

Status of Substance Evaluation of BPA by MS - Rapporteur Germany

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Substance Evaluation under REACH – Community Rolling Action Plan (CoRAP) I

First CoRAP published on February 29th, 2012

90 Substances are scheduled for evaluation in the years 2012, 2013 and 2014, further nominations expected

36 Substances will be evaluated in 2012.

Substance Evaluation under REACH – Community Rolling Action Plan (CoRAP) II

Substance Evaluation Report on BPA by Germany

When necessary, Member states will prepare a Draft Decision requesting further information to clarify the concern.

Submission date by February 28th, 2013

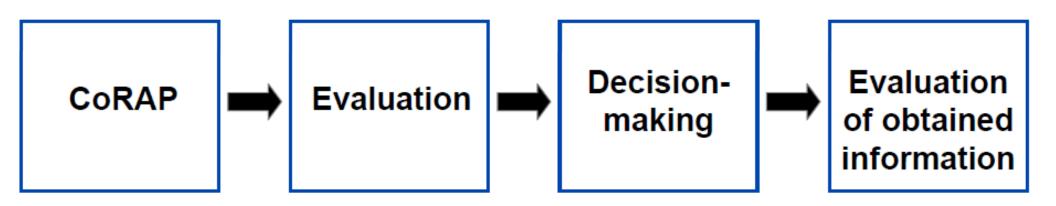
Grounds for Concern (BPA)

- 1. Environment monitoring data for sediment concentrations indicate underestimated exposure
- 2. Information on toxicity towards snails indicate underestimated effects.
- 3. Production volume & exposure estimates based on production volumes from past 15 Member States only. Current registrations include those from Member States that joint later indicate higher exposure than calculated in the EU risk assessment.
- 4. Overestimation of degradation in sewage plant might result in underestimation of exposure, e.g., by the use of recycled toilet paper. It contains BPA due to fractions of thermal paper used for recycling in which Bisphenol A acts as developer.
- 5. Several studies indicate that BPA is an endocrine disruptor resulting in adverse effects at very low concentrations (at least low µg/L range) in aquatic organisms. Risk calculated by PEC/PNEC ratios might underestimate the concern for the environment due to the endocrine disrupting mechanism of action.

Grounds for Concern (BPA): Summary

- 1. Suspected endocrine disruptor (environment)
- 2. Exposure/wide dispersive use
- 3. Consumer use
- 4. High aggregated tonnage

Substance evaluation – Process steps



Follow up actions

From ECHA, 2012

Substance evaluation – Process for decision making

ebruary 29th, 2012 February 28th, 2013 MSCA MSCA MSCA ECHA Evaluation of Consistency Amendments Preparation of draft available data to DD screening decision (DD) Preparation of DD to ECHA DD to ECHA evaluation report (2 months before deadline) Ν New data needed? MSCA Consider how to use information CoRAP list 12 months after Inform ECHA of published publication of conclusions CoRAP

From ECHA, 2012

Substance evaluation – State of play

The evaluation is still in progress therefor no information can be given.

Possible Draft Decision outcome:

- Requirement of further studies (even non standard information requirements)
- Requirement of further data on exposure
- Recommendation of risk management measures (EU-wide restriction, EU-wide authorisation, Non-REACH measures ...)



Thank you for your attention

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SEV decision making process timelines

