



# EU Collaboration on assessment of Bisphenols

**Claudia Roncancio**

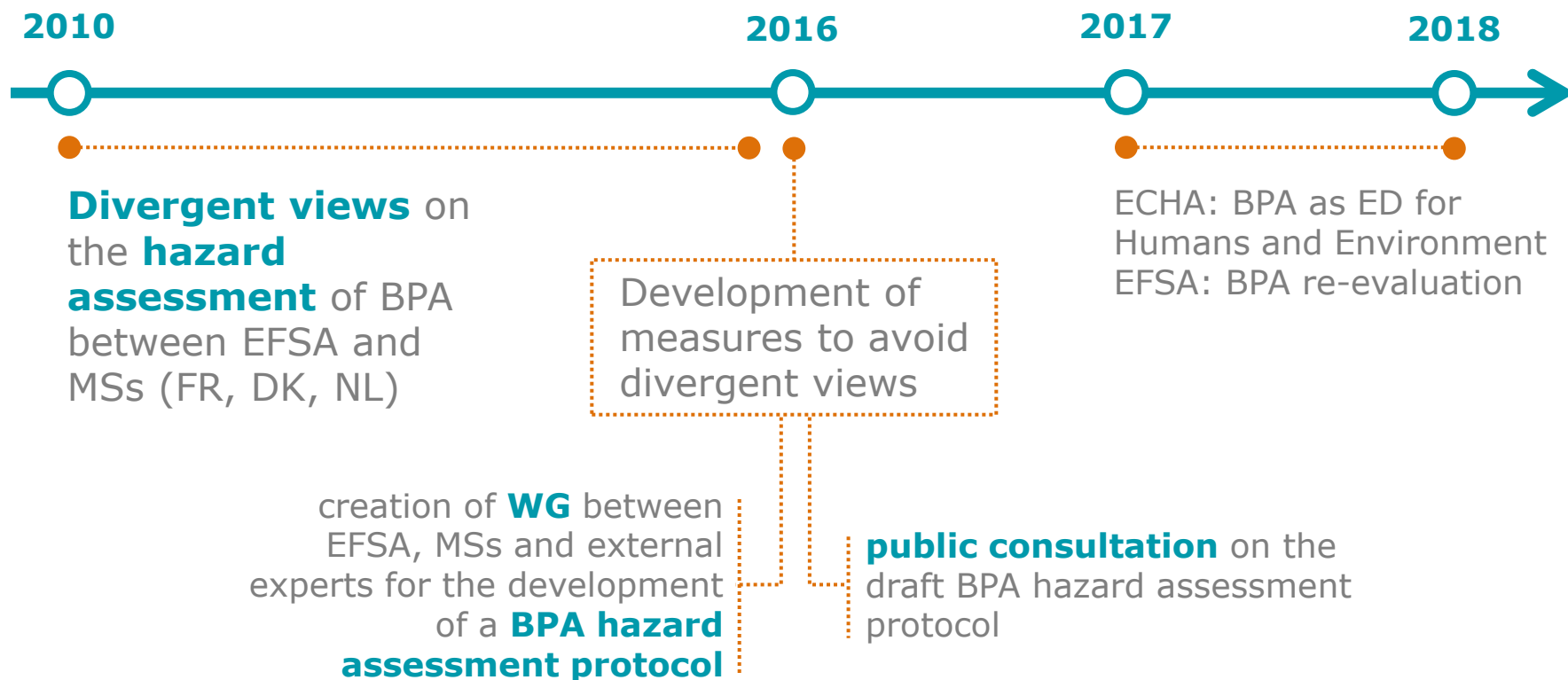
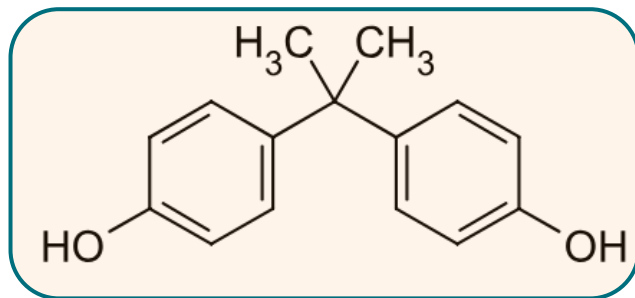
Head of FIP Unit

17 September 2018

# OUTLINE

- **Background:** past work and divergences on assessment of **Bisphenol A** (BPA)
- **Current work:** assessment of **Bisphenol S** (BPS)
  - *a case study for a broader cooperation?*
- **Future tasks:** assessment of all **other bisphenols**
  - *need for a more effective collaboration on assessment of Bisphenols?*

# Bisphenol A (BPA) – divergent views



# Bisphenol S (BPS) – current work

- BPA and **BPS** under EFSA's Food Contact Materials remit
- EC aware of current work on BPS and liaison between authorities on possible co-operation



- BPS Registered under **REACH**
- BPS placed on the Community Rolling Action Plan (**CoRAP**) list for **Substance Evaluation** as **suspected CMR** and **potential ED**

## EU Member States



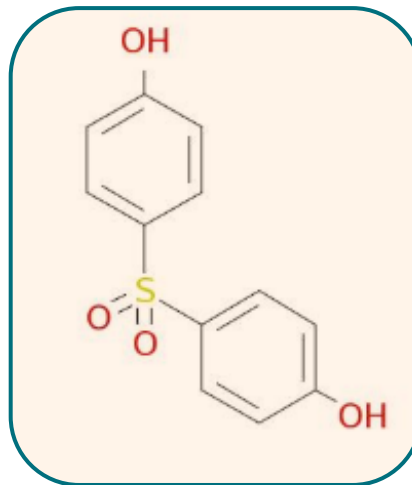
- **Substance Evaluation** of BPS by **Belgium**
- BPS **new toxicological and exposure data**  
**DL: 20.09.2018** but delay is expected



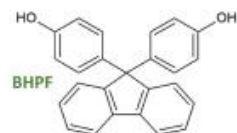
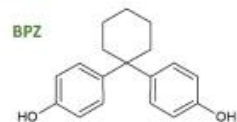
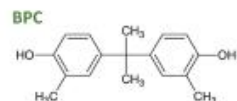
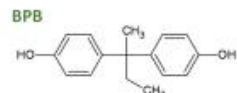
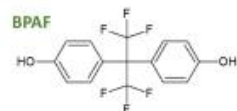
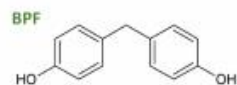
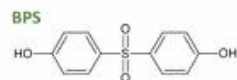
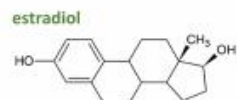
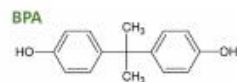
- Expected EC mandate to **re-evaluate BPS** as **Food Contact Material**
- Communication with ECHA, MS and Industry to obtain the new data generated

# BPS: a case study for a broader cooperation?

- **EFSA** proposes to align the **evaluation of the new studies** generated under REACH **with Belgium and ECHA**
- A **BPS Task Force** (Belgium, ECHA, EFSA, other MSs?) could promote interagency and member states' cooperation and engagement while avoiding duplication of work and possible divergent opinions



# BPA, BPS, ... and what is next?



**CHEMTrust**

Protecting humans and wildlife from harmful chemicals

## From BPA to BPZ: a toxic soup?

How companies switch from a known hazardous chemical to one with similar properties, and how regulators could stop them

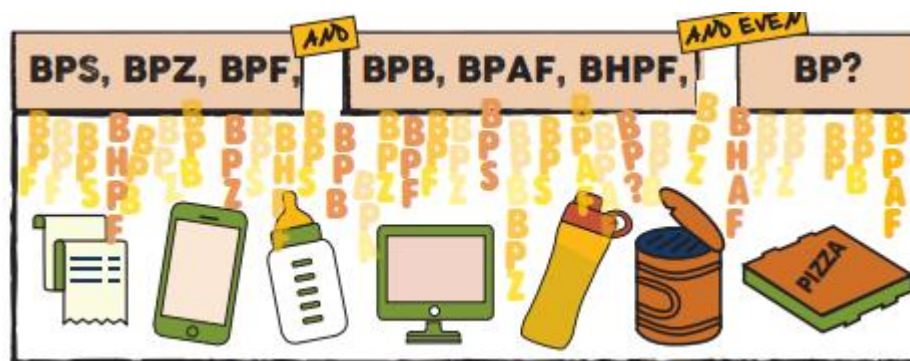


Figure 1: Structures of selected bisphenols (estradiol given for reference)

- <http://www.chemtrust.org/wp-content/uploads/chemtrust-toxicsoup-mar-18.pdf>

# ECHA: current work on bisphenols/1

- Further data generation and assessment
  - Evaluation processes
  - Assessment of ED properties: in addition to BPA and BPS, the ED expert group has also discussed BPM (BE), DGEBA and TBBPA (both from DK), TMBPF (FR)
- Hazard identification
  - Harmonised classification
    - E.g 2,2-bis(4'-hydroxyphenyl)-4-methylpentane as Repro 1B
  - Identification of substances of very high concern (SVHC)
    - 2,2-bis(4'-hydroxyphenyl)-4-methylpentane currently in the identification process

# ECHA: current work on bisphenols/2



Commission requests  
ECHA to conduct a  
market research on the  
use of BPA and  
alternatives in thermal  
paper \*



Second report published

2016

2017

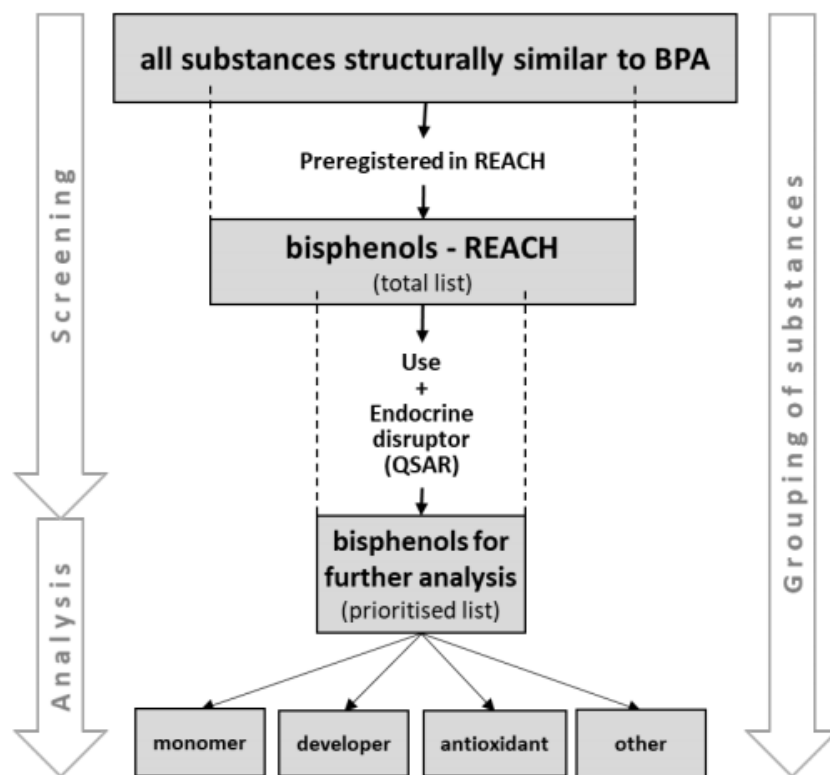
2018

First report published



[https://echa.europa.eu/documents/10162/22863068/bpa\\_in\\_thermal\\_paper\\_report\\_en.pdf/0d93cd76-345e-2ed4-698f-a3beaea6d755](https://echa.europa.eu/documents/10162/22863068/bpa_in_thermal_paper_report_en.pdf/0d93cd76-345e-2ed4-698f-a3beaea6d755).

# KEMI: grouping approach on Bisphenols



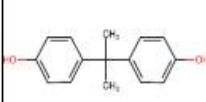
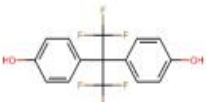
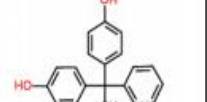
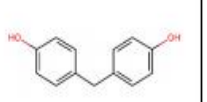
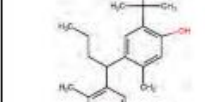
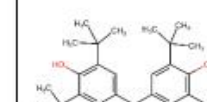
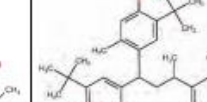
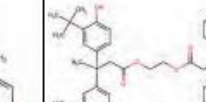
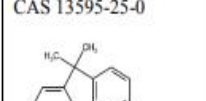
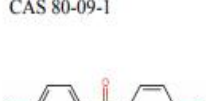
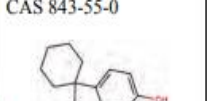
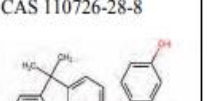
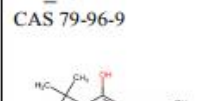
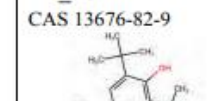
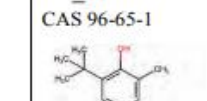
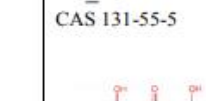
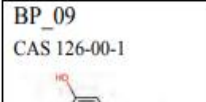
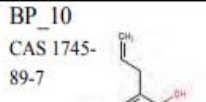
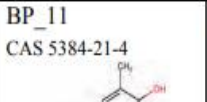
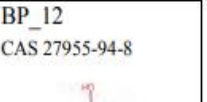
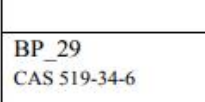
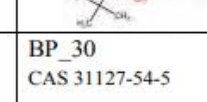
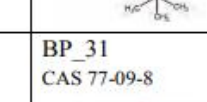
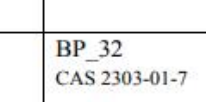
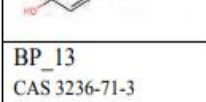
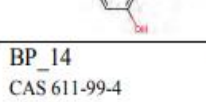
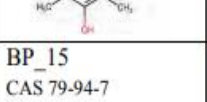
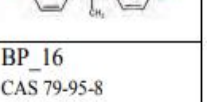
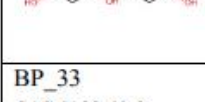
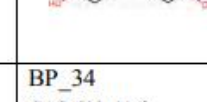
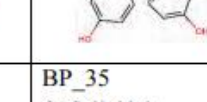
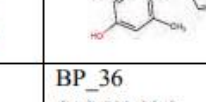
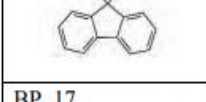
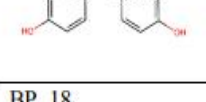
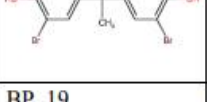
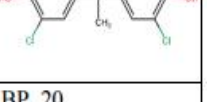
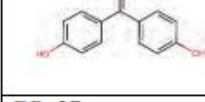
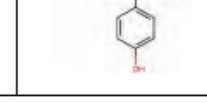
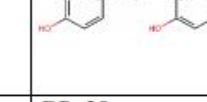
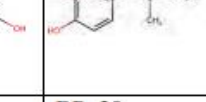
**KEMI**  
 Swedish Chemicals Agency

Grouping of chemical substances in the REACH and CLP regulations

Figure 9. Method for identifying and prioritising bisphenols. 39 bisphenols were subject to a more detailed review.

- <https://www.kemi.se/en/global/rapporter/2017/rapport-5-17-bisfenoler-en-kartlaggning-och-analys.pdf>
- <https://www.kemi.se/global/pm/2018/pm-2-18-grouping-of-chemical-substances-in-the-reach-and-clp-regulations1.pdf>

# KEMI: grouping approach on Bisphenols

|                                                                                                                          |                                                                                                                           |                                                                                                                           |                                                                                                                         |                                                                                                                        |                                                                                                                       |                                                                                                                        |                                                                                                                        |
|--------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------|
| <b>BP_01 (BPA)</b><br>CAS 80-05-7<br>    | <b>BP_02 (BPAF)</b><br>CAS 1478-61-1<br> | <b>BP_03 (BPAP)</b><br>CAS 1571-75-1<br> | <b>BP_04 (BPF)</b><br>CAS 620-92-8<br> | <b>BP_21</b><br>CAS 85-60-9<br>      | <b>BP_22</b><br>CAS 118-82-1<br>   | <b>BP_23</b><br>CAS 1843-03-4<br>   | <b>BP_24</b><br>CAS 32509-66-3<br>  |
| <b>BP_05 (BPM)</b><br>CAS 13595-25-0<br> | <b>BP_06 (BPS)</b><br>CAS 80-09-1<br>    | <b>BP_07 (BPZ)</b><br>CAS 843-55-0<br>   | <b>BP_08</b><br>CAS 110726-28-8<br>    | <b>BP_25</b><br>CAS 79-96-9<br>      | <b>BP_26</b><br>CAS 13676-82-9<br> | <b>BP_27</b><br>CAS 96-65-1<br>     | <b>BP_28</b><br>CAS 131-55-5<br>    |
| <b>BP_09</b><br>CAS 126-00-1<br>         | <b>BP_10</b><br>CAS 1745-89-7<br>        | <b>BP_11</b><br>CAS 5384-21-4<br>        | <b>BP_12</b><br>CAS 27955-94-8<br>     | <b>BP_29</b><br>CAS 519-34-6<br>     | <b>BP_30</b><br>CAS 31127-54-5<br> | <b>BP_31</b><br>CAS 77-09-8<br>     | <b>BP_32</b><br>CAS 2303-01-7<br>   |
| <b>BP_13</b><br>CAS 3236-71-3<br>        | <b>BP_14</b><br>CAS 611-99-4<br>         | <b>BP_15</b><br>CAS 79-94-7<br>          | <b>BP_16</b><br>CAS 79-95-8<br>        | <b>BP_33</b><br>CAS 5189-40-2<br>    | <b>BP_34</b><br>CAS 603-41-8<br>   | <b>BP_35</b><br>CAS 60-82-2<br>     | <b>BP_36</b><br>CAS 500-38-9<br>    |
| <b>BP_17</b><br>CAS 93589-69-6<br>     | <b>BP_18</b><br>CAS 6807-17-6<br>      | <b>BP_19</b><br>CAS 74462-02-5<br>     | <b>BP_20</b><br>CAS 96-69-5<br>      | <b>BP_37</b><br>CAS 36062-04-1<br> | <b>BP_38</b><br>CAS 97-29-0<br>  | <b>BP_39</b><br>CAS 6386-73-8<br> | <b>BP_39</b><br>CAS 6386-73-8<br> |

# Regulatory status/actions under REACH and CLP for registered substances

☐ Under SEV or CoRAP

☐ RMOA under development

☐ Candidate list

☐ SVHC intention

☐ Restriction (Annex XVII)

|                                 |                               |                               |                         |
|---------------------------------|-------------------------------|-------------------------------|-------------------------|
| BP_01 (BPA)<br>CAS 80-05-7 ★    | BP_02 (BPAF)<br>CAS 1478-61-1 | BP_03 (BPAP)<br>CAS 1571-75-1 |                         |
| BP_05 (BPM)<br>CAS 13595-25-0 ★ | BP_06 (BPS)<br>CAS 80-09-1    |                               |                         |
|                                 | BP_10<br>CAS 1745-89-7        | BP_11<br>CAS 5384-21-4        | BP_12<br>CAS 27955-94-8 |
| BP_13<br>CAS 3236-71-3          | BP_14<br>CAS 611-99-4         |                               |                         |
| BP_17<br>CAS 93589-69-6         | BP_18<br>CAS 6807-17-6 ★      | BP_19<br>CAS 74462-02-5       | BP_20<br>CAS 96-69-5    |

|                      |                       |                                  |                         |
|----------------------|-----------------------|----------------------------------|-------------------------|
| BP_21<br>CAS 85-60-9 | BP_22<br>CAS 118-82-1 | BP_23<br>CAS 1843-03-4           | BP_24<br>CAS 32509-66-3 |
|                      |                       |                                  |                         |
|                      |                       | BP_31<br>CAS 77-09-8 ★<br>★<br>★ |                         |
|                      | BP_34<br>CAS 603-41-8 |                                  |                         |
|                      |                       |                                  |                         |

CLH

- ★ Repr 1B
- ★ Repr. 2
- ★ Carc 1B
- ★ Muta 2

# ANSES assessment of Bisphenols

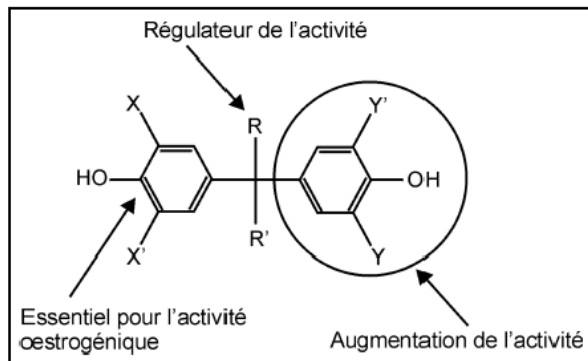


Figure 18 : Relations entre structure et activité oestrogénique pour les bisphénols (Figure extraite du rapport d'expertise collective de l'Inserm « Reproduction et environnement », 2011)

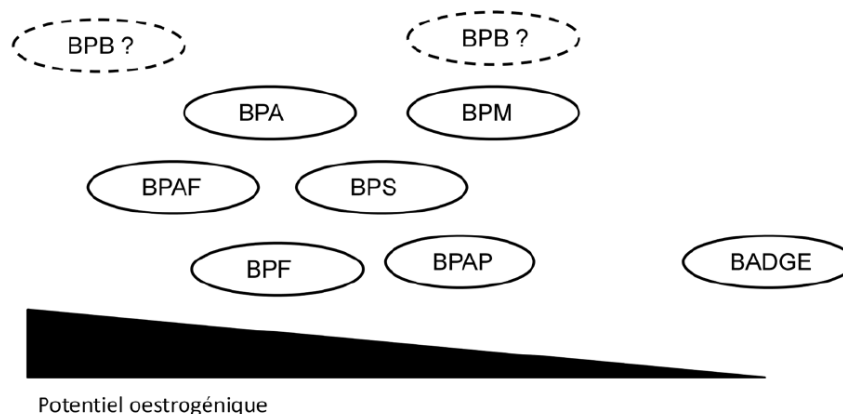


Figure 19 : Illustration de l'activité oestrogénique des différents composés de la famille des bisphénols.

- [“Assessment of the hazards of bisphenol-group compounds” in 2013](#)
- [Substances reprotoxiques et perturbateurs endocriniens Composés de la famille des bisphénols : bisphénols M, S, B, AP, AF, F et BADGE Rapport d'expertise collective, 2013](#)
- [major research programme announced by ANSES](#)

# DG Santé activities

- **DG Santé commitment** to investigate the future of BPA alternatives with a survey with IND on their potential uses
- DG Santé bilateral with EFSA supportive of a **more effective collaboration on assessment of Bisphenols**

# CONCLUSIONS

- **BPS Task Force** as a **case study** which could lead to a broader EU collaboration on bisphenols later
- Advantages of an ***EU Collaboration on assessment of Bisphenols***
  - Better coordination of different activities on bisphenols alternatives, avoiding duplication of work and divergent opinions
  - Promote inter-agency and member states' cooperation and engagement
  - A single EU voice to consumers
- ***What's your view?***