PLANT PROTECTION

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

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

Health
Food Chain Safety
Environment

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## DOCUMENT INFORMATION

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

*Version 6*
*04/03/2024*

# 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: second name 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 |

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| | 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 |

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| | 3.2 | Clarification: products that belong to a range |
| | 3.2 | Addition: commercial 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 repect 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 commercial name |
| | 5.1.8 | Clarification: second name 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 |

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| | 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 | Update: New fees for several types of applications, as set out by the Royal Decree of 08/07/2019 amending the Royal Decree of 13/11/2011 |
| | 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. |
| **Version 5 June 2023** | 2.1.1 | Because of the Brexit, United Kingdom was removed from the list of member states belonging to the central zone. |
| | 2.1.2 | Update Guidance Document SANCO/13169/2010 rev. 11 must now be used |
| | 2.1.3 | Clarification: Acceptance and planning of applications for which Belgium is inquired to act as (i)zRMS are, without exception, done on a "first come, first served" basis. However in some cases Belgium by default cannot agree to act as (i)zRMS. These cases are now listed here as well.<br><br>Update: The applicant must draw up a proposal for a meeting agenda and send this to the zonal |

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| | | coordinators at least 3 weeks before the meeting instead of 2 weeks.<br><br>Clarification: in some exceptional cases, a provisional authorisation is granted for a shorter period of time (transitional measure for new national requirements (bees), comparative assessment,…). |
| | 2.2.2 | Addition: paragraph about applications for the mutual recognition of 'generics', authorized according to art.34 and what they should contain. |
| | 2.4.3 | Addition: the list of protected and unprotected data of a reference product in Belgium can be obtained on request against a fee of € 1500,- . |
| | 2.4.3 | Addition: according to Article 34. 2, the comparability of the formulations (physico-chemistry, composition to the extent as possible (e.g. based on the information on the MSDS) and of the effects of the products need to be shown. |
| | 3.1 | Update: All applications must be sent by email to the Service Plant Protection and Fertilising Products via secret.div1@health.fgov.be. Dossiers submitted electronically no longer need a submission in writing, with the exception of letters of appeal, that should be submitted both by registered mail (legally required) and by email. |
| | 3.1 | Update: denomination of files: Due to technical reasons, a maximum of 40 characters is allowed for denomination of each file or folder, whereas a maximum total path length of 140 characters is allowed. |
| | 3.1.1 | Update of table 'Application for a zonal authorisation'- Full application<br><br>Filled out form to request for certain information to be kept confidential (template in Annex 10 of SANCO/13169/2010 Rev. 11) |
| | 3.1.1 | Update of table 'Application for a zonal authorisation'- Enforcement of the formulation<br><br>• By mail: Specimen of 100 – 200 mg pure certified a.s.<br>Adaptation of recipients |

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| | 3.1.1 | Update of table 'Application for a zonal authorisation'- Vulgarisation<br>• dRR part B3<br>• Trial reports relied on in the BAD<br>Adaptation of recipients |
| | 3.1.2 | Update of table 'application for a mutual recognition – Full application<br>• -A copy of the acknowledging receipt of packages 2 and 3 in the Federal Laboratory for Food Safety and Sciensano respectively<br>• -Filled out form to request for certain information to be kept confidential (template in Annex 10 of SANCO/13169/2010 Rev. 11)<br>• -The complete equivalence dossier1 (even if the equivalence of all sources of active substances has been approved previously)<br>- The first aid dossier |
| | 3.1.2 | Update of table 'Application for a mutual recognition'- Enforcement of the formulation<br>• By mail: Specimen of 100 – 200 mg pure certified a.s.<br>• Electronic copy of analytical method for determining the concentration of a.s. in the formulation<br>Adaptation of recipients |
| | 3.1.2 | Update of table 'Application for a mutual recognition'- Enforcement of residues<br>• Electronic copy can be submitted<br>Adaptation of recipients |
| | 3.1.2 | Update of table 'Application for a mutual recognition'- Vulgarisation<br>• To each recipient: CD-ROM or electronic copy of:<br>o - dRR part B3<br>o - BAD (SANCO 7600/VI/95)<br>o - Trial reports relied on in the BAD<br>o Adaptation of recipients |

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| | 3.2 | Addition: it is the applicant's responsibility to verify that the proposed commercial name does not violate trademark law as provided for in the Benelux Convention on Intellectual Property. |
| | 3.3 | Addition: For products for non-professional users, the label proposal should be a full label project in colour in the actual size of the smallest proposed packaging volume. |
| | 3.1.2 | Update concerning twin packs |
| | 3.5 | Addition: A unique formula identifier (UFI) must be notified with each declaration to the Belgian Poison Centre. |
| | 3.7 | Clarification concerning where to find the information published by the CZSC that is publicly available on CIRCABC |
| | 4.3 | Update toxicology: Co-formulants which are listed in Regulation (EU) 2021/383, amending Annex III of Regulation (EC) No. 1107/2009 will automatically be refused. |
| | 5.1.2 | Clarification about the application for prolongation |
| | 5.1.5 | Addition: an adapted UFI-code must now also be submitted. |
| | 5.1.12 | Clarification about grace period of the authorisation when no active substance renewal dossier has been submitted at EU level. |
| | 5.2.2 | Update about grace period of the authorisation when no art. 43 renewal dossier for the formulation has been submitted at member state. |
| | Annex 5 | Update text concerning what to do with empty packaging and product surplus |
| | Annex 6 - 3.3 | Update concerning the specific assessment criteria for products for non-professional users – Human health |
| | Annex 6 – 3.4 | Update: The description of non-professional uses will be made using the lists of crops and enemies suitable for the non-professional uses presented on www.phytoweb.be (Search authorisations < Consult lists). |

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| | Annex 6 – 3.4 | Update concerning the application dose for products for non-professional use. |
| | Annex 6 - 3.5 | Update concerning product packaging and labeling for products for non-professional users |
| | Annex 7 | Update of check-list |
| **Version 6 March 2024** | General | Update: New fees for several types of applications, as set out by the Royal Decree of 18/02/2024 amending the Royal Decree of 13/11/2011 |
| | Annex 2 | Addition of new fees applicable from 01/01/2025 or 01/01/2026 |

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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 types 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 Guidances | 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 (R.D.) 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 (FASFC). The approval of these companies is regulated by the R.D. 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 R.D. 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.

- The financial aspects are regulated by the R.D. 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: Fees (overview) 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 and Fertilising Products 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 and Fertilising Products 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 and Fertilising Products. 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 and Fertilising Products, 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, and Czech Republic.

In order to reduce the workload for the industry and for the competent authorities and to avoid different MS 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 (MS), the zonal Reporting Member State (zRMS) shall evaluate the entire dossier. The other concerned Member States (cMS) will adopt the evaluation of the zRMS where possible, 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) No 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 Adjuvants | 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 cMS 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. 11 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 MS 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 MS 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),
- MS 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 MS 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 MS 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 MS (and not only the uses that shall be defended in one specific MS). Any differences with regard to the same use in different MS must be justified.

For the submission of the dossier, the applicant shall use the format of the draft Registration Report (please see Section 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 MS which have specific national requirements. Section 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 MS 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 MS 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 the applicant and other MS 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 MS 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 MS in the zone through CIRCABC. Again, an accompanying notification e-mail will be sent. Finally, the other MS 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 MS, 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 MS still has concerns with regard to an acceptable risk for human and animal health or for the environment, then this MS can refuse to grant an authorisation in its territory. In such case, the MS 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. 11.

## 2.1.3. BE = (i)zRMS

### Fees[1]

In accordance with the R.D. of 13/11/2011 establishing the fees and contributions owed to the Budgetary Fund for raw materials and products, a fee of € 25000 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
- € 1860 if the active substance has been authorised for 15 to 25 years in Belgium
- € 3700 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 (i)zRMS only for a limited number of applications a year. A distinction is made between strictly (inter)zonal applications according to Article 33 (e.g. for new authorisations and label extensions) on the one hand and applications for renewal 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 at zonal level.

If the applicant wishes to have Belgium act as (i)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 at least 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). Acceptance and planning of applications for which Belgium is inquired to act as (i)zRMS are, without exception, done on a "**first come, first served**" basis. However in the following cases Belgium by default cannot agree to act as (i)zRMS:

[1] Please note that on 29/02/2024, the R.D. of 18/02/2024 amending the R.D. of 13/11/2011, defining new fees, has been published. New fees will enter into force at 01/01/2025 for applications related to plant protection products and adjuvants and at 01/01/2026 for applications related to active substances. Current and future fees can be consulted in Annex 2 of this guide.

- If it concerns a product containing an active substance for which the expected date of expiration of approval at EU level falls within 18 months after the planned submission date. This is to avoid that an application based on old active substance endpoints is still ongoing at the time of **renewal** of the active substance.
- When an application for amendment of authorisation under art. 33 (e.g. label extension) is intended to be submitted 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. During this period, no applications for which a technical (and therefore zonal) assessment is necessary are possible.

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

- the preferred date of submission
- the other cMS
- the product composition
- the renewal status of the active substance(s)
- a GAP table that is as complete as possible for all the CMS 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. The applicant shall provide the official notification form (stating BE as (i)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 (i)zRMS before submitting the application. Every applicant who wishes to have BE acting as (i)zRMS should therefore present his application dossier(s) at a pre-submission meeting. Belgium will only formally accept the role of (i)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 3 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 3 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 3 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. In some exceptional cases, a provisional authorisation is granted for a shorter period of time (transitional measure for new national requirements (bees), comparative assessment,...), then the Service Plant Protection and Fertilising Products will notify the company in an official letter which additional information ("conditions for prolongation") must be supplied before which deadline. For more information with respect to the conditions for prolongation, please consult Section 5.1.2 Application for prolongation.

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 MS in the Zone will be notified and their period of 120 days can start.

## 2.1.4. BE = cMS

### Fees[2]

In accordance with the R.D. of 13/11/2011 for establishing the fees and contributions owed to the Budgetary Fund for raw materials and products, a fee of € 6000 applies (for exceptions: see Annex 2: Fees (overview)).

[2] Please note that on 29/02/2024, the R.D. of 18/02/2024 amending the R.D. of 13/11/2011, defining new fees, has been published. New fees will enter into force at 01/01/2025 for applications related to plant protection products and adjuvants and at 01/01/2026 for applications related to active substances. Current and future fees can be consulted in Annex 2 of this guide.

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
- € 1860 if the active substance has been authorised for 15 to 25 years in Belgium
- € 3700 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 cMS. 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 MS where the applicant wishes to place the product on the market. After receipt of the application dossier, a national dossier number 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 requirements 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 in one MS may apply for the authorisation for the same plant protection product, the same uses and under comparable agricultural and climatic conditions in another MS in the following cases:

- the original authorisation was granted by a MS (reference MS) which belongs to the same zone (see Annex I of Regulation (EC) No 1107/2009);
- the original authorisation was granted by a MS (the reference MS) 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 MS 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 MS 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 MS 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 MS as well as a translation of the authorisation into an official language of the MS receiving the application;
- a formal statement that the plant protection product is identical to that authorised by the reference MS;
- a complete dossier as required in Article 33(3);
- an assessment report by the reference MS 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[3]

In accordance with the R.D. of 13/11/2011 for establishing the fees and contributions payable to the Budgetary Fund for raw materials and products a fee of € 6000 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
- € 1860 if the active substance has been authorised for 15 to 25 years in Belgium
- € 3700 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 MS
- 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 MS
- 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 MS

Uses applied for shall be the same as or fewer than the reference product in the reference MS, extension of uses are not allowed in this type of application. Once the product is authorised in Belgium, the applicant can apply for an extension of uses.

The applicant must be able to demonstrate that the risk assessment that supports the original authorisation in the reference MS (all the safety aspects, efficacy and selectivity) is also relevant

[3] Please note that on 29/02/2024, the R.D. of 18/02/2024 amending the R.D. of 13/11/2011, defining new fees, has been published. New fees will enter into force at 01/01/2025 for applications related to plant protection products and adjuvants and at 01/01/2026 for applications related to active substances. Current and future fees can be consulted in Annex 2 of this guide.

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 MS must be either available on CIRCABC or validated by the authorities of the reference MS. 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.

Concerning applications for the mutual recognition of 'generics', authorized according to art. 34, 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 only 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.

In accordance with the current guidance document on zonal evaluation and mutual recognition, withdrawal and amendment of authorisations under Regulation (EC) No 1107/2009 (SANCO/13169/2010 rev. 11), in the submitted dRR, applicants should provide a list of studies or data which, for each data point for the active substance(s) and formulation, are available to support the application, or a correct reference to the registration report of the reference product.

In accordance with the SANCO guidelines, the mutual recognition of a generic product approved via Article 34 of Regulation (EC) No 1107/2009 is only possible if the reference product to which the evaluation of the reference MS refers is also approved in Belgium and the data protection period for this product has also expired in Belgium. Reference to more than one plant protection product within the same application is not possible.

The reference product in Belgium must have been authorised according to the current endpoints after an evaluation according to Directive 91/414/EEC or Regulation (EC) No 1107/2009 and to the Uniform principles.

An overview of specific Belgian requirements and guidance documents can be found in Chapter 4 Technical data requirements of this guide. Moreover, Belgian requirements for plant protection products 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 MS 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 Application for mutual recognition 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 MS. 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) No 1107/2009 requires MS to perform a comparative assessment when evaluating applications for plant protection products containing an active substance approved as a candidate for substitution. MS 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.

MS 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 MS and as such this aspect of the EU regulation requires specific consideration by individual MS.

Comparative assessment has to be performed for applications (new authorisation, new crop, renewal) submitted from August 1st 2015. More details are available on Comparative assessment | 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 an application for a second name authorisation. As described in the table about types of applications in appendix 1 in the

European Guidance Document SANCO/13169/2010 rev. 11 on zonal evaluation and mutual recognition under Regulation (EC) No 1107/2009 (see point 1a/1b), a second name authorisation applied by the same authorisation holder or by a different authorisation holder (usually with access agreement) is granted without technical assessment. A substitution of a second name authorisation would have no effect on the market (except if the substitution occurs also for the reference product). A second name authorisation will be modified in the same way as the authorisation of the reference product once this has been modified.

5. Comparative assessment will not be carried out for an application for a parallel trade permit. A parallel trade permit is granted without risk evaluation[4]. A substitution of a parallel trade permit would have no effect on the market (except if the substitution occurs also for the reference product). A parallel trade permit will be modified in the same way as the authorisation of the reference product once this has been modified.
6. 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.
7. Comparative assessment will not be carried out for applications for minor use extensions.
8. 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.
9. If no minor use is supported by the authorisation holder in the renewal application and if the withdrawal procedure of the authorisation has 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.
10. Acceptable alternatives have to be safer than the product under evaluation and this for all aspects and parts of the evaluation.
11. 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.

[4] Guidance document SANCO/10524/2012 vers. 5.2 concerning the parallel trade of plant protection products.

12. 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 (EC) No 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.
13. A decision tree has been developed and is available on Comparative assessment | 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

## 2.4.1. Data protection for applications submitted according to the Directive 91/414/EEC

Directive 91/414/EEC has been revoked and replaced by Regulation (EC) No 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 (EC) No 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 (EC) No 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).

### 2.4.2. Data protection for applications submitted according to the Regulation 1107/2009.

For applications submitted according to Regulation (EC) No 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<br><br>* application submitted by authorisation holder at the latest within 5 years from the date of 1st authorisation | Max 13 years from authorisation date in BE |
| Studies for a low risk product (art. 47) | 13 years (+ 3 months/new minor crop*) from authorisation date in BE<br><br>* application submitted by authorisation holder at the latest within 5 years from the date of 1st authorisation | Max 15 years from authorisation date in BE |

| Type of application | Period of protection | Maximum period of protection |
|---|---|---|
| Studies necessary for renewal (art. 43) or review** of an authorisation<br><br>** 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 Commission notice *Technical guideline on data protection according to Regulation (EC) No 1107/2009 (2019/C 229/01)*. 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 (EC) No 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 MS 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.

### 2.4.3. 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 MS 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 (EC) No 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.
    1) The list of protected and unprotected data of a reference product in Belgium can be obtained on request against a fee of € 1500,- [5].
2) According to Article 34. 2, the comparability of the formulations (physico-chemistry, composition to the extent as possible (e.g. based on the information on the MSDS)) and of the effects of the products need to be shown.

[5] Please note that on 29/02/2024, the R.D. of 18/02/2024 amending the R.D. of 13/11/2011, defining new fees, has been published. New fees will enter into force at 01/01/2025 for applications related to plant protection products and adjuvants and at 01/01/2026 for applications related to active substances. Current and future fees can be consulted in Annex 2 of this guide.

# 3. Administrative requirements

## 3.1. Presentation and submission of the application dossier

All applications must be sent by email to the Service Plant Protection and Fertilising Products via secret.div1@health.fgov.be. The email must clearly state all the information that enables to identify the application and product concerned and make reference to any additional information that can be submitted either as an attachment to the email or via another channel (e.g. a cloud system). Dossiers submitted electronically no longer need a submission in writing, with the exception of letters of appeal, that should be submitted both by registered mail (legally required) and by email.

After receipt of the application dossier an invoice will be drawn up, which can be considered as the confirmation of receipt. All details considering the payment are mentioned on the invoice.

To simplify the administration, the following administrative procedures apply:

- Accompanying letter: The authorisation number or dossier number (if known), the commercial 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.
- 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 are 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: Due to technical reasons, a maximum of 40 characters is allowed for denomination of each file or folder, whereas a maximum total path length of 140 characters is allowed.

Please refer to Chapter 4 Technical data requirements 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 | Supporting documents |
|---|---|---|
| 1. Full application | **Belgian Federal Public Service Health, Food Chain Safety and Environment**<br>Service Plant Protection and Fertilising Products<br>Secret.div1@health.fgov.be<br><br>For the attention of:<br>- biopesticides:<br>**Mr. J. Denis**<br>- adjuvants:<br>**Mr. B. Paulus**<br><br>- all other applications for new products via the zonal system (including products for non-professional use):<br>**Mr. D. Maerschalck** | ! Max. 40 characters for file or folder denomination and max. 140 characters per path<br><br>Electronic copy of the complete dossier, including:<br><br>- A complete dRR<br>- All study reports<br>- The Belgian presentation of the GAP (NL, FR and EN), as presented in annex 3 of this guidance document<br>- A Belgian label proposal in NL and FR<br>- A checklist for comparative assessment when the product contains one or more active substances which are candidate for substitution<br>- The composition of the formulation, UFI-code and safety data sheets (SDS) of the formulation and of all the active substances and co-formulants<br>- A copy of the acknowledging receipt of packages 2 and 3 by the Federal Laboratory for Food Safety and Sciensano respectively<br>- Filled out form to request for certain information to be kept confidential (template in Annex 10 of SANCO/13169/2010 rev. 11)<br><br>- The complete equivalence dossier[1] (even if the equivalence of all sources of active substances has been approved previously), including:<br>  ○ The manufacturing process of the technical active substance<br>  ○ The 5-batch analysis<br>  ○ Analytical methods<br>  ○ The specification of the source |

| | | |
|---|---|---|
| | | ○ Toxicological and ecotoxicological data in case of relevant or new impurities<br>○ Letter of access (if applicable)<br>○ Letter of supply (if applicable)<br><br>- The first aid dossier (see instructions on First aid \| Phytoweb.be) |
| 2. Enforcement of the formulation[2] | **Federal Laboratory for Food Safety**<br>Rue de Visé 495<br>4020 Wandre (Liège)<br><br>**Recipients:**<br>admin.lfsal@favv-afsca.be | By mail:<br><br>- specimen of 100 – 200 mg pure certified a.s.<br><br>Electronic copy of:<br><br>- analytical method for determining the concentration of a.s. in the formulation |
| 3. Enforcement of residues[2] | **Sciensano**<br>DS Chemical and physical health risks<br>Service organic contaminants and additives<br><br>**Recipient:**<br>Ms. Laure Joly<br>PPP.registration-methods@sciensano.be | Electronic copy of:<br><br>- analytical method for determining the concentration of the active substance in the formulation<br>- analytical method for determining the residue in crops and edible products |
| 4. Vulgarisation[2] | **Government of Flanders**<br>**Department of Agriculture and Fisheries** | To each recipient: CD-ROM or electronic copy of:<br><br>- dRR part B3<br>- BAD (SANCO 7600/VI/95)<br>- Trial reports relied on in the BAD |

| | | |
|---|---|---|
| | Policy Coordination and Environment Division<br>Koningin Maria Hendrika-plein 70 bus 101<br>9000 Gent<br><br>**Recipient**: Mr. Pascal Braekman<br>pascal.braekman@lv.vlaanderen.be<br><br>**Walloon Agricultural Research Center (CRA-W)**<br>Sustainability, systems and prospectives Department<br>Soil, water and integrated production Unit<br>Location Alfred Serge Balachowsky<br>Rue de Liroux 2<br>5030 Gembloux<br><br>**Recipient**: Mr. Bernard Weickmans<br>b.weickmans@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 active substance specimen of package 2 and packages 3 (enforcement of residues) and 4 (vulgarisation) and are only necessary if this concerns the first ever application for an active substance in Belgium. The analytical methods used in package 2, however, must be e-mailed to the Federal Laboratory for Food Safety **for each application for authorisation**.

## 3.1.2. Application for mutual recognition

| Package | To be sent to | CD-ROM |
|---|---|---|
| 1. Full application | **Belgian Federal Public Service Health, Food Chain Safety and Environment**<br>Service Plant Protection and Fertilising Products<br>Secret.div1@health.fgov.be<br><br>For the attention of:<br>- biopesticides:<br>**Mr. J. Denis**<br>- adjuvants:<br>**Mr. B. Paulus**<br><br>- all other applications for new products via mutual recognition<br>**Mr. P. Nadin** | ! Max. 40 characters for file or folder denomination and max. 140 characters per path<br><br>Electronic copy of the complete dossier, including:<br><br>- A copy of the authorisation granted by the reference MS as well as a translation of the authorisation into English or an official Belgian language (French or Dutch)<br>- A formal statement that the plant protection product is identical to that authorised by the reference MS<br>- A complete and summary dossier as required in Article 33(3)<br>- A Registration Report (Part B and C) of the reference MS containing information on the evaluation and decision on the plant protection product if not available on CIRCA BC<br>- 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<br>- The Belgian presentation of the GAP (NL, FR and EN), as presented in annex 3 of this guidance document<br>- A Belgian label proposal in NL and FR<br>- A comparison of the agricultural and climatic conditions (if necessary)<br>- A checklist for comparative assessment when the product contains one or more active substances which are candidate for substitution<br>- The composition of the formulation, UFI-code 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 2 and 3 by the Federal Laboratory for Food Safety and Sciensano respectively<br>- Filled out form to request for certain information to be kept confidential (template in Annex 10 of SANCO/13169/2010 rev. 11)<br><br>- The complete equivalence dossier[1] (even if the equivalence of all sources of active substances has been approved previously), including:<br>o The manufacturing process of the technical active substance<br>o The 5-batch analysis<br>o Analytical methods<br>o The specification of the source<br>o Toxicological and ecotoxicological data in case of relevant or new impurities<br>o Letter of access (if applicable)<br>o Letter of supply (if applicable)<br><br>- The first aid dossier (see instructions on First aid \| Phytoweb.be) |
| 2. Enforcement of the formulation[2] | **Federal Laboratory for Food Safety**<br>Rue de Visé 495<br>4020 Wandre (Liège)<br><br>**Recipients:**<br>admin.lfsal@favv-afsca.be | By mail:<br><br>- specimen of 100 – 200 mg pure certified a.s.<br><br>Electronic copy of:<br><br>- analytical method for determining the concentration of a.s. in the formulation |
| 3. Enforcement of residues[2] | **Sciensano**<br>DS Chemical and physical health risks<br>Service organic contaminants and additives | Electronic copy of:<br><br>- analytical method for determining the concentration of the active substance in the formulation |

| | | |
|---|---|---|
| | **Recipient:**<br>Mrs. Laure Joly<br>PPP.registration-methods@sciensano.be | - analytical method for determining the residue in crops and edible products |
| 4. Vulgarisation[2] | **Government of Flanders**<br>**Department of Agriculture and Fisheries**<br>Policy Co-ordination and Environment Division<br>Koningin Maria Hendrika-plein 70 bus 101<br>9000 Gent<br><br>**Recipient:**<br>Mr. Pascal Braekman<br>pascal.braekman@lv.vlaanderen.be<br><br>**Walloon Agricultural Research Center (CRA-W)**<br>Unit Plant Protection and Ecotoxicology<br>Location Alfred Serge Balachowsky<br>Rue de Liroux 2<br>5030 Gembloux<br><br>**Recipient:**<br>Mr. Bernard Weickmans<br>b.weickmans@cra.wallonie.be | To each recipient: CD-ROM or electronic copy of:<br><br>- dRR part B3<br>- BAD (SANCO 7600/VI/95)<br>- Trial reports relied on in the BAD |

## 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 active substance specimen of package 2 and packages 3 (enforcement of residues) and 4 (vulgarisation) and are only necessary if this concerns the first ever application for an active substance in Belgium. The analytical methods used in package 2, however, must be e-mailed to the Federal Laboratory for Food Safety for **each application for authorisation**.

## 3.2. Commercial name

The requested commercial 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 commercial name:

- If the applicant wishes to use a commercial 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 commercial 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 commercial name may not not give rise to confusion with that of an active substance that is not relevant. Therefore, the same commercial name may not be used for formulations that contain a different active substance. An example:
    - if "BANZAI" is a product based on active substance x, then the name "BANZAI 500 SC" may never be proposed for a product based on active substance y.

  The only exception to this rule are 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:
    - if BANZAI PLUS contains active substances x and y, BANZAI EXTRA may contain active substances x and z.
- It is not allowed to re-use a commercial 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.
- It is the applicant's responsibility to verify that the proposed commercial name does not violate trademark law as provided for in the Benelux Convention on Intellectual Property.
- If the commercial name refers to the formulation type, then this may only be done using the full and correct name of the formulation type or by using the correct abbreviation. Some examples:
    - Not allowed:
      BANZAI LIQUID, BANZAI FLOWABLE, BANZAI FLOW, BANZAI FL, ...
    - Allowed:
      BANZAI SUSPENSION CONCENTRATE (complete name of the type of formulation), BANZAI SC (correct formulation code)

- If the commercial name is followed by an abbreviation consisting of two letters, then this may only relate to the formulation type. Some examples:
    - Not allowed:
      BANZAI VG (whereby "VG" stands for "Very Good")
    - Allowed:
      BANZAI (no abbreviation), BANZAI SC (correct formulation code), BANZAI ZZG (3 letters), BANZAI N Z G (spaces)
- The same commercial 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 http://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. For products for non-professional users, this should be a full label project in colour in the actual size of the smallest proposed packaging volume (see Annex 6). According to the R.D. of 07/09/2012[6], the listing of the CLP classification must be in the 3 national languages (Dutch, French and German).

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

[6] A R.D. amending the R.D. of Sept. 7, 2012 became available on March 19, 2015

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 and Fertilising Products.

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) No 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 or on plastic films*, as shown in the example below:

Commercial name: Koper/Cuivre/Copper garden

Toelatingsnummer / Numéro d’authorisation : ..../B

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

Pictogrammen/Pictogrammes : GHS07 (for example)

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

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

## Labelling of treated seeds

Following the publication of the Regulation (EC) No 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 MS.** 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 meantime, 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 MS 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, the 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 and Fertilising Products 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 commercial 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 (Regulation (EC) No 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 expiration 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 shelf 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 letter that accompanies the authorisation certificate. This information will, however, never figure on the authorisation certificate itself. If the product has a shelf life shorter than 2 years and/or at a lower temperature than room temperature, this will be mentioned on the authorisation certificate and should be clearly indicated on the product label.

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 the safe disposal of the empty packaging and product surplus are mentioned in Annex 5 of this guidance document
12. the uses for which the product is destined, always including
    - the directions for use
    - the dose
    - the periods between the application and
        - the sowing or planting of the crop to be protected and/or succeeding crop
        - the access to the treated crop
        - the harvest/slaughter
        - the use/the consumption
    - any agricultural-technical, phyto-sanitary and environmental-technical conditions under which the product may or may not be applied
13. information on first aid

14. a section entitled "instructions for physicians", in accordance with the instructions of the Belgian Poison Centre (please see section 3.4)
15. the labelling approved by the Authorisation Committee
    - Classification and labelling under Regulation (EC) No 1272/2008 (CLP):
        - hazard pictograms,
        - the relevant signal word,
        - hazard (H) and precautionary (P) statements,
        - EUH-statements and other supplemental hazard information.
    - Other mentions on the authorisation: e.g. standard phrases for special risks (RSh) or for safety precautions (SP) under Regulation (EC) No 547/2011; national statements, …

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

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

Minimum dimensions of labels and pictograms (according to Regulation (EC) No 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<br>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 R.D. 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 (EC) No 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 expiration 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 Adaptation to Technical Progress (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 (MRL)). 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 in regard to the product's identification
- it is not clear who can be held liable if the product is poured into the packaging of another plant protection product and when a treated crop is damaged as a result of this

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

Some products already can be traded in 640-litre Intermediate Bulk Containers (IBC), 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 are packages in which two separate plant protection products are marketed together. Distinction has to be made between “mandatory” twin packs and “other” twin packs.

A “mandatory” twin pack requires an authorisation and is only allowed under one of the following conditions:

- It is impossible to mix both active substances; or
- Differents products are precursors and have to be applied together in order to be effective (e.g. additives to be added to a plant protection product).

For these mandatory twin packs, an application has to be submitted for each of the individual components/products. Instructions for submission need to be respected in order to obtain their authorisation. Each product needs an authorisation.

Others twin packs include combinations of already authorised products, sold together in order to obtain a broader spectrum of action. These kinds of twin packs do not have to be authorised by the FPS Public Health, Security of the Food chain and Environment. Individual products should be packaged in their original commercial packaging, which have already been approved after risk assessment during the initial application. The commercial package of the twin pack needs to contain the labels of the individual products. The products have to be used in accordance with their authorisations.

### 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 7: 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 First aid | Phytoweb (fytoweb.be). A unique formula identifier (UFI) must be notified with each declaration to the Belgian Poison Centre.

## 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. 11, 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.

The Central Zone Steering Committee (CZSC) makes various types of information publicly available on the non-confidential part of CIRCABC, such as:

- the bullets points: the decisions taken in the CZSC

- a detailed overview of all the national requirements for each MS of the central zone
- the agenda and minutes of the CZSC
- other information, such as communication on (i)zRMS and Brexit, CZ Evaluation Manual ecotoxicology,...

The decisions taken on this level should by any means be respected in any zonal application for a new authorisation, use extension, etc.

The following steps must be taken to access this information on the non-confidential part of CIRCABC:

- Go to: **circabc.europa.eu/ui/welcome**
- Sign in as **visitor**
  - (any stakeholder will only be able to see the public information as long as you do not login but browse CIRCABC as a **visitor**)
- Click on Header: **European commission**
- Click on Category: **Health and Food Safety**
- Click on List of Interest Groups: **PPP Zonal**
  - If you are not yet a member of this interest group, you must register once by clicking on "join the group". After you have been admitted, you will have access to all documents present in this group.
- Click on the button 'Library' at the top left of the screen, next to 'PPP zonal': **Library**
- Choose the folder(s) of interest: **Zonal Steering Committee Center**
- Choose the folder: **Public information.**

# 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 MS 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 renewal of the 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.

### 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 microbial pest control agent**. An updated version is available and will be required for applications from 21/11/2024 onwards. More information can be found in the technical guidelines.

The draft Registration Report (dRR) is drawn up as a MS 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 MS. 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 MS in question. As a result, Part A is a national document and can be different for every cMS.

The following factors are specific for Belgium:

#### Proposal for classification and labelling

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

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

#### GAP tables

As Part A is a national document, only the GAP that was requested in Belgium must be mentioned in the Belgian Part A. The GAP table must be filled in in the EU format (see dRR templates) as well as in the Belgian national format in English, French and Dutch (see annex 3 of this guidance document). Please make sure that the GAP's in EU format, Belgian format and the 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 have 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 and Fertilising Products 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 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 Physico-chemistry | 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

Co-formulants which are listed in Regulation (EU) 2021/383, amending Annex III of Regulation (EC) No 1107/2009 will automatically be refused, as well as formaldehyde-releasers (since formaldehyde is included in Annex III of Regulation (EC) No 1107/2009).

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

- methanol
- n-hexane
- methoxy, ethoxy, propoxy, isopropoxy and butoxy ethers of ethylene glycol and their acetate derivatives
- n-hexane + methyl ethyl ketone (butanone)
- alkylphenol ethoxylate

## 4.4. Residues

Specific guidance is available on Residues | Phytoweb.be.

## 4.5. Behaviour in the environment

Specific guidance is available on Behaviour in the environment | Phytoweb.be.

## 4.6. Ecotoxicology

Specific guidance is available on Ecotoxicology | 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
E-mail: Adrien.dewalque@health.fgov.be

**Bertrand Ducattillon**
Telephone: +32 (0)2 524 72 87
E-mail: Bertrand.ducattillon@health.fgov.be

**Cedrick Matthys**
Telephone : +32 (0)2 524 73 94
E-mail : Cedrick.matthys@health.fgov.be

**Stefanie Polyn**
Telephone: +32 (0)2 524 73 95
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 Administrative requirements 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 MS. 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 Efficacy.
- 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 is available on Adjuvants | Phytoweb.be.
- national requirements with respect to dose expression of vertical crops: specific guidance is available on Vertical crops | Phytoweb.be.
- national requirements with respect to the risk assessment for bees: specific guidance is available on Bees | 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 Plant Protection and Fertilising Products. 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 preventive 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 MS or third countries. The treatment of seeds has to be done in line with the authorisation delivered by the MS 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 (EC) No 1272/2008;*
- *ecotoxicological properties limited to the data that are needed to label the seed treatment product according to Regulation (EC) No 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 MS:*

- *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 of 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 MS) 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 CLP Procedure & Checklist | CLP Safety recommendations | Phytoweb.be.

## 4.10. GEP and test products

Specific guidance is available on GEP and trial products | Phytoweb.be.

# 5. Procedures following the original authorisation

## 5.1. Applications after the authorisation

An application must be submitted to the Service Plant Protection and Fertilising Products for any changes to the commercial 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 (EC) No 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: Fees (overview) 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 untill 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 sent to secret.div1@health.fgov.be and a fee of € 6000 will apply (€ 1500 for the renewal of a second name authorisation)[7].

### 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) No 1107/2009 (see Section 5.2 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 and Fertilising Products 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 and Fertilising Products

[7] Please note that on 29/02/2024, the R.D. of 18/02/2024 amending the R.D. of 13/11/2011, defining new fees, has been published. New fees will enter into force at 01/01/2025 for applications related to plant protection products and adjuvants and at 01/01/2026 for applications related to active substances. Current and future fees can be consulted in Annex 2 of this guide.

will notify the company in an official letter which additional information ("conditions for prolongation") must be supplied before which deadline.

Currently there are in Belgium only 2 exceptional cases for zonal applications in which an provisional authorization is granted for a short period of time:

1. Transitional measures for data requirements and risk assessment for bees specific for Belgium

   In case studies to address the chronic toxicity to adult honeybees, the chronic toxicity to honeybees larvae or the acute toxicity to bumblebes cannot be included in the dossier, a justification needs to be provided. Furthermore, these data have to be used to assess the risk according to the national approach, mainly based on EFSA Journal 2013;11(7):3295. Provided that all other aspects of the dossier would result in an authorisation of the plant protection product, the absence of data requirements and risk assessment for bees specific for Belgium alone will not result in a refusal of the product approval. However, only a provisional product authorisation will be granted for a limited time period of 2 years for insecticides and 3 years for fungicides and herbicides. As a condition for prolongation of the authorisation, the data and and the risk assessment in line with the national procedure need to be submitted within those 2 or 3 years. This provisional authorization is only possible for a dossier submitted between 1/01/2016 and 1/01/2019 or 1/01/2020; more information in the National approach for Belgium – Belgian national approach for the risk assessment for bees.

2. Comparative assessment

   If for the comparative assessment there has been made use of the derogation Article 50(3) of Regulation (EC) No 1107/2009 that states that for the requested uses it is necessary to acquire experience first through using that product in practice, then an authorisation will be limited to a shorter period. Those provisional authorisations can only be granted for one-time for a limited time period of maximum 5 years. The condition for prolongation is then that the applicant needs to submit the comparative assessment within those 5 years.

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.

If the prolongation conditions are not met, the product will be withdrawn. There is a grace period of up to 6 months for the marketing and storage by third parties that starts from the day of

deadline to submit the condition for prolongation and an additional 12 months for use. No grace period is provided for sales and storage by the authorisation holder. These periods are limited by the validity period of the active substance approval + 12 months and will be updated as necessary at the time of any administrative renewals. These grace periods are specified at the conditions for prolongation on the authorization certificate.

The application for prolongation can be done by letter sent to secret.div1@health.fgov.be and a fee of € 3000 will apply if Belgium acts as cMS or for national applications (see Annex 2: Fees (overview) for more details[8]).

Whenever an authorisation is administratively prolonged (i.e. without the evaluation of data), a fee of € 250 applies (see Annex 2: Fees (overview) for more details[8]).

### 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 and Fertilising Products.

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 Extension / Minor crop | 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 section 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 (EC) No 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

[8] Please note that on 29/02/2024, the R.D. of 18/02/2024 amending the R.D. of 13/11/2011, defining new fees, has been published. New fees will enter into force at 01/01/2025 for applications related to plant protection products and adjuvants and at 01/01/2026 for applications related to active substances. Current and future fees can be consulted in Annex 2 of this guide.

80 of Regulation (EC) No 1107/2009. If the applicant has doubts about which procedure to follow, then the Service Plant Protection and Fertilising Products can be contacted for further information.

The application for an extension of use can be done by letter sent to secret.div1@health.fgov.be and the fee[9] of € 6000 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 € 3000 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 € 3000 applies if Belgium acts as cMS or for national applications (see Annex 2: Fees (overview) for more details). 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
- € 1860 if the active substance has been authorised for 15 to 25 years in Belgium
- € 3700 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 sent to secret.div1@health.fgov.be.

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

[9] Please note that on 29/02/2024, the R.D. of 18/02/2024 amending the R.D. of 13/11/2011, defining new fees, has been published. New fees will enter into force at 01/01/2025 for applications related to plant protection products and adjuvants and at 01/01/2026 for applications related to active substances. Current and future fees can be consulted in Annex 2 of this guide.

on the label. If the holder of the authorisation does not wishes to do so, the granted extension will be published on Fytosearch | 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 and Fertilising Products. The complete new composition and adapted UFI-code (if applicable) 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 section 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 commercial 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 sent to secret.div1@health.fgov.be and the fee[10] for the application for a change in composition amounts to € 6000 if Belgium acts as zRMS for a significant change, € 1500 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 MS (see Annex 2: Fees (overview) for more details). 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 commercial name

An application for a change of the commercial name may be requested by letter sent to secret.div1@health.fgov.be. Moreover, the Authorisation Committee does not need to approve this application as this can be dealt with on the administrative level. Obviously the new commercial name must comply with the conditions as stipulated under section 3.2 of this guidance document. A label proposal that features the new commercial name should be appended to the application.

A fee[10] of € 500 will apply (see Annex 2: Fees (overview) for more details). 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 sent to secret.div1@health.fgov.be.
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;

[10] Please note that on 29/02/2024, the R.D. of 18/02/2024 amending the R.D. of 13/11/2011, defining new fees, has been published. New fees will enter into force at 01/01/2025 for applications related to plant protection products and adjuvants and at 01/01/2026 for applications related to active substances. Current and future fees can be consulted in Annex 2 of this guide.

- 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 letter of supply 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).
- If relevant, the new UFI-code and proof of receipt by the Antipoison Centre

In both cases a fee[11] of € 500 will apply (see Annex 2: Fees (overview) for more details). 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.

### 5.1.8. Application for a second name authorisation

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 commercial 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 second name 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;

[11] Please note that on 29/02/2024, the R.D. of 18/02/2024 amending the R.D. of 13/11/2011, defining new fees, has been published. New fees will enter into force at 01/01/2025 for applications related to plant protection products and adjuvants and at 01/01/2026 for applications related to active substances. Current and future fees can be consulted in Annex 2 of this guide.

- 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 (second name) 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 second name authorisation can be done by letter and a fee[12] of € 1500 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 and Fertilising Products. 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. 11, an application for an amendment of the packaging or additional packaging needs to follow the zonal procedure as described in section 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.

[12] Please note that on 29/02/2024, the R.D. of 18/02/2024 amending the R.D. of 13/11/2011, defining new fees, has been published. New fees will enter into force at 01/01/2025 for applications related to plant protection products and adjuvants and at 01/01/2026 for applications related to active substances. Current and future fees can be consulted in Annex 2 of this guide.

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[13] to be paid for an application of an amendment of the packaging or an additional packaging depends on the situation:

- € 6000 if the zonal procedure needs to be followed, BE acts as zRMS and more cMS are involved ("additional data (BE = zRMS)", R.D. 13/11/11, Art. 1. § 1.2°)
- € 3000 if the zonal procedure needs to be followed, BE acts as zRMS but no other MS are involved ("additional data (BE≠zRMS)", R.D. 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", R.D. 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 te be submitted:

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

The fee[11] to be paid for an application of an amendment of the CLP classification depends on the situation:

- € 6000 if the zonal procedure needs to be followed and BE acts as zRMS (R.D. 13/11/11, Art. 1. § 1.2°)
- € 3000 if BE does not act as zRMS (R.D. 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.

[13] Please note that on 29/02/2024, the R.D. of 18/02/2024 amending the R.D. of 13/11/2011, defining new fees, has been published. New fees will enter into force at 01/01/2025 for applications related to plant protection products and adjuvants and at 01/01/2026 for applications related to active substances. Current and future fees can be consulted in Annex 2 of this guide.

## 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. 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 a press release 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 fulfill 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.

The specific withdrawal dates and grace periods for each authorisation can be consulted on Fytosearch | Phytoweb.be.

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 and Fertilising Products

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 and Fertilising Products 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 a press release 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 case no active substane renewal dossier has been submitted at EU level, sales by the authorisation holder are not allowed after the expiration date of the active substance. A maximum grace period of 18 months after the expiration date of the active substance can be awarded, with a maximum of 6 months for sales by distributors and traders and an additional 12 months for use by the end user.

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. The specific withdrawal dates and grace periods for each authorisation can be consulted on Fytosearch | Phytoweb.be.

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

## 5.2.1. Introduction

Regulation (EC) No 540/2011 provides an overview of all the active substances that have been approved at European level and the expiration date of this approval. An active substance is always approved for a limited period of time. If the company wishes to keeps its active substance on the market, then it must submit an application for the renewal of the active substance in the MS 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 MS must review all the authorisations of plant protection products that contain the relevant active substance. The Service Plant Protection and Fertilising Products 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 Rev. 14.

## 5.2.2. 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 MS 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 Rev. 14 for a detailed explanation.

This revision which the MS 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 submitted:

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 Rev. 14, 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 and Fertilising Products.

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 MS 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 into 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 21 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 3 months after renewal of this approval. Sale and storage of the existing stocks by third parties will be authorised until 9 months after renewal of the approval while the use will be authorised until 21 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 to 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 to 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 going into force of the renewal regulation and the decision of the product authorisation to be renewed, only applications for which no technical assessment is needed, may be possible. These applications may include:

- Administrative applications for changes in an existing product's commercial 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.

### 5.2.3. Fees[14]

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

- € 25000 for an application for renewal of a product for which BE acts as zRMS (R.D. 13/11/11, Art. 1. § 1.1° a)

[14] Please note that on 29/02/2024, the R.D. of 18/02/2024 amending the R.D. of 13/11/2011, defining new fees, has been published. New fees will enter into force at 01/01/2025 for applications related to plant protection products and adjuvants and at 01/01/2026 for applications related to active substances. Current and future fees can be consulted in Annex 2 of this guide.

- € 6000 for an application for renewal of a product for which BE acts as cMS (R.D. 13/11/11, Art. 1. § 1.1° b)
- € 1500 for an application for renewal of a second name authorisation (R.D. 13/11/11, Art. 1. § 1.1° b)

## 5.3. Certificates of approval

On the company's request, the Service Plant Protection and Fertilising Products can issue a certificate of approval 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 and Fertilising Products.

In such cases a proposal for a certificate of approval must be sent by e-mail to the secretariat of the Service Plant Protection and Fertilising Products (secret.div1@health.fgov.be). After the certificate has been checked, an approved certificate of approval will be sent to the company.

The fee for obtaining a certificate amounts to € 250[15].

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

Specific guidance is available on MRL | Phytoweb.be.

## 5.5. Parallel trade

Specific guidance is available on Parallelhandel | Commerce parallèle | Phytoweb.be.

[15] Please note that on 29/02/2024, the R.D. of 18/02/2024 amending the R.D. of 13/11/2011, defining new fees, has been published. New fees will enter into force at 01/01/2025 for applications related to plant protection products and adjuvants and at 01/01/2026 for applications related to active substances. Current and future fees can be consulted in Annex 2 of this guide.

# 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 |
| **MS** | member state(s) |
| **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 an authorisation of a plant protection product and a permit for parallel trade. These fees and contributions which are owed to the Budgetary Fund for raw materials and products are determined in a R.D.[16]. 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.

As the fees will be adapted from 2025 for national authorisations and from 2026 for EU applications, the new fees are added in an extra column.

## Plant protection products

| Type of application<br>Reference Royal Decree 13/11/2011 | Amount (€) currently | Amount (€) from 1/01/2025 |
|---|---|---|
| **Authorisation or modification of an authorisation of a plant protection product** | | |
| BE = zRMS for an application for authorisation of a PPP<br><br>Art 1. § 1.1° a | 25 000 | 80 000 |
| BE = zRMS for an application for authorisation of a PPP, based on a previously refused application<br><br>Art 1. § 1.1° a and d | 12 500 | 40 000 |
| BE = zRMS for an application for authorisation of a PPP for non-professional use, based on a previously evaluated application for professional use<br><br>Art 1. § 1.1° a and e | 12 500 | 40 000 |
| 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<br><br>Art 1. §1.1° a | 6 000 | 55 000 |

[16] R.D. of 13 November 2011 determining fees and contributions to the budgettary fund for raw materials and product

| Type of application<br>Reference Royal Decree 13/11/2011 | Amount (€) currently | Amount (€) from 1/01/2025 |
|---|---|---|
| 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<br><br>Art 1. §1.1° a and d | 3 000 | 27 500 |
| BE ≠ zRMS for an application for authorisation of a PPP for professional use<br><br>Art 1. § 1.1° b | 6 000 | 25 000 |
| BE ≠ zRMS for an application for authorisation of a PPP for non-professional use<br><br>Art 1. § 1.1° b | 6 000 | 8 000 |
| BE ≠ zRMS for an application for authorisation of a PPP, based on previously refused application<br><br>Art 1. § 1.1° b and d | 3 000 | 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<br><br>Art 1. § 1.1° b and e | 3 000 | 8 000 |
| Application for a second name authorisation (with access)<br><br>Art 1. § 1.1° b | 1 500 | 1 000 |
| Application for a second name authorisation (with access), based on previously refused application<br><br>Art 1. § 1.1° b and d | 750 | 500 |
| Requested missing data in the frame of an application for authorisation<br><br>Art 1. § 1.1° g | € 100 per hour of evaluation | € 100 per hour of evaluation |

| Type of application<br>Reference Royal Decree 13/11/2011 | Amount (€) currently | Amount (€) from 1/01/2025 |
|---|---|---|
| BE = zRMS for an application for renewal of a PPP<br><br>Art 1. § 1.1° a | 25 000 | 60 000 |
| BE ≠ zRMS for an application for renewal of a PPP for professional use<br><br>Art 1. § 1.1° b | 6 000 | 20 000 |
| BE ≠ zRMS for an application for renewal of a PPP for non-professional use<br><br>Art 1. § 1.1° b | 6 000 | 8 000 |
| Application for renewal of a second name authorisation<br><br>Art 1. § 1.1° b | 1 500 | 1 000 |
| BE = zRMS for an application for a change of the use<br><br>Art 1. § 1.2° | 6 000 | 20 000 |
| BE = zRMS for an application for a change of classification or labelling<br><br>Art 1. § 1.2° | 6 000 | 6 000 |
| BE = zRMS for any other type of application for which additional data are required<br><br>Art 1. § 1.2° | 6 000 | 20 000 |
| BE = zRMS for an application for amendment of the a.s. content<br><br>Art 1. § 1, 1.2° | 6 000 | (application no longer accepted) |
| BE ≠ zRMS for an application for a change of the use of a PPP for professional use<br><br>Art 1. § 1.2° | 3 000 | 12 500 |

| Type of application<br>Reference Royal Decree 13/11/2011 | Amount (€) currently | Amount (€) from 1/01/2025 |
|---|---|---|
| BE ≠ zRMS for an application for a change of the use of a PPP for non-professional use<br><br>Art 1. § 1.2° | 3 000 | 8 000 |
| BE ≠ zRMS for an application for a change of classification or labelling<br><br>Art 1. § 1.2° | 3 000 | 3 000 |
| BE ≠ zRMS for any other type of application for which additional data are required<br><br>Art 1. § 1.2° | 3 000 | 12 500 |
| BE ≠ zRMS for any other type of application for a PPP for non-professional use for which additional data are required, for a PPP for non-professional use<br><br>Art 1. § 1.2° | 3 000 | 8 000 |
| BE ≠ zRMS for an application for amendment of the a.s. content<br><br>Art 1. § 1, 1.2° | 1 000 | (application no longer accepted) |
| Prolongation<br><br>(BE = zRMS)<br><br>Art 1. § 1, 1.2° | 6 000 | 20 000 |
| Prolongation<br><br>(BE ≠ zRMS)<br><br>Art 1. § 1, 1.2° | 3 000 | 12 500 |
| Prolongation of an authorisation without evaluation of data (administrative prolongation)<br><br>Art 1. § 1.2° | 250 | 500 |

| Type of application<br>Reference Royal Decree 13/11/2011 | Amount (€) currently | Amount (€) from 1/01/2025 |
|---|---|---|
| BE = zRMS for an application for a minor use extension<br><br>Art 1. § 1.2° | 3 000 | 5 000 |
| BE = zRMS for an application for a change of the composition<br><br>Art 1. § 1.3° | 6 000 | 12 000 |
| BE ≠ zRMS for an application for a significant change of the composition<br><br>Art 1. § 1.3° | 1 500 | 3 500 |
| BE ≠ zRMS for an application for a non-significant change of the composition<br><br>Art 1. § 1.3° | 750 | 2 000 |
| Application for a change of the composition by mutual recognition<br><br>Art 1. § 1, 1.3° | 250 | 3 500 |
| Application for a change of the commercial name of the authorisation<br><br>Art 1. § 1, 1.4° | 500 | 500 |
| Application for a change of the name or legal status of the authorisation holder<br><br>Art 1. § 1, 1.4° | 500 | 500 |
| Application for a transfer of the authorisation<br><br>Art 1. § 1, 1.4° | 500 | 500 |
| BE = zRMS for a change of the origin/specification of the a.s.<br><br>Art 1. § 1.5° | 3 000 | 12 500 |

| Type of application<br>Reference Royal Decree 13/11/2011 | Amount (€) currently | Amount (€) from 1/01/2025 |
|---|---|---|
| BE ≠ zRMS for a change of the origin/specification of the a.s.<br><br>Art 1. § 1.5° | 1 500 | 1 500 |
| Application for a change of production site of the formulation<br><br>Art 1. § 1.6° | - | 250 |
| BE = zRMS for the evaluation of compliance with the approval conditions for technical equivalence<br><br>Art 1. § 2° a | 3 000 | 12 500 |
| BE ≠ zRMS for the evaluation of compliance with the approval conditions for technical equivalence<br><br>Art 1. § 2° a | 1 500 | 1 500 |
| BE = zRMS for the evaluation of compliance with the approval conditions with assessment of new studies<br><br>Art 1. § 2° b | 50 000 | 25 000 |
| BE ≠ zRMS for the evaluation of compliance with the approval conditions with assessment of new studies<br><br>Art 1. § 2° b | 1 500 | 3 000 |
| Modification of a second name authorisation following from modification of the reference authorisation<br><br>Art 1. § 7 | same as for reference authorisation | 500 |
| Application for an additional packaging or packaging type<br><br>Art 1. § 10 | 500 | 2 000 |
| Modification of classification and labelling of authorisation following from a revision of Reg (EC) N° 1272/2008 | 80 | 1 500 |

| Type of application<br>Reference Royal Decree 13/11/2011 | Amount (€) currently | Amount (€) from 1/01/2025 |
|---|---|---|
| Art 1. §9.2° | | |
| Application to obtain a list of protected and unprotected data<br><br>Art 1. § 11 | 1 500 | 4 000 |
| Application for exemption from the submission of studies<br><br>Art 1. § 12 | 3 500 | 7 000 |
| Evaluation of a co-formulant<br><br>Art 1. § 13 | 12 000 | 15 000 |
| Evaluation of the equivalence of a co-formulant<br><br>Art 1. § 14 | 500 | 1 000 |
| Other application (without evaluation)<br><br>Art 1. § 15 | 750 | 1 000 |
| Other application (minimal evaluation)<br><br>Art 1. § 15 | 1 500 | 8 000 |
| Other application (extensive evaluation)<br><br>Art 1. § 15 | 3 000 | 20 000 |
| Other application (extra extensive evaluation)<br><br>Art 1. § 16 | € 100 per hour of evaluation | € 100 per hour of evaluation |
| Additional Contribution (a.s. on the market at least 30 years)<br><br>Art 2. § 1.1° | 370 | - |
| Additional Contribution (a.s. on the market for 25 to 30 years) | 750 | - |

| Type of application<br>Reference Royal Decree 13/11/2011 | Amount (€) currently | Amount (€) from 1/01/2025 |
|---|---|---|
| Art 2. § 1.2° | | |
| Additional Contribution (a.s. on the market for 15 to 25 years)<br><br>Art 2. § 1.3° | 1 860 | - |
| Additional Contribution (a.s. < 15 years on the market)<br><br>Art 2. § 1.4° | 3 700 | - |
| Additional contribution for referring to non-owned data<br><br>Art 2. § 1 | - | 1 500 |

# Adjuvants

| Type of application<br>Reference Royal Decree 13/11/2011 | Amount (€) currently | Amount (€) from 1/01/2025 |
|---|---|---|
| **Authorisation or modification of an authorisation of an adjuvant** | | |
| Application for an authorisation of an adjuvant<br><br>Art 1. § 1.1° c | 6 000 | 6 000 |
| Application for an authorisation of an adjuvant based on a previously refused application<br><br>Art 1. § 1.1° c and d | 3 000 | 3 000 |
| Application for a second name authorisation of an adjuvant (with access)<br><br>Art 1. § 1.1° c | 1 500 | 750 |
| Application for a second name authorisation of an adjuvant (with access), based on a previously refused application | 750 | 375 |

| Type of application<br>Reference Royal Decree 13/11/2011 | Amount (€) currently | Amount (€) from 1/01/2025 |
|---|---|---|
| Art 1. § 1.1° c and d | | |
| Application for prolongation of an authorisation of an adjuvant<br><br>Art 1. § 1.1° c | 6 000 | 6 000 |
| Application for prolongation of an authorisation of an adjuvant based on a previously refused application<br><br>Art 1. § 1.1° c and d | 3 000 | 3 000 |
| Application for prolongation of a second name authorisation of an adjuvant (with access)<br><br>Art 1. § 1.1° c | 1 500 | 750 |
| Application for prolongation of a second name authorisation of an adjuvant (with access), based on a previously refused application<br><br>Art 1. § 1.1° c and d | 750 | 375 |
| Requested missing data in the frame of an application for authorisation<br><br>Art 1. § 1.1° g | € 100 per hour of evaluation | € 100 per hour of evaluation |
| Prolongation of an authorisation without evaluation of data (administrative prolongation)<br><br>Art 1. § 1.2° | 250 | 500 |
| Application for a change of the commercial name of the authorisation<br><br>Art 1. § 1, 1.4° | 500 | 500 |
| Application for a change of the name or legal status of the authorisation holder<br><br>Art 1. § 1, 1.4° | 500 | 500 |

| Type of application<br>Reference Royal Decree 13/11/2011 | Amount (€) currently | Amount (€) from 1/01/2025 |
|---|---|---|
| Application for a transfer of the authorisation<br><br>Art 1. § 1, 1.4° | 500 | 500 |
| Application for a change of production site of the formulation<br><br>Art 1. § 1.6° | - | 250 |
| Application for an additional packaging or packaging type<br><br>Art 1. § 10 | 500 | 2 000 |
| Modification of classification and labelling of the authorisation following from a revision of Reg (EC) N° 1272/2008<br><br>Art 1. §9.2° | 80 | 1 500 |
| Evaluation of the equivalence of a co-formulant<br><br>Art 1. § 14 | 500 | 1 000 |
| Other application (without evaluation)<br><br>Art 1. § 15 | 750 | 1 000 |
| Other application (minimal evaluation)<br><br>Art 1. § 15 | 1 500 | 8 000 |
| Other application (extensive evaluation)<br><br>Art 1. § 15 | 3 000 | 20 000 |
| Other application (extra extensive evaluation)<br><br>Art 1. § 16 | € 100 per hour of evaluation | € 100 per hour of evaluation |

# Permits for parallel trade

| Type of application<br>Reference Royal Decree 13/11/2011 | Amount (€) currently | Amount (€) from 1/01/2025 |
|---|---|---|
| **Permit for parallel trade** | | |
| Application for a permit for parallel trade<br><br>Art 1. § 5 | 1 500 | 2 500 |
| Application for prolongation of a permit for parallel trade<br><br>Art 1. § 5 | 1 500 | 1 500 |
| Application for prolongation of a permit for parallel trade, < 2 years after first application or last prolongation (no technical evaluation)<br><br>Art 1. § 5 | - | not applicable |
| Application for prolongation of a permit for parallel trade, < 5 years after first application or last prolongation (no technical evaluation)<br><br>Art 1. § 5 | not applicable | - |
| Application for a change of the commercial name of a parallel trade permit<br><br>Art 1. § 5.1° | 500 | 500 |
| Application for a change of the name or legal status of the permit holder<br><br>Art 1. § 5.2° | 500 | 500 |
| Application for transfer of a permit for parallel trade<br><br>Art 1. § 5.3° | 500 | 500 |
| Modification of a permit for parallel trade following from modification of the reference authorisation | - | 500 |

| Type of application<br>Reference Royal Decree 13/11/2011 | Amount (€) currently | Amount (€) from 1/01/2025 |
|---|---|---|
| Art 1. § 7 | | |
| Application for an additional packaging or packaging type<br><br>Art 1. § 10 | 500 | 2 000 |
| Modification of classification and labelling of the permit following from a revision of Reg (EC) N° 1272/2008<br><br>Art 1. §9.2° | 80 | 1 500 |

# Active substances

| Type of application<br>Reference Royal Decree 13/11/2011 | Amount (€) currently | Amount (€) from 1/01/2026 |
|---|---|---|
| **Approval or renewal of active substances** | | |
| BE = RMS for an application for approval/renewal of a type A a.s. – introduction of dossier<br><br>Art 1. § 3.2° a | 60 000 | 200 000 |
| BE = RMS for an application for approval/renewal of a type A a.s. – DAR + peer review<br><br>Art 1. § 3.2° a | 140 000 | 300 000 |
| BE = RMS for an application for approval/renewal of a type B a.s. – introduction of dossier<br><br>Art 1. § 3.2° b | 19 000 | 60 000 |
| BE = RMS for an application for approval/renewal of a type B a.s. – DAR + peer review<br><br>Art 1. § 3.2° b | 40 000 | 140 000 |

| | | |
|---|---|---|
| BE = coRMS for an application for approval/renewal of a type A a.s.<br><br>Art 1. § 3.2° c | 100 000 | 100 000 |
| BE = coRMS for an application for approval/renewal of a type B a.s.<br><br>Art 1. § 3.2° d | 37 500 | 90 000 |
| BE ≠ RMS or coRMS for an application for approval/renewal of an a.s.<br><br>Art 1. § 3.2° e | 1 250 | - |
| BE = RMS for an application for a change of "end point"<br><br>Art 1. § 3.3° a | 3 000 | 20 000 |
| BE = RMS for assessment of the technical equivalence of the origin of the a.s.<br><br>Art 1. § 3.3° b | 3 000 | 12 500 |
| BE = RMS for amendment of the approval conditions of the a.s.<br><br>Art 1. § 3.3° c | 25 000 | 70 000 |
| BE = RMS for evaluation of additional studies (per "open point")<br><br>Art 1. § 3.3° d | 5 000 | 75 000 |
| BE = RMS for notification of a potential adverse or unacceptable effect<br><br>Art 1. § 3.3 e° | 5 000 | 100 000 |
| BE = RMS for an alternative a.s. dossier<br><br>Art 1. § 3.3° f | 50 000 | 40 000 |
| Peer review | 10 000 | 15 000 |

| | | |
|---|---|---|
| Art 1. § 3.3° | | |
| BE = RMS for the evaluation of the notification for approval/renewal of an a.s.<br><br>Art 1. § 3.4° | 750 | - |

# Maximum Residue Limit

| Type of application<br>Reference Royal Decree 13/11/2011 | Amount (€) currently | Amount (€) from 1/01/2025 |
|---|---|---|
| **Applications related to MRL** | | |
| BE = RMS for setting an MRL<br><br>(Art 1. § 4.1° | 1 000 | 6 000 + 1 000 per MRL (maximum total of 20 000 per application) |
| BE = RMS for the evaluation of a study for setting an MRL (by study)<br><br>Art 1. § 4.1° | 3 000 | 5 000 |
| BE = RMS for setting an MRL with evaluation of a toxicological dossier<br><br>Art 1. § 4.1° | 50 000 | 75 000 |
| Peer review for setting an MRL<br><br>Art 1. § 4.1° | 10 000 | 12 500 |
| BE = RMS for evaluation of existing MRLs for an a.s.<br><br>Art 1. § 4.2° | 10 000 | 50 000 |
| BE = RMS for evaluation of a study for an existing MRL (per submitted study report) Art 1. § 4.2° | 1 000 (maximum total of 10 000 per application | 2 000 (maximum total of 20 000 per application) |

| Type of application<br>Reference Royal Decree 13/11/2011 | Amount (€) currently | Amount (€) from 1/01/2025 |
|---|---|---|
| Peer review for evaluation of an existing MRL<br><br>Art 1. § 4.2° | - | 5 000 |
| Verification of authorisation(s) after MRL review<br><br>Art 1. § 4.3° | 2500 | 5 000 |

# GEP authorisations

| Type of application<br>Reference Royal Decree 13/11/2011 | Amount (€) currently | Amount (€) from 1/01/2025 |
|---|---|---|
| **GEP authorisations** | | |
| Application for GEP recognition<br><br>Art 1. § 6 | 3 000 | 5 000 |
| Application for GEP recognition by mutual recognition<br><br>Art 1. § 6 | 2 500 | 5 000 |
| Application for renewal of a GEP recognition<br><br>Art 1. § 6 | 750 | 750 |
| Application for extension of a GEP recognition<br><br>Art 1. § 6 | 750 | 750 |
| Audit of GEP/surveillance audit<br><br>Art 1. § 6 | 5 000 | 5 000 |

# Certificate of approval

| Type of application<br>Reference Royal Decree 13/11/2011 | Amount (€) currently | Amount (€) from 1/01/2025 |
|---|---|---|
| Application for a certificate of approval<br><br>Art 1. § 8 | 250 | 600 |

# Change of classification of substances

| Type of application<br>Reference Royal Decree 13/11/2011 | Amount (€) currently | Amount (€) from 1/01/2025 |
|---|---|---|
| **Classification and labelling of substances** | | |
| BE = submitting or reporting MS for an application for change/harmonisation of classification and labelling of an a.s. (Reg (EC) N° 1272/2008)<br><br>Art 1. § 9.1° | 10 000 | 30 000 |
| BE = RMS for an application for change/harmonisation of classification and labelling (67/548/EEC or 1999/45/EC)<br><br>Art 1. § 9.1° | 5 000 | - |

# Annex 3: Belgian national presentation of the GAP

| To be treated | (crop + Latin name + EPPO code) | Te behandelen | (gewas + Latijnse naam + EPPO code) | A traiter | (culture + nom latin + code EPPO) |
|---|---|---|---|---|---|
| Stage | First node – second node (BBCH 31-32) | Stadium | Eerste knoop – tweede knoop (BBCH 31-32) | Stade | Premier noeud – deuxième noeud (BBCH 31-32) |
| Remark | Max (number) applications per crop, season, year, production cycle | Opmerking | max. (aantal) toepassingen per teelt, seizoen, jaar, productiecyclus | Remarque | max (nombre) applications par culture, saison, an, cycle de production |
| PHI | … days | Wachttijd | … dagen | Délais | … jours |
| Precautions for succeeding crops | / | Voorzorgen voor volggewassen | / | Précautions pour les cultures suivantes | / |
| Enemy + Latin name + EPPO code | Mould… (mention only more enemies in this cell if stage, remark, rate, number of applications and application method are identical) | Vijand + Latijnse naam + EPPO code | Roest, Papiervlekkenziekte, … + Latijnse naam + EPPO Code | Ennemi + nom latin + code EPPO | Rouille, Mildiou, … + nom latin + code EPPO |
| Stage (of the enemy) | Preventively or at the appearance of the first symptons | Stadium (van de vijand) | Preventief of bij het verschijnen van de eerste symptomen | Stade (de l'ennemi) | Préventivement ou à l'apparition des premiers symptômes |
| Remark | / | Opmerking | / | Remarque | / |
| Rate | 1 l/ha | Dosis | 1 l/ha | Dose | 1 l/ha |
| N° applications | 1-3 applications, with an interval of 21 days | Aantal toepassingen | 1-3 toepassingen, met een interval van 21 dagen | Nombre de traitements | 1-3 applications, à intervalle de 21 jours |
| Application method | Field sprayer, at 200-500 l water/ha | Toepassingsmethode | Veldspuittoestel, à 200-500 l water/ha | Méthode d'application | Pulvérisateur de champ, à 200-500 l d'eau/ha |

| Enemy + Latin name + EPPO code | Oidium + EPPO Code | Vijand | Witziekte + EPPO Code | Ennemis | Oïdium + EPPO Code |
|---|---|---|---|---|---|
| Stage (of the enemy) | Preventively or at the appearance of the first symptons | Stadium (van de vijand) | Preventief of bij het verschijnen van de eerste symptomen | Stade (de l'ennemi) | Préventivement ou à l'apparition des premiers symptômes |
| Remark | / | Opmerking | / | Remarque | / |
| Rate | 1,5 l/ha | Dosis | 1,5 l/ha | Dose | 1,5 l/ha |
| N° applications | 1-3 applications, with an interval of 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 Fytosearch | Phytoweb.be.

# Annex 4: Warning phrases concerning the labelling of treated seeds

| French: | **Dutch:** | **English:** |
|---|---|---|
| La protection de ces semences est effectuée selon un niveau convenu de qualité industrielle. Pour votre propre sécurité et pour protéger l'environnement, les précautions suivantes doivent-être suivies :<br><br>En général:<br><br>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. | De bescherming van deze zaden wordt uitgevoerd volgens een overeengekomen industrie-kwaliteitsnorm. Om uw eigen veiligheid en het milieu te beschermen, moeten de volgende voorzorgs-maatregelen in acht worden genomen:<br><br>Algemeen:<br><br>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. | 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:<br><br>In general:<br><br>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.<br><br>Before sowing: Avoid exposure to dust when opening the bags and when filling or |

| | | |
|---|---|---|
| Conserver les semences traitées à l'écart de tout cours d'eau.<br><br>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.<br><br>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.<br><br>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. | 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 eventueel aanwezige stof uit de zaaizaadzak niet over in de zaaimachine. Behandel het reeds ontsmette zaaizaad niet met andere producten.<br><br>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.<br><br>Na het zaaien: Laat geen lege zakken of behandelde zaden onbedekt achter in het milieu. Verwijder ze volgens locaal geldende voorschriften. Zorg er voor dat restanten behandeld zaad weer in de originele zaken worden gedaan. Gebruik lege zaaizaadzakken niet voor andere doeleinden. | emptying the sowing equipment. Avoid the transfer of possible dust from the seed bag to the sowing equipment. Do not treat already treated seeds with other products.<br><br>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.<br><br>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

| French: | Dutch: | English: |
|---|---|---|
| Emballages vides et surplus de traitement<br><br>L'emballage de ce produit, soigneusement vidé, doit être rincé, soit 3 fois de suite à l'eau selon un système manuel (avec agitation), soit à l'aide du dispositif de nettoyage fourni sur le pulvérisateur. 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.<br><br>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 | Lege verpakkingen en spuitoverschotten<br><br>De zorgvuldig geledigde verpakking van dit product dient, ofwel 3 opeenvolgende malen gespoeld te worden met water, ofwel handmatig (met schudden) met behulp van het voorziene reinigingstoestel op de spuitmachine. 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.<br><br>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 | Empty packaging and product surplus<br><br>The carefully emptied packaging of this product must be rinsed, either three consecutive times with water manually (with shaking) or by using the provided cleaning system mounted on the sprayer. The obtained rinse water should be diluted approximately 10 times and should be sprayed on the already treated area in accordance with the instructions for use. The rinsed packaging must be handed in by the user to a foreseen collection point.<br><br>Do not contaminate ponds, watercourses or ditches with the product or the empty packaging. In no case may empty packaging be re-used for other purposes. To avoid surplus spray after the treatment, the required quantity of spray liquid must be accurately calculated, according to the area to be treated and the flow rate per hectare. |

| | | |
|---|---|---|
| quantité à appliquer, en fonction de la superficie à traiter et du débit par hectare. | spuitvloeistof nauwkeurig worden berekend aan de hand van de te behandelen oppervlakte en van het debiet per hectare. | |

# Annex 6

# INSTRUCTIONS FOR THE APPLICANT FOR AN AUTHORISATION OF 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 R.D. of 31 August 2007 (for contributions and remunerations) and the R.D. of 10 January 2010 (split of authorisations).

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

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

## 1.2. Objectives and content of the annex

This annex completes the "Guidance for the applicant for 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 use.

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

## 2.1. General provisions

The submission of applications for products for non-professional use does not differ fundamentally from applications for products for professional use 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 use may be submitted via three different channels:

- Zonal assessment with Belgium as zRMS;
- Zonal assessment with Belgium as cMS;
- 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 trade

A parallel trade permit may only be issued for a product for non-professional use if an identical product (reference product) is authorised for non-professional use 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 retribution 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 use. 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. Commercial name

The product's commercial 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 use

### Human health

In general, products that fall within one of the following risk categories may not be sold for non-professional use (see article 10/1 of the R.D. of 28/02/1994 as inserted by article 6 of the R.D. 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 (EC) No 1272/2008 (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**<br>Causes severe skin burns and eye damage |

| 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**:<br>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)<br>H360FD<br>H360D<br>H360F |

Products classified as Eye Damage Category 1 (H318) are authorised for non-professional use 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 risk of eye exposure when using the product is negligible. To our knowledge, there is

no standardised test for this purpose. If the risk of contact with eyes is negligible and if the risk assessment models show that the user's exposure is acceptable without wearing personal protective equipment (except gloves), the Committee may authorise the product for non-professional use. In that case, the phrase P280 "wear eye and face protection" (mandatory for products for professional use) will be replaced by precautionary statement P262 "Do not get in eyes, on skin, or on clothing".

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 use 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 use will not be authorised if this product contains an active substance that is classified as a Category 1A/1B carcinogen (H350), a Category 1A/1B mutagen (H340) or a Category 1A/1B reproductive toxicant (H360).

As for professional use, products for non-professional use cannot contain co-formulants 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 use:

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

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

- EFSA (AOEM) calculator model: hand-held-knapsack application refined for a treatment area of 0.05 ha/day (operator) and re-entry tasks of 2 hours/day (worker). For operator and worker risk assessment, only potential exposure without work wear should be considered.

- [older model:] English model (*UK_POEM Model*) in which the following data is introduced:
    - duration of application: 0.5 hour;
    - application equipment: "Home garden sprayer (5 litre tank). Outdoor, low level target";
    - 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);
    - container: "5 litre narrow closure" or “1 l container”

- 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)"

The Authorisation Committee is of the general opinion that only protective gloves may be imposed for handling and applying products for non-professional use. Therefore, products that – based on their intrinsic hazard (*e.g.* H318, H319, H317) – would require the precautionary statement P280 "Wear protective clothing and/or eye protection and/or face protection" are, in principle, forbidden for non-professional use. However, the Committee may grant the authorisation for such products if the risk assessment models show that the user's exposure is below the toxicological threshold values (AOEL and AAOEL) without the use of personal protective equipment (except gloves) and if the product's packaging is such that the risk of contact of the concentrate with the eyes or skin is negligible. The applicant may, for example, offer to market this product as a single-use hydrosoluble sachet. In such cases, the Committee may propose to replace the statement P280 with precautionary statement P262 "Do not get in eyes, on skin, or on

clothing". In some well-argued cases for certain micro-organisms, a dust mask (P3/FFP3) may exceptionally be accepted as personal protective equipment for handling and applying products by non-professional use. In that case the phrase P284 "Wear respiratory protection" is added.

### 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 lists of crops and enemies suitable for the non-professional uses presented on www.phytoweb.be (Search authorisations > Consult lists).

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
    - impermeable not cultivated area (paving, concrete, stabilised, roadbed, etc.)
    - permeable not cultivated area;
    - permanently not cultivated areas;
    - 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 (R.D. 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).

- Application dose
    - The application dose should be supplied for each application method and each use.
    - Doses concerning products for non-professional use are not expressed by "ha" or by "ha of hedge" but by $m^2$.
    - For treatments applied by spraying or by watering,, doses should be expressed in g/l spraying solution or ml/l spraying solution; as well as the number of l spraying solution needed per $m^2$, in order to be able to accurately estimate the amount of mixture to prepare. Expressing the dose per l of spraying solution is considered to be the standard, because it leaves flexibility for the user and prevents that the user is obliged to prepare too much mixture. Only in exceptional cases, the Authorisation Committee can consider to allow a larger amount of minimal spraying solution. It is important to note that the maximal content of most backpack sprayers available on the market is limited to 5 l. Therefore, **products for which the minimal amount of spraying solution to be prepared exceed a volume of 5 l, will no longer be accepted.**
    - For ready-to-use products sold or designed to be applied by a hand sprayer, the dose to apply needs to be expressed in the number of sprays or the number of seconds spent spraying per $m^2$ to be treated. It is important to note that for these types of products, the sprayer is considered to be a measuring device. As such, the amount of product delivered per spray needs to be determined by the applicant (see Annex 7 – determination of the precision of the measuring device).

    - For molluscicides (anti-slug granules), doses need to be expressed in granules/$m^2$ 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 use:

- 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 sprays per $m^2$. The same products sold in cans of 5 l or more and intended to be applied with a backpack sprayer, are considered to be concentrated products that require dilution. 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 R.D. 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 it 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 use are defined in article 10/1 of the R.D. of 28/02/1994 as inserted by article 6 of the R.D. of 10/01/2010 and have been stipulated by the Authorisation Committee. In order for authorisation applicants to assess the conformity of packaging and measuring devices they want to submit beforehand, a checklist has been drawn up which is included in annex 7.

The maximum volume of each package should not treat more than 5 ares (500 $m^2$), unless an exemption is granted after positive evaluation by the Authorisation Committee of the arguments provided by the applicant. The maximum surface area that may be treated

must be calculated for the main use taking into account 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 needs to be implemented by the applicant, who will provide its protocol and results to the efficacy experts. Reference is made to annex 7 for further details on how to implement the precision of the measuring device. For ready-to-use trigger sprays, the dispensed amount of product per trigger should be determined in a similar way in order to be able to convert the dose in ml/$m^2$ to a dose in number of triggers per $m^2$.

An empty sample of the packaging, accompanied by the label in actual size and colours, with final art-work and written in the national languages (NL + FR) needs to be provided with each authorisation request for a product for non-professional use. When different sizes of packaging are proposed, the project corresponding to the smallest size must be provided, in order to verify whether the used font size is still large enough to be easily read.

Information that cannot be provided digitally, such as the sample of the packaging, should be sent to the following address:

**FPS Health, Food Chain Safety and Environment**
**Service Plant Protection and Fertilising Products**
**Avenue Galilée 5/2**
**1210 Bruxelles**

The dossier number that of the specific application should always be clearly mentioned on every correspondence.

For all products authorised for non-professional use, 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 a retribution is required in order to cover administrative costs.

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 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" (e.g for 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** |
|---|---|---|
| **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. *Weed killer for roses* or *Soil insect repellent* are examples of simple phrases of use but NOT *Multi-purpose Fungicide*. 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. *Herbicide*, etc.). | Front face box and primary packaging | YES |
| **Package content** (net weight or volume) **and total surface area** that it can treat. | Front or rear face box and | YES |

| | | |
|---|---|---|
| | primary packaging | |
| **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. *concentrated suspension*). | | 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 Service Plant Protection and Fertilsing Products. | 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, active substance content, 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. *systemic insecticide against whitefly*), which enables users to be informed simply about the way in which the product works and to provide with details about any selectivity or phytotoxicity. | | YES |
| **Data concerning the dose**.<br>The application dose should be supplied for each application method and each use;<br>For treatments applied by spraying, express the doses in g/l or ml/l. Mention that the treatment should be applied to the point of runoff. In order to be able to accurately estimate the amount of mixture to prepare, indicate the number of l/m$^2$ required for this application. The minimum amount of spraying solution that needs to be prepared has to be 1 l, except for exceptions granted by the Authorisation Committee. However, products for which the minimal | | YES |

<table>
<tr><td>amount of spraying solution to be prepared exceed a volume of 5 l, will no longer be accepted.<br>For treatments applied to the soil by watering (herbicides, products against soil insects, etc.), provide the doses in g/l or ml/l. In order to be able to evaluate the amount of mixture to prepare, indicate the number of l/m$^2$ required for this application.</td><td></td><td></td></tr>
<tr><td>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.<br><table><tr><th>Crops</th><th>Pests</th><th>Dose</th><th>Period</th></tr><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></table></td><td>Rear face or side</td><td>YES</td></tr>
<tr><td>The phrase: 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.</td><td></td><td>YES</td></tr>
<tr><td>Other references: concerning buffer zones, for example</td><td></td><td>YES</td></tr>
<tr><td>A pictogram depicting a glove in the case of the non-professional risk assessment having shown that it was necessary to wear gloves.</td><td></td><td>YES</td></tr>
<tr><td>A pictogram identifying the product as designed specifically for non-professional users.</td><td></td><td>NO</td></tr>
</table>

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** |
|---|---|---|
| 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. | Rear face or side and primary packaging | YES |
| **User protection**<br>▪ Specific dangers: danger phrases and symbols<br>▪ If the product is classified as Acute Tox., Skin Corr., Muta. 2, Carc. 2, Repr. 2, Resp. Sens., STOT 1 or 2, Asp. Tox., Flam. Gas 1 or 2 , Flam. Liq. 1 or 2, Flam. Sol.: The packaging should bear a tactile warning of danger in accordance with section 3.2.2 of Annex II of Regulation (EC) No 1272/2008.<br>▪ Precautions for use: safety advice (phrases P: P102, P270, P501, P101 (if classified for health hazards) and other phrases imposed by the authorisation .<br>▪ First-aid instructions and telephone number of the Poison Control Centre (see First aid \| Phytoweb (fytoweb.be)) | Rear face or side and primary packaging | YES |
| **Environmental protection**<br>▪ Specific dangers: danger phrases and symbols<br>▪ SP1: Do not pollute water with the product or its packaging.<br>▪ Precautions for use: safety phrases and other phrases imposed by the authorisation specific to environmental protection.<br>▪ For all products applied on impermeable not cultivated areas, 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 |

| | | |
|---|---|---|
| **Storage**<br>▪ Specific dangers: danger phrases and symbols<br>▪ Precautions: caution advice (phrases P) | | YES |
| **Treatment of empty packaging and surplus**<br>▪ Other phrases imposed by the authorisation:<br>– SP1: Do not pollute water with the product or its packaging.<br>– P501: Discard the contents and the recipient at a dangerous or special waste collection centre. | | YES |

- **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.

**If the applicant decided to provide a syringe as measuring device, also a cleaning procedure to rinse the (inside of the) syringe needs to be described. This is because the inside of a syringe is more difficult to clean compared to a common measuring cup. Improper cleaning may result in product build-up and clogging of the syringe, especially with viscous products.**

- **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 use 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: 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 use and to allow the application of the correct dose of product, following conditions should be taken into account (for a full description of the requirements (including labelling), please also refer to Annex 6):

**Packaging:**

- The maximal content of each packaging should not allow to treat more than 5 ares (500 $m^2$) 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 (CRC closures).
- Aerosols must be sealed and protected with a cap.
- For bottles and bags: the provisions of art. 10/1 of the R.D. of February 28, 1994 as inserted by art.6 of the R.D. of the R.D. of January 2010 apply (bottle with security tap for liquids and solids or re-sealable bag for solids). However, **for small amounts (< 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) needs to be foreseen for solid products (powders or granules) commercialised in bags or boxes.

- 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 monodosis (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 conversion 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.
- If a syringe is provided as measuring device, a cleaning procedure to rinse the (inside of the) syringe needs to be described. This is because the inside of a syringe is more difficult to clean compared to a common measuring cup. Improper cleaning may result in product build-up and clogging of the syringe, especially with viscous products.
- 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.
- Only for specific cases, the use of a (micro)spoon and spatula can be considered acceptable as measuring cups. This will be evaluated by the Authorisation Committee on a case-by-case basis.

With each application for a new authorisation, a sample of the packaging, accompanied by the label in actual size and colours, with final art-work and written in the national languages (NL + FR) needs to be provided. When different sizes of packaging are proposed, the project corresponding to the smallest size must be provided, in order to verify that the used font size is still large enough to be easily readable.

Reminder: for all authorised plant protection products, packaging and measuring cups which will be commercialised in Belgium must correspond to those described on the authorisation certificate. The extension of the range of packaging authorised will need an evaluation for which a fee will be applicable.

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

**Test of precision for the measuring device and ready-to-use spray:**

For products to be used with a measuring cup, the precision of the measuring device needs to be determined. Results of the test together with the followed protocol have to be

submitted with the application. There is no imposed protocol/procedure that needs to be followed, but the following guidelines apply:

- The test is independently realised by at least three non-qualified people (corresponding to a gardener). These non-qualified people are to be asked to read the label and apply the product as indicated.
- Two reference doses (minimal and maximal) are measured with the measuring cup
- The accuracy of the weight or volume is verified with a balance.
- The maximum difference of weight or volume for each tested dose must be reported for at least three (technical) 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.

For ready-to-use trigger sprays, the dispensed amount of product per trigger should be determined in a similar way in order to be able to convert the dose in ml/$m^2$ to a dose in number of triggers per $m^2$. The content of e.g. 10 triggers should be collected in a recipient. By weighing and taking into account the density of the product, the volume per trigger can be calculated. The same general guidelines apply as for measuring cups, as explained above.