The Application of Regulation EC 1107/2009 in Austria

Institute for Plant Protection Products Evaluation and Authorisation

October, 2011

Legal Basis

- **Regulation (EC) 1107/2009** – direct application

- **Plant Protection Products Act 2011**, BGBl. I Nr. 10/2011

- **Plant Protection Products Ordinance 2011**, BGBl. II Nr. 233/2011

Plant Protection Products Act 2011

- **Main features:**

- **Enforcement of Reg. (EC) 1107/2009**
- **Authorisation of beneficial organisms**
- **Definition of competences:**
  - Federal Office for Food Safety (BAES) = competent authority (submissions to be made to BAES)
  - Minister of Agriculture and Forestry, Environment and Watermanagement = coordinative authority

Plant Protection Products Act 2011

- Labelling and documentation (origin – destination) of products that are provably destined for disposal

- Customers entitled to return to the distributor products which may not be brought on the market any more

- Registers: 1.) register of authorised PPPs
  2.) register of outlets and storage facilities

Plant Protection Products Act 2011

- **Control of the bringing on the market of PPPs**
  - authorisation and duties of inspectors
  - sampling
  - control measures (effective, proportionate)
  - confiscation
  - duties of proprietors and company owners
  - import of PPPs

Plant Protection Products Act 2011

- **General Principles for the use of PPPs**
  - implementation of Dir. 2009/128/EEC by regional legislation
  - regional action plans and national action plan

- **Fines:** up to 15.000€ (up to 30.000€ in case of repetition of the infringement)

Plant Protection Products Ordinance 2011

- More detailed regulations to the legislative framework

(e.g. transitional measures, authorisation of beneficials, authorisations for home and garden use, notification requirements, labelling, training of distributors ect.)

Application of (EC) 1107/2009

Current Situation:

- **Tasks** of the Institute for the Evaluation & Authorization of Plant Protection Products:

  - Evaluation of active ingredients
  - Evaluation and Authorization of PPP´s
  - international cooperation (within EC, OECD…)
  - MRL setting
  - control of the bringing on the market of PPP´s

Application of (EC) 1107/2009

- **Capacity of the Institute:**

31.07.2011: **45** FTE

31.12.2011: **51** FTE

31.12.2012: **54** FTE

Austrian experiences/work load

- Number of applications (AT zonal RMS) in total before 14th June 2011 including re-registrations after 14th June 2011 – i.e. voluntary Work sharing:
  - finalised: 6 formulations
  - in progress: 17 formulations (i.a. co-operation with SL, FR)
  - planned (2012/2013): 23 formulations (i.a. co-operation with SL, CZ)

- Number of applications (AT zonal RMS) after 14th June 2011 ("new" applications)
  - in progress: 14 formulations
  - planned (2012/2013): 12 formulations

Applications: developement since 2008

§§ according to PMG 97	2011 since 14.6	1.1.-14.6.2011	1.1.-31.12.2010	1.1.-31.12.2009	1.1.-31.12.2008
8 ppp with a.i. in Annex I		**39**	**20**	**5**	**8**
9 provisional authorisations		**6**	**11**	**2**	**2**
10 old a.i.s		**9**	**2**	**2**	**12**
10 *therefrom Makro's*		*7*	*1*	*1*	*4*
11 parallel imports		**3**	**8**	**10**	**6**
12 mutual rec.		**114**	**86**	**21**	**14**

Applications: developement since 2008

§§ according to PMG 97	2011 since 14.6	1.1.-14.6.2011	1.1.-31.12.2010	1.1.-31.12.2009	1.1.-31.12.2008
13 imminent danger		**22**	**20**	**21**	**22**
14 extensions in public interest		**34**	**9**	**13**	**11**
18 extensions		**14**	**12**	**6**	**5**
19 post Annex I		**1**	**11**	**3**	**6**
19 renewal in connection with **12**		**5**	**2**	**5**	**8**
19 renewal Provisional auth.		**0**	**0**	**5**	**3**
19 renewal Macro´s		**0**	**2**	**0**	**0**

Applications since 14.6.2011

Procedures according. Reg. (EC) 1107/200	Since 14.06.2011
33 AT = zRMS	**14**
33 AT = cRMS	**6**
40 Mutual Recognition	**1**
52 Parallel Trade	**4**

Authorisations 2011

- **93 PPPs authorized Jan. – Oct. 2011**

- Total number of PPPs authorized in AT: 592
- Total number of actives in auth. PPPs: 216

- **Number of Applications >> Number of Authorizations !**
- **No capacities for additional zRMS evaluations during 2012 available in AT any more!**

  (in ca. 10 cases we already had to advise Industry not to choose AT as zRMS for 2012)

Active ingredients workload

- **2011: 15 a.i.** (finalizations, MRL harmonisation)
- **2012: 1 OECD worksharing (US, CAN, AT)**
- **2012: AIR II:** Pyridate, Thifensulfuron, Cyhalofop
- **2013: 1 a.i. RMS** announced
- **End of 2013: AIR III: 2 a.i. RMS + 2 a.i. coRMS** suggested

Zonal system/experiences

- Notification sheet (including new GAP table) to be submitted to zRMS and cMS
- dRR **recommended** to be submitted (including supporting documents/studies and information about formulations and GAPs) one month prior to application in order to avoid "clock stop" and possible issues during evaluation (work load, financial issues!)
- Austria will invite MSs **and applicant** for peer-review (comments to be inserted in the reporting table) even for voluntary worksharing programme; only Core assessment should be peer reviewed, not national addenda

Lessons learned

In case of re-registrations (voluntary worksharing programme even after 14th June 2011 – COM to clarify):

- The latest date of application is stated in the GD on re-registration (2 years before finalisation of the re-registration according to the Inclusion Directive)
- The evaluation should be performed within one year after official application, i.e. evaluation ready for commenting 8 months after application, 6 weeks commenting period and 10 weeks implementing of comments (according to GD)
- Individual MS may decide on the re-registration until the official deadline as stated in the Inclusion Directive
- A national application according to Austrian Plant Protection Product law for at least one of the formulations containing the active ingredient in question is necessary for each applicant (in order to satisfy Austrian legal requirements)

Lessons learned

- Two meetings prior to application are possible (not obligatory)

  - A) First meeting should inform the applicant about the procedure, format (dRR), time frame, fees, recommendations, principal requirements (data to be provided), specific issues (e.g. confirmatory data), how to deal with new Annex II data (Annex II data must be evaluated by Annex I RMS if more adverse risk assessment, e.g ADI, ARfD, "new" groundwater metabolites…) , etc..

  - B) Second meeting (pre-submission meeting) should clarify technical issues/problems considering risk assessment where the experts from all sections will participate (phone conference, e-mail?)

- AT internal coordinator will be responsible for the corresponding Core assessment and is the primary contact person for the applicant (will attend meetings from the start of the project). In addition, the internal coordinator is responsible for administration/management of data, transmission of information, time keeping,…

Format (dRR)

- Format for section efficacy is still under discussion in the zone (dRR – BAD?)
- Studies and dRR should be provided electronically (dRR and BAD preferably as word files) and as hard copy
- For each formulation a separate dRR should be provided (especially important for re-registrations)
- Each active to be addressed! Reference to existing evaluations possible (e.g. DAR, EFSA Conclusion), but relevant summary in the dRR necessary!
- For interzonal projects (e.g. glasshouse uses: separate dRR) – "mixed" products: 1 dRR for field use, 1 dRR for glasshouse use
- New dRR formate (separate section for assessment of groundwater metabolites; improved residue section) – to be used by 1.6.2012

GAP

- All intended/current uses should be addressed in the Core assessment
- New harmonised GAP table (part of the new notification sheet)
- Important: "forgotten" uses/GAPs and cMS might mean a new application!
- Minor uses/minor crops via core assessment (confirmed by COM)

New Annex II Data

- In general, new Annex II data should not be evaluated for Core assessment according to GD SANCO/10328/2004 rev 6 (re-newal issue only)
- Exceptions:
  - Confirmatory data (to be evaluated by RMS)
  - "Adverse data" showing no safe use (Standing Committee)
  - New data showing a safe use (compared to LoEP)
  - ADI, ARfD, AOEL (favourable risk assessment) – Standing Committee
- Revised GD (to take note at the SC)

Classification and Labelling: Challenges

- Differences in Timelines between EFSA and ECHA
  - e.g. NAS: after submission of the DAR: 8 months for EFSA
  - Conclusion and 6 months for COM decision
  - For C&L: RAC opinion 18 months after publication of the CLH-report
  - on the ECHA website, no fixed timeline from RAC opinion until
  - inclusion into Annex VI of Regulation (EC) No 1272/2008
- Classification of PPPs: MS or IND issue (self-classification)?
  - AT position: MS issue (see Art. 31 of Regulation (EC)
  - No 1107/2009: "The authorisation shall include a
  - classification of the plant protection product

Classification and Labelling- challenges

- EFSA proposal often not considered by ECHA

  (additional data required)

  - Consequence: The same product may be classified differently in
  - individual MS (problem for Core Assessment: Groundwater
  - metabolites- Relevance is linked to classification, cut-off criteria)
  - AGES position paper for C&L of PPPs
- IUCLID format
  - For NAS the NOT has to submit a IUCLID format
  - Lack of experience of pesticide authority in Austria with IUCLID
  - For EAS: Interim solution (IUCLID without Robust Study
  - Summaries)

Classification and labelling:

- Draft Position Paper agreed within the central zone (with the exception of 2 MS)
- Use the most recent evaluation (EFSA conclusion, RAC opinion)
- To be discussed for the other zones as well
- Impact on groundwater metabolites!

Challenges

- Work load
- More harmonisation in risk assessment, risk management and C & L, national data requirements
- Data protection: according to Reg. 1107/2009: to be dealt on MS level separately (Transitional period)
- Article 61 and 62 of Reg 1107/2009 (“sharing of data”) – GD considered necessary?

Special issue – „data sharing“:

- Article 61 and 62 of 1107/2009 (“data sharing”)

  - applicant checks with every concerned MS prior to submission, indicating which studies they would need
  - feed-back of the concerned MS (which could be confirmation of availability, a summary, an assessment or even a registration report) is fed into the application
  - the zRMS examines the provided information and comparability, and the need to generate new data, still prior to submission
  - the concerned MS follow in principle the zRMS conclusions

- Link to relevant Guidance documents:
  http://ec.europa.eu/food/plant/protection/resources/publications_en.htm

Challenges

- No registration in zRMS – registration in concerned MS possible? (COM to clarify – not yet decided)
- Confirmatory data: In case of new applications of PPP containing active substances for which **confirmatory data** has to be evaluated by RMS advice should be given to the applicant to await the evaluation of RMS before application for zonal assessment of the PPP

MRL setting:

- Without MRL – no registration possible; i.e. MRL is to be established (published) according to Reg. 396/2005 first
- Zonal RMS is the MS evaluating possible changes in MRL´s as well
- If new MRL is necessary, a corresponding application for setting a new MRL to EFSA to be provided by zRMS as soon as possible in order to avoid prolongation of authorisation

  - MRL setting process of at least 1 year (due to EFSA´s workload) -> recommendation: application for MRL setting in advance to the application for registration
- Residue definition according to Reg. 396/2005 same as stated in EFSA Conclusion Report – to be considered!

Control of the bringing on the market of PPP´s

- **Counterfeited products and PPPs not registered in the country of destination**
- **Fraudulent marketing as parallel import products**
- **Mislabelling**
- **Misbranding (patent or trademark infringements)**
- **Inappropiate composition**
- **Presence of impurities of concern**
- **Unapproved or nonexistent manufacturing facilities in the country of origin**

Austrian recommendations for improvement

- **Regulation on cooperation between national authorities for enforcement of pesticide laws concerning control matters**
- **Increased legal powers for custom authorities**
- **Increased border controls and training for custom officials**
- **"hotline" (rapid alert system) between the competent authorities in Europe to ensure immediate action**
- **Periodical cross-border exchange of views and mutual assistance in training of inspectors**

European network of authorities

Thank you for your attention!