Endocrine Disruptors and Impact on Health

WORKSHOP

EN 2012
DIRECTORATE GENERAL FOR INTERNAL POLICIES
POLICY DEPARTMENT A: ECONOMIC AND SCIENTIFIC POLICY

WORKSHOP

Endocrine Disruptors and Impact on Health

Brussels, 18 September 2012

WORKSHOP DOCUMENTS
WORKSHOP ON
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 - 12.40
Gustaaf Borchardt, Director, Directorate D - "Water, Marine Environment & Chemicals" DG Environment, EC
"Commission Strategy on Endocrine Disruptors"

12.40 - 12.50
Tapani Piha, Head of Unit SANCO D3 Risk assessment (incl. Health Technologies), DG SANCO, EC
"Health and Consumers science and regulation perspective"

12.50 - 13.00
Jacqueline McGlade, Director, European Environment Agency

13.00 - 13.10
Peter Korytar, D3 Unit - Chemicals, Biocides and Nanomaterials, DG Environment, EC
13.10 - 13.20
Jim Bridges, University of Surrey, chairman of SCENIHR, (EC Scientific Committee)
"Challenges in assessing the risks from potential endocrine disruptors"

13.20 - 13.30
Andreas Kortenkamp, Institute for the Environment, Brunel University, London
"Endocrine disruption and human health - a role for chemical exposures?"

13.30 - 14.00
Q&A, open discussion

Part 2: Exposure to EDCs: Effects on human health

14.00 - 14.10
Alberto Mantovani, National Health Institute of Health (ISS), Italy
"Vision from a public health center"

14.10 - 14.20
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 - 14.30
Yannick Vicaire, Réseau Environment Santé (RES)
"French NGO with successful results of awareness campaigns"

14.30 - 14.55
Q&A, open discussion with Shadow rapporteurs

14.55 - 15.00
Final remarks Åsa Westlund, Rapporteur
SHORT BIOGRAPHIES OF EXPERTS

Jacqueline McGlade, Executive Director of the European Environment Agency, (Denmark)

Professor Jacqueline McGlade became Executive Director of the European Environment Agency in Copenhagen in 2003. The EEA is a vital source of information for the European Commission, the European Parliament EU Member States and other EEA member countries in developing and implementing environment and climate policies, and in providing the knowledge base to help Europe make informed decisions about improving the environment and integrating environmental considerations into economic policies so as to develop along a sustainable low-carbon and resource efficient path. Professor McGlade is currently on leave from her post as Professor in Environmental Informatics in the Department of Mathematics at University College London.

Prior to this, she was Director of the Centre for Coastal and Marine Sciences of the UK Natural Environment Research Council, Professor of Biological Sciences at the University of Warwick, Director of Theoretical Ecology at the Forschungszentrum Jülich and Senior Scientist at the Bedford Institute of Oceanography in the Federal Government of Canada.

Her research is focused on the governance of resources and environmental informatics with particular reference to ecosystems, marine resources and climate change. She has more than 100 peer-reviewed papers and more than 200 articles, books and legal submissions and has produced and presented a number of TV and radio series and programmes plus three feature films. She has been awarded international prizes and honours from Czech Republic, Germany, Italy, Monaco, Romania, Sweden, UK and the USA.

Professor McGlade has held a number of key advisory roles and chairs at national level, including Trustee of the Natural History Museum and Board Member of the Environment Agency, at European level, including the European Bank for Reconstruction and Development, and at international levels including for the United Nations and the Consultative Group on International Agriculture Research. She has also run her own company specialising in the area of software development and intelligence systems.

Jim Bridges, BSc, PhD, DSc, Hon DSc, Professor of Toxicology and Environmental Health and Dean for International Strategy at the University of Surrey, Guilford, (United Kingdom)

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.

**Andreas Kortenkamp, Professor for human toxicology at the Institute for the Environment, Brunel University, (United Kingdom)**

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.

**Alberto Mantovani, National Health Institute of Health (ISS), (Italy)**

Mr 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 Mr Mantovani has also contributed, and is contributing to several EU projects on ED (CASCADE, ReProTect, AQUAMAX, TDS-Exposure).

Since 2011 Mr 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.
**Peter Smith, Executive Director of the Programme Product Stewardship, European Chemical Industry Council (CEFIC), (Belgium)**

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.

Peter is married and has two school-aged children.

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

**Yannick Vicaire, Chemicals policy officer for Réseau Environnement Santé (RES), (France)**

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).
PRESENTATIONS

Presentation by Andreas Kortenkamp

Committee on the Environment, Public Health and Food Safety (ENVI)

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

Testicular cancer, 1970-1976
Incidence / 100,000.
Testicular cancer, 1974-1979
Incidence / 100,000.

Testicular cancer, 1977-1982
Incidence / 100,000.
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

Time

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
Presentation by Alberto Mantovani

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

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

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.isss.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!
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.y.vicaire@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

Introducing RES: 4 PRIORITY TOPICS
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 AFSSSET 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/VpV (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
POLICY DEPARTMENT
ECONOMIC AND SCIENTIFIC POLICY A

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