

Applications for registration of plant protection products *- The applicant's view*



EuropaBio Workshop
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Current legislative situation

Legislative framework for plant protection products in the European Union

- ***Directive 91/414/EEC*** currently in place
- New Regulation agreed between Council & Parliament
- Publication expected in Oct/Nov 2009

Basics of Directive 91/414/EEC

Active substance

- approved at EU level

Plant protection product

- Authorised at Member State level
 - *Authorisation includes details of each authorised use*

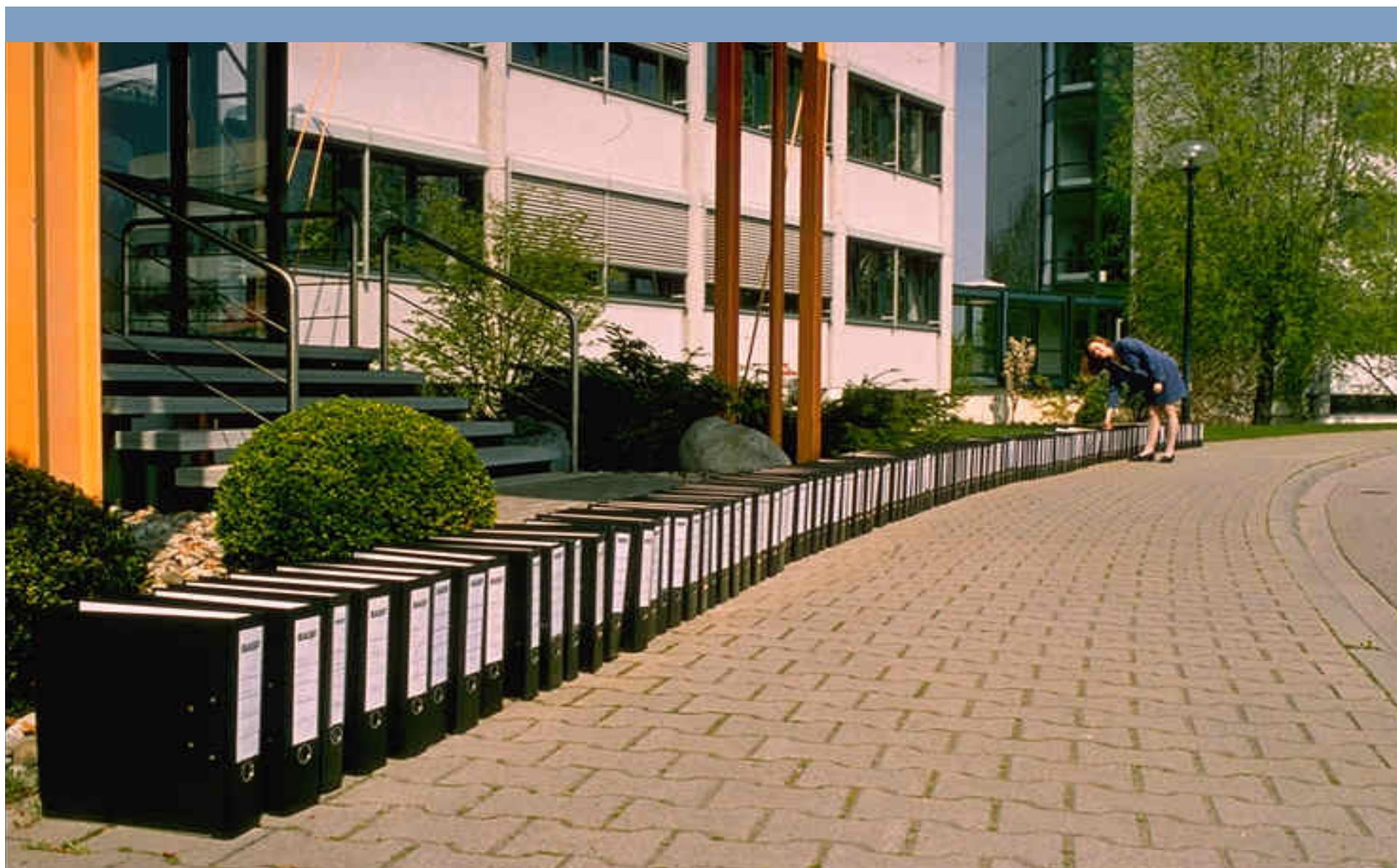
PPP dossiers are substantial

The legislation detailing the data requirements and evaluation principles are substantial

➤ *(150+ pages)*

➤ The evaluation work covers 200+ studies per active substance with additional studies for each product and use

PPP dossiers are substantial



Basics of Directive 91/414/EEC

Data requirements and evaluation:

- **Annex II** – Requirements for the dossier to be submitted for the inclusion of an active substance in Annex I
- **Annex III** - Requirements for the dossier to be submitted for the authorization of a plant protection product
- **Annex VI** – Uniform principles for evaluation and authorisation of chemical plant protection products

Directive 91/414: Ensuring safe PPP use

“one of the most important ways of protecting plants and plant products ... is to use plant protection products”

□ recognises that pest control must have an environmental impact that needs to be managed:

- *Article 4.1(b)(v) “it has no unacceptable influences on the environment, having proper regard to ... its impact on non-target species”*
- *Annex III, 6.2 “... assess whether the dose is the minimum necessary to achieve the desired effect”*
- *development of resistance: Annex III, 6.3 “.... management strategy designed to minimise the likelihood of resistance ...”*

PPP authorisation: Provisions in new Regulation

A plant protection product...shall meet the following requirements:

- (a) be sufficiently effective;
- (b) have no... harmful effect on human health...
- (c) not have any unacceptable effects on plants or plant products;
- (d) not cause unnecessary suffering and pain to vertebrates to be controlled;
- (e) have no unacceptable effects on the environment, having particular regard to...:
 - (i) its fate and distribution in the environment...;
 - (ii) its impact on non-target species...;
 - (iii) its impact on biodiversity and the ecosystem.

PPP authorisation: Provisions in new Regulation

1. The authorisation shall define ***plants or plant products...on which*** and ***the purposes for which*** the plant protection product may be used.
2. The authorisation shall set out the requirements relating to the... use of the plant protection product...
3. The requirements... shall... include where applicable:
 - (a) *the maximum dose per hectare in each application;*
 - (b) *the period between the last application and harvest;*
 - (c) *the maximum number of applications per year.*

Efficacy and resistance reporting in new Regulation

The holder of an authorisation for a plant protection product ***shall report annually*** to the competent authorities of the Member States which authorised his plant protection product if he has ***any information*** available ***relating to the lack of expected efficacy, the development of resistance and to any unexpected effect on plants, plant products or the environment***

Article 56.4

Conclusion

- Directive 91/414/EEC (and the new Regulation) requires a detailed evaluation (and monitoring) of:
 - The active substance
 - The plant protection product, and
 - Each authorised use of the product

- Data on PPP uses on GM crops have been submitted and evaluated in a number of MSs

- Authorities responsible for 91/414 and successor legislation will continue to have jurisdiction in PPP approval and monitoring matters - for all uses!