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
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
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


- 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!