

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**



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DOCUMENT INFORMATION

Guidance for the applicant of an authorisation of a plant protection product

Version 4.1

04/03/2020

REVISION HISTORY

Version and date	Point	Changes
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 authorisations 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
Version 4 June 2019	General	Update: the e-mail domain of the FPS has been changed to @health.fgov.be
	Table of contents	Addition: annexes are included in the table of contents
	2.1 + 3.1 + 4.7	Update: the efficacy package will from now on be evaluated by experts of the SPF; the evaluation of the toxicological package is now done by experts of the SPF in cooperation with Sciensano (the former Belgian Scientific Institute for Public Health WIV-ISP)
	2.2.3 + 2.2.4	Addition: a contribution for the use of unprotected data

2.2.3	Correction: only the applicant shall notify member states when Belgium agreed to be zRMS
2.2.3	Clarification: an application will not be accepted if it concerns a product containing an active substance for which the date of expiration of approval at EU level falls within 18 months after the planned submission date
2.2.4	Update: notification forms of intended application should only be sent by e-mail
2.3.2	Clarification: requirements for the reference product are specified
2.4	Clarification: conditions under which a comparative assessment is (not) needed are clarified
3.1	Addition: for denomination of files and folders on CD-ROMs, a maximum path length of 216 characters is allowed
3.1	Addition: a product that is formulated by blending two existing products, is considered as a completely new product and therefore, a complete dossier is required upon application for authorisation
3.1.1 + 3.1.2	Update: only the official letter and, if relevant the letter(s) of access/supply should be submitted on paper
3.1.1 + 3.1.2	Update: the list of documents to be submitted on CD-ROM has been amended
3.1.1 + 3.1.2	Update: a CD-ROM with the equivalence dossier is requested upon application for authorisation
3.1.1 + 3.1.2 + 4.3	Update: contact information of Sciensano (the former Belgian Scientific Institute for Public Health WIV-ISP) and the Government of Flanders
3.1.2	Correction: address of the Federal Laboratory for Food Safety
3.2	Clarification: products that belong to a range
3.2	Addition: trade names of previously withdrawn products can only be re-used 10 years after withdrawal (if different a.s.)
3.3.1	Addition: labels of treated seeds should also mention a minimum buffer zone of one meter with respect to surface water
3.3.2	Clarification: an authorisation holder can submit a 3-year stability study for evaluation
3.3.2	Addition: mention of mandatory and non-mandatory tank mixtures
3.4	Addition/move: paragraph on commercial packaging, including restrictions for large packages, twin packs and packaging of products for non-professional users
4.2	Addition: reference to the national guidance concerning extrapolation of packaging materials
4.3	Update: contact information for questions with regard to toxicology

	4.3	Update: removal of gamma-butyrolactone from the list of unacceptable co-formulants
	4.7	Update: contact information for questions with regard to efficacy
	4.8	Addition: specific Belgian requirements for seed treatments
	5.1	Clarification: the fee must only be paid by the applicant after receipt of the invoice; the applications will only be treated after receipt of the payment by the FPS
	5.1.3	Clarification: for Art. 51 applications, the classic dRR format needs to be used; if an extension under Art. 51 is requested, this needs to be indicated in the cover letter
	5.1.7	Clarification: an application for a change of the authorisation holder can be combined with an application for amendment of trade name
	5.1.8	Clarification: duplicate authorisations will always receive a new authorisation number
	5.1.8	Addition: a notification stating the production site of the formulation and a letter of supply (if relevant) need to be submitted
	5.1.10	Addition: section on applications for an amendment of the CLP classification
	5.1.12	Addition: paragraph about the determination of the grace period in case of non-renewal of an active substance
	5.3.2	Clarification: also when Belgium is zRMS for a renewal of an authorisation, a pre-submission meeting should be held
	5.3.2	Clarification: only applications that do not require a technical assessment are allowed during the frozen period
	Annex 3	Clarification: to fill out the GAP tables in the Belgian format, relevant cultures and enemies should be consulted via the search tool on Phytoweb
	Annex 6 + 7 + 8 + 9	Addition: new national guidance document concerning applications for authorisation of products for non-professional users
	Version 4.1 March 2020	General
2.3		Update: Applications for mutual recognition should always be supported by a complete and stand-alone dossier
3.1.1 + 3.1.2		Update: only 1 copy of the CD-ROM with the complete dossier is requested
5.1.9. + Annex 6		Deletion: no physical sample of the commercial packaging should be provided.

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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 harmonised 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
- 3 members of Sciensano (the former Belgian Scientific Institute of Public Health)
- 1 member of the Federal Agency for the Safety of the Food Chain
- 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, the data (analyses and methods of analysis, physical and chemical properties, residues, ecotoxicology, fate and behaviour in the environment, efficacy and selectivity) are entirely evaluated by the experts of the service Plant Protection Products and Fertilisers. The data relating to toxicology and health effects are evaluated in cooperation with Sciensano (the former Belgian Scientific Institute for Public Health).

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 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.

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

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 I) 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.

2.1.2. 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 finalised 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.

2.1.3. 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, a fee of € 25 000 applies (for exceptions: see Annex 2: Fees (overview)).

An additional contribution will be charged if the use of unprotected data 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

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.fgov.be). To avoid that an application based on old active substance endpoints is still ongoing at the time of renewal of the active substance, an application will in principle not be accepted if it concerns a product containing an active substance for which the date of expiration of approval at EU level falls within 18 months after the planned submission date.

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. 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 acting as zRMS should therefore present his application dossier(s) at a pre-submission meeting. Belgium will only formally accept the role of zRMS after this meeting, although a preliminary (conditional) agreement could be reached beforehand based on the information outlined above. A date for the pre-submission meeting can be set 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, although exceptionally specific experts can be invited if this is deemed necessary. The applicant will be given the opportunity to present the application dossier in detail. Only administrative and procedural questions can be discussed in detail, no questions related to evaluation issues.

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 ultimately 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.

2.1.4. 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, a fee of € 3 000 applies (for exceptions: see Annex 2: Fees (overview)).

An additional contribution will be charged if the use of unprotected data 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

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 e-mail (zonal.applications@health.fgov.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.

An overview of specific Belgian requirements and guidance documents can be found in Section 4 of this guide. Moreover, Belgian requirement for plant protection product for non-professional use are available in Annex 6.

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

2.2.1. 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 I 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 dossier as required in Article 33(3);
- an assessment report by the reference Member State containing information on the evaluation and confirmation that the evaluation was performed according to the Uniform Principles and based on the last approved endpoints.

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

2.2.2. 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 € 6 000 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 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.

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.

The assessment report by the reference Member State must be either available on CIRCABC or validated by the authorities of the reference Member State. It must be a stand-alone report presented in a comprehensive way covering all the aspects of article 29. The evaluation report should be written or translated in English. The risk assessments must have been carried out with the relevant endpoints and according to the guidance in force at the time of submission of the application for approval of the product in the reference MS.

In accordance with these principles and with the position adopted by other Member States, it is **not possible in Belgium to apply for the authorisation by mutual recognition of a generic plant protection product approved via Article 34** of Regulation 1107/2009.

The Regulation does not provide the basis for the delivery of an authorisation without a dossier. It is therefore not possible to make an application in Belgium that refers to a reference product with open data, without an application dossier. It is always required to submit a dRR with the application. The Authorisation Committee will only consider the application when the dossier is complete.

The risk assessment will consist of an assessment under the current review framework. The Authorisation Committee is of the opinion that the authorisation procedure for 'generics' cannot be limited to an 'administrative procedure' using the outcome of the risk assessment of the reference product. Because different dossier requirements may apply under the current assessment framework than under the assessment framework under which the reference product was assessed, the studies from the original registration dossier may not be sufficient to identify a safe use. As a result, additional studies/statements may be required for a complete dossier.

Applications for 'generics' can be submitted as zonal applications with Belgium as zRMS. Extension to other Member States can be achieved by either participating in the zonal assessment as Concerned Member States (cMS), or after decision-making, through mutual recognition.

An overview of specific Belgian requirements and guidance documents can be found in Section 4 of this guide. Moreover, Belgian requirements for plant protection product for non-professional use are available in Annex 6.

Please note that:

- 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.

A summary of the content of the submission dossier for a mutual recognition application can be found in section 3.1.2 of this guide.

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.

2.3. 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. A concise comparative assessment will be performed for products containing at least one new active substance approved as a candidate for substitution less than 5 years ago. A provisional authorisation can be granted once for 5 years in order to acquire experience first through using that product in practice.
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 the product remains authorised for at least one minor use, which is supported by the authorisation holder

by means of studies. 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 decision tree has been developed and is available on www.phytoweb.be. Applicants have to fill in and submit this decision tree (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. The decision tree may be terminated at any stage and it might not be necessary to continue through all steps.

2.4. 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 1 st 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 1 st authorisation	Max 15 years from authorisation date in BE
Studies necessary for renewal (art. 43) or review** of an authorisation ** on request of the Authorisation 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 application of article 34 of Regulation 1107/2009 in Belgium:

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 or other data out of protection, 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. Moreover, a legal argumentation demonstrating that any

study to which the dossier makes reference is not or no longer protected in Belgium needs to be submitted.

- 3) It is not possible in Belgium to apply for the authorisation by mutual recognition of a generic plant protection product approved via Article 34 of Regulation 1107/2009 (see section 2.3.2 Mutual recognition in Belgium).

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 must send the main dossier to the central administration at the Service Plant Protection Products and Fertilisers (consisting of the packages "administration", "physico-chemistry", "toxicology", "residue", "fate and behaviour in the environment", "ecotoxicology", "efficacy" 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 package "toxicology" will be sent by the Service Plant Protection Products and Fertilisers to the concerned external expert if needed.

It is worth noting however that for applications concerning existing authorisations 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" 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 or folder on the CD-ROM, whereas a maximum path length of 216 characters is allowed.

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

Remark

A product that is formulated by blending two existing products will be considered as a completely new product. Hence, all administrative and technical requirements that apply for an application for a new authorisation apply, even if the products that are used to formulate the blend are already authorised.

3.1.1. Application for a zonal authorisation

Package	To be sent to	Paper copy	CD-ROM
1. Administration 2. Physico-chemistry 3. Toxicology 4. Residues 5. Behaviour in the environment 6. Ecotoxicology 7. Efficacy 8. First aid	<p>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</p> <p>Recipient: - biopesticides: Mr. J. Denis</p> <p>- all other new applications (including products for non-professional use,...): Mr. D. Maerschallck</p>	<p>- Official letter</p> <p>- Letter of access (if applicable)</p> <p>- Letter of supply (if applicable)</p> <p><u>If an EU-MRL has to be set or amended:</u></p> <p>- a copy of the official letter for a separate application (please see instructions on www.phytoweb.be)</p>	<p><u>! Max. 40 characters for file or folder denomination and max. 216 characters per path</u></p> <p><u>- 1 CD-ROM or DVD with the complete dossier, including:</u></p> <ul style="list-style-type: none"> - 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 - A Belgian label proposal in NL and FR - A checklist for comparative assessment when the product contains one or more active substances which are candidate for substitution - The composition of the formulation and safety data sheets (SDS) of the formulation and of all the active substances and co-formulants - A copy of the acknowledging receipt of packages 10 and 11 in the Federal Laboratory for Food Safety and the Belgian Scientific Institute for Public Health respectively <p><u>- 1 CD-ROM OR DVD with the complete equivalence dossier¹ (even if the equivalence of all sources of active substances has been approved previously), including:</u></p> <ul style="list-style-type: none"> - The manufacturing process of the technical active substance - The 5-batch analysis - Analytical methods - The specification of the source - Toxicological and ecotoxicological data in case of relevant or new impurities - Letter of access (if applicable)

			<ul style="list-style-type: none"> - Letter of supply (if applicable) - <u>1 CD-ROM OR DVD with the first aid dossier</u> (see instructions on www.phytoweb.be)
9. Enforcement of the formulation ²	<p>Federal Laboratory for Food Safety Rue de Visé 495 4020 Wandre (Liège)</p> <p>Recipients: Mr. F. Etienne-Thewissen Fabian.Etienne@afsca.be</p> <p>Ms. I. Monisse Isabelle.Monisse@afsca.be</p>	- specimen of 100 – 200 mg pure certified a.s.	<p><u>1 CD-ROM or electronic copy of:</u></p> <ul style="list-style-type: none"> - analytical method for determining the concentration of a.s. in the formulation
10. Enforcement of residues ²	<p>Sciensano DS Chemical and physical health risks Service organic contaminants and additives Rue Juliette Wytsman 14 1050 Brussels</p> <p>Recipient: Mrs. Laure Joly PPP.registration-methods@sciensano.be</p>	/	<p><u>1 CD-ROM or electronic copy of:</u></p> <ul style="list-style-type: none"> - analytical method for determining the concentration of the active substance in the formulation - analytical method for determining the residue in crops and edible products
11. Vulgarisation ²	<p>Government of Flanders Department of Agriculture and Fisheries Policy Co-ordination and Environment Division</p>	/	<p><u>2 CD-ROMs or electronic copies (1 to each recipient) of:</u></p> <ul style="list-style-type: none"> - BAD (SANCO 7600/VI/95)

<p>Koningin Maria Hendrikaplein 70 bus 101 9000 Gent</p> <p>Recipient: Mr. Pascal Braekman pascal.braekman@lv.vlaanderen.be</p> <p>Walloon Agricultural Research Center (CRA-W) Unit Plant Protection and Ecotoxicology Location Alfred Serge Balachowsky Rue de Liroux 2 5030 Gembloux</p> <p>Recipient: Mr. Michel De Proft m.deproft@cra.wallonie.be</p>		
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Remarks:

¹ Not necessary if it concerns the reference source from the DAR/RAR or if the equivalence dossier has been submitted previously in the context of another application. In case of the latter, a copy of the approval letter of the source should be added.

² 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 be e-mailed to Fabian Etienne-Thewissen and Isabelle Monisse for each application for authorisation.

3.1.2. Application for mutual recognition

Package	To be sent to	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, 7 th floor Victor Hortaplein 40 box 10 1060 Brussels <u>Recipient:</u> - <u>biopesticides:</u> Mr. J. Denis - <u>other</u> Mr. P. Nadin	- Official letter	<u>! Max. 40 characters for file or folder denomination and max. 216 characters per path</u> <u>- 1 CD-ROM or DVD with the complete dossier, including:</u> <ul style="list-style-type: none"> - All the information that was supplied on paper - A copy of the authorisation granted by the reference Member State as well as a translation of the authorisation into English or an official Belgian language (French or Dutch) - A formal statement that the plant protection product is identical to that authorised by the reference Member State - A complete and summary dossier as required in Article 33(3) - A Registration Report (Part B and C) of the reference Member State containing information on the evaluation and decision on the plant protection product if not available on CIRCA BC - All the study reports and/or a legal argumentation demonstrating that any study to which the dossier makes reference is not or no longer protected in Belgium - The Belgian presentation of the GAP (NL, FR and EN), as presented in annex 3 of this guidance document - A Belgian label proposal in NL and FR - A comparison of the agricultural and climatic conditions (if necessary) - A checklist for comparative assessment when the product contains one or more active substances which are candidate for substitution - The composition of the formulation and safety data sheets (SDS) of the formulation and of all the active substances and co-formulants
2. Physico-chemistry		- Letter of access (if applicable)	
3. Toxicology		- Letter of supply (if applicable)	
4. Residues			
5. Behaviour in the environment			
6. Ecotoxicology			
7. Efficacy			
8. First aid			

			<ul style="list-style-type: none"> - A copy of the acknowledging receipt of packages 10 and 11 in the Federal Laboratory for Food Safety and the Belgian Scientific Institute for Public Health respectively - <u>1 CD-ROM OR DVD with the complete equivalence dossier¹</u> (even if the equivalence of all sources of active substances has been approved previously), including: <ul style="list-style-type: none"> - The manufacturing process of the technical active substance - The 5-batch analysis - Analytical methods - The specification of the source - Toxicological and ecotoxicological data in case of relevant or new impurities - Letter of access (if applicable) - Letter of supply (if applicable) - <u>1 CD-ROM OR DVD with the first aid dossier</u> (see instructions on www.phytoweb.be)
9. Enforcement of the formulation ²	<p>Federal Laboratory for Food Safety Rue de Visé 495 4020 Wandre (Liège)</p> <p>Recipients: Mr. F. Etienne-Thewissen Fabian.Etienne@afsca.be</p> <p>Ms. I. Monisse Isabelle.Monisse@afsca.be</p>	<p>- specimen of 100 – 200 mg pure certified a.s.</p>	<p><u>1 CD-ROM or electronic copy of:</u></p> <ul style="list-style-type: none"> - analytical method for determining the concentration of a.s. in the formulation

10. Enforcement of residues ²	<p>Sciensano DS Chemical and physical health risks Service organic contaminants and additives Rue Juliette Wytsman 14 1050 Brussels</p> <p>Recipient: Mrs. Laure Joly PPP.registration-methods@sciensano.be</p>	/	<p><u>1 CD-ROM or electronic copy of:</u></p> <ul style="list-style-type: none"> - analytical method for determining the concentration of the active substance in the formulation - analytical method for determining the residue in crops and edible products
11. Vulgarisation ²	<p>Government of Flanders Department of Agriculture and Fisheries Policy Co-ordination and Environment Division Koningin Maria Hendrikaplein 70 bus 101 9000 Gent</p> <p>Recipient: Mr. Pascal Braekman pascal.braekman@lv.vlaanderen.be</p> <p>Walloon Agricultural Research Center (CRA-W) Unit Plant Protection and Ecotoxicology</p>	/	<p><u>2 CD-ROMs or electronic copies (1 to each recipient) of:</u></p> <ul style="list-style-type: none"> - BAD (SANCO 7600/VI/95)

Location Alfred Serge Balachowsky Rue de Liroux 2 5030 Gembloux		
Recipient: Mr. Michel De Proft m.deproft@cra.wallonie.be		

Remarks:

¹ Not necessary if it concerns the reference source from the DAR/RAR or if the equivalence dossier has been submitted previously in the context of another application. In case of the latter, a copy of the approval letter of the source should be added.

² 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 be e-mailed to Fabian Etienne-Thewissen and Isabelle Monisse for each application for authorisation.

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 in the cover letter of the application.
- 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.
- The trade name may not give rise to confusion with that of an active substance that is not relevant. Therefore, the same trade name may not be used for formulations that contain a different active substance. An example:
 - o 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 products belonging to a range. A range is a group of products of the same category (professional or non-professional use) and same nature (fungicide, herbicide, insecticide, ...). Products belonging to a range should have at least one active substance in common. For example:

- o if BANZAI PLUS contains active substances x and y, BANZAI EXTRA may contain active substances x and z.

Moreover, it is not allowed to re-use a trade name (or range name) of a product that is withdrawn from the market for a product with a different active substance during the first 10 years after withdrawal of the former.

- 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:
 - o Not allowed:
BANZAI LIQUID, BANZAI FLOWABLE, BANZAI FLOW, BANZAI FL, ...
 - o 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:
 - o 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.

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'autorisation :/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 authorised 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 harmonised 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 authorised 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 authorisation 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 authorisation of certain plant protection products provides for specific measures which should also be mentioned on the bags of the treated seeds. In Belgium, a standard buffer zone of 1 m between the treated crop and surface water needs to be respected, also when it concerns treated seeds. Hence, following risk mitigation measure has to be mentioned on the packaging of treated seeds: *“To protect aquatic organisms do not sow treated seeds at less than one meter distance from surface water.”* Additional measures are imposed for insecticides (for example an SPe8 sentence). 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.

For more information with respect to the labelling of treated seeds, please consult www.phytoweb.be.

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. If an authorisation holder provides a 3-year stability study within an application dossier, this will be evaluated as such and, if acceptable, the 3-year stability will be confirmed in the cover letter that accompanies the authorisation certificate. This information will, however, never figure on the authorisation certificate itself.

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
 - o the sowing or planting of the crop to be protected and/or succeeding crop
 - o the access to the treated crop
 - o the harvest/slaughter
 - o 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):
 - o hazard pictograms,
 - o the relevant signal word,
 - o hazard (H) and precautionary (P) statements,
 - o 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 cm².

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

Remarks:

- 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.
- 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.
- Non-mandatory tank mixes are allowed to be mentioned on the label under the responsibility of the authorisation holder if they reflect existing agricultural practices. Only mandatory tank mixtures will figure on the authorisation certificate (if the necessary data requirements are met).

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. through 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. Commercial packaging

3.4.1. Restrictions

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 if 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.

3.4.2. Twin packs

Twin packs, i.e. packages in which two separate plant protection products are marketed together, are only allowed under one of the following conditions:

- It is impossible to mix both active substances; or
- One active substance is complementary to another in order to be effective.

The commercial package of a twin pack needs to contain the labels of the individual products. The twin pack can receive an additional trade name but no separate authorisation number. Authorisation for a twin pack has to be requested by means of an official letter mentioning the justification of such a twin pack. This application will be examined by the Authorisation Committee.

3.4.3. Packaging of products for non-professional users

Specific guidance and a check-list with requirements for packaging and measuring devices for products for non-professional users are presented in Annex 6 and Annex 9: Check-list « Conformity and precision of packaging and measuring device for products for non-professional use submitted for authorisation in Belgium », respectively.

3.5. 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.

3.6. 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.

3.7. 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:

https://ec.europa.eu/food/plant/pesticides/approval_active_substances/guidance_documents_en

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. This is available online at:
https://ec.europa.eu/food/plant/pesticides/approval_active_substances/guidance_documents_en

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
- Section 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 on the data requirements and extrapolation of packaging materials is available on www.phytoweb.be.

4.3. Toxicology

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

Julie Verhelst

E-mail: Julie.verhelst@health.fgov.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 (see Annex 6).

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

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 recognised 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 is no specific guidance available for the efficacy part of the dossier. Please contact one of the following persons with specific questions concerning efficacy:

Adrien Dewalque

Telephone: +32 (0)2 524 72 91

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E-mail: Stefanie.Polyn@health.fgov.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 products for non-professional uses: specific guidance concerning products for non-professional users is available in Annex 6 of this document.
- national requirements for adjuvants: specific guidance concerning adjuvants available is available at www.phytoweb.be.
- national requirements with respect to dose expression of vertical crops: specific guidance is available at www.phytoweb.be.
- national requirements with respect to the risk assessment for bees: specific guidance is available at www.phytoweb.be.

Specific requirements for products containing fertilisers

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.

Specific requirements for seed treatments

In Belgium, the authorised dose for uses other than seed treatments, which figures on the authorisation certificates, is a maximum dose. It is therefore not allowed to apply a dose exceeding this one. Nevertheless, a lower dose can be applied under the responsibility of the user, without increasing the maximum number of treatments or shortening the PHI. In contrast, for seed treatments it is not allowed to lower the dose, given that it concerns a preventative treatment and that on the moment of the treatment it is not possible to accommodate to unknown factors in the field after sowing. The authorised dose for a seed treatment in Belgium is therefore fixed, i.e. it is a maximum dose that cannot be lowered either.

Several seed treatment facilities located in Belgium not only treat seeds destined for the Belgian market, but also seeds destined for other Member States or third countries. The treatment of seeds has to be done in line with the authorisation delivered by the member state in which the seed treatment takes place (cfr. *Draft Guidance document for the autorisation of plant protection product for seed treatment, version 16*), in this case in accordance with the authorisation delivered in Belgium.

Whatever the destination market of the treated seeds, products used for seed treatments that are carried out in Belgium must be authorised in Belgium. These authorisations rely on the evaluation of the submitted application dossier. Applicants must therefore take the following into account in their applications for authorisation of seed treatment products:

- A) If the seeds to be treated in Belgium are only destined for export to a third country, the applicant needs to submit all information necessary to allow a risk evaluation for all relevant aspects in accordance with the Draft Guidance Document stated above.

*The following sections are considered **to be relevant for the EU**:*

- *composition, physical-chemical properties, analytical methods : in order to characterize and identify the concerned seed treatment product and to allow enforcement and monitoring;*
- *occupational health assessment limited to seed treatment (operator exposure for the operator that treats the seed and workers in the seed treatment facility) and to toxicity data that are needed to label the seed treatment product according to Regulation 1272/2008;*
- *ecotoxicological properties limited to the data that are needed to label the seed treatment product according to Regulation 1272/2008 and to the emission from the seed treatment facility.*

*Following sections are considered **to be not relevant for the EU**, as they are depending on circumstances, crops, cultivation practices, harmful organisms that can widely vary and may be unfamiliar to the evaluating Member State:*

- *Operator exposure during sowing of the seeds*
- *Efficacy*
- *Residues*
- *Environmental exposure, Fate and behaviour in the environment*
- *Risk assessment for non-target organisms, and risk mitigation measures for the environment and for non-target organisms.*

Furthermore, analytical methods for residues in environment and for consumer are not considered relevant in case of authorisation for export outside the EU.

On the authorisation certificate it will be mentioned that the treated seeds are destined for export to a third country.

- B) If the seeds to be treated are destined both for Belgium (or another member state) and for a third country, 2 cases can be distinguished:

1° The dose needed in the third country is lower or equal to the dose authorised in Belgium: the seed treatment for this third country can take place in Belgium without a specific mention on the Belgian authorisation certificate.

2° The dose needed in the third country is higher than the dose authorised in Belgium: an application that takes into account the dose in the third country should be furnished. This application dossier should allow a risk assessment for all relevant aspects (in accordance with the Draft Guidance document mentioned above) at this higher dose. If this evaluation is positive, the product can be authorised in Belgium for the treatment of seeds destined for export. On the authorisation certificate, two distinct uses will be indicated: one for the treatment of seeds destined for the Belgian (and/or EU) market, the other for the treatment of seeds destined for third countries.

4.9. Instructions for the CLP classification

Specific guidance is available on www.phytoweb.be.

4.10. 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)

For products containing active substances approved by the EU, authorisations in general remain valid until one year after the end of the approval at EU-level. For products which do not contain active substances authorised at EU-level (adjuvants, safeners,...) the authorisations generally remain valid for ten years. An application for renewal for these products 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 a fee of € 6 000 will apply (€ 1 500 for the renewal of a duplicate authorisation).

Remark:

The national-level application for renewal for products containing active substances approved by the EU 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 Renewal (according to Art. 43 of Regulation (EC) 1107/2009) must be submitted.

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 generally 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, for applications submitted under Directive 91/414/EEC or as transitional measure for new national requirements), 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 a fee of € 3 000 will apply if Belgium acts as CMS or for national applications.

Whenever an authorisation is administratively prolonged (i.e. without the evaluation of data), a fee of € 250 applies.

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 uses, and where necessary, with residue trials and other studies or information that demonstrate that the conditions for authorisation are still fulfilled. An adapted (d)RR, which lists any

additional information, must therefore be joined to the application. For applications under Article 51 of Regulation (EC) No 1107/2009, the classic (d)RR format must be used (for more information, see www.phytoweb.be). 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 2.1.1 of this guidance document must be followed for this type of application unless it 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 an extension of use can be done by letter and the fee of € 6 000 will apply if Belgium acts as zRMS. If the extension of use concerns a minor use (under Article 51 of Regulation (EC) No 1107/2009) the fee is reduced to € 3 000 if Belgium acts as zRMS. (In this case the applicant has to indicate in his letter that he applies for a minor use under Art. 51.) A fee of € 3 000 applies if Belgium acts as cMS or for national applications. An additional contribution must be paid if the application dossier refers to unprotected data owned by another company. 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 wish 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 2.1.1 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. An invoice will be drawn up after receipt of the application. The application will only be treated once the payment of the fee has been received.

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 should be appended to the application.

A fee of € 500 will apply. An invoice will be drawn up after receipt of the application. However, the application will only be treated once the payment of the fee has been received.

5.1.7. Application for a change of the holder of the authorisation (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 € 500 will apply. An invoice will be drawn up after receipt of the application. However, the application will only be treated once the payment of the fee has been received. The

Authorisation Committee does not need to approve this application as this can be dealt with on the administrative level.

An application for transfer of an authorisation can be combined with an application for amendment of the trade name. In such case, both fees will still be charged.

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 authorisation will receive a new authorisation number, but apart from that, it will be completely identical to the reference product. This means that the compositions should be identical, the authorised 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, a 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;
- if relevant, a letter of supply;
- a label proposal for the new product;
- a dossier for first aid;
- a notification stating the production site(s) of the formulation.

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 a fee of € 1 500 will apply. An invoice will be drawn up after receipt of the application. However, the application will only be treated once the payment of the fee has been received.

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 2.1.1 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.

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. § 1.2°)
- € 3 000 if the zonal procedure needs to be followed, BE acts as zRMS but no other MS are involved (“additional data (BE≠zRMS)”, Royal Decree 13/11/11, Art 1. § 1, 1.2°)
- € 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)

An invoice will be drawn up after receipt of the application. However, the application will only be treated once the payment of the fee has been received.

5.1.10. Application for an amendment of the CLP classification

When an authorisation holder wishes to apply for an amendment of the CLP classification of a certain product, the following documents need to be submitted:

- A proposal for amended CLP classification
- A justification for this new classification, e.g. supporting studies
- Updated safety data sheets

The fee to be paid for an application of an amendment of the CLP classification depends on the situation:

- € 6 000 if the zonal procedure needs to be followed and BE acts as zRMS (Royal Decree 13/11/11, Art. 1. § 1.2°)
- € 3 000 if BE does not act as zRMS (Royal Decree 13/11/11, Art 1. § 1.2°)

An invoice will be drawn up after receipt of the application. However, the application will only be treated once the payment of the fee has been received.

5.1.11. 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 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.).

5.1.12. Withdrawal 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.

In case of non-renewal of an active substance at EU level, the Authorisation Committee will determine a grace period for the products concerned, based on the transitional measures and the maximum grace period as set out in the relevant non-renewal regulation. The Authorisation Committee further takes into account several elements, such as the reasons for the non-renewal of the active substance, the application period of the product(s) in Belgium, ...

In general, the Authorisation Committee attempts to provide separate deadlines for sales by the authorisation holder, for sales by distributors and traders and for use by the end user. These deadlines are communicated to the authorisation holders and by press release on www.phytoweb.be in order to inform all the stakeholders.

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@health.fgov.be or nathalie.pynket@health.fgov.be). After the certificate has been checked, an approved certificate will be sent to the company.

The fee for obtaining a certificate amounts to € 250.

5.3. Renewal (according to Art. 43 of Regulation (EC) 1107/2009)

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 keep 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.

Reference can be made to Guidance Document SANCO/2010/13170.

5.3.2. Renewal of authorisation (article 43)

According to article 43 of Regulation (EC) No 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 ("Category 4 data"). See Guidance Document SANCO/2010/13170 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 (EC) No 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 a pre-submission meetings);
- A data matching list should be furnished for the references which are relied upon (where relevant).

When Belgium acts as zRMS for the renewal of an authorisation, at this point in time a pre-submission meeting should be organised where the previously stated points will be discussed. A pre-submission meeting can be set by contacting the zonal coordinators (zonal.applications@health.fgov.be).

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;
- A comparative assessment dossier, where necessary.

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.
- Toxicological and ecotoxicological data in case of relevant or new impurities

Regarding the second point a new version of the guidance document SANCO/2010/13170, 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 points (except for letters of supply and letters of access) to the RMS, with a copy of the accompanying letter and a copy of the data mentioned under the first point 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 generated in time, then no complete dossier has to be 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”, as provided on the website of the European Commission, these dossiers have to be drafted according to the new dRR-format.

The dossier should be submitted as foreseen by the scheme in the table “Application for a zonal authorisation”. All points of Regulation (EC) No 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 date of application of the decision on 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.

Remarks:

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.

During the “frozen period”, i.e. the time between the date of application of the renewal regulation and the decision of the product to be renewed, only applications for which no technical assessment is needed, may be possible. These application may include:

- Administrative applications for changes in an existing product's name or authorisation holder.
- Applications for authorisation of a parallel import where the parent or master product is still authorised according to the Uniform Principles. The conditions of authorisation will need to be identical or within those of the currently authorised product. It is not possible to allow any variation (e.g. new packaging);
- Applications for extensions of authorisations for minor use (Article 51 applications), if they are within the risk envelope of existing uses, if the ADI en ARfD did not change during the EU review, and if the residue definition was agreed prior to EU-review and did not change;
- Applications for a change in the source of active substance, providing the proposed source complies with the relevant inclusion/approval conditions of the active substance.

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:

- € 25 000 for an application for renewal of a product for which BE acts as zRMS (Royal Decree 13/11/11, Art. 1. § 1.1° a)
- € 6 000 for an application for renewal of a product for which BE acts as cMS (Royal Decree 13/11/11, Art. 1. § 1.1° b)
- € 1 500 for an application for renewal of a duplicate authorisation (Royal Decree 13/11/11, Art. 1. § 1.1° b)

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 Decree¹. 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	
BE = zRMS for an application for authorisation of a PPP Royal Decree 13/11/11, Art 1. § 1.1° a	25 000
BE = zRMS for an application for authorisation of a PPP, based on a previously refused application Royal Decree 13/11/11, Art 1. § 1.1° a and d	12 500
BE = zRMS for an application for authorisation of a PPP for non-professional use, based on a previously evaluated application for professional use Royal Decree 13/11/11, Art 1. § 1.1° a and e	12 500
BE = zRMS for an application for authorisation of a PPP identical to the reference product from the DAR with BE = RMS and with a similar GAP Royal Decree 13/11/11, Art 1. §1.1° a	6 000
BE = zRMS for an application for authorisation of a PPP identical to the reference product from the DAR with BE = RMS and with a similar GAP, based on previously refused application Royal Decree 13/11/11, Art 1. §1.1° a and d	3 000
BE ≠ zRMS for an application for authorisation of a PPP Royal Decree 13/11/11, Art 1. § 1.1° b	6 000

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

<p>BE ≠ zRMS for an application for authorisation of a PPP, based on previously refused application</p> <p>Royal Decree 13/11/11, Art 1. § 1.1° b and d</p>	3 000
<p>BE ≠ zRMS for an application for authorisation of a PPP for non-professional use, based on a previously evaluated application for professional use</p> <p>Royal Decree 13/11/11, Art 1. § 1.1° b and e</p>	3 000
<p>Application for a duplicate authorisation (with access)</p> <p>Royal Decree 13/11/11, Art 1. § 1.1° b</p>	1 500
<p>Application for a duplicate authorisation (with access), based on previously refused application</p> <p>Royal Decree 13/11/11, Art 1. § 1.1° b and d</p>	750
<p>Application for an authorisation of an adjuvant</p> <p>Royal Decree 13/11/11, Art 1. § 1.1° c</p>	6 000
<p>Application for an authorisation of an adjuvant based on a previously refused application</p> <p>Royal Decree 13/11/11, Art 1. § 1.1° c and d</p>	3 000
<p>Application for a duplicate authorisation of an adjuvant (with access)</p> <p>Royal Decree 13/11/11, Art 1. § 1.1° c</p>	1 500
<p>Application for a duplicate authorisation of an adjuvant (with access), based on a previously refused application</p> <p>Royal Decree 13/11/11, Art 1. § 1.1° c and d</p>	750
<p>Requested missing data in the frame of an application for authorisation</p> <p>Royal Decree 13/11/11, Art 1. § 1.1° g</p>	100 EUR per hour of evaluation

BE = zRMS for an application for renewal of a PPP Royal Decree 13/11/11, Art 1. § 1.1° a	25 000
BE ≠ zRMS for an application for renewal of a PPP Royal Decree 13/11/11, Art 1. § 1.1° b	6 000
Application for renewal of a duplicate authorisation Royal Decree 13/11/11, Art 1. § 1.1° b	1 500
BE = zRMS for an application for a change of the use, classification or labelling Royal Decree 13/11/11, Art 1. § 1.2°	6 000
BE = zRMS for any other type of application for which additional data are required Royal Decree 13/11/11, Art 1. § 1.2°	6 000
BE = zRMS for an application for amendment of the a.s. content Royal Decree 13/11/11, Art 1. § 1, 1.2°	6 000
BE ≠ zRMS for an application for a change of the use, classification or labelling Royal Decree 13/11/11, Art 1. § 1.2°	3 000
BE ≠ zRMS for any other type of application for which additional data are required Royal Decree 13/11/11, Art 1. § 1.2°	3 000
BE ≠ zRMS for an application for amendment of the a.s. content Royal Decree 13/11/11, Art 1. § 1, 1.2°	1 000
Prolongation (BE = zRMS) Royal Decree 13/11/11, Art 1. § 1, 1.2°	6 000

Prolongation (BE ≠ zRMS) Royal Decree 13/11/11, Art 1. § 1, 1.2°	3 000
Prolongation of an authorisation without evaluation of data (administrative prolongation) Royal Decree 13/11/11, Art 1. § 1.2°	250
Application for a minor use extension Royal Decree 13/11/11, Art 1. § 1.2°	3 000
BE = zRMS for an application for a significant change of the composition Royal Decree 13/11/11, Art 1. § 1.3°	6 000
BE ≠ zRMS for an application for a significant change of the composition Royal Decree 13/11/11, Art 1. § 1.3°	1 500
BE ≠ zRMS for an application for a non-significant change of the composition Royal Decree 13/11/11, Art 1. § 1.3°	750
Application for a change of the composition by mutual recognition Royal Decree 13/11/1, Art 1. § 1, 1.3°	250
Application for a change of the trade name of the authorisation Royal Decree 13/11/11, Art 1. § 1, 1.4°	500
Application for a change of the name or legal status of the authorisation holder Royal Decree 13/11/11, Art 1. § 1, 1.4°	500
Application for a transfer of the authorisation	500

Royal Decree 13/11/11, Art 1. § 1, 1.4°	
BE = zRMS for a change of the origin/specification of the a.s.	3 000
Royal Decree 13/11/11, Art 1. § 1.5°	
BE ≠ zRMS for a change of the origin/specification of the a.s.	1 500
Royal Decree 13/11/11, Art 1. § 1.5°	
BE = zRMS for the evaluation of compliance with the approval conditions for technical equivalence	
Royal Decree 13/11/11, Art 1. § 2° a	3 000
BE ≠ zRMS for the evaluation of compliance with the approval conditions for technical equivalence	
Royal Decree 13/11/11, Art 1. § 2° a	1 500
BE = zRMS for the evaluation of compliance with the approval conditions with assessment of new studies	
Royal Decree 13/11/11, Art 1. § 2° b	50 000
BE ≠ zRMS for the evaluation of compliance with the approval conditions with assessment of new studies	
Royal Decree 13/11/11, Art 1. § 2° b	1 500
Approval/renewal of active substances (EU applications)	
BE = RMS for an application for approval/renewal of a type A a.s. – introduction of dossier	60 000
Royal Decree 13/11/11, Art 1. § 3.2° a	
BE = RMS for an application for approval/renewal of a type A a.s. – DAR + peer review	140 000
Royal Decree 13/11/11, Art 1. § 3.2° a	

BE = RMS for an application for approval/renewal of a type B a.s. – introduction of dossier Royal Decree 13/11/11, Art 1. § 3.2° b	19 000
BE = RMS for an application for approval/renewal of a type B a.s. – DAR + peer review Royal Decree 13/11/11, Art 1. § 3.2° b	40 000
BE = coRMS for an application for approval/renewal of a type A a.s. Royal Decree 13/11/11, Art 1. § 3.2° c	100 000
BE = coRMS for an application for approval/renewal of a type B a.s. Royal Decree 13/11/11, Art 1. § 3.2° d	37 500
BE ≠ RMS or coRMS for an application for approval/renewal of an a.s. Royal Decree 13/11/11, Art 1. § 3.2° e	1 250
BE = RMS for an application for a change of “end point” Royal Decree 13/11/11, Art 1. § 3.3° a	3 000
BE = RMS for assessment of the technical equivalence of the origin of the a.s. Royal Decree 13/11/11, Art 1. § 3.3° b	3 000
BE = RMS for amendment of the approval conditions of the a.s. Royal Decree 13/11/11, Art 1. § 3.3° c	25 000
BE = RMS for evaluation of additional studies (per “open point”) Royal Decree 13/11/11, Art 1. § 3.3° d	5 000
BE = RMS for notification of a potential adverse or unacceptable effect Royal Decree 13/11/11, Art 1. § 3.3 e°	5 000
BE = RMS for an alternative a.s. dossier	50 000

Royal Decree 13/11/11, Art 1. § 3.3° f	
Peer review Royal Decree 13/11/11, Art 1. § 3.3°	10 000
BE = RMS for the evaluation of the notification for approval/renewal of an a.s. Royal Decree 13/11/11, Art 1. § 3.4°	750
Residues	
BE = RMS for setting an MRL (Royal Decree 13/11/11, Art 1. § 4.1°)	1 000
BE = RMS for the evaluation of a study for setting an MRL (by study) Royal Decree 13/11/11, Art 1. § 4.1°	3 000
BE = RMS for setting an MRL with evaluation of a toxicological dossier Royal Decree 13/11/11, Art 1. § 4.1°	50 000
Peer review for setting an MRL Royal Decree 13/11/11, Art 1. § 4.1°	10 000
BE = RMS for evaluation of existing MRLs for an a.s. Royal Decree 13/11/11, Art 1. § 4.2°	10 000
BE = RMS for evaluation of a study for an existing MRL (per submitted study report) (max 10 000 EUR) Royal Decree 13/11/11, Art 1. § 4.2°	1 000
Verification of authorisation(s) after MRL review Royal Decree 13/11/11, Art 1. § 4.3°	2500

Parallel authorisations	
Application for a permit for parallel trade Royal Decree 13/11/11, Art 1. § 5	1 500
Application for prolongation of a permit for parallel trade Royal Decree 13/11/11, Art 1. § 5	1 500
Application for prolongation of a permit for parallel trade, < 2 years after first application or last prolongation (no technical evaluation) Royal Decree 13/11/11, Art 1. § 5	0
Application for a change of the trade name of a parallel trade permit Royal Decree 13/11/11, Art 1. § 5.1°	500
Application for a change of the name or legal status of the permit holder Royal Decree 13/11/11, Art 1. § 5.2°	500
Application for transfer of a permit for parallel trade Royal Decree 13/11/11, Art 1. § 5.3°	500
GEP authorisations	
Application for GEP recognition Royal Decree 13/11/11, Art 1. § 6	3 000
Application for GEP recognition by mutual recognition Royal Decree 13/11/11, Art 1. § 6	2 500
Application for renewal of a GEP recognition Royal Decree 13/11/11, Art 1. § 6	750
Application for extension of a GEP recognition Royal Decree 13/11/11, Art 1. § 6	750

Audit of GEP/surveillance audit Royal Decree 13/11/11, Art 1. § 6	5 000
Application for a certificate Royal Decree 13/11/11, Art 1. § 8	
Classification and labelling	
BE = submitting MS for an application for change/harmonisation of classification and labelling of an a.s. (67/548/EEC or 1999/45/EC) Royal Decree 13/11/11, Art 1. § 9.1°	10 000
BE = RMS for an application for change/harmonisation of classification and labelling (67/548/EEC or 1999/45/EC) Royal Decree 13/11/11, Art 1. § 9.1°	5 000
Other	
Application for an additional packaging or packaging type Royal Decree 13/11/11, Art 1. § 10	500
Application to obtainain a list of protected and unprotected data Royal Decree 13/11/11, Art 1. § 11	1 500
Application for exemption from the submission of studies Royal Decree 13/11/11, Art 1. § 12	3 500
Evaluation of a co-formulant Royal Decree 13/11/11, Art 1. § 13	12 000

Evaluation of the equivalence of a 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) Royal Decree 13/11/11, Art 2. § 1.3°	1 860
Additional Contribution (a.s. < 15 years on the market)	3 700

Royal Decree 13/11/11, Art 2. § 1.4°	
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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, productiecycclus	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 symptoms	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 + Latin name + EPO code	Oidium + EPPO Code	Vijand	Witziekte + EPPO Code	Ennemis	Oïdium + EPPO Code
Stage (of the enemy)	Preventively or at the appearance of the first symptoms	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 at least 21 days	Aantal toepassingen	1-3 toepassingen, met een interval van ten minste 21 dagen	Nombre de traitements	1-3 applications, à intervalle d'au moins 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
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, please consult our online search tool on www.phytoweb.be.

Annex 4: Warning phrases concerning the labelling of treated seeds

French:	Dutch:	English:
<p>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-êtré suivies :</p> <p>En général:</p> <p>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.</p>	<p>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:</p> <p>Algemeen:</p> <p>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.</p> <p>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</p>	<p>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:</p> <p>In general:</p> <p>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.</p> <p>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</p>

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 lokaal 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:
<p>Emballages vides et surplus de traitement</p> <p>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.</p> <p>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.</p>	<p>Lege verpakkingen en spuitoverschotten</p> <p>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.</p> <p>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.</p>	<p>Empty packaging and product surplus</p> <p>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.</p> <p>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.</p>

Annex 6

INSTRUCTIONS FOR THE APPLICANT OF AN AUTHORISATION FOR A PRODUCT FOR NON-PROFESSIONAL USE



1. Context, objectives and presentation of the guidance

1.1. Implementation of the split of authorisations

Listed on the "Federal programme for reducing pesticides for agricultural use and biocides", the "split of authorisations" was legally implemented by the publication of the Royal Decrees of 31 August 2007 (for contributions and remunerations) and of 10 January 2010 (split of authorisations).

The split of authorisations implies the creation of specific acts for plant protection products for professional and non-professional users. Authorisation numbers are distinguished by different letters:

- xxxxxG/B for products for non-professional users (xxxxG/P for parallel imports) with "G" for Garden;
- xxxxxP/B for products for professional users (xxxxP/P for parallel imports) with "P" for Professional;

1.2. Objectives and content of the annex

This annex completes the "Guidance for the applicant of an authorisation of a plant protection product " and aims to help the applicant to prepare the dossier designed to support the application for the authorisation of a plant protection product for non-professional users.

2. Procedure for the authorisation of a product for non-professional use

2.1. General provisions

The submission of authorisation requests for products for non-professional users does not differ fundamentally from applications for products for professional users and therefore the applicant is invited to refer to the general section of the guide for more details about the procedure to follow.

Authorisation requests for products for non-professional users may be submitted via three different channels:

- Zonal assessment with Belgium as reporter Member State;
- Zonal assessment with Belgium as concerned Member State;

- Mutual intra-zonal recognition (for products used outdoors, under protection or indoors) or inter-zonal recognition (for products used under protection or indoors).

2.2. Parallel import

A parallel trade permit may only be issued for a product for non-professional users if an identical product (reference product) is authorised for non-professional users in Belgium. Alongside the general requirements for parallel trade, information concerning packaging and the measurement device may be necessary for non-professional products. These requirements are stipulated in the checklist provided at the end of this guide. Concerning packaging that will be marketed in Belgium for the imported product, several cases are possible:

- The product will be sold in packaging identical to the reference product: the product should no longer be assessed. The applicant just has to provide a packaging and label model so that the experts are able to verify the equivalence with the packaging and labelling of the reference product.
- The product will be sold in different packaging from that of the reference product but which has already been assessed in the frame of the authorisation in Belgium of a product for non-professional use of the same type of formulation which the applicant holds: the packaging should no longer be assessed. The applicant should, however, provide a packaging and label model so that the experts are able to verify the equivalence with the packaging and labelling of the product for which these types of packaging and labelling have been assessed.
- The product will be sold in packaging that has not yet been assessed: the applicant must provide all the elements presented in the checklist. Given that new packaging should be assessed, an application for another type of packaging will be invoiced in addition to the remuneration for the parallel trade application.

3. Specific information for products for non-professional use

3.1. Type of product

Only ready-to-use products and products that need to be diluted or dissolved in water may be authorised for non-professional users. Products which should be mixed with another one before use (for example, products that require the addition of an adjuvant during preparation) may only benefit from an authorisation for professional use.

3.2. Trade name

The product's trade name must comply with the general criteria described in the general section of the guide.






3.3. Specific assessment criteria for products for non-professional users





Risk assessment for the non-professional users





In general, products that fall within one of the following risk categories may not be sold for non-professional users (see article 10/1 of the Royal Decree of 28/02/1994 as inserted by article 6 of the Royal Decree of 10/01/2010):




- explosive (E);
- extremely flammable (unless it is presented in an aerosol) (F⁺);
- very toxic (T⁺) or toxic (T);
- corrosive (C);
- carcinogenic (labelled R45);
- mutagenic (labelled R46);
- toxic for reproduction (labelled R60 or R61).


The hazard categories according to the regulation 1272/2008/CE (CLP) which correspond to the risk categories established according to the directive 67/548/EEC are as follows:




Label elements for explosives					
Classification	Unstable explosive	Division 1.1	Division 1.2	Division 1.3	Division 1.4
Pictogram					
Signal word	Danger	Danger	Danger	Danger	Warning
Hazard statement	H200: Unstable explosives	H201: Explosive; mass explosion hazard	H202: Explosive, severe projection hazard	H203: Explosive; fire, blast or projection hazard	H204: Fire or projection hazard


Label elements for self-reactive substances and mixtures				
Classification	Type A	Type B	Types C and D	Types E and F
Pictogram				
Signal word	Danger	Danger	Danger	Warning
Hazard statement	H240: Heating may cause an explosion	H241: Heating may cause a fire or explosion	H242: Heating may cause a fire	H242: Heating may cause a fire

Label elements for organic peroxides				
Classification	Type A	Type B	Types C and D	Types E and F
Pictogram				
Signal word	Danger	Danger	Danger	Warning
Hazard statement	H240: Heating may cause an explosion	H241: Heating may cause a fire or explosion	H242: Heating may cause a fire	H242: Heating may cause a fire




Label elements for flammable substances and mixtures				
	Flammable gas		Flammable liquids	Flammable solids
Classification	Category 1	Category 2	Category 1	Category 1
Pictogram				
Signal word	Danger	Warning	Danger	Danger
Hazard statement	H220: Extremely flammable gas	H221: Flammable gas	H224: Extremely flammable liquid and vapour	H228: Flammable solid

Label elements for self-heating substances and mixtures	
Classification	Category 1
Pictogram	
Signal word	Danger
Hazard statement	H251: Self-heating: may catch fire

Label elements for acute toxicity			
Classification	Category 1	Category 2	Category 3
Pictogram			
Signal word	Danger	Danger	Danger
Hazard statement: oral	H300 Fatal if swallowed	H300 Fatal if swallowed	H301 Toxic if swallowed
Hazard statement dermal	H310 Fatal in contact with skin	H310 Fatal in contact with skin	H311 Toxic in contact with skin
Hazard statement inhalation	H330 Fatal if inhaled	H330 Fatal if inhaled	H331 Toxic if inhaled

Label elements for skin corrosion	
Classification	Category 1/1A/1B/1C
Pictogram	
Signal word	Danger
Hazard statement	H314 Causes severe skin burns and eye damage



Products classified as Eye Damage Category 1 (H318) are authorised for non-professional users provided that these products do not present a risk of splashing in the eyes. When submitting an application, the applicant should develop and carry out a test to prove that the exposure risk for eyes when using the product is negligible. (To our knowledge, there is no standardised test for this purpose.) If the risk assessment is acceptable, it is not necessary to wear protective eyeglasses.

Label elements			
	for carcinogenicity	for germ cell mutagenicity	for reproductive toxicity
Classification	Category 1A and 1B	Categories 1A and 1B	Category 1A and 1B
Pictogram			
Signal word	Danger	Danger	Danger
Hazard statement	H350: May cause cancer (state route of exposure if it is conclusively proven that no other routes of exposure cause the hazard)	H340 May cause genetic defects (state route of exposure if it is conclusively proven that no other routes of exposure cause the hazard)	H360 May damage fertility or the unborn child (state the effect if it is known) (state route of exposure if its conclusively proven that no other routes of exposure cause the hazard) H360FD H360D H360F

Products classified as a Category 2 carcinogen (H351), a Category 2 mutagen (H341) or a Category 2 reproductive toxicant (H361) are currently still authorised for non-professional users provided that the exposure estimations show that wearing protective gloves offers enough protection for the user.

It should be noted that a product for non-professional users will not be authorised if this product contains an active substance or a coformulant that is classified as a Category 1A/1B carcinogen (H350), a Category 1A/1B mutagen (H340) or a Category 1A/1B reproductive

toxicant (H360), even if the product is not classified as carcinogenic/mutagenic/toxic for reproduction.

Label elements for specific target organ toxicity after single or repeated exposure		
	Single exposure	Repeated exposure
Classification	Category 1 (STOT SE 1)	Category 1 (STOT RE 1)
Pictogram		
Signal word	Danger	Danger
Hazard statement	H370 Causes damage to organs (or state all the organs affect, if they are known) (state route of exposure if it is conclusively proven that no other routes of exposure cause the hazard)	H372 Causes damage to organs (or state all the organs affected if they are known) through prolonged or repeated exposure (state route of exposure if it is conclusively proven that no other routes of exposure cause the hazard)

Apart from these hazard categories, the following EU-special hazard statements are also excluded for non-professional users:

- EUH070: Toxic by eye contact;
- EUH071: Corrosive to the respiratory tract.

The risk evaluation specifically adapted to the non-professional users is implemented according to the following models:

- English model (*UK_POEM Model*) in which the following data is introduced:
 - o duration of application: 0.5 hour;
 - o application equipment: "Home garden sprayer (5 litre tank). Outdoor, low level target";
 - o surface area treated: 0.05 ha (except in the case of exemption granted on advice of the Authorisation Committee; the maximum surface area of the treatment which has been authorised should then be used);
 - o container: "5 litre narrow closure" or "1 L container"
- EFSA (AOEM) calculator model
- Jardin amateur UPJ French model

For application types not provided for in the afore-mentioned models, the applicant may submit an argument or use another exposure calculation model (such as "CRD model for

amateurs (Puffer Pack model)" or, for granules, "PHED granule model (hand held application)").

Furthermore, the Authorisation Committee considers that only protective gloves may be imposed for handling and applying products for non-professional users. Therefore, the products that require the precautionary statement P280 "Wear protective gloves/protective clothing/eye protection/face protection" are, in principle, forbidden for non-professional users. However, the Committee may grant the authorisation for such products if the risk assessment models show that the user's exposure is negligible even if not wearing protective clothing and/or if the product's packaging is such that the risk of contact with the eyes is non-existent. In such cases, the Committee may propose to replace phrase P280 with precautionary statement P262 "Do not get in eyes, on skin, or on clothing". In the specific case of the product containing a micro-organism, an authorisation for non-professional users may be granted provided that the product does not contain any substance with sensitising properties (to be shown via *ad hoc* studies) and that, because of this, it is not necessary to wear a protective mask. The applicant may, for example, offer to market this product as a single-use hydrosoluble sachet.

Behaviour in the environment

Specific guidance is available on www.phytoweb.be.

No environmental assessment is required for ready-to-use products in sprays or aerosol generators (AE) in packaging with a volume of less than 5 L.

Ecotoxicology

Specific guidance is available on www.phytoweb.be.

No ecotoxicological assessment is required for ready-to-use products in sprays or aerosol generators (AE) in packaging with a volume of less than 5 L.

3.4. Description of non-professional uses

The description of non-professional uses will be made using the list of crops suitable for the non-professional uses presented in annex 7.

It will be specified if it is for:

- outdoor or under protection uses,
- the treatment of indoor plants,
- applications on the ground (e.g.: on grass and lawns), low-lying applications (e.g.: on strawberries) or vertical applications (e.g.: fruit trees, hedges),

- the storage of vegetable products (e.g.: potatoes),
- killing weeds
 - o impermeable not cultivated area (paving, concrete, stabilised, roadbed, etc.)
 - o permeable not cultivated area;
 - o permanently not cultivated areas;
 - o other (to be specified);

Please note that only certain categories of herbicides are authorised in Belgium, such as low-risk herbicides and herbicides of which the active substance(s) exclusively consist of micro-organisms, plant extracts and natural substances from animal, plant, microbial or mineral origin (Royal Decree of 16/09/2018).

Only herbicides authorised on impermeable not cultivated areas may be used on surfaces paved, covered by concrete, dolomite, gravel or roadbed, such as pavements, courtyards, verges, etc. Herbicides authorised on permeable not cultivated areas may be used on permeable surfaces (waste ground, etc.) which are not destined to be sown or planted in the short term (waiting period of 6 to 12 months before sowing or planting).

The names of the pests to fight will be made using the list of pests suitable for the non-professional uses presented in annex 8.

- Application dose
 - o The application dose should be supplied for each application method and each use.
 - o Doses concerning products for non-professional users are not expressed by "ha" or by "ha of hedge" but by m².
 - o For foliar treatments applied by spraying (contact fungicides, insecticides, etc.), the treatment is usually carried out to the point of runoff. However, doses will be expressed in g/l or ml/l as well as the number of l/m² needed in order to be able to evaluate the amount of mixture to prepare.
 - o For treatments applied to the soil by watering (herbicides, products against soil insects, etc.), doses will be provided in g/l or ml/l as well as the number of l/m² in order to be able to evaluate the amount of mixture to prepare.
 - o For ready-to-use products sold or designed to be applied by a hand sprayer, the dose to apply will be expressed whenever possible in the number of sprays or the number of seconds spent spraying per m² of surface area to be treated.
 - o For molluscicides (anti-slug granules), doses will be expressed in granules/m² and the distance to respect between two granules should be indicated.
- Application method

Describe *in full*

- The application method: watering, spraying, spreading, powdering, soaking, baiting, coating, other (to be specified).
- The type of equipment to use (among the equipment listed below) as well as the volume of water to use per surface unit or volume: watering can, trigger sprayer, hand held pressure duster, constant pressure duster, aerosol, manual spreader (boxes of DP for non-germination of potatoes, etc.) or setting up of bait boxes, other (to be specified).

Principles of the Authorisation Committee concerning specific non-professional uses:

- Ready-to-use products:

Ready-to-use products sold in hand sprayers are, in principle, designed for localised use. These are not subject to any specific ecotoxicological assessment. Furthermore the dose is expressed for these products in number of trigger spray per m². These same products sold in 5 l cans or more designed to be applied with a backpack sprayer, are considered to be concentrated products to dilute. Therefore, they are subject to an ecotoxicological assessment and likely to impose a water protection zone greater than the standard untreated zone as provided for in the Royal Decree of 19/03/2013. Furthermore, the dose must be expressed in a similar way as for a concentrated product.

- Treatment of ponds:

The Authorisation Committee does not consider appropriate to authorise herbicides in order to control weeds in aquatic environments.

3.5. Packaging and label

Legal provisions concerning product packaging for products for non-professional users are defined in article 10/1 of the Royal Decree of 28/02/1994 as inserted by article 6 of the Royal Decree of 10/01/2010 and have been stipulated by the Authorisation Committee. In order for authorisation applicants to judge the conformity of packaging and measuring devices they want to submit beforehand, a checklist has been drawn up and is available in annex 9.

The maximum volume of each package should not treat more than 5 ares (500 m²), unless an exemption is granted after positive evaluation by the Authorisation Committee of the argument provided by the applicant. The maximum surface area that may be treated should be calculated for the main use taking account of the number of treatments mentioned in the authorised uses.

The measuring device should be designed to allow an easy measurement of the recommended doses without complicated calculations and multiple measurements. If the dosing device can be separated from the packaging it should be both included in a box.

The control of the precision of the measuring device may be implemented by the applicant which will provide its protocol and control results to the efficacy experts.

For all products authorised for non-professional users, the packaging and measuring tools that will be sold in Belgium must correspond to those described in the authorisation certificate. The addition of new packaging in the range that has already been authorised must be subject to an application for which remuneration is required in order to cover administrative costs.

A full label project in the actual size and colours and written in national languages (FR + NL) should be provided with each authorisation request for a product for non-professional users. When different sizes of packages are proposed, the project corresponding to the smallest size must be provided.

In order to clarify the information (concerning the dose, pests, application methods and period, etc.) and to benefit from quick access to it in the case of an emergency (first-aid, telephone number of Antipoison Centre, etc.), it is necessary to standardise the way in which the product information is presented to the user.

In concrete terms, the information must be divided up into three sections:

- Identity
- Use
- Security

Product identity

The information presented in this section must appear on the rear face of the box (if there is one) and on the primary packaging (bottle, resealable bag, aerosol can, etc.). In the case of the product not being placed inside a box or of it being impossible to place all the information required in "Identity" (aerosols), it must appear on the first page of a booklet attached to the primary packaging. In the case of hydro-soluble sachets, it is mandatory for some information described in the general section of the guide to appear on each sachet.

The information concerning the identity of the product that must appear on the label is presented in the following table:

Information to be provided	Location	Mandatory
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Commercial name. The product name appearing on the packaging should be the name under which the product has been authorised.	Front face box and primary packaging	YES
Simple phrase about use. This will help to quickly identify the product's function. Nevertheless, this cannot be presented in a font size larger than that of the commercial name. Indeed, in the case of an accident, it is necessary to quickly provide the commercial name accompanied by its authorisation number to the Poison Control Centre. <i>Weed killer for roses</i> or <i>Soil insect repellent</i> are examples of simple phrases of use but NOT <i>Multi-purpose Fungicide</i> . The term "multi-purpose" presents the product as effective against all fungal diseases but such a product does not exist.	Front face box and primary packaging	YES
Action exerted (e.g. <i>Herbicide</i> , etc.).	Front face box and primary packaging	YES
Package content (net weight) and total surface area that it can treat.	Front or rear face box and primary packaging	YES
Address of authorisation holder.	Front or rear face box and primary packaging, except dispensation (granted by the Committee)	YES
The type of formulation e.g. <i>concentrated suspension</i>).		YES
Name and content (in g/l or %) of the active substance(s).		YES
Representation of the main pests targeted and the plants to treat. In this case, any photos or drawings of crops can only depict those for which the product has been approved. These depictions are assessed by the Plant Protection Products and Fertilisers Service.	Front face box and primary packaging	To be submitted on a case by case basis to the Committee
Authorisation number	Front or rear face box and primary packaging + inset for Poison Control Centre	YES

Batch number	Free, on box and primary packaging + inset for Poison Control Centre	YES
Best-before-date	Free, on box and primary packaging	
Address of the person responsible for labelling and packaging		

It is important to recall that:

Concerning molluscicides, it is not allowed to place a logo representing a dog and/or a cat accompanied or not by the reference "*protected by bitrex*".

Comments:

Following the publication of the standard NBN EN 15178:2007 (Moniteur Belge of 10 January 2008) for the identification of products in the case of emergency (call to the Antipoison Centre), applicants are advised to place an inset on the label containing at the very least the following symbol  and citing the product's commercial name, authorisation number, its batch number, the telephone of the Antipoison Centre and, if applicable, the product's barcode.

Use

The information presented in this section must be placed on the front or sides of the box (if there is one) and on the primary packaging. In the case of the product not being placed inside a box or of it being impossible to place all the information required in "Use" on the primary packaging, it must appear in a booklet attached to the primary packaging.

The information concerning the product's use that must appear on the label is presented in the following table:

Information to be provided	Location	Mandatory
The phrase "Read the instructions enclosed before use" in the case that the information concerning the section "Use" cannot appear on the primary packaging (lack of space) and it is not presented in a box (often the case of aerosols). This information is presented in booklet attached to the primary packaging.	Rear face or sides	YES
Clarification about the product's action (e.g. <i>systemic insecticide against whitefly</i>), which enables users to be informed simply about the way in which the product		YES

works and to provide with details about any selectivity or phytotoxicity.															
<p>Data concerning the dose.</p> <p>The application dose should be supplied for each application method and each use;</p> <p>For <u>foliar treatments applied by spraying</u> (fungicides, insecticides, contact herbicides, etc.), express the doses in <u>g/l or ml/l</u>. Mention that the treatment should be applied to the point of runoff. In order to be able to evaluate the amount of mixture to prepare, indicate the number of l/m² required for this application.</p> <p>For <u>treatments applied to the soil by watering</u> (herbicides, products against soil insects, etc.), provide the doses in <u>g/l or ml/l</u>. In order to be able to evaluate the amount of mixture to prepare, indicate the number of l/m² required for this application.</p>		YES													
<p>Data concerning application. Methods, doses and application periods for the product should be explained as clearly as possible. The use of a table (example below) is recommended but not mandatory.</p> <table border="1" data-bbox="229 1055 946 1218"> <thead> <tr> <th>Crops</th> <th>Pests</th> <th>Dose</th> <th>Period</th> </tr> </thead> <tbody> <tr> <td>C1</td> <td rowspan="3">E1</td> <td rowspan="2">D1</td> <td>P1</td> </tr> <tr> <td>C2</td> <td>P2</td> </tr> <tr> <td>C3</td> <td>D2</td> <td>P3</td> </tr> </tbody> </table>	Crops	Pests	Dose	Period	C1	E1	D1	P1	C2	P2	C3	D2	P3	Rear face or side	YES
Crops	Pests	Dose	Period												
C1	E1	D1	P1												
C2			P2												
C3		D2	P3												
<p>The phrase: <i>In order to avoid any surplus of the treatment after application, try to calculate the quantity of mixture to prepare as precisely as possible or the quantity to apply according to the surface area to be treated.</i></p>		YES													
<p>Other references: concerning buffer zones, for example</p>		YES													
<p>A pictogram depicting a glove in the case of the non-professional risk assessment having shown that it was necessary to wear gloves.</p>		YES													
<p>A pictogram identifying the product as designed specifically for non-professional users.</p>		NO													

Comment: for molluscicides, the labelling project should include a diagram, a photo or a drawing explaining the distribution of the granules by surface unit.

Security

The information presented in this section must be placed on the front or sides of the box (if there is one) and on the primary packaging. In the case of the product not being placed inside a box or of it being impossible to place all the information required in "Security" on the primary packaging, it must appear in a booklet attached to the primary packaging.

The information to be provided is as follows:

Information to be provided	Location	Mandatory
<p>For all products, indicate the EUH401 on the label: Comply with the instructions for use in order to avoid risks for humans and the environment.</p>	Rear face or side and primary packaging	YES
<p>User protection</p> <ul style="list-style-type: none"> ▪ Specific dangers: danger phrases and symbols ▪ Precautions for use: safety advice (phrases P) and other phrases imposed by the authorisation (<i>Wash hands after use, Avoid contact with the mouth, Avoid splashing, etc.</i>) P102, P270, P101 ▪ First-aid instructions and telephone number of the Poison Control Centre 	Rear face or side and primary packaging	YES
<p>Environmental protection</p> <ul style="list-style-type: none"> ▪ Specific dangers: danger phrases and symbols ▪ SP1: Do not pollute water with the product or its packaging. ▪ Precautions for use: safety phrases and other phrases imposed by the authorisation specific to environmental protection. ▪ For <u>all products applied on impermeable not cultivated areas</u>, indicate on the label: "Do not apply to hard surfaces, permanently uncultivated (paved, concrete, stabilised or asphalt areas, areas covered with dolomite, gravel or ballast), connected to a sewage network (kerbs, gully-pots,...) or connected to a surface water (watercourses, lakes, ponds, canals, drainage networks, surface water ditches,...)." 		YES
<p>Storage</p> <ul style="list-style-type: none"> ▪ Specific dangers: danger phrases and symbols ▪ Precautions: caution advice (phrases P) 		YES
<p>Treatment of empty packaging and surplus</p> <ul style="list-style-type: none"> ▪ Other phrases imposed by the authorisation: 		YES

<ul style="list-style-type: none"> - SP1: Do not pollute water with the product or its packaging. - P501: Discard the contents and the recipient at a dangerous or special waste collection centre. 		
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- **Method for cleaning the equipment used for application**

Describe in detail the cleaning methods to use for the application equipment. No specific protective equipment may be required except for gloves.

The method usually recommended is as follows:

Clean your equipment as follows:

- add ten times the amount of water if some product is left over and shake the sprayer;
- spread the rinsing water over an area of grass (unless it is a herbicide) or over an area covered with bark or mulch;
- rinse three times in order to remove all residue.

- **Period of time before returning to the zone treated**

This is the waiting time, for example between an application of herbicide or moss remover in grass or an application of a product in a greenhouse and the moment when people and pets are able to enter the treated zone again.

The Authorisation Committee believes that a period before returning that exceeds 24 hours is incompatible with the usual practices of a non-professional user. Thus, products for which such a period applies are forbidden for these uses.

For all products for non-professional users for which a period before returning is less than 24 hours, this period is defined by default at 24 hours.

For all products applied to lawns, a waiting time of 24 hours is imposed by default.

Annex 7: List of crops adapted for non-professional users

Crops – Cultures - Gewassen		
fruit trees and shrubs	arbres et arbustes fruitiers	fruitbomen en -struiken
apples	pommiers	appelbomen
pears	poiriers	perenbomen
cherries and morello cherries	cerisiers et griottiers	kersen- en kriekenbomen
peaches and nectarines	pêchers et nectariniers	perzik- en nectarinebomen
plums	pruniers	pruimenbomen
apricots	abricotiers	abrikoos
hazelnuts	noisetiers	hazelaars
common walnut	noyer commun	notelaars (walnoten)
vine	vigne	druivelaars
strawberries	fraisiers	aardbeien
raspberries	framboisiers	frambozenstruiken
cranberries	airelles canneberges	veenbessen
currants (white, red, black)	groseilliers (blancs, rouges, cassis)	aalbes (witte, rode, zwarte)
gooseberries	groseilliers à maquereau	stekelbes (kruisbes)
blueberries	myrtilles/airelles rouges	blauwe/rode bosbessen
blackberries	ronces (mûres)	braamstruiken
apricots	abricotiers	abrikoos
Vegetables	Légumes	Groenten
beetroot	betterave rouge	rode biet (kroten)
carrots	carottes	wortelen
celeriac	céleri-rave	knolselder
parsnip	panais	pastinaak
radish	radis	radijs
black and white radish	radis noir et radis rave	rammenas en rettich
horseradish	raifort	mierikswortel
black salsify	scorsonère	schorseneren

swede, rutabaga	chou-navet, rutabaga	koolraap
turnip	navet	raap (stoppelraap, meiraap)
garlic	ail	knoflook
spring onion	oignon de printemps	bosuien (lente-ui)
onions	oignons	uien
shallot	échalote	sjalot
tomato	tomate	tomaten
pepper/chilli pepper	poivron/piment	paprika/Spaanse peper
eggplant and pepino	aubergine et pépinos	aubergine/eierplant en pepino
cucumber	concombre	komkommer
gherkin	cornichon	augurk
courgette/squash	courgette/pâtisson	courgette/patisson
melon	melon	meloen
pumpkin	potiron	pompoen
broccoli	chou brocoli	broccoli
Chinese cabbage, pak choi, tat soi and komatsuna	Chou Chinois, pakchoï, pakchoï en rosette et komatsuna	Chinese kool, paksoi, tatsoi en komatsuna
Brussel sprouts	chou de Bruxelles	spruitkool
curly kale (lacinato kale)	chou frisé (chou palmier)	boerekool (krulkool, palmboerenkool)
kohlrabi	chou rave	koolrabi (koolraap-boven-de-grond)
cauliflower (white and green)	chou-fleur (blanc et vert)	bloemkool (witte en groene)
head cabbage	choux pommés (blanc, rouge, chou cabus et chou de savoie)	sluitkool (kabuiskool, witte, rode, savooi- en spitskool)
watercress	cresson alénois	tuinkers
watercress	cresson de fontaine	waterkers
lamb's lettuce	mâche	veldsla
lettuces	laitues	slasoorten
chicory, radicchio rosso, common chicory	endives, radicchio rosso, pain de sucre	andijvie, radicchio rosso, suikerbrood
spinach	épinard	spinazie
chard/Swiss chard	bette / blette	warmoes (snijbiet)
bleached celery (bleached, green)	céleri (à côtes, blanc et vert)	selderij (bleek-, groene, witte)
celery (consumption of leaves and/or stalks)	céleri à couper (consommation des feuilles et/ou tiges)	snijselder (consumptie bladeren en/of stengels)
chervil (consumption of leaves and/or stalks)	cerfeuil (consommation des feuilles et/ou tiges)	kervel (consumptie bladeren en/of stengels)
fennel	fenouil	knolvenkel
parsley (consumption of leaves and/or stalks)	persil (consommation des feuilles et/ou tiges)	peterselie (consumptie bladeren en/of stengels)

parsley root (consumption of root)	persil à grosses racines (consommation de la racine)	wortelpeterselie (consumptie wortels)
purslane (consumption of leaves and/or stalks)	pourpier (consommation des feuilles et/ou tiges)	postelein (consumptie bladeren en/of stengels)
rocket (consumption of leaves and/or stalks)	roquette (consommation des feuilles et/ou tiges)	rucola (consumptie bladeren en/of stengels)
leek	poireau	prei
faba and field beans (dry harvested)	fèves et féveroles (recoltées sèches)	vicia-bonen (paarde-, duiven-, tuin-,...) (drooggeogst)
faba and field beans (fresh harvested)	fèves et féveroles (récoltées fraîches, sans cosse)	vicia-bonen (paarde-, duiven-, tuin-,...) (groengeogst, zonder peul)
beans harvested dry	haricot récolté sec	drooggeogste stamslabonen
green beans	haricots verts	stamslabonen (groengeogst) (prinsessen-, snijbonen)
peas	pois	erwten
peas (shelled)	petit pois (sans cosse)	groengeogste erwten (zonder peul)
peas (mange-tout)	pois verts (mange-tout)	groengeogste erwten (met peul)
potatoes	pommes de terre	aardappelen
stored potatoes	pommes de terre stockées	aardappelen (na-oogst)
rhubarb	rhubarbe	rabarber
witloof chicory roots	culture de racines de witloof	witloofwortelteelt
witloof chicory (forcing in soil)	witloof et chicon rouge (forcerie en fosse)	witloof en roodloof (forcerie grondteelt)
asparagus	asperge	asperge
Ornamental plants	Plantes ornementales	Sierplanten
ornamental deciduous trees and shrubs	arbres et arbustes feuillus ornementaux	loofbomen en -heesters (sierbomen)
ornamental resinous plants	résineux ornementaux	coniferen (sierbomen)
roses	rosiers	rozen
ornamentals (terrace, balcony and bedding plants (not destined for consumption)	plantes de parterre, de terrasse et de balcon (non destinées à la consommation)	perk-, terras- en balkonplanten (niet bestemd voor consumptie)
interior plants (not destined for consumption)	plantes d'intérieur (non destinées à la consommation)	kamerplanten (niet bestemd voor consumptie)
cuttings (ornamental plants)	boutures (plantes ornementales)	stekken (sierplanten)
rose (not destined for consumption)	rose (non destinées à la consommation)	rozen (niet bestemd voor consumptie)
rose geranium (not destined for consumption)	rose geranium (non destinées à la consommation)	geranium (niet bestemd voor consumptie)
Meadows, lawns and grass	Prairies, gazons et pelouses	Grasland-weiland, gazons en grasvelden
lawns and grass	gazons et pelouses	gazons en grasvelden
meadows	prairies	grasland-weiland
Specific uses	Usages spécifiques	Specifieke gebruiken
all crops (<i>Herbicides</i>)	toutes cultures (<i>Herbicides</i>)	alle teelten (<i>Herbiciden</i>)
permanently uncropped soil (<i>Herbicides only</i>)	terrains meubles, non cultivés en permanence (<i>Uniquement herbicides</i>)	niet verharde permanent onbeteelde terreinen (<i>ALLEEN herbiciden</i>)

not cultivable soil covered by any material (stone, gravel, concrete, ...) (<i>Herbicides only</i>)	terrains revêtus, non cultivables (<i>Uniquement herbicides</i>)	verharde permanent onbeteelde terreinen (<i>Uitzonderlijk herbiciden</i>)
farming tools	outils en agriculture	gereedschap gebruikt in land- en tuinbouw
greenhouses	serres	kassen
<p>Note: The list above presents the names of crops to use for any authorisation request. The terms appearing in grey are only group tiles and many not be used. This list is indicative and the Authorisation Committee reserves the right to indicate, for example, if the treatment concerns specific species or crops grown outdoors or under protection.</p>		

Annex 8: List of pests adapted for non-professional users

Scientific name	Name (EN)	Naam (NL)	Nom (FR)	for these crops	op deze gewassen	sur ces cultures
Diseases - Ziekten - Maladies						
<i>Albugo candida</i>	rust white	witte roest	rouille blanche	Brassicaceae (cabbage, radish, horseradish, black radish), ornamentals	Brassicaceae (kolen, radijs, mierikswortel, rammenas), sierplanten	Brassicaceae (choux, radis, raifort, radis noir), cultures ornementales
<i>Albugo tragopogonis</i>	rust, white (scorzonera)	witte roest	rouille blanche	salsify	schorseneer	scorsonère
<i>Alternaria</i>	leaf spot	bladvlekkenziekte	taches foliaires	ornamental plants	sierplanten	plantes ornementales
<i>Alternaria brassicae</i>	leaf spot	bladvlekkenziekte	taches foliaires	cabage, rapeseed, turnip	kool, koolzaad, rapen	chou, colza, navet
<i>Alternaria cichorii</i>	leaf spot	bladvlekkenziekte	taches foliaires	chicory, French endive	cichorei, witloof	chicorée, witloof
<i>Alternaria dauci</i>	leaf spot	bladvlekkenziekte	taches foliaires	carrot, Apiaceae	wortel, Apiaceae, pastinaak	carotte, Apiaceae, panais
<i>Alternaria porri</i>	leaf spot	bladvlekkenziekte	taches foliaires	leek	prei	poireau
<i>Alternaria solani</i>	leaf spot	bladvlekkenziekte	taches foliaires	Solanaceae	nachtschade-achtigen	solanacées
<i>Alternaria, Ascochyta, Colletotrichum, Cylindrosporium, Marssonina, Drepanopeziza, Cladosporia,...</i>	leaf spot	bladvlekkenziekte	taches foliaires	ornamental plants	sierplanten	plantes ornementales
<i>Aspergillus</i>	aspergillus	aspergillus	aspergillus			
Bacteria	bacteria	bacteriën	bactéries			
<i>Blumeriella jaapii</i>	leaf spot	bladvlekkenziekte	taches foliaires	cherry	kers, kriek	cerise, griotte
<i>Botrytis cinerea</i>	grey mould	grauwe schimmel	pourriture grise	(not for beans)	(niet voor bonen)	(sauf pour haricot et fèves)
<i>Botrytis fabae</i>	grey mould (bean)	grauwe schimmel	pourriture grise	beans, broad beans	boon, viciabonen	haricot, fèves et féveroles
<i>Botrytis tulipae</i>	tulip fire	vuur	feu de la tulipe	tulip	tulp	tulipe
<i>Bremia lactucae</i>	downy mildew (lettuce)	valse meeldauw	mildiou de la laitue	lettuces	slasoorten	laitues
<i>Calonectria</i> spp.	<i>Calonectria</i> (Cylindrocladium)	<i>Calonectria</i> (Cylindrocladium)	<i>Calonectria</i> (Cylindrocladium)	ornamental plants	sierplanten	plantes ornementales
<i>Ceratocystis ulmi</i>	Dutch elm disease	olmenziekte	graphiose de l'orme			
<i>Chondrostereum purpureum</i>	silver blight (stone fruit)	loodglansziekte	plomb des arbres fruitiers	stone fruit	steenvruchten	arbres fruitiers à noyau
<i>Cladosporium cucumerinum</i>	leaf spot	bladvlekkenziekte	taches foliaires	courgette	courgette	courgette

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<i>Colletotrichum acutatum</i>	leaf spot	bladvlekkenziekte/vruchtrot	taches foliaires/pourriture du fruit	strawberry	aardbei	friasier
<i>Colletotrichum coccodes, C. atramentarium</i>	leaf spot	bladvlekkenziekte	taches foliaires	tomato	tomaat	tomate
<i>Colletotrichum lagenarium (C. orbiculare)</i>	leaf spot	bladvlekkenziekte	taches foliaires	cucurbits	Cucurbitaceae	Cucurbitaceae
<i>Corioli</i> <i>versicolor</i>	wood decay (raspberry, ornamentals)	zacht witrot	carie de la tige	raspberry, ornamental plants	framboos, sierbomen	framboisier, ornamentales
<i>Cronartium ribicola</i>	rust (currant)	roest	rouille du groseillier	currant	bessen	groseillier
<i>Didymascella thujina</i>	needle blight	naaldverbruining	brunissure des résineux	conifers	coniferen	résineux
<i>Didymella applanata, ...</i>	spur blight	stengelziekten/twijgsterfte	brûlure des dards	raspberry, blackberry	framboos, braam	framboise, ronce, mûre
<i>Didymella pisi, Ascochyta pisi</i>	leaf spot	bladvlekkenziekte	taches foliaires	peas	erwt	pois
<i>Diplocarpon earlianum</i>	leaf scorch (strawberry)	rode vlekkenziekte	maladie des taches pourpres du fraisier	strawberry	aardbei	fraisier
<i>Diplocarpon rosae</i>	black spot (rose)	sterroetdauw/zwartevlekkenziekte	maladie des taches noires du rosier	rose	roos	rosier
<i>Erwinia amylovora</i>	fireblight	bacterievuur	feu bactérien	apple, pear	appel, peer	pommier, poirier
Erysiphaceae	Powdery mildew	echte meeldauw/witziekte	oïdium	ornamental plants	sierplanten	plantes ornementales
<i>Erysiphe betae, E. polygoni</i>	powdery mildew	echte meeldauw/witziekte	oïdium	red beet, lamb's lettuce	rode biet, veldsla	betterave rouge, mâche
<i>Erysiphe cruciferarum</i>	Ppowdery mildew	echte meeldauw/witziekte	oïdium	cabbage, turnip	kool, raap	chou, navet
<i>Erysiphe heraclei</i>	powdery mildew	echte meeldauw/witziekte	oïdium	carrot, parsley, other fresh herbs	wortel, Peterselie, dille, kervel, lavas, koriander...	carottes, persil, aneth, cerfeuil, livèche, coriandre, ...
<i>Erysiphe pisi</i>	powdery mildew	echte meeldauw/witziekte	oïdium	pulses	peulvruchten	légumineuses
<i>Exobasidium vaccinii var. japonicum</i>	leaf gall (Azalea)	oortjesziekte (azalea)	fausse cloque de l'azalée	azalea	azalea	azalée
<i>Fulvia fulva - Cladosporium fulvum</i>	leaf spot	bladvlekkenziekte	taches foliaires	tomato	tomaat	tomate
<i>Fusarium culmorum</i>	Fusarium (leek)	fusarium-vlekkenziekte	fusariose	leek	prei	poireau
<i>Fusarium oxysporum f.sp.asparagi</i>	root rot	wortelziekten	maladie des racines	asparagus	asperge	asperge
<i>Fusarium solani var. coeruleum</i>	dry rot (potato)	droogrot	pourriture sèche de la pomme de terre	potato	aardappel	pomme de terre
<i>Fusarium spp.</i>	fusarium	fusarium	fusariose	(not for lawns and grass and golf courts)	(niet voor gazons en grasvelden en golfterreinen)	(sauf gazons et pelouses et terrains de golf)
<i>Gloeosporium sp.</i>	Sour rot (apple, pear)	gloeosporiumrot/vruchtrot	pourriture amère	apple, pear, cherry	appel, peer, kersen, krieken	pomme, poire, cerise, griotte
<i>Golovinomyces cichoracearum</i>	powdery mildew	echte meeldauw/witziekte	oïdium	salsify, chicory, French endive, lettuce	schorseneer, cichorei, witloof, sla	scorsonère, chicorée, witloof, laitue

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<i>Golovinomyces orontii</i> , <i>Erysiphe polyphaga</i> , <i>E. orontii</i> , <i>Sphaerotheca fuliginea</i>	powdery mildew	echte meeldauw/witziekte	oïdium	cucurbits	cucurbitaceae	cucurbitaceae
<i>Guignardia bidwellii</i>	black rot (grape)	zwartrot	black-rot de la vigne	vine	druif	vigne
<i>Gymnosporangium fuscum</i>	Rust	roest	rouille	pear	peer	poire
<i>Helminthosporium solani</i>	silver scurf (potato)	zilvereschurft (aardappel)	gale argentée de la pomme de terre	potato	aardappel	pomme de terre
<i>Hyaloperonospora brassicae</i>	downy mildew	valse meeldauw	mildiou du chou	cabbage, rocket, radish	kool, rucola, radijs	choux, roquette, radis
<i>Laetisaria fuciformis</i>	red thread disease	rooddraadziekte	maladie du fil rouge du gazon	lawns and grass and golf courts	gazons en grasvelden en golfterreinen	gazons et pelouses et terrains de golf
<i>Leveillula taurica</i>	powdery mildew	echte meeldauw/witziekte	oïdium	tomato, eggplant, pepper	tomaat, aubergine, paprika	tomate, aubergine, poivron
<i>Melampsora</i> spp.	rust (poplar)	populierenroest	rouille du peuplier	poplar, forestry	populier, bosbouw	peuplier, peuplement forestier
<i>Microdochium panattonianum</i>	leaf spot	bladvlekkenziekte/vuur	taches foliaires	chicory, lettuces	andijvie, slasoorten	scarole, laitues
<i>Monilinia fructigena</i> / <i>M. laxa</i>	brown rot (fruit)	vruchtrot (Monilinia)	moniliose (fruits)			
<i>Monilinia fructigena</i> / <i>M. laxa</i>	blossom blight (flowers and stems)	tak- en bloesemsterfte (Monilinia)	moniliose (bouquets floraux et rameaux)	ornamental plants	sierplanten	plantes ornementales
<i>Mycosphaerella brassicicola</i>	ring spot (cabbage)	zwartevlekkenziekte	maladie des taches noires	cabbage, turnip	kool, rapen	chou, navet
<i>Mycosphaerella</i> spp.	leaf spot	bladvlekkenziekte	taches foliaires	ornamental plants	sierplanten	plantes ornementales
<i>Nectria cinnabarina</i>	coral spot (currant, ornamentals)	rode puistjesziekte	maladie du corail	currents, ornamental plants	aalbessen, sierbomen	groseilliers, ornementales
<i>Neonectria</i>	European canker	kanker	chancre	ornamental plants	sierplanten	plantes ornementales
<i>Pectobacteria carotovorum</i>	bacterial rot	bacterierot	pourriture bactérienne			
<i>Penicillium expansum</i>	blue mould	zachtrot	pourriture bleue	apple, pear	appel, peer	pommes, poires
<i>Penicillium</i> spp.	blue mould	vruchtrot	pourriture du fruit	berries	kleinfruit	petits fruits
<i>Peronospora destructor</i>	leaf spots	bladvlekkenziekte	taches foliaires	onion, shallot, garlic	uien, sjalot, look	oignon, échalotte, ail
<i>Peronospora farinosa</i> f.sp. <i>spinaciae</i>	downy mildew (spinach)	valse meeldauw (wolf)	mildiou de l'épinard	spinach	wolf spinazie, amaranth	épinard
<i>Peronospora hyoscyami</i>	downy mildew (tobacco)	valse meeldauw /blauwe schimmel	mildiou du tabac	tobacco	tabak	tabac
<i>Peronospora valerianellae</i>	downy mildew (lamb's lettuce)	valse meeldauw	mildiou	lamb's lettuce	veldsla	mâche
<i>Peronospora viciae</i>	downy mildew (pea)	valse meeldauw	mildiou du pois	pea	erwt	pois
<i>Phoma</i>	phoma	phoma	phoma	ornamental plants	sierplanten	plantes ornementales
<i>Phoma betae</i>	phoma (beet)	phoma (zwartrot)	phoma	beet	biet	betterave
<i>Phoma exigua</i>	phoma (witloof)	zwart wortelrot	pourriture brune	chicory	witloof	witloof

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<i>Phoma exigua var. foveata</i>	gangrene (potato)	gangreen	gangrène de la pomme de terre	potato	aardappel	pomme de terre
<i>Phragmidium rubi-idaei</i>	rust	roest	rouille du framboisier	raspberry	framboos	framboise
<i>Phragmidium violaceum</i>	rust (blackberry)	roest	rouille noire des ronces	blackberry	braam	ronces
<i>Phytophthora cactorum</i>	collar rot (apple, pear)	stambasisrot	pourriture du collet	apple, pear	appel, peer	pommier, poirier
<i>Phytophthora cinnamomi</i>	root and crown rot	wortelrot	maladies des racines			
<i>Phytophthora cryptogea, P. erythroseptica</i>	root rot	wortelziekten	maladies des racines	chicory	witloof	witloof
<i>Phytophthora fragariae</i>	red core (strawberry)	rood wortelrot	maladie du coeur rouge des racines	strawberry	aardbei	fraisier
<i>Phytophthora infestans</i>	Downy mildew	aardappelziekte	mildiou	potato, tomato, eggplant	aardappel, tomaat, aubergine	pomme de terre, tomate, aubergine
<i>Phytophthora megasperma, P. rubi</i>	root rot (raspberry)	wortelsterfte, afsterven scheuten	dépérissement des tiges	raspberry, blackberry	framboos, bramen	framboisier, mûres
<i>Phytophthora porri</i>	downy mildew (leek)	papierplekkenziekte	mildiou du poireau	leek, onion	prei, uien	poireau, uien
<i>Plasmopara viticola</i>	downy mildew (grape)	valse meeldauw	mildiou de la vigne	vine	druif	vigne
<i>Pleospora allii</i>	purple spot (Asparagus)	stengelsterfte/bladvlekken	taches foliaires	asparagus	asperge	asperge
<i>Podosphaera aphanis</i>	powdery mildew	echte meeldauw/witziekte	oïdium	strawberry, raspberry, hops	aardbei, frambozen, hop	fraisier, framboisier, houblon
<i>Podosphaera clandestina</i>	powdery mildew	echte meeldauw/witziekte	oïdium	cherry, plum	kers, pruim	cerise, prunes
<i>Podosphaera leucotricha</i>	powdery mildew	echte meeldauw/witziekte	oïdium	apple, pear	appel, peer	pommier, poiriers
<i>Pseudomonas syringae</i>	bacterial die-back of flower buds	bloembotsterfte	bactériose des boutons floraux	pome fruit	pitfruit	fruitiers
<i>Pseudomonas syringae pv. mors-prunorum</i>	bacterial canker	bacteriekanker	chancre bactérien			
<i>Pseudonectria spp.</i>	volutella spp.	Volutella spp.	Volutella spp	buxus (deciduous trees and shrub)	buxus (loofbomen en heesters)	buxus (arbres et arbustes feuillus ornementaux)
<i>Pseudopeziza tracheiphila</i>	red fire disease (grape)	rode brand	rougeot parasitaire	vine	druif	vigne
<i>Puccinia asparagi</i>	rust	roest	rouille de l'asperge	asparagus	asperge	asperge
<i>Puccinia cichorii</i>	rust	roest	rouille	chicory, French endive	cichorei, witloof	chicorée, witloof
<i>Puccinia menthae</i>	rust (mint)	roest	rouille de la menthe	mint	munt	munt
<i>Puccinia porri, P. allii</i>	rust (leek)	roest	rouille des alliaceae	leek, onion, shallot, garlic, spring onion	prei, uien, sjalot, look, bosuien	poireau, oignon, écotte, ail, oignon de printemps
<i>Puccinia, Uromyces, Phragmidium,...</i>	rust	roest	rouilles	ornamental plants	sierplanten	plantes ornementales
<i>Pythium</i>	pythium wilt	kiemschimmels	fontes de semis			
<i>Ramularia pratensis</i>	leaf spot of dock sorrel	bladvlekkenziekte/ramularia	ramulariose de l'oseille	sorrel	zuring	oseille

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<i>Rhizoctonia solani</i>	black scurf	zwartrot (rhizoctonia)	rhizoctone			
<i>Rhizoctonia solani</i>	black scurf (potato)	lakschurft	rhizoctone de la pomme de terre	potato	aardappel	pomme de terre
<i>Sclerotinia minor (S. sclerotiorum)</i>	sclerotinia	sclerotienrot (sclerotinia)	sclérotiniose	(not for lawns and grass and golf courts, ornamental plants, Alliaceae)	(niet voor gazons en grasvelden, golfterreinen, sierplanten, Alliaceae)	(sauf pour gazons et pelouses, terrains de golf, plantes ornementales, Alliaceae)
<i>Sclerotinia spp.</i>	sclerotinia	sclerotienrot	sclérotiniose	ornamental plants	sierplanten	plantes ornementales
<i>Sclerotinia squamosa - Botrytis squamosa</i>	neck rot (onion)	witvlekkenziekte	brûlure des feuilles de l'oignon	onion, shallot, garlic	ui, sjalot, knoflook	oignon, échalotte, ail
<i>Sclerotium cepivorum</i>	white rot (onion)	witrot	pourriture blanche	onion, shallot	ui, sjalot	oignon, échalotte
<i>Septoria</i>	leaf spot	bladvlekkenziekte	taches foliaires	ornamental plants	sierplanten	plantes ornementales
<i>Septoria apiicola</i>	leaf spot	bladvlekkenziekte	taches foliaires	celery	selder	céleri
<i>Septoria petroselini</i>	leaf spot	bladvlekkenziekte	taches foliaires	carrot, parsley, other fresh herbs	peterselie, wortel, dille, kervel, lavas, koriander,...	carottes, persil, aneth, cerfeuil, livèche, coriandre, ...
<i>Septoria pisi</i>	leaf spot	bladvlekkenziekte	taches foliaires	pea	erwt	pois
<i>Sphaerotheca mors-uvae</i>	powdery mildew	echte meeldauw/witziekte	oïdium	currants	bessen	groseilles
<i>Sphaerotheca pannosa</i>	powdery mildew	echte meeldauw/witziekte	oïdium	rose	roos	rosa
<i>Sphaerulina rubi</i>	leaf spot (raspberries)	bladvlekkenziekte	septoriose du framboisier	raspberry, blackberry	framboos, bramen	framboises, mûres, ronces
<i>Stagonosporopsis cucurbitacearum</i>	stem-end rot (cucurbits)	stengelbrand	brûlure des tiges des cucurbitacées	cucurbits	cucurbitaceae	cucurbitaceae
<i>Stagonospora spp.</i>	stagonospora (amaryllis)	stagonospora	rougeot parasitaire de l'amaryllis	amaryllis	amaryllis	amaryllis
<i>Stemphylium vesicarium</i>	pear brown spot	zwartvruchtrot	stemphyliose	pear, onion, asparagus	peer, ui, asperge	poiriers, oinon, asperge
<i>Stigmia carpophila (Coryneum beijerinckii)</i>	shoot blight (cherry, plum)	hagelschotziekte	maladie criblée	cherry, plum, peach, apricot, ornamental plants (Prunus spp.)	kers, pruim, perzik, abrikoos, sierteelt (Prunus spp.)	cerisier, prunier, pêcher, abricot, plantes ornementales (Prunus spp.)
<i>Taphrina deformans</i>	leaf curl (peach)	krulziekte	cloque du pêcher	peach	perzik	pêcher
<i>Taphrina pruni</i>	plum pockets	hongerpruimziekte	maladie des pochettes du prunier	plum tree	pruim	prunier
<i>Thielaviopsis sp., ...</i>	root diseases	wortelziekten	maladies des racines	ornamental plants	sierplanten	plantes ornementales
<i>Tranzschelia spp</i>	red rust of stone fruit	roest	rouille des arbres fruitiers à noyau	stone fruit	steenfruit	arbres fruitiers à noyau
<i>Uncinula necator</i>	powdery mildew	echte meeldauw/witziekte	oïdium	vine	druif	vignes
<i>Uromyces appendiculatus</i>	rust	roest	rouille du haricot	bean	stamslaboon	haricot
<i>Uromyces pisi</i>	rust	roest	rouille du pois	pea	erwt	pois

Scientific name	Name (EN)	Naam (NL)	Nom (FR)	for these crops	op deze gewassen	sur ces cultures
<i>Venturia carpophila</i>	scab (peach, plum, cherry)	schurft	tavelure	peach, plum, cherry, apricot	perzik, pruim, kers, abrikoos	pêcher, prunier, cerisier, apricot
<i>Venturia inaequalis</i>	scab (apple)	schurft	tavelure du pommier	apple	appel	pommier
<i>Venturia pirina</i>	scab (pear)	schurft	tavelure du poirier	pear	peer	poirier
<i>Venturia, Sphilocaea</i>	scab	schurft	tavelure	ornamental plants	sierplanten	plantes ornementales
<i>Verticillium sp.</i>	verticillium	verwelkingsziekte	verticilliose	ornamental plants, strawberry	sierplanten, aardbei	plantes ornementales, fraises
<i>Volutella buxi/Cylindrocladium buxicola</i>	decay of branches	taksterfte	dépérissement des rameaux du buis	buxus (deciduous trees and shrub)	buxus (loofbomen en heesters)	buxus (arbres et arbustes feuillus ornementaux)
	soil fungi	bodemschimmels	cryptogames du sol			
	tree wound infections	boomwondinfecties	infection de blessures des arbres			
Weeds, etc. - Onkruiden, ... - Mauvaises herbes, ...						
Bryophyta	mosses	mossen	mousses			
<i>Cirsium / Carduus</i>	thistles	distels	chardons			
<i>Convolvulus arvensis/Convolvulus sepium</i>	field bindweed/hedge bindweed	akkerwinde/haagwinde	liseron des champs/liseron des haies			
Dicotyledoneae	broad-leaved plants (annual, perennial)	tweezaadlobbige onkruiden (eenjarige en doorlevende)	dicotylées (annuelles et vivaces)			
Dicotyledoneae (annual)	broad-leaved plants (annual)	eenjarige tweezaadlobbige onkruiden	dicotylées annuelles			
Dicotyledoneae (perennial)	dicot weeds broad-leaved plants (perennial)	doorlevende tweezaadlobbige onkruiden	dicotylées vivaces			
<i>Equisetum</i>	horsetail	paardenstaart	prêles			
<i>Fallopia japonica/ Fallopia sachalinensis / Fallopia x bohémica</i>	Japanese knotweed, giant knotweed and Bohemian knotweed	Japanse duizendknoop, Sachalinse duizendknoop en Boheemse duizendknoop	Renouée du Japon, de Sakhaline et de Bohème			
Poaceae	grasses (annual and perennial)	grasachtige onkruiden (eenjarige en doorlevende)	graminées (annuelles et vivaces)			
Poaceae (annual)	grasses (annual)	eenjarige grasachtige onkruiden	graminées annuelles			
Poaceae (perennial)	grasses (perennial)	doorlevende grasachtige onkruiden	graminées vivaces			
Pteridopsida	ferns	varens	fougères			
<i>Rubus fruticosus</i>	bramble	braamstruiken	ronce commune			
<i>Urtica</i>	nettle	brandnetels	ortie			
	succers and regrowth	opslag en scheuten	rejets et repousses			
	lichen/moss/liverworts	korstmossen/mossen/levermossen	lichens/mousses/hépatiques			

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	lichens	korstmossen	lichens			
	weeds	onkruiden	mauvaises herbes			
	woody plants	houtige planten	plantes ligneuses			
	algae	wieren / algen	algues			
	aquatic plants	waterplanten	plantes aquatiques			
Mites, insects, slugs, mammals - Mijten, insecten, duizendpoten, slakken, zoogdieren - Acariens, insectes, mille-pattes, limaces, mammifères						
Acarida (Tetranychidae, Eriophyidae, Tarsonemidae,...)	mites	mijten	acariens			
Acaridae	mites (stored commodities)	voorraadmijten	acariens ravageurs des denrées entreposées			
Adelgidae	gall aphids	galluizen (chermes-, sparappel-, dennewolluis)	chermès galligènes des conifères	conifers	coniferen	conifères
<i>Agriotes</i>	wireworms	ritnaalden (kniptor)	taupins			
Agromyzidae	leaf miners	mineerrupsen/motten	chenilles mineuses/teignes			
Anthomyiidae, Psilidae,....	vegetable fly	groentevliegen	mouches de légumes			
Aphididae	aphids	bladluizen	pucerons			
<i>Apodemus sylvaticus</i>	long-tailed field mouse	bosmuizen	mulots			
Arionidae-Limacidae-Milacidae	slugs	naaktslakken	limaces			
<i>Arvicola terrestris</i>	large vole	woelrat	grand campagnol/campagnol terrestre			
Aves	birds	vogels	oiseaux			
<i>Blaniulus, lulus et Scutigera</i>	millipedes, centipedes	miljoen- en duizendpoten	blaniules et scutigérelles			
Cecidomyiidae	midges	galmuggen	cécidomyies			
Cervidae	game damages (deers)	schade door groot wild (hertachtigen)	dégâts de gros gibier (cervidés)			
Cicadellidae	leafhoppers	cicaden	cicadelles			
Coccoidea	scale insects	dop-, schild- en wolluizen	cochenilles			
Coleoptera (Chrysomelidae, Halticini, Curculionidae...)	beetles	kevers (adulten, larven)	coléoptères (adultes, larves)			
Collembola	springtails	collembolen	collemboles			
Formicidae	ants	mieren	fourmis			
Insecta	insects	insecten	insectes			

Scientific name	Name (EN)	Naam (NL)	Nom (FR)	for these crops	op deze gewassen	sur ces cultures
Lagomorpha	small game damages (hare, rabbit)	schade door klein wild (haas, konijn)	dégâts de petit gibier (lièvre, lapin)			
Mamestra, Spodoptera, Autographa, Orthosia, Thaumetopoeidae, Agrotis, Noctua, Euxoa...	catterpillars	rupsen	chenilles			
<i>Microtus arvalis</i>	small vole	veldmuizen	petit campagnol			
Miridae	slant bugs	wantsen	punaises			
<i>Mus musculus</i>	mouse	muizen	souris			
<i>Ondatra zibethica</i>	musk rat	muskusrat	rat musqué			
<i>Psylla</i> spp.	psyllids	bladvlo	psylle			
<i>Rattus norvegicus/Rattus rattus</i>	brown rat or black rat	bruine of zwarte rat	rat brun ou rat noir			
<i>Rattus rattus</i>	black rat	zwarte rat	rat noir			
<i>Rhagoletis cerasi</i>	fruit flies	fruitvliegen	mouche/ver des fruits	cherry	kers/kriek	cerise, prunes
<i>Talpa europaea</i>	mole	mol	taupe commune			
<i>Thysanoptera</i>	thrips	trips	thrips			
<i>Tortricidae</i>	codling moth	fruitrupsen/motten	chenilles des fruits/carpocase	apple, pear	appel, peer	poiriers, pommiers
<i>Trialeurodes vaporariorum, Bemisia tabaci</i>	white flies	witte vliegen	mouches blanches			
<i>Trichodorus, Pratylenchus</i>	free-living nematods	vrijlevende aaltjes	nématodes libres			
	soil insects	bodeminsecten	insectes de sol			
Other - Andere - Autres						
	bud formation	spruitvorming	formation des germes			
	insufficient root development	onvoldoende wortelvorming	développement racinaire insuffisant			
	late flowering	laattijdige bloei	floraison tardive	ornamental plants	sierteelt	plantes ornementales

Annex 9: Check-list « Conformity and precision of packaging and measuring device for products for non-professional use submitted for authorisation in Belgium »

In order to limit the risks of human, animal and environmental exposure during handling of products for non-professional users and to allow the application of the correct dose of product, following conditions should be taken into account:

Packaging:

- The maximal content of each packaging should not allow to treat more than 5 ares (500 m²) except when exemptions are obtained after evaluation by the Authorisation Committee. In that case, a packaging allowing the treatment of a smaller area (≤ 5 ares) should also be available on the market, to the same extent as the bigger packaging for > 5 ares.
- The maximum area treated should be calculated for the main usage with the maximum dose and taking into account the number of treatments mentioned in the authorised GAPs: the label should mention for instance “sufficient to treat 5 ares, 3 times”.
- In no case should an indication appear on the label giving the impression that more than 5 ares can be treated.
- Bottles and sprays must be equipped with a security stopper.
- Aerosols must be sealed and protected with a cap.
- For bottles and bags: the provisions of art. 10/1 of the Royal Decree of February 28, 1994 as inserted by art.6 of the Royal Decree of the Royal Decree of January 2010 apply (bottle with security tap for liquids and solids or re-sealable bag for solids). However, for small volumes (< 5 kg) of solids, a security closing is recommended and the use of boxes or plastic tanks should be preferred to bags.
- A re-sealable system (e.g. with a sticker, a zip, etc) should be foreseen for solid products (powders or granules) commercialised in bags or boxes. Bags without re-sealable system will not be accepted anymore.
- For ready to use liquid products (mainly sprays): the packaging must have an on/off position which cannot be dismantled and the compartment containing the liquid should be protected from opening, re-use or re-filling (only separate trigger should be reusable). Clear indications on how to correctly use the spray should be provided on the label (how to lock-unlock, when to use the different spray positions, how to adapt the trigger to the liquid compartment, etc.).
- For products commercialised in monodoses (for example WP in water-soluble bags) the content of each dose should be adapted to the area to be treated to avoid that gardeners open the bags.

- It must be possible to empty the packaging completely (a particular attention should be paid for sprays in which the quantity of gas should be sufficient to expulse the whole quantity of product).
- If the primary packaging is in a sealed box: a method should clearly indicate how to properly open the box (dotted line with pre-cut opening, easy opening system, etc) in order to avoid damage to the primary packaging.
- Opening the packaging should not lead to unwanted spreading of the products (dusts, bottles filled up over the maximal capacity).
- The primary packaging should be and remain clean on the outer face (no dusts or leakage).
- The design of the packaging (size, form, weight) should allow easy manipulation.
- The size of the opening must be suited to the physical state of the product (WP, WG, liquid) and allow an easy flow of the product, without being too fast, which could cause leaching or splashing of product in the surrounding environment or emission of dusts.
- Diameter of the opening must be adapted to the length or diameter of the measuring cup.

Measuring device

- The measuring device should allow the measurement of all reference doses with a limited number of manipulations (max. two fillings). It is possible to provide cups of different sizes corresponding to different uses.
- The measuring device is combined with the main packaging or included with it in a box.
- For products applied in large amounts (e.g. fertilisers or products against mosses, ...) mechanical spreading should be recommended (with indications on how to adjust the spreading device). A suitable way of measuring the quantity to put in the spreader must be provided (either integrated in the packaging or separate).
- All reference doses mentioned on the product label should be easily identified on the measuring cup.
- Units should be adapted to the physical state of the product (ml for liquids, mg for solids). For solids with a measuring cup in ml, a converting factor can be accepted.
- Levels and quantities printed on the measuring cup should be readable, when the measuring cup is either empty or full.
- For solids, the diameter of the measuring cup must allow an easy horizontal levelling of the product.
- After use, fixation of the measuring cup on the packaging should not contaminate the outer face of the bottle/box with product. The adequate method to clean up and fix the measuring cup on the packaging without unnecessary contact of the operator with the product or environmental contamination should be provided.

- The size, material and design of measuring device should be adapted to the product formulation to avoid for instance plugging, excessive adherence, electrostatic effects or deformation of the cup.
- Spoons cannot be submitted as measuring cups.

With each authorisation application, a paper or electronic copy of the proposed packaging in colours and real size should be submitted, with a complete label project and technical description (with pictures) for each packaging model that will be placed on the market. If different sizes are proposed for one packaging model, the smallest size label must be submitted to check its readability.

Reminder: for all registered plant protection products, packaging and measuring cups which will be commercialised in Belgium must correspond to those described on the registration document or in the registration application. The extension of the range of packaging authorised will need an evaluation for which a fee (of 500 €) will be applicable.

The applicant will be informed about the reasons for the refusal of any packaging.

Test of precision for the measuring device:

For products to be used with a measuring cup, the following test should be carried out:

The test is realised by non-qualified people (corresponding to a gardener). Two reference doses (minimal and maximal) are measured with the measuring cup and the accuracy of the weight or volume is verified with a balance or a graduated test tube. The maximum difference of weight or volume for each tested dose must be reported for three repetitions (for example, if the three repetitions give a variation of, respectively, -12 %, - 8 % and -17 %, the maximal variation is - 17 %). A variation of +/- 25 % between the measure realised with the measuring cup and the laboratory tools is allowed.

Results of the test together with the followed protocol have to be submitted with the application.