TEMPLATE

for third party submission of information on alternatives for

Applications for Authorisation

NON-CONFIDENTIAL

Legal name of submitter(s): *CHEM Trust*

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1. ALTERNATIVE ID AND PROPERTIES

DEHP has already been replaced by many companies in numerous applications with different alternatives (see Ref 1-3) and the development of safer alternatives has been ascribed to regulatory measures (Ref 4). Granting this authorization would undermine those companies' efforts that already substituted DEHP with less toxic alternatives and help laggards to make continued profits from toxic chemicals which have already been replaced by other substances, materials or technical solutions and are available on the market.

CHEM Trust considers that the authorization application is not specific enough with regard to the use and should therefore not be accepted. The application covers a large variety of different consumer products (except for a few excluded ones) which would lead to human and environmental exposure during the production, use and disposal. We would have expected the broad scope to be a reason for a rejection during the ECHA conformity check, as the applicant seems to seek a general authorization and not a use-specific one.

2. TECHNICAL FEASIBILITY

[Insert text here]

3. ECONOMIC FEASIBILITY

[Insert text here]

4. HAZARDS AND RISKS OF THE ALTERNATIVE

[Insert text here]

5. AVAILABILITY

[Insert text here]

6. CONCLUSION ON SUITABILITY AND AVAILABILITY OF THE ALTERNATIVE

[Insert text here]

7. OTHER COMMENTS

a) Limited information provided in public consultation

The information provided in the public consultation on ECHA's website has some important gaps, in particular the exposure levels as well as substance quantities produced and used are missing for this application. We also expressed this concern in the joint NGO letter to ECHA, sent on 16.12.2013.

The non-confidential version of the exposure scenario is very general and basically meaningless without the CSR which is kept confidential. Instead of giving details on exposure levels the summary simply states: "The CSR demonstrates that there is no risk from exposure to DEHP for industrial/professional workers and to consumers. The risks are adequately controlled."

It is not possible to know the relevance and implications of the applications without the total volumes involved in that use. It is estimated that 70 000-120 000 tonnes of DEHP are currently placed on the market in the EU (Ref 5). The majority of DEHP produced is thought to be used as PVC plasticizer so the authorization is likely related to a very significant proportion of DEHP use and production.

b) Procedure should use "Socio-economic route" instead of "adequate control"

In our opinion it is not appropriate to consider the authorization of DEHP through the adequate control route but instead the socio-economic route should be applied: DEHP is classified as a reprotoxic substance and it is a known endocrine disrupter. We are aware that RAC argues that only the specified property in Annex XIV has to be addressed (classification as reprotoxic) and therefore a DNEL can be set. However, RAC's decision to set reference DNELs pre-empted the result of the analysis of whether a safe DNEL can be derived at all. If all available literature were considered from the start it would have become evident that it is very difficult, if not impossible, to set a reliable threshold for DEHP given that the reprotoxicity is endocrine mediated. We consider that as DEHP clearly has endocrine disrupting properties, which result in its reprotoxicity, this gives rise to increased uncertainties in the risk assessment.

In addition, it is well-known that the general population all over Europe is widely exposed to several phthalates at the same time, DEHP just being one of them (Ref 6). In fact, many consumer articles contain a mixture of different phthalates, several of them have already been included in the REACH candidate list. Research has demonstrated additive effects for the anti-androgenic properties of several phthalates which target the male reproductive tract and contribute to the same adverse effects (Ref 7). Even though authorization is substance-specific in our view the science available clearly shows that a single level based on considering a single substance in isolation will not be protective for human health and environment.

REFERENCES

1) RIVM, Final report, December 2013: Analysis of alternatives for a group of phthalates, AMEC Environment and Infrastructure UK Limited

2) Electronics without flame retardants and PVC, a market overview, ChemSec, 2010, http://chemsec.org/what-we-do/influencing-public-policy/rohs/alternatives-are-available

3) SUBSPORT Database, http://www.subsport.eu/case-stories

4) Driving Innovation – how stronger laws help bring safer chemicals to the market, The Center for International Environmental Law (CIEL), February 2013 http://www.ciel.org/Publications/Innovation_Chemical_Feb2013.pdf

5) Non-confidential summary of SEA by ARKEMA, Azoty and Deza, *e.g.* here: http://www.echa.europa.eu/documents/10162/eb8396e6-1657-46dc-b01f-1a95e60da90f

6) EU Biomonitoring, Democophes, http://www.eu-hbm.info/democophes

7) National Academy of Sciences (NAS) Final report: Phthalates and Cumulative Risk Assessment, 2008, http://cfpub.epa.gov/ncea/cfm/recordisplay.cfm?deid=202508

APPENDIXES

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