

DTU



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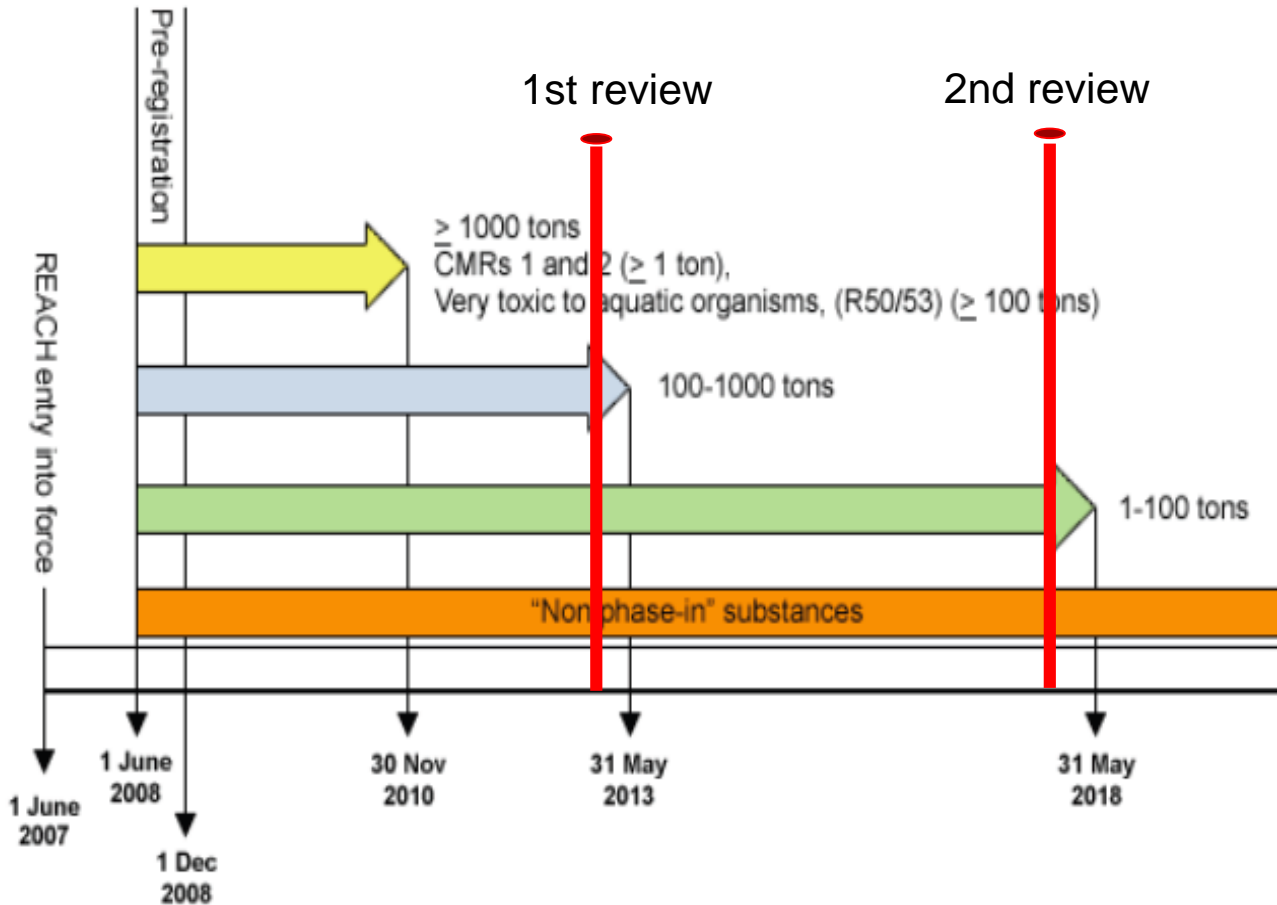
Forsigtighed, usikkerhed og regulering af kemikalier

Opgave stillet

- ”Hvordan **håndteres balancen** mellem forsigtighedsprincip, usikkerhed om kendte og ukendte forureninger og usikkerheden om toksicitet?”
- ”Hvad findes der af **(nye) principper** for regulering af risici/kemikalier?”



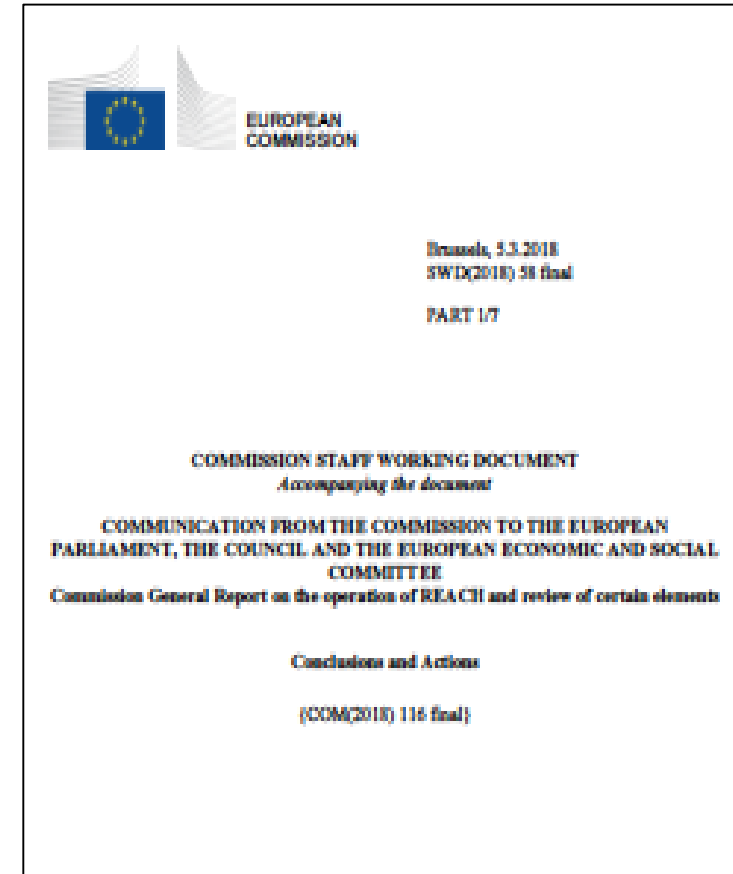
REACH



- Registrations: **97 162**
- Substances: **22 607**
- Companies: **15 076**
- Candidate List of substances of very high concern: **201**
- Authorisation: **43**
- Restriction: **48**

Commission Communication

”As stated in the legal text, **REACH's provisions are underpinned by the precautionary principle**, however, since the entry into force of the legislation, the **risk management actions proposed by the Commission have been limited.**”



Mechanism 4 app of PP under REACH

- **A scientific step**, where the responsible scientific body (ECHA) assesses
 - if the uncertainties are bigger than normal and
 - if the consequences of those uncertainties could lead to a significant undesirable impact;
- **A risk management step**, where the responsible risk management body (the Commission and REACH Committee) decide what action, if any, is required.

Mechanism 4 app of PP under REACH

- A scientific step, where the responsible scientific body (ECHA) assesses
 - if the **uncertainties are bigger than normal** and
 - if the consequences of those uncertainties could lead to a **significant undesirable impact**
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”Bigger than normal uncertainties identified...”

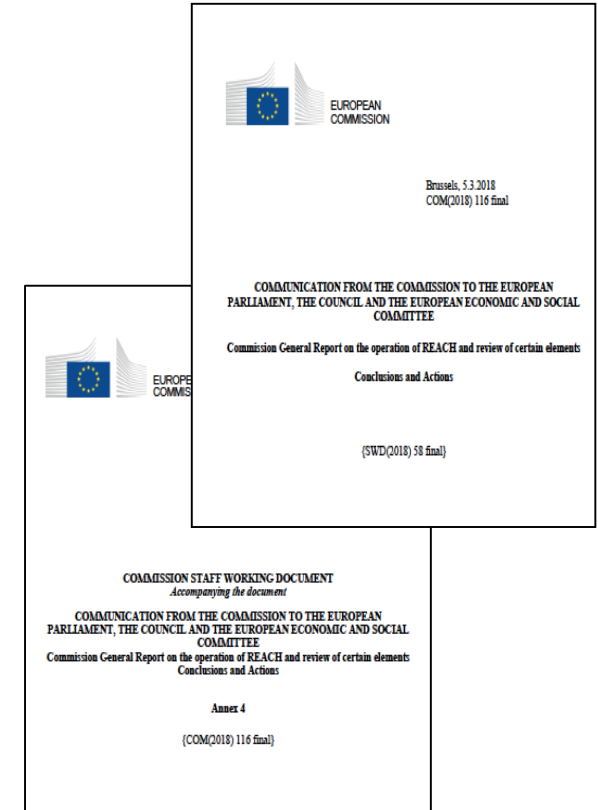
- Bisphenol-A
 - more information where requested on the alternative Bisphenol-S (same risk profile)
- D4/D5
 - more information was requested on products similar to the ones restricted

But so far...

Is this surprising?

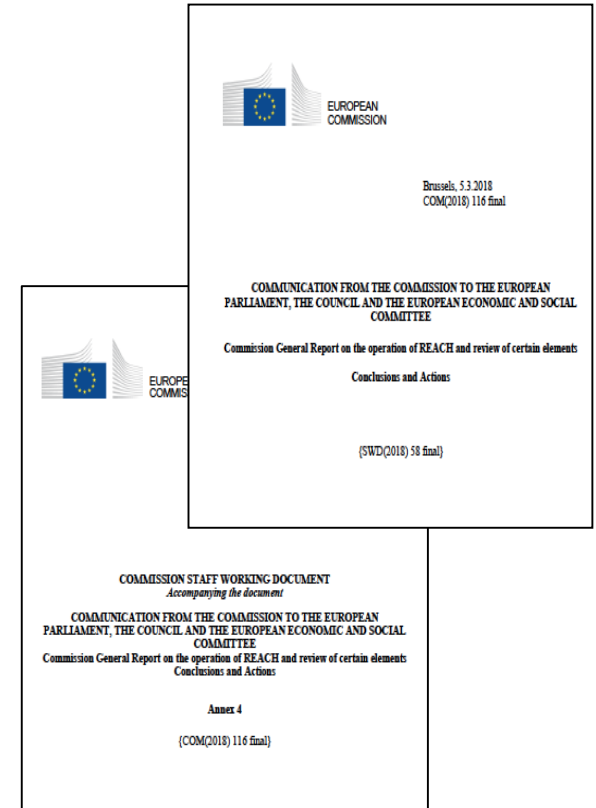
- How much uncertainty is there really about the SVHC?

- The available evidence has in all cases allowed the RAC to conclude **existence**, or **absence** of an unacceptable risk or that **additional information** was needed to concluded.
- As a consequence, ECHA opinions have **not triggered the PP**
- As a consequence, the Commission has **not proposed** measures where action was based on the PP



So in Conclusion

- In most cases, ECHA and its Committees **did not assess** scientific uncertainties to **enable** the Commission to consider possible action based on the PP

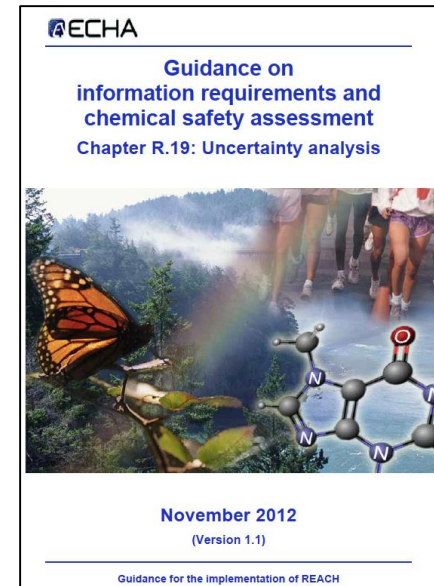


Blaming ECHA - Fair?

- "The principle **could be invoked by ECHA** in cases where there are indications of potential risks while the insufficiency of data, their inconclusive or imprecise nature makes it impossible to determine with sufficient certainty the risk in question."
- "In such cases, **ECHA should highlight to the Commission** which information is needed to clarify the uncertainties, the timeline for generating such information and provide an assessment of the potential consequences of inaction. The restriction task force has identified this issue and recently the Committee assessment on uncertainties has been conducted." **How does ECHA assess/communicate uncertainties?**

How does ECHA assess/communicate uncertainties?

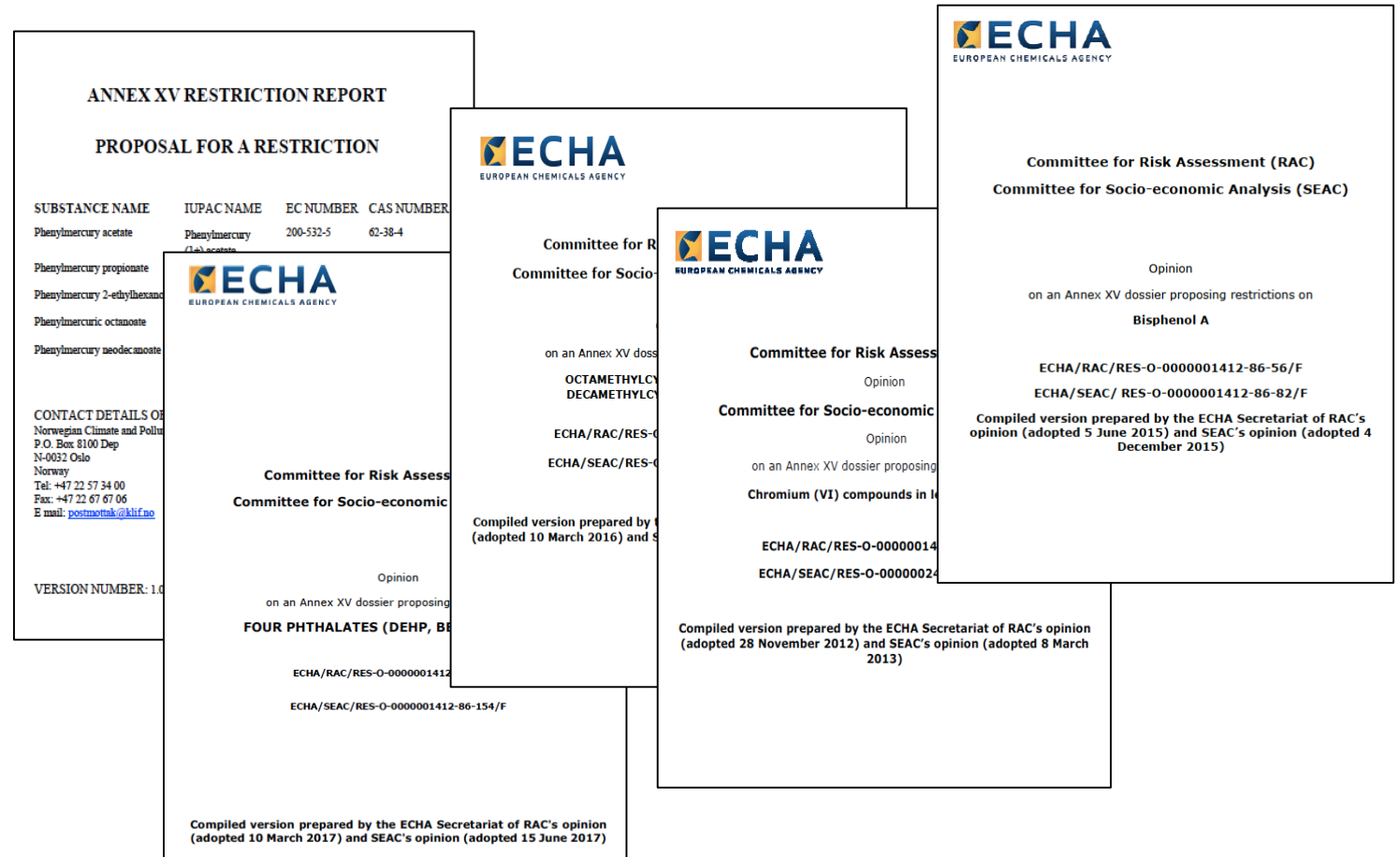
- Tier approach recommended
- Sources of uncertainty
 - Scenario
 - Model
 - Parameter
- ...
- R.19.3.2 Level 1 - Qualitative uncertainty analysis.....16
- R.19.3.3 Level 2 - Deterministic uncertainty analysis.....23
- R.19.3.4 Level 3 - Probabilistic Uncertainty Assessment.....26



Committee for Risk Assessment (RAC)

Committee for Socio-economic Analysis (SEAC)

- Bisphenol A
- Chromium VI
- D4/D5
- Phenylmercury
- Phthalates



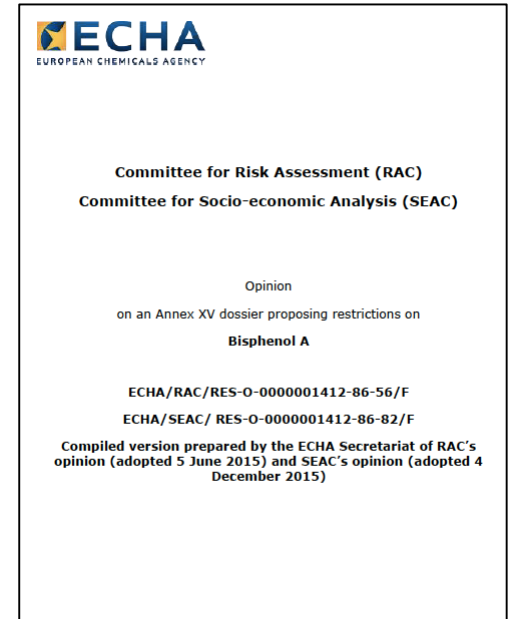
Bisphenol A

1.3.1. Uncertainties in the risk characterisation

The main source of uncertainty to the risk estimates comes from the uncertainties in the derivation of the DNELs. In particular, the available hazard data did not allow for a quantification of the dose-response relationship for effects on the mammary gland, or for the reproductive, immunotoxic, metabolic and neurobehavioural effects. Taking into account the uncertainty analysis carried out by EFSA (2015) and their consequent use of an assessment factor of 6, RAC accounted for these effects by also applying an additional assessment factor of 6 in the DNEL derivation.

The exposure estimates for consumers carry relatively few uncertainties, in part, because biomonitoring data confirms exposure does not exceed the DNEL. Thus the confidence about a correct conclusion is relatively high.

Regarding workers, the available biomonitoring data is scarce and of limited nature, thus providing a lower confidence level to the modelling results when compared to consumer exposure. However the integrated assessment of worker exposure performed by RAC is based on both modeling data and available biomonitoring data, giving reasonable consistency.



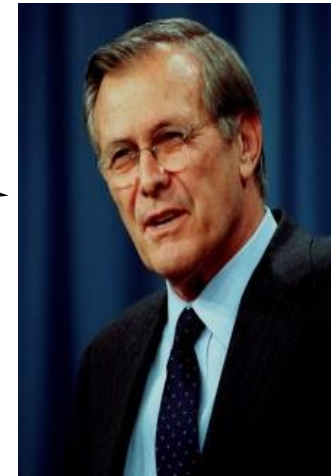
Uncertainty defined narrowly by RAC & SEAC

- The variable chosen
- Measurement made
- Sampling completed
- Selection of the data
- Extrapolation of data



Uncertainty defined too narrowly

"As we know, there are no knowns. There are things, we know we know. We also know there are known unknowns. That is to say we know there are some things we do not know. But there are also unknown unknowns, the ones we don't know we don't know".



Rumsfeld, Former US Secretary of Defense

Opgave stillet

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Principle of Necessity

“In cases where there is a **potentially widespread use** of a chemical, material, technology, care should be taken not only to ensure environment and health and safety, **but also that is really necessary.** **Necessary** defined as absolutely needed and unable to be changed or avoided”

Hansen et al. *In prep.*



Tons of “Useless Products”

The Nanodatabase

SEARCH DATABASE NEWS ANALYSIS NANORISKAT REPORT PRODUCT ABOUT US

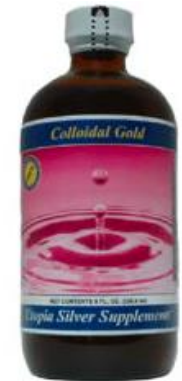
LOGIN ENGLISH

SEARCH THE NANODATABASE

Your inventory for products that contain Nanomaterials

Search for Product Name, Nano Material, Manufacture

There are currently **2,325** products in our database



3. Radiation: early warnings; late effects

Barrie Lambert

“The widespread use of Pedascopes for fitting children’s shoes. These X-ray fluoroscopy devices were in nearly every shoe store in the 1940s and 1950s and could produce reported dose rates of 1 roentgen per minute. They did no more than keep children amused whilst their parents selected shoes and thus the radiation doses received by children and shop staff were **totally unnecessary.**”





**SCIENTIFIC
SHOE FITTING
AT ITS BEST**

On Dr. Scholl's Fluoroscopic Shoe X-ray you can see the position of the bones in your feet right through the shoe. In addition to this checkup other methods of scientific shoe fitting will be employed here during this special demonstration.

Dr. Scholl's **SHOE FITTING
EXPERTS FROM THE
CHICAGO FACTORY**

will be in our store
Monday, February 15th

They bring with them the complete line of Dr. Scholl's Shoes (622 fittings) . . . every size, width and style — for every type foot. X-ray fitting—as well as other Dr. Scholl shoe fitting devices. Now you can obtain the shoe that will give you perfect satisfaction. You will be shown how to fit shoes inexpensively. Be sure to attend this special **DEMONSTRATION**

**GEORGE
WILSON**



Thank you for your attention!

DTU



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