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AGROCHEMICALS

# German BVL Conference on the National Registration of Plant Protection Products

The German Federal Office for Consumer Protection and Food Safety (BVL) regularly updates applicants on the development on European and international levels, and how the new requirements are to be implemented on the national level in Germany. The latest information pertaining to the registration of plant protection products (PPPs) was held on 21 September 2010 in Braunschweig. The following provides a summary of the pertinent information covered during this meeting.

## Status of national registrations of plant protection products

**Dr. Henning Bruno**
BVL

Dr. Bruno gave an overview of the applications for the registration of plant protection products in Germany as of 15 September 2010. The number of applications filed up to this date in 2010 totals 364. Of these, 78 are currently in the pre-evaluation, with 29 of them blocked. There are 151 in the main evaluation, 21 in the management phase, and 23 are in the final stage of issuing the registration certificate. A total of 62 applications have been blocked after the main evaluation. The number of blocked evaluations is increasing but it was emphasized that this also includes blockages of plant protection product applications which are due to voluntarily withdrawal of active substances.

In 2008, 82 applications according to § 15, § 15b, § 15c PflSchG were received by the BVL, 98 in 2009 and in 2010 a total of 140 applications are expected until December of this year.

The total number of applications according to § 15, § 15b, § 15c PflSchG from January to August 2010 was 90, with 30 % of these applications presented electronically to the BVL. The BVL is aware that the very strict requirements for this application type, i.e. reference can only be made to applications which are already available electronically; limit the number of electronic applications.

The speaker emphasized that in addition to Annex II studies which are to be submitted to Germany, reference lists (Document L) and Document M must also be presented. The active ingredient dossier can still be submitted in the old EU format (document 1663VI94 rev. 8, 22 April 1998), but the reference list should then be giving all Annex points according to the EU as well as to the OECD numbering. If CADDY dossiers are submitted, each active ingredient and each plant protection product should be dealt with in an individual CADDY. Also, active ingredient information (Annex II) and plant protection product (Annex III) information must not be mixed in the CADDY. BVL accepts CADDY 2.0 as well as CADDY XML (version 1.0). Currently, the BVL asks not to submit CADDY XML (version 3.0) dossiers. This will only be possible as of January 2011.

In the CADDY dossier, the Annex points should be given as presented in the BVL guidance document regarding electronic applications. Refer to:

http://www.bvl.bund.de/cln_027/nn_745304/DE/04__Pflanzenschutzmittel/00__doks__downloads/eAntrag-Leitfaden,templateId=raw,property=publicationFile.pdf/eAntrag-Leitfaden.pdf,

pages 7 to 12. This is also valid and important for applications on mutual recognition.

Applications can be made by submitting one copy of the dossier. If, in addition, a CADDY dossier is provided, 4 copies of the CADDY dossier are required. The BVL assumes by default that the CADDY documents and the paper documents submitted are identical. If this should not be the case, the BVL requests that the applicant clearly indicate this fact.

If reference is made in a dossier to documents previously submitted by the same applicant, the BVL asks that a pertinent reference list also be submitted. Reference to a company's own application made prior to 1998 should be re-submitted to facilitate the work of the BVL.

The BVL issued 20 registrations in 2000, rising to approximately 130 registrations in 2006 and decreasing again to approximately 59 in 2009. The number

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of mutual recognition applications is on the rise and was very high in 2009.

The BVL is also already active in the pilot phase of zonal registrations. It was emphasized that, although the zonal approach is chosen in these cases and Germany acts as the Zonal Rapporteur Member State, the evaluations are actually conducted under Council Directive 91/414/EEC and the currently existing German plant protection law.

Germany already accepts the draft Registration Report (dRR) format as submission format for national applications. According to SANCO 6896/2009 rev. 1 dated 02 January 2009, the Member States will be required to accept this format as of 2 October 2010. Nevertheless, the draft Registration Report format is not mandatory, and after the October deadline – and even after 14 June 2011 – dossiers in the old OECD format can be submitted and will have to be accepted.

## The new plant protection products regulation and its national implementation

**Dr. Steffen Beerbaum**
Federal Ministry of Food, Agriculture and Consumer Protection (BMELV)

Dr. Beerbaum emphasized the importance of maintaining a very high level of protecting human health and the environment, which is also guaranteed in the new Regulation (EC) No 1107/2009. Secondly, a harmonization of the registration procedures is expected, and a more transparent and open registration procedure will be ensured with the new Regulation (EC) No 1107/2009.

The main changes of the new Regulation (EC) No 1107/2009 as compared to Council Directive 91/414/EEC are as follows:

- mandatory mutual recognition
- very detailed criteria defined for the evaluation
- comparative assessment and substitution
- if public interest is ensured, a mutual recognition can also be initiated even if the registration holder is opposed to it
- mutual recognition can only be refused in very limited cases
- an application for the registration of a plant protection product can be submitted from companies as well as associations
- active ingredients with significant risks cannot be registered
- candidates for substitution are identified
- very tight time tables for the evaluation process are set requiring very efficient and timely registration processes.

The above points will result in a more coordinated cooperation between the different Member States. They will also lead to a harmonization of the registration requirements. The speaker expects a competition between the different regulatory authorities, as they now compete in becoming Zonal Rapporteur Member States. The new Regulation (EC) No 1107/2009 sets incentives to develop new plant protection products with less risks and at the same time to also register plant protection products in minor uses. The bureaucratic overhead in the authorities will decrease and decisions will be taken quicker.

Although Regulation (EC) No. 1107/2009 is directly applicable in all Member States, Germany has to amend its national plant protection law to regulate the cooperation of the different German authorities (BVL, BfR, JKI, UBA) involved in the national registration process. The German plant protection law is currently being discussed within the BMELV ministry. Discussion between the various ministries is expected to begin in October 2010. Subsequently the German federal states and associations will be included in the discussion.

The ministry expects that the new Regulation (EC) No 1107/2009 will increase the availability of new plant protection products.

## Defining zonal registration and mutual recognition in Europe

**Dr. Hans-Gerd Nolting**
BVL

With zonal evaluations, Dr. Nolting emphasized, the need for a meeting between the applicant and the Zonal Rapporteur Member State approximately half a year before the submission is to be made.

In the zonal evaluation, the communication between the different Member States is of utmost importance. To simplify this communication, zonal steering committees have been introduced. Also, an inter-zonal steering committee exists. A data base, important

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mainly for the exchange of data, is planned and will be developed at EU level.

In the zonal evaluation it is expected that the Member States (concerned Member States, cMS) do not assess the data available, but await the evaluation of the Zonal Rapporteur Member State. Nevertheless, all countries should receive the data at the same time, if possible. The national addenda are only intended for the respective countries.

The Zonal Rapporteur Member State is proposed by the applicant and only under exceptional circumstances can the zonal steering committee overrule this wish.

The BVL expects that the current draft Registration Report format will be amended.

Also, Member States to which no application has been submitted can comment on the draft Registration Report during the zonal evaluation period. It was emphasized that the core assessment should be as broad as possible and the national addenda should be limited as much as possible. Nevertheless, national addenda are still necessary as there might be differences in the applications in the different countries. Also, there is currently not a sufficient level of harmonization of the evaluations.

The timeframe of the evaluation as provided in Regulation (EC) No 1107/2009:

- 6 months before submission: pre-meeting
- 8 months after submission: publication of the draft registration report
- 9.5 months after submission: comments of the cMS on the dRR
- 12 months after submission: registration in the Zonal Rapporteur Member State
- 120 days after this first authorization the registration in all other Member States should be granted.

The speaker considered this timeframe as very ambitious.

As of 14 June 2011 only the zonal application procedure will be possible. Even if an application is submitted to one Member State only, the zonal procedure is started.

## Procedures for handling applications for zonal registration in Germany

**Dr. Axel Wilkening**
BVL

Dr. Wilkening presented different possible regulatory cases. Because consultations within and between the authorities are still ongoing, it was emphasized that the information provided is to be considered preliminary.

Different possible cases for Germany were presented:

- VZZ 11: zonal evaluation, Germany as Zonal Rapporteur Member State, first application
- VZZ 12: zonal registration, Germany as Zonal Rapporteur Member State, re-registration
- VZZ 21: zonal registration, Germany as concerned MS, first application
- VZZ 22: zonal registration, Germany as concerned MS, re-registration
- VZZ 3: zonal registration, Germany not involved
- VG: mutual recognition.

The most important changes introduced into the registration process by Regulation (EC) No 1107/2009 as seen by Germany are as follows:

- Reduced timeframes for the evaluation (12 months for a normal application and 9 months for a re-registration)
- New members involved in the process (in addition to the German authorities there are Member States and applicant)
- The German expert committee (SVA, Sachverständigen-Ausschuss) cannot be involved in the registration process as it currently is. But it will remain with important consulting functions.
- The evaluation process cannot be stopped any more to await pre-payment of registration fees.
- The electronic application must be redefined (BVL would prefer e-applications to be mandatory, but certain requirements changes, e.g. mandatory CADDY submission and restrictive use of references to other applicants, must be reduced.
- The German application form sheet must be altered, e.g. physical-chemical data of the active ingredient are not necessarily required, as the active ingredient is, in most cases, already listed on Annex I.
- An EU database must be established.

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Changes with respect to post-submissions during the evaluation process:

- The BVL will not scientifically evaluate the incoming post-submissions.
- The post-submissions will be forwarded to the authorities within one week by the BVL.
- The differentiation between relevant and not relevant application points will be deleted.
- After stopping the evaluation for the receipt of post-submissions, there will be no blockage or re-setting of the clock.

The pre-meetings between applicant and Zonal Rapporteur Member State should encompass the following points:

- They should be held six months prior to submission.
- The agreements should be binding to both sides as much as possible.
- The necessity of an equivalence evaluation must be assessed.
- For the BVL it is very important to clearly set and define the application areas, as this can no longer be done by the BVL during the evaluation.
- Data requirements and formats must be set and clarified.
- The applicant's intention to revert to other applications or documents should be addressed to allow the BVL to retrieve the pertinent documents in time.
- The BVL would ask the applicant to confirm that an application is truly intended.

The detailed registration process as currently outlined by the BVL, if Germany is considered to be the Zonal Rapporteur Member State, is as follows: The evaluation starts with a completeness check, which will be conducted within one week. No stoppage of work or rejection of the application is foreseen at this point.

In parallel, an equivalence evaluation of the active ingredient can be started in parallel to the normal evaluation process. This is considered to be a stand-alone procedure, for which 60 days are intended. It is obligatory to involve the German Federal Environment Agency (Umweltbundesamt, UBA) if ecotoxicological assessments are necessary. The German Federal Institute for Risk Assessment (Bundesamt für Risikobewertung, BfR) will only be involved, if it is considered necessary by the BVL.

Subsequent to the completeness check, a pre-evaluation is foreseen, intended to gather the meta data of the documents submitted. After five weeks the BVL will issue the request for checking the data to the German authorities involved and at the same time will submit the documents to these authorities. At this time, possible MRL applications are tied into the process. The payment is also foreseen at this time. After the full 8 weeks, a first interim report is to be provided to the applicant containing the equivalence statement of the active ingredient. No blockage or interruption of the evaluation is foreseen at this stage.

Fifteen weeks after the start of the main evaluation, the German authorities involved in the evaluation process are to submit their reports to the BVL. At this stage a blockage and post-submission requirements can be set. The BVL is given two weeks to issue the report to the applicant. An interruption of the process for a maximum of six months to generate post-submission data by the applicant is foreseen. These post-submissions will be forwarded by the BVL to the authorities involved within one week (as described above). The German authorities involved in the evaluation process again have six weeks for the evaluation of the post-submitted documents.

The dRR is compiled by the BVL within two weeks. Commenting by the other Member States will take six weeks and subsequently ten weeks are available to evaluate and integrate the comments into the draft Registration Report including a period where the other German authorities are involved. At the end of this time a further interim report is sent to the applicant. The formal authorization of the registration will be compiled by the BVL within two weeks.

Within this timeframe the BVL has foreseen a two-week buffer, which is not planned for specific tasks yet.

## Format for the draft Registration Reports (dRR) for submission in Germany

**Dr. Birgit Schreiber**
BVL

Dr. Schreiber presented SANCO/6896/2009, which regulates the zonal approach. This SANCO is important for the standardization of the core assessment and it envisages the risk envelope approach. Concurrent with this document, SANCO/6895/2009, describing the dRR format, must be considered.

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The dRR is the preferred format for the following applications:

- Zonal registrations (Regulation (EC) No 1107/2009, Articles 33 – 39)
- Renewal of a registration (Regulation (EC) No 1107/2009, Article 43)
- Changing of an application (Regulation (EC) No 1107/2009, Article 44) (must be done by one Member State who is required to inform all other Member States of the changes)
- Applications for additional areas of use (Regulation (EC) No 1107/2009, Article 45)
- Mutual recognitions (Regulation (EC) No 1107/2009, Articles 40 – 42)

The dRR replaces the currently valid Registration Report. It is to be written and presented to the authorities by the applicant. The Zonal Rapporteur Member State assesses the applicant's draft Registration Report and modifies or amends it, as needed. In Germany, the current OECD structure will be maintained and will be transferred into the dRR format as follows:

- dRR part A is equivalent to Document N,
- dRR part B is equivalent to Document M Annex III,
- dRR part C is equivalent to Document J.

The studies to be submitted together with the dRR are equivalent to the Document K.

In addition to the dRR as described above, Germany requires the following information:

- A table of metabolites, names and code names
- A complete reference list (can be submitted on paper only; it is currently discussed whether this requirement will be upheld)
- Documents O, H, I (unless H and I are integrated into the dRR)
- Documents A to G are no longer required.

It was emphasized that the dRR must be submitted as a pdf format and a word format. Germany strongly proposes to use the standard titles in naming the dRR documentation.

The currently available dRR is foreseen for chemical plant protection products only. It cannot be used for micro-organisms. Currently, work is in progress to provide a pertinent format for the dRR submission of micro-organisms.

## Concept for possible transition regulations

**Susanne Scholz**
BVL

Ms. Scholz emphasized that the information presented can only be considered preliminary, as the details have to be laid down in national laws. As these laws are currently under discussion, the final provisions cannot be foreseen.

According to Art 80.5 of the new Regulation (EC) No 1107/2009, applications for authorizations of plant protection products:

(a) under Article 4 of Directive 91/414/EEC which are pending in the Member States; or

(b) which are due to be amended or withdrawn following an inclusion in Annex I to Directive 91/414/EEC or following an approval in accordance with paragraph 1 of this Article;

shall be decided on the basis of national law in force before 14 June 2011. After that decision, the new Regulation (EC) No 1107/2009 shall apply.

Many different situations were presented in detail. The BVL has provided overviews of the very complex conditions presented on its homepage:

http://www.bvl.bund.de/cln_007/nn_492040/DE/04__Pflanzenschutzmittel/11__AntragstellerAnwender/01__Bekanntmach__und__Hinweise/psm__bekannt__hinw__AntrStKonf2010__basepage.html

In cases where the BVL registration certificate (Zulassungsbescheid) is issued after the deadline for the application of the new Regulation (EC) No 1107/2009, the rules of the new regulations apply for subsequent steps. Also, when after 14 June 2011 an active substance is approved at EU level, the national procedures in Germany will follow the prescriptions of the new Regulation (EC) No 1107/2009.

It is currently discussed within the BVL, whether a national plant protection product registration can be extended, if an Annex I evaluation is expected shortly after the formal expiry of the national registration of the plant protection product, i.e. national registrations concerned with active ingredients which are currently called up for evaluation under the AIR 2 project.

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## Frequently Asked Questions and Answers regarding the implementation of the new Regulations (EC) 1107/2009) (FAQ Table)

**Dr. Susanne Guske**
BVL

Dr. Guske provided answers to frequently asked questions.

Should an application be submitted to only one country, the same timeframes as for a full zonal evaluation apply and the possibility of all Member States commenting the dRR is foreseen.

If a plant protection product contains more than one active ingredient, an abridged application is required for the plant protection product each time an active ingredient contained in this plant protection product is newly enclosed into Annex I.

If the Zonal Rapporteur Member State refuses a registration on the basis of unsafe national risk assessment, the other Member States can continue their evaluation and should also be able to provide registrations. A practical problem raised is the requirement in the new Regulation (EC) No 1107/2009 to provide the copy of the registration document of the Zonal Rapporteur to the other Member States. The EU is aware of this problem and is considering possibilities to resolve it.

In the different Member States different application areas can be registered. It is not necessary for the Zonal Rapporteur Member State to also register all these different application areas.

The concerned Member States (cMS) can require post-submission during the 120 days of their evaluation. However, the evaluation process is not stopped. It is the opinion of the BVL that these post-submissions requested by only one Member State must be sent only to this Member State.

If there are additional application areas to be evaluated, this evaluation should be done by the Zonal Rapporteur Member State.

A second applicant is free to choose its own Zonal Rapporteur Member State and is not bound to the Zonal Rapporteur Member State chosen by the first applicant.

The future handling of plant strengthening agents in Germany is as of yet completely unclear. Details need to be addressed in a national law. It is expected that the German plant protection law will clarify the situation.

In the future, the BVL intends to provide the electronic application form in German and English versions.

If you have questions regarding the above topics, the new Regulation (EC) No 1107/2009, generation of dRRs or AIR-2 projects, please contact Dr. Albrecht Heidemann at albrecht.heidemann@scc-gmbh.de.

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REGULATORY SCIENCE

# Impacts of SANCO 11802/2010/rev. July 2010

Currently the draft Commission Regulation laying down the requirements for the dossier to be submitted for the approval of active substances contained in plant protection products is under discussion.

This new regulation should enter into force in August 2011 with a transition period of at least two years.

In the following important points for the residue section are summarized:

- The OECD guidelines and guidance documents for the residue section will be binding and will replace the EU guidelines and guidance documents. Only the EU guidance document "Guidelines on comparability, extrapolation, group tolerances and data requirements for setting MRLs" (SANCO 7525/VI/95) will remain binding.

- **Plant metabolism studies** should be provided fitting to the intended worst case GAP.

  It should be distinguished between the site of uptake and the path of uptake in plant metabolism studies, as the distribution pattern may differ.

  According to the draft regulation metabolites not found in toxicology studies but identified in metabolism studies (plant, livestock, processing and rotational crops) at levels of or greater than 0.01 mg/kg are relevant for the consumer risk assessment, unless it can be shown by scientific evidence (e.g. structure-activity relationship, toxicological bridging studies) that they cause no potential risks to the consumer.

- **Metabolism studies on poultry/lactating** ruminants are always required when the plant protection product is used in crops whose parts or products, also after processing, are fed to poultry / lactating ruminants. Thus, the trigger value of 0.01 mg/kg in diet as received for metabolism studies is not relevant anymore.

  Metabolism studies on freshwater fish are required when the plant protection product is used in crops whose parts or products, also after processing, are fed to fish. Discussion on the development of a specific guideline has started. This guideline will also include feed items.

- The number of **residue trials** should be 8 for major crops and 4 for minor crops.

  For minor uses with comparable GAP in the different zones it will be sufficient to conduct six residue trials equally distributed in the main growing areas. Additionally, provided that conditions are comparable and that trials are widely spread over different zones, it is generally sufficient to carry out trials over one growing season. Additionally, for minor uses non-GLP data are acceptable.

  Residue trials from outside Europe can replace the number of needed trials to a maximum of 50 %, if the residue trials correspond to the European critical GAP and if the production conditions are comparable.

  If field and greenhouse use for one crop has the same GAP, only a full data package for the critical use is required. If the residues of both uses are comparable, half of the set of trials is sufficient.

  The number of residue studies to be performed can be reduced if it can be justified that the residue levels in plants/plant products will be lower than the limit of determination. This is the case for many herbicides applied early in the season.

  In all cases where reduction of the number of trials is envisaged, the minimum number of residue trials is three.

  If the consumable part has already been formed at application it is required to report one to three residue decline curve trials.

  A PHI of 0 days will not be accepted any more.

  The LOQ should not exceed 0.05 mg/kg

  Recoveries from stability studies as well as procedural residue recoveries in samples should be reported uncorrected.

- For **livestock feeding studies** the trigger values are:
  - 0.01 mg/kg bw, when log POW is greater than or equal to 3
  - 0.02 mg/kg bw, when log POW is less than 3

  For livestock feeding study in fish a respective guideline should be available when the regulation comes into force at the latest.

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- **Processing studies** covering industrial processing will always be required. Thus, the trigger of 0.1 mg/kg in diet as received or the exhaustion of the ADI is no trigger any more.
  - Industrial processing studies are not needed when residues are ≤ LOQ in the raw agricultural commodity.

    However, in case of a concentration potential a processing study (considering up to 5x exaggerated application) will be necessary even when the residues are lower than 0.1 mg/kg.
  - For domestic processing or home transformation processes and minor industrial ones, no processing studies are needed when residues are ≤ LOQ in the raw agricultural commodity.

- Residues in **rotational crops**: Please note that the trigger value of DT90 > 100 days is no longer valid. Metabolism studies in rotational crops are necessary if metabolites in soil occur, which were not found in primary plant metabolism studies and cannot be explained as an intermediate in primary plant metabolism. In case that the rotational field studies show detectable residues and risk mitigation measures are not feasible further rotational field studies are required (8 crops with 4 trials at 4 locations, i.e. up to 32 trials). These trials are not necessary, when the active substance is used on a wide variety of crops.

- The **residue level in honey** has to be investigated when:

  - a product is used during or shortly before blossom of the crop or
  - a product is used before blossom and the active substance used has a low degradation rate and/or is systemic
  - these flowering crops are used to produce pure blossom honey

  The respective guideline should be available when the regulation enters into force at latest (preparation by France).

In conclusion it should be noted that especially with respect to plant and livestock metabolism studies, processing studies and studies in rotational crops, the draft regulation indicates that further studies will be needed for defending plant protection product in the future. On the other hand in some cases less residue trials might be sufficient in the future.

For more information regarding MRLs and the impact of the new SANCO, please contact Dr. Monika Eder at monika.eder@scc-gmbh.de.


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