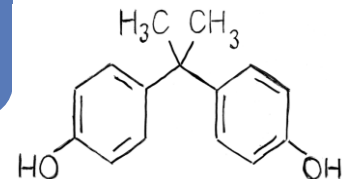


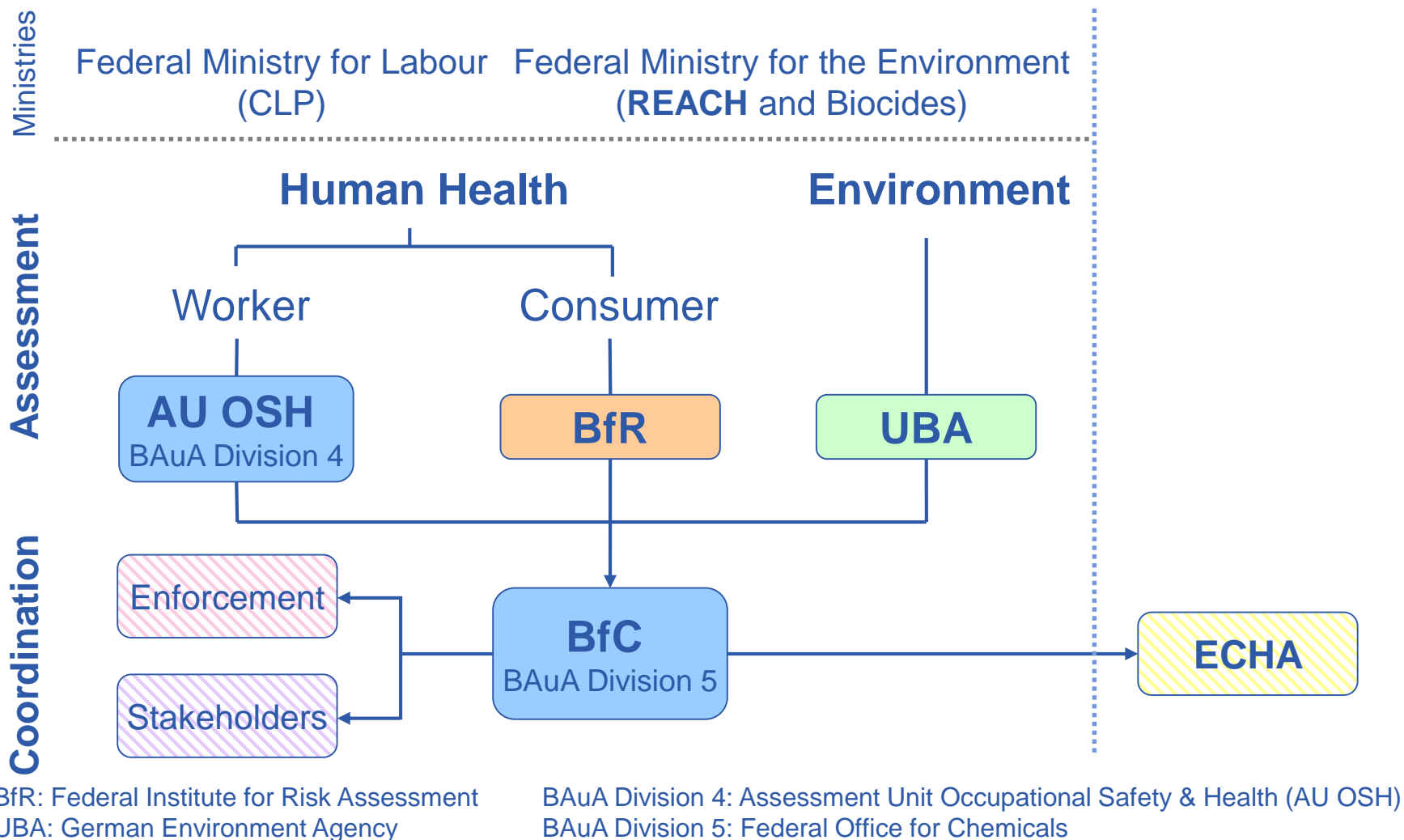


Bundesanstalt für Arbeitsschutz und Arbeitsmedizin

Bisphenol A
State of play of
REACH processes



REACH – Involved agencies in Germany



Substance evaluation of BPA by Germany (1)

03/2012: Inclusion of BPA on the first Community Rolling Action Plan (CoRAP) for substance evaluation; formal start of the assessment by DE (*BfC, BfR and UBA*)

Initial concerns: Suspected endocrine disruptor; Exposure/
Wide dispersive use; consumer use; high aggregated tonnage

12/2013: Decision sent to BPA registrants with further information requirements to clarify concerns

- *in vitro* skin Absorption test (OECD 428)
- **Further information on emission pathways of Bisphenol A to the environment**

12/2016: Conclusion of evaluation without further information requests

05/2017: Publication of BPA substance evaluation report

CoRAP 2012-2014: https://echa.europa.eu/documents/10162/13628/corap_2012_en.pdf/0f6967f5-b6b3-484b-896f-32bfb3598ba9

Substance evaluation of BPA by Germany (2)

Conclusion of the substance evaluation:

Human health:

- No further regulatory measure necessary.
- Risk characterisation ratio >1 for specific article categories based on worst-case assumptions.

Environment:

- The available data on BPA is sufficient to conclude on endocrine disrupting properties for the environment and SVHC identification according to Art. 57 f) REACH.
- Further measures will be necessary to minimise emissions to the environment.

Initiation of a Regulatory Management Option Analysis by DE

Substance evaluation report on BPA: <https://echa.europa.eu/documents/10162/2e8ac666-fae6-2e54-f0eb-ef4a5da819ed>

Regulatory Management Option Analysis (RMOA)

- The endocrine disrupting properties of BPA for environmental organisms require addressing via a regulatory measure
- Initiation of the national RMOA process
- 01/2017: Inclusion of BPA RMOA by DE in ECHA's PACT (Public Activities Coordination Tool) overview
- Start of two-month consultation of registrants and downstream users of BPA and related associations
- 05/2017: Meeting with commenting parties on status of RMOA
- 07/2017: Publication of the RMOA conclusion document on ECHA's website (PACT section)

Identified RMO: SVHC identification (ENV ED) followed by restriction

Published RMOA Conclusion on BPA: <https://echa.europa.eu/documents/10162/816f026b-e24c-5600-3beb-6696976d5044>

SVHC identification of BPA by DE and FR

Identification according to Art. 57 c) due to reprotoxic properties and due to Art. 57 f) due to endocrine disrupting properties for human health by FR

- 08/2016: Annex XV (Art. 57 c) dossier submitted by FR
- 12/2016: First inclusion of BPA on the candidate list
- 02/2017: Annex XV (Art 57 f) dossier submitted by FR
- 07/2017: Update of candidate list entry for BPA

Identification according to Art. 57 f) due to endocrine disrupting properties for the environment by DE

- 08/2017: Annex XV dossier submitted by DE
- 12/2017: Update of candidate list entry for BPA
- Legal action against the identification is still pending (T-207/18).

DE Annex XV dossier on BPA: <https://echa.europa.eu/documents/10162/12d03565-e386-c6cd-0f5b-4851d2dd2767>

T-207/18: https://eur-lex.europa.eu/legal-content/EN/TXT/?toc=OJ%3AC%3A2018%3A190%3ATOC&uri=uriserv%3AOJ.C_.2018.190.01.0035.01.ENG

Recommendation of BPA for Inclusion in Annex XIV

- ECHA is required to recommend substances from the candidate list (SVHCs) to the Commission for inclusion in Annex XIV („Authorisation list“) at least biannually.
- The prioritisation for recommendation is points-based and the score for substances is composed of intrinsic properties, tonnage and use profiles of the substances (3 criteria with max. 15 points/criterion → maximum score of 45 for prioritisation candidates)
- BPA is included in the 9th recommendation of ECHA on 1st place.
- Including BPA, the 9th recommendation contains 18 substances which were submitted to the Commission by ECHA in October 2019.

Status of the Prioritisation for Annex XIV

- The last inclusion of substances on Annex XIV REACH by the Commission occurred in February 2019 on the basis of the 7th and 8th recommendation of ECHA (submitted in November 2016 and February 2018 to the Commission).
- The German Regulatory Management Option Analysis (RMOA) concludes that the Authorisation procedure triggered by inclusion on Annex XIV is not the most suitable regulatory measure for BPA.
- Instead, a **tailored restriction should be pursued for BPA** which regulates those uses which lead to an emission into the environment.

Restriction under REACH (1)

Definition (Art 3.31 REACH)

Restriction: means any condition for or prohibition of the manufacture, use or placing on the market

Restrictions are a tool to protect human health and/or the environment from unacceptable risks posed by chemicals

Restrictions are a first hand choice when

- Introducing bans on substances of very high concern when authorisation is no option
- Eliminating unacceptable risks from chemicals by imported articles (cloth, plastics, toys, etc.)

Restrictions are included in Annex XVII REACH.

Restriction under REACH (2)

Restrictions may be imposed on (acc. to Art. 67 and 68)

- manufacture, use and/or placing on the market
- a substance on its own, in a preparation or in an article

when

- there exists an unacceptable risk to human health or the environment
- this risk needs to be addressed on a Community-wide basis

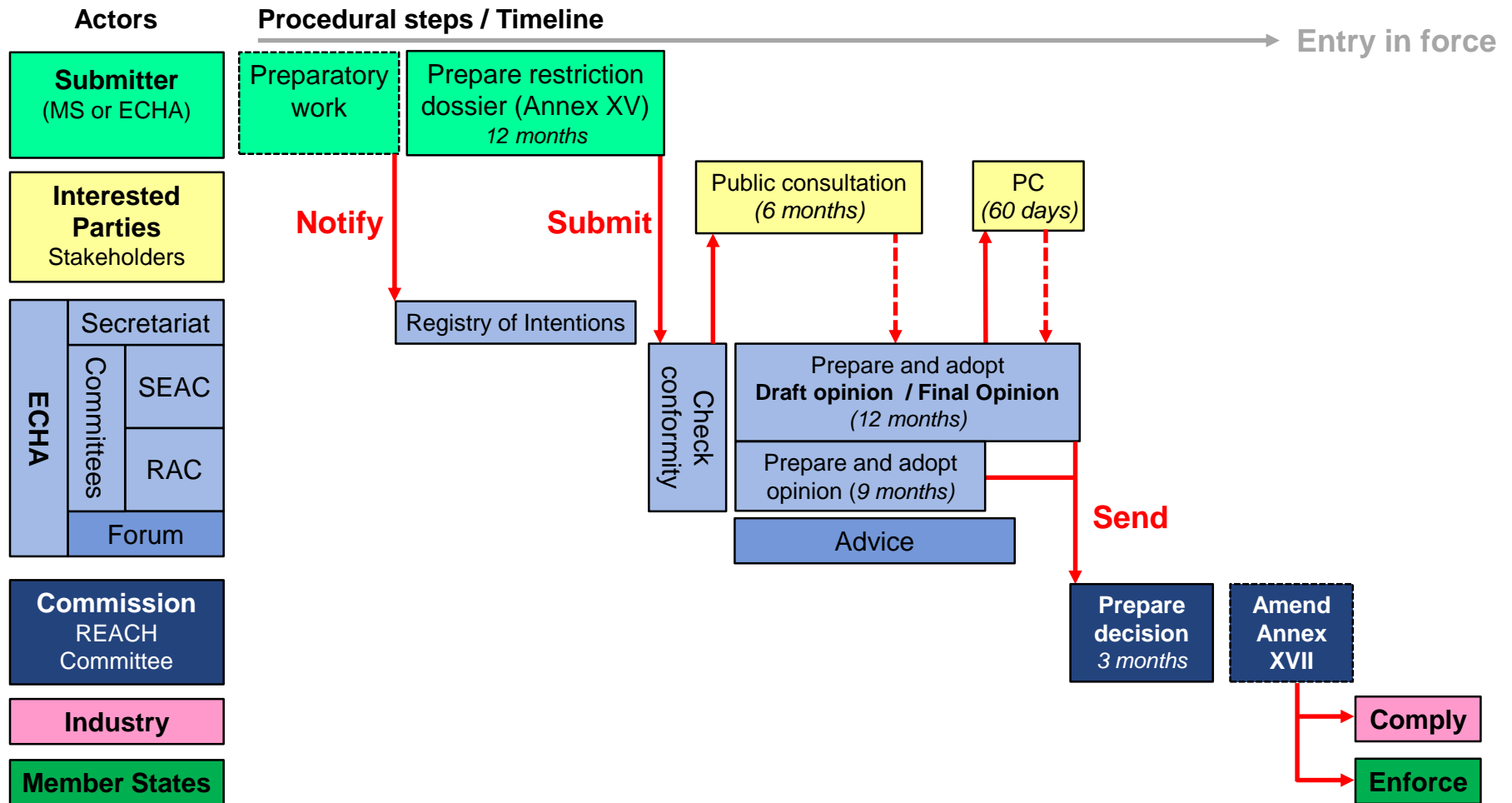
Restrictions are applicable to products from EU and non-EU origin (i.e. also imports)!

General exemptions (Art. 67):

scientific research and development

risks to human health due to use in cosmetic products (76/768/EEC)

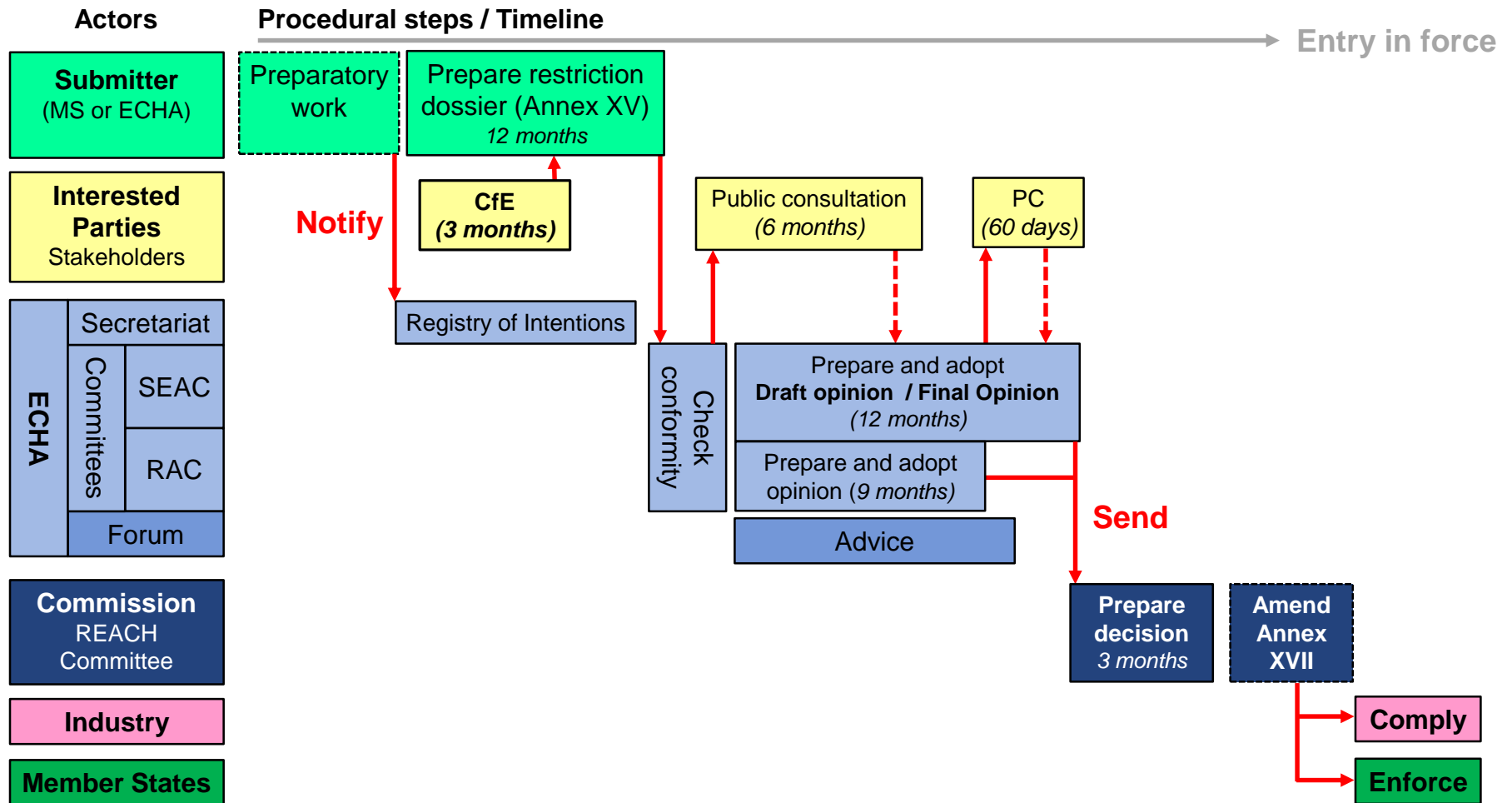
Restriction Procedure under REACH



Planned Restriction on BPA – Next Steps

- The intention to restrict BPA is intended to be published on **1 October 2020** in the „Registry of Intentions“ at ECHA’s website.
- Consequently, the Annex XV restriction dossier has to be submitted on **1 October 2021** at the latest.
- **Formal public consultation** of the dossier will be launched after the conformity of the dossier has been approved by ECHA’s scientific committees.
- Before submission, it is intended to hold an additional, informal „**Call for Evidence**“ („CfE“, 3 months duration, start of the consultation currently anticipated for November 2020)

Restriction Procedure under REACH



Thank you very much for your kind attention!

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PACT (Public Activities Coordination Tool)

https://echa.europa.eu/de/pact?p_p_id=disspact_WAR_disspactportlet&p_p_lifecycle=0&disspact_WAR_disspactportlet_substanceId=100.001.133&disspact_WAR_disspactportlet_jspPage=%2Fhtml%2Fportlet%2Fdisspact%2FdetailsPage%2Fview_detailsPage.jsp

ECHA Website: CoRAP Section on REACH Substance Evaluation of BPA

<https://echa.europa.eu/de/information-on-chemicals/evaluation/community-rolling-action-plan/corap-table/-/dislist/details/0b0236e1807e375d>

ECHA Website: Resources on the SVHC identification procedures on BPA

https://echa.europa.eu/de/proposals-to-identify-substances-of-very-high-concern-previous-consultations?diss=true&search_criteria_ecnumber=201-245-8&search_criteria_casnumber=80-05-7&search_criteria_name=4%2C4%27-isopropylidenediphenol