Preparations in Sweden for the requirements of the Biocidal Products Directive

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Who we are and where we come from

- **About us**
- Helena Casabona - Head of Unit for biocidal products and GMO
- Jenny Rönngren - National coordinator for applications

- **About the Swedish Chemicals Agency (KemI)**
- A supervisory authority under the Ministry of the Environment.
- Assesses the risk of chemicals under REACH and CLP.
- Approves plant protection and biocidal products.
- Works in Sweden and in the EU to promote legislation and rules that contributes to achieving the environmental quality objective of ´A non-toxic environment´.
- Maintains a number of databases and keeps a products register.
- Checks companies´ compliance with applicable regulations.
- Provides support to local authorities and to other countries.

- **About the unit for biocidal products and GMO**
- Assesses the applications for authorizations of biocidal products
- Participates in certain EU and OECD meetings

Current situation in Sweden

- Authorization scheme for 13 product types

- **PT 2** * *Applies only to products for use against microorganisms in chemical toilets and products against algea and microorganisms in the sea, lakes and watercourses*
- **PT 8** Wood preservatives
- **PT 9 *** *Applies only to products for use against microorganisms on leather*
- **PT 10** Masonry preservatives
- **PT 12** * *Applies only to products used for the prevention or control of slime growth on machine systems in industrial processes on wood and paper pulp*
- **PT 14** Rodenticides
- **PT 15** Avicides
- **PT 16** Molluscicides
- **PT 17** Piscicides
- **PT 18** Insecticides, acaricides and products to control other arthropods
- **PT 19** Repellents and attractants
- **PT 21** Antifouling products
- **PT 23** Control of other vertebrates

- * = This product type is exempted from the authorisation requirements except for the biocidal products indicated

Current situation in Sweden continued

- Approx. 300 authorized biocidal products on the market at the moment (main groups insecticides, slimicides and wood preservatives)
- 173 authorization holders and representatives for plant protection products and biocidal products
- Fee system – application fee and annual fee, based on cost for actual work
- Requirements almost fully adapted to BPD, except requirement for efficacy data
- Goal from the government for handling of applications – 1 year
- A large number of re-newals between 2008-2010
- Product register for identification of non-authorized biocidal products

Getting ready for the BPD

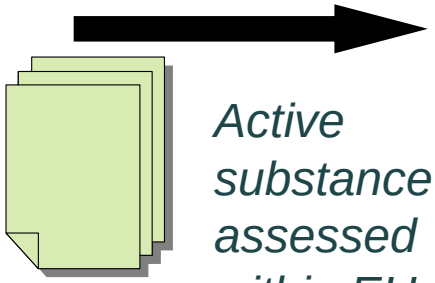
- Preparation in house
  - Internal processes slime lined
  - Coordination function established
  - Clear internal deadlines
  - Increased number of staff (approx. 26 persons)
  - The unit organized in groups per product type
  - Each application handled by a team (tox, ecotox, chemistry)

Getting ready for the BPD, continued

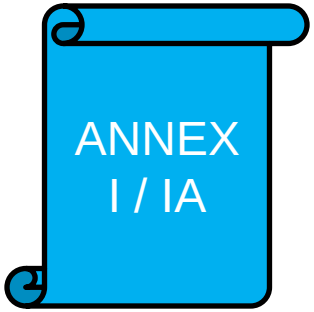
- Information to companies
  - Coordinators responsible for telephone and mail questions
  - Project for updating the KemI website
  - Development of a guide for applicants
  - Letters informing companies of requirements and timelines
  - Meetings with companies with focus on specific product types

Information to companies

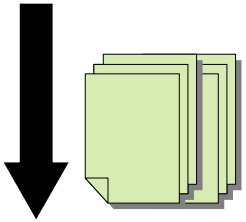
- The following information has been presented to the Swedish companies with rodenticides, wood preservatives, insecticides, repellents and attractants

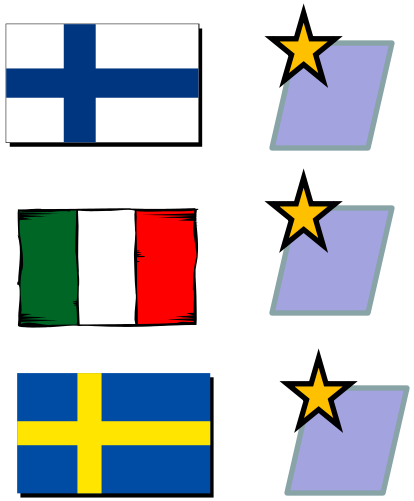


Active substance assessed within EU



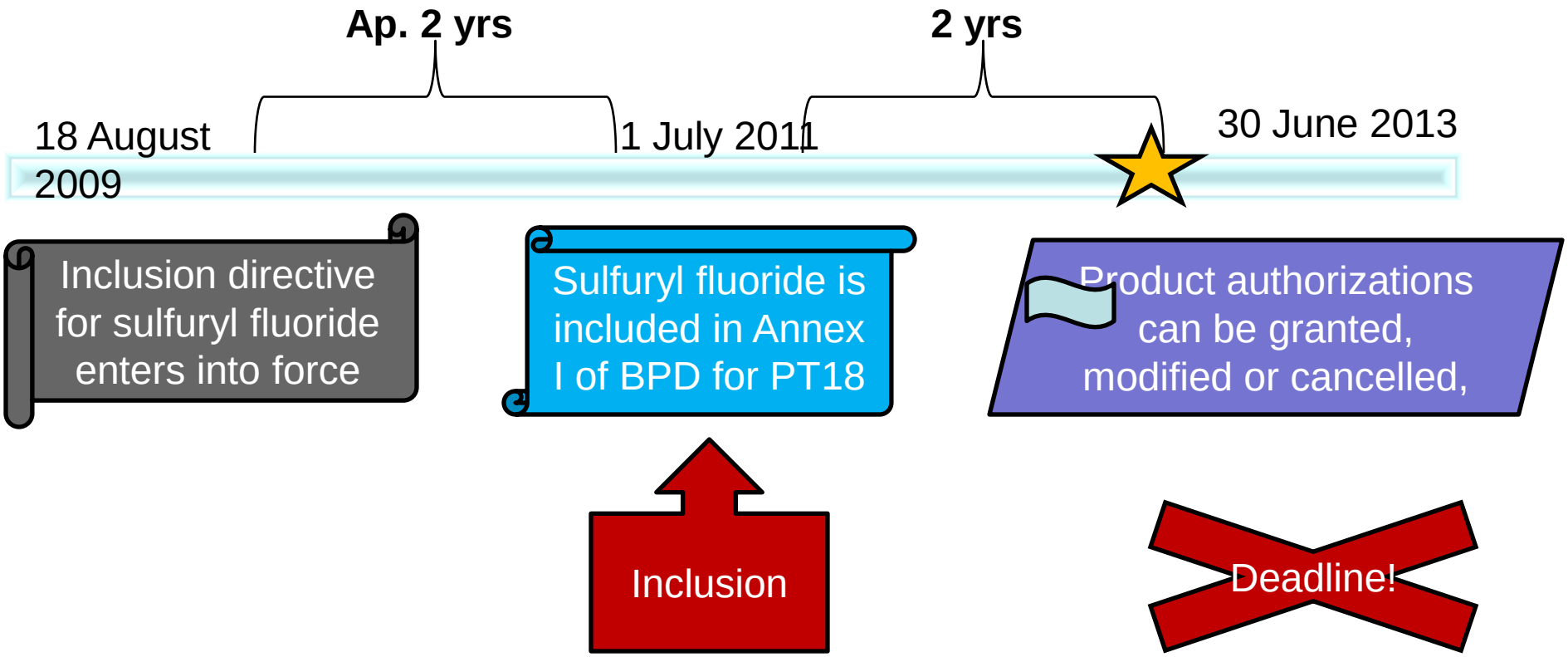
A company applies for product authorization…





…which can be mutually recognized in other MS

Inclusion directive – Sulfurylfluoride PT18



Is the active substance included in Annex I?

- http://ec.europa.eu/environment/biocides/annexi_and_ia.htm
- http://eur-lex.europa.eu/en/index.htm

Restrictions in the inclusion directive

- Examples:
  - Only ready-to-use products
  - Only professional use
  - Not for use on children under a certain age

- To be able to authorize a product according to the BPD, the provisions in the inclusion directive need to be fulfilled.

- If not, the provisions in the inclusion directive need to be modified before a product can be auhtorized.

Non-inclusion decisions

- Non-inclusion decisions can be found at the website of the EU Commission:

http://ec.europa.eu/environment/biocides/non_inclusions.htm

- The last non-inclusion decision was published 8 February 2010 (Commission decision 2010/72/EU)
- Consolidated list of decisions
- Products which contain active substances for which a non-incusion decision has been made should be phased out from the market at the latest 12 months after the decision has entered into force (if nothing else is mentioned).

Non inclusion decisions, continued

- If a product has several areas of use and one of them is not supported within the review program anymore, the area of use for that product must be changed.

Authorization according to the BPD

Conditions for issue of an authorizations according to BPD (Art. 5)

– The active substance is included into Annex I or IA

– The product is sufficiently effective

– No unacceptable effects on:
  - Target organisms
  - On human or animal health
  - Surface water or ground water
  - The environment

Unacceptable effects?

- The applicant should submit documentation for the product and the active ingredient (Art. 8)

- The product has to fulfill the provisions in Art. 5. This should be assessed according to the common principles in Annex VI of the BPD

The application for authorization according to the BPD

- **Application for authorization (art. 8 BPD)**
  The first application can be submitted to any MS, the so called **Reference MS**

- **Application for mutual recognition (art. 4 BPD)**
  Can be submitted to any other MS, in which the product will be placed on the market, to the so called **Concerned MS**

How?

- The application should be submitted via R4BP. The applicant indicate in R4BP in which MSs he will apply for mutual recognition.
- The application for authorization is submitted to the reference MS according to Art. 8.
- The application for mutual recognition is submitted to all concerned MSs according to Art. 4.
- After a decision has been made in the reference MS the decision and the product assessment report shoould be sent to the concerned MS.
- Already authorized products under national law can stay on the **Swedish** market as long as they are authorized (at the most 2 years after the date of inclusion).

When?

- Both applications for authorization and mutual recognition should be sent to **KemI (Sweden)** at the latest at the day of inclusion.
- There might be different deadlines in different MS. Contact points in MS are found at the Commission website.
- When there are several active substances in a product the last date for inclusion applies.

Mutual recognition

- Can be approved as soon as the Reference MS has made a decision for authorization.
- Within 120 days the Concerned MS has to make a decision after having received the first decision from the Reference MS (60 days for low-risk biocidal products).
- The Concerned MS have certain possibilities to include provisions in their own authorizations.

Provisions for mutual recognitions of authorizations

- Concerned MS may request that certain conditions be adjusted to different circumstances

  - *Resistence of the target organism*
  - *The target species is not present in harmful quantities*
  - *Relevant circumstances such as climate or breeding period of the target species*

The Commission, other MS and the applicant should be notified regarding the reason for such specific conditions.

MS´s possibility to refuse mutual recognition

- Concerned MS can refuse mutual recognition of product authorizations
  - granted for product types 15, 17 and 23 (avicides, piscicides and control of other vertebrates)
  - in case the concerned MS believes that the assessment by the reference MS is incorrect.
  - In case of refusal the COM, other MS and the applicant should be notified

Timelines

- Submission of application at the latest at the day of inclusion of the active ingredient into Annex I
- Completeness check – 3 months
- Evaluation – 12 months
- Submission of decision and assessment from reference MS – at the latest 2 months after decision in reference MS
- Evaluation of application for mutual recognition – 120 days
- The last day for authorizations according to national legislation – the date in the inclusion directive (two years after day of inclusion)

R4BP

- **R4BP** – Register for Biocidal Products

  - EU database for handling of applications for authorizations and mutual recognition
  - To be used by both applicants and authorities
  - All products for which an application has been submitted will be listed in R4BP with the specific step in the process:
  - https://webgate.ec.europa.eu/env/r4bp/user.login.cfm
  - User guide: http://circa.europa.eu/Members/irc/env/bio_reports/library?l=/r4bp

Questions regarding the scope of the BPD

- Guidance is found on the Commission website:
  - MOD (”Manual of decisions”)
  - Biocidal products and cosmetic products
  - Biocidal products and medicinal products
  - Etc.
- The guidance is not legally binding!

PA&MRFG

- **PA&MRFG –** Product Authorization and Mutual Recognition Facilitation Group

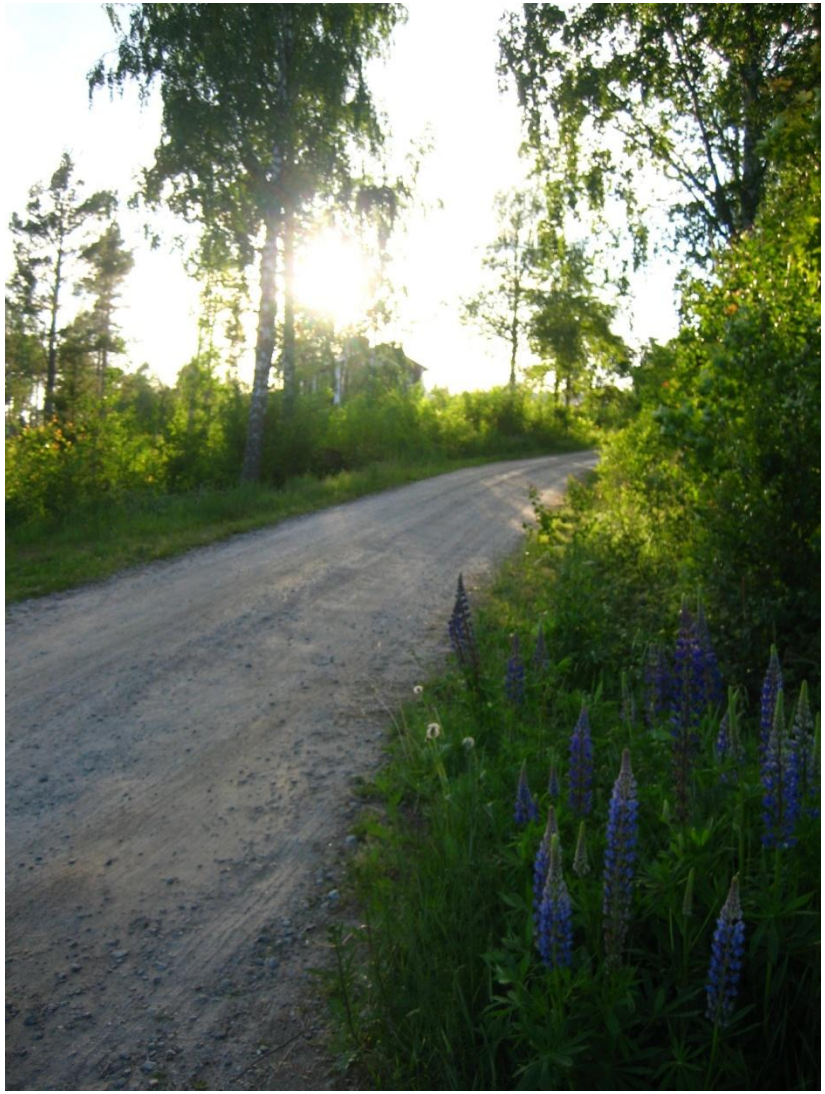
  - Harmonization of application forms
  - Letter of Access - questions regarding the data requirement for product authorization
  - Harmonization of terminology and concepts

Suggestions!

- As a formulator, make sure to have a close relationship with the producer of the active ingredient for the latest update regarding the status within the EU and the review program

- If the source of the active substance is different to the source that was evaluated in connection with the inclusion of the substance in Annex I to the Biocidal Products Directive, make sure that the source is equivalent with the one used for the Annex I inclusion (purity etc.)

- Contact the relevant authority in the Reference MS as soon as you know that you are going to submit an application for authorization.



Thank you for your attention!

Any further questions?

Contact points and websites

- Swedish Chemicals Agency

  Web site: www.kemi.se

  E-mail: biocider@kemi.se

  Telephone: 08 – 519 411 00

- EU Commission – biocides

  Web site: ec.europa.eu/environment/biocides

- Ex-ECB – biocides

  Web sites: ecb.jrc.ec.europa.eu/biocides