Process of authorisation of Plant Protection Product according to EU Regulation 1107/2009

Przemysław Kiełek
przemyslaw.kielek@minrol.gov.pl,
Ministry of Agriculture and Rural Development, Division of Registration of Plant Protection Products

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Regulation 1107/2009/EEC

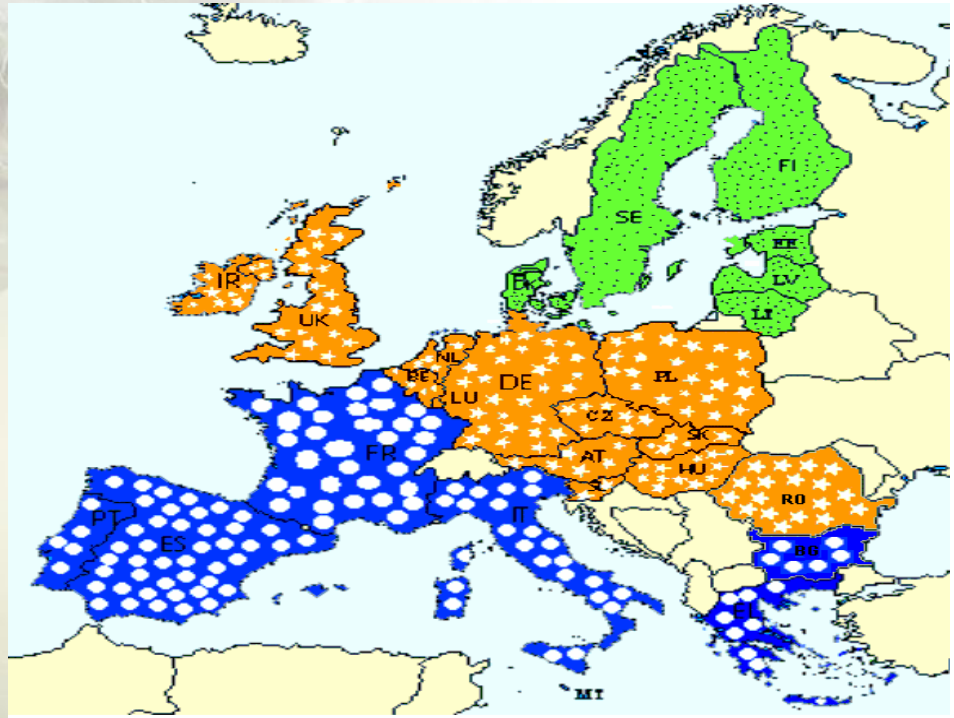
Directive 91/414/EEC replaced by Regulation.

Significant step forward - regulation applies directly in all MS since 14 June 2011.

Active substances, safeners, synergists approval: EU level.

PPP authorisations ⟶ zonal evaluation.

Zones



North Zone: SE, FI, DK, EE, LV, LT
Central Zone: BE, CZ, DE, IR, LU, HU, NL, AU, PL, RO, SL, SK, UK
South Zone: BG, ES, EL, FR, IT, CY, MT, PT

To facilitate and avoid duplication of „registartion work" Community was divided into 3 zones with comparable conditions.

No repetitions of assessments.

Any authorization in one MS can be used for mutual recognition in another MS.

Zones

- Northern zone: Denmark, Estonia, Latvia, Lithuania, Finland, Sweden
- Central zone: Belgium, Czech Republic, Germany, Ireland, Luxembourg, Hungary, Netherlands, Austria, Poland, Romania, Slovenia, Slovakia, United Kingdom
- Southern zone: Bulgaria, Greece, Spain, France, Italy, Cyprus, Malta, Portugal, Croatia

Zonal authorisation

Actual provisions relating to zonal authorisations

Application – art. 33-37

Subsection 2

Procedure

Article 33

Application for authorisation or amendment of an authorisation

1. An applicant who wishes to place a plant protection product on the market shall apply for an authorisation or amendment of an authorisation himself, or through a representative, to each Member State where the plant protection product is intended to be placed on the market.

2. The application shall include the following:

(a) a list of intended uses in each zone as indicated in Annex I and the Member States where the applicant has made or intends to make an application;

(b) a proposal as to which Member State the applicant expects to evaluate the application in the zone concerned. In the case of an application for use in greenhouses, as post-harvest treatment, for treatment of empty storage rooms and for seed treatment, only one Member State shall be proposed, which evaluates the application taking account of all zones. In this case the applicant shall send the summary or complete dossier as referred to in Article 8 to other Member States on request;

(c) where relevant, a copy of any authorisations already granted for that plant protection product in a Member State;

(d) where relevant, a copy of any conclusion of the Member State assessing equivalence as referred to in Article 38(2).

3. The application shall be accompanied by the following:

(a) for the plant protection product concerned, a complete and a summary dossier for each point of the data requirements of the plant protection product;

(b) for each active substance, safener and synergist contained in the plant protection product, a complete and a summary dossier for each point of the data requirements of the active substance, safener and synergist;

(c) for each test or study involving vertebrate animals, a justification of the steps taken to avoid animal testing and duplication of tests and studies on vertebrate animals;

(d) the reasons why the test and study reports submitted are necessary for first authorisation or for amendments to the conditions of the authorisation;

(e) where relevant a copy of the application for a maximum residue level as referred to in Article 7 of Regulation (EC) No 396/2005 or a justification for not supplying such information;

(f) where relevant for an amendment of an authorisation an assessment of all information submitted in accordance with point (h) of Article 8(1);

(g) a draft label.

4. When submitting the application, the applicant may pursuant to Article 63, request certain information, including certain parts of the dossier, to be kept confidential and shall physically separate that information.

The applicant shall at the same time submit the complete list of studies submitted pursuant to Article 8(2) and a list of test and study reports for which any claims for data protection pursuant to Article 59 are requested.

Upon a request for access to information the Member State examining the application shall decide what information is to be kept confidential.

5. Where requested by the Member State the applicant shall submit his application in the national or official languages of that Member State or one of those languages.

6. On request, the applicant shall provide the Member State with samples of the plant protection product and analytical standards of its ingredients.

Article 34

Exemption from the submission of studies

1. Applicants shall be exempted from supplying the test and study reports referred to in Article 33(3) where the Member State to which an application is made has the test and study reports concerned and the applicants demonstrate that they have been granted access in accordance with Article 59, 61 or 62 or that any data protection period has expired.

2. However, applicants to whom paragraph 1 applies shall provide the following information:

(a) all necessary data for the identification of the plant protection product including its complete composition as well as a declaration that no unacceptable co-formulants are used;

(b) the information needed to identify the active substance, safener or synergist, where they have been approved, and to establish whether the conditions for approval are met and comply with point (b) of Article 29(1), where appropriate;

(c) on the request of the concerned Member State, the data needed to demonstrate that the plant protection product has comparable effects to the plant protection product for which they show access to the protected data.

Article 35

Member State examining the application

The application shall be examined by the Member State proposed by the applicant, unless another Member State in the same zone agrees to examine it. The Member State which will examine the application shall inform the applicant.

Actual provisions relating to zonal authorisations

To fully understand process of registration and to make it harmonised in all MS provisions of Regulation 1107/2007 was completed with COM GD „Guidance document on zonal evaluation and mutual recognition under Regulation (EC) No 1107/2009 (SANCO/13169/2010).

Actual provisions relating to zonal authorisations

Application – art. 33

- Need to cover all intended uses for the zone.
- Proposal for MS to evaluate the application (zonal RMS) unless another MS in the same zone agrees to examine it (ZRMS – **evaluation for the entire zone).**
- Only one ZRMS for certain uses (greenhouse, post-harvest treatments, empty stores, seed treatments).
- MS Cooperate to ensure a fair distribution of the workload

Actual provisions relating to zonal authorisations

Application – art. 33 – guidance clarifies

- 6 months before application: pre-application proposal of zonal RMS (appendix 3 of GD, in the future (2016?) electronic system).
- A priori to application – pre-submission meeting - inform applicant about procedure, format (dRR), time frame, fees, recommendations, principal requirements (data to be provided), specific issues.
- Final ZRMS shall be based on a fair and proportional distribution of application amongst MS in the zone.
- ZRMS located in different zones shall cooperate for the assesment of common section of the dossier (worksharing).

Actual provisions relating to zonal authorisations

Application – art. 33 – guidance clarifies

- Application in each MS where an application is envisaged at the same time.
- List of all intended uses in each MS of the zone.
- Differences within the same use for different MS should be justified.
- Covering letter.
- Other national requirements (e.g application forms) relevant to the receiving MS.
- Confidential information.
- Core assessment and the national addenda – dRR format (GD/6895/2009).
- Language English.

Actual provisions relating to zonal authorisations

Application – art. 33 – guidance clarifies

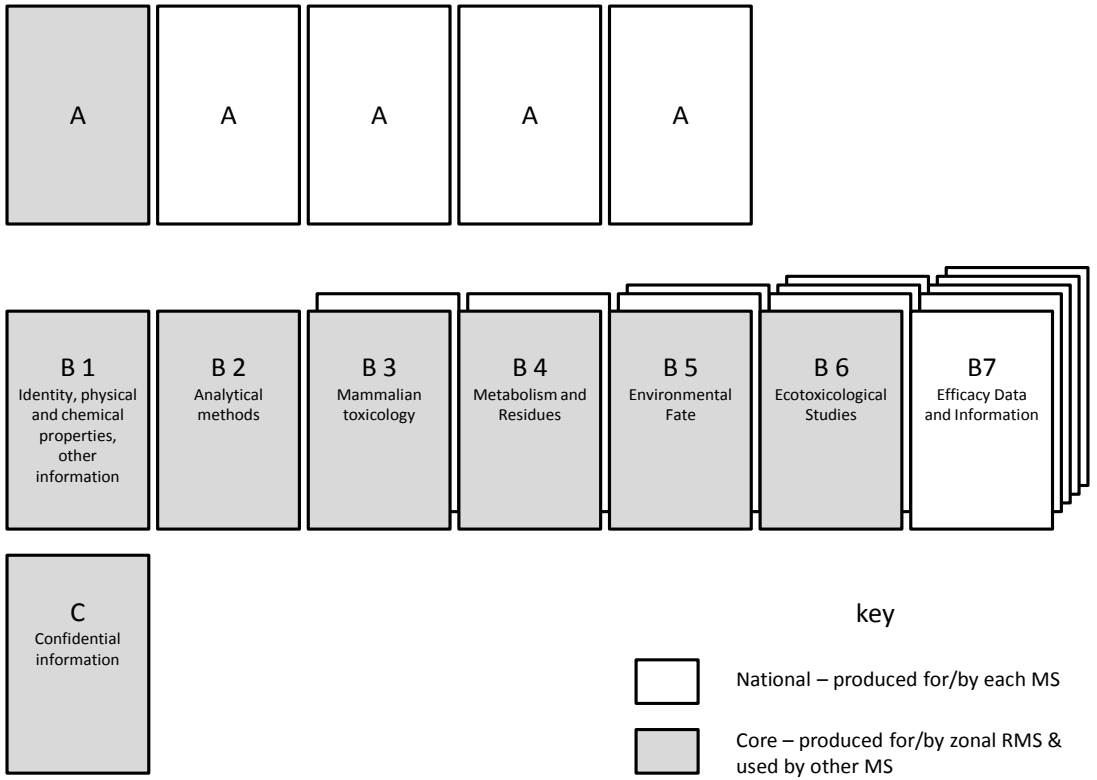
- Product dossier provided in dRR format.
- One product – one dRR.

DRR format Guidance document (SANCO/6895/2009)

The dRR is split into 3 main sections:
Part A – risk managment.
Part B – data evaluation and risk assessment.
Part C – confidential information.

Part B is split further into specialist sections, and may be further divided into core assessments (to be assessed by the zonal RMS) and national addenda (covering each MSs specific national requirements).

DRR format Guidance document (SANCO/6895/2009)



DRR format Guidance document (SANCO/6895/2009)

- For new products and re-registartion.
- Document K – study reports shall be submitted.
- Divided in core assessment and national addendas numbering in the documents follows OECD dossier format
- Risk envelope approach.
- The core data evaluation and risk assessment in each zone covers all uses required across the zone. When using the dRR, the applicant proposes which uses in the zone reflect the worst case assessment in each technical area – this then checked by the ZRMS evaluator.

Actual provisions relating to zonal authorisations

Application – art. 33 – guidance clarifies

- Each active of the product to be adressed (and described in dRR).
- Reference to EFSA conclusion and DAR including a short summary and justification when appropriate.
- dRR should be stand alone document without references to other registration report.
- Contains in princple only information relevant for the applied uses.

- After assessment of ZRMS dRR will „become” the registartion report.
- MS must ensure that all of the important information provided is correct and compliant with the UPs.
- All study reports assessment have an associated commenting box (shaded in grey) for the assesment of the MS expert.
- Commenting box is not provided for risk assessment section. MS must check that the text of the risk assessment is in compliance with requirements and guidance.
- MS should highlight at the end of each risk assessment area that suitable UP assesment was conducted, and that on this basis no harm to (e.g. operators/bystanders/consumer/ enviroment) is anticipated if the product is used with the proposed uses and proposed risk management tools.

Actual provisions relating to zonal authorisations

Timelines for evaluation art. 36

- ZRMS has 12 months from application to decide if authorisation can be granted, including comments from other MS.
- Clock stop for up to 6 months where further data requested.
- Timelines also suspended if an equivalence check is required.
- Other MS have 120 days from receipt of ZRMS assessment decision to decide on their authorisation.

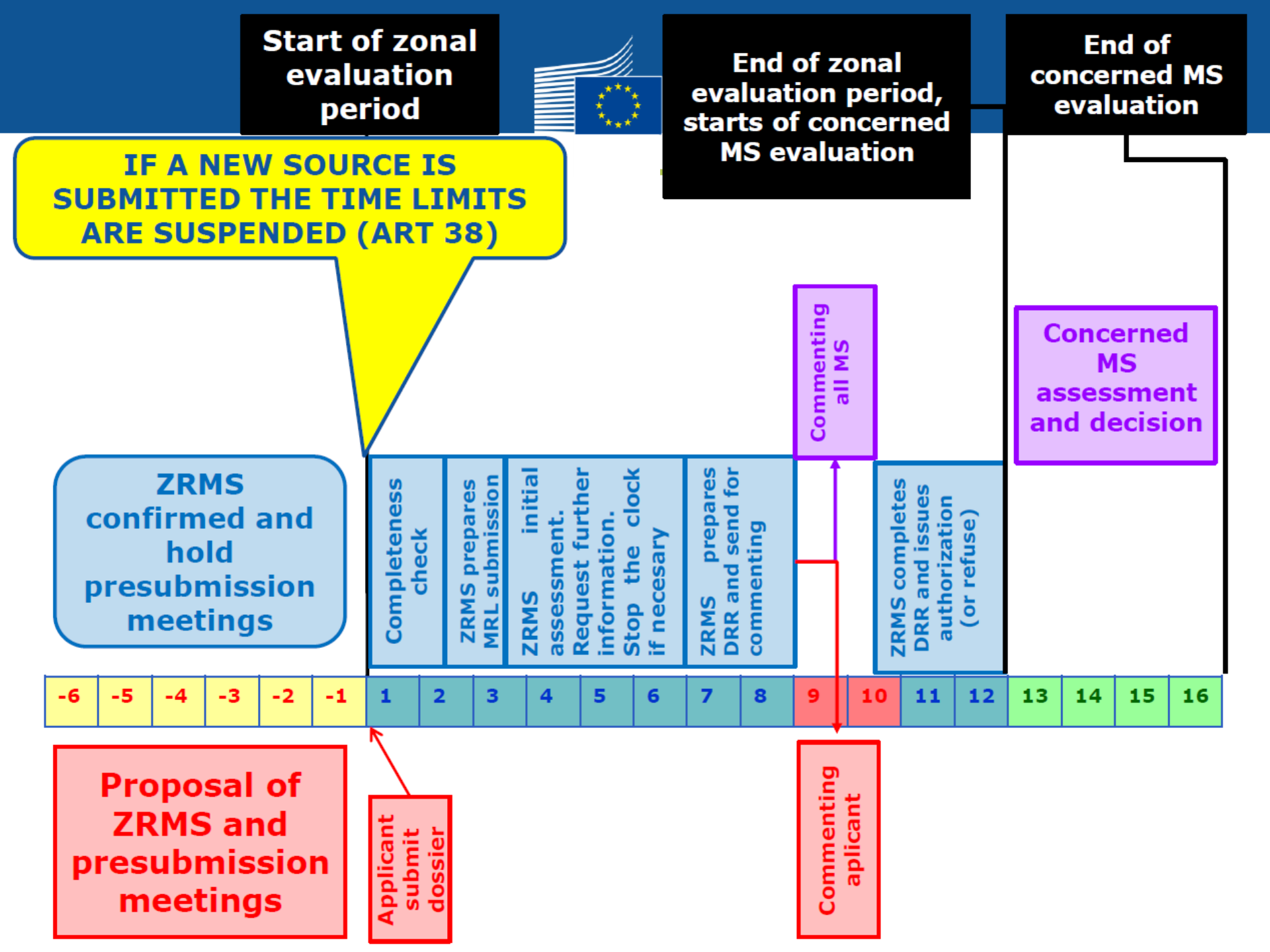
Actual provisions relating to zonal authorisations

Evaluation art. 36

- ZRMS assesment to be made available to other MS in same zone – (CIRCABC).
- Other MS grant or refuse authorisation based on conclusions of the assessment of ZRMS.
- Derogation introduced, allowing flexibility to apply alternative risk mitigation measures.
- Or refuse authorisations if the use under specific national circumstances poses unacceptable risk to human or animal health or to the enviroment (refusal with posssibility of appeal).

Actual provisions relating to zonal authorisations

- MS who refused authorisation to inform immediately applicant + COM.
- Technical or scientific justification necessary!
- No authorisation by ZRMS – authorisation in concerned MS (cMS) possible (result of assessment is crucial for cMS).


Start of zonal evaluation period
End of zonal evaluation period, starts of concerned MS evaluation
End of concerned MS evaluation
IF A NEW SOURCE IS SUBMITTED THE TIME LIMITS ARE SUSPENDED (ART 38)
ZRMS confirmed and hold presubmission meetings
Completeness check
ZRMS prepares MRL submission
ZRMS initial assessment. Request further information. Stop the clock if necesary
ZRMS prepares DRR and send for commenting
Commenting all MS
ZRMS completes DRR and issues authorization (or refuse)
Concerned MS assessment and decision
-6 -5 -4 -3 -2 -1 1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16
Proposal of ZRMS and presubmission meetings
Applicant submit dossier
Commenting aplicant

Completeness check (zonal application)

- Not a direct legal requirement in Regulation (EC) 1107/2009.
- But Regulation (EC) No 1107/2009 set out in art. 33 and 34 the requirements for the application. Implies that a completeness check to establish the completeness of the application is carried out.
- An administrative check to establish that the required elements of the application are present.
- The check shall be conducted by the zonal RMS within 6 weeks.

<u>Completeness check</u> (zonal application)– PL examples

Completeness check procedure is not harmonised within Member States of Central Zone.

Some Member States have to decide to omit completeness check and start scientific evaluation as soon as possible.

The procedure of completeness should be adjusted to the available resources and specific of the country.

Completeness check (zonal application)– PL examples

In PL it was decided, taking into account very short deadlines described in 1107/2009 and limited human resources in the authority (and huge resources in experts units), to perform completeness check of submitted applications only from administrative point of view, and send dossiers for scientific evaluation as soon as possible.

Completeness check (zonal application)– PL examples

Data requirements described not only Regulation 1107/2009 but also in national Law (fee, transaltions, power of attorneys etc).

For the purpose of completeness check „special” national form has been prepared.

Completeness check form contains a set of simple 45 questions addressed to submitted applications (additional value – it can be used by employee with basic expierence in area of registration of ppp).

Completeness check (zonal application)– PL examples

Following elements of applications are checked:

- Proof of payment of registration fee
- Power of attorney
- Letter of access (to active substance and ppp data)
- Status of active substance (possible restrictions in regulation)
- Equivalence of technical material of active substance
- Internal coherence of dRR
- Application for data protection
- Confidentiality
- Vertebrate studies

Completeness check (zonal application)– PL examples

To make life of industry easier, several additional documents were prepared and uploaded on Ministry of Agriculture and Rural Development web site (application form, guidance for applicants, self-control form for applicants).

Workshops/trainings sessions organized regularly by the authority – applicants are aware of procedures used by Ministry (we need that information due to …).

Applicants are asked to check quality of dossier before submission.

Mutual recognition

Mutual recognition

Differences between mutual recognition under Directive 91/414/EEC and Regulation 1107/2009.

Directive 91/414/EEC – art. 10 not obligatory, depends on MS.

Regulation 1107/2009 – art. 40-42 obligatory.

Mutual recognition

The same procedures, different time of application.

Zonal authorization (after authorisation of ZRMS)

Mutual recognition (at any time after zonal authorisation)

Mutual recognition

Art. 40 – mutual recognition applies once a zonal authorisation for products exists.

Applicant (authorisation holder) can apply for mutual recognition where:

- The authorisation was granted by a MS in the same zone (comparability is crucial)
- Regardless of the originating zone where the authorisation is for greenhouse use, a post harvest treatment, storage use or a seed treatment use.

Third parties (e.g. growers associations may apply for mutual recognition providing the authorisation holder agrees and the use is in the „public interest”.

Mutual recognition

Art. 42 – procedure for mutual recognition

Applicants must include:

- Copy of the reference authorisation certificate (with translation into an official language of the Member State receiving the application).
- Formal statement on identically.
- Copy of the assesment report.
- Full dossier (study reports) on request.
- Fee.

120 days to take decision.

Mutual recognition

If registration report covers all national specific risk assessment, no need for any expert evaluation.

Only check of draft label (risk mitigation and risk managment) and proceed with procedures for authorisation.

If registration report do not covers national specific risk assessment, the limited expert evaluation can be introduced.

<u>Completeness check</u> (mutual recognition)– PL examples

Following elements of applications are checked:

- Proof of payment of registration fee
- Who applies (only holder!)
- Power of attorney
- Letter of access - if needed (AS and PPP data)
- Status of active substance (possible restrictions in regulation)
- Technical equivalence of technical material of active substance

<u>Completeness check</u> (mutual recognition)– PL examples

- Is the report prepared according to UPs?
- Is the report still up to date?
- Are the proposed uses the same as evaluation in registration report?
- Report – whether contains all sections.
- Possible references to different registration reports.
- Application for data protection
- Confidentiality

Benefits

No duplication of work.

Evaluation is:

- Cheaper tha standard route for assessement.
- Quicker, limited expert evaluation.

Main obstacles for mutual recognition

- Comparability between the relevant conditions of use between MS, enviroment, climate and agronomical.
- Quality of registration reports used for MR (prepared under 91/414 – data protection, references).
- Limited number of MS used mutual recognition as standard registration producedure.

Conclusions

- **Trust is crucial.**
- Try to use much as possible.
- Good tool for learning and gain expierence in the area of authorisation of ppp.
- To avoid obstacles (comparison of agricultural condition and enviromental condition in countries, which are not covered in any national legislation or where no specific national data requirements exists).
- Use the work done already in MS it can by used in mutual recognition procedures.

Thank you for your attention