PLANT PROTECTION

GUIDANCE FOR THE APPLICANT OF AN AUTHORISATION OF A PLANT PROTECTION PRODUCT

Procedures and administrative requirements for obtaining and/or amending the authorisation for a plant protection product

Federal Public Service **Health, Food Chain Safety and Environment**
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Version 2 February 2016	3.3.1	Update: Labelling of small water soluble bag
	3.3.1 + Annex 4 : Warning phrases concerning the labelling of treated seeds	Addition: Labelling of treated seeds
	3.3.4	Addition: Deadline for adapting the labels after a change in the authorisation certificate
	4.3	Correction: Phone number expert Toxicology
	Annex 2 : Fees (overview)	Modification: Fees (modified by the Royal decree of 26/01/16)
Version 3 August 2016	3.1.1 and 3.1.2	Clarification: addition of the term “certified” concerning the specimen of pure a.s. that needs to be submitted in package 9
	4.7	Addition: national requirements for biological assessment dossiers
	4.8	Addition: cross-reference to requested national addendum for biological assessment dossiers as described in section 4.7.
	5.1.8	Clarification: duplicate authorization shall be completely identical to the reference product

	5.1.9	Clarification: Different situations for an application for amendment of the packaging or an additional packaging
	5.1.10	Correction: 6 months for sale (grace period) is for third parties and not for authorisation holders
	Annex 2	Correction: fee for an amendment of origin / specification a.s. (BE≠zRMS) is € 1 500 instead of €750

TABLE OF CONTENTS

1. Objectives of this guidance document

This guide aims to explain the various procedures to be followed to obtain an **authorisation** for a plant protection product or an adjuvant in Belgium.

"Authorisation" shall be understood as:

- the authorisation of a plant protection product or adjuvant: before such a product may be used, stored or placed on the market in Belgium, these type of products require an authorisation;
- the parallel trade permit of such a plant protection product: under specific conditions such products may be imported from other countries in the European Economic Area to be placed on the market in Belgium;
- the permit of products for experimental purposes: limited quantities of an unauthorised plant protection product or adjuvant may be imported and used in Belgium if intended for scientific experiments and if the product has been authorised for experiments;
- the certificates relating to the above authorisations or permits.

This specific guide mainly focuses on the procedures for obtaining an authorisation of a plant protection product. Also the possible procedures after the first authorisation (e.g. certificates) are explained in this guide. However, procedures for obtaining a parallel trade permit or a permit of a product for experimental purpose are explained in different guidance documents that can be found on www.phytoweb.be.

The **legislation** pertaining to the first three points (except for adjuvants) is set out in Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing on the market of plant protection products and repealing Council Directives 79/117/EEC and 91/414/EEC. Requirements applicable in order to obtain an authorisation for an adjuvant or a permit of product for experiments have not yet been harmonized within the European Union. For such authorisations or permits, the legal basis is present in the Royal Decree of 28 February 1994 concerning the conservation, placing on the market and using pesticides for agricultural use.

Remarks:

- The approval of companies that manufacture, import, export and package pesticides for agricultural use: these companies must also be approved and must submit an annual declaration of their activities. The approval of companies operating in the food chain falls under the competence of the Federal Agency for the Safety of the Food Chain. The approval of these companies is regulated by the Royal Decree of 16/01/2006, which lays down the

procedures for the approvals, authorisations and prior registrations issued by the FASFC. The approval of pesticide manufacturers, including processors and formulators, pesticide packaging companies, the importers and exporters of pesticides, companies which have pesticides packed, prepared or manufactured by third parties with a view to placing these products on the market under their own name is regulated by the Royal Decree of 28 February 1994 concerning the approval of companies that manufacture, import, export or package agricultural pesticides. Any enquiries about this aspect may be sent to the following address: s1.pesticide.pccb@afsca.be. The lists of companies with such an authorisation or approval are available online on the FASFC's website at: http://www.afsca.be/productionvegetale/produitsphytopharmaceutiques/default.asp

- The financial aspects are regulated by the Royal Decree of 13 November 2011, which sets out the fees and contributions to be paid to the Budgetary Fund for raw materials and products. An overview of the fees is given in Annex 2 of this guidance document.

2. Procedure for obtaining an authorisation

2.1. Functioning of the Authorisation Committee

In Belgium the authorisation of plant protection products is a federal competence. The service Plant Protection Products and Fertilisers of the Directorate General for Animals, Plants and Food of the Federal Public Service Public Health, Food Chain Safety and Environment is the competent authority for the authorisation of plant protection products.

The service Plant Protection Products and Fertilisers examines the application for authorisation which is submitted by the applicant and, if necessary, requests additional information to complete the dossier for examination by the **Authorisation Committee for pesticides for agricultural use**. This Committee is established with the Federal Public Service Health, Food Chain Safety and Environment. It consists of 12 members presented by the federal or regional ministers who are competent for the various matters involved:

- 3 members of the Directorate General Animals, Plants and Food of the Federal Public Service Health, Food Chain Safety and Environment
- 1 member of the Directorate General Environment of the Federal Public Service Health, Food Chain Safety and Environment
- 2 members of the Belgian Scientific Institute of Public Health
- 1 member of the Federal Agency for the Safety of the Food Chain
- 1 member of the Veterinary and Agrochemical Research Centre
- 1 member of the Federal Public Service Employment and Social Dialogue
- 1 member of the Brussels-Capital Region
- 1 member of the Flemish Region
- 1 member of the Walloon Region.

The Committee can always call on the collaboration of other competent persons, for example from any laboratory or institute specialising in the subject areas of the dossiers to be examined.

With the exception of data relating to toxicology and the efficacy and selectivity of the products, the other data (analyses and methods of analysis, physical and chemical properties, residues, ecotoxicology and fate and behaviour in the environment) are evaluated by the experts of the service Plant Protection Products and Fertilisers. The data relating to toxicology and health effects are

evaluated by the experts of the Belgian Scientific Institute for Public Health. The data relating to the products' efficacy and selectivity are evaluated by the experts of the Plant Protection and Ecotoxicology Unit of the Walloon Agricultural Research Center in Gembloux.

The Authorisation Committee meets at least once a month and issues an advice on the applications that were subscribed to the agenda of the meeting. These advices and all eventual requests for additional information are communicated to the applicant, usually within a six-week period following the meeting, by the service Plant Protection Products and Fertilisers, on behalf of the competent minister.

These advices will only be confirmed by the Minister if they result in the withdrawal or refusal of an authorisation. The Minister then notifies the applicant of his decision.

2.2. Zonal procedure according to Regulation (EC) No 1107/2009 (Art. 28 – 39 + annex I) for a plant protection product

2.2.1. Introduction

On 14 June 2011, Regulation (EC) No 1107/2009 came into effect, immediately repealing Council Directive 91/414/EEC, which was applicable at the time. All the Member States of the European Union were subdivided into three zones with comparable agricultural, plant health and environmental (including climatic) conditions. Belgium was grouped in the Central Zone, along with Germany, Luxembourg, Hungary, Ireland, the Netherlands, Austria, Poland, Romania, Slovenia, Slovakia, Czech Republic and the United Kingdom.

In order to reduce the workload for the industry and for the competent authorities and to avoid different Member States having to repeat the evaluation of the same application, Regulation (EC) No 1107/2009 (Art. 28 through 39 and Annex 1) describes the new principle of the ***zonal evaluation***. In every zone, only one Member State, the zonal Reporting Member State (zRMS) shall evaluate the entire dossier. The other concerned Member States (cMS) where possible will adopt the evaluation of the zRMS, taking into account any possible national requirements. This also provides for a more harmonised availability of plant production products within the European Union.

Remark:

Also adjuvants fall within the scope of the Regulation (EC) N° 1107/2009. However, currently no specific rules for the authorisation of adjuvants (including data requirements, notification, evaluation,

assessment and decision making procedures) have been set out at EU level. As long as this is the case, approval of adjuvants will be treated at national level. In Belgium, a specific guidance concerning adjuvants can be found on www.phytoweb.be.

2.2.2. General procedure

Prior to the submission of the application dossier

The applicant shall provide a summary of the product for which an application is submitted, no later than six months before the planned date of submission, listing all the concerned Member States where the authorisation shall be requested. A standard notification form has been drawn up for this purpose, which has been approved at European level and which is included in Appendix 3 of the Guidance Document SANCO/13169/2010 rev. 9 on zonal evaluation and mutual recognition under Regulation (EC) No 1107/2009.

Regulation (EC) No 1107/2009 states that the applicant must already formulate a proposal for a zRMS at this point of the process. The applicant must check whether this Member State has sufficient capacity to act as zRMS. The applicant's proposal shall be followed where possible. The final decision may also need to take into account a fair and proportional distribution of applications amongst Member States in the zone. In addition the following should also be taken into account:

- identity of the original RMS for the approval of the active substance (noting that it will not always be possible to allocate the work to the original RMS),
- Member States where authorisation is sought,
- relevance/importance of the products in each MS,
- impact of products containing more than one active substance (e.g. if a MS has evaluated a product containing one of the active substances and thereby gained knowledge it would be efficient if the same MS also evaluated the next product),
- resource availability in each MS, and
- if a MS has previously examined the application and rejected the application due to the fact that the missing data could not be received within the time limits.

A zRMS must be allocated in every zone where the applicant wishes to place the product on the market. In special cases, where the product is used in greenhouses, as post-harvest treatment, for the treatment of empty storage rooms or for seed treatment, only one Member State shall evaluate the application on behalf of the 3 zones.

In practice, this means that applications for products used in a protected environment as well as in open air must be split up. Thus, for products containing indoor uses as well as outdoor uses, 2

separate dRR's must be submitted: 1 zonal dRR for the outdoor uses (evaluated by 1 or more zonal RMS's) and one interzonal dRR (evaluated by 1 EU-wide RMS).

Submission and evaluation of the application

The application for authorisation must be submitted at the same time in all the Member States where the applicant wishes to place the product on the market. The application shall contain a clear and detailed description of all the uses that will be defended in every Member State (and not only the uses that shall be defended in one specific Member State). Any differences with regard to the same use in different Member States must be justified.

For the submission of the dossier, the applicant shall use the format of the draft Registration Report (please see Chapter 4.1). The draft Registration Report consists of a core dossier which is valid for the entire zone and of possible national addenda for all the Member States which have specific national requirements. Point 4.8 of this guidance document elaborates on the specific national requirements for Belgium.

If the product contains one or more sources of one or more active substances that have not yet been approved at European level, the "clock" will immediately be stopped for maximum 60 days. The technical equivalence of this source/these sources shall be evaluated according to the procedure as set out in Article 38 of Regulation (EC) No 1107/2009. The "clock" will only restart after this period. The assessment of this technical equivalence shall be assessed by the MS which acted as rapporteur for the active substance unless the MS examining the application as referred to in Article 35 agrees to assess the equivalence.

The zRMS will launch the evaluation after the dossier has been submitted. The cMS will await the draft evaluation of the zRMS to avoid double work. The zRMS has a maximum of 12 months to evaluate the application and to decide whether the product complies with the Uniform Principles. If the zRMS is of the opinion that additional information and/or clarification is required, the "clock" can be stopped for a maximum of 6 months.

Once the zRMS has finalized its draft evaluation, he shall give the applicant and the other Member States in the zone a 6 week period to send in comments on this draft evaluation. This is the so called peer review period. To this end, the draft evaluation is sent to the applicant and shared with the other Member States of the zone through CIRCABC (the European communication platform). Also an accompanying notification e-mail shall be sent. The six-week peer review period is included in the 12-month deadline for evaluation (+ another six months in case of stop-the-clock). Eventual comments should be submitted according to the commenting table format. Blank commenting tables will be attached to the notification mail that will be sent to applicant and other Member States of the zone.

After the peer review period, the zRMS will formulate a motivated and scientifically reasoned justification to all the comments it may have received. In case of significant differences of opinion between the Member States or with the applicant bilateral consultations may be necessary. Only after this process an authorisation of the product can be granted by the zRMS. The final Registration Report, the authorisation certificate and the completed commenting table shall be sent to the applicant and shall be shared with the other Member States in the zone through CIRCABC. Again, an accompanying notification e-mail will be sent. Finally, the other Member States have 120 days to make a decision, taking into account the zRMS's conclusions as well as any possible national requirements and conditions.

Regulation (EC) No 1107/2009 specifies that the Member States, by way of derogation, may impose specific conditions as regards

- the maximum dose rate
- the interval between applications
- the pre-harvest interval
- the maximum number of applications per year
- the waiting period before re-entry of the agricultural parcels
- a restriction with respect to the distribution and use of the plant protection product to protect public health (of the distributors, the users, the bystanders, residents and consumers) or of the environment
- the need of informing any resident that may be exposed to spray drift or any resident who has asked to be informed
- the correct application according to the principle of integrated pest management
- the designation of categories of users
- the approved labelling
- the dimension of the packaging and the material that it is made of
- the definition of national risk mitigation measures

If, even with the implementation of national risk mitigation measures, a Member State still has concerns with regard to an acceptable risk for human and animal health or for the environment, then this Member State can refuse to grant an authorisation in its territory. In such case, the Member State shall immediately inform the applicant and the European Commission of this refusal.

Further information in relation to the zonal procedure can be found in the European Guidance Document SANCO/13169/2010 rev.9.

2.2.3. BE = zRMS

Fees

In accordance with the Royal Decree of 13/11/2011 establishing the fees and contributions owed to the Budgetary Fund for raw materials and products the following fees apply:

- € 15,000 for a product which only contains active substances approved according to Regulation (EC) 1107/2009 or for a product containing one or more active substances which are not yet approved and for which an application for the active substance in question and relevant GAP has already been submitted in Belgium
- € 20,000 for a product which contains an active substance that's currently not yet approved according to Regulation (EC) No 1107/2099 or in the case of the first application for the active substance in question and relevant GAP

Prior to the submission of the application dossier

Due to capacity reasons, Belgium can act as zRMS only for a limited number of applications a year. A distinction is made between strictly zonal applications for new authorisations on one hand and applications for renewal (according to Directive 91/414/EEC under the so-called "Voluntary Work-sharing Programme" or according to Article 43 of Regulation (EC) No 1107/2009) on the other hand. The number of accepted applications for renewal depends on the work distribution that has been agreed upon on zonal level.

Only one rule applies for the acceptance of zonal dossiers as zRMS, namely "first come, first served". However, in addition efforts shall be made to achieve a feasible division between insecticides and fungicides on the one hand and herbicides and growth regulators on the other hand .

If the applicant wishes to have Belgium act as zRMS for one or more of its applications, it is in the applicant's interest to contact Belgium as early as possible in the process (preferably two years before the planned date of submission) and to enquire about the available capacity. This can be done by contacting the zonal coordinators (zonal.applications@health.belgium.be).

The following information should already be available at this time to allow the coordinators to properly assess the workload:

- the planned date of submission
- the other concerned Member States
- the product composition

- a GAP table that is as complete as possible for all the concerned Member States with a justification of any differences
- minor crops that may/will be defended
- the possible sources of the active substance(s), of which the technical equivalence must still be evaluated
- MRLs for which an application must still be submitted
- the possible impact of new Annex II data (confirmatory data, ...)
- any studies that may fall under Art. 62 of Regulation (EC) No 1107/2009 (avoiding unnecessary repetition of tests with vertebrate animals)

Taking into account the previously accepted zonal dossiers and the above conditions, the applicant shall be notified as soon as possible of the available capacity and the decision made. Belgium shall also notify the other Member States. The applicant shall provide the official notification form (stating BE as zRMS) to all the contact points of the Central Zone no later than six months before the planned date of submission.

Although not legally required under Regulation (EC) No 1107/2009, it is recommended to organise a pre-submission meeting with the applicant and the zRMS before submitting the application. Every applicant who wishes to have BE as zRMS should therefore present his application dossier(s) at a pre-submission meeting. Without this meeting, BE in principle shall not accept to act as zRMS. A date can be set for the pre-submission meeting in consultation with the zonal coordinators. The applicant must draw up a proposal for a meeting agenda and send this to the zonal coordinators at least 2 weeks before the meeting.

No evaluation work shall be conducted during the pre-submission meetings but some answers can be given on technical aspects if a detailed agenda is provided at least 2 weeks before this pre-submission meeting. The only definite representatives for Belgium during this meeting are the zonal coordinators. The efficacy experts are always invited to this meeting but may not necessarily attend. The applicant will be given the opportunity to present the application dossier in detail. Administrative and procedural questions can be discussed in detail.

The agenda shall at least contain the following information: name of product and active substances, type of formulation, intended GAP, technical equivalence of active substance, strategy followed by the applicant (for example, submission of a full dossier (with new studies according to all points of applicable requirements) or light dossier, concrete questions for all or some parts of the application. If the full agenda is not available at least 2 weeks before the pre-submission meeting, this meeting will be cancelled and the applicant may lose a free spot in the pipeline.

Belgium will inform the applicant generally within the month following this pre-submission meeting if it accepts to act as zRMS.

Submission and evaluation of the application

To avoid the exceedance of the strict deadlines as set out in Regulation (EC) No 1107/2009, it is important that the agreed timelines concerning the dossier submission are respected at all times. If this would be impossible for any reason whatsoever, the applicant must notify Belgium as soon as possible.

After receipt, the dossier shall be subscribed to the monthly agenda of the Authorisation Committee as soon as possible, where it will be evaluated by the different experts. To avoid losing time, the expert reports will be e-mailed to the applicant as soon as they are available. The official letter will only follow once the last expert opinion is available. Any stop-the-clock procedures will only start at this time. The relevant timelines are specified in the official letter.

After receipt of all the requested additional information the procedure is re-launched. The dossier will be subscribed to the agenda of the Authorisation Committee a second time as soon as possible. The additional information will be evaluated during the meeting. If additional information is still required, the "clock" can be stopped again (as long as the maximum period of 6 months has not yet been exceeded). If the application dossier cannot be completed in time, the application shall be refused.

Remark:

Under Regulation (EC) No 1107/2009 conditions for prolongation are no longer possible. The application must address all the requirements as set out at European level. The only derogation to this is the physical-chemical stability study after two years of storage at room temperature. If the stability study after accelerated storage returns acceptable results, a provisionally positive advice can be given and the stability study after two years could be submitted at a later stage.

As soon as the application is deemed complete, the adapted draft Registration Report shall be uploaded to CIRCABC and shall be sent to the applicant. This marks the start of the six-week peer review period. After the peer review period has ended, the dossier will be placed on the agenda of the Authorisation Committee one last time. The draft Registration Report will be converted into a final Registration Report, the commenting table will be completed and the official letter and authorisation drawn up. The other Member States in the Zone will be notified and their period of 120 days can start.

2.2.4. BE = cMS

Fees

In accordance with the Royal Decree of 13/11/2011 for establishing the fees and contributions owed to the Budgetary Fund for raw materials and products the following fees apply:

- € 3,000 for a product which only contains active substances approved according to Regulation (EC) 1107/2009 or for a product containing one or more active substances which are not yet approved and for which an application for the active substance in question and relevant GAP has already been submitted in Belgium
- € 6,000 for a product which contains an active substance that is currently not yet approved according to Regulation (EC) No 1107/2099 or in the case of the first application for the active substance in question and relevant GAP

Prior to the submission of the application dossier

The applicant shall send the official notification form (stating which country acts as zRMS) to all the contact points of the Central Zone no later than six months before the planned date of submission. In Belgium, this notification form must only be submitted if Belgium is effectively concerned Member State. This can be done by regular post or by e-mail (zonal.applications@health.belgium.be).

Submission and evaluation of the application

In principle, the application for authorisation must be submitted at the same time in all the Member States where the applicant wishes to place the product on the market. After receipt of the application dossier, a national reference number (Nxxxxx) will be assigned and an invoice will be established.

Belgium will wait with its evaluation until the draft evaluation by the zRMS is available. As a result, a later submission date (i.e. 2 to 3 months later) shall be deemed acceptable, subject to clear communication and reasoned justification by the applicant.

Where possible, Belgium shall actively participate in the peer review, subject to planning and available capacity. The experts will review the zRMS's draft version and will comment where necessary.

As soon as the zRMS notifies Belgium that the final Registration Report, with the duly completed commenting table and the eventual authorisation certificate, is available on CIRCABC, the dossier will be subscribed to the agenda of the first possible meeting of the Authorisation Committee, where a decision will be made whether to authorise this product for use in Belgium.

2.3. Mutual recognition according to Regulation (EC) No 1107/2009 (Art. 40)

2.3.1. General procedure

The principle of the mutual recognition of plant protection products is described in Article 40 of Regulation (EC) No 1107/2009. According to this principle, the holder of an authorisation for a plant protection product may apply for the authorisation for the same plant protection product, the same uses and under comparable agricultural and climatic conditions in another Member State in the following cases:

- the original authorisation was granted by a Member State (reference Member State) which belongs to the same zone (see Annex 1 of Regulation (EC) No 1107/2009);
- the original authorisation was granted by a Member State (the reference Member State) which belongs to a different zone provided that the authorisation for which the application was made is not used for the purpose of mutual recognition in another Member State within the same zone (in the case of “optional” mutual recognition, BE will generally only accept to examine applications for mutual recognition if this application is submitted in order to authorise a product evaluated and authorised by France);
- the authorisation was granted by a Member State for use in greenhouses, or as post-harvest treatment, or for treatment of empty rooms or containers used for storing plant or plant products, or for seed treatment, regardless of the zone to which the reference Member State belongs.

According to Article 42 of Regulation (EC) No 1107/2009 the application for mutual recognition shall be accompanied by the following:

- a copy of the authorisation granted by the reference Member State as well as a translation of the authorisation into an official language of the Member State receiving the application;
- a formal statement that the plant protection product is identical to that authorised by the reference Member State;
- a complete or summary dossier as required in Article 33(3) when requested by the Member State;
- an assessment report by the reference Member State containing information on the evaluation.

The decision about the application shall be made within 120 days of receipt of the application.

2.3.2. Mutual recognition in Belgium

Fees

In accordance with the Royal Decree of 13/11/2011 for establishing the fees and contributions payable to the Budgetary Fund for raw materials and products a fee of € 3,000 applies for the application for an authorisation of a plant protection product under mutual recognition. An additional contribution will be charged if the use of unprotected data (demonstrating efficacy and selectivity of the product) of a reference product is necessary to obtain the authorisation. This additional contribution is inversely proportionate to the duration of the authorisation of the active substance on the Belgian market:

- € 370 if the active substance has been authorised for over 30 years in Belgium
- € 750 if the active substance has been authorised for 25 to 30 years in Belgium
- € 1,860 if the active substance has been authorised for 15 to 25 years in Belgium
- € 3,700 if the active substance has been authorised for less than 15 years in Belgium

Submission and evaluation of the application

The procedure for mutual recognition can be used in Belgium in the following cases:

- application for obtaining a new authorisation for a plant protection product that has already been authorised in a reference Member State

- application for obtaining an additional use (minor or major crops) for a plant protection product that is already authorised in Belgium, on condition that the requested use is already authorised in a reference Member State
- application to adapt a Belgian authorisation (change of the composition, change of packaging...) on condition that this change has already been authorised for the same product in a reference Member State

Only uses (GAP) that are covered under the evaluation of the reference Member State may be included in an application for mutual recognition. The authorisation cannot be extended to other uses through mutual recognition if the reference Member State has not evaluated these uses. In the interest of the agricultural sector, the Authorisation Committee, however, can also decide to authorise a number of minor crops (e.g. oats, triticale...) with a comparable GAP in addition to the major crop for which an application was submitted. Such extensions may be proposed in the application for mutual recognition.

The applicant must be able to demonstrate that the risk assessments that support the original authorisation in the reference Member State (all the safety aspects, efficacy and selectivity) are also relevant under Belgian conditions. In certain cases, small differences in agricultural, phytosanitary and environmental (including climatic) conditions may be accepted. The Authorisation Committee can however propose changes to the original authorisation or impose additional restrictions to overcome these differences.

If the reference Member State's evaluation refers to a reference product to which the plant protection product is deemed comparable or identical, then the Authorisation Committee will compare the GAP authorised by the reference Member State and the GAP of the Belgian reference product. If the reference Member State evaluated a GAP that is less critical than the GAP requested in Belgium, then the GAP that was evaluated by the reference Member State shall also be adopted in Belgium.

Considering the absence of specific Belgian requirements for the sections Toxicology, Analyse (analytical methods, physical chemical properties), Residues, Fate and Behaviour in the environment and Ecotoxicology, no additional studies should be submitted.

However:

- Concerning the Fate and Behaviour part of the dossier, all relevant PEC calculations using the relevant FOCUS models (up to Step 4, when necessary) should be addressed in the Belgian dossier, even if the reference Member State has not used or evaluated these FOCUS models.
- Submitted efficacy trials should be in accordance with the relevant EPPO guidelines.

Remark:

Even if the reference Member State has evaluated the application and delivered the authorisation under Directive 91/414/EEC then mutual recognition can still be applied for in Belgium. Naturally the product and the uses need to be the same and the agricultural and climatic conditions must be comparable. In such case it must be guaranteed that the reference Member State's evaluation was carried out in accordance to the Uniform Principles.

Validity of the authorisation

If the dossier is deemed to be complete, an authorisation shall be granted with the same validity period as granted in the reference Member State. The maximum authorisation period shall be 12 months after the expiration of the approval of the active substance at European level.

2.4. Comparative assessment

Regulation (EC) 1107/2009 requires Member States to perform a comparative assessment when evaluating applications for plant protection products containing an active substance approved as a candidate for substitution. Member States are not to authorise, or must restrict the use of such products, where a comparative assessment in accordance with the regulation demonstrates that there is a significantly safer option for that use. This is called substitution.

Member States must weigh up the risks and benefits of the use and must include consideration of resistance risk management and minor uses, and ensure that the alternatives do not present significant practical or economic disadvantages. The alternative controls available will differ between Member States and as such this aspect of the EU regulation requires specific consideration by individual Member States.

Comparative assessment has to be performed for applications (new authorisation, new crop, renewal) submitted from August 1st 2015. More details are available on www.phytoweb.be but the principles adopted by the Authorisation Committee are the following:

1. Comparative assessment has to be carried out for each association crop/enemy.
2. Comparative assessment will be performed for both products for professional use or non-professional use.
3. Comparative assessment will be performed for an application for mutual recognition.
4. Comparative assessment will not be carried out for application for a second commercial name (duplicate authorisation) or for a permit for parallel trade because a substitution would have no effect on the market (except if the substitution occurs also for the reference product). A duplicate authorisation or a permit for parallel trade will be modified in the same way as the authorisation of the reference product once this is modified.
5. Comparative assessment will not be performed for products containing a new active substance approved as a candidate for substitution in order to acquire experience first through using that product in practice and the authorisation will be granted once for 5 years.
6. Comparative assessment will not be carried out for applications for minor use extensions.
7. For renewal applications (according to article 43), substitution will not happen if no acceptable alternative exists for the granted minor uses. In this case, all uses will be kept, major uses included even if acceptable alternatives are available for the major uses. Risk assessment for minor crops have nevertheless to be positive, authorisation in these minor uses has to remain possible and no safer alternatives for the concerned minor uses should be available.
8. If no minor use is supported by the authorisation holder in the renewal application and if the withdrawal procedure of the authorisation is started following the result of the comparative assessment, the appeal against the withdrawal procedure will not be valid if only based on

submission of an application for minor use. The appeal shall be based on the reasons causing the withdrawal following the comparative assessment.

9. Acceptable alternatives have to be safer than the product under evaluation and this for all aspects and parts of the evaluation.
10. In the framework of an application for authorisation, no substitution will be performed if this application supports at least one minor use and if the authorisation can be granted for at least one minor use.
11. Optional comparative assessment (meaning for a product not containing an active substance approved as a candidate for substitution) will usually not be performed. However, for each application for authorisation, article 29 1. d) of Regulation 1107/2009 has to be respected : the technical formulation of a product is such that the operator exposure or other risks are limited as much as possible without compromising the functioning of the product.
12. A checklist has been developed and is available on www.phytoweb.be. Applicants have to fill in and submit this checklist (addendum of part A of dRR) for each application for authorisation, amendment (new crop) and renewal for a plant protection product containing a candidate for substitution.

2.5. Data protection

Directive 91/414/EEC has been revoked and replaced by Regulation 1107/2009.

Data protection has been granted for applications submitted and evaluated according to the Directive. Provisions are laid down in article 13 (3) and (4) of the Directive. According to article 80 (2) of Regulation 1107/2009, article 13 (1) to (4) shall continue to apply with respect to active substances included in Annex I to that Directive and to active substances approved in accordance with article 80 (1) of Regulation 1107/2009:

a) For a period of 5 years from the date of their inclusion or approval, for active substances covered by article 8 (2) of Directive 91/414/EEC (= existing active substances);
b) For a period of 10 years from the date of their inclusion or approval, for active substances which were not on the market on 26 July 1993 (= new active substances);
c) For a period of 5 years from the date of the renewal of the inclusion or renewal of the approval, for active substances whose inclusion in Annex I to Directive 91/414/EEC expires by 24 November 2011.

That means that data protection granted by Belgium for a new product according to Directive 91/414/EEC ends on a date calculated from the date of approval of the active substance and not any longer calculated from the date of first authorisation of the product. The duration of this protection depends on the status of the active substance: up to 5 years from the inclusion on Annex I of Directive

91/414/EEC of the existing active substance for products containing an existing active substance (and not anymore 10 years starting from the authorisation of the product in Belgium) and 10 years from the inclusion on Annex I of Directive 91/414/EEC of the new active substance for products containing a new active substance (and not anymore 10 years starting from the authorisation of the product in Belgium).

For applications submitted according to the Regulation 1107/2009, article 59 applies:

Type of application	Period of protection	Maximum period of protection
Studies for a new PPP (art. 33) or MR (art. 40)	10 years (+ 3 months/new minor use*) from authorisation date in BE * application submitted by authorisation holder at the latest within 5 years from the date of 1st authorisation	Max 13 years from authorisation date in BE
Studies for a low risk product (art. 47)	13 years (+ 3 months/new minor crop*) from authorisation date in BE * application submitted by authorisation holder at the latest within 5 years from the date of 1st authorisation	Max 15 years from authorisation date in BE
Studies necessary for renewal (art. 43) or review** of an authorisation ** on request of the Registration Committee	30 months from renewal in BE (applicable starting from AIR 2 substances) or 30 months from review of authorisation	/

More information about data protection can be found in the Guidance Document SANCO/12576/2012 concerning data protection. Belgium applies the provisions of this guidance document except for data protection granted according to article 13 (3) and (4) of Directive 91/414/EEC, in which case the transitional measures of art. 80(2) are strictly applied (see above).

Data protection under paragraph 1 of article 59 of Regulation 1107/2009 shall only be granted where the first applicant has claimed data protection for test and study reports concerning the active substance, safener or synergist, adjuvant and the plant protection product at the time of submitting the dossier and has provided to the Member State concerned for each test or study report the information referred to in point (f) of Article 8 (1) and in point (d) of Article 33 (3) as well as confirmation that a period of data protection has never been granted for the test or study report or that any period granted has not expired. The necessity of submitted studies, claim for data protection and whether submitted studies have been previously protected must be specified by the applicant in their authorisation submissions. The applicant must also identify vertebrate studies. The applicant has to define which legal basis is applicable when he requests data protection.

When submitting the application, the applicant shall at the same time submit the complete list of studies submitted pursuant to Article 8(2) and a list of test and study reports for which any claims for data protection pursuant to Article 59 are made. This list has to be present at the end of each part B of the dRR.

Remark concerning article 34:

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

In the case where an applicant wishes to refer to data out of protection, for example by referring to a re-registration product dossier examined following Annex I inclusion of an active substance (old “step 2 procedure”), two important elements have to be taken into account:

1) Information mentioned in article 34 (2) has to be provided;
2) According to article 33 (3) (a), the application for the plant protection product has to be accompanied by a complete and a summary dossier for each point of the data requirements of the plant protection. In others words, when referring to a non-protected re-registration dossier under Directive 91/414/EEC, the applicant still has to complete his application by means of studies or data applicable for applications submitted after entry into force of the Regulation 1107/2009.

3. Administrative requirements

3.1. Presentation and submission of the application dossier

The application dossier must be drawn up according to the package system as stipulated in the tables as mentioned under points 3.1.1 and 3.1.2 of this guidance document. For new applications, the applicant in first instance must only send the packages destined for the central administration at the Service Plant Protection Products and Fertilisers (the packages "administration", "physico-chemistry", "toxicology", "residue", "fate and behaviour in the environment", "ecotoxicology" and "first aid"). After receipt of these packages an invoice will be drawn up stating the reference number that has been allocated to the application dossier (Nxxxx). The invoice can be considered as the confirmation of receipt of the dossier. All details considering the payment are mentioned on the invoice. The applicant only has to send the remaining "efficacy" package to the external experts in Gembloux, clearly stating this N- number, after receipt of the invoice. The package “toxicology” will be sent by the Service Plant Protection Products and Fertilisers to the concerned external expert.

This presentation in packages must also be respected when completing the original dossier (submission of additional data in the course of the evaluation process) or for applications concerning existing authorisations (see Chapter 5.1). In these cases, the N-number, which remains the same for the same formulation, is already known and the applicant can immediately send all the packages, clearly indicating this N-number, to the relevant agencies. It is worth noting however that a specific package is only necessary if underlying data need to be provided and evaluated by the relevant expert. For instance, in general no "physico-chemistry" or "toxicology" package will be required for an application for an extension.

To simplify the administration, the following administrative procedures apply:

- accompanying letter: The dossier number (if known), the trade name and the type of application must always be clearly stated in the letter. The letter must also draw attention to all the important information in the application. The letter must always be addressed to the application manager as stated in the tables under 3.1.1 and 3.1.2 or to the earlier assigned application manager for applications under evaluation. The original accompanying letter must always be sent by post (in an envelope) (and not in a box together with the entire application dossier, where it could be overlooked).
- number of submissions per application: The applicant must try to send all the data together as much as possible for every application and therefore avoid to send the application in different submissions. However, in case of a zonal application, for which strict timelines apply, it is

recommended to submit all requested additional information for the same expertise domain as soon as possible. For zonal applications, it's not necessary to wait until all requests for additional data for all expertise domains is available.

- number of applications per submission: One submission may only contain one type of application and one product. Different applications or dossiers shall not be mentioned in the same letter, even if they relate to the same product. All the procedures must be kept separate.
- Denomination of files on the CD-ROMs: Usually, the entire dossier will be saved on the internal server. Therefore, due to technical reasons, a maximum of 40 characters is allowed for denomination of each file on the CD-ROM.

Please refer to Chapter 4 for the technical requirements of the dossier.

3.1.1. Application for a zonal authorisation

Package	To be sent	Paper copy	CD-ROM
1. Administration	**Belgian Federal Public Service Health, Food Chain Safety and Environment** DG Plant, Animal and Food Plant protection products and Fertilisers Service Eurostation block II, 7th floor Victor Hortaplein 40 box 10 1060 Brussels **Recipient:** - biopesticides: Mr. J. Denis - all other new applications (including amateur products,...): Mr. D. Maerschalck	- Official letter - 5-batch analysis for the production of the active substance on an industrial scale (if available since authorisation at European level) - Belgian label proposal in NL and FR - Composition of the formulation, safety data sheets (SDS) of the formulation and of all the active substances and co-formulants - Letter of access (if applicable) - Copy of the acknowledging receipt of packages 9 and 10 in the Federal Laboratory for Food Safety and the Belgian Scientific Institute for Public Health respectively In case of a new source or production site or specification of an approved active substance: - all the documents needed to demonstrate the technical equivalence to the studied source for approval at European level (please see instructions on www.phytoweb.be) If an EU-MRL has to be set or amended:	1 CD-ROM or DVD ! Maximum 40 characters for file denomination - all the information that was supplied on paper - a complete dRR - all the study reports - the Belgian presentation of the GAP (NL, FR and EN), as presented in annex 3 of this guidance document If BE = zRMS: - filled-out checklist: see www.phytoweb.be **= complete dossier**

		- a copy of the official letter for a separate application (please see instructions on www.phytoweb.be)	
2. Physico-chemistry 3. Toxicology 4. Residues 5. Behaviour in the environment 6. Ecotoxicology	See administration package	- A copy of the official letter	5 CD-ROMs or DVDs (1 per package) ! Maximum 40 characters for file denomination - **complete dossier** (see administration package)
7. Efficacy	**Walloon Agricultural Research Center** Pesticide Research Department Rue du Bordia 11 5030 Gembloux **Recipient:** - herbicides/growth regulators:	- A copy of the official letter stating the reference number (Nxxxxx) that was allocated to the dossier - Clarification of the structure of the CD-ROM (dossier names and subfolders)	1 CD-ROM or DVD ! Maximum 40 characters for file denomination - **complete dossier** (see administration package), including BAD (SANCO 7600/VI/95)

	Mr. B. Weickmans - fungicides/insecticides: Mr. P. Hucorne		
8. First aid	See administration package	- A copy of the official letter - A dossier with a proposal for first aid advice (please see instructions on www.phytoweb.be)	1 CD-ROM or DVD - all the information that was supplied on paper
9. Enforcement of the formulation	**Federal Laboratory for Food Safety** Rue de Visé 495 B-4020 WANDRE (LIEGE) BELGIQUE **Recipient:** Mr. F. Etienne-Thewissen	- specimen of 100 – 200 mg pure certified a.s.	Send 1 CD-ROM or electronic copy to: Fabian.Etienne@afsca.be Isabelle.Monisse@afsca.be - analytical method for determining the concentration of a.s. in the formulation
10. Enforcement of residues	**Belgian Scientific Institute for Public Health** Food, Medicines and Consumer Safety	/	Send 1 CD-ROM or electronic copy to: Mirjana.Andjelkovic@wiv-isp.be Svetlana.Malysheva@wiv-isp.be

	Rue Juliette Wytsman 14 1050 Brussels **Recipient:** Mrs Mirjana Andjelkovic Mrs Svetlana Malysheva		- analytical method for determining the concentration of a.s. in the formulation - analytical method for determining the residue in crops and edible products
11. Vulgarisation	**Government of Flanders** **Department of Agriculture and Fisheries** Department of Public Information, Target Group Policy and Plant Quality Ellipsgebouw, ground floor Koning Albert II-laan 35, box 42 1030 Brussels **Recipient:** Mrs. A. Demeyere	/	Send 1 CD-ROM or electronic copy to: Annie.Demeyere@lv.vlaanderen.be - BAD (SANCO 7600/VI/95)

Remark:

The packages 9 (enforcement of the formulation), 10 (enforcement of residues) and 11 (vulgarisation) are only necessary if this concerns the first ever application for an active substance in Belgium. The analytical methods used in package 9, however, must always be e-mailed to Fabian Etienne-Thewissen and Isabelle Monisse.

3.1.2. Application for mutual recognition

Package	To be sent	Paper copy	CD-ROM
1. Administration 2. Physico-chemistry 3. Toxicology 4. Residues 5. Behaviour in the environment 6. Ecotoxicology	**Belgian Federal Public Service Health, Food Chain Safety and Environment** DG Plant, Animal and Food Plant protection products and Fertilisers Service Eurostation block II, 7th floor Victor Hortaplein 40 box 10 1060 Brussels **Recipient:** - biopesticides: Mr. J. Denis - other Mr. P. Nadin	- Official letter - Belgian label proposal in NL and FR - Composition of the formulation, safety data sheets (SDS) of the formulation and of all the active substances and co-formulants - Copy of the acknowledging receipt of packages 9 and 10 in the Federal Laboratory for Food Safety and the Belgian Scientific Institute for Public Health respectively	3 CD-ROMs or DVDs ! Maximum 40 characters for file denomination - all the information that was supplied on paper - complete RR - Registration Report of the reference Member State (if available) - all the study reports - the Belgian presentation of the GAP (NL, FR and EN), as presented in annex 3 of this guidance document - Comparison of the agricultural and climatic conditions (if necessary) **= complete dossier**

7. Efficacy	**Walloon Agricultural Research Center** Pesticide Research Department Rue du Bordia 11 5030 Gembloux **Recipient:** -herbicides/growth regulators: Mr. B. Weickmans - fungicides/insecticides: Mr. P. Hucorne	- A copy of the official letter stating the reference number (Nxxxxx) that was allocated to the dossier - Clarification of the structure of the CD-ROM (dossier names and subfolders)	1 CD-ROM or DVD ! Maximum 40 characters for file denomination - **complete dossier** (see administration package), including BAD (SANCO 7600/VI/95)
8. First aid	See administration package	- A copy of the official letter - A dossier with a proposal for first aid advice (please see instructions on www.phytoweb.be)	1 CD-ROM or DVD - all the information that was supplied on paper
9. Enforcement of the formulation	**Federal Laboratory for Food Safety** Rue Louis Boumal 5 4000 Liège	- specimen of 100 – 200 mg pure certified a.s.	Send 1 CD-ROM or electronic copy to: Fabian.Etienne@afsca.be Isabelle.Monisse@afsca.be

	Recipient: Mr. F. Etienne-Thewissen		- analytical method for determining the concentration of a.s. in the formulation
10. Enforcement of residues	**Belgian Scientific Institute for Public Health** Food, Medicines and Consumer Safety Rue Juliette Wytsman 14 1050 Brussels **Recipient:** Mrs Mirjana Andjelkovic Mrs Svetlana Malysheva	/	Send 1 CD-ROM or electronic copy to: Mirjana.Andjelkovic@wiv-isp.be Svetlana.Malysheva@wiv-isp.be - analytical method for determining the concentration of a.s. in the formulation - analytical method for determining the residue in crops and edible products
11. Vulgarisation	**Government of Flanders** **Department of Agriculture and Fisheries** Department of Public Information, Target Group Policy and Plant Quality Ellipsgebouw, ground floor	/	Send 1 CD-ROM or electronic copy to: Annie.Demeyere@lv.vlaanderen.be - BAD (SANCO 7600/VI/95)

	Koning Albert II-laan 35, box 42 1030 Brussels **Recipient:** Mrs. A. Demeyere		

Remark:

The packages 9 (enforcement of the formulation), 10 (enforcement of residues) and 11 (vulgarisation) are only necessary if this concerns the first ever application for an active substance in Belgium. The analytical methods used in package 9, however, must always be e-mailed to Fabian Etienne-Thewissen and Isabelle Monisse.

3.2. Trade name

The requested trade name shall be included as such on the authorisation certificate, except for any changes as imposed by the Authorisation Committee. The following general rules apply to the trade name:

- If the applicant wishes to use a trade name in the country's two official languages, then it must be stated as such in the two official languages on the application form.
- The trade name may not give rise to confusion with that of an already authorised product. A difference of at least two consecutive letters is essential. Nor may the trade name give rise to confusion with that of an active substance that is not relevant.
- The same trade name may not be used for formulations that contain a different active substance. An example:
    - if "BANZAI" is a product based on active substance x, then the name "BANZAI 500 SC" may never be proposed for a product based on active substance y.

      The only exception to this rule are additional trade names, which indicate that the products belong to a range.

- If the trade name refers to the formulation type, then this may only be done using the full and correct name of the formulation type or by using the correct abbreviation. Some examples:
    - Not allowed:
      BANZAI LIQUID, BANZAI FLOWABLE, BANZAI FLOW, BANZAI FL, …
    - Allowed:
      BANZAI SUSPENSION CONCENTRATE (complete name of the type of formulation), BANZAI SC (correct formulation code)
- If the trade name is followed by an abbreviation consisting of two letters, then this may only relate to the formulation type. Some examples:
    - Not allowed:
      BANZAI VG (whereby "VG" stands for "Very Good")
    - Allowed:
      BANZAI (no abbreviation), BANZAI SC (correct formulation code), BANZAI ZZG (3 letters), BANZAI N Z G (spaces)
- If the trade name refers to the percentage of the active substance with a figure, then this figure must always be the guaranteed percentage of this active substance. An example:

  - Not allowed:
    BANZAI 400 WP (because the active substance for WPs is expressed in %)
    BALALAIKA 20 SC (because the product BALALAIKA contains 200 g/l a.s.).
  - Allowed:
    BANZAI 40 WP
    BALALAIKA 200 SC
- The same trade name for different products that contain more than one active substance is only possible if the active substances are the same and the ratios are the same. An example:
  - If BANZAI 40 WP is composed of 30% active substance x and 10% of active substance y, then the name BANZAI 600 SC will only be accepted for a product that contains 450 g/l of active substance x and 150 g/l of active substance y (30/10 = 450/150)
- Mentions such as "BIO" are not acceptable, except if the products are used for organic farming purposes. Further information can be found at www.phytoweb.be
- Mentions such as "CLEAN" are only acceptable for products that have a cleansing effect.

3.3. Instructions for the label

A bilingual (Dutch and French) label proposal should be added to the dossier. After receipt of the authorisation, this design can be adapted into the final label, in accordance with the decisions of the Authorisation Committee. The label proposal must be as complete as possible upon submission of the application. The Authorisation Committee does not approve any labels however. The holder of the authorisation is responsible at all times and must always ensure that the commercial label corresponds with the approved authorisation certificate.

3.3.1. Restrictions

The label of the commercialised product may not deviate from the content of the authorisation certificate in any case, in terms of the uses, the counter indications and instructions, hazard pictograms, hazard statements and precautionary statements. Nothing may be omitted. However not all the applications (crops, enemies) must be stated on the label as listed in the authorisation. In the latter case, however, the holder of the authorisation must explain the reason for this to the Service Plant Protection Products and Fertilisers.

Claims such as "not toxic", "not harmful" or "natural" may not be used on the label. Statements such as "readily biodegradable" may only be included on the label if this can be substantiated with scientific studies (Annex I, 4.1.2.9.2. of Regulation (EC) 1272/2008).

The statement “may be used for organic farming" is only allowed for substances that are included on the list for organic farming, insofar as they are authorised as a plant protection product. Per

definition this is impossible for herbicides as mechanical weeding is always considered as an alternative.

(http://www.fytoweb.be/biopesticidesweb/docs/Annexe%20II%20du%20reglement%20(CE)%20889-2008_fr%202014.pdf)

Labelling of soluble bags

The commercial label must be used on every packaging that contains a plant protection product. If the product consists of several packages ("secondary packaging"), then the label must be applied on every package (including on the secondary packaging). If the package is water-soluble, then exceptions to this rule are possible on condition that the water-soluble packaging is packaged in a packaging with the label. The approval of the Authorisation Committee is always required for this exception.

However, a minimum of information must always be stated on small water-soluble bags, as shown in the example below:

E.g.

Trade name: Koper/Cuivre/Copper garden

Toelatingsnummer / Numéro d'authorisation : …./B

Samenstelling/Composition : 25% koperhydroxide/25 % hydroxide de cuivre/25% copper hydroxide

Pictogrammen/Pictogrammes : GHS07 (for example)

Relevante te behouden zinnen (acute giftigheid) / Phrases pertinentes à conserver (toxicité aiguë)/Relevant statements to be retained (acute toxicity): H332, H317 (for example)

Antigifcentrum/Centre anti-poison/Poison Centre: 070/245.245

Labelling of treated seeds

Following the publication of the Regulation (EC) N° 1107/2009 concerning the placing of plant protection products on the market, treated seeds can henceforth only be imported and sown if the plant protection product that was used for the seed treatment has been authorized as such in at least

one Member State. Moreover, the accompanying label of treated seeds should henceforward contain the commercial name of the relevant plant protection product, the active substance(s), the warning phrases and eventual risk mitigation measures.

However, this mandatory information is not clearly defined. Therefore a clarifying European Guidance Document is under construction. Taking into account the free movement of these seeds within the European Union, the determination of harmonized rules is quite important. In the meanwhile, at Belgian national level this mandatory information was interpreted as follows:

- Commercial name of the plant protection product in question: the name of the plant protection product as authorized in the Member State where the treatment took place and, if necessary to increase the transparency for the end user, the main different commercial names in other countries.
- The name of the active substance(s) and the eventual risk mitigation measures. This information should be in accordance with the indications as mentioned on the authorization certificate of the applied plant protection product.
- Warning phrases: agreed warning phrases, which were developed specifically within this framework, are listed in Annex 4 **: Warning phrases concerning the labelling of treated** seeds of this guide.
- Risk mitigation measures: the authorization of certain plant protection products provides for specific measures which should also be mentioned on the bags of the treated seeds. In Belgium, such measures are imposed for insecticides. A deflector should be used when sowing treated seeds. This measure is already covered by the general indications (see above), so no additional warning should be mentioned on the bags.

Nevertheless, for plant protection products containing imidacloprid, clothianidin or methiocarb, the following should be mentioned: "When sowing treated seeds, appropriate sowing equipment allowing a high degree of incorporation in the soil and minimizing the spillage while applying the product and the emission of dust should be used".

The Service Plant Protection Products and Fertilisers will apply and control the legislation accordingly. All packages of treated seeds need to comply with the above mentioned rules. This concerns all treated seeds on the market, regardless of who carried out the treatment, e.g. Belgian and foreign seed treatment companies as well as seed processors.

3.3.2. Mandatory particularities

The following mandatory particulars must always be included on the label. For already authorised products all the statements in accordance with the decisions of the Authorisation Committee (as included in the authorisation) must be included.

1. The name and address of the natural or legal person who has obtained the authorisation or requests it as well as the name and address of the person responsible for the final packaging and/or final label of the product.
2. the product's trade name
3. the formulation type
4. the product's nature and mode of action (e.g. insecticide, growth regulator...)
5. the name of every active substance (including synergists and safeners) and its guaranteed concentration in the product, expressed as follows:
   i. for solids, aerosols, volatile liquids (maximum boiling point 50 °C) or viscous liquids (lower limit 1 Pa s at 20 °C), as % w/w and g/kg,
   ii. for other liquids/gel formulations, as % w/w and g/l,
   iii. for gases, as % v/v and % w/w.

   If the active substance is a micro-organism, its content shall be expressed as the number of active units per volume or weight or any other matter that is relevant to the micro-organism, e.g. colony forming units per gram (cfu/g);

   Also, the identity of all substances in the mixture that contribute to the classification of the mixture as regards acute toxicity, skin corrosion or serious eye damage, germ cell mutagenicity, carcinogenicity, reproductive toxicity, respiratory or skin sensitisation, specific target organ toxicity or aspiration hazard (Reg. (EC) 1272/2008 Art. 18 §3 (b)) must be mentioned on the label.

6. the authorisation number (e.g. “toelatingsnummer / numéro d’autorisation / authorisation number 1234567P/B”)
7. the batch number and production date
8. the net quantity of plant protection product given in: g or kg for solid formulations, g, kg, ml of l for gases and ml or l for liquid formulations
9. the expiration date (month + year)
   Remark: the expiry date for normal conditions of storage should strictly spoken only be mentioned “where necessary”. However, it should be noted that a packaging that does not state an expiration date will be considered as having a never-ending storage life. This means that the product in question must comply at all times with the applicable physical, chemical and technical standards. Therefore it is recommended to always state an expiration date.

10. the prohibition on re-using the packaging of very toxic, toxic or harmful products (except when the packaging is suited for re-use or refilling by the holder of the authorisation)
11. instructions about a suitable method for safely disposing of the empty packaging and product surplus are mentioned in annex 5 of this guidance document
12. the uses for which the product is destined, always including
    - the directions for use
    - the dose
    - the periods between the application and
        - the sowing or planting of the crop to be protected and/or succeeding crop
        - the access to the treated crop
        - the harvest/slaughter
        - the use/the consumption
    - any agricultural-technical, phyto-sanitary and environmental-technical conditions under which the product may or may not be applied
13. information on first aid
14. a section entitled "instructions for physicians", in accordance with the instructions of the Belgian Poison Centre (please see section 3.4)
15. the labelling approved by the Authorisation Committee
    - Classification and labelling under Regulation (EC) No 1272/2008 (CLP):
        - hazard pictograms,
        - the relevant signal word,
        - hazard (H) and precautionary (P) statements,
        - EUH-statements and other supplemental hazard information.
    - Other mentions on the authorisation: e.g. standard phrases for special risks (RSh) or for safety precautions (SP) under Regulation 547/2011/EC; national statements, …

A proposal for labelling (including CLP) in accordance with the results of any studies that have been provided, must always be mentioned on the label proposal.
Hazard pictograms shall be in the shape of a square set at a point. Hazard pictograms as laid down in Annex V shall have a black symbol on a white background with a red frame sufficiently wide to be clearly visible. Each hazard pictogram shall cover at least one fifteenth of the minimum surface area of the label dedicated to the information required by Article 17. The minimum area of each hazard pictogram shall not be less than 1 cm^2.

The dimensions of the label and of each pictogram shall be as follows:

Minimum dimensions of labels and pictograms (according to Regulation (EC) 1272/2008:

Capacity of the package	Dimensions of the label (in mm) for the information required by article 17 of Regulation (EC) 1272/2008	Dimension of each pictogram (in mm)
< 3 liters	If possible and at least 52 x 74	If possible, at least 16 x 16 Not smaller than 10 x 10
3 liters ≤ Capacity < 50 liters	At least 74 x 105	At least 23 x 23
50 liters ≤ Capacity < 500 liters	At least 105 x 148	At least 32 x 32
Capacity ≥ 500 liters	At least 148 x 210	At least 46 x 46

Remark:

For the labelling under Regulation 99/45/EC (dangerous preparations) and Directive 03/82/EC (special risk and hazard warnings) concerning danger symbols and the relevant hazardous indications, R/S statements, the following conclusion is valid:

Existing stocks on the market may carry this classification until 01/06/2017. For new stocks, this classification must not be mentioned anymore on the label. However, this classification allows to calculate the number of points coming from R-phrases, for each product, which is one of the parameters used for the calculation of the annual fee (please see www.phytoweb.be for further explanations concerning the annual fee).

16. In the case of plant protection products that contain fertilisers, the label must also comply with the Royal Decree of 28 January 2013 on the placing on the market and the use of fertilisers, soil improvers and cultivation substrates.

3.3.3. Package leaflet

To ensure that the label is sufficiently legible, the producer may use a package leaflet to provide the specific information as set out in section 3.3.2. The actual package leaflet (a separate document that is appended to the package) must be distinguished from a booklet that is integrated in the label.

Package leaflet

Annex I 2. of Regulation 547/2011 allows some information to be indicated on a separate leaflet accompanying the package if the space available on the package is too small. Such a leaflet shall be regarded as part of the label.

This information concerns:

- directions for and conditions of use and the dose rate including where appropriate the maximum dose per hectare per application and the maximum number of applications per year. The dose rate is expressed in metric units, for each use provided for under the terms of the authorisation;
- where appropriate, the safety interval for each use between the last application and sowing or planting of the crop to be protected, sowing or planting of succeeding crops, access by humans or animals, harvesting, use or consumption;
- particulars of possible phytotoxicity, varietal susceptibility, and any other direct or indirect adverse side effects on plants or products of plant origin together with the intervals to be observed between application and sowing or planting of the crop in question or subsequent and adjacent crops;
- directions for appropriate conditions of storage, safe disposal of the plant protection product and of the packaging;
- where necessary, the expiry date for normal conditions of storage;
- any information required by the authorisation in accordance with Articles 31, 36(3), 51(5) or 54 of Regulation (EC) No 1107/2009.

A booklet that is integrated in the label

For these booklets, a distinction should be made between information that must be immediately visible for the user and information that may be provided on the inner pages of the booklet (not immediately visible).

The following information must not be immediately visible and may be provided on the inner pages of the booklet:

- the guidelines for application of the allowed uses and doses
- the waiting periods and "other information" (including information about reducing the dose, buffer zone, miscibility, anti-resistance strategy...)
- all information in regard to surplus spray and empty packagings
- the information on first aid and instructions for the physician.

All other necessary information as stated in 3.3.2 must be immediately visible for the user. A reference to a booklet, if present, must be included for all information that is not immediately visible. All this information may be split on the packaging (i.e. front and back). The information provided on the first page of the booklet (which therefore is immediately visible for the user) must be repeated on the label under the booklet. This ensures that the information remains available after the booklet is removed. However, the possibility to remove the booklet must be avoided as much as possible.

Naturally the producer may repeat information that is already immediately visible on the inner pages of the booklet.

3.3.4. Deadline for adapting the labels after a change in the authorisation certificate

In general, following deadlines apply for adapting the commercial labels on the packaging of plant protection products after a change in the authorisation certificate:

- **Plant protection products for professional use**
  After a change on the authorisation certificate in year x, the labels of the marketable products (at stores, distribution, etc.) should be in accordance with this authorisation certificate on the 1st of July of the year x+2. This corresponds with a period of 18 months, starting from the year following the change on the certificate.
  For example, a change of the authorisation certificate in April 2015 should be implemented on the labels of all marketable products (at stores, distribution, etc.) on 1/07/2017.

- **Plant protection products for non-professional use**
  After a change on the authorisation certificate in year x, the labels of the marketable products (at stores, distribution, etc.) should be in accordance with this authorisation certificate on the 1st of January of the year x+4. This corresponds with a period of 3 years, starting from the year following the change on the certificate.
  For example, a change of the authorisation certificate in April 2015 should be implemented on the labels of all marketable products (at stores, distribution, etc.) on 1/01/2019.

These general deadlines do not apply if more stringent deadlines are imposed by the European Union (e.g. trough ATP-Regulations) or if the labels have to be adapted faster for reasons of public health (e.g. immediate withdrawal of a use because of exceedance of the Maximum Residue Limits). These shorter deadlines will be communicated in the accompanying letter to the authorisation holders and by a press release on the website Phytoweb.

3.4. Instructions for drawing up the dossier for information on first aid

Instructions for drawing up the first aid dossier are available at www.phytoweb.be.

3.5. Letter of access

If certain essential information is not provided but reference is made to the dossier of another applicant and if this data is not out of protection, then the latter must grant permission to use this data. This is done with a letter of access. This letter can be very general (access to all the data in a specific dossier) or very specific (e.g. only a specific study in the dossier). In any event, the letter must clearly state to what the access specifically relates:

- the information to which access is granted
- the authorisation number and name of the product, of which the authorisation dossier contains the designated information
- the name of the company that has been granted access to this information
- the name (and dossier number or even authorisation number) of the product for which this information may be used

It is recommended to indicate whether the letter grants full access to these data. The letter of access must grant access to a dossier that effectively contains this information. A letter of access that grants access to a dossier that is founded on a letter of access can therefore not be taken into account.

A company that granted access to a dossier can revoke this access at any time. The dossier can also pass into the hands of another company (e.g. through transfer of the authorisation) and the latter company may no longer grant access to these data. In these cases, the access, which was based on the letter of access, will be revoked as the conditions for obtaining the authorisation are no longer fulfilled. This can only be prevented if the holder of the authorisation can submit the information to which access was granted, equivalent data or a new letter of access to the same or equivalent data.

3.6. Decisions of the Central Zone Steering Committee

As described in the European Guidance Document SANCO/13169/2010 rev.9, a Northern, Central and Southern Zonal Steering Committee as well as an interzonal Steering Committee were established. Composition, scope and competences of these working groups are explained in detail in the Guidance Document.

On a regular basis, teleconferences and/or face-to-face meetings are being organised in the Central Zone Steering Committee (CZSC). Possible harmonisation and optimisation of the zonal procedure are two important subjects of the CZSC.

All decisions taken by the CZSC are summarised in bullet points and in one summary table. These conclusions will be communicated to the industry via the non-confidential part of CIRCABC and/or via communication with ECHA, ECPA, IBMA and national industry associations. The decisions taken on this level should by any means be respected in any zonal application for a new authorisation, use extension, etc.

4. Technical data requirements

4.1. (draft) Registration Report

Since October 2010, the applicant has to use the (draft) Registration Report format for every dossier that is submitted, in order to reduce the workload of the evaluating Member States as much as possible. This relates to every zonal application (new authorisation, extension, major change to the composition...) as well as to all applications for the re-authorisation of an already existing product.

For applications submitted until December 31st 2015, the old format according to Guidance Document SANCO/6895/2009 should be used. For applications submitted as from January 1st 2016, the new format according to Guidance Document SANTE/6895/2009 should be used. This new format is available online at:

http://ec.europa.eu/food/plant/pesticides/guidance_documents/docs/gd_doc_reg-report-draft_2015_with-report.zip

Remarks:

- For renewals under AIR2, there is an exception. In this case, the old dRR format can still be used. However, when acting as a zRMS, Belgium prefers to receive the dossier according to the new dRR-format. When acting as a cMS, Belgium would like to receive the same format which was submitted in the zRMS.
- A separate (d)RR template exists for products containing micro-organisms as active substance. It is available online at: http://ec.europa.eu/food/plant/pesticides/guidance_documents/docs/templates_draft_registration_report_micro-organisms.zip

The draft Registration Report (dRR) is drawn up as a Member State evaluation and exists of three parts:

- Part A – Risk Management
- Part B – Data Evaluation and Risk Assessment
- Part C – Confidential Information

The (d)RR must be drawn up in English to facilitate the exchange of evaluations between the different Member States. Blank templates as well as a number of general guidelines for each section are available in the relevant guidance as mentioned above.

A complete (d)RR must be drawn up for every application, i.e. every application must include parts A, B and C. Obviously, only the relevant information for the specific application must be mentioned in the (d)RR. However, the (d)RR must be a stand-alone document, meaning that it must be a complete document that does not refer to another document so that it allows experts to conduct a complete evaluation and make a decision within the established timelines.

4.1.1. Part A – Risk Management

Part A of the (d)RR contains a general summary of the evaluation and all the risk mitigation measures that are imposed by the Member State in question. As a result, Part A is a national document and can be different for every concerned Member State.

The following factors are specific for Belgium:

Proposal for classification and labelling

Part A of the dRR must also already contain a proposal for classification and labelling under Regulation (EC) no. 1272/2008 (CLP). This proposal should be in accordance with the national label proposal and should be mentioned under:

- Section 2.2 for the old dRR format
- Seciton 2.4 for the new dRR format

GAP tables

As Part A is a national document, only the GAP that was requested in Belgium must be mentioned in the Belgian Part A. The GAP table must be filled in in the EU format (see dRR templates) as well as in the Belgian national format in English, French and Dutch (see annex 3 of this guidance document). Please make sure that GAP's in EU format, Belgian format and Belgian label proposal correspond. Both GAP-tables should be mentioned under:

- Section 2.3 for the old dRR format
- Section 2.6 for the new dRR format

Bilingual label proposal

As already described under section 3.3 of this guide, the applicant must submit a bilingual label proposal in Dutch and French. This label proposal must be included in Appendix 2 of the national Part A.

4.1.2. Part B – Data Evaluation and Risk Assessment

Part B of the (d)RR is subdivided into eight different sections (10 sections for the new format of dRR). Each section contains a summary of the new studies that were submitted and the necessary and relevant risk evaluations. To avoid unnecessary double work, where possible the document may refer to data that has been evaluated at European level (e.g. to the DAR or the EFSA Conclusion). However, as the dRR should be a standalone document, a short summary of these data should be mentioned.

Each section of Part B of the (d)RR may be split into a core part and national addenda. The zRMS shall evaluate the core part in full. The applicant must provide as much information as possible in the core. The core part always comprises each use that is requested in the Central Zone and not just the uses for which an application is submitted in the zRMS. The national addenda are only submitted and evaluated in the relevant cMS. Only specific national requirements must be stated in these national addenda. The specific Belgian national requirements are listed under Section 4.8 of this guidance.

To reduce the workload of the zRMS, where possible the applicant must apply the principle of the risk envelope as described in Guidance Document SANCO/11244/2011 rev. 5. The principle of the risk envelope means that a worst-case use is defined for every individual expertise domain. If the risks for this worst-case use are deemed acceptable, then one may assume that this will also be the case for all other uses for which an application was submitted.

The end of each section of the (d)RR consists of a “List of data submitted in support of the evaluation” (Appendix 1). This table must be duly completed by the applicant and will be used by the Service Plant Protection Products and Fertilisers to make a decision in relation to data protection. If this table was not filled in, no data protection can be granted.

The specific content requirements for each expertise domain are listed in sections 4.2 to 4.7 of this guidance.

4.1.3. Part C

Part C of the (d)RR shall contain all the confidential information in the dossier, including the complete composition of the formulation and all the contact details of the production sites of the active

substance and the formulation. The percentage of solvent must be provided in a quantitative manner. Statements such as "make up to 1 litre" are not accepted. All the safety data sheets of the formulation, of the active substance(s) and of each co-formulant must also be added to Part C.

4.2. Physico-chemistry

Specific guidance is available on www.phytoweb.be.

4.3. Toxicology

Currently there's no specific guidance available for the toxicological part of the dossier. Please contact the following person with specific questions concerning toxicology:

Dr. Christiane Vleminckx

Belgian Scientific Institute for Public Health
Rue Juliette Wytsman 14
1050 Brussels

Telephone: +32 (0)2 642 53 51
E-mail: Christiane.Vleminckx@wiv-isp.be

All active substances classified as carcinogenic (C), mutagenic (M) or toxic to reproduction (R) in categories 1A/1B (CLP Regulation 1272/2008) (formerly categories 1 and 2 under Directive 1999/45/EEC) or as endocrine disruptors will be refused if they are present in a concentration of or above 0.1% (C, M) or 0.3% (R) in products for professional use. Exceptions will be made for products for professional use if exposure to humans is excluded.

No authorisation will be granted for a non-professional use product if this product contains a substance classified as carcinogenic, mutagenic or toxic for reproduction.

Co-formulants classified as carcinogenic, mutagenic or toxic for reproduction in categories 1A/1B (CLP) (formerly categories 1 and 2 under Directive 1999/45/EC) will automatically be refused.

The following solvents are not accepted by the Authorisation Committee unless it can be demonstrated scientifically that they are technologically essential:

- Methanol
- N-methylformamide
- Benzene

- N, N-dimethylformamide
- n-hexane
- methoxy, ethoxy, propoxy, isopropoxy and butoxy ethers of ethylene glycol and their acetate derivatives
- n-hexane + methyl ethyl acetone
- 1, 2 - dichloroethane
- 2-nitropropane
- Nitrobenzene
- N-methylpyrrolidone
- alkylphenol ethoxylate
- Gamma-butyrolactone

4.4. Residues

Specific guidance is available on www.phytoweb.be.

4.5. Behaviour in the environment

Specific guidance is available on www.phytoweb.be.

4.6. Ecotoxicology

Specific guidance is available on www.phytoweb.be.

4.7. Efficacy

In general, all submitted efficacy trials should be compliant with the EPPO requirements. However, in practice some crucial data such as field observations, statistical analysis, meteorological data or the GEP certificate are often missing. Moreover, an officially signed report is not always available. As a consequence, the submitted trial reports often don't meet the Belgian interpretation of the EPPO requirements. Henceforth, a national addendum is requested concerning the biological assessment dossier.

For each requested use, a minimum of 8 trial reports, deemed fully compliant by the Belgian authorities, should be submitted. If necessary, existing non-compliant trial reports could be completed with field observations, statistical analysis, meteorological data and GEP certificates. In addition, the submitted

reports should be the original and officially signed reports, as issued by the official GEP instance. If this would not be possible, an official confirmation of compliance signed by the GEP instance should be added to the dossier.

For new zonal applications, with Belgium acting as zRMS or as cMS, the additional data should be presented in a national addendum. If Belgium acts as zRMS, this national addendum should be available at the time of the dossier submission. If Belgium acts as a cMS, this national addendum could be submitted once the zRMS has published its Registration Report.

For already submitted applications for renewal and for already submitted zonal applications according to Regulation (EC) No 1107/2009, a total number of compliant studies of less than 8 could eventually be accepted. However, this needs to be well-argued by the applicant. Applications that were submitted according to Directive 91/414/EEC should be completed as much as possible with all available data. The eventual unavailability of an insufficient number of compliant trial reports should also be well-argued.

Additional trial reports shall be requested if insufficient trial reports (completed a posteriori or not) are available. Also if no justified conclusion concerning the requested GAP could be taken based on trials which are deemed compliant, additional trial reports shall be requested.

Finally, applicants for whom an official or an officially recognized GEP instance carries out the trials, should ensure that the issued trial reports are complete and fully compliant to EPPO guideline 181. These applicants should also ensure that the trial reports are being prepared by the same GEP organization that has carried out the trials. In the case of a GEP instance which is active in several countries, the trial report should be prepared by the same affiliate which has carried out the trials.

Currently there's no specific guidance available for the efficacy part of the dossier. Please contact the following persons with specific questions concerning efficacy:

Herbicides/growth regulators:

Bernard Weickmans

Walloon Agricultural Research Center
Rachel Carson Building
Rue du Bordia 11
5030 Gembloux

Telephone: +32 (0)81 62 52 77 or +32 (0)81 62 52 62
E-mail: b.weickmans@cra.wallonie.be

Or

Françoise Lallemand

Walloon Agricultural Research Center
Bâtiment Rachel Carson
Rue du Bordia 11
5030 Gembloux

Telephone : +32 (0)81 62 52 77 or +32 (0)81 62 52 62
E-mail : f.lallemand@cra.wallonie.be

Fungicides/insecticides:

Pierre Hucorne

Walloon Agricultural Research Center
Rachel Carson Building
Rue du Bordia 11
5030 Gembloux

Telephone: +32 (0)81 62 52 75 or +32 (0)81 62 52 62
E-mail: p.hucorne@cra.wallonie.be

4.8. Belgian national requirements

As mentioned in Section 4.1.2 of this guidance document, specific national requirements must be addressed in the national addenda to the (d)RR that is submitted. The specific Belgian administrative requirements are listed in Chapter 3 of this guidance document.

In addition, other specific Belgian national requirements are listed in detail in the following documents:

- general national requirements: please see the EU summary table with the national requirements for every Member State. It was agreed on CZSC-level that this table will be communicated to the industry (via non-confidential part of CIRCABC or via the website of DG SANTE).
- national requirements for efficacy: please see section 4.7
- national requirements for home & garden products: specific guidance concerning products for home & garden use is available at www.phytoweb.be.

- national requirements for adjuvants: specific guidance concerning adjuvants available is available at www.phytoweb.be.

In the specific case of a plant protection product to which fertilisers are added, the following principles apply:

- the product must be considered as a plant protection product and must therefore comply with all the requirements for a plant protection product.
- the compliance of the fertilisers content with the relevant legislation is the company's full responsibility. If the product does not comply with the fertiliser legislation then the company must submit an application for exemption to the Service PPP and Fertilisers If the fertilisers in the product are not on the positive list of fertilisers, then the company must also submit an application for exemption. The opinion of the Fertilisers team of the Service will always be requested.

4.9. Checklist for drafting a sufficiently qualitative dRR

The submission of a sufficiently qualitative draft Registration Report by the applicant should accelerate and simplify the work of the experts of the evaluating Member State. In practice however, the (d)RRs that are submitted are often of an insufficient quality. Examples of such insufficient quality include the use of incorrect end points or parameters in the risk evaluation models (or a lack of argumentation for the use of certain end points), not following the relevant Guidance Documents, an ambiguous application of the risk envelope, etc.

In such cases, the (d)RR is either sent back to the applicant and an adapted version is awaited or the Belgian experts adapt the (d)RR themselves. In both cases, the use of the (d)RR format loses its original objective, namely to save time.

In order to prevent this as much as possible in the future, the Service Plant Protection Products and Fertilisers has drawn up a checklist designed to help the applicant submit a complete and sufficiently qualitative Registration Report. This checklist is based on the existing and known data requirements for an application for authorisation of a plant protection product and on the available and approved European Guidance Documents. Consequently, the checklist does not contain any new requirements but does take into account the currently frequently occurring and recurring comments of the Belgian experts during the evaluation of a submitted (d)RR.

Since 01/08/2012, the applicant must append a duly completed checklist to every dossier that is submitted in Belgium for which Belgium acts as zRMS. The applicant must confirm for every item on

the checklist that it was addressed in the dossier or must motivate why this is not the case. If, at any point during the evaluation, the application manager or the evaluating experts notice that one of the requirements in the checklist was not sufficiently addressed, the (d)RR will be immediately returned to the applicant who will be asked to amend it.

In the longer term, the checklist should help the applicant to write sufficiently qualitative Registration Reports, which fulfil all the requirements. The checklist should thus help prevent that large parts of the submitted (d)RR must be rewritten. Consequently, the correct use of the checklist must prevent the loss of precious time as much as possible (both for the evaluating experts and the applicant), which only will improve the efficiency of the evaluation.

The checklist can be found on www.phytoweb.be.

4.10. Instructions for the CLP classification

Specific guidance is available on www.phytoweb.be.

4.11. GEP and test products

Specific guidance is available on www.phytoweb.be.

5. Procedures following the original authorisation

5.1. Applications after the authorisation

An application must be submitted to the Service Plant Protection Products and Fertilisers for any changes to the trade name or to the authorised product's composition, any changes to the requested dose rate, any extension of the original authorisation to include other uses (crops, enemies, etc.), any transfer of the authorisation from one company to another (also in case of a change of the company's name or legal status) and any prolongation of the authorisation. Where necessary, the principles of the zonal procedure must always be complied with.

The current holder of the authorisation must always submit the application, except in case of a transfer (Section 5.1.7) or in case of an application for a use extension introduced by a third party (Section 5.1.4). The complete product composition shall be provided for every application and an

adapted label (proposal) for the commercial product should be submitted. Generally, reference can be made to the existing authorisation dossier for other information. Only additional applications for products authorised before entry into force of Regulation 1107/2009 and which have not yet been re-registered after approval of their active substance at European level can be dealt with on the national level. The zonal procedure must be followed for every other application.

The required fees for the different applications are summarised in Annex 2 of this guidance document, but are also listed below for every type of application.

5.1.1. Application for renewal (at Belgian national level, pending Art. 43 evaluation)

In general, an authorisation is valid for a period of maximum 10 years. An application for renewal must be submitted at the end of the ten-year validity period. Taking into account the time necessary for the Authorisation Committee to examine the application for renewal, the request for renewal must be submitted at least six months before the authorisation expires. If this is not the case, it is assumed that the applicant waives its authorisation. In principle, a letter will be sent in advance, reminding the applicant of the expiration date of the authorisation. If the applicant did not receive the letter, however, this cannot be invoked as an excuse for any delays when submitting the application.

The request for renewal can be done by letter and the fee to be paid upon application is € 3,000 (€ 1,500 for the renewal of a duplicate authorisation).

Remark:

The application for a renewal will be phased out over time. Where possible, authorisations are granted for a period of up to 12 months after the expiration of the approval of the active substance. After every renewal of the approval of the active substance, an application for renewal according to Art. 43 of Regulation (EC) 1107/2009 (see section 5.3**Error! Reference source not found.**) must be ubmitted.

5.1.2. Application for prolongation

In principle, conditions for prolongation can no longer be imposed for zonal applications evaluated under Regulation (EC) No 1107/2009. The application can only be approved if the dossier is deemed complete. An agreement was made at European level (zonal Steering Committees of every zone) that there can only be one exception to this rule. The submission of the complete results of the stability study after two years of storage at room temperature (part physico-chemistry) can be submitted at a later stage as a condition for prolongation. The dossier must be complete for all other aspects after

the eventual stop-the-clock period(s). If specific non-essential information is missing, the application can nonetheless be approved based on expert judgement. The Service Plant Protection Products and Fertilisers will then ask the applicant to provide the missing non-essential information when submitting a future request for renewal (according to Art. 43). This approach is also applied for older applications, which were still submitted under Directive 91/414/EEC.

In the majority of the cases, the approved authorisation will be valid for a period of up to 12 months after the expiration of the approval of the active substance at European level. If, in some exceptional cases, a provisional authorisation is granted for a shorter period of time (e.g. on the advice of the zRMS or for applications submitted under Directive 91/414/EEC), then the Service Plant Protection Products and Fertilisers will notify the company in an official letter which additional information ("conditions for prolongation") must be supplied before which deadline.

If the applicant plans to not conduct (some of) the requested studies or only conduct them at a later date, then the required motivations for this must be submitted within three months of receipt of the provisional authorisation and not just at the end of the validity period of the authorisation. If the argument is not accepted by the Authorisation Committee, then the applicant can still react by having the studies carried out nonetheless.

The application for prolongation can be done by letter and the fee upon application is € 1,000 if Belgium acts as cMS or for national applications.

5.1.3. Request for a use extension by the holder of the authorisation

For any change with regard to the applied dose rates or with regard to an extension of the original authorisation to include other uses (crops, enemies, application method, etc.), an application must be submitted to the Service Plant Protection Products and Fertilisers.

The application must be supported with studies (or an argumentation) which demonstrate the efficacy of the new applications, and where necessary, with residue trials and other studies or information that demonstrate that the conditions for the authorisation are still fulfilled. An adapted (d)RR, which lists any additional information, must therefore be joined to the application. Also an adapted label proposal, containing the requested additional use(s) (which ha(s)(ve) not yet been authorised), must be submitted.

The zonal procedure set out in point 2.2 of this guidance document must be followed for this type of application unless this concerns a product authorised before entry into force of Regulation 1107/2009

and which has not yet been renewed after approval of the active substance at European level. In that case, the application can still be evaluated at the national level under Article 80 of Regulation (EC) No 1107/2009. If the applicant has doubts about which procedure to follow, then the Service Plant Protection Products and Fertilisers can be contacted for further information.

The application for a use extension can be done by letter and the fee upon application is € 6,000 if Belgium acts as zRMS and €1,500 if Belgium acts as cMS or for national applications. An additional contribution must be paid if the application does not supply efficacy or phytotoxicity studies but refers to the dossier of a product of another company, which does contain studies performed according to EPPO standards. This additional contribution amounts to

- € 370 if the active substance has been authorised for over 30 years in Belgium
- € 750 if the active substance has been authorised for 25 to 30 years in Belgium
- € 1,860 if the active substance has been authorised for 15 to 25 years in Belgium
- € 3,700 if the active substance has been authorised for less than 15 years in Belgium

5.1.4. Application for a use extension by a third party

In addition to the holder of the authorisation, official or scientific institutions involved in agricultural activities, professional agricultural organisations and professional users can also submit an application for the extension of an already existing authorisation if this extension is minor in nature (Art. 51 of Regulation (EC) No 1107/2009). This may relate to a minor crop (limited surface area in Belgium) or a very specific application (even in a major crop) or an illness that occurs only very rarely. In any event, this concerns a use that is less interesting for the holder of the authorisation, economically speaking. As a result, he is not inclined to make far-reaching efforts to obtain an extension of the authorisation.

If such an extension is necessary, however, a third party can request this. This third party will then supply the information needed to support the additional authorisation. The application is done by letter.

Once the use extension is authorised by the Authorisation Committee, the holder of the authorisation will be notified of this and will be asked whether the approved use will be mentioned on the label. If the holder of the authorisation does not wishes to do so, the granted extension will be published on www.phytoweb.be.

This type of application is exempt from fees.

5.1.5. Application for the amendment of the composition

For every change in the composition of an already authorised product, an application must be submitted to the Service Plant Protection Products and Fertilisers. The complete new composition must be submitted. If the change necessitates this, an analysis of the new formulation must be conducted. The parameters that have to be determined, depend on the extent of the change to the composition. This must be checked on a case-by-case basis. The applicant can submit an argumentation to support the choice of the specific parameters. An adapted (d)RR must therefore be joined to the application, which lists any additional information (studies, MSDS, etc.). Also an adapted dossier for first aid, in accordance with the instructions as mentioned under 3.4, must be submitted.

If the formulation type or the active substance changes, then the change of the composition is too drastic and the product will no longer be considered as the same product. Consequently, an application for authorisation of the new product must be submitted in such cases.

Guidance Document SANCO/12638/2011 distinguishes between significant and non-significant formulation changes. The significant changes to the composition must be evaluated under the zonal procedure, as described in section 2.2 of this guidance document (zRMS, draft evaluation, peer review, final evaluation). Non-significant changes to the composition can still be evaluated at national level.

The non-significant changes to the composition as mentioned below are dealt with on the administrative level. The opinion of the relevant experts will be asked for every other application (non-significant and significant changes).

- change to the trade name of a co-formulant, identical CAS number
- replacement of one co-formulant by another with the same CAS number but with an unchanged percentage (same concentration)
- additional co-formulant with the same CAS number within the framework of a set of identical co-formulants

The application for the amendment of the composition can be done by letter and the fee for the application for a change in composition amounts to € 6,000 if Belgium acts as zRMS for a significant change, € 1,500 if Belgium acts as a cMS for a significant change, € 750 for a non-significant change to the composition and € 250 for a change of composition through mutual recognition with another Member State.

5.1.6. Application for the amendment of the trade name

An application for a change of the trade name may be requested by letter. Moreover, the Authorisation Committee does not need to approve this application as this can be dealt with on the

administrative level. Obviously the new trade name must comply with the conditions as stipulated under point 3.2 of this guidance document. A label proposal that features the new trade name will be appended to the application.

The fee to be paid upon application amounts to € 250.

5.1.7. Application for a change of the holder of the application (transfer)

There are two options.

1. If the name (or the legal status) of the holder of the authorisation changes, then an application for transfer must be submitted. The application is done by letter.
2. An application for transfer must also be submitted if another company wishes to take over the existing authorisation. The following documents are required for this:
   - A letter which explains the transfer;
   - A written confirmation from the current holder of the authorisation which agrees with the transfer;
   - The future holder of the authorisation shall always supply the full product composition in the application. It is essential that the future holder of the authorisation supplies the full product composition. The Authorisation Committee is of the opinion that the composition influences the toxicological and biological (selectivity) properties of the product. In view of the fact that only the holder of the authorisation can be held responsible for this, this means he must prove that he is aware of the composition;
   - A delivery note by the supplier of the active substance (stating the new holder of the authorisation);
   - If relevant, a letter of access to protected data (in case certain protected data are not the property of the original holder of the authorisation).

In both cases a fee of € 250 needs to be paid upon application. The Authorisation Committee does not need to approve this application as this can be dealt with on the administrative level.

5.1.8. Application for a duplicate authorisation (or a second trade name)

A company may want to, under its own name, bring a product on the market that has already been authorised in the name of another company. Or, a company may also want to place an existing product on the market under two different trade names (e.g. for commercial reasons or through two different distributors). In both cases, an application for a new authorisation must be submitted, which

then refers to the dossier of the already authorised product. This type of application does not fall under the zonal procedure and can be evaluated at national level. The duplicate authorization will be completely identical to the reference product. This means that the compositions should be identical, the authorized GAP will be completely identical and even the same type of packaging needs to be used.

The following documents must be appended to the application:

- the complete product composition;
- if relevant, an letter of access in which the holder of the already authorised product grants the applicant permission to refer to its original file. However, no reference can be made to a dossier that is based on a third dossier;
- a label proposal for the new product;
- a dossier for first aid.

It is essential that the future holder of the (duplicate) authorisation supplies the full product composition. The Authorisation Committee is of the opinion that the composition influences the toxicological and biological (selectivity) properties of the product. Taking into account that only the holder of the authorisation can be held responsible for its product, this means the authorisation holder must prove that he is aware of the composition.

The request for a derived or duplicate authorisation can be done by letter and the fee to be paid upon application is € 1,500.

5.1.9. Application for an amendment of the packaging or additional packaging

Taking into account that information concerning the used packaging is a part of the authorisation dossier, any desired additional packaging for the product must be applied for to the Service Plant Protection Products and Fertilisers. This includes every type of other packaging material (e.g. HDPE in addition to the originally requested/approved PET) and every other content (e.g. 20 l bottle in addition to the originally requested/approved bottles of 1, 2 and 5 l).

According to Annex 5 of the Guidance Document SANCO/13169/2010 rev. 9, an application for an amendment of the packaging or additional packaging needs to follow the zonal procedure as described in point 2.2 if new data or a new risk assessment is required. If no new data or risk assessment is required, the evaluation can be done at national level.

The application shall always be accompanied by all the required information as stated under point 4.1 of Regulation (EC) No 545/2011 or point 4.4 of Regulation No 284/2013. The additional information

must be listed in an adapted (d)RR. If the product is also destined for non-professional use, a full new package and measuring cup must be supplied to the Walloon Agricultural Research Center in Gembloux.

The Authorisation Committee is reluctant to authorise very large packagings for the following reasons:

- if the packaging leaks, the quantities that are at risk of leaching into nature or to which bystanders are at risk of being exposed can be quite large
- when (illegally) pouring the contents into smaller packaging, problems may arise as regards the product's identification
- it is not clear who can be held liable if the product is poured into the packaging of another plant protection product and when a treated crop is damaged as a result of this

If a system eliminating the above objections could be proposed, then larger packaging may be authorised. This is the case for example for 200 kg packaging if sufficiently sturdy containers are used which are directly designed for the end user (spray contractors). For packagings of more than 500 kg or l a system is required whereby the holder of the authorisation remains the owner of the container.

Some products already can be traded in 640-litre Schütz containers, made of plastic with a metal protection frame, which are sealed after filling. The holder of the authorisation delivers these to the end user (spray contractor) and these are also emptied by the holder of the authorisation in the designated 1,000-litre container, with a leak-proof double wall. When pouring over the product, a new label with the batch number is applied to the 1,000-litre container. This label features the statement "not suitable for repackaging". After transferring the product to the new tank, the loading side of the 1,000-litre container is sealed with a lock system. The key remains in the possession of the holder of the authorisation. The holder of the authorisation is the owner of both containers and thus also holds responsibility for it. As such, he can control the labelling and refills.

Such a system will also be required for all large packaging that is destined for re-use.

Seed disinfectants may be placed on the market in larger packaging when this is destined for traders-seed disinfectants, subject to the authorisation by the Authorisation Committee.

Generally speaking, the packaging must always be adapted to the requested applications, in function of the quantities used by the potential users.

The fee to be paid for an application of an amendment of the packaging or an additional packaging depends on the situation:

- € 6.000 if the zonal procedure needs to be followed, BE acts as zRMS and more cMS are involved (“additional data (BE = zRMS)”, Royal Decree 13/11/11, Art. 1. § 1, 1.3°)

- € 1.500 if the zonal procedure needs to be followed, BE acts as zRMS but no other MS are involved “New data (with evaluation) (BE≠zRMS)”, Royal Decree 13/11/11, Art 1. § 1, 1.3°
- € 500 if BE acts as a cMS or if the evaluation can be handled at national level (“additional packaging/packaging type”, Royal Decree 13/11/11, Art 1. § 10)

5.1.10. Application for the withdrawal and liquidation of stocks (by the applicant)

At a given point, a company can decide to no longer wish to place a certain product on the market. The holder of the authorisation must always respect an 18-month phase-out period because stocks of the product may still be available on the market, either with the holder of the authorisation, his distributor, or in the trade, or with the end user. As a matter of fact, these stocks must no longer be marketed, sold or used when the product is no longer authorised. Then the holder of the authorisation sends back the authorisation to the Service Plant Protection Products and Fertilisers. Obviously this is only the case if there are no immediate problems with the product. If the reason for withdrawal is based on possible health or environmental risks, the Authorisation Committee may consider publishing press releases in which the user's attention is drawn to possible problems or in which it is stated that the product may no longer be used. In case of risk for human health, the authorisation can be suspended with immediate effect, without any grace period for selling, distributing or using the existing stocks.

The reason for withdrawing the authorisation may also be that the holder of the authorisation can no longer fulfil the conditions for maintaining the authorisation (conditions for prolongation, requirements when renewing the authorisation...). If the applicant then withdraws the authorisation, these conditions also no longer apply. The permission of the Authorisation Committee must be asked to sell or use all remaining stocks of the product (or have them sold or used). This is done by submitting the application for renewal or extension, by paying the required fee and stating in an accompanying letter that the only objective of this application is to sell the remaining stocks, to have them sold and used by the end user. Generally speaking, the Committee will grant permission for an 18-month period to do this:

- 6 months for sales by third parties such as the distributor and traders
- 12 additional months for use by the end user

Depending on the case, the duration of this period can be adapted however. If necessary, a new document can be issued with a limited validity period that will not be extended.

It goes without saying that this concerns available stocks and that the objective is not to import or produce new stocks.

A similar procedure can be followed for an amendment of the authorisation (change of label, composition, etc.).

5.1.11. Application for the withdrawal and liquidation of stocks (by the Service Plant Protection Products and Fertilisers)

If new available information would indicate that an acceptable risk for human health, the environment and/or non-target organisms cannot be guaranteed anymore, the Service Plant Protection Products and Fertilisers may also take the initiative to withdraw (some approved uses of) an existing plant protection product.

In such case, the Authorisation Committee may consider publishing press releases in which the user's attention is drawn to possible problems or in which it is stated that the product may no longer be used. In case of risk for human health, the authorisation can be suspended with immediate effect, without any grace period for selling, distributing or using the existing stocks.

5.2. Certificates

On the company's request, the Service Plant Protection Products and Fertilisers can issue a certificate to

- confirm that the company's specific product is effectively authorised in Belgium and to confirm that the company may produce a product even if it is not authorised in Belgium if destined for export
- deliver an official authorisation certificate in any other language besides French or Dutch. In this case, the applicant should submit a proposal for the translation, which will be corrected and validated by the Service Plant Protection Products and Fertilisers.

In such cases a proposal for a certificate must be sent by e-mail to the secretariat of the Plant Protection Products and Fertilisers Service (anouck.frulleux@gezondheid.belgie.be or nathalie.pynket@gezondheid.belgie.be). After the certificate has been checked, an approved certificate will be sent to the company.

The fee for obtaining a certificate amounts to € 80.

5.3. Renewal (according to Art. 43 of Regulation (EC) 1107/2099)

5.3.1. Introduction

Regulation (EC) No 540/2011 provides an overview of all the active substances that have been approved at European level and the expiration date of this approval. An active substance is always approved for a limited period of time. If the company wishes to keeps its active substance on the market, then it must submit an application for the renewal of the active substance in the Member State that will act as rapporteur, taking into account the most recent guidelines and data requirements.

After the possible approval of the renewal of this active substance, the Member States must review all the authorisations of plant protection products that contain the relevant active substance. The Service Plant Protection Products and Fertilisers will send instructions for this at due time, stating the information to be submitted and the applicable deadlines to all holders of an authorisation.

At European level the active substances have been subdivided into different lists (AIR 1, 2 and 3). Currently renewals of active substances in the second list (AIR II) are still being evaluated.

The renewal of formulations that contain one of these AIR I active substances still fall under Article 80 (transitional measures) of Regulation (EC) No 1107/2009. Consequently these re-authorisations are still evaluated under Directive 91/414/EEC.

In the future (starting with the active substances on the second list, AIR 2), these renewals will be evaluated under Article 43 of Regulation (EC) No 1107/2009. This has significant consequences for the procedures and timelines. Currently, however, a discussion is ongoing at European level about how the process described in Article 43 will actually be organised.

Reference can be made to Guidance Document SANCO/2010/13170 rev. 13 (14 July 2015).

5.3.2. Renewal of authorisation (article 43)

According to article 43 of Regulation 1107/2009, an authorisation shall be renewed upon application by the authorisation holder. After renewal of the approval of the active substance, the EU member states have to review all authorisations for plant protection products containing this active substance and shall decide at the latest 12 months after the renewal of the approval of the active substance. There are exceptions to this rule for products containing multiple active substances, and for products for which the dossiers could not be completed on time, because of new endpoints at the renewal of

the approval of this active substance. See Guidance Document SANCO/2010/13170 rev. 13 (14 July 2015) for a detailed explanation.

This revision which the Member States have to conduct implies that they have to ascertain whether plant protection products comply with the provisions of regulation 1107/2009. In this regard specifically the following points are of importance:

Within 2 months of the publication of the EFSA conclusion, authorisation holders have to submit the following information to the zRMS, copies have to be delivered to the cMS:

- The updated template for notification of intended zonal applications;
- It has to be indicated that there is an agreement regarding the necessary studies, and where possible a foreseen time schedule should be provided;
- It has to be indicated which parts of the risk assessment should be updated. (preferably, an agreement with the zRMS is reached beforehand, during pre-submission meetings);
- A data matching list should be furnished for the references which are relied upon (where relevant).

Within 3 months following the entry into force of the decision to renew the active substance, the following information should be delivered:

1. The comparability of the manufacturing process, the degree of purity and the nature of the impurities of the active substance, in the plant protection product which is to be reviewed, with the active substance which was examined with the intent of renewing the approval of the active substance;
2. The availability of the protected data or the authorisation of the owner of these data to make reference to them;
3. The dossier for the formulation and the examination thereof
   - This dossier should contain the following, according to article 43(2):
     - A copy of the authorisation certificate of the plant protection product ;
     - All new information which is required as a result of amendments in data requirements or criteria (changes in the endpoints as a result of the renewal of the active substance) ;
     - Proof/Justification that the newly submitted data are the result of changes to the data requirements or criteria which were not in force when the plant protection product was authorised, or that these data are necessary in order to adapt the conditions for approval;

- All information which demonstrates that the product meets the requirements (conditions and limitations) stipulated in the regulation regarding the renewal of the active substance;
- A report of the monitoring data, if the authorisation was subject to monitoring.

The information for these three steps has to be submitted within 3 months from the renewal of the approval of the active substance. Data submitted for the first point will be examined by the RMS for the active substance. Data submitted for the second point will be examined by the zRMS for the product. Data submitted for the third point will in theory be examined by the zRMS which coordinates the applications, in application of article 43.

Regarding the first point the authorisation holders are requested to submit the following information (1 copy, on CD-ROM), also if this has been submitted earlier at European level, or during the process for renewal:

- A statement of the manufacturer of the technical active substance which indicates that he supplies the authorisation holder (with mention of the concerned products) or the producer; in this last case, the producer in turn adds a statement that he supplies the authorisation holder in order to guarantee traceability;
- A full specification of the technical active substance backed by a 5 batch analysis with clear indication of the producer, the minimal purity and the location of production;
- The manufacturing process of the manufacturer of the technical active substance.

Regarding the second point a new version of the guidance document 13170 rev. 13 14 July 2015, is awaited, in which this subject will be explained.

As a result authorisation holders are requested to supply the information which is required under the first two point (except for letters of supply and letters of access) to the RMS address, with a copy of the accompanying letter to the Service Plant Protection Products and Fertilisers.

In order to comply with the third point, dossiers for formulations for plant protection products containing the renewed active substance as the only active substance or together with other approved active substances have to be submitted at the latest 3 months from the renewal of the approval**.** If due to new endpoints, some required new studies cannot be be generated in time, then no complete dossier has to submitted. In this case, 3 months after renewal of approval of the active substance the available studies should be submitted, accompanied of a list of the studies which are still being conducted together with a foreseen timeline for these studies. When all these studies are ready, they are submitted together with the dRR.

When the product contains a second active substance which will be renewed within a year of the first active substance, there exists an adapted procedure: The studies which are required for the renewal of such a product , which have to indicate that the product is acceptable as regards the first active substance should be submitted prior to the regular deadline. The dRR has to be submitted at that time, but in mutual agreement with the Member State where this dossier will be submitted, it can be decided that no dRR has to be submitted. After renewal of the second active substance, the studies for this second active substance have to be submitted, and a completed dRR has to be submitted. This information should be submitted three months after the approval of the renewal of the second active substance. The application will only be examined after reception of all studies for the formulation.

As explained in the documents: “Format of a draft Registration Report – version 2015”, these dossiers have to be drafted according to the new dRR-format.

For renewals under AIR2, there is an exception. In this case, the old dRR format can still be used. However, when acting as a zRMS, Belgium prefers to receive the dossier according to the new dRR-format. When acting as a cMS, Belgium would like to receive the same format which was submitted in the zRMS.

The dossier should be submitted as foreseen by the scheme in the table “Application for a zonal application”. All points of Regulation nr. 284/2013 have to be addressed. This is also valid for point 6 (data regarding efficacy), taking account the fact that for some points reference can be made to practical knowledge gained since the original authorisation; i.e. for point 6.1.3 reference can be made to the known efficacy of the active substance. On the other hand, it will always have to be proven that the authorised dose is the lowest possible dose to obtain the desired effect, whilst controlling resistance. Biological dossiers should comply with the EPPO-requirements.

In addition to this, the dossiers for formulations will have to contain the necessary information to allow evaluation of those points for which special attention was required, according to the Implementing Regulation Part B. If a Registration Report has already been submitted, an update for this dossier can be submitted. This should be made clear in the application.

If the requested dossiers for the formulations have not been submitted at the latest 3 months after the renewal of the approval of the active substance, the concerned authorisations will be withdrawn 30 months after renewal of the approval of the active substance. In this case, the authorisation holder is not allowed to place new stocks of the product on the market beyond 12 months after renewal of this approval. Sale and storage of the existing stocks by third parties will be authorised until 18 months after renewal of the approval while the use will be authorised until 30 months after renewal of the approval.

Authorisation holders which will not submit the requested information are asked to notify as soon as possible, in written form, that they agree with the withdrawal according to the abovementioned delays, in order to avoid the procedure for withdrawal.

Remark:

In order to guarantee the efficiency of the entire process, significant changes of the composition (in the sense of the guidance document on significant and non-significant changes of the chemical composition of authorised plant protection products SANCO/12638/201120 November 2012 rev. 2) are not allowed. Likewise, changes of the GAP which are not occasioned by new endpoints are not allowed within the framework of the procedure for renewal.

In case of non-significant changes to the composition, or changes of the GAP which are the result of new endpoints, these should be clearly mentioned in the accompanying letter.

5.3.3. Fees

In accordance with the Royal Decree of 13/11/2011 establishing the fees and contributions owed to the Budgetary Fund for raw materials and products, the following fees apply:

Re-authorisation a.s. (step 1) admin **Royal Decree 13/11/11, Art 1. § 2, 1°**	750
Re-authorisation a.s. (step 1) equivalence (BE≠zRMS) **Royal Decree 13/11/11, Art 1. § 2, 1°**	1 500
Re-authorisation a.s. (step 1) equivalence (BE=zRMS) **Royal Decree 13/11/11, Art 1. § 2, 1°**	3 000
Re-authorisation a.s. (step 1) alternative studies (BE≠zRMS,) **Royal Decree 13/11/11, Art 1. § 2, 1°**	1 500
Re-authorisation a.s. (step 1) alternative studies (BE=zRMS,) **Royal Decree 13/11/11, Art 1. § 2, 1°**	50 000

Re-authorisation (step 2) **(BE=zRMS; BE≠zRMS)** **Royal Decree 13/11/11, Art 1. § 2, 1°**	15 000
Re-authorisation (step 2) **(BE=zRMS, BE≠zRMS, renewal < 2 years)** **Royal Decree 13/11/11, Art 1. § 2, 1°**	12 000
Duplicate re-authorisation (with access) **Royal Decree 13/11/11, Art 1. § 2, 1°**	1 500
Re-authorisation (step 1+2) new a.s. **(BE≠zRMS)** **Royal Decree 13/11/11, Art 1. § 2, 3°**	1 500
Re-authorisation (step 1+2) new a.s. **(BE=zRMS)** **Royal Decree 13/11/11, Art 1. § 2, 3°**	15 000

5.4. Application for an (amendment of the) MRL at European level

Specific guidance is available on www.phytoweb.be.

5.5. Parallel trade

Specific guidance is available on www.phytoweb.be.

ANNEXES

Annex 1: Abbreviations used

a.s.	active substance
BAD	Biological Assessment Dossier
cZSC	Central Zone Steering Committee
DAR	Draft Assessment Report
dRR	draft Registration Report
GAP	Good Agricultural Practice
izRMS	InterZonal Reporting Member State
iZSC	InterZonal Steering Committee
MRL	Maximum Residue Limit
PPP	plant protection product
R.D.	Royal Decree
RMS	Reporting Member State (level a.s.)
zRMS	Zonal Reporting Member State (level of the formulation)

Annex 2 : Fees (overview)

A number of fees or contributions must be paid in relation to the authorisation of a plant protection product for agricultural use. These fees and contributions which are owed to the Budgetary Fund for raw materials and products are determined in a Royal Decree[1]. The table below gives a detailed overview of each type of application and the related fee. Moreover, the relevant fees are specified for the various types of applications in this guidance.

Type of application + reference Royal Decree	Amount (EUR)
Authorisation of formulations (National)	
zRMS first product or GAP with a not yet approved a.s. **Royal Decree 13/11/11, Art 1. § 1, 1.1° a**	20 000
zRMS first product or GAP with a not yet approved a.s., based on previously refused application **Royal Decree 13/11/11, Art 1. § 1, 1.1° a and d**	10 000
zRMS first product or GAP for non professional use with a not yet approved a.s., based on previously evaluated application for professional use **Royal Decree 13/11/11, Art 1. § 1, 1.1° a and e**	10 000
zRMS second product or GAP with a not yet approved a.s. **Royal Decree 13/11/11, Art 1. § 1, 1.1° a**	15 000
zRMS second product or GAP with a not yet approved a.s.,based on previously refused application **Royal Decree 13/11/11, Art 1. § 1, 1.1° a and d**	7 500
zRMS second product or GAP for non-professional use with a not yet approved a.s.,based on previously evaluated application for professional use **Royal Decree 13/11/11, Art 1. § 1, 1.1° a and e**	7 500

[1] Royal Decree of 13 November 2011 determining fees and contributions to the budgettary fund for raw materials and product

zRMS product approved a.s. **Royal Decree 13/11/11, Art 1. § 1, 1.1° a**	15 000
zRMS product approved a.s., based on previously refused application **Royal Decree 13/11/11, Art 1. § 1, 1.1° a and d**	7 500
zRMS product non professional use and approved a.s., based on previously evaluated application for professional use **Royal Decree 13/11/11, Art 1. § 1, 1.1° a and e**	7 500
zRMS for reference product DAR/similar GAP/approved a.s. **Royal Decree 13/11/11, Art 1. §1, 1.1° a**	6 000
zRMS for reference product DAR/similar GAP/approved a.s., based on previously refused application **Royal Decree 13/11/11, Art 1. §1, 1.1° a and d**	3 000
Duplicate authorisation (with access) **Royal Decree 13/11/11, Art 1. § 1, 1.1° a or b**	1 500
Duplicate authorisation (with access) based on previously refused application **Royal Decree 13/11/11, Art 1. § 1, 1.1° a or b and d**	750
National provisional authorisation (first product with as yet not approved a.s., BE≠zRMS) **Royal Decree 13/11/11, Art 1. § 1, 1.1° b**	6 000
National provisional authorisation (first product with as yet not approved a.s., BE≠zRMS) based on previously refused application **Royal Decree 13/11/11, Art 1. § 1, 1.1° b and d**	3 000
National provisional authorisation (second product with as yet not approved a.s., BE≠zRMS) **Royal Decree 13/11/11, Art 1. § 1, 1.1° b**	3 000

National provisional authorisation (second product with as yet not approved a.s., BE≠zRMS) based on previously refused application **Royal Decree 13/11/11, Art 1. § 1, 1.1° b and d**	1 500
National provisional authorisation (second product non-professional use with as yet not approved a.s., BE≠zRMS) based on previously evaluated application for professional use **Royal Decree 13/11/11, Art 1. § 1, 1.1° b and e**	1 500
Zonal mutual recognition(authorised a.s., BE≠zRMS) **Royal Decree 13/11/11, Art 1. § 1, 1.1° b**	3 000
Zonal mutual recognition (authorised a.s., BE≠zRMS) based on previously refused application **Royal Decree 13/11/11, Art 1. § 1, 1.1° b and d**	1 500
Zonal mutual recognition for non professional use (authorised a.s., BE≠zRMS) based on previously evaluated application for professional use **Royal Decree 13/11/11, Art 1. § 1, 1.1° b and e**	1 500
Authorisation of adjuvant **Royal Decree 13/11/11, Art 1. § 1, 1.1° c**	6 000
Authorisation of adjuvant based on previously refused application **Royal Decree 13/11/11, Art 1. § 1, 1.1° c and d**	3 000
Duplicate authorisation of adjuvant (with access) **Royal Decree 13/11/11, Art 1. § 1, 1.1° c**	1 500
Duplicate authorisation of adjuvant (with access) based on previously refused application **Royal Decree 13/11/11, Art 1. § 1, 1.1° c and d**	750
Renewal **(BE≠zRMS)**	3 000

Royal Decree 13/11/11, Art 1. § 1, 1.2°	
Renewal derived authorisation **(BE≠zRMS)** **Royal Decree 13/11/11, Art 1. § 1, 1.2°**	1 500
Renewal **(BE=zRMS)** **Royal Decree 13/11/11, Art 1. § 1, 1.2°**	15 000
Amendment (extension) / new data **(BE≠zRMS)** **Royal Decree 13/11/11, Art 1. § 1, 1.3°**	1 500
Amendment (labelling) **(BE≠zRMS)** **Royal Decree 13/11/11, Art 1. § 1, 1.3°**	1 500
New data (with evaluation) **(BE≠zRMS)** **Royal Decree 13/11/11, Art 1. § 1, 1.3°**	1 500
Prolongation **(BE≠zRMS)** **Royal Decree 13/11/11, Art 1. § 1, 1.3°**	1 000
Amendment a.s. content **(BE≠zRMS)** **Royal Decree 13/11/11, Art 1. § 1, 1.3°**	1 000
Amendment (extension) / new data (BE=zRMS)	6 000

Royal Decree 13/11/11, Art 1. § 1, 1.3°	
Amendment (labelling) **(BE=zRMS)** **Royal Decree 13/11/11, Art 1. § 1, 1.3°**	6 000
Additional data **(BE=zRMS)** **Royal Decree 13/11/11, Art 1. § 1, 1.3°**	6 000
Extension **(BE=zRMS)** **Royal Decree 13/11/11, Art 1. § 1, 1.3°**	6 000
Extension for minor use **(BE=zRMS)** **Royal Decree 13/11/11, Art 1. § 1, 1.3°**	3 000
Amendment a.s. content **(BE=zRMS)** **Royal Decree 13/11/11, Art 1. § 1, 1.3°**	6 000
Amendment of composition **(BE≠zRMS)** **Royal Decree 13/11/11, Art 1. § 1, 1.4°**	1 500
Non significant change to composition (BE≠zRMS) **Royal Decree 13/11/11, Art 1. § 1, 1.4°**	750
Amendment of composition through mutual recognition **(BE≠zRMS)** **Royal Decree 13/11/11, Art 1. § 1, 1.4°**	250

Amendment of composition **(BE=zRMS)** **Royal Decree 13/11/11, Art 1. § 1, 1.4°**	6 000
Amendment trade name **Royal Decree 13/11/11, Art 1. § 1, 1.5°**	250
Amendment of holder of authorisation/legal status **Royal Decree 13/11/11, Art 1. § 1, 1.5°**	250
Amendment of origin/specification a.s. **(BE≠zRMS)** **Royal Decree 13/11/11, Art 1. § 1, 1.6°**	1 500
Amendment of origin/specification a.s. **(BE=zRMS)** **Royal Decree 13/11/11, Art 1. § 1, 1.6°**	3 000
Re-authorisation (National)	
Re-authorisation a.s. (step 1) admin **Royal Decree 13/11/11, Art 1. § 2, 1°**	750
Re-authorisation a.s. (step 1) equivalence (BE≠zRMS) **Royal Decree 13/11/11, Art 1. § 2, 1°**	1 500
Re-authorisation a.s. (step 1) equivalence (BE=zRMS) **Royal Decree 13/11/11, Art 1. § 2, 1°**	3 000
Re-authorisation a.s. (step 1) alternative studies (BE≠zRMS,) **Royal Decree 13/11/11, Art 1. § 2, 1°**	1 500

Re-authorisation a.s. (step 1) alternative studies (BE=zRMS,) **Royal Decree 13/11/11, Art 1. § 2, 1°**	50 000
Re-authorisation (step 2) **(BE=zRMS; BE≠zRMS)** **Royal Decree 13/11/11, Art 1. § 2, 1°**	15 000
Re-authorisation (step 2) **(BE=zRMS, BE≠zRMS, renewal < 2 years)** **Royal Decree 13/11/11, Art 1. § 2, 1°**	12 000
Duplicate re-authorisation (with access) **Royal Decree 13/11/11, Art 1. § 2, 1°**	1 500
Re-authorisation (step 1+2) new a.s. **(BE≠zRMS)** **Royal Decree 13/11/11, Art 1. § 2, 3°**	1 500
Re-authorisation (step 1+2) new a.s. **(BE=zRMS)** **Royal Decree 13/11/11, Art 1. § 2, 3°**	15 000
Approval of active substances (EU applications)	
DAR Chemical-part 1, BE = RMS **Royal Decree 13/11/11, Art 1. § 3, 2°**	10 000
DAR Chemical-part 2, BE = RMS **Royal Decree 13/11/11, Art 1. § 3, 2°**	140 000
DAR Non-chemical-part 1, BE = RMS	5 000

Royal Decree 13/11/11, Art 1. § 3, 2°	
DAR Non-chemical-part 2, BE = RMS **Royal Decree 13/11/11, Art 1. § 3, 2°**	54 000
DAR Chemical , BE = co-RMS **Royal Decree 13/11/11, Art 1. § 3, 2°**	75 000
DAR Non-chemical, BE=co-RMS **Royal Decree 13/11/11, Art 1. § 3, 2°**	37 500
European application dossier - no RMS **Royal Decree 13/11/11, Art 1. § 3, 2°**	1 250
Change of "end point", BE=RMS **Royal Decree 13/11/11, Art 1. § 3, 3°**	3 000
Technical equivalence BE=RMS **Royal Decree 13/11/11, Art 1. § 3, 3°**	3 000
amendment of the conditions for authorisation a.s. (BE= RMS) **Royal Decree 13/11/11, Art 1. § 3, 3°**	25 000
Additional studies (per "open point"), BE=RMS **Royal Decree 13/11/11, Art 1. § 3, 3°**	5 000
Adverse data, BE=RMS **Royal Decree 13/11/11, Art 1. § 3, 3°**	5 000
Alternative annex II dossier, BE=RMS **Royal Decree 13/11/11, Art 1. § 3, 3°**	50 000

Peer review (BE= RMS) **Royal Decree 13/11/11, Art 1. § 3, 3°**	10 000
Notification for authorisation/renewal a.s., BE=RMS **Royal Decree 13/11/11, Art 1. § 3, 4°**	750
Residues	
MRL/residues **(BE=RMS)** **Royal Decree 13/11/11, Art 1. § 4, 1°**	1 000
MRL/residues (per submitted study report) **(BE=RMS)** **Royal Decree 13/11/11, Art 1. § 4, 1°**	3 000
MRL/residues (with tox evaluation) **(BE=RMS)** **Royal Decree 13/11/11, Art 1. § 4, 1°**	50 000
MRL/Peer review (BE= RMS) **Royal Decree 13/11/11, Art 1. § 4,1°**	10 000
Review EU-MRL **(BE=RMS)** **Royal Decree 13/11/11, Art 1. § 4, 2°**	10 000
Review EU-MRL (per submitted study report) (max 10 000 EUR) **(BE=RMS)** **Royal Decree 13/11/11, Art 1. § 4, 2°**	1 000

Verification authorisation after MRL review **Royal Decree 13/11/11, Art 1. § 4, 3°**	2500
Parallel authorisations	
Authorisation for parallel trade **Royal Decree 13/11/11, Art 1. § 5**	1 000
Extension of authorisation (parallel trade) **Royal Decree 13/11/11, Art 1. § 5**	1 000
Extension of authorisation (parallel trade) < 2 years **Royal Decree 13/11/11, Art 1. § 5**	0
Amendment of trade name (authorisation of parallel trade) **Royal Decree 13/11/11, Art 1. § 5**	250
Amendment of the holder of the authorisation/legal status (parallel trade) **Royal Decree 13/11/11, Art 1. § 5**	250
GEP authorisations	
Authorisation GEP **Royal Decree 13/11/11, Art 1. § 6**	3 000
Mutual recognition GEP **Royal Decree 13/11/11, Art 1. § 6**	2 500
Renewal GEP	750
Extension of GEP	750
Audit of GEP/surveillance audit	5 000

Royal Decree 13/11/11, Art 1. § 6	
Certificate **Royal Decree 13/11/11, Art 1. § 8**	80
Labelling	
Amendment/harmonisation classification and labelling a.s. **(67/548/EEC or 1999/45/EC, BE= submitting MS)** **Royal Decree 13/11/11, Art 1. § 9, 1°**	10 000
Amendment/harmonisation classification and labelling **(67/548/EEC or 1999/45/EC, BE=RMS)** **Royal Decree 13/11/11, Art 1. § 9,1°**	5 000
Labelling CLP **Royal Decree 13/11/11, Art 1. § 9, 2°**	80
Other	
Additional packaging/packaging type **Royal Decree 13/11/11, Art 1. § 10**	500
List of test and study reports **Royal Decree 13/11/11, Art 1. § 11**	1 500
Exemption from the submission of studies **Royal Decree 13/11/11, Art 1. § 12**	3 500

Acceptance of co-formulant **Royal Decree 13/11/11, Art 1. § 13**	12 000
Equivalence of co-formulant **Royal Decree 13/11/11, Art 1. § 14**	500
Other application (without evaluation) **Royal Decree 13/11/11, Art 1. § 15**	750
Other application (minimal evaluation) **Royal Decree 13/11/11, Art 1. § 15**	1 500
Other application (extensive evaluation) **Royal Decree 13/11/11, Art 1. § 15**	3 000
Other application (extra extensive evaluation) **Royal Decree 13/11/11, Art 1. § 16**	100 EUR per hour of evaluation
Additional Contribution	
Additional Contribution **(a.s. on the market at least 30 years)** **Royal Decree 13/11/11, Art 2. § 1, 1°**	370
Additional Contribution **(a.s. on the market for 25 to 30 years)** **Royal Decree 13/11/11, Art 2. § 1, 2°**	750
Additional Contribution **(a.s. on the market for 15 to 25 years)**	1 860

Royal Decree 13/11/11, Art 2. § 1, 3°	
Additional Contribution **(a.s. < 15 years on the market)** **Royal Decree 13/11/11, Art 2. § 1, 4°**	3 700

Annex 3: Belgian national presentation of the GAP

To be treated	(crop + Latin name + EPPO code)	Te behandelen	(gewas + Latijnse naam + EPPO code)	A traiter	(culture + nom latin + code EPPO)
Stage	First node – second node (BBCH 31-32)	Stadium	Eerste knoop – tweede knoop (BBCH 31-32)	Stade	Premier noeud – deuxième noeud (BBCH 31-32)
Remark	- Max (number) applications per crop, season, year, production cycle	Opmerking	- max. (aantal) toepassingen per teelt, seizoen, jaar, productiecyclus	Remarque	- max (nombre) applications par culture, saison, an, cycle de production
PHI	… days	Wachttijd	… dagen	Délais	… jours
Precautions for succeeding crops	/	Voorzorgen voor volggewassen	/	Précautions pour les cultures suivantes	/
Enemy + Latin name + EPO code	Mould… (mention only more enemies in this cell if stage, remark, rate, number of applications and application method are identical)	Vijand + Latijnse naam + EPPO code	Roest, Papiervlekkenziekte, … + Latijnse naam + EPPO Code	Ennemi + nom latin + code EPPO	Rouille, Mildiou, … + nom latin + code EPPO

Stage (of the enemy)	Preventively or at the appearance of the first symptons	Stadium (van de vijand)	Preventief of bij het verschijnen van de eerste symptomen	Stade (de l'ennemi)	Préventivement ou à l'apparition des premiers symptômes
Remark	/	Opmerking	/	Remarque	/
Rate	1 l/ha	Dosis	1 l/ha	Dose	1 l/ha
N° applications	1-3 applications, with an interval of 21 days	Aantal toepassingen	1-3 toepassingen, met een interval van 21 dagen	Nombre de traitements	1-3 applications, à intervalle de 21 jours
Application method	Field sprayer, at 200-500 L water/ha	Toepassingsmethode	Veldspuittoestel, à 200-500 l water/ha	Méthode d'application	Pulvérisateur de champ, à 200-500 l d'eau/ha
Enemy	Oidium	Vijand	Witziekte	Ennemis	Oïdium
Stage (of the enemy)	Preventively or at the appearance of the first symptons	Stadium (van de vijand)	Preventief of bij het verschijnen van de eerste symptomen	Stade (de l'ennemi)	Préventivement ou à l'apparition des premiers symptômes
Remark	/	Opmerking	/	Remarque	/
Rate	1,5 l/ha	Dosis	1,5 l/ha	Dose	1,5 l/ha
N° applications	1-3 applications, with an interval of 21 days	Aantal toepassingen	1-3 toepassingen, met een interval van 21 dagen	Nombre de	1-3 applications, à intervalle de 21 jours

				traitements	
Application method	Field sprayer, at 200-500 L water/ha	Toepassingsmethode	Veldspuittoestel, à 200-500 l water/ha	Méthode d'application	Pulvérisateur de champ, à 200-500 l d'eau/ha
Buffer zone	20 m with classical technique	Bufferzone	20 m met klassieke techniek	Zone tampon	20 m à technique classique

Remark: In order to fill out the crops to be treated and the enemies to be dealt with as adequately as possible, lists of cultures and enemies must be consulted online on the website www.phytoweb.be.

Annex 4 : Warning phrases concerning the labelling of treated seeds

French:	**Dutch:**	**English:**
La protection de ces semences est effectuée selon un niveau convenu de qualité industrielle. Pour votre propre sécurité et pour protéger l'environnement, les précautions suivantes doivent-être suivies : En général: Ne pas utiliser les semences traitées pour la consommation humaine ou animale ou pour la production de produits dérivés. Tenir hors de portée des enfants, des animaux d'élevage et de la faune sauvage. Manipuler les sacheries de semences avec le plus grand soin. Eviter le contact avec la peau et le système respiratoire et utiliser un équipement de protection individuelle adapté durant la manipulation des semences et le nettoyage des installations. Se laver les mains et les parties exposées du corps avant le repas et après le travail. Récupérer toutes semences accidentellement répandues en surface. Conserver les semences traitées à l'écart de tout cours d'eau.	De bescherming van deze zaden wordt uitgevoerd volgens een overeengekomen industrie-kwaliteitsnorm. Om uw eigen veiligheid en het milieu te beschermen, moeten de volgende voorzorgsmaatregelen in acht worden genomen: Algemeen: Gebruik geen behandeld zaad voor menselijke of dierlijke consumptie of voor andere verwerking. Buiten bereik van kinderen en dieren houden. Behandel verpakkingen met zaad voorzichtig. Vermijd contact met de huid en ademhalingswegen en draag beschermende kleding gedurende handelingen met het behandelde zaad en het schoonmaken van zaaiapparatuur. Was handen en blootgestelde huid vóór maaltijden en na het werk. Bedek of verwijder gemorst zaad. Houd behandelde zaden weg van oppervlaktewater. Voor het zaaien: Vermijd blootstelling aan stof wanneer de zakken worden geopend, en bij het vullen of leegmaken van de zaaimachine. Breng bij het vullen het	The protection of these seeds is carried out in accordance with an agreed industry quality standard. To protect your own safety and the environment, the following precautions should be observed: In general: Do not use treated seeds for human or animal consumption or for processing. Keep out of the reach of children and of animals. Treat packages with seeds carefully. Avoid contact with the skin and with the respiratory system and wear protective clothing during operations with treated seeds and during cleaning of the sowing equipment. Wash hands and wash exposed skin before meals and after work. Cover or remove spilled seeds. Keep treated seeds away from all surface waters. Before sowing: Avoid exposure to dust when opening the bags and when filling or emptying the sowing equipment. Avoid the transfer of possible dust from the seed bag

Avant le semis: Lors de l'ouverture des sacs de semences et pendant le remplissage ou la vidange de la trémie du semoir, éviter l'exposition aux poussières. Eviter le transfert de la poussière présente dans le sac de semences dans la trémie du semoir. Ne pas retraiter les semences traitées avec des produits supplémentaires. Pendant le semis: Lors de l'utilisation d'un semoir pneumatique à dépression, les poussières provenant des semences traitées devront-être dirigées vers la surface du sol ou dans le sol au moyen de déflecteurs. Semer à la dose de semis recommandée. Pour protéger les oiseaux et les mammifères, les semences traitées doivent être bien recouvertes de terre y compris en bout de sillons. Après le semis: Ne pas laisser les sacs vides ou les semences traitées inutilisées dans l'environnement. Les éliminer selon la législation en vigueur. Remettre toutes les semences traitées non utilisées dans leurs sacs d'origine et ne pas réutiliser les sacs vides pour d'autres usages.	eventueel aanwezige stof uit de zaaizaadzak niet over in de zaaimachine. Behandel het reeds ontsmette zaaizaad niet met andere producten. Bij het zaaien: Wanneer een pneumatische zaaimachine met vacuüm wordt gebruikt, moet de luchtstroom met eventueel daarin aanwezig stof van behandeld zaad naar het grondoppervlak of in de grond worden gericht via zogenaamde deflectoren. Zaai de aanbevolen hoeveelheid zaad. Om vogels en zoogdieren te beschermen moeten behandelde zaden volledig in de bodem worden ondergewerkt, ook aan het begin en einde van de rij. Na het zaaien: Laat geen lege zakken of behandelde zaden onbedekt achter in het milieu. Verwijder ze volgens locaal geldende voorschriften. Zorg er voor dat restanten behandeld zaad weer in de originele zaken worden gedaan. Gebruik lege zaaizaadzakken niet voor andere doeleinden.	to the sowing equipment. Do not treat already treated seeds with other products. At sowing: If a pneumatic seed drill with vacuum is being used, the air flow containing any possible dust from treated seeds should be directed directly to or into the ground surface by so-called deflectors. Sow the recommended sowing dose rate. To protect birds and mammals, treated seeds should be entirely incorporated into the soil, including at the beginning and at the end of the rows. After sowing: Do not leave empty seed bags or treated seeds uncovered in the environment. Remove them in accordance with local legislation. Make sure that any unused treated seeds are put back in their original seed bags and do not use empty seed bags for other purposes.

Annex 5 : Standard phrases to be mentioned on the label of products applied undiluted

French:	Dutch:	English:
Emballages vides et surplus de traitement L'emballage de ce produit, soigneusement vidé, doit être rincé à l'eau suivant un système manuel (trois agitations successives). Diluer les eaux de ce nettoyage environ 10 fois et pulvériser celles-ci sur la parcelle déjà traitée suivant les prescriptions d'emploi. L'emballage ainsi rincé devra être ramené par l'utilisateur aux points de ramassage prévus à cet effet. Ne pas contaminer les étangs, les cours d'eau ou les fossés avec le produit ou l'emballage vide. L'emballage ne peut, en aucun cas, être réutilisé à d'autres fins. De façon à éviter tout surplus de traitement après l'application, on s'efforcera de calculer au mieux la quantité de bouillie à préparer, ou la quantité à appliquer, en fonction de la superficie à traiter et du débit par hectare.	**Lege verpakkingen en spuitoverschotten** De zorgvuldig geledigde verpakking van dit product dient met water gespoeld te worden (drie opeenvolgende malen schudden). Het bekomen spoelwater ca. 10 maal verdunnen en verspuiten op het reeds behandeld perceel volgens de gebruiksvoorschriften. De aldus gespoelde verpakking moet door de gebruiker ingeleverd worden op een daartoe voorzien inzamelpunt. Vijvers, waterlopen of grachten niet vervuilen met het product of de lege verpakking. In geen geval mag de lege verpakking opnieuw gebruikt worden voor andere doeleinden. Om spuitoverschotten na de behandeling te vermijden, moet de benodigde hoeveelheid spuitvloeistof nauwkeurig worden berekend aan de hand van de te behandelen oppervlakte en van het debiet per hectare.	**Empty packaging and product surplus** The carefully emptied packaging must either be rinsed with water, either manually (shake three consecutive times) or by using a cleaning system with water under pressure which is mounted on the sprayer. The obtained rinse water must be poured into the sprayer tank. The rinsed packaging must be disposed of by the user at the designated collection point. Surplus spray must be diluted about 10 times and sprayed on the previously sprayed parcel in accordance with the instructions. Ponds, watercourses or ditches must not be polluted with the product or the empty packaging. In no case may the empty packaging be re-used for other purposes. To avoid surplus spray after the treatment, the required quantity of spray liquid must be carefully calculated based on the

		surface area to be treated and the flow per hectare.