NATIONAL FOOD CHAIN SAFETY OFFICE

DIRECTORATE
FOR PLANT PROTECTION, SOIL CONSERVATION AND AGRI-ENVIRONMENT

AUTHORISATION OF PLANT PROTECTION PRODUCTS AND YIELD ENHANCING SUBSTANCES

NEWSLETTER

January 2016
Written by the authorisation experts
Editor in chief: Dr Gábor Tőkés

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Introduction

Dear authorisation holders, manufacturers and distributors,

It has become necessary again to inform you about the up-to-date issues as well as the recent changes in authorisation.
In 2015 new measures of the Regulation 1107/2009/EC turned to be a "hot issue". The most exciting debate was raised by **Article 43** on the renewal of authorisation. Though the European Commission supported the modification of the procedure but, impossible to do it at present, a convenient practice under the actual legal frames should be followed by the member states, in spite of the extremely short deadlines. Comparative assessment is another challenge with the procedure which may change in each member states, because it is of national competence.
As no prior consent was reached, no final guidance document has been prepared for the handling of applications under **Article 34** (exemption from data supply), however the draft text approved as working document by the great majority can be used by the authorities. In this Newsletter we shall write about the procedure to be followed. Based on our experiences some precisions on the shelf-life of formulations and the collective packages have become necessary.
One of the most important new tasks of the year was the **CLP classification** of the formulations. **Let us thank our clients for their co-operations** thus the work could be divided between the applicants and the competent authority. It is an on-going process to amend the authorisation according the CLP criteria.
The regular use of **PPP AMS software** is an important novelty in the Community authorisation system. The newly submitted application for zonal authorisation will be included as of 2016.
Finally we are glad to inform you that the Ecological Working Committee (including the competent organisations) responsible for the plant protection products and yield enhancing substances to be used in organic farming has supported the decision on the official list of products subject to authorisation. They are available on the website of NÉBIH.

Gábor Tőkés

Content

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II. Legal and other important information of authorisation

1. Information on the renewal of PPP authorisation according to the zonal system (Article 43)

The PPPs containing the so-called AIR-2, AIR-3, AIR-4 active substance groups and the newly approved active substances according to the *Regulation No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market* are renewed in zonal procedure (Article 43(2) of Regulation 1107/2009/EC).

The renewal of PPPs is based on active substances, made by taking the new end-points into consideration originating from the renewal of the active substances. **Within 3 months of the renewal of the approval of active substances** the authorisation holder **has to submit the application** in the central zone to the member state (MS) where the given PPP has already been granted an authorisation. The zonal Rapporteur Member State (zRMS) shall make the evaluation of the PPP, on the basis of which the other MSs, i.e. the concerned Member State (cMS) shall decide upon the renewal of national authorisation. The evaluation and this take-over by the cMS shall take 9 months.
If **the renewal of the approval of two active substances of a formulation is expected within 12 months**, only a cover letter should be submitted by the submission deadline of the **first active substance** and no dossier submission (draft Registration Report – dRR) is required. The submission of the complete documentation (containing risk assessment for both active substances) is required only after the renewal of the second active substance.

Following the publication of the decision concerning the renewal of active substances, the Hungarian competent authority shall send out a letter calling upon all the authorisation holders to start the procedure.

The compliance check of active substance *(present step 1)* shall not be separated from the review of formulation *(present step 2)* however it has to be proven in the formulation-dossier that the requirements for the active substances have been met. So it is a basic condition for the renewal of a formulation to comply with the new end-points and the changed data requirements stated during the renewal of active substances. Further requirement is to certify the protection of necessary new data submitted for the renewal of active substances according to the valid guidance documents.

Further information on the renewal of the authorisations of PPPs can be obtained from the *Guidance Document on the Renewal of Authorisations according to Article 43 of Regulation (EC) No 1107/2009* (SANCO 13170/2010 (rev.13))

In the following we summed up the major information you have to consider for your submissions. ***Detailed documentation will appear under "Frequently Asked Questions" on the new website of NÉBIH after the negotiations with the MSs have been finalised. The applicants will be informed thereof.***

Prior notification for the renewal of formulation:

In order to be able to plan the zonal assessment, the authorisation holders must indicate, a.s.a.p., to the zRMS, if possible during the renewal of the active substances, the PPP they intend to renew. The notification form is available in the *Guidance Document on Template to notify intended zonal applications under Article 33 and Article 43 of Regulation (EC) No 1107/2009* (SANCO/12544/2014.)
Within 2 months of the publication of the EFSA-conclusion, the authorisation holder of the PPP has to submit the notification form. For an easier planning of the work, the zRMS and the cMSs shall be named in this phase of the notification. If Hungary is the zRMS, please make prior agreement with the Competent Authority on the necessary risk assessment and data access (if the authorisation holder of the PPP is not the same as the owner of active substance dossier).

As the data protection of PPPs is made at national level, the reference list of the active substances is useful but not enough for stating the national level data protection. Useful information for data protection and reference list are available in the *Guidance Document on data protection* (SANCO 12576/2012) and *Guidance Document on preparing lists of test and study reports according to Article 60 of Regulation (EC) No 1107/2009* (SANCO 12580/2012), respectively. Data protection of 30 months can be given for the new studies necessary for the renewal of formulations.

Submission of formulation dossier (dRR - draft Registration Report):

The application for PPP renewal shall basically contain all information of the renewal guidance document. **All data should be submitted in an electronic format. Only the application and the eventual Letter of Access may be submitted in paper document.**

In order that the authorisation of the re-registered formulation meets the requirements of Regulation 1107/2009/EC, the Competent Authority requests that the formulation-dossier be submitted in accordance with the form of the draft registration report (dRR)(*Guidance document on the presentation and evaluation of dossiers according to annex III of Directive 91/414/EEC in the format of a (draft) Registration Report*, SANCO/6895/2009). *The formulation-dossier submitted in the earlier OECD version for the zonal assessment and the national authorisation shall not be accepted.*
We ask you to copy the data already included in the OECD dossier and eventually evaluated by another MS into the dRR dossier and **highlight with yellow background the data and risk assessment renewed according to the new endpoints**, as they are necessary for the formulation renewal.

The Competent Authority ***provides exemption*** *for certain studies* from the 3-month **deadline for the data submission**. These are requirements (lack of data required by EFSA, lack of confirmatory data, study necessary for the new endpoints, information concerning new data or new guidance documents) which cannot be met within three months thus the MSs accept 2 years of delay for the submissions from the approval of the renewal of active substance. They have to be evaluated by the zRMS within 6 months of the submission then the cMS shall make the approval.
If this is the case, please indicate it on the notification from, if possible. In case the “stopping the clock” is accepted, the zRMS shall make the decision and inform the other MSs.

When a PPP is renewed the authorised uses (Good Agricultural Practice-GAP) **cannot be changed.** Compared to the current authorised uses, any new use should be authorised in the zonal system as laid down in Articles 33 or 40 of the Regulation 1107/2009/EC and the extension for minor uses may be applied for in accordance with Article 51. It is considered a new use e.g. the

extension of use to crop or pest but not the slight change in the growth stage of a crop, the decrease of dose or cancelling of a crop (due to the new endpoint of an active substance).
In the process of renewal a new use (GAP) other than the dose decrease due to the new endpoints of an active substance, compared to the current authorised use, can only be accepted if the Competent Authority has not carried out the earlier supervision of formulation (step2) and the previously submitted documentation contains the eventual extension to other crops. (In this case the documents should also contain the trial results.)
If the **dose is decreased because of the new a.s. endpoints**, this should be **supported by efficacy trials** and the biological assessment dossier (BAD) should also be submitted.
If the GAP is not changed, no BAD submission is necessary. In this case the detailed evaluation of efficacy (dRR Part B Section 7, efficacy) is not required only the "summary results" is necessary describing the efficacy of the formulations. Section 7 should contain an up-dated analysis of resistance.

We call your attention that if Hungary is the cMS we shall re-register the formulation only according to the documents evaluated by the zRMS therefore you should consider this fact in the process of submissions. With other words the **dRR should clearly contain the proper uses for Hungary**. No general GAP table – referring only to the central zone, can be accepted. **If the PPP is authorised for minor uses also, please indicate it in the GAP table. The risk assessment should cover the minor uses too.**
In addition, if the PPP is authorised only in Hungary for aerial application and that is intended to be maintained, the relevant risk assessment should be described in the National Addendum with reference in the application (cover letter).

Note: only the non-significant formulation changes can be accepted in the process of renewal at national level (Guidance document SANCO 12638/2011).

Lack of application for renewal:

If the authorisation holder **fails to apply for renewal (re-registration)** of the PPP within 3 months of the active substance renewal, the validity of authorisation cannot be prolonged **over 1 year from the original approval of the active substance (Annex I + 1 year)** and the authorisation must be withdrawn in accordance with Article 44(3) of Regulation 1107/2009/EC by granting a grace period set out in Article 46.
The authorisation holders are kindly asked to inform us, a.s.a.p., if they do not want to further market the PPPs subject to renewal or if they cannot comply with the above obligation of data requirements.

By Adél Janka, dr Ágnes Pethő, Éva Somogyiné Pálos

2. Candidates for substitution and comparative assessment

"Candidates for substitution" is a new term in Regulation 1007/2009/EC. In the European Union comparative assessment shall be performed by MSs when evaluating an application for authorisation for a PPP containing an active substance approved as a candidate for substitution (Articles 24 and 50) in order to replace it with use of a more adequate method or with low-risk product. The European Commission has established the list of candidates for substitution specified in Regulation 1007/2009/EC (*Commission Regulation (EU) 2015/408 on implementing Article 80(7) of Regulation (EC) No. 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market and establishing a list of candidates for substitution*). In Hungary it means 305 PPPs containing 58 active substances that is some one-third

of the authorised formulations. As of **1 August 2015**, comparative assessment has to be made with the formulations containing these active substances in all cases where a review or amendment of an already authorised product is requested, i.e. in case of re-registration; amendment of the authorisation of the PPP; and an application for authorisation of a new PPP is submitted.

The authorisation holder of a PPP has to submit the necessary documentation to the Competent Authority in accordance with the available guidance documents (EPPO PP 1/271, SANCO 11507/2013 [*Guidance document on Comparative Assessment and Substitution of Plant Protection Products in accordance with Regulation (EC) No 1107/2009*] and Guide for UK applicants for Plant Protection Product authorisation). As evaluation is made at MS level, the Competent Authority shall work out a special guidance document (using the guidance document of the authority of the United Kingdom), but it will take the characteristics of the Carpathian basin into consideration. Main aspects of the evaluation: efficiency, crop safety, evaluation of risk of resistance, evaluation of practical or economic disadvantages, including effects on minor use, and evaluation of effects on human health and the environment.

If Hungary is the zRMS in the central zone, the authorisation holder of the PPP has not to submit the „Benefit Case" documents available for the other cMSs (only the Hungarian), to the Competent Authority together with the zonal application.

The „Benefit Case" documents necessary for the comparative assessment shall be submitted **only if the company request the Competent Authority, as cMS to grant the national authorisation in compliance with the zonal assessment and the authorisation by the zRMS.**

The Competent Authority thinks that keeping the already authorised minor uses is of great importance in the comparative assessment, however the authorisation granted for the minor uses does not automatically mean that the comparative assessment is ended in the first step. No assessment has to be made if only one PPP is authorised in a particular minor crop for the control of a given pest.

By Péter Gál

3. Authorisation with reference to Article 34 of Regulation 1107/2009/EC

Exemption from the submission of studies

Article 34 of Regulation 1107/2009/EC states that the applicants of the authorisation shall be exempted from supplying the test and study reports where **the MS has data concerned** and the applicants demonstrate that they have been granted access (**Letter of Access**) or that any data protection period has expired.

For the purpose of Article 34, other conditions for exemption:

- the reference product – of which the applicant referred to the expired data protection period or has access to – has authorisation which complies with the uniform principles laid down in either Directive 91/414/EEC or Regulation 1007/2009/EC;
- no reference to more than one reference product can be made;
- in the cMSs the same reference product must be authorised as in the zRMS.

The application shall include the following:

- name, authorisation status of the reference product in the zRMS and cMSs;
- data protection status of the reference product in the zRMS and cMSs (expiry date of data protection may be different in the various MSs);

- eventual study and test reports and the Letter of Access;
- identity data of the PPP (Regulation 284/2013/EU A or B/ 1.1-1.6.);
- detailed composition of the PPP with MSDS;
- equivalence of the active substance (equivalence report, 5-batch analysis);
- declaration that the PPP does not contain unacceptable co-formulant;
- physical and chemical properties of the PPP (Regulation 284/2013/EU A or B/2.);
- recommended uses (GAP) – it should be the same as that of the reference product, with eventually less crops;
- adequate number of efficacy trials from the SE EPPO zone;
- hazard classification and safe use provisions of the PPP;
- reference list;
- text of product label

These data shall be submitted in dRR form / (composition: Part C, information on use, hazard classification: Part A, identity, physical-chemical properties: Part B).
In case of these applications, the authorisation procedure is also made in zonal process with 12 (+6) months for the deadline of evaluation. The zRMS studies the equivalence of the active substance and the comparability of the formulation (equivalence: Article 38, DG SANCO 10597/2003 /*Guidance document on the assessment of the equivalence of technical materials of substances regulated under Regulation (EC) No 1107/2009/*; comparability: DG SANCO 12638/2011 /*Guidance document on significant and non-significant changes of the chemical composition of authorised plant protection products under Regulation (EC) No 1107/2009 on placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC*).

If Hungary is **the cMS**, it shall check the data protection status of the reference product authorised in Hungary and compare it with the formulation for which an authorisation application is made (equivalence, comparability).
With regard for **mutual recognition** of a formulation, Articles 40-42 shall apply. Furthermore the reference product authorised in Hungary shall be compared with the formulation for which an authorisation application is made (data protection, equivalence, comparability).

Before the submission of an application and the request for the (EPPO) efficacy trials to be carried out in Hungary, it is recommended to contact the Competent Authority in order to examine the position of the formulation for which an authorisation application is made, the reference product and the data requirements.

By Mária Nagyné dr Kelemen

4. Parallel trade and authorisations of second name (duplicate)

In case of the review of a formulation (reference product) (Step2), the Competent Authority withdraws the existing authorisation document. The formulation shall be granted a new authorisation with a new authorisation number. The **authorisations of second name (duplicate)** granted before the review of the authorisation **and the parallel trade permits (referring to the previous authorisation number) shall be automatically withdrawn.**
As for the withdrawn parallel trade permits, the Competent Authority shall grant the owners a grace period for the placing on the market and use of PPP stocks available on the market. If the holder of parallel trade permit wants to place the formulation on the market for a period longer than granted in the grace period, a new authorisation procedure must be applied for.

By: Nóra Varga-Bagi

5. Shelf-life of the formulations

Several questions have recently been raised concerning the determination of shelf-life and the packaging materials that can be used for the formulations. Now we try to clarify some principles and let you know our views.

Principle for the determination of shelf-life: maximum 2 years may be obtained if the trials were properly carried out and in accelerated procedure. In this case the on-going and planned 2-year GLP study is required as confirmatory data. If the manufacturer applies for longer shelf-life, he has to submit the 2-year storage stability test performed at ambient temperature, not later than at the end of the evaluation. The formulation may get a shelf-life longer than 2 years only after its evaluation and approval. In such cases the responsibility lies upon the authorisation holder.
If the shelf-life is changed, the product must get a supplementary label.

In cooperation with the plant protection inspectors the Competent Authority checked the activity of formulators/contractual formulators in 2014 and paid special attention, in 2015, for studying the small packing units (ampoules) and their indications (labels). It was clearly stated that the right for further marketing has been transferred by the authorisation holder to certain market actors who do not properly know the relevant legislation. Thus traceability, in most cases, is not granted.
A warning for filling the data gap was sent out to those clients whose authorisation did not contain the indication of packing units presently on the market and the name of packaging materials. The deadline for submitting the missing data was 31/12/2015.
Experience obtained with the ampoules shows that indications must be more precise in the authorisations.
The authorisation holders must apply for the amendment of authorisation, a.s.a.p. if they market ampoules but this fact is not included in the authorisation.
In case the authorisation document contains indication for a 3 ml packing and the formulation is put in 1 x 3 ml, 3 x 3 ml, and 5 x 3 ml packages, the authorisation holder must apply for the amendment of the authorisation. It should be noted that the ampoule of 5 x 3 ml units cannot be marketed alone, therefore such packings is not considered as collective packages.
The packings shall be described in the same way in all cases where the packing unit is not considered as individual commercial unit.

By Adrienn Botyánszki

6. Approval for collective packages

Article 2(5) and Article 9(2) of Decree 89/2004. FVM state that the Competent Authority has to be informed about the sales in collective packages before this activity. In collective packages ***exclusively PPPs subject to authorisation*** with identical or different function ***can be placed on the market*** and until the validity of the authorisation. The individual packing units in the collective packages may be placed on the market as individual sale unit in accordance with the authorisation with the consent of the client who made notification of the collective packages.

The notification shall contain the following:

- data and approval of the authorisation holder of the PPPs in the package,
- accepted label of the PPPs in the packing unit,
- data of the notifier and the person who made the packages.

The Competent Authority shall grant a **simplified decision** on the notification of placing the collective packages on the market, after the approval.
If the Competent Authority does not approve the placing of collective packages on the market, it shall issue an order on refusal.
Shall be refused any collective packages:

- if they contain PPP with expired validity,
- notification on placing PPP not subject to authorisation on the market in collective packages (EC-fertilizer is a product subject to notification)
- they are no more on the market.

The Competent Authority shall review the collective packages included in the database. The clients are requested to ***notify Competent Authority of the collective packages which are no longer marketed to the.***

By Nóra Varga-Bagi

7. Classification of authorised PPPs under the CLP regulation

In the last year the Competent Authority reviewed the classification of some 700 PPPs in the so-called CLP procedure laid down in the *Regulation 1272/2008/EC on the classification, labeling and packaging of substances and mixtures (*CLP regulation). Special thanks for the cooperation and help of authorisation holders and their representatives.

There are some PPPs for which no CLP application has been submitted. If these PPPs have valid authorisation but are not placed at present on the market and it is even not planned, you may decide, at your own responsibility, not to submit the CLP application for the particular PPP.

In case of a formulation which is on the market but for which no CLP applications have been submitted or the label according to CLP has not been finalized, you are kindly asked to proceed accordingly a.s.a.p. in order that the Competent Authority can perform the evaluation. It is to be noted that following each submission the procedure lasts 90 days. You should think of that period in case of placing new manufactured PPPs on the market and the new classification must be indicated on the label.

In the near future we plan to include the CLP evaluations in the authorisations. By putting the H and P statements into the authorisations all the authorisation documents will be issued in a uniform structure.

If therefore certain changes (e.g. up-dating of MSDS; harmonized classification or amendment of an active substance) occur in the classification (H-statements) a new amendment shall be necessary for the authorisation. In this case the following documents shall be attached to the application:

1. the most recent MSDS
2. technical justification of the change in the classification of PPP
3. if the classification of PPP is changed due to the harmonized classification of the active substance or other components, reference should be made to the relevant legislation

In addition, we call your attention that according to the Newsletter sent out in 2014 we controlled exclusively the CLP classification and the hazard properties in our procedure. The old R and S phrases had to be changed for H and P statements in the approved label (or in the label claim made accordingly). In our procedure we controlled the compulsory label elements and the hazard classification therefore if any other changes are put on the label, they can be used at your own

responsibility. If you think of any administrative or other amendments, they shall be applied for in a special procedure.

If the authorisation holder submits a new and changed CLP classification the existing label which is on the market cannot be amended until the amendment of the authorisation or the amendment of the CLP label (if it is not yet in the authorisation). In such cases it may happen that the up-dated MSDS is not identical with the label.

By Adél Janka

8. Basic substances

Article 23 of Regulation 1107/2009/EC introduced the term of basic substances which have to comply with the following criteria. The basic substance

- is not a substance of concern;
- does not have an inherent capacity to cause endocrine disrupting, neurotoxic or immunotoxic effects;
- is not predominantly used for plant protection purposes (e.g. foodstuff, plant extract),
- nevertheless is useful in plant protection either directly or in a product consisting of the substance and a simple diluent; and
- is not placed on the market as a plant protection product.

The application for basic substance shall be submitted to the European Commission (pppadmin@ec.europa.eu). Applicants may study the Annex I of *Working document on the procedure for application of basic substances to be approved in compliance with Article 23 of Regulation (EC) No 1107/2009* (SANCO/10363/2012) to prepare the dossier. The chapters concerning the PPPs and the basic substances show certain similarities. But the data requirements for basic substances can also be met by evaluations properly made in accordance with certain Community legislation. Additional risk assessment may also be requested for certain uses. If some points of the forms are not relevant for the products, it should be justified.
The approval procedure of the submitted dossiers is similar to that of the PPPs. The dossier is commented by both the MSs and the EFSA for a period of half a year. The European Commission makes a review report and the draft regulation concerning the inclusion of the basic substance within another half a year of the EFSA evaluation. The applicant has the right to comment the report. The Standing Committee of Plants, Animals, Foods and Feeds (SCoPAFF) approves the inclusion of basic substances. The basic substances included in the list of approved substances will be listed in the Annex C of Regulation 540/2011/EU.
For the purpose of Regulation 1107/2009/EC the Community approval of basic substances shall be for an unlimited period. The approval may be reviewed at any time where the criteria for a basic substance are no longer satisfied.

The following table contains the basic substances already in the list and those substances which will be included. The approved basic substances are indicated as new substances and the uses are also shown. Thus lecitins are qualified as basic substances with fungicidal function but they are not fungicides. The regulations and review reports on basic substances do not only determine the purity as foodstuff of the substances but also the way of use (e.g. extent of dilution).
Information on basic substances are available on the website of DG SANTE .
Use provisions for each basic substance are available in the review reports of the European database
European database for PPP active substances

List of basic substances, December 2015

Substance	Use	Status	Date of inclusion	Expiry	Regulations
Artemisia absinthium L.		refused			Reg. (EU) 2015/2046
Artemisia vulgaris L.		refused			Reg. (EU) 2015/1191
calcium-hydroxide		included	01/07/2015	no	Reg. (EU) 2015/762
Chitosan-hydrochloride		included	01/07/2014	no	Reg. (EU) 540/2011, Reg. (EU) 563/2014
Equisetum arvense L.		included	01/07/2014	no	Reg. (EU) 462/2014, Reg. (EU) 540/2011
lecitins	FU	included	01/07/2015	no	Reg. (EU) 2015/1116, Reg. (EU) 540/2011
Rheum officinale Baill.		refused			Reg. (EU) 2015/707
Salix spp. cortex	FU	included	01/07/2015	no	Reg. (EU) 2015/1107, Reg. (EU) 540/2011
saccharose	EL	included	01/01/2015	no	Reg. (EU) 916/2014
Tanacetum vulgare L.		refused			Reg. (EU) 2015/2083
vinegar	BA, FU	included	01/07/2015	no	Reg. (EU) 2015/1108, Reg. (EU) 540/2011
baking soda	FU	included	8/12/2015	no	Reg. (EU) 2015/2069
fructose	EL	included	01/10/2015	no	Reg. (EU) 2015/1392

So the Competent Authority is not obliged to grant the authorisation for placing on the market and use of PPPs for the basic substances, i.e. no application for the use of basic substances should be submitted at national level, either. But the Authority may grant the authorisation, at request, for the products of basic substances for 10 years in accordance with Part A of Annex 9 to Decree 89/2004 FVM.
In order that the basic substances comply with the review report and the specific provisions of relevant legislation concerning the substances concerned, the Authority makes the conditions of use of the basic substances available on the official website.
Though the product of basic substance cannot be a PPP, the label may refer to the fact that it was approved in accordance with the Article 23 of Regulation 1107/2009/EC and it should contain the conditions of approval typical for the product. The product must be safe i.e. shall comply with the Directive 2001/95/EC on product safety.

By dr Ágnes Pethő

9. Accepting the residue trials carried out in the South zone

At the meeting of the Residue Section of SCoPAFF on 30 November 2015 the *Guidance Document Guidelines on comparability, extrapolation, group tolerances and data requirements for setting MRLs* (SANCO/7525/VI/95 10.1) was approved. However neither the proposals for amendment by the Competent Authority nor other proposals were included in this version. The European Commission plans the general review of this guidance document on medium-term after the on-going amendment of Crop Field Trial No OECD 509 has been internationally accepted. The OECD proposals for amendment include a.o. acceptance of residue trials carried out in the different zones.

The recent version of SANCO guidance confirms that only the trials carried out in well defined residue zones can be accepted for the PPP authorisation. It means that the relevant status quo does not change.

The Competent Authority has paid particular attention to overcome the pest management concerns in minor uses. One possible way could be that the residue trials carried out with the crops grown in the South zone are first used in the authorisation process. The respective crop list has been sent out by the HUCPA. The Competent Authority makes efforts to make the authorisation of minor uses easier by accepting the results of residue trials carried out in the South zone. However the trials are not automatically approved. Prior to submissions of such applications, it is recommended to contact the Competent Authority.

It should be noted that certain crops may be deleted from the list during the PPP reviews made following the renewal of active substances or following the review of MRLs of active substances, if it results in decrease of MRLs.

By Tamás Griff

10. Authorisation granted for emergency situations in plant protection

Article 53 of Regulation 1107/2009/EC states that the authorisation holder or any other pulic bodies (commissioned by the users), other than the agricultural producers may submit, if emergency situations in plant protection prevails, application for authorisation for a particular PPP and for its use in a particular crop.

Evaluation of emergency situations is of national competence but the European Commission may ask the Competent Authority to justify the issuance of authorisation – as this has happened several times.
It should be noted that emergency authorisation is only a transitional procedure to solve certain plant protection problems and cannot be used instead of long-term authorisation. The applications have been often refused if no sound basis was provided.
Therefore the clients are asked that in case of annually repeated demand for emergency authorisation they submit their applications in the regulatory procedure for the extension of authorisation or acceptance of not authorised PPP.

By Tibor Baranyi

11. A European Union software database for the issuance of zonal authorisation and emergency authorisations

For the zonal authorisation of PPPs the European Commission has set up a new system, the so-called PPP Application Management System, the PPP AMS. It is a web surface which is subject to registration for both the applicants/authorisation holders and the Competent Authority representatives. It is now operated on a voluntary basis but the European Commission plans, in 2016 to enter a regulation into force making the use of this system compulsory for all PPPs the application of which is submitted in accordance with Regulation 1107/2009/EC for a new zonal authorisation, zonal amendment or the PPP renewal set out in Article 43. This web surface will be extended also to emergency authorisations but no clear information are yet available.

The applicants/authorisation holders who are members of ECPA, ECCA or IBMA working groups shall have access to the system from the working groups concerned. Those who are not members of these working groups and want to submit new zonal authorisations or applications for zonal renewals (Article 43) after 2016 shall obtain the right for access from the Competent Authority . In such cases please send information to the following e-mail address jankaa@nebih.gov.hu.

For further information on the PPP AMS, please visit the website of DG SANTE:
http://ec.europa.eu/food/plant/pesticides/authorisation_of_ppp/pppams/index_en.htm

By Adél Janka

12. Ecological Working Committee

In 2014 the Ecological Working Committee was set up with the task of working out a uniform list of PPPs for use in organic farming. The activity of the Ecological Working Committee became necessary because no such list was available before in Hungary.

Members of the Ecological Working Committee: experts and representatives of Biokontroll Hungária Kft., Hungária Öko Garancia Kft., Kárpát-medencei Ökogazdálkodók Szövetsége (Association of Organic Farmers in the Carpathian basin), Magyar Biokultúra Szövetség, Ökológiai Mezőgazdasági Kutatóintézet (Research Institute for Ecological Agriculture) and NÉBIH Plant Protection, Soil Conservation and Agri-environment. Coordinator: NÉBIH. The uniform list of PPPs was approved at the Ecological Working Committee meeting held on 1 October 2015 and can be downloaded from the NÉBIH website:
https://www.nebih.gov.hu/szakteruletek/szakteruletek/noveny_talajvedelmi_ig/kozerdeku_adatok/lejart_novved_szerek_jegyzeke/Oko_lista.html

The list of PPPs for use in organic farming is regularly up-dated. The process of including a new PPP in the list is the following: filling-in the form downloaded from the NÉBIH website, submission to the NÉBIH NTAI Department of Authorisation of Plant Protection Products and Yield Enhancing Substances and approval by the Ecological Working Committee.

By Dóra Ácsné dr. Szekeres

13. Methodology

On 15 June 2015, the Plant Protection Committee decided with uniform votes on the approval and acceptance of compulsory provisions concerning the PPP authorisation and of the following four chapters of the Plant Protection Methodology:

- Guidance document on design and setting of efficacy trials
- Guidance document on the official recognition of testing facility (Good Experimental Practice-GEP)
- Environmental evaluation of PPP use
- Risk assessment of PPP use for non-target organisms

The chapter on efficacy trials contains the rules concerning the number of trials in force in Hungary as they are not harmonised at Community level. Certain amendments is expected in this field in the near future as the EPPO has decided to modify the relevant standard, but the basic principle will not change (i.e. necessity of trials carried out in each EPPO zone).

The above chapters can be downloaded from the following website:

http://elelmiszerlanc.kormany.hu/?_preview=613a32f3-67e6-c2c9-829e-00004a4f830f

The Plant Protection Methodology is in Hungarian but the table with the number of trials may be available in English.

14. Addresses, office hours, application submissions

As no fax machines are operated at NÉBIH in the future, it is not possible to receive applications and labels by fax.
For the submissions of applications, questions and labels we set up the following two e-mail addresses:

- for plant protection products: ppp.registration@nebih.gov.hu
- for yield enhancing substances: tea@nebih.gov.hu

If you know the experts responsible for your subject, you may directly write them.
Please contact the authorisation secretary **on work days between 9 a.m. and 3 p.m.** to fix a date to submit the applications or to receive the decisions.
The date for a meeting should be discussed by phone with Ms Rita Takácsné Kiss, the department heads or the expert concerned.

According to the Government measures concerning transparency and traceability of the administration in 2015, the applications submitted to the Competent Authority via mail do not directly reach NÉBIH NTAI, but through electronic files of the Government Reception System (KÉR). We have however realized that the clients' applications through the KÉR system are transferred to our electronic filing and reception system (FIKSz) with several week delays.
We therefore call the attention of authorisation holders and individual applicants to submit the applications for authorisation to the Competent Authority either personally or via the following PO Box (instead of the official postal address):

NÉBIH Directorate for Plant Protection, Soil Conservation and Agri-environment, H-1537 Budapest, Pf. 407., Hungary

The applicants are asked to indicate the type of product (herbicide, fungicide, insecticide, adjuvant, etc.) in the accompanying letters of applications for PPP or other products because thus the case concerned will reach sooner the coordinators.

15. Information on compulsory data supply as regards the PPP turnover in 2015

Dear authorisation holders,

In accordance with Article 67 of Regulation 1107/2009/EC, authorisation holders shall provide the Competent Authority of the MSs with all data relating to the volume of sales of PPPs in accordance with Community legislation concerning statistics on plant protection products. The following data requirements shall not apply to sales data requested by the Central Office of Statistics (KSH) or the Research Institute of Agricultural Economics (AKI).
Article 17(5) of *Act XLVI of 2008 on food chain and its official control* (Act XLVI/2008) states that before 1 March of every year, the holder of authorization for use and placing on the market of PPP shall prepare a report on the product turnover in Hungary of the previous year to the Competent Authority, containing the name and quantity of the PPPs as well as the quantity and type of the used packaging. The authorisation holder has to include all the PPPs having a valid authorisation into the

below table. If there were no sales of a given PPP in 2015, '0' shall be put under the heading "Marketed volumes".
The authorisation holders are asked not to send data on their return sales. Only data relating to the volume of sales should be submitted ***which were marketed in 2015*** *by the authorization holders or representative* ***as first salers****.*
If the authorisation holder has certificate for ***collective package****, data of each PPP in the collective package should be sent. No data on PPPs in the collective package marketed in return sales are required. Data on all PPPs shall be provided by their own authorisation holder.*
The required data (in Word or Excel file) should be sent in the Annex to the address of NÉBIH Directorate of Plant Protection, Soil Conservation and Agri-environment (**Nemzeti Élelmiszerlánc-biztonsági Hivatal** Növény-, Talaj- és Agrárkörnyezet-védelmi Igazgatóság, H-1118 Budapest, Budaörsi út 141-145., Hungary) and to the e-mail address bleichere@nebih.gov.hu not later than **1 March 2016**. The form can be downloaded:

www.nebih.gov.hu/szakteruletek/szakteruletek/noveny_talajvedelmi_ig/kozerdeku_adatok/szerforgalom

The Article 91(1) point a) of *Act CXL of 2004 on general rules of administrative official procedure and service* states that the Competent Authority may grant a 15-day "grace period" to the data supplier after the expiry of the deadline.
If after the expiry of the grace period the authorisation holder does not fulfil the obligation of data supply, plant protection penalty shall be imposed specified in Article 60(1) point o) of Act XLVI/2008. According to paragraph (2) the penalty can be repeatedly imposed.

In case of **parallel trade**, Article 20(11) of Decree 89/2004. FVM states that the importer shall inform the Competent Authority on the quantity of PPP imported according to the authorisation (as laid down in Article 17(5) of the Act XLVI/2008) not later than 15 days of the importation, whereby the importer meets his obligation of data supply. **In addition, the importer shall prepare a report on the PPP turnover specified in Article 17(5) of Act XLVI/2008 respecting the deadline laid down.**
Thank you for your cooperation.

By dr Edit Bleicher

Annex: Report on the PPP turnover in 2015

REPORT ON THE PPP TURNOVER IN 2015

Name of data supplier:
address:

Required by: **National Food chain safety Office**
Directorate for Plant Protection, Soil Conservation and Agri-environment
H-1118 Budapest, Budaörsi út 141-145., Hungary

Name and marketed volumes of plant protection products

Products	**Marketed volumes (kg)**	**Total value of the marketed volume (HUF)**	**Quantity of packaging materials (kg)**					
			Plastic	Paper	Wood	Metal	Glass	Other
I. Fungicides								
Total								
II. Insecticides								
Total								
III. Herbicides								
Total								
IV. Other formulations								
Total								
V. Seed dressing								
Total								
VI. Soil disinfectants								
Total								
VII. Fumigants								
Total								
Great total								

Date: …/…/2016

…….

stamp signature