expert agencies (EFSA, ECHA) to provide independent assessments of specific substances (or mixtures) leading when establishing which substances conform to the definition of an Endocrine Disruptor or not.

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Addressing Endocrine Disruptors
Step 2: Risk Assessment

Risk = Hazard x Exposure

- Risk assessment provides us with an evaluation of the likelihood that the potential harm (ED) will actually occur by introducing exposure to the substance into the equation.
- Risk assessment takes us beyond identifying a hazard and enables us to identify the risk management measures necessary to prevent harm from actually occurring.
Addressing Endocrine Disruptors
Step 3 : Risk Management

- The final step in the process details what measures need to be taken to safely manage a hazardous substance so that it does not present harm to either humans or the environment.
- Risk management covers the different uses of the substance and whether it is being encountered within a manufacturing context (occupational health) or every life (consumer health).
- Risk management measures can take various forms; protective clothing (PPE), rigorous containment, bound end use, thresholds with sufficient safety margin to ensure that the actual exposure level is well below the level at which no adverse effect is seen, reduction/substitution.
- Regulatory controls also contribute to the final risk management measures (RMM). For ED, existing legislation applies (REACH, BPR...) maintaining a proportionate regulatory response to the risk.

Best practices in substances reduction/ substitution

- Reduction/substitution tends to feature when improving product performance (innovation) and in this context follows a period of research/discovery for improved substances (new/new to the application).
- Occasionally, reduction/substitution can be driven by safety concerns if it has been established that there is an adverse effect and that no other risk management measures are appropriate.

Decision tree (for the replacement substance)
  Is there a technical replacement?
  Is the technical replacement safe?
    - human health and environment
  Is the replacement affordable?
    - producers and customer/consumers
Concluding remarks

- A science-based approach to determine substances of regulatory concern
- Establish criteria for each stage in the evaluation of Endocrine Disruptors:
  - Stage 1 Hazard: Evidence of causation and adversity
  - Stage 2: Risk of exposure to the hazard
  - Stage 3: Evidence of safety and proportionality
- Develop and validate robust test methods
- Continue to collaborate with all stakeholders to establish a common understanding of Endocrine Disruptors, their impact on human health and environmental safety leading to the use of appropriate risk management measures.
Presentation by Yannick Vicaire

Bridging science, policy and society: Lessons learnt from our success in influencing the Franco-European debate on EDCs

Yannick Vicaire, Chemicals policy officer
Réseau Environnement Santé
res.yvicaire@gmail.com

Introducing Réseau Environnement Santé

- created in 2009 to follow-up on national implementation of REACH and WHO Health and Environment Plan
- a national association and network (environmental groups, health professionals, ill people associations, scientists)
- member of HEAL and EEB
- member of EDC NGO working group (15+ organisations and networks)
Introducing RES: our goals

- Place environmental health at the core of public policies and economic decisions by:
  - Using the best available science (peer-reviewed academic studies)
  - Implementing preventive and precautionary policies
  - Encouraging the development and adoption of safer alternatives
  - Promoting institutional reforms, reflecting the necessary shift of paradigm: expertise, RAs, indicators,
  - Building a «health democracy» through the extension of public participation and the protection of whistle-blowers
Why EDCs?

Damage to reproductive health

Hormonal cancers

ENDOCRINE DISRUPTION

Metabolic diseases

Neurodevelopmental disorders

RES & EDCs: the way we work

• Science monitoring: publication and dissemination of regular bulletins (BPA, phthalates, ...) or comprehensive reviews (eg. report on chemical exposure and metabolic diseases)

• Organising scientific conferences and public debates

• Building a critical dialogue with French and EU authorities including official requests to health safety agencies

• Awareness raising and training workshops for health professionals and private companies

• Involving media and the general public
Outcomes (1): French parliamentarians, spearheading the EDCs agenda

- **Bisphenol A:**
  - 2010: *unanimous ban* on BPA baby bottles by Senators (despite ANSES/EFSA/govt positions)
  - October 2011: *unanimous ban* on BPA linings and food containers by MPs (should be confirmed by Senate soon)

- **Phthalates:**
  - May 2011: short majority in Parliament on a general ban on phthalates-alkylphenols-parabens
  - Should be soon revised into a more focussed *ban similar to Danish proposal* (4 phthalates in consumer goods + medical devices)

- Towards a national **EDCs framework legislation**? (inspired by US Senator John Kerry's bill)

Outcomes (2): French agencies - from skepticism to adoption of the new paradigm

- **ANSES:**
  - Up to early 2011: followed EFSA opinion on BPA
  - Sept 2011: *recognition of low doses effects* of BPA and recommendations for substitution in food contact materials. On *precautionary basis of hazard assessment* report
  - November 2011: Call to stakeholders for submitting data on substitutes for BPA
  - March 2012: position paper on **EDCs definition, close to Danish position**
  - Hosted the May 2012 PPtox meeting and participated in Sept 2012 Berlin low doses conference

- **AFSSAPS/ANSM:**
  - Bans and recommendations on various ED-suspected sunscreen chemicals
Outcomes (3): French government drawing lessons from health scandals

- **France – background:**
  - Late lessons: high toll from delayed ban on asbestos
  - Reach adoption: turning point, supported compromise between substitution and adequate control of SVHCs
  - Continuous institutional reforms to reinforce health safety: creation of AFSSA and AFSSET then merged into ANSES

- **Health institutions in crisis of public trust:**
  - 2003 mismanaged heatwave (5000 deaths)
  - PIP implants and Mediator (diet) scandals
  - Early opposition to BPA ban in baby bottles → support of ban in food containers

- **Ministry of Environment:**
  - Common statement with Sweden
  - Close cooperation with Denmark
  - Not supportive of the « ED-pesticides » part of ANSES paper on definition of EDCs

Outcomes (4): Awareness and visibility

- **Journalists write about EDCs:**
  - Popular press and TV reports → consumers angle
  - High level press (Le Monde) → shift of paradigm, epigenetics, developmental origins of diseases, expertise and conflicts of interests ...

- **Documentaries broadcast on public TV channels:**
  - Notre Poison Quotidien on ARTE
  - La grande invasion on France 5

→ **Heightened public awareness of endocrine disruption**

- US EDCs experts known in France: Soto, Swan, Vom Saal, ...
- French EDC research getting visibility: Barouki (INSERM), Zaiko (INRA), Slama (CEA), ...

→ **Research science getting mainstream**

- **Other stakeholders:**
  - **Health insurances getting mobilised**
  - Business moving away from BPA and other EDCs

→ **Opening doors for bolder policies?**
Conclusions (1): MS initiatives, what are they good for?

- Chemicals policy is normally at EU level
- Yet, unilateral MS initiatives can
  - Initiate EU-wide action like DK-FR’s ban on BPA baby bottles
  - Spearhead a shift of paradigm like BE-FR’s law on BPA in food containers
  - Champion the implementation of PP like DK on phthalates
  - Speed up the process of EDC regulation and urge other EU players
  - Challenge the unwillingness of industry and the inertia of institutions

Especially as EDCs are a high stakes topic and a very complex issue questioning a lot of what we thought we knew !!!!

Conclusions (2): EP own initiative report, what can you do?

- Request review/revision of relevant laws to take EDCs in account and as high priority, in particular:
  - REACH: EDCs should get equal treatment to PBT/vPvB (substitution)
  - Pesticides/biocides: quick review of authorisations likely to be EDCs
  - Pharmaceuticals, Cosmetics, Toys, Food contact materials, ...
  - Water/EQS: don’t forget damage to biodiversity

- EDCs definition:
  - A hazard-based definition allowing preventive and precautionary action
  - Science is moving fast: keep the regulative framework dynamic
  - Update the list of priority EDCs

- Mixtures: require a precautionary strategy to deal with effects of common human exposure to mixtures of EDCs

- Updated tests and assays to reflect real life exposure to EDCs
Conclusions (3):
EP own initiative report, what can you do?

- Support EU-wide human biomonitoring: to help prioritising and to track exposure to mixtures and verify effectiveness of laws
- Research:
  - Fund multi-disciplinary research on endocrine disruption
  - Evaluate economic impacts of EDCs on public health (e.g. IQ/fertility damage).
- Institutional reforms:
  - Reform agencies, experts committees and division of competencies to reflect the shift of paradigm of EDCs and DOHaD

Conclusions (4):
EP own initiative report, what can you do?

- Talk to other MEPs
- Involve more stakeholders
- Require update of EC’s Health and environment strategy (SCALE)

Above all, demand a quick reduction of exposure and ultimate phase-out ...
… to protect this and future generations!

Thank you
Role

Policy departments are research units that provide specialised advice to committees, inter-parliamentary delegations and other parliamentary bodies.

Policy Areas

- Economic and Monetary Affairs
- Employment and Social Affairs
- Environment, Public Health and Food Safety
- Industry, Research and Energy
- Internal Market and Consumer Protection

Documents