



**Ministry of Environment  
of Denmark**  
Environmental  
Protection Agency

# Toxicology in pesticide & biocide evaluation

DSTF  
21. april 2022  
Charlotta Wallensten

# Centre for SAFE CHEMISTRY

## *Pesticides & Biocides Unit*



- Approval of pesticides, biocides and GMOs.
- Evaluation of active substances in the EU.
- Political action plans - pesticides strategy and biocides strategy.
- Framework directive concerning sustainable use of pesticides.
- The Pesticide Regulation.
- The Biocidal Regulation.
- Administration of subsidies for research on pesticides and biocides.
- Management of subsidies for alternative pesticides.



# Organizations of Pesticides & Biocides Unit



- ~ 70 employees
- 43 working with biocides and pesticides evaluation:
  - Toxicology: 18
  - Ecotoxicology and fate in the environment: 22
  - Physical and chemical properties: 2
  - Efficacy: 1

...and administration, legal issues and management

All pesticides and biocides are evaluated at the active substance level and as a product before they can be placed on the market.

# What do our toxicologists do?



The risk assessment process, in relation to human health entails a sequence of actions which is outlined below.

(1) Assessment of effects, comprising:

(a) hazard identification: identification of the adverse effects which a substance has an inherent capacity to cause; and

(b) hazard characterisation: dose (concentration) - response (effects) assessment: estimation of the relationship between dose, or level of exposure to a substance, and the incidence and severity of an effect, where appropriate.

(2) Exposure assessment: estimation of the concentrations/doses to which human populations (i.e. workers, consumers and human exposed indirectly via the environment) or environmental compartments (aquatic environment, terrestrial environment and air) are or may be exposed.

(3) Risk characterisation: estimation of the incidence and severity of the adverse effects likely to occur in a human population or environmental compartment due to actual or predicted exposure to a substance, and may include “risk estimation”, i.e. the quantification of that likelihood.

Combined exposure to multiple chemicals and dietary risk assessment should also be considered where relevant.

# What do our toxicologists do?



The fundamental concept underlying the approach for human exposure assessment is the need to establish the full range of human exposure situations that could occur from the use of a biocidal product and to consider all routes of exposure. The exposure assessment process therefore requires determination of the:

- Product type / formulation that will be the source of exposure; identification of the exposed population (industrial, professional, non-professional, general public);
- identification of exposure scenarios / patterns of use for each population including routes of exposure;
- calculation & quantification of potential chemical intake

*(from Guidance on the Biocidal Products Regulation Volume III Human Health - Assessment & Evaluation (Parts B+C))*

# What are the specific challenges when dealing with exposure assessment?



**Finding and evaluating safe use – knowledge of how these products are used and what realistic risk mitigation methods are there?**

**What is a realistic worst case scenario?**

**If there are no harmonized scenarios for the exposure of a particular use, how to modify/create one?**

**Assessing risk for ED properties – can acceptable risk or threshold be found?**

