



CEUREG FORUM XIII

SESSION I - LEGAL ASPECTS OF PLANT PROTECTION

"PESTICIDE REGISTRATION SYSTEM IN POLAND - PROBLEMS EXPECTED IN THE LIGHT OF NEW EU REGULATION"

Ministry of Agriculture and Rural Development
Department of Plant Breeding and Protection

Poznań 2009



Directive 91/414/EWG

Law of 18 December 2003 *on Protection of Plants* regulates placing plant protection products on the market in Poland since 1 May 2004.

Regulation of the European Parliament and of the Council *concerning the placing of plant protection products on the market shall:*

"... enter into force on the twentieth day following that of its publication in the Official Journal of the European Union."

"... apply from 18 months from the date of entry into force"



Legal effect of new regulation

Art. 84 "This Regulation shall be binding in its entirety and directly applicable in all Member States."

- Do not to be transposed into national law.**
 - In principle, overrides all national laws dealing with the same subject matter.**
 - National legislation must be consistent with and made in the light of the regulation.**
-



Legal effect of new regulation

Provisions on placing plant protection products on the market at Law of 18 December 2003 *on Protection of Plants* to be amended or replaced by new ACT.

New ACT would also implement the directive *of the European Parliament and of the Council establishing a framework for Community action to achieve a sustainable use of pesticides.*

Changes to be adopted in 2010/11.



What in national legislation ?

Adoption of national laws, regulations and administrative provisions, to comply with the regulation, is necessary when*:

- ❑ regulation obliges or authorises MS to adopt such measures,**
- ❑ it is required to specify responsibilities/properties of national competent authorities,**
- ❑ to establish a system of penalties for infringements of the regulation.**

*** *"Guidance documents concerning legislative policy and legal techniques."* - the Office of the Committee for European Integration and the Government Legislation Centre.**



Examination of applications

Requirements and procedure for the authorisation for placing plant protection products on the market established by Regulation (chapter III, sections 1).

Article 35 - Member State examining the application
"...the other MS within the zone to which an application has been submitted shall refrain from proceeding with the file pending assessment by the Member State examining the application."

Article 36 - Examination for authorisation
"...the MS examining the application shall give all Member states in the same zone the opportunity to submit comments to be considered in the assessment."

=> We need tools not only for evaluating but commenting.



Granting authorisation

The Member States grant or refuse authorisations on the basis of the conclusions of the assessment of the Member State examining the application.

"...appropriate conditions may be imposed with respect to the requirements referred to in Article 31 (3) and (4) and other risk mitigation measures deriving from specific conditions of use."

".. a Member State may refuse authorisation of the plant protection product in its territory if, due to its specific environmental or agricultural circumstances, it has substantiated reasons to consider that the product in question still poses an unacceptable risk to human or animal health or the environment."

=> How to do it predictable? - Would national system set specific environmental or agricultural conditions? In what way?



Efficacy

Regulation of the Minister of Agriculture and Rural Development of 4 August 2004 *on efficacy evaluation of plant protection products* will be revoked. (e.g. number of required trials, rules for extrapolations).

Data requirement to be established in COM regulation (plus EPPO guidances).

Art 3"zone - Group of Member states as defined in Annex I"

=> Practical implication - Till now, in Poland efficacy data from other MS were used for limited number of authorised products.



Organisation

Art. 75 Competent authority

"1. Each Member State shall designate a competent authority or authorities to carry out the obligations of the Member states as defined in this Regulation."

"2. Each Member State shall designate a coordinating national authority to coordinate and ensure all the necessary contacts with applicants, other Member states, the Commission and the Authority."

=> National laws would improve organisation and procedure of assesment and decision making.



Transitional measures

Art. 80 - Transitional measures

"...Applications for authorisations of plant protection products:

*(a) under Article 4 of Directive 91/414/EEC which are pending in the Member states, ...on ...** shall be decided on the basis of national law in force before that date.*

*** Note to OJ: 18 months from the date of entry into force of this Regulation.*

=> More than 200 applications for registration/re-registration ongoing in Poland.

=> How to enter into new system without delays?



Derogation in art 4(7)

Active substances that do not satisfy the criteria set out in points 3.6.3, 3.6.4, 3.6.5 or 3.8.2 of Annex II can be approved for a limited period (not not exceeding five years) necessary to control that serious danger.

art. 4 - Approval criteria

"...Members States may authorise plant protection products containing active substances approved in accordance with this paragraph only when it is necessary to control that serious danger to plant health in their territory.

At the same time, they shall elaborate a phasing out plan on how to control the serious danger by other means, including non-chemical methods ...

=> National law would set way of practical realisation.



Adjuvants

Art. 81 - Derogation for safeners and synergists, co-formulants and adjuvants.

"By way of derogation from Article 58(1) Member states may apply national provisions for authorisation of adjuvants until the adoption of detailed rules referred to in Article 58(2).. "

=> Curently no specific provisions on adjuvants in Law on *Protection of Plants*. To consider/decide if there is need to establish temporary national system?



Treated seeds

art. 49 - Placing on the market of treated seeds

"...Member states shall not prohibit placing on the market and use of seeds treated with plant protection products authorised for that use in at least one Member State."

=> National law may decide on detailed rules on placing on the market and possibility of taking the protective measures.



Authorisation for PPP is granted for up to 10 years

1995 ⇨ 2002 ⇨ 2004 ⇨ 2011

On average each 5 years there is a change in system of registration of ppp in Poland.

MRL

REACH

GHS



CEUREG FORUM XIII

THANK YOU FOR YOUR ATTENTION

Ministry of Agriculture and Rural Development
Department of Plant Breeding and Protection
30, Wspolna Street
00-930 Warszawa
