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NGO comments on the RAC and SEAC opinion on the Danish phthalate dossier

Dear Commissioners,

Our nine organisations are writing to you jointly as a response to the conclusions drawn by the two scientific committees of the Chemicals Agency (ECHA), the Committee for Risk Assessment (RAC) and the Committee for Socio-economic Analysis (SEAC), that the Danish proposal of restriction of four classified phthalates (DEHP, DBP, BBP, and DIBP) in articles is not justified.

We welcome that the RAC, based on the Danish proposal, now recognizes in principle the potential for "combination effects", and thus has enabled the future banning of substances based on their combined effects due to the same mechanism of action. This conclusion is extremely important as it acknowledges reality where chemicals don't act in isolation but people and wildlife are exposed to multiple substances at the same time.

This recognition also emphasizes that epidemiology needs to abandon its outdated focus on single endocrine disrupters and has to embrace the reality of endocrine disrupter mixture effects by developing biomarkers that capture cumulative exposure to endocrine disrupters. Moreover it shows that in the absence of epidemiological and toxicological data that deals with mixtures, it is questionable to assume that chemicals are not exerting combination effects, and do not pose a risk.

Therefore we strongly disagree with the conclusion from RAC and SEAC that the available data in the Danish dossier does not indicate that currently (2012) there is a risk from combined exposure to the four phthalates. Given that the RAC accepts that the Danish dossier may have over-estimated or indeed under-estimated some current exposure routes we do not consider that the RAC's conclusion is robust. The RAC should decide on whether there is a need for restriction based on the best available data at this time, and the available biomonitoring data shows that there could be a risk from the combined exposure to the four phthalates both for children and for adults. An ongoing EU research project on human biomonitoring, Democophes, in preliminary results is showing combined exposures. In Germany for example researchers taking samples over

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this last year found slightly higher exceedance of (German) reference values for the phthalate DEHP compared to a prior biomonitoring project (GerES, which in 2003-06 already found exceedance), and for some phthalates higher maximum levels.

One of the committee's arguments to not support the Danish proposal is that the risk characterization ratios (RCRs) are only slightly above 1, and that a reduction of phthalates used in the last couple of years might have further lowered this value. In light of this our organisations want to draw attention to the data available on low-dose effects and the scientifically proven effects due to concurrent exposure to several chemicals with combination effects[1,2,3,4]. Even though the amount of the four phthalates in use might be decreasing, there will still be an exposure – a low dose exposure that could result in adverse combination effects. Here, it should be also borne in mind that there will be other anti-androgenic substances to which the human population is exposed, in addition to these 4 phthalates. For example, a recent report (sampling performed between April and June 2011) done by the Swedish Society for Nature Conservation ("Home sweet home? – dusty surprises under the bed"[5]) shows that we are exposed to a wide range of substances from the dust in our homes. Just considering dust from homes, the findings showed that the total level of phthalates (BBP[*], DBP[*], DEHP[*] and DINP), were in some countries found to be higher than what public authorities today consider to be safe, if the combination effects were considered. And since Europeans spend as much as 90 percent of their time indoors, it is very important to find a way to deal with the problem of combination effects – most effectively done through legislation by restrictions.

This Swedish report is based on samples that were collected between April and June 2011 and thus originate after the restrictions on three of the four phthalates in toys and childcare articles.

Another study[6], just published (2012) by the Danish Ministry of the Environment, shows that pregnant rats' exposure to a combination of five different endocrine disrupting chemicals, at very low doses, can have adverse effects on the rat pups. The rats were given drugs at doses which individually do not cause an effect. The study showed that the combination of drugs prolonged gestation in dams, had serious effects on male offspring genitals, and led to a higher level of pesticides in the pups' blood than when they were exposed to

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[1] Silva E, Rajapakse N, Kortenkamp A 2002 Something from "nothing": eight weak estrogenic chemicals combined at concentrations below NOECs produce significant mixture effects. Environ Sci Technol 36:1751–1756

[2] Benachour N, Moslemi S, Sipahutar H, Seralini GE 2007 Cytotoxic effects and aromatase inhibition by xenobiotic endocrine disrupters alone and in combination. Toxicol Appl Pharmacol 222:129–140

[3] Rajapakse N, Silva E, Kortenkamp A 2002 Combining xenoestrogens at levels below individual no-observed-effect concentrations dramatically enhances steroid hormone activity. Environ Health Perspect 110:917–921

[4] Laura N. Vandenberg, Theo Colborn, Tyrone B. Hayes et al., Hormones and Endocrine-Disrupting Chemicals: Low-Dose Effects and Nonmonotonic Dose Responses. Endocrine Reviews, June 2012, 33(3): 0000-0000. Edrv.endojournals.org

[5] The report was presented as supportive data during the public consultation process. Reference number: 07d62328-e727-437f-ae58-d23e72f76324
http://www.naturskyddsforeningen.se/upload/Foreningsdokument/Rapporter/Dammrapport_eng_klar_lowres.pdf

[*] The same phthalates as in the Danish proposal

[6] http://www.food.dtu.dk/upload/fødevareinstituttet/food.dtu.dk/publikationer/2012/developmental_toxicity_effects_in_experimental_animals.pdf

one chemical at a time. The study did not specifically include phthalates but other endocrine disrupters that are likely to have similar mechanism of action as phthalates.

Besides the real concern about low-dose effects and combination effects, it is a fact that the products used as examples in the Danish Annex XV dossier are still on the market. In general it cannot be assumed that the authorisation process will reject the use of phthalates in all relevant consumer products in the EU. Moreover, the authorization process will evaluate the phthalates as separate substances and does not take into account that they act as a chemical cocktail. Furthermore, products that are imported from non-EU countries are not subject to the authorisation process. The fact that in 2010, 60 % of all products that were included in the EU RAPEX list for products posing a serious risk to the health and safety of consumers were made in China makes clear that there is a significant loophole in the authorization process.

Very worryingly, the RAC argumentation that the RCRs calculated in the Danish dossier are not sufficiently above 1 is in direct conflict with the EU chemical legislation. Risk assessment officially is based on the precautionary principle[7]. The Committees should follow the REACH legal text, which says; "To ensure a sufficiently high level of protection for human health, including having regard to relevant human population groups and possibly to certain vulnerable sub-populations, and the environment, substances of very high concern should, in accordance with the precautionary principle, be subject to careful attention". So even a RCR at or slightly above 1 should be taken very seriously and acted upon!

In their rejection of the Danish proposal, RAC also uses the "very worst case" scenarios that are used in the dossier as an argument. These scenarios show that the total RCR for each age-group is above 1. It might be an overestimated exposure scenario, but taking into account that the articles used as examples in the dossier are just a limited selection of all the sources of exposure that we are exposed to, the scenario presented in the Danish dossier could as well be underestimated[8]. Given these uncertainties, the application of the precautionary principle is all the more warranted.

NGOs are urging the European Commission to take a decision on the restriction of the four phthalates that is based on the precautionary principle. Furthermore, it should prepare concrete amendments to deal with the combination effects of chemicals in existing EU legislation, in particular REACH, in order to protect the health of Europe's citizens and environment. We also call on companies and EU Member States to enhance the substitution of hazardous chemicals with safer alternatives and adopt reduction measures to reduce exposures to hormone disrupting chemicals.

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[7] "The precautionary principle provides justification for public policy actions in situations of scientific complexity, uncertainty and ignorance, where there may be a need to act in order to avoid, or reduce, potentially serious or irreversible threats to health or the environment, using an appropriate level of scientific evidence, and taking into account the likely pros and cons of action and inaction". Gee D 2006 Late Lessons from Early Warnings: Towards Realism and Precaution with Endocrine Disrupting Substances. Environmental Health Perspectives, Vol 114, Supplement 1

[8] see for example list of article notifications for Dibutyl phthalate (DBP), the phthalate driving the combined risk assessment in the restriction proposal, http://echa.europa.eu/documents/10162/a8cb2dfb-5d3c-4401-b72c-417bcce716a5

Yours sincerely,

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