



EUROPEAN ENVIRONMENTAL BUREAU

The European Environmental Bureau supports the identification of BBP, DEHP, DBP and DIBP as substances of high concern because of their endocrine disrupting properties as proposed by Denmark.

The endocrine disrupting properties of these four phthalates have been well described in the scientific literature (see references below), as summarized in the Annex XV dossier presented by Denmark.

BBP, DEHP, DBP and DIBP are present in a wide range of consumer articles. They are ubiquitous contaminants that can be found in all European Environment compartments (air, waters -even rain water, soils) as well as in blood and urine samples of all sampled European population (see references below).

These phthalates have already been identified as SVHC on the basis that they are toxic to reproduction (Repr. 1B), and, although it is known that the reprotoxic effects of phthalates are endocrine mediated, the endocrine disrupting properties of these substances have not been taken into account by RAC during the opinion development on several applications for authorization.

Furthermore, RAC derived reference DNEL for several phthalates (DEHP, DBP, BBP). In our view, it is not scientifically possible to establish a safe level of exposure for endocrine disruptors. Indeed, EU scientists have reached a consensus that there may be no thresholds for endocrine disrupting chemicals (EDC) as concluded at the Meeting on EDCs at the Office of the European Commission's Chief Scientific Adviser, held in Brussels on 24 October 2013.

According with REACH article 60(3a), adequate control route shall not apply for substances meeting the criteria in CMR or article 57(f) for which it is not possible to determine a threshold in accordance with Section 6.4 of Annex I;

However, RAC dismissed the ED properties of the stated phthalates and assumed that (by default) a DNEL can be set for all reprotoxicants disregarding the reprotoxicity and endocrine disruption overlapping endpoints of phthalates as well as its mixture effects.

As a consequence, using these reference DNELs and not taking into account ED properties, RAC has concluded in several opinions on applications for authorization, that the risks posed by some of these phthalates (DEHP, DBP) to the general public and in many cases also to workers are adequately controlled.

Therefore, the identification of BBP, DEHP, DBP and DIBP as substances of high concern on the basis of their endocrine disrupting properties is necessary in order to phthalates being considered as non threshold substances and hence adequately protect European citizens' health and the environment from their risks.

REFERENCES ENDOCRINE DISRUPTING PROPERTIES

- **The European OBELIX (Obesogenic endocrine disrupting chemicals: linking prenatal exposure to the development of obesity later in life)**
- Reproduction research. **The influence of antenatal exposure to phthalates on subsequent female reproductive development in adolescence: a pilot study.** Roger Hart¹, Dorota A Doherty^{1,2}, Hanne Frederiksen³, Jeffrey A Keelan^{1,2}, Martha Hickey⁴, Deborah Sloboda⁵, Craig E Pennell^{1,2}, John P Newnham^{1,2}, Niels E Skakkebaek³ and Katharina M Main³
- **Marine Environmental Research. Volume 96**, May 2014, Pages 19–28. Pollutant Responses in Marine Organisms” (PRIMO17). **Intersex condition and molecular markers of endocrine disruption in relation with burdens of emerging pollutants in thicklip grey mullets (*Chelon labrosus*) from Basque estuaries (South-East Bay of Biscay).** C. Bizarro^{a,b}, O. Ros^c, A. Vallejo^c, A. Prieto^c, N. Etxebarria^{b,c}, M.P. Cajaraville^{a,b}, M. Ortiz-Zarragoitia^a: <http://www.sciencedirect.com/science/article/pii/S014111361300189X>
- **High plasticizer levels in males linked to delayed pregnancy for female partners.** <http://www.nih.gov/news/health/mar2014/nichd-05.htm>
- **Teen health problems linked to BPA, phthalates.** <http://www.mnn.com/health/fitness-well-being/stories/teen-health-problems-linked-to-bpa-phthalates>
- **Urinary phthalates linked to early puberty in boys.** <http://www.healio.com/endocrinology>
- **Study finds possible link between phthalates and endometriosis.** <http://chemicalwatch.com/15912/study-finds-possible-link-between-phthalates-and-endometriosis>
- **Adverse Effects of Phthalates On Ovarian Response to IVF.** <http://www.sciencedaily.com/releases/2013/07/130708103428.htm>
- **JPEN J Parenter Enteral Nutr.** 2007 May-Jun;31(3):188-93. **Diethylhexylphthalate extracted by typical newborn lipid emulsions from polyvinylchloride infusion systems causes significant changes in histology of rabbit liver.** Loff PD, Subotic U, Oulmi-Kagermann J, Kränzlin B, Reinecke MF, Staude C.
- Report shows that **blood bags made of DEHP-plasticised PVC pose a significant risk to human health, due to both DEHP and PVC.** <http://www.pvcfreebloodbag.eu/>
- **International Journal of Andrology. Special issue on the Impact of Endocrine Disrupters on Reproductive Health :** <http://onlinelibrary.wiley.com/doi/10.1111/ija.2012.35.issue-3/issuetoc>

- **Phthalates and Perfluorooctanesulfonic Acid in Human Amniotic Fluid: Temporal Trends and Timing of Amniocentesis in Pregnancy:** <http://dx.doi.org/10.1289/ehp.1104522>
- **Common Plastics Chemical Might Boost Diabetes Risk:** http://health.usnews.com/health-news/news/articles/2012/04/12/common-plastics-chemical-might-boost-diabetes-risk_print.html
- **Maternal Prenatal Urinary Phthalate Metabolite Concentrations and Child Mental, Psychomotor, and Behavioral Development at 3 Years of Age.** Robin M. Whyatt, Xinhua Liu, Virginia A. Rauh, Antonia M. Calafat, Allan C. Just, Lori Hoepner, Diurka Diaz, James Quinn, Jennifer Adibi, Frederica P. Perera, Pam Factor-Litvak
 - [http://reseau-environnement-sante.fr/wp-content/uploads/2012/04/Veille_phtalates_au_1-04-12.pdf](http://reseau-environnement-sante.fr/wp-content/uploads/2012/04/Veille-phtalates-au-1-04-12.pdf)
 - http://reseau-environnement-sante.fr/wp-content/uploads/2012/03/Veille_phtalates_au_16-03-12.pdf
- Ecotoxicol Environ Saf. 2007 Sep;68(1):118-25. Epub 2006 Jun 30. **Toxicity study of maternal transfer of polychlorinated biphenyls and diethyl phthalate to 21-day-old male and female weanling pups of Wistar rats.** Pereira C, Rao CV.
- Environmental Health Perspectives. **Association between pregnancy loss and urinary phthalate levels around the time of conception.** Toft, G, BAG Jönsson, CH Lindh, TK Jensen, NH Hjollund, A Vested and JP Bonde. 2011:
<http://dx.doi.org/10.1289/ehp.1103552>.
- **Prenatal Exposure to Phthalates and Infant Development at 6 Months: Prospective Mothers and Children's Environmental Health (MOCEH) Study.** Yeni Kim, Eun-Hee Ha, Eui-Jung Kim, Hyesook Park, Mina Ha, Ja-Hyeong Kim, Yun-Chul Hong, Namsoo Chang, Bung-Nyun Kim

- **Phthalates and Cumulative Risk Assessment. The Task Ahead** (2008)
- Environment International journal homepage: www.elsevier.com/locate/envint.
Phthalates exposure of Chinese reproductive age couples and its effect on male semen quality, a primary study. Liangpo Liu a,1, Huaqiong Bao b,1, Feng Liu a, Jie Zhang a, Heqing Shen a,? a Key Lab of Urban Environment and Health, Institute of Urban Environment, Chinese Academy of Sciences, Xiamen 361021, PR China b Chongqing Institute of Science and Technology for Population and Family Planning, Chongqing, 400020, PR China, E-mail address: hqshen@iue.ac.cn (H. Shen) Corresponding author at:1799JimeiDa Dao,Xiamen,361021,PRChina.Tel./fax:+86 592 6190771.
- Endocrinology. 2010 Jul;151(7):3348-62. Epub 2010 May 12. **Molecular mechanisms mediating the effect of mono-(2-ethylhexyl) phthalate on hormone-stimulated steroidogenesis in MA-10 mouse tumor Leydig cells.** Fan J, Traore K, Li W, Amri H, Huang H, Wu C, Chen H, Zirkin B, Papadopoulos V. The Research Institute of the McGill University

Health Centre, Montreal General Hospital, 1650 Cedar Avenue, Room C10-148, Montreal, Quebec, Canada H3G 1A4.

REFERENCES EXPOSURE

- http://www.naturalnews.com/046602_French_wines_phthalates_lab_tests.html#
- Inherent to inhalers: **Phthalates leach into pharmaceutical contents.**
<http://www.separationsnow.com/details/ezine/14512d2ec17/Inherent-to-inhalers-Phthalates-leach-into-pharmaceutical-contents.html?tzcheck=1>
- **Food Control, Volume 41**, July 2014, Pages 185–192. **Plasticizer residues by HRGC–MS in espresso coffees from capsules, pods and moka pots.** [Giuseppa Di Bella, Angela Giorgia Potortì, Vincenzo Lo Turco, Marcello Saitta, Giacomo Dugo:](https://doi.org/10.1016/j.foodcont.2014.04.011)
<http://www.sciencedirect.com/science/article/pii/S0956713514000401>
- **GLOBAL 2000 campaign on EDCs in cosmetics:** <https://www.global2000.at/hormonell-wirksame-chemikalien-kosmetika>
- **Swedish tests highlight plastic contaminants:** <http://www.endseurope.com/36731/swedish-tests-highlight-plastic-contaminants>
- **PVC: a unique story.** Chemical Watch. Global Business Briefing, April 2014 / Europe, United States
- **Plasticiser DEHP is ingested mainly through food:**
 1. [Phthalat-Belastung der Bevölkerung in Deutschland: Expositionsrelevante Quellen, Aufnahmepfade und Toxikokinetik am Beispiel von DEHP und DINP Band I: Exposition durch Verzehr von Lebensmitteln und Anwendung von Verbraucherprodukten](#)
 2. [Phthalat-Belastung der Bevölkerung in Deutschland: Expositionsrelevante Quellen, Aufnahmepfade und Toxikokinetik am Beispiel von DEHP und DINP Anhang zu Band I: Datenbasis zur Exposition durch Lebensmittelverzehr und Verbraucherprodukte](#)
 3. [Phthalat-Belastung der Bevölkerung in Deutschland: Expositionsrelevante Quellen, Aufnahmepfade und Toxikokinetik am Beispiel von DEHP und DINP Band II: Ergänzende Messungen von DEHP, DINP und DiNCH in Lebensmitteln und Migrationsmessungen in Verbraucherprodukten](#)
 4. [Phthalat-Belastung der Bevölkerung in Deutschland: Expositionsrelevante Quellen, Aufnahmepfade und Toxikokinetik am Beispiel von DEHP und DINP Band III: Humane Toxikokinetikstudie](#)
- **Infant bodies absorb phthalates in floors:** <http://scienceblog.com/54605/infant-bodies-absorb-phthalates-in-floors/>
- http://reseau-environnement-sante.fr/wp-content/uploads/2012/02/Veille_Internet_phtalates_a_28-02-12.pdf

- Chemosphere. Volume 81, Issue 10, November 2010, Pages 1171-1183. **Exposure patterns of UV filters, fragrances, parabens, phthalates, organochlor pesticides, PBDEs, and PCBs in human milk: Correlation of UV filters with use of cosmetics.** Margret Schlumpfa, Karin Kypkeb, Matthias Wittassekc, Juergen Angererc, 1, Hermann Mascherd, Daniel Mascherd, Cora Vökte, Monika Birchlere and Walter Lichtensteigera a GREEN Tox and Institute of Anatomy, University of Zurich, Winterthurerstrasse 190, Zurich, Switzerland b State Institute for Chemical and Veterinary Analysis of Food, Bissierstrasse 5, Freiburg, Germany c Occupational Toxicology and Food Chemistry, Institute and Outpatient Clinik of Occupational, Social and Environmental Medicine, Friedrich-Alexander-University, Kochstrasse 19, Erlangen, Germany d Pharm-analyt Labor, Ferdinand-Pichler-Gasse 2, Baden, Austria e University Women's Hospital, Spitalstrasse 21, Basel, Switzerland Received 5 August 2010; accepted 29 September 2010. Available online 27 October 2010.