IBMA
International Biocontrol Manufacturers' Association

Annual Biocontrol Industry Meeting Lucerne

The New European PPP Regulation : General Improvements and Perspectives for BCAs

presented by Ulf HEILIG - IBMA

The New E.U. PPP Regulation
Status and Implementation

Regulation of the European Parliament and of the Council concerning the placing of PPP on the market

and repealing Council Directives 79/117/EEC and 91/414/EEC

Institutional ref :	2006/0136(COD)
E.P. vote in 2nd reading :	13th Jan. 2009
Council of E.U. vote :	24th Sept. 2009
Publication :	Imminent
Coming into force :	Day 20 following publication
Implementation :	18 month after into force

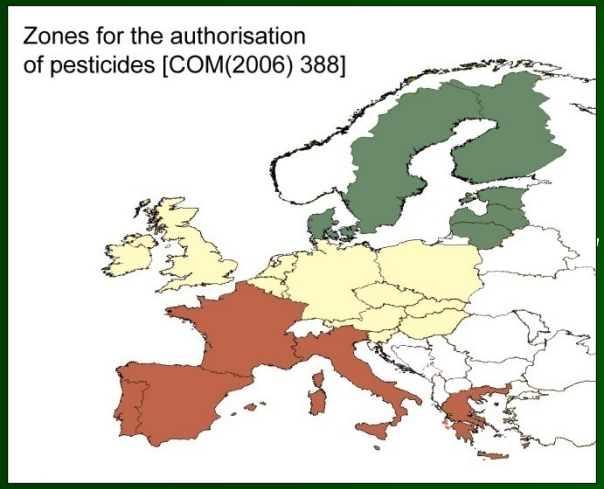
The New E.U. PPP Regulation
Subject of Presentation

- *Creation of zones improved mutual recognition by MS*
- *Improved time lines for evaluation and inclusion*
- *Low-risk Active Substances*
- *Basic Substances*
- *Guidance documents*

Perspectives for BCAs

The New E.U. PPP Regulation
Creation of zones

Definition of three zones



.. and a **single zone** for **greenhouses**, **seed** & **post** treatments, empty premises &

North: Denmark, Estonia, Finland, Latvia, Lithuania, Sweden

Centre: Austria, Belgium, Czech Republic, Germany, Hungary, Ireland, Luxembourg, Netherlands, Poland, Romania, Slovakia, Slovenia , UK

South: Bulgaria, Cyprus, France, Greece, Italy, Malta, Portugal, Spain

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Mutual Recognition

[art 40]

Conditions

Reg holder may apply if

- ✧ same PPP and
- ✧ same use and
- ✧ comparable agricultural practice

3rd parties can apply if use in general interest

Initial authorisation by

- ✧ MS in same zone
- ✧ No MS in same zone but in other zone for same purpose
- ✧ Any MS for greenhouses, post-harvest, seed, empty rooms & container

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Mutual Recognition
[art 35]

RMS and other MSs

RMS: In general application examined by MS proposed by applicant (unless another MS in same zone volunteers)

If application in other MSs in same zone

⇨ co-operation and work sharing

⇨ other MSs stop processing

If application in several zones

⇨ RMSs shall agree on evaluation of data not related to envi and agri conditions

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Mutual Recognition

[art 36 & 41]

Recognition of authorisation decision

Other MSs shall examine application with regard to circumstances in its territory

If appropriate ⇨ authorisation under same conditions as by RMS

IF MS has **concerns for human or animal health or envi**

⇨ **Can be controlled** by risk mitigation measures **?**

YES ➔ authorisation with restrictions

NO ➔ refusal

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Mutual Recognition
[art 36]

Refusal of authorisation decision

MS must have **substantiated reasons** that use of product still causes unacceptable risk due to **specific** envi and agri circumstances

MS must provide technical or scientific **justification**

MS must provide for **instances of appeal** (ex. courts) to challenge decision

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Mutual Recognition
[art 44 (4)]

Amendment or withdrawal

If any MS in same zone amends or withdraws an authorisation

⇨ other MSs in same zone amend and withdraw taking into account national conditions and risk mitigation measures

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Mutual Recognition

Not all aspects detailed here

Interaction between MSs during examination [art 36]

Procedure [art 42]

decision within 120 days (unless additional data requirements)

Derogation from authorisation under same condition [art 41]

Impact of National Action Plans [Framework Directive]

How will Mutual Recognition operate in practice ? ? ?

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Mutual Recognition

3rd GTZ Workshop in Vilnius

In framework of EU programme “Better Training for better food”, contractor : German GTZ

Organiser session on New PPP Regul. including Mutual Recognition: CRD Pestic. (UK)

2 out of 4 days in Nov. 2009 (2nd half of week 46)

Closed meeting for regulators of all 27 EU MS

Preparation of a guidance doc on zonal authorisation, renewal, withdrawal, amendment

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Mutual Recognition

Commission Workshop in Braunschweig

Organised by COM Steering Group (lead: DG SANCO)
in coll. with German BMEVL & BVL

Planned for 26th to 28th January 2010

At least partially closed meeting for regulators (2 reps / MS)

Attending of stakeholder / industry still under discussion in Steering Group

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Mutual Recognition

French Colloquium for South European Zone

Organised by MAAP & Afssa-DiVE

Planned for May or June 2010

C.As, evaluators and open to all stakeholders of South European zone

(Bulgaria, Cyprus, France, Greece, Italy, Malta, Portugal, Spain)

Subject : practical aspects (organisation, procedures …)

The New E.U. PPP Regulation
Improved time lines for act. subst. inclusion

Admissibility of the application [art 9] **45 days**

DAR by RMS [art 11] **12 months**

Conclusion by the Authority [art 12]

- EFSA circulate the DAR within **30 days**
- Applicant designate confidential sections within 2 weeks
- MSs & applicant comment in writing within **60 days**
- EFSA consult experts where appropriate

➔ adopt conclusion after the end of the commenting period **120 days**

Approval regulation [art 13]

COM shall present Review Report and draft Regulation within **6 months**

Regulation shall be adopted by COM and SCoFCAH within **3 months**

The New E.U. PPP Regulation

Improved time lines

for act. subst. inclusion

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Conclusion by the Authority [art12]

- EFSA circulate the DAR within **30 days**
- applicant designat… within 2 weeks
- MSs &… writing within **60 days**
- …perts where appropriate

➔ …t conclusion after the end of the commenting period **120 days**

~30 months (2,5 years), plus ≤ 15 add. months if all additional time periods and clock stops used

Approval regulation [art13]

COM shall present Review Report and draft Regulation within **6 months**

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The New E.U. PPP Regulation
Low-risk Active Substances
[Annex II section 5]

Exclusion criteria

a) classification (according to regul. **1272/2008/EC**)

- ✧ carcinogenic, mutagenic, toxic to reproduction **= CMR**
- ✧ very toxic or toxic = **T+ et T**
- ✧ sensitising **chemicals**
- ✧ explosive
- ✧ corrosive

b) or if following criteria met:

- ✧ **persistent** (½ life in soil is > 60 days)
- ✧ bioconcentration factor > 100
- ✧ deemed to be endocrine disrupter
- ✧ neurotoxic or immunotoxic

Inadequate for MBCAs

The New E.U. PPP Regulation
Low-risk Active Substances
[art 22 & 47]

Advantages

1st approval of substance: ≤ 15 years
(instead of 10 years standard)

Fast decision on authorisation of PPP by MS: ≤ 120 days
(plus ≤ 6 months if data missing)

Submission of a **reduced dossier** for PPP containing them
(including demonstration of sufficient efficacy,
no substance of concern in PPP)

In adverts: *"Authorised as low-risk PPP in accordance with [Regul. ref.] "*

➔ **but no low-risk claim on PPP label !**

The New E.U. PPP Regulation
Low-risk Active Substances
[art 22]

Implementation

According to article 22, low-risk active substances shall be listed separately in the Regulation [art. 78 (3)] which contains the list of active substance included in annex I to 91/414/EEC.

Implementation measures must be taken within 18 months after coming into force of New PPP Regul..

COM is currently setting priorities for those measures.

Low risk criteria exist in New PPP Regul. but categorisation might depend on outcome of peer review.

The New E.U. PPP Regulation

Basic substances

[art 23]

Criteria

Not substance of concern
endocrine disrupter, neurotox, immunotox

Not predominantly used for PPP purposes but
useful in PP, either undiluted or with simple diluent

Not placed on the market as PPP

Evaluation under other EU legislation ⇨ **no** undesirable effect

Applies to: " foodstuff " as defined in Article 2 of Regulation (EC) No 178/2002

➔ potential approval of BCAs ?

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Basic substances

[art 23]

Questions asked in ENDURE - COM meeting and

⇨**informal** answers and interpretation by reps of DG SANCO & EFSA

➔ Details on procedure ?	⇨ Need to be defined !
➔ "COM **shall** ask authority" ?	⇨ EFSA **must** be involved !
➔ Dossier from which domains ?	⇨ Foodstuff OK, others to clarify !
➔ Data protection possible ?	⇨ No, once listed: basic substance available to all!

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Basic substances

[art 23]

⇨ informal answers and interpretation (2)

➔ Labelling and advertising ?

Intent of legislator : Create a legal base for PP advisors, especially in organic farming

⇨ No specific marketing as PPP
⇨ No plant protection claims on label
⇨ No advertising for plant protection properties

➔ Status if annex I inclusion ?

⇨ Once included, a substance cannot be approved at the same time as basic substance !

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Basic substances

[art 23]

⇨ informal answers and interpretation (3)

➔ Formulation for PP uses ?
Substance used either directly or with simple diluent

⇨ No addition of co-formulants for use in PP
⇨ No mixtures of basic substances

➔ Candidates ?

⇨ Substances used as **food ingredients** are in good position if food definition compliance !
⇨ Substances used in bakery, brewery, dairy are likely candidates

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Basic substances

[art 23]

Opportunity for BCAs ?

➔ **Very limited potential and commercial interest**

Disappointing !

Provisions for guidance documents

Article 77

COM "may […] adopt or amend technical and other guidance documents e.g. explanatory notes or guidance documents on the content of the application concerning micro-organisms, pheromones and biological products, for the implementation of this regulation"

COM may ask EFSA to prepare or to contribute to such guidance documents

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Opportunity

Provisions for guidance documents

Different EFSA panels which can take forward guidance documents but EFSA planning is full for 2010 (and 2011 ?)

Industry should fix priorities and make substantiated proposals

➔ *to EFSA* ← *via Member State C.As*

← *via (groups of) companies involved*

➔ *keep COM involved (key position in art. 77)*

⇨ ***Co-ordinated approach of IBMA members***

in particular in Professional Groups !

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Pending issue

Specific status of non chemical methods

Recital 35 (to be related to Framework Directive) mentions :

"priority to non-chemical & natural alternatives wherever possible"

Definition of *non-chemical methods* [art. 3 (8)] mentions :

" […] *physical, mechanical or biological pest control"*

➔ We must make sure that all BCAs, not only microbials but also **semiochemicals, botanicals and other natural substances** in particular with **non-toxic mode of action** are covered !

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Pending issue

Generic waivers

justifications of non submission of data or exemptions for groups of substances and products

- Not provided for in regulation

⇨ **perspective ?**

Merci !

Ulf HEILIG http://register.consilium.europa.eu/pdf/en/09/st03/st03608.en09.pdf