

# Newsletter

Volume 11, No. 2S, October 2011



**SPECIAL EDITION**

## AgChem Forum:

### A Review of Presentations

As a sponsor of this year's CIR 2011 Conference, which included the 11<sup>th</sup> annual AgChem Forum, SCC was a major participant, both at the exhibition and as presenters. Dr. Brielbeck made a presentation and Dr. Weissmann hosted the pre-conference workshop on the consequences of new efficacy data requirements for dossier generation.

In addition to SCC's participation, a number of other presentations were made regarding the current status of regulatory frameworks, including the transition between 91/414 and 1107/2009, Annex I Renewal Project, data protection issues, zonal approach, sustainable use, MRLs and the registration of biopesticides.

This special edition SCC Newsletter will summarize the presentations pertinent to the regulatory aspects of plant protection, providing you with new information and insights in the regulation of plant protection products.

For more information, please contact Dr. Bernd Brielbeck ([bernd.brielbeck@scc-gmbh.de](mailto:bernd.brielbeck@scc-gmbh.de)) or Dr. Albrecht Heidemann ([albrecht.heidemann@scc-gmbh.de](mailto:albrecht.heidemann@scc-gmbh.de)).

Please note that the following abbreviations appear in the summaries below:

EFSA =	European Food Safety Authority	ARM =	Agricultural Research Manager (software for evaluation of efficacy trials)
RAC =	Committee for Risk Assessment	dRR =	draft Registration Report
MS =	Member State	AIR =	Annex I Renewal
RMS =	Rapporteur Member State	C&L =	Classification and Labelling
zRMS =	zonal Rapporteur Member State	MRL =	Maximum Residue Level
EIF =	Entry into Force	NGO =	Non-Government Organization
MR =	Mutual Recognition		

\*\*\*\*\*

## EFSA: Feedback, progress and future initiatives

**Herman Fontier**

EFSA, Italy

The new EFSA structure, specifically the new Pesticides Units, which was put into place on 1 May 2011 consisting of PRAPeR and the Plant Protection Product Unit, and the EFSA work program were presented.

Regulation 188/2011, which deals with the evaluation of new active substances, applies to 71 dossiers: 15 peer reviews are currently ongoing; dates for commenting have to be set by the Commission a date for 12 dossiers; DAR finalization at the RMS level applies to 27 dossiers; finally, 17 draft assessment reports are under preparation. Most EFSA conclusions for those new active substances can be expected to be delivered in 2012, with some spilling over into 2013.

For green track substances, EFSA still needs to deliver 59 conclusions by the end of 2012. Five have been finalized with 45 under peer review. Commenting still

needs to be launched for 9 substances, which will happen in the very near future.

Classification and labelling of active substances and plant protection products was also presented. This issue was the subject of a workshop at the BfR in Berlin in the spring of this year, initiated by EFSA's pesticides steering committee. Participants at this workshop were the MSSs, the Commission, ECHA and EFSA. The main concern was that the CMR properties might be evaluated disjointedly. As these are the cut-off criteria in Regulation 1107/2009, they must be transparent in the evaluation. Industry was not involved because the coordination between the different authorities was the emphasis of this meeting. The outcome will be made available to the public.

In the long term, a single evaluation system is envisioned, even with an electronic system. EFSA's recommends applicants to now already start using IUCLID as the preferred electronic submission system for parts of the dossier.



### Successful transition between the old and new regulations - MS feedback

**Darren Flynn**  
CRD, UK

Regulation 1107/2009 is a regulation and not a Directive, and therefore applies directly to the MSs. This leaves little or no room to maneuver, despite some concerns that the actual wording could be seen as opposed to the initial “intentions” of a given paragraph. It is clear, however, that there is a very strong political desire to make Regulation 1107/2009 work. The MRL and the C&L processes have to be included in the evaluation procedure and the timelines set by Regulation 1107/2009. Work in these three areas must be done in parallel.

The timeline for new active substance evaluation under Regulation 1107/2009 was explained using the following example:

1. January 2012: application
2. March 2012: completeness check
3. March 2013: DAR available
4. June 2013: EFSA peer review
5. Earliest possibility for starting a product registration process through submission of the draft registration report to a zRMS
6. November 2013: EFSA conclusion report
7. May 2014: Approval vote, MRL set
8. July 2014: entry into force of the inclusion Regulation.

It is certainly questionable whether these tight timelines can be met. In principle, it should be possible, but it is difficult to assess the MRL and C&L processes in parallel to the active substance assessment. This could lead to delays.

The zRMS has to come up with its decision on registration within one year plus 120 days for the concerned MSs to deliver their national decisions. If an equivalence check of the active substances is included into the process, an additional six months for this equivalence check is required. It was emphasized that according to Regulation 1107/2009, the steering committee should agree to the zRMS originally requested by the notifier.

In the evaluation process at the zRMS level, the main concern about keeping the set timelines stems from the unknown amount and quality of comments that will be given by the concerned MS on the dRR.

With respect to mutual recognition, it was the original intention that all registrations granted under Directive 91/414 and Regulation 1107/2009 would be eligible for mutual recognition. Unfortunately, not all MS are of that same opinion.

The renewal process for plant protection products after Annex I inclusion of the active substance consists of three months for the submission by the applicant and nine months for the evaluation by the authority. If new uses or additional uses compared to the previous registration are included in this re-evaluation, article 33 of Regulation 1107/2009 will take effect and a normal twelve-month evaluation process will result.

A still unresolved issue is what happens if the zRMS refuses to grant authorization based on its national review. It should be possible to interpret Regulation 1107/2009 in such a way that a decision by the zRMS is necessary. This decision can result in an authorization or the rejection of an authorization. The issue is currently being discussed by the Commission and guidance on the interpretation is expected soon.

### Switching regulatory systems: What will remain, what will change – An industry perspective

**Jean-Pierre Busnardo**  
DuPont Crop Protection, Belgium

Here the focus was on the issues that have remained unchanged in the transition from Directive 91/414 to Regulation 1107/2009. These include:

- Safety first!
- Active substances to be evaluated and registered at EU level.
- Plant protection products to be evaluated and registered at MS level (although using the zonal evaluation approach).
- Approvals and authorizations can expire.
- MR principles are maintained.
- The dossier structure (not necessarily the dossier format) is maintained.
- Emergency authorizations are possible (giving the needed flexibility to the system).
- The intention to minimize animal testing (was already a provision in Directive 91/414, but was only poorly applied).
- One safe representative use is sufficient for active substance registration (subsequently introduced into



the process by legislation following but based on Directive 91/414).

- Evaluation process for the active substances is retained.
- Mandatory reporting of adverse effects or adverse data.

Changes that came into force with Regulation 1107/2009 include:

- Directive replaced by a Regulation.
- Approvals of active substances done in the form of Regulations not Directives.
- The scope of legislation was extended by making clear reference to human health.
- Scope covered by the new Regulation extended to include safeners, synergists and formulators.
- Document much better organized (articles with proper titles make it easier to navigate through the document).
- Criteria and conditions are more numerous (although some remain undefined).
- Efficacy for the active substances to be shown.
- Three layers of assessment introduced: hazards, risks and substitution.
- Variable approval periods from five to fifteen years
- Mandatory MR
- Introduction of benefit elements (though not yet a clear risk/benefit comparison and evaluation is introduced, article 4.7 considers the problem of the substitution principle when making such an assessment)
- Basic substances
- Low risk substances and plant protection products
- Candidates for substitution principles
- Minor uses (including the principle that other parties can apply for them and that the evaluation period is set to 120 days. Also, an extension of the data protection period is associated with such uses).
- Binding and shorter evaluation timelines (similar provisions were not introduced with Directive 91/414 but in subsequent guidance documents)
- Limited ability to supplement a submitted dossier
- Simplified admissibility (completeness check)
- Adequate EU MRLs to be required
- Zonal evaluation process for plant protection products, which minimizes redundancy of work to be done.

- Comparative assessment
- Provisions on parallel trade
- Record keeping
- Data protection and mandatory data sharing
- Public access

The Sustainable Use Directive and the Classification and Labelling Regulation must also be considered in connection with the Regulation 1107/2009.

### EU Commission feedback on the Annex I Renewal project

**Jeroen Meeussen**  
DG SANCO, Belgium

The renewal program for active substances currently consists of AIR-1, AIR-2 and AIR-3. For the AIR-1 project, all seven active substances have been re-evaluated and re-included in Annex I. The Regulation concerning AIR-2 was published in December 2010 and guidance documents are being published to clarify specific issues. In the third step (AIR-3), meetings were held to specify the needs and the requirements.

The provisions of Directive 91/414 continue to apply for all active substances renewed under AIR-1. A Step 1 check is due six months after entry into force (EIF) and Step 2 has to be completed four years after the EIF date. From the experience with AIR-1, only two lessons learned were not implemented in subsequent legislation: the request to establish a procedure to amend the specification of the active substance, and the request to link the dossier format to the intended output format generated by the authorities.

The AIR-2 project covers 31 active substances with expiry dates in 2011 and 2012. The expiration of the Annex I listing for these substances has been extended to 31 December 2015. The project is governed by the transition from Directive 91/414 to Regulation 1107/2009. AIR-2 Regulation 1141/2010, with an entry into effect date of 28 December 2010, received 29 admissible applications. Out of the 31 active substances under AIR-2, two will not be included in Annex I. The timeline for AIR-2 from dossier submission to the Commission decision is 29 months, not including the provision for a three-month period to stop of the clock.

The AIR-3 process will be conducted fully under Regulation 1107/2009. Article 14 describes the approval and cut off criteria, as well as the maximum period of fifteen years for approval. Article 15 stipulates that the

# Newsletter

Volume 11, No. 2S, October 2011



## *SPECIAL EDITION*

application should be submitted three years before the expiration date of the first approval, and that new data are to be identified clearly in the updating statement. Article 17 allows for the approval period to be extended.

AIR-3 will cover all active substances expiring between 2013 and 2018. It does not include the big peak of expiring active substances in 2019. These will be included in a subsequent AIR-4 project. The AIR-3 project covers a total of 149 active substances. The intention is for all decisions to be made before 2018. It is currently envisioned that the submission should be done in waves over a period of three years. The same timelines should apply for the evaluation as for AIR-2. Submissions are planned for 2014 to 2015. No grouping of active substances is intended; instead, the waves should in principle follow the expiration dates.

It is reasonable to assume that approximately 50 active substances can be evaluated per year. Based on this experience, the approval period for substances expiring in 2013 and following years will have to be extended accordingly.

The new data requirements that will enter into force in 2014 are to be taken into account in the evaluation of AIR-3 substances. The new data requirements are to take effect starting 1 January 2014.

In the AIR-1 process, fourteen MSs were involved as rapporteur and co-rapporteur. Twenty-one MSs are currently dealing with the AIR 2 substances, and it is intended that all 27 (or 28) MSs participate in the AIR 3 evaluations.

In addition, in these evaluations, the rapporteur/co-rapporteur system should be maintained, with the co-rapporteur being from a different zone than the RMS.

In the AIR-3 program, the old data requirements will formally apply to the first waves of submissions. It is clear, however, that the new data requirements will be in place once the plant protection products containing these active substances are up for registration. For all other waves, the new data requirements will be in place and must be applied. Alternatively, the new data requirements could apply to all waves of the AIR-3 process, which in turn would require more extensions of expiry dates. It is the Commission's opinion, however, that if the old data requirements apply to the active substance evaluation, they should also apply in the subsequent plant protection product authorization processes.

For EU submissions, the OECD dossier format should be followed for the active substance and the dRR format for the subsequent authorization of the plant protection product. The AIR-2 guidance documents should be closely followed. In the evaluation process, the authorities will issue a Renewal Assessment Report (RAR) for the active substances. The numbering of the RAR should be the same as is being used for the OECD format.

It is expected that the Commission will issue a draft registration on the AIR-3 process early in 2012.

### **Industry feedback on the Annex I Renewal (AIR) process**

**Dr. Michael J. Carroll**  
Dow AgroSciences, UK

Worldwide there are three different ways under which plant protection products dossiers are reviewed: spontaneous review, as done in Australia, where the authorities start their review independent of the notifier; data call-in, where the notifier is requested by the authorities to submit data for the re-registration of their products (this is the type of review used in the US); and finally, the fixed-date procedure for re-submission of an application, as is practiced within the EU.

A description of the AIR-1 process used as an example the active substance Fluroxypyr, which was evaluated and will be successfully re-included into Annex I starting 1 January 2012. It was noted that only two of the seven active substances re-registered under AIR-1 were able to get Annex I re-inclusion without a request for confirmatory data.

Carroll foresees the technical specification of active substances as the key area for AIR-2. He emphasized that the MRL and C&L dossiers should and must be evaluated and submitted together with the full re-registration dossier for active substances.

The data protection period under Regulation 1107/2009 for active substances commences with the first registration of a plant protection product and not, as under Directive 91/414, with the inclusion of the active substance into Annex I.

Possible problems occurring with the AIR-3 review program might stem from the fact that formulations from AIR-2 active substances will also be under review in the MSs. The RMSs for this wave of active substance re-evaluation will change to further spread the work to



# Newsletter

Volume 11, No. 2S, October 2011



## SPECIAL EDITION

all EU countries. It is expected that the list of designated RMSs will be available in the beginning of 2012.

The new data requirements voted upon this year will be applicable at the beginning of 2014. Still to be considered is which AIR-3 wave will fall under the new data requirements and which might remain under the old data requirement regime.

### Data protection and sharing under the Regulation 1107/2009

**Claudio Mereu**

Field Fisher Waterhouse, Belgium

Regulation 1107/2009 prescribes a data protection period of 30 months for data on active substances. This data protection period starts from the date of the first product registration in a given MS. For plant protection product data, the usual ten-year data protection period also applies under Regulation 1107/2009. It is stipulated in the Regulation that the same study cannot receive data protection more than one time. If a study is submitted to the authorities to support two different molecules, this provision applies.

The MSs are requested to prepare lists of studies for all interested parties, naming the studies for which the first applicant has applied for data protection. In this list, reasons why they should be applicable for data protection must be given. The Regulation is unclear about the definition of third parties: whether this description only applies to a future prospective applicant, or if it also includes other parties, such as NGOs.

Articles 61 and 62 of Regulation 1107/2009 stipulate the rules for data sharing. For all studies, the following applies:

- Parties should take reasonable steps to reach agreement on sharing studies.
- The compensation for the original data owner must be fair.

The provisions above do not provide for any sanctions if no agreement has been reached on non-vertebrate studies.

If agreement has not been reached on the sharing of vertebrate studies, the MSs are authorized to use these studies for the second applicant's submission.

Under these provisions, it is unclear what a "best effort" is that should be undertaken to reach an agreement.

Furthermore, it is unclear what the procedure should be if no agreement is reached. The UK CRD has a good website defining information on data protection and the data sharing provisions of the Regulation. The UK is one of the few MSs that has an arbitration system in place.

With respect to confirmatory data submitted after Annex I inclusion of an active substance, a new guidance document is available stipulating what data are applicable for data protection if their evaluation triggers an amendment to the Annex I inclusion Directive:

([http://ec.europa.eu/food/plant/index\\_en.htm](http://ec.europa.eu/food/plant/index_en.htm)) [Refer to Publications section found on this website.]

If not triggered, the provisions of the previous guidance document apply, i.e. data protection is not applicable to these data.

### EFSA initiatives on Endocrine Active Substances

**Dr. Hans Steinkellner**  
EFSA, Italy

A scientific report from the Endocrine Active Substances Task Force was published on 30 November 2010 and is available from the EFSA website. This report gives an overview on the ongoing activities of EFSA with respect to endocrine disrupting properties.

EFSA is currently compiling and revising the data requirements on endocrine disrupting properties and expects to publish this information in two independent Regulations in the near future. Currently, dialog is ongoing between EFSA and ECHA, as well as the pesticide unit of EFSA and the US EPA on endocrine disrupting properties, cumulative risk assessments and probabilistic risk assessments.

Member State activities include, e.g. the position paper published by Germany and UK introducing the concept of threshold concentrations with respect to the regulatory definition of endocrine disrupting properties. Furthermore, the Danish EPA has also published a paper on the endocrine disruption issue. It was acknowledged that the two concepts are very different. Furthermore, France and Italy are also active in this respect.

On an international scale, the OECD, WHO, the US EPA, Canada and Japan are researching the issue. OECD guidance documents are currently under preparation.

# Newsletter

Volume 11, No. 2S, October 2011



## SPECIAL EDITION

EFSA is also working on the assessment of cumulative effects and cumulative risk assessments, and has published two opinions on this issue, which are available from the EFSA homepage. EFSA considers the cumulative assessment to be an important issue. It should be ready to conduct cumulative risk assessments by the end of 2013.

Another important issue currently under investigation by EFSA is the non-dietary exposure to pesticides, which is to be taken into account in future risk assessments.

### Coming to sensible regulatory criteria for ED – an industry view

**Coralie von Breukelen-Groeneveld**  
Bayer CropScience, Germany

The assessment of endocrine disrupting systems is extremely complex and must be seen under multiple toxicological endpoints (not only reproductive endpoints). A wide range of chemical agents, natural as well as artificial, influence the endocrine system. Contrary to the current toxicological risk assessment by the assessment of endpoints derived from toxicological studies, endocrine disrupting properties can only be properly assessed based on mechanistic data.

As an example of the impact for a wide definition of endocrine disrupting properties, fungicides were assessed. Thirty years of toxicological research are available for the main fungicides. Strobilurines have been widely used, but between 2000 and 2008, a significant resistance of the target organism arose. To overcome this resistance, the use of Triazoles has significantly increased. In the future, SDHI fungicides, which apply a new and different mechanism in fighting fungi, should enlarge the portfolio of plant protection products.

### Work Sharing in the Northern Zone

**Tove Jern**

Ministry of Agriculture and Forestry, Finland

The first pilot project on work sharing, began in the northern zone in 2005. The idea was to harmonize the assessment criteria and to form expert groups for discussions on controversial areas. The results of this first round were requirements on the harmonization of the formulation and the GAPs across the northern zone. In 2009, a second round on work sharing began to focus

on re-registration, the harmonization of assessment reports, and the need for guidance documents on the assessment criteria and national requirements.

Today, as a result of these two rounds of pilot projects in the northern zone, a good network of experts and guidance documents are available. The application form has been harmonized across the zone, as are the templates of the notification, the completeness check and the letters to ask the applicants' comments.

In the re-registration process now under way, the zRMS is assigned to the applicant on a case-by-case basis. The assessors have so far given positive feedback on the use of the dRR and the risk envelope approach. It was acknowledged that the timeframes set in the Regulation 1107/2009 are challenging.

For the authorities, the companies are in a key position to prepare an effective pre-meeting as required by Regulation 1107/2009. In the northern European zone, plans include further workshops for assessors on different subjects. The importance of such meetings was highlighted and also the importance of regular meetings of the zonal steering committee.

### Feedback from the Central Zone

**Maarten Trybou**

Federal Public Service of Public Health,  
Food Chain Safety and Environment, Belgium

In the central zone, a notification form for the intended zonal applications including a new GAP table format has been approved by the zonal steering committee. New guidance documents on renewal, withdrawal and amendment of authorizations, as well as a second guidance document on zonal evaluation and mutual recognition have been noted by the SCoFCAH in July 2011. These have since been published and are available on the Internet.

- Zonal Evaluation and Mutual Recognition
- Renewal, Withdrawal and Amendment of Authorizations

([http://ec.europa.eu/food/plant/index\\_en.htm](http://ec.europa.eu/food/plant/index_en.htm)) [Refer to Publications section found on this website.]

It is expected that applicants actively seeking a zonal Rapporteur Member State for the re-registration of products, will submit a true zonal dossier. For the dRR, (which the speaker considers to be the obligatory format since October 2010), new templates have been noted by the SCoFCAH. The amendments include a modification

# Newsletter

Volume 11, No. 2S, October 2011



## *SPECIAL EDITION*

of the residues section, as well as a new section eight dealing with the assessment of ground water metabolites. A specific template for microbials as active substances is available. The need to use the agreed EU endpoints in the risk assessments was emphasized. In addition, the applicant should clearly state which risk assessment models have been used and from where the endpoints originate, particularly, if they deviate from the agreed List of Endpoints.

Currently, there are new checklists under development for the dRR. The northern European zone is introducing a tick box version, while Belgium is developing a true list of requirements as given in Regulation 1107/2009.

The application database under development at the EU level currently only consists of overview tables on zonal applications. The Commission is generating a full database that can also be used by applicants in the future.

Mixed uses (outdoor and greenhouse use) should be split into separate applications and separate dRRs, one for the entire EU and one for the outdoor use in each zone. Currently, a pilot project with Fenpyroximate is ongoing.

The availability of vertebrate studies from previous applicants should be checked by the subsequent applicant in all MSs. This information should then be provided to the zRMS for evaluation. It was emphasized that if a new vertebrate study was submitted without adequate justification, the whole application would be rejected and the applicant would then have to re-submit the application, referring to the available study.

The national requirements in the central European zone have not yet been compiled into a single guidance document, but the MSs have been requested to minimize such national particularities.

A possible conflict between the sustainable use Directive 2009/128 and Regulation 1107/2009 was identified. While the Directive foresees that MSs can set national requirements for home and garden uses, the Regulation strives for more harmonization in all areas. Belgium has established many new data requirements for home and garden uses.

In the central European zone, the concerned MSs can be supplied with the dossier one to three months after the submission of the dossier to the zRMS. Nevertheless, a notification of the submissions should be sent to all MSs.

In the efficacy section, the use of ARM listings in the dossier have become common. Applicants should submit full Eppo trial reports. It is possible that some MSs may then request the submission of ARM files in addition (e.g. Germany).

If during evaluation under Regulation 1107/2009 a change of GAP is necessary to generate a safe use, this can be accepted by the MSs if no extra work is required. Otherwise, the applicant must re-submit the full application.

Applicants are requested to use the review report of the zRMS to re-register or amend existing registrations. The original dRR should not be used as a basis.

Currently, a new guidance document is under development to define the requirements of a major formulation change in the composition.

### **Feedback from the Southern Zone**

**Hara Panagopoulos**

Ministry of Rural Development and Food, Greece

The southern Member States (SIMS) started work sharing in 2004. Work sharing will be made if a minimum of three MSs are involved. Until now, two zonal applications have been made and a further fifteen are expected in 2011/2012. Currently, Greece is already planning the acceptance of work as zRMS for the third quarter of 2012. With this experience, it is strongly proposed to contact the intended zRMS at least two years prior to submission.

Portugal, on behalf of the southern MSs, is developing a new zonal MS applications database that will include the entire life cycle of an application. It will be oriented to the Eppo standard definitions of uses. This seems to be a duplication of work, as the other zones appear to have developed equivalent systems!

According to Panagopoulos, the aim of harmonization within and between the zones is challenging. A solid and efficient platform for communication exchange between the authorities is needed, as even within countries, the assessors often have different views.

The risk envelope approach is widely adopted and has to be developed further. Applicants are encouraged to rationalize uses and to even consider coordinating their uses with other applicants in order to make the system as efficient as possible.



### Practical experiences with zonal dossier preparation using the dRR format

**Dr. Bernd Brielbeck**

SCC Scientific Consulting Company, Germany

Experience gained in the authorization of plant protection products done at the MS level through the zonal approach was presented and the generation of efficacy studies under the new zonal approach highlighted.

The zones, as prescribed in Regulation 1107/2009, were put into context of the existing EPPO zones. Three special cases were identified: France, which belongs to the southern zone for the Regulation 1107/2009 and two different EPPO zones; Bulgaria, which belongs to the southern zone according to Regulation 1107/2009, but also to the southeastern EPPO zone; and finally, Poland, which is the only central zone country belonging to the northeastern EPPO zone. With these special cases in mind, it is important to discuss the intended efficacy program with the involved MSs or the zRMS prior to initiating studies. Although SANCO/6895/2009 considers the efficacy data evaluation to be in the responsibility of the individual MS, in practice the zRMSs will already conduct the assessment as part of their core dossier evaluation. Therefore, initial discussions with the zRMS might be necessary two or three years prior to the intended submission of a plant protection product dossier. Nevertheless, harmonization can already be seen in this field, as many MSs are now moving from requesting efficacy trials from their own national territory to trials conducted in the respective EPPO zone.

The use of new Annex II data was then considered. Normally, in a plant protection product dossier, only the agreed endpoints as provided in the List of Endpoints for the active substance should be used. New Annex II data can be introduced into the product dossier only, if they show adverse effect, are required to fill data gaps (i.e. extend the range of uses) or are needed to render a risk assessment safe that was previously not/no longer safe with the agreed endpoints. If, for example, such studies are generated and result in a new DT50 value, this value could be used in the risk assessment if it renders a previously unsafe assessment safe. If, in the same study, new relevant metabolites are found, that eventually are shown not to leach into groundwater, and thus do not generate adverse effects, they should not be

used in the assessment. Details must be discussed in the pre-meeting with the zRMS.

A number of national particularities in the submission of dossiers, particularly the staggered submission of dossiers to different authorities, as in Belgium, the Czech Republic and Slovakia, were highlighted.

With respect to the evaluation criteria of dossiers, there are certainly some that are inherent to the national conditions, such as the acceptance or non-acceptance of a 50 m buffer zone. Others seem to contradict the intention of harmonizing the procedure.

An example presented was the assumption that an active substance equivalence has been shown and agreed upon by the EU RMS and been submitted subsequently in a zonal evaluation to a zRMS. Assuming the equivalence accepted by the EU RMS would have been questioned by some MSs on the basis that an updated five-batch analysis would be necessary, what would be the outcome of the zonal evaluation if one of those MSs would subsequently become the zRMS?

Finally, difficulties in selecting a zRMS were highlighted. Although SANCO/13169/2010 indicates that “the applicant’s preference should be taken into consideration wherever possible”, it is the zonal steering committee that decides. It cannot be guaranteed that the intended zRMS will also be the MS finally selected for this task. This in turn raises questions as to who should be contacted to discuss all the previously mentioned cases.

### Practical experience with the MRL regulation – Member State Feedback

**Claude Vergnet**  
AFSSA, France

France’s experience with the evaluation process for MRL dossiers according to Regulation (EC) 396/2005 has been that bottlenecks in the MS evaluation mostly depend on the completeness and the quality of the dossier submitted. France has as of now processed 53 applications: of these 53 dossiers, six were subsequently withdrawn by the applicant. In France, the “stop-of-the-clock” period was up to eighteen months due to the lack of data. The evaluation period was between fourteen and twenty-three months from acceptance of the dossier to issuance of the Regulation.

MRL applications can be submitted to the MS before any application for the registration of the product has



been submitted if a use in the MS is envisaged. It was emphasized that a parallel evaluation of the MRL dossier and the Regulation 1107/2009 active substance dossier is necessary. MRL settings must be clear before a plant protection product authorization can be granted.

Currently, new guidelines on the setting of MRLs are under discussion, including MRLs for honey and fish, and also consider MRL setting based on monitoring data. Two main areas of future work envisioned: the setting of MRLs for feed and consideration of the outcome of the cumulative risk assessment.

### **Practical implications of the Sustainable Use Directive**

**Romano De Vivo**  
Syngenta, Switzerland

The Sustainable Use Directive 2009/128/EC calls upon the MSs to develop National Action Plans (NAPs) and implement measures to reduce the risk of pesticide use and is to be transposed into national legislation by the end of 2011. NAPs are to be drafted by the end of 2012.

In the view of the speaker, the final risk manager is the farmer. Incentives are needed to ensure implementation of the intended measures. It should be kept in mind that risk perception is a major consideration: "what does my neighbor think about my applying pesticides."

It is important for the authorities to assess the success of the implementation of NAPs at an economic and social level, as well as under environmental aspects.

While the Sustainable Use Directive focuses on the use phase of plant protection products, Regulation 1107/2009 focuses on the evaluation of active substances and of plant protection products. Both pieces of legislation must therefore be seen as complementary.

### **Registration of Off-Patent Products**

**Dr. Pavel Minár**  
State Phytosanitary Administration  
Czech Republic

The head of the Plant Protection Product Registration Department in the Czech Republic complained about the uncertainties associated with generic applications. Clear rules are required to define the comparability of formulations and for data compensation.

One of the most frequent questions addressed to his authority is "how many efficacy trials would be required for the Czech Republic territory?" He referred to the relevant EPPD standards defining the number of fully supportive trials required from one climatic zone. Minár emphasized that the relevance of the trials which should be fully supportive for the use is important, not the territory from where they come.

### **Minor use crops and the authorization procedure**

**Euros Jones**  
ECPA, Belgium

"What can be done at the EU level to ensure availability of crop protection products for minor uses?" The answer from the industry perspective was presented. Incentives for applications for minor uses given in Regulation 1107/2009 were highlighted, in particular, the additional three months of data protection for each minor use authorized. Nevertheless, the impact on the investment is unclear and there is currently no list of eligible minor uses. Furthermore, Article 51 of Regulation 1107/2009 gives an exemption stipulating that no efficacy package be requested for minor uses. Even so, some MSs still request some data and these data requirements are still different according to the MS involved.

Currently, a consultant evaluation is available on the SANCO website and a Commission report is due in early December. The general conclusions of the report will be that the economic impact of minor uses is more than €1 billion (over nine million hectare), with a significant impact on many sectors.

Strong support exists for the creation of an EU fund, which would reinstate working groups or create a minor use database. From the view of food chain associations, such an EU-wide or zonal list of minor uses as well as a common system for label extension (off label uses) and a simplified study protocol for studies conducted to support minor uses would be helpful. Furthermore, an advisory group to assess future needs was proposed by the speaker. The cost and complexity of the regulatory process should be addressed in new data requirements and new guidance documents.

According to the Jones, the root of all current problems is the growing complexity of the regulatory process.

# Newsletter

Volume 11, No. 2S, October 2011



## *SPECIAL EDITION*

### **Biocontrol Products and European Legislation**

**Ulf Heilig**

International Biocontrol Manufacturers' Association  
France

The three classes of biocontrol agents, pheromones (semiochemicals), natural substances (botanicals) and microbials, were presented. There is a need for guidance documents for the evaluation of microorganisms and the many disadvantages basic substances have facing the rules of Regulation 1107/2009. Most annoying is: they must not be used in mixtures; their data are not protected; and they may not be advertised as plant protection products. In order to follow the idea of

promoting non-chemical plant protection measures according to Regulation 1107/2009 and Directive 2009/128/EC, Heilig stated that biopesticides should not be summed up as pesticides in the statistical evaluations of pesticide use in the EU, because biopesticides should not be subject to national pesticide reduction programs.

He further criticized the disadvantage for many biopesticides due to the unclear MRL situation (no endpoints available) caused by their pending status in the EU review.

**SCC Scientific Consulting Company Chemisch-Wissenschaftliche Beratung GmbH**  
Dr. Friedbert Pistel, President  
Am Grenzgraben 11 · D-55545 Bad Kreuznach  
Phone +49 (0) 671-29846-0 · Fax +49 (0) 671-29846-100  
scc@scc-gmbh.de · [www.scc-gmbh.de](http://www.scc-gmbh.de)

**SCC Liaison Office Japan**  
14-24 Tokiwadai,  
Kashiwa-shi  
Chiba-Ken 277-0087, Japan  
Phone/Fax.: +81 (0)4-7162-4262

**Mr. Toshiyasu (Ted) Takada, Director**  
e-mail: [toshiyasu.takada@scc-japan.com](mailto:toshiyasu.takada@scc-japan.com)

**SCC Liaison Office Japan**  
6-2-14 Asagayakita,  
Suginami-ku  
Tokyo 166-0001, Japan  
Phone/Fax.: +81 (0)3-6762-5261

**Mr. Kenji Makita, Senior Consultant**  
e-mail: [kenji.makita@scc-japan.com](mailto:kenji.makita@scc-japan.com)

Previous Newsletters can be found on our website [www.scc-gmbh.de](http://www.scc-gmbh.de), under *Newsletter Archive*. You can also subscribe to the Newsletter (free-of-charge) at this site.

**NOTICE:** While we have compiled the enclosed information with the utmost care, SCC GmbH is not liable for the consequences of anyone acting or refraining from acting in reliance on any information. Further, SCC has no control over the websites that the reader is linked with using our Homepage/Newsletter. Users linking to other websites do so at their own risk and use these websites according to the appropriate laws governing their usage