

Endocrine disrupting Substances and the Danish and European Authorities

Pia Juul Nielsen & Marie Holmer
Chemicals Division
Danish EPA

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Brief overview of Danish work on EDC plus the EU-work



- **National strategy**
- **How we work in practise**
- **Examples of new initiatives**
- **From science to regulation**
- **Brief status for the EU-work**
- **International activities**
- **Future work**

National Strategy in 2002



In line with the EU-strategy

- 1. Knowledge building and development of test methods**
- 2. Action-orientated investigations**
- 3. Regulation**

How we work – elements



- **Governmental Research Programmes**
 - Cause-effect relationship
 - Increases knowledge about specific substances or specific problems

- **Development of assessment tools**
 - development, validation and standardisation of OECD TG's & drafting of DRP's and GD's

DK contribution to OECD TGP



- **Fish Sexual Development Test (FSDT)**
 - **Reproduction of springtails (TG232)**
 - **GD on reproductive toxicity (*co-operation with U.S.*)**
 - **Uterothrophic assay (TG440)**
 - **Hershberger assay (TG441)**
 - **Fish short term reproduction assay (TG230)**
 - **Fish screening assay (TG229)**
 - **In vitro steroid synthesis assay (H295R)**
 - **Extended one-generation reproduction toxicity**
 - **Revision of 2-generation study (TG416)**
 - **Developmental neurotoxicity (TG426)**
 - **Repeated dose 28-day study (TG 407)**
- Research/development*
- *In vivo* thyroid assay
 - *In vitro* screen for effects on the thyroid receptor
 - Method to include metabolism in *in vitro* ED assays with cell lines

How we work – elements



- **Development of assessment tools**
 - development of (Q)SAR models
 - investigation of tools for assessment of combination effects

How we work - co-operation



- **ED network**
fruitful integration of research and test method development
- **important new findings**
- **new regulatory interventions**

- **Centre for Endocrine Disruptors**
applied research directed towards the preventive work, including regulation

New initiatives



- **Pesticides (azolefungicides) in greenhouses**
 - *new risk assessment*
 - *more strict guidelines for handling*
 - *work for cut-off values in the new EU- pesticides regulation*

- **Combination effects**
 - *expert workshop on combination effects of endocrine disrupters and regulatory aspects*
 - *use of the recommendations from the workshop for investigation of 2-year old childrens combined exposure to chemicals*
 - *the Minister raised the issue with combination effects of chemicals and in particular endocrine disrupters in EU*

From science to regulation - Assessment of EDC's



General approach in relation to testing, assessment and management of substances with especially concerning hazardous properties

2 categories for EDC's - depending on the level of evidence

1. ED *in vivo* (confirmed)
2. a. Suspected ED (*in vivo*)
b. Potential ED (*in vitro/in silico*)

From science to regulation - Assessment of EDC's



■ EDC *in vivo*

If risk ⇒ **risk reduction** (restriction of production/use or authorisation)

■ Suspected EDC *in vivo*

- preliminary risk assessment – additional assessment factor

If risk ⇒ **soft regulatory intervention** and/or **definitive testing, evidence** required from industry

From science to regulation

-Soft regulatory interventions



Aims

- Avoid unnecessary use of /minimize exposure to the chemical
- Promote generation of definitive evidence

How to make this operational

- Incentives for industry
- Proposal for/promotion of regulatory action at the EU level
- Communication / advice to the public

Advice to the public - 9 good habits for pregnant and nursing mothers



- 2006
- Political focus, request from public
- No scientific proof, but serious concern
- General recommendations – reduce exposure
- Sensitive period, limited time

- Very effective – 70% of target group saw the information – 2/3 of those not already following the habits, changed behaviour.
- www.babykemi.dk

Survey - 2-year olds combined exposure to endocrine disruptors



- 17 EDCs (known effects in animals + anticipated exposure)
- Consumer products, food and indoor environment
- Literature studies + new analyses of consumer products on DK market
- NOAELs/LOAELs based on ED effects
- Dose addition
 - $DNEL = (N/L)OAEL / AF$
 - $RCR = Exposure / DNEL$
 - $RCR(total) = RCR(1) + RCR(2)....$

Survey - 2-year olds -Conclusions



- Single products with a high content of an endocrine disrupter (e.g. DBP in rubber clogs) may result in a critical risk to the 2 year-old
- Exposure to the phtalate DBP (food, *rubber clogs*) and dioxin and dioxin-like PCBs (food, *indoor climate*) can constitute a risk for antiandrogenic disruption
- Exposure to parabens (cosmetic products) can constitute a risk for estrogenic disruption
- There is a need to reduce exposure to antiandrogenic and estrogen-like substances from food and the indoor climate, but also from consumer products.

Survey - 2-year olds -Follow-up



- Campaign: 65.000 reasons for better chemicals (www.65000.dk)
- 8 recommendations:
 - Make sure there is a good indoor climate – air out and clean rooms
 - Serve varied food and use appropriate kitchen utensils
 - Buy swan-labelled personal care products
 - Buy personal care products without perfume
 - Avoid the most dangerous phthalates
 - Wash new products before use
 - Throw away old soft plastic toys
 - Buy CE-labelled and unscended toys
- Combination effects – Council Conclusions at the Environment Council december 2009?

EU – ongoing activities



- **Survey on approaches and practical experiences in assessing the mixture toxicity of complex environmental samples and waste samples in EU MS**
- **Tender – State-of-the-art of the assessment of endocrine disrupters - 2011**
- **2010 – Report on the implementation of the Community Strategy**

Status for the EU strategy



- **Community Strategy 1999**
 - Identify problem of ED
 - Identify policy action
- **Short-term action**
 - priority list of substances for further evaluation
- **Medium term action**
 - research and development (FP-programmes)
 - identification and assessment (OECD-TGP, ECVAM, EDTA AG)
- **Long term action**
 - legislative action
 - REACH 2013
 - PPP 2013
 - Cosmetics 2014

International activities



- Denmark hosted an OECD workshop on testing, assessment and management of endocrine disruptors 22-24 september 2009
- Regional 5th WHO Ministerial Conference on Environment and Health in March 2010
 - focus on endocrine disruptors and combination effects of chemicals
- Nordic & Arctic Council

Future



- **4-year action plan – to significantly strengthen consumer protection from harmful compounds - 173 mio. DKK**

- **Important elements in EDC work:**
 - **Combined exposure**
 - **Development of criteria**
 - **Continued focus on TG development**
 - **Continued close co-operation**
 - **Integration into REACH, other EU regulation and international activities**

- **Thank you for your attention!**