General introduction to Directive 98/8/EC

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The Biocides Directive

- was modelled after the Plant Protection Products Directive (91/414/CEE)
- concerns the placing on the EU market of biocidal products, i.e. the non-agricultural pesticides
- time limit for its implementation
  - In the 15 Member States : 14 May 2000
  - In the 10 new Member States: 5 May 2004
- the situation in Member States is diverging; depending on the previous existence of national authorisation systems for biocides

Objectives

- to establish a harmonised regulatory framework for the placing of biocidal products on the market;
- while ensuring a high level of protection for human health and the environment; and the proper functioning of the common market

What is a biocidal product?

(Article 2 (1) (a) of the Directive)

- ***Active substances and preparations containing one or more active substances,***
- ***put up in the form in which they are supplied to the user,***
- ***intended to destroy, deter, render harmless, prevent the action of, or otherwise exert a controlling effect on any harmful organism…***
- ***by chemical or biological means.***

- ***An exhaustive list of 23 product types with an indicative set of descriptions within each type is given in Annex V***

What is an active substance?

(Article 2 (1) (d) of the Directive)

- **A substance or micro-organism, including a virus or a fungus**
- **having general or specific action on or against harmful organisms**

Basic principles (1)

- Only authorised biocidal products may be placed on the market
- Biocidal products are authorised by the Member States' competent authorities
- Only biocidal products containing active substances included in Annex I or IA of the Directive may be authorised
- Mutual recognition of authorisations issued by a Member State

Basic principles (2)

- The active substances are evaluated and approved at Community level (inclusion in Annex I, IA or IB)
  - Annex I : 'normal' active substances
  - Annex IA : active substances that can be used in 'low risk' biocidal products
  - Annex IB : basic substances; i.e. active substances used in products, which are not primarily marketed as biocides

Basic principles (3)

- the Member States establish fee systems to cover their costs in carrying out the Directive's procedures
- fees for evaluation of active substances and authorisation of biocidal products are paid by the applicant enterprises
- The amounts are not harmonised

Conditions for product authorisation

- The active substance must be listed in Annex I of the Directive
- The biocidal product must be:
  - Sufficiently effective
  - no unacceptable effects on target organisms
  - no unacceptable effects on human or animal health
  - no unacceptable effects on the environment

Conditions for product registration

- The active substance must be listed in Annex IA of the Directive
- The biocidal product must be ‘low risk’
- It should not contain a substance of concern

- The registration procedure is faster and requires less data than an authorisation!

- A *basic substance* must be listed in Annex IB but it cannot be directly marketed for biocidal use!

Transitional arrangements

- **'existing' active substances**
  - contained in biocidal products which were present on the EU market before 14 May 2000
  - they are systematically examined within a 10-year review programme
  - they may remain on the market under national rules until a decision is taken at Community level
- **'new' active substances**
  - not contained in biocidal products before 14.5.2000; prior Annex I inclusion decision is necessary (but: provisional authorisation is possible via Art. 15(2)!)

Other provisions

The Directive also contains provisions for:

- Confidentiality and data protection
- Classification, packaging and labelling
- Establishment of safety-data sheets
- Advertising
- Information for poison control

The review programme

1. Commission Regulation 1896/2000 on the first phase of the review programme
   - Identification of existing active substances
   - Notification of those existing active substances that industry wants to have included into one of the Annexes to Directive 98/8/EC
   - Notification also counts as identification

   ⟶ to the Commission by 28 March 2002

Results

- About 2700 identifications for 955 substances
- About 500 notifications for 370 substances

The review programme

2. Commission Regulation 1687/2000 establishing an additional period for notification

New deadline: 31 January 2003, but **only** for:

- 'only-identified' substances
- other product types than already notified

Results

- notifications for 25 additional substances
- notifications for 50 additional product types for already notified substances

The review programme

3. Commission Regulation 2032/2003 on the second phase of the Review Programme

- Exhaustive list of existing active substances
- List of notified substances that will be evaluated during the second phase of the review programme
- Deadlines for placing on the market of non-notified substances
- Designated Rapporteur Member State for each notified active substance / product type combination
- Deadlines for submission of complete dossiers
- Procedural details on dossier preparation and evaluation

The review programme

Substances listed in Annex III (i.e. only identified),

will **not** be included in Annex I, IA or IB of the BPD

in the framework of the Review-Programme;

they can stay on the market until **01.09.2006** in any biocidal product.

Same rule: notified substances in non-notified PTs

As of **14 December 2003:**
substances not listed in Annex I of the 2nd RR (i.e. substances neither identified nor notified) will be considered as **new substances**

The review programme

Evaluation of notified substances

- Basis: complete Dossier and summary in accordance with Annex IV (Reference to annexes and Art. 11(1)(b) of BPD + ‚Practicalities Guidelines‘)
- Submission within delays given in Annex V
  - 28.03.2004: wood preservatives (PT08) and rodenticides (PT14)
  - 01.11.2005 - 30.04.2006: PT 16, 18, 19 and 21
  - 01.02.2007 - 31.07.2007: PT 1, 2, 3, 4, 5, 6 and 13
  - 01.05.2008 - 31.10.2008: PT 7, 9-12, 15, 17, 20, 22, 23
- RMS in Annex V for Lists 1 and 2

The review programme

Completeness check by RMS

Normal time frame: 3 months

In case of consultations with COM and MS: max. 6 months

Evaluation by RMS

Evaluation of dossier by RMS within 12 months – additional data requirements ⇒ Suspension

Commission procedures

- 90 days commenting period for other MS and applicant. If necessary: consultation of SCHER (ex SCTEE).
- Commission proposal for decision
- MS vote by qualified majority

The review programme

New legislation: the 3rd **Review Regulation 1048/2005**

- Designation of Rapporteurs for Lists 3 and 4
- Updating of Annexes II and III of Regulation 2032/2003 to reflect:
  - **withdrawals, non-submission of dossiers**
  - **equivalent to non-inclusion decision for substances / PT combinations concerned**
- Solutions for non-identified substances in new MS and for ‘forgotten substances’ in old MS
- Extension of phase-out deadline for ‘essential’ substances
- Extension of phase-out deadlines for non-notified substance / PT combinations, where companies want to prepare full dossiers now

TECHNICAL NOTES FOR GUIDANCE (Art. 33)

- Data Requirements
- Dossier Preparation and Evaluation
- Exposure Scenarios for Humans and the environment
- Risk Assessment of Active Substances
- Annex I Entry Criteria (Active Substances)
- Common Principles (Biocidal Products, Annex VI)

all available at: http://ecb.jrc.it/biocides

Impact of the Directive so far

A reminder:

While recognising the benefits of biocidal products, the Directive intends to ensure a high level of protection for human and animal health and the environment

Situation today:

- **After identification/notification: More than 950 substances often badly assessed have been used in biocidal products**
- **Clearly not all of them are essential or irreplaceable**
- **Industry has made the commitment to demonstrate the safety of use for 370 notified substances**

Conclusions

- A lot of progress since adoption of Directive 98/8/EC
- Much more work needs to be done by all stakeholders
- Parallels to initial situation with Directive 91/414/EEC!

⇒Challenges are big but not insurmountable !