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Biocides Regulation in the UK

Chemicals Regulation Directorate

Established 1 April 2009

Bringing together the UK Competent

Authorities for:

Pesticides

Biocides

Detergents

Industrial chemicals (REACH)

Wider roles for CRD

- HSE delivers Competent Authority role for:
 - pesticides
 - biocides
 - industrial chemicals (REACH)
 - classification, labelling and packaging (CLP)
 - prior informed consents (PIC)
- Policy support to Defra and DWP
- Regulation, authorisation etc.
- Monitoring
- Enforcement
- Research and Development

Regulation of “biocides” pre-BPD

UK

- Control Of Pesticides Regulations (1986)
 - (Agricultural pesticides)
 - non-agricultural pesticides [wood preservatives; public hygiene insecticides; anti-fouling paints; masonry (surface) biocides; rodenticides]

other Member States

- Some had national legislation (e.g. The Netherlands, Scandinavian countries); not others (e.g. Germany, France)

plus EU Marketing & Use Directives

- for specific substances (e.g. pentachlorophenol, creosote)

Biocides alongside Pesticides

- Historical connection between “PSD – pesticides” and “HSE - biocides” under national legislation
- Biocides Products Directive (BPD - 98/8EC)
- Plant Protection Products Directive (PPPD -91/414EC)
 - have similar regulatory shape and similar demands, requirements, process principles, (including cost recovery from business)
 - some common substances
 - but differences in scale (regulatory throughput, company size, amounts used, £, public/political/media interest)

BPD (BPR in UK): 23 product types (PTs)



- **DISINFECTANTS AND GENERAL BIOCIDAL PRODUCTS**

PT1 human health; PT2 private and public health area; PT3 veterinary; PT4 food and feed area; PT5 drinking water

- **PRESERVATIVES**

PT6 in-can; PT7 film; PT8 wood; PT9 fibre, leather, rubber, polymer; PT10 masonry; PT11 liquid-cooling and processing systems; PT12 slimicides; PT13 metal-working fluids

- **PEST CONTROL**

PT14 rodenticides; PT15 avicides; PT16 molluscicides; PT17 piscicides; PT18 insecticides, ascaricides and control of other arthropods; PT19 repellents and attractants

- **OTHER BIOCIDAL PRODUCTS**

PT20 food and feedstock preservation; PT21 antifouling; PT22 embalming and taxidermy; PT23 control of other vertebrates

BPD (BPR in UK)

regulatory concepts – two tier process

- ACTIVE SUBSTANCE agreed by EU as appropriate for use in specified biocidal product type(s) → Annex I
- PRODUCT containing Annex I - listed substance(s) then authorised for use by a “first” Member State (MS);
then “Mutual Recognition” by other MSs of acceptability of product.

BPD (BPR in UK)

A biocidal product can be authorised if it:

“has no unacceptable effects on”

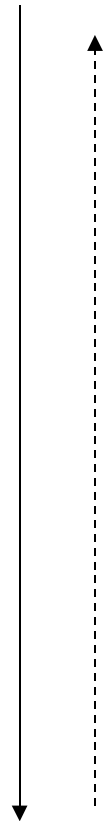
- human or animal health
- the environment
- the target organisms (resistance; suffering)

and “is sufficiently effective”

In seeking Annex I listing, data for active substance, plus characterisation of a representative (“dummy”) product.

BPD: substance evaluation process

- lead company: substance data package
- rapporteur MS [completeness, then evaluation]
- draft evaluation to EC: CIRCA consultation
- Technical Meeting (TM)
- Competent Authorities (CA) meeting
- Standing Committee on Biocidal Products (SCBP): vote
- Further EC/EU processing → Annex I



BPD (BPR in UK)

- EU review programme, 2000–2010 (now 2014)
- in four tranches (“Lists”),
- via “Review Regulations” – listing supported (“notified”) active substance linked to specified PT(s);
- also removal from market of products containing unsupported active substances
- each substance to be reviewed allocated to a rappporteur Member State

BPD (BPR in UK)

ACTIVE SUBSTANCE evaluation

- commenced about 04/05
- deadline for completion of existing active substances was 2010, now 2014

PRODUCT AUTHORISATION (& Mutual Recognition)

- starting 09/10; processes still under discussion

*PRODUCT APPROVAL UNDER COPR

- through to mid-late next decade, with gradual tailing off

CRD's "Biocides" (BPD/COPR) work 09/10: anticipated throughputs

ACTIVE SUBSTANCE EVALUATION (BPD/R)

- 13 "UK rms" substances being worked on
- commenting on > 40 draft evaluations from other ms

PRODUCT APPROVAL (COPR)

- 300-400 applications

PRODUCT AUTHORISATION (BPD/R) ****all new!**

- 100-150 applications (very few mutual recognitions)

Opportunity for work share?

- Within EU and/or wider
- With new active substances
- With review programmes
- With product authorisations
- With agricultural pesticide evaluators
- Lessons learned from OECD Vision for agricultural pesticides

Thank You for your attention

