

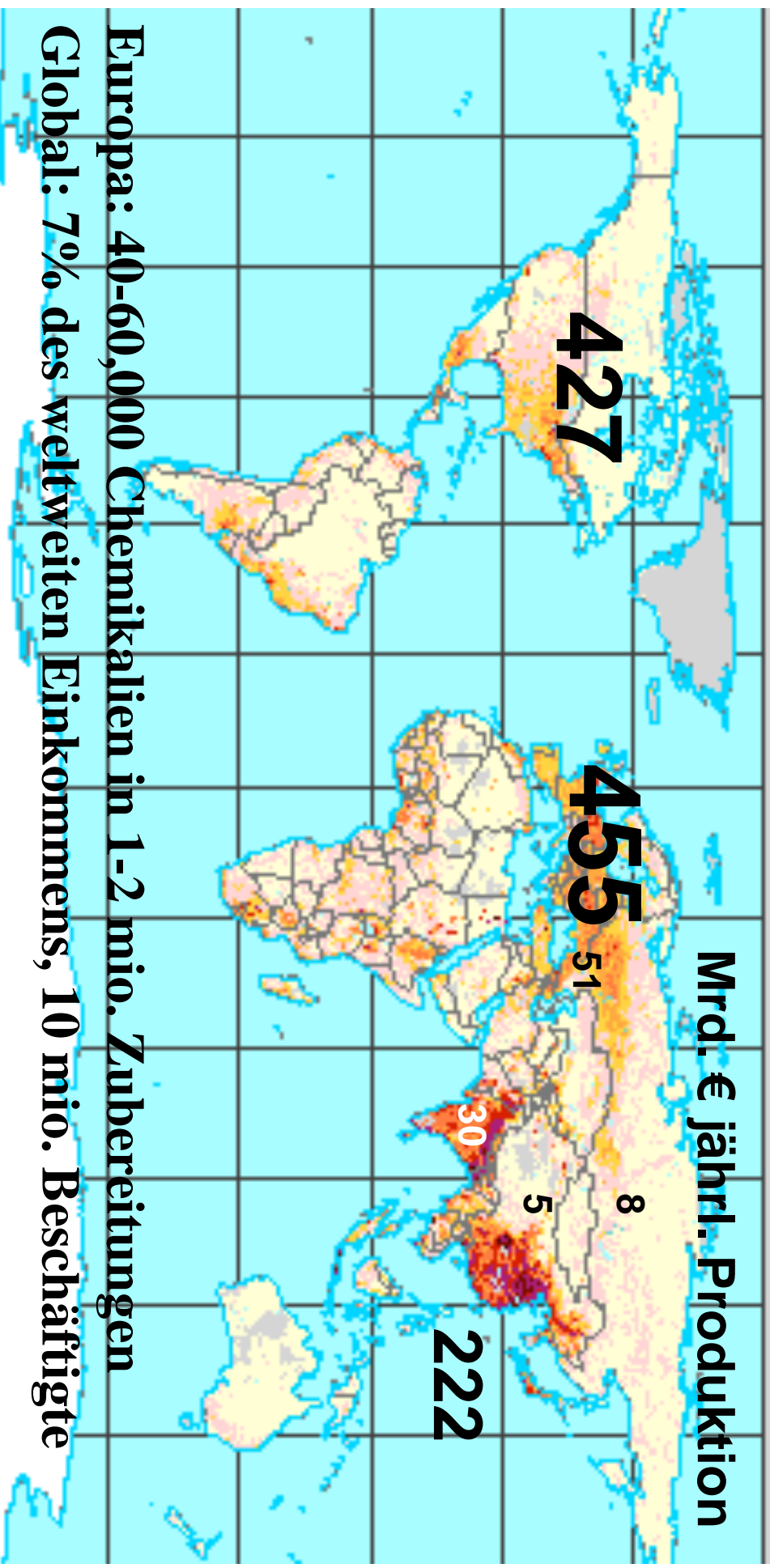


**Endokrin wirksame chemische
Substanzen:
Perspektiven internationaler strategischer
Zusammenarbeit**

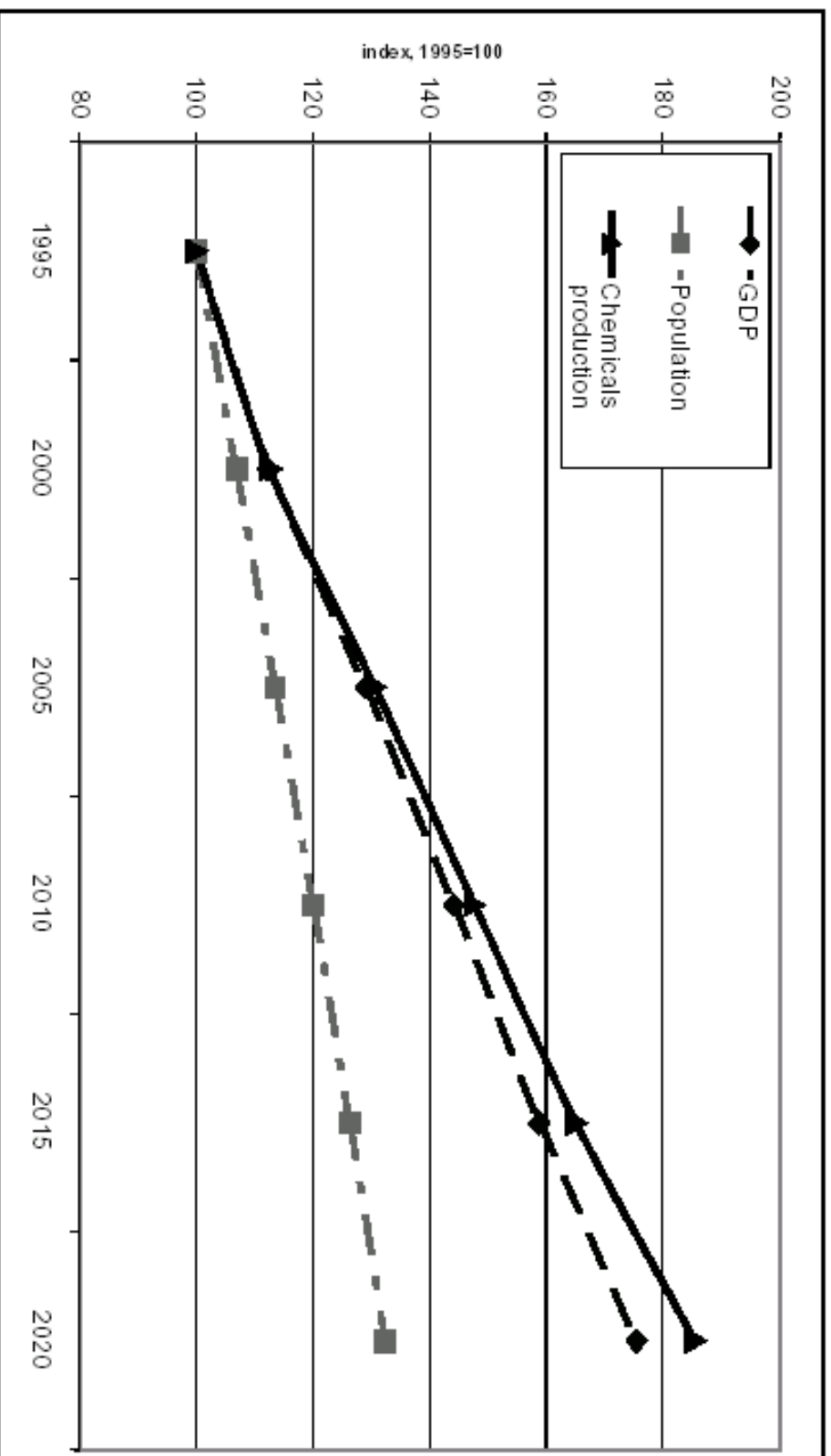
Dr. Andreas Gies
Umweltbundesamt

14. November 2006

Chemieproduktion und Bevölkerungsdichte



Projected growth in chemicals production, world GDP and world population (1995-2020)





UNITED NATIONS

JOHANNESBURG SUMMIT 2002



WORLD SUMMIT ON SUSTAINABLE DEVELOPMENT | JOHANNESBURG, SOUTH AFRICA | 26 AUGUST-4 SEPTEMBER 2002

Aim, by 2020, to use and produce chemicals in ways that do not lead to significant adverse effects on human health and the environment.

Foto: © Thorsten Klapsch/Greenpeace

Was sind Umwelthormone?



Was sind Umwelthormone?

Die Definition von Weybridge (1996):



An endocrine disruptor is an exogenous substance that causes adverse health effects in an intact organism, or its progeny, secondary (consequent) to changes in endocrine functions.



Ein Umwelthormon ist eine von außen kommende Substanz, die nachteilige Gesundheitseffekte bei einem intakten Organismus oder seinen Nachkommen dadurch erzeugt, dass es die endokrinen Funktionen verändert.
(endokrin: mit innerer Sekretion)

Umwelthormone

- in sensiblen Zeitfenstern, meist um die Geburt / Juvenilentwicklung
- wirken in geringen Konzentrationen
- zeitverzögert
- irreversibel
- in niedrigen Konzentrationen oft stärker oder anders als in hohen



Östrogen + Xenoöstrogene

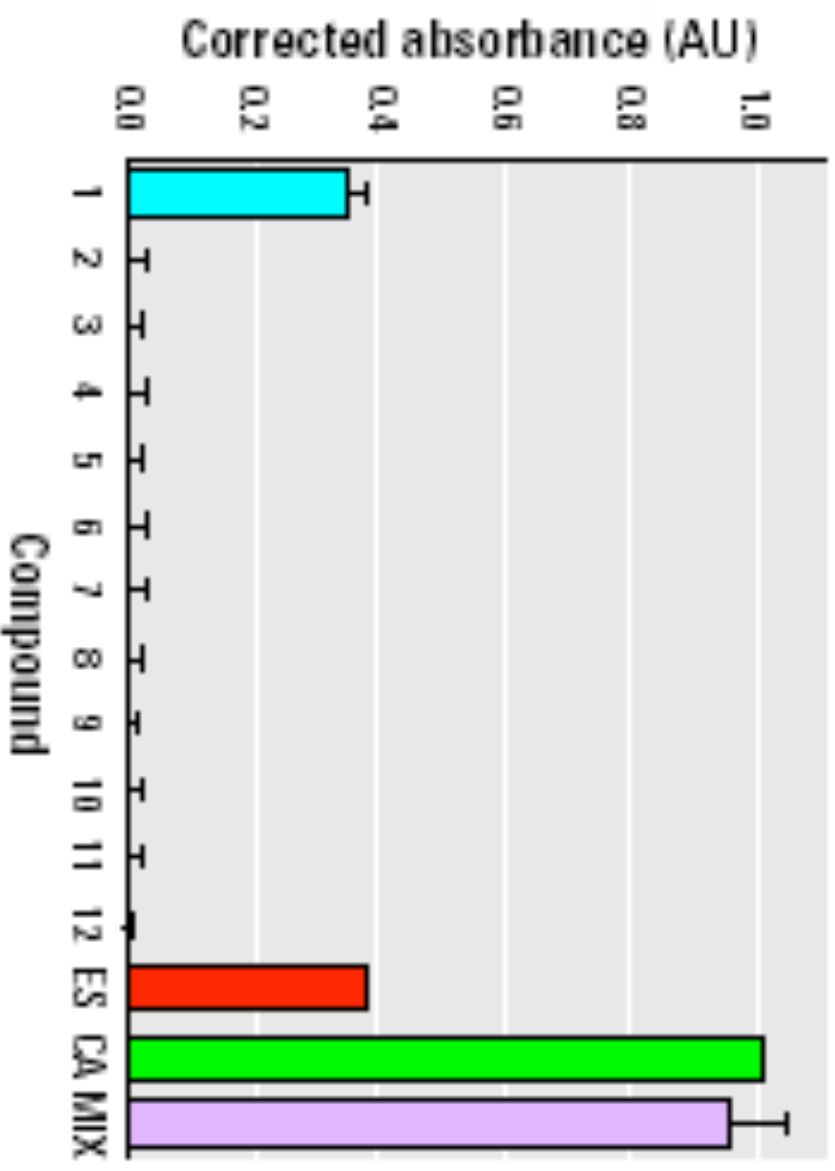
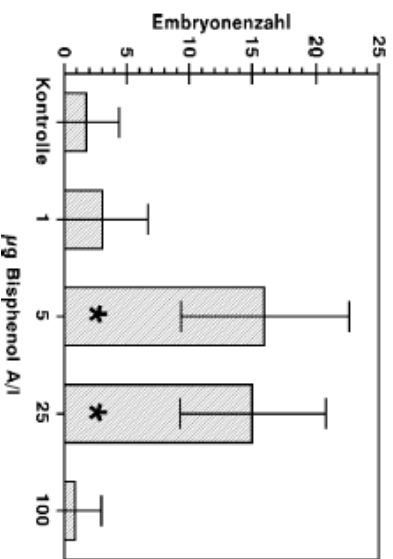


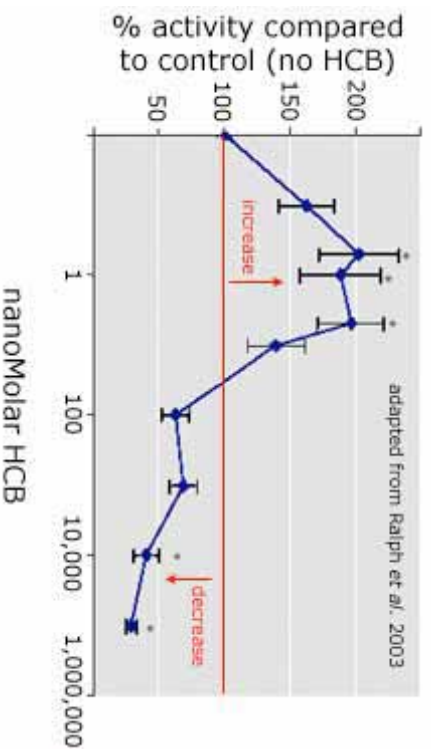
Figure 4. The effects produced by each mixture component at the concentrations present in 5 µM of the 1:50,000 mixture. Also shown are the predicted mixture effects calculated by using ES and CA and the observed mixture effect (MIX). Test agents (individual concentration): 1) 17β-estradiol (100 pM); 2) 2',3',4',5'-tetrachlorobiphenyl-4-ol (1.9 nM); 3) 2',5'-dichlorobiphenyl-4-ol (4.6 nM); 4) 4-chlorobiphenyl-4-ol (26.9 nM); 5) genistein (37.1 nM); 6) 2,4-dihydroxobenzophenone (71.9 nM); 7) benzyl-4-hydroxyparabene (71.9 nM); 8) 2,3,4,5-tetrachlorobiphenyl (795 nM); 9) bisphenol A (276.4 nM); 10) resorcinol monobenzoate (974.7 nM); 11) 2,3,4-trichlorobiphenyl (795.9 nM); 12) phenyl salicylate (2.68 µM). Error bars indicate the upper 95% confidence limit of responses. In view of the good agreement between CA prediction and experimental observation (MIX) the combined effect of all agents may be called (concentration) additive.

Nicht monotone Dosis-Wirkungs-Kurven

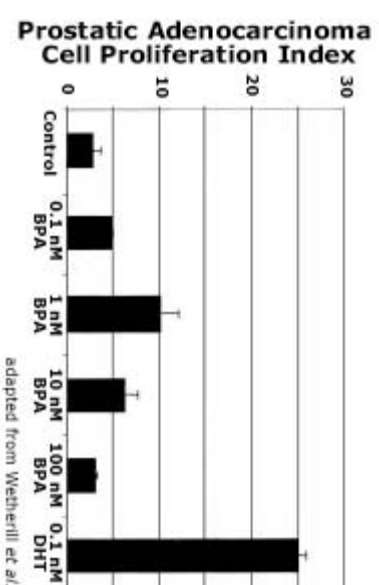
Schulte-Oehlmann et al. 2001



BPA and no. of embryos in snails



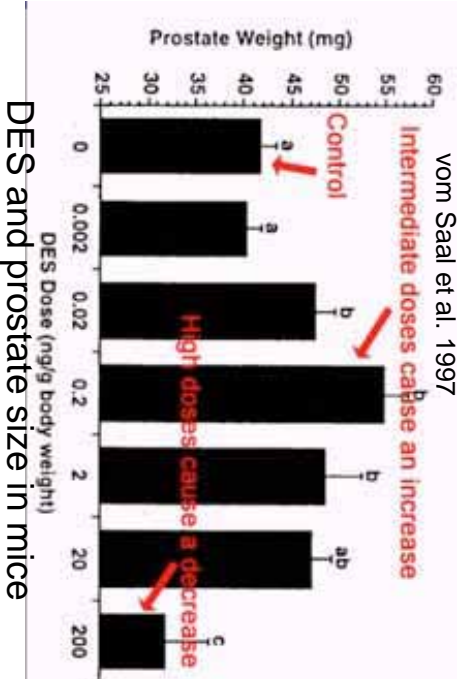
HCB and prostate cell androgen activity



adapted from Wetherill et al.

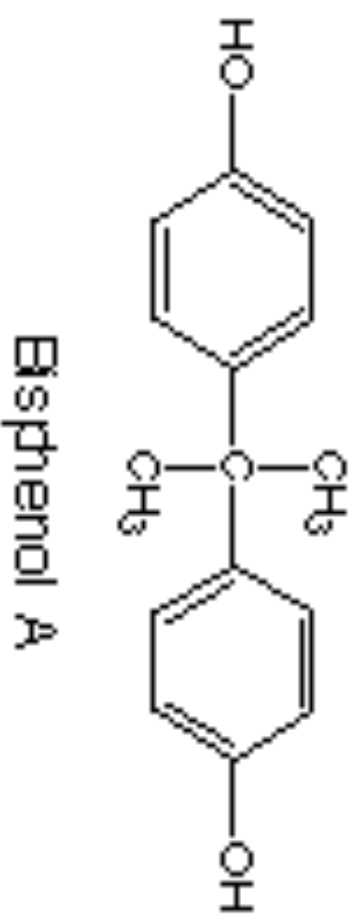
BPA and Cell proliferation

von Saal et al. 1997



DES and prostate size in mice

Die Stoffe

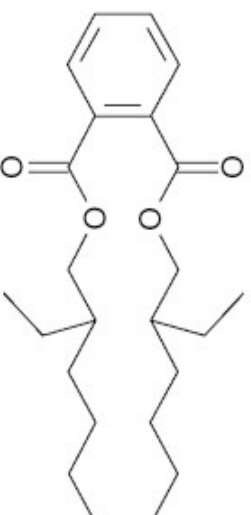


▪ 700,000 t werden jährlich in der EU produziert

- Polycarbonate und Epoxidharze
- GE, Bayer und Dow Hauptproduzenten
- 0.2 – 9.2 µg/L im fötalen Plasma
- 0.1-1 µg/L in europäischen Flüssen



Die Stoffe



DEHP - C₂₄O₄H₃₈
M = 390 g/mol

Diethylhexylphthalat

Anti-androgen

1-2 µg/ml im Nabelschnurblut

12 % der Bevölkerung überschreiten

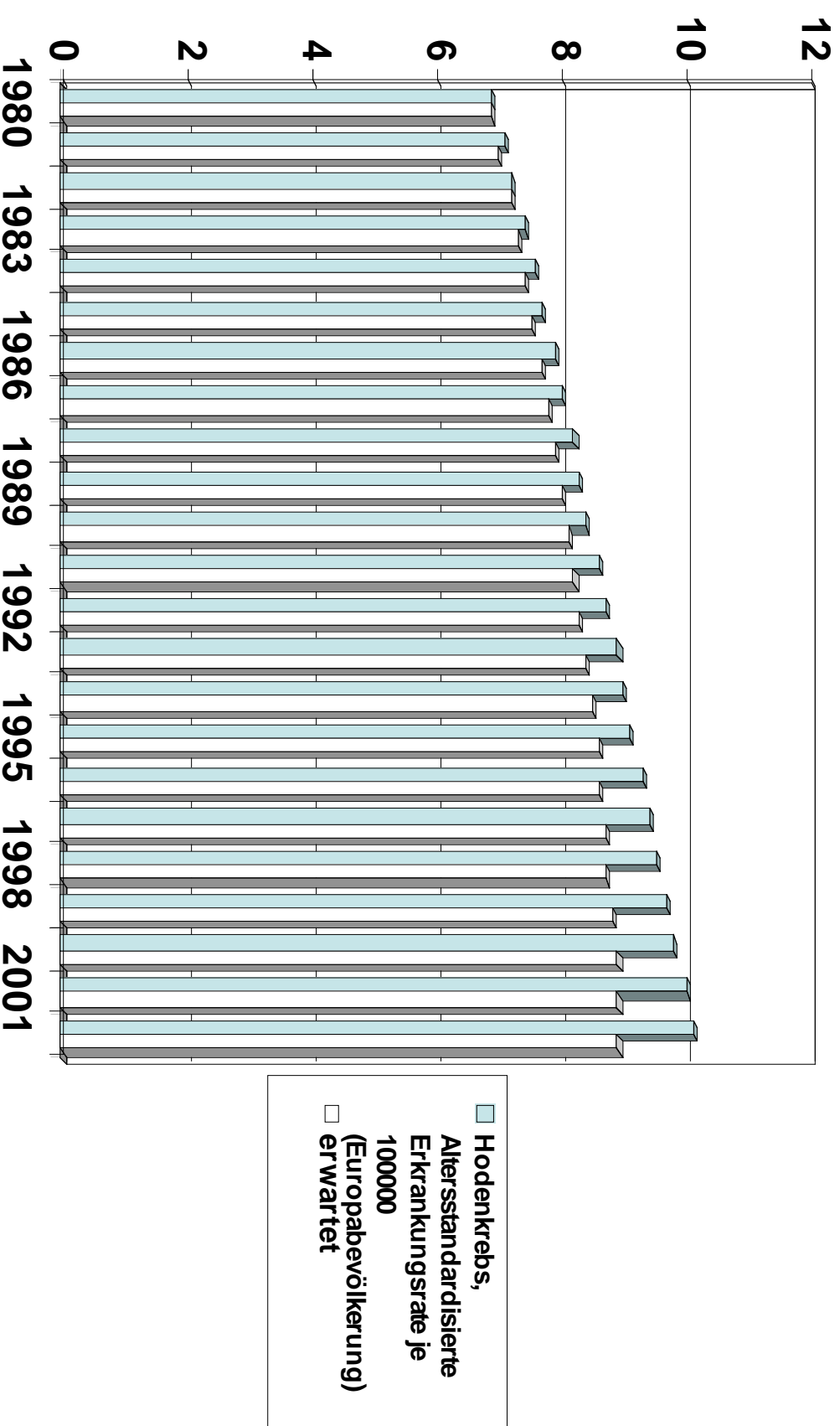
empfohlene tägliche Aufnahme

Kinder nehmen doppelt so viel auf

wie Erwachsene

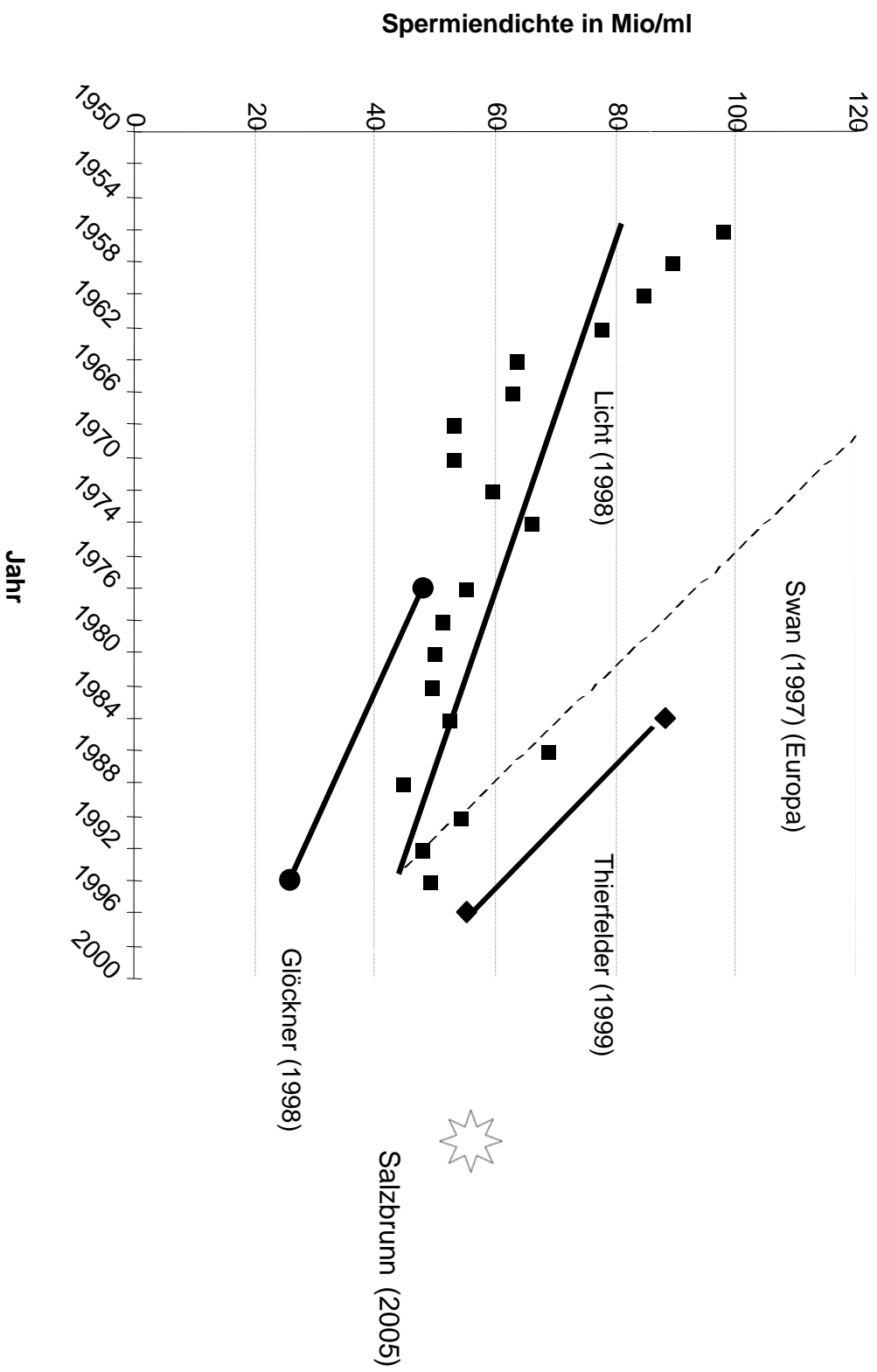


Hodenkrebs: Trend in Deutschland 1980-2002

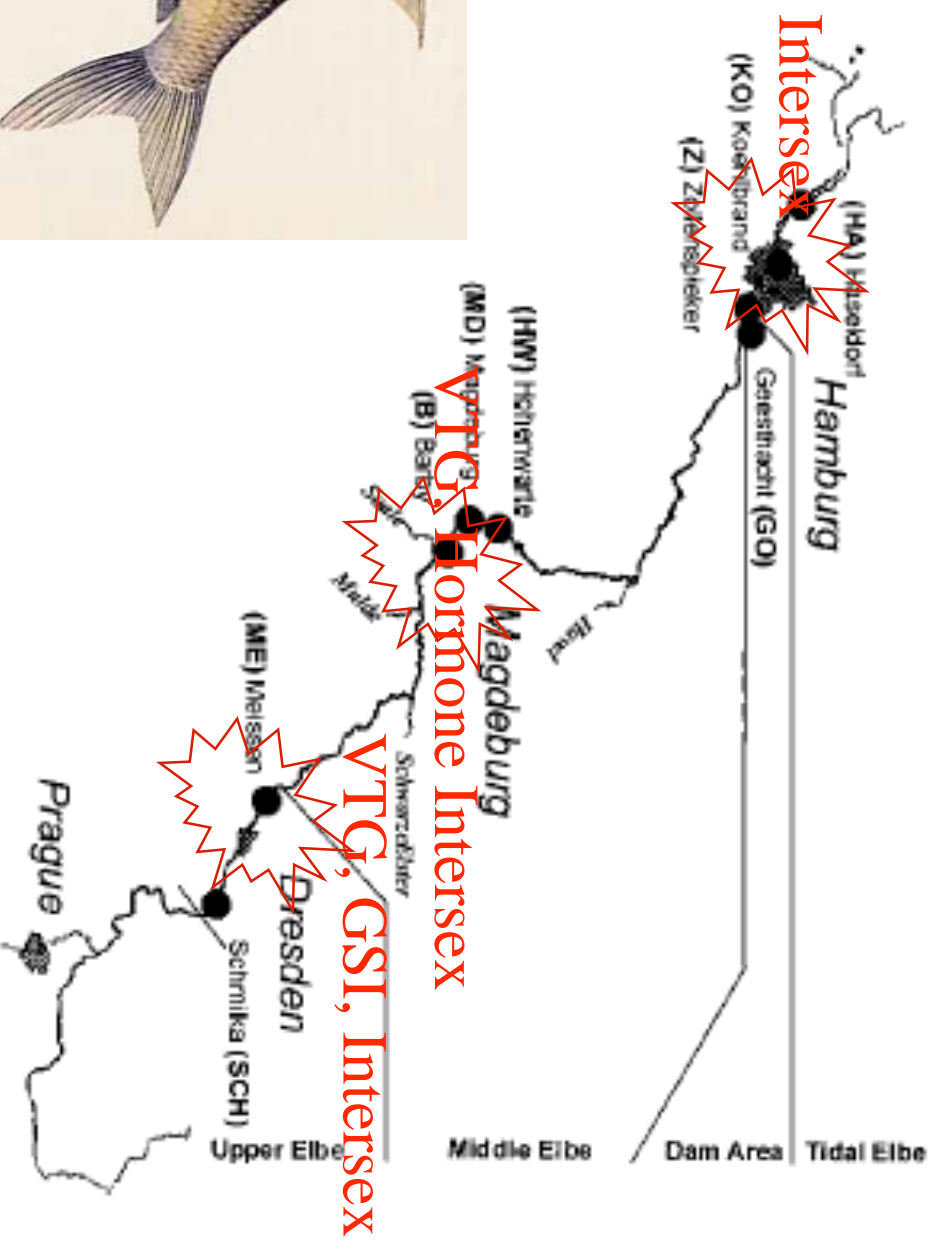


Quelle: Schätzung des RKI 2006

Trend der Spermindichten aus verschiedenen Untersuchungen

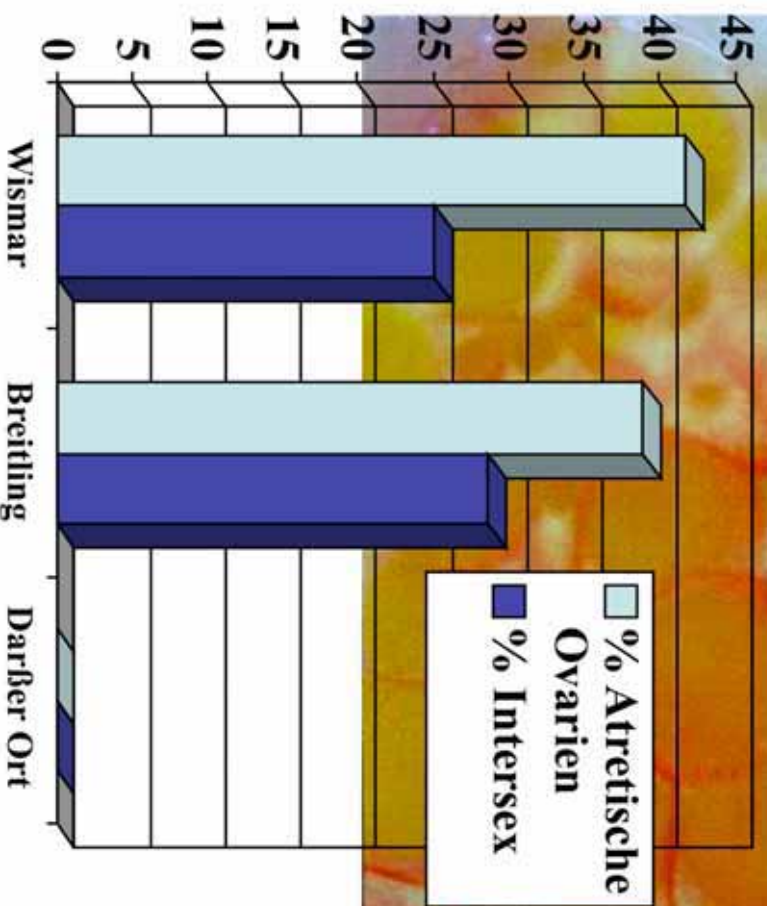
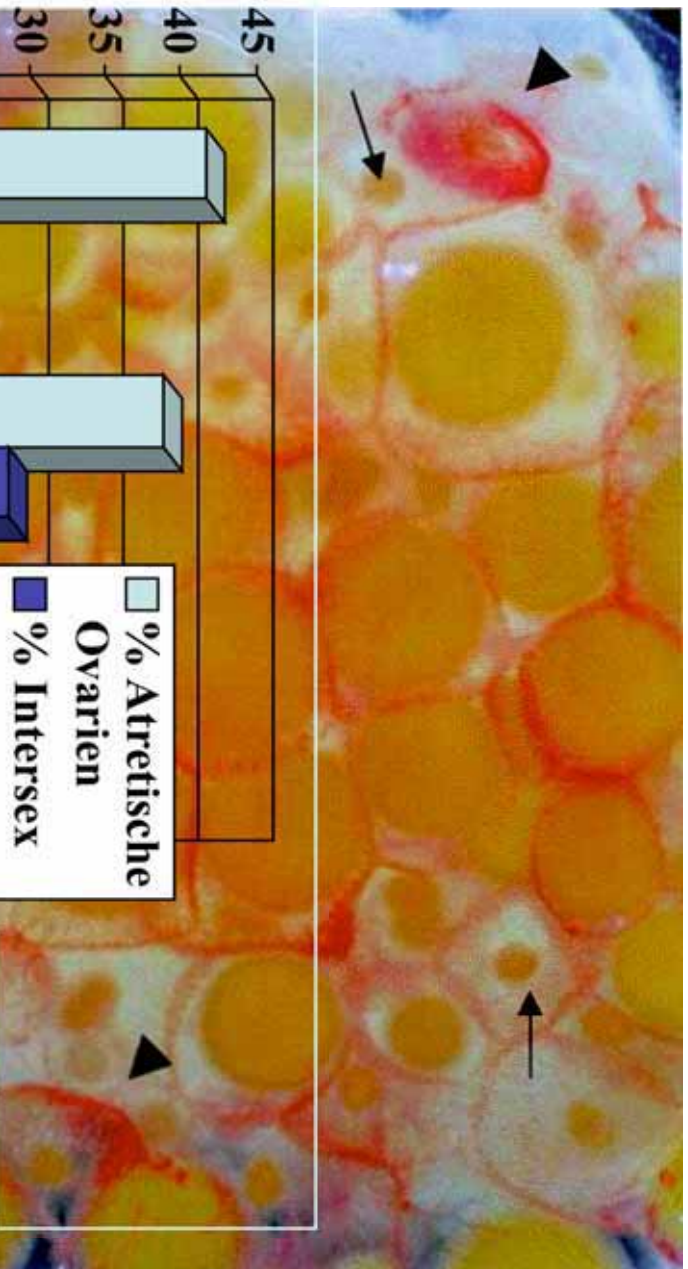


Reproduktionsgesundheit von Fischen in der Elbe



Hecker et al. 2002

Reproduktionsgesundheit von Fischen in der Ostsee



Internationale Initiativen zu Umwelthormonen

- **EU**
 - Liste der Umwelthormone
 - Forschung
 - REACH – neue Chemikalienpolitik
- **OECD**
 - Testentwicklung (EDTA)
- **WHO / IPCS**
- **Wissenschaftliche Gemeinde**



Decisions of the European Parliament 1999

- Risk assessment for 100,000 chemicals impossible
- Proposes group assessments
- Demands to set up a list of known ED
- Demands integrated strategy for PPP reduction including promotion of ecological farming
- Demands to develop test methods
- Demands intense research programme

EU



Liste der Umwelthormone

Forschung

REACH – neue

Chemikalienpolitik



Community Strategy for Endocrine Disruptors (1999)

- need for further research
- need for international co-ordination
- need for communication to the public
- need for policy action

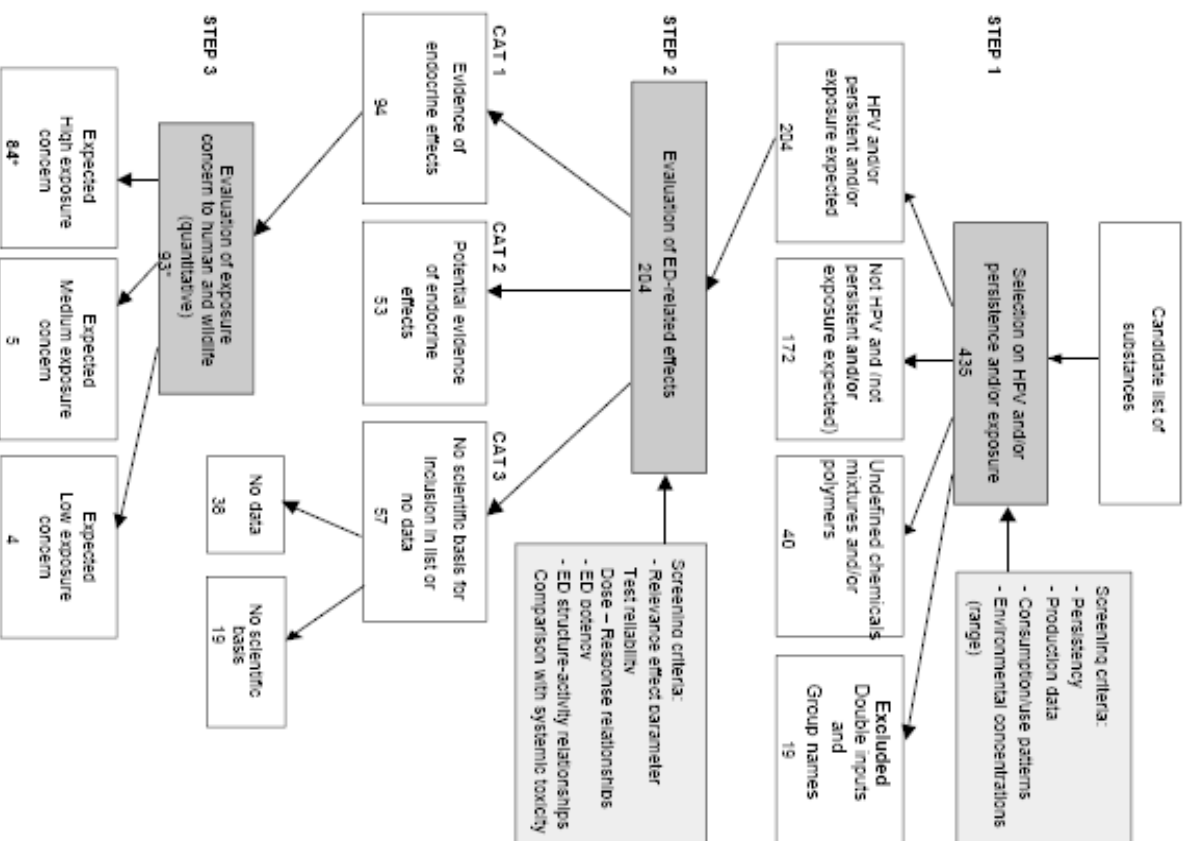


Decisions of the European Parliament 2000

EP asks for:

- Identification of ED for immediate action without further tests
- European screening and testing strategy with special emphasis to low dose effects
- Legal framework for ED based on the precautionary principle and shifting the burden of proof to the producer
- Intense research again

EU Liste der Umwelthormone



+28 Substanzen
DHI-Liste (LPV)

EU- Umwelthormone und REACH

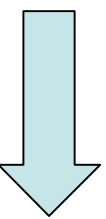
Folgende Substanzen bedürfen einer Zulassung unter REACH:

- a) substances meeting the criteria for classification as **carcinogenic** category 1 or 2 in accordance with Directive 67/548/EEC;
- b) substances meeting the criteria for classification as **mutagenic** category 1 or 2 in accordance with Directive 67/548/EEC;
- c) substances meeting the criteria for classification as **toxic for reproduction** category 1 or 2 in accordance with Directive 67/548/EEC;
- d) substances which are **persistent, bioaccumulative and toxic** in accordance with the criteria set out in Annex XII;
- e) substances which are **very persistent and very bioaccumulative** in accordance with the criteria set out in Annex XII;
- f) substances, such as those having **endocrine disrupting properties** or those having persistent, bioaccumulative and toxic properties or very persistent and very bioaccumulative properties, which do not fulfil the criteria of points (d) and (e) and which are identified as **giving rise to a similar level of concern** as substances listed in points (a) to (e) **on a case-by-case basis** in accordance with the procedure set out in *Article 65*
- g) **substances which are ingredients added to tobacco products ...**

EU- Umwelthormone und REACH

Vorschlag Guido Sacconi (Berichterstatter EP) vom 9. November 2006

- Zulassung über fünf Jahre hinaus
- Versicherung der Firmen, Risiko adäquat zu kontrollieren
 - Keine „sicheren Schwellen“
- Es gibt keine hinreichenden (suitable) Alternativen zu der Chemikalie:
 - Substitutionsplan



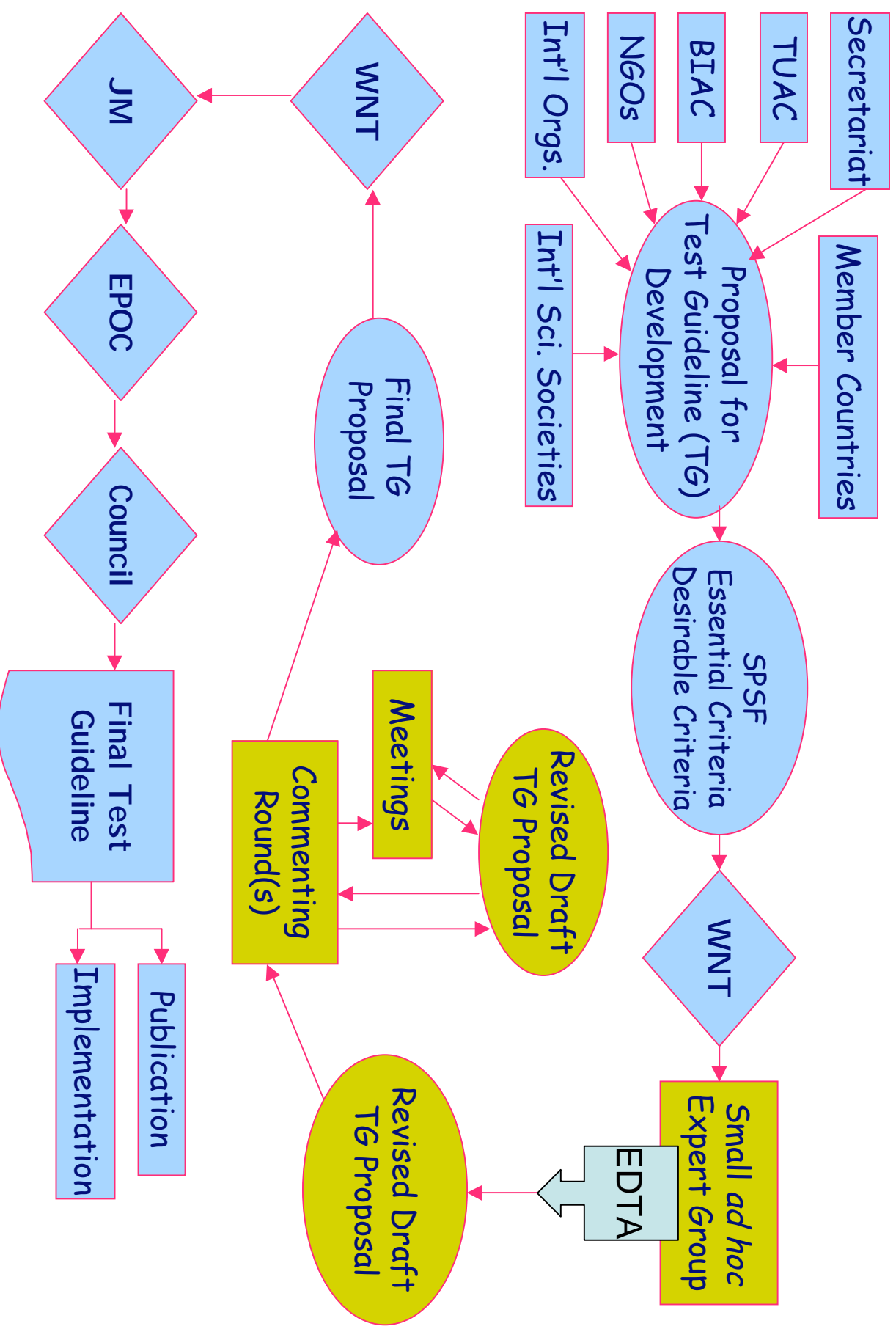
20. November Trialog EP / COM / Rat



OECD

Testrichtlinien

OECD Test Guideline Development Process



OECD Testaktivitäten Umwelthormone

Note: Document prepared by the Secretariat of the Test Guidelines Programme based on the agreement reached at the 6th Meeting of the EDTA Task Force

OECD Conceptual Framework for the Testing and Assessment of Endocrine Disrupting Chemicals

<p>Level 1</p> <p>Sorting & prioritization based upon existing information</p>	<ul style="list-style-type: none"> - physical & chemical properties, e.g., MW, reactivity, volatility, biodegradability, - human & environmental exposure, e.g., production volume, release, use patterns - hazard, e.g., available toxicological data
<p>Level 2</p> <p><i>In vitro</i> assays providing mechanistic data</p>	<ul style="list-style-type: none"> - ER, AR, TR receptor binding affinity - Transcriptional activation - Aromatase and steroidogenesis <i>in vitro</i> - Aryl hydrocarbon receptor recognition/binding - QSARs - High Through Put Prescreens - Thyroid function - Fish hepatocyte VTG assay - Others (as appropriate)
<p>Level 3</p> <p><i>In vivo</i> assays providing data about single endocrine Mechanisms and effects</p>	<ul style="list-style-type: none"> - Uterotrophic assay (estrogenic related) - Hershberger assay (androgenic related) - Non-receptor mediated hormone function - Others (e.g. thyroid) - Fish VTG (vitellogenin) assay (estrogenic related)
<p>Level 4</p> <p><i>In vivo</i> assays providing data about multiple endocrine Mechanisms and effects</p>	<ul style="list-style-type: none"> - enhanced OECD 407 (endpoints based on endocrine mechanisms) - male and female pubertal assays - adult intact male assay - Fish gonadal histopathology assay - Frog metamorphosis assay
<p>Level 5</p> <p><i>In vivo</i> assays providing data on effects from endocrine & other mechanisms</p>	<ul style="list-style-type: none"> - 1-generation assay (TG415 enhanced)¹ - 2-generation assay (TG416 enhanced)¹ - reproductive screening test (TG421 enhanced)¹ - combined 28 day/reproduction screening test (TG 422 enhanced)¹ - Partial and full life cycle assays in fish, birds, amphibians & invertebrates (developmental and reproduction) <p><small>1 Potential enhancers will be considered by VMG mamm</small></p>

OECD Task Force on Endocrine Disrupters Testing and Assessment (EDTA)

Tasks:

- Enhancements and modifications of existing Test Guidelines;
- Development of new Test Guidelines;
- Management of validation work, as appropriate;
- Development of harmonised strategy for the screening and testing of endocrine disrupters;
- Sharing testing and assessments

Endocrine Disrupters Testing and Assessment

Development of new test methods:

- Uterotrophic assay
- Hershberger assay
- Fish screening tests (3 tests)
- Fish full life cycle test
- Amphibian screening and testing methods

OECD Endocrine Disrupters Testing and Assessment

Revision of existing test methods:

- TG 407: 4-week systemic toxicity study,
- TG 416: 2-generation reproduction study,
- TG 206: avian reproduction study



WHO IPCS



Global Assessment

of the
State-of-the-Science of

Endocrine Disruptors

WHO/PCS/EDC/02.2

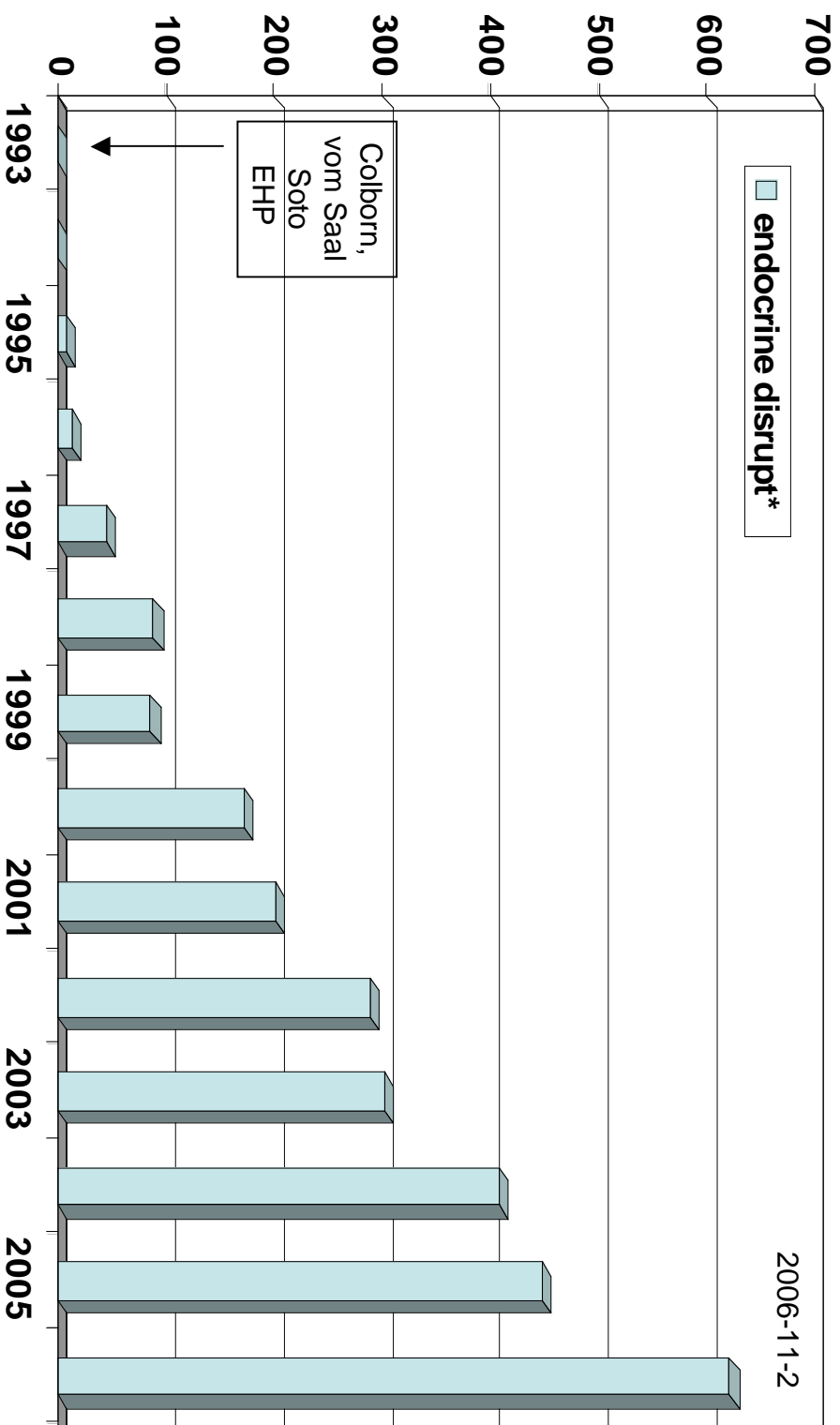
<http://ehp.niehs.nih.gov/who>

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Die Wissenschaftliche Gemeinde

Paper über Umwelthormone



Verbreitung von Fehlverhalten

Nature 435, 737-738 (9 June 2005)

Scientists behaving badly

Martinson et al.



Fehlverhalten	%
Grobe Verstöße (Datenfabrikation usw.)	≈ 0.5
Inadäquate Protokollierung	27.7
Design, Methode oder Ergebnisse auf externen Druck geändert	20.6
Einzelne Ergebnisse gefühlsmäßig entfernt	14.3
Fehlverhalten anderer ignoriert	12.2
Widersprechende Ergebnisse ignoriert	6.5

Nach Schäfer & Liess 2006

Über die Unabhängigkeit der Wissenschaft

Parteilichkeit in der wissenschaftlichen Diskussion

Die Weinberg Gruppe:

„ In Europe, THE WEINBERG GROUP and its associates have had a five-year long history of working on the polycarbonates/bisphenol A issue, It also includes identification of opponent's likely arguments, and formation of responses to counter these arguments.

THE WEINBERG GROUP contributed its academic and regulatory network to the advocacy effort.

This approach proved very effective, as ultimately the C&L working group did not follow the recommendation of the Rapporteur Member State to classify bisphenol A as a Category 2 reproductive toxicant, agreeing instead on the more benign Category 3 classification.

We have a long-term relationship with this client, and will continue to support this industry as it faces persistent NGO attacks on its products.”



The Prague Declaration on Endocrine Disruption 2005

- Europeans are exposed to low levels of a large number of endocrine disrupters which can act in concert. Many of these chemicals, drugs or natural products are found in human tissues and in breast milk. Humans are exposed to these chemicals from very early on in their lives when the developing organism can be particularly sensitive.
- The existing safety assessment framework for chemicals is ill-equipped to deal with endocrine disrupters. Testing does not account for the effects of simultaneous exposure to many chemicals and may lead to serious underestimations of risk.
- In view of the magnitude of the potential risks associated with endocrine disrupters, we strongly believe that scientific uncertainty should not delay precautionary action on reducing the exposures to and the risks from endocrine disrupters.

The Prague Declaration on Endocrine Disruption 2005

Dr Romy van Aerle (University of Exeter, UK) Dr Radka Alexy (Institute of Environmental Medicine and Hospital Epidemiology, Germany) Prof. Felix Althaus (University of Zurich, Switzerland) Dr. Anna Maria Andersson (University Department of Growth and Reproduction, Rigshospitalet, Denmark) Christian Anussek (Johann-Wolfgang Goethe Universität Fankfurt am Main, Germany) Dr Jean Bachmann (Johann-Wolfgang Goethe Universität Fankfurt am Main, Germany) Dr. Thomas Backhaus (University of Göteborg, Sweden) Alice Barbado (University of Milan, Italy) Prof. Dominique Bealonne (Association for Research and Treatment's Againts Cancer, Hospital Georges Pompidou, France) Prof. Vladimir Bencko (Charles University in Prague, Czech Republic) Patrizia di Benedetto (Johann-Wolfgang Goethe Universität Fankfurt am Main, Germany) Dr Emilio Benfantei (University of Milan "Mario Negri", Italy) Nicola Beresford (Brunel University, United Kingdom) Dr Pia Bernsson (Lund University, Sweden) Dr Linda S. 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Das ist wichtig

- Problem Umwelthormone nur in internationaler Kooperation lösbar
- Erforschen, Erkennen, Bewerten, Regulieren bedürfen der Zusammenarbeit
- Ist REACH ein Schritt voran oder ein Schritt im Kreis?
- Die entscheidenden Beratungen finden in dieser Woche statt.



18/02/2004
Press Release
UNEP/204

**STOCKHOLM CONVENTION ON PERSISTENT
ORGANIC POLLUTANTS**

TO ENTER INTO FORCE 17 MAY 2004

GENEVA/NAIROBI, 18 February (UNEP) -- The 2001 Stockholm Convention on Persistent Organic Pollutants (POPs) will become legally binding on 17 May 2004, the United Nations Environment Programme (UNEP) announced today.

1962

2004

Vielen dank für Ihre Aufmerksamkeit

