Gestautor

User Manual

« Application Form Generator »

Content

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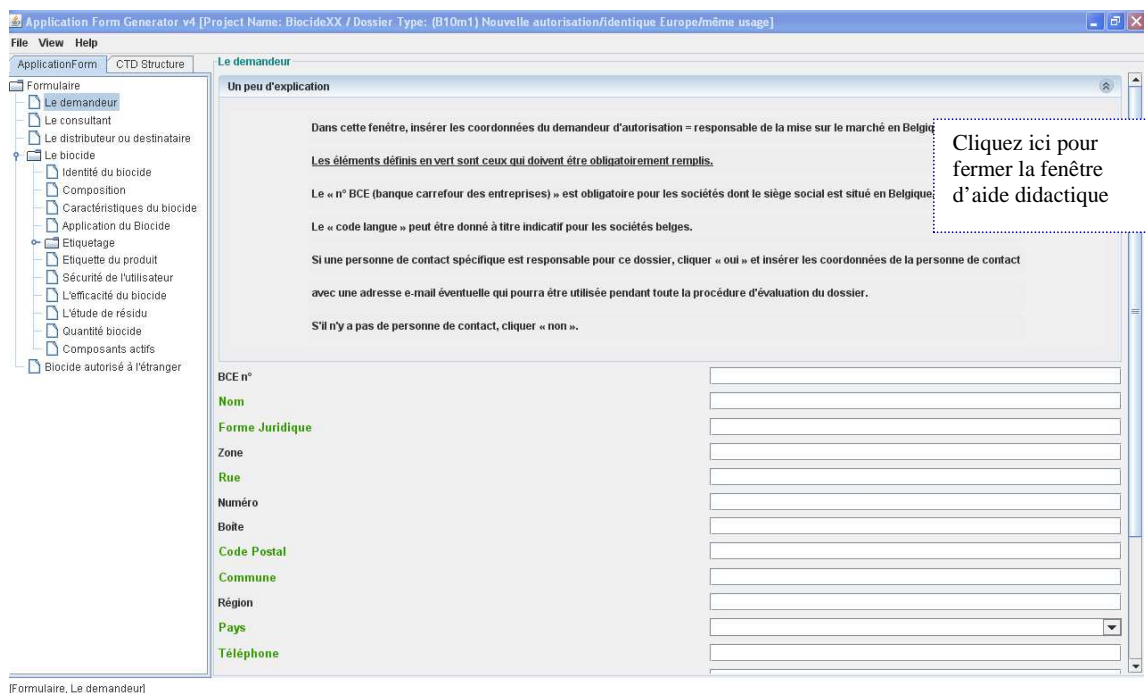HEALTH, FOOD CHAIN SAFETY AND ENVIRONMENT

A.   INTRODUCTION

THE "**APPLICATION FORM GENERATOR"** SOFTWARE HAS TO BE INSTALLED

LOCALLY ON YOUR PC.

That software will allow you to fill in the data required for your applications for authorisation concerning biocidal products (new application, renewal, extension, etc).

1. *Useful information*

There are "educational" help windows in each screen of the program. Those windows open by default but you can shut them if you don't need them.
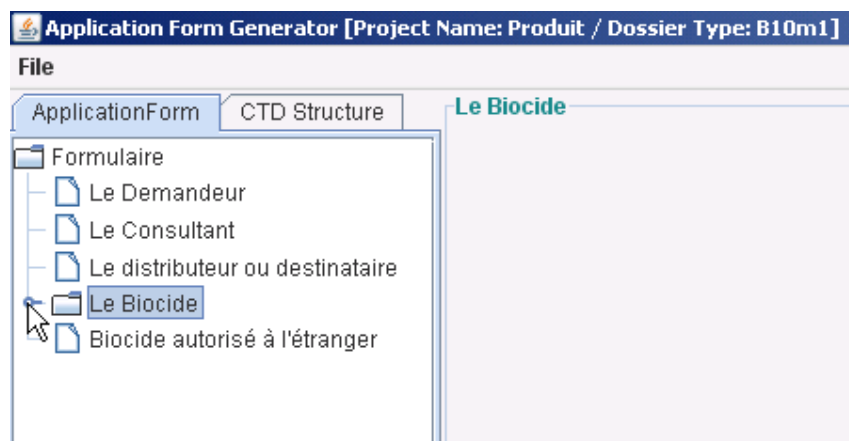

The different headings open by clicking the ⊗ button on the right side of the screen.

The different headings close by clicking the ⊗ button on the right side of the screen.

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To expand the tree structure, click ⊶ or double-click ⊶ 🗀 Le Biocide

This makes the different secondary headings appear on the screen.

2. How to add data to a table?

To **add or remove an** (active or inactive) **ingredient** in one of the tables above, you just have to click the "Ajouter"(add)/ "Supprimer" (remove) button to add or remove a line in the table.

Example

A new row appears in the "active substances" table where you can add data concerning a second active substance.

To add data to a column, click in the chosen cell.

nom substance en angl...	nom commercial	numéro CAS	teneur %age m/m	range	numéro CE	ID
POTASSIUM BENZOATE	Potassium	582-25-2	5	pas d'application	209-481-3	10475

Composants Actif (% m/m)

Supprimer   Ajouter

Caution: If you do not add data to a table, there will always be a visible empty row. You cannot delete that empty row.

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3. How to start

1) Click on the "Start" button (in the lower left corner of your computer screen), then choose "**Application Form Generator"** in the list of programs;
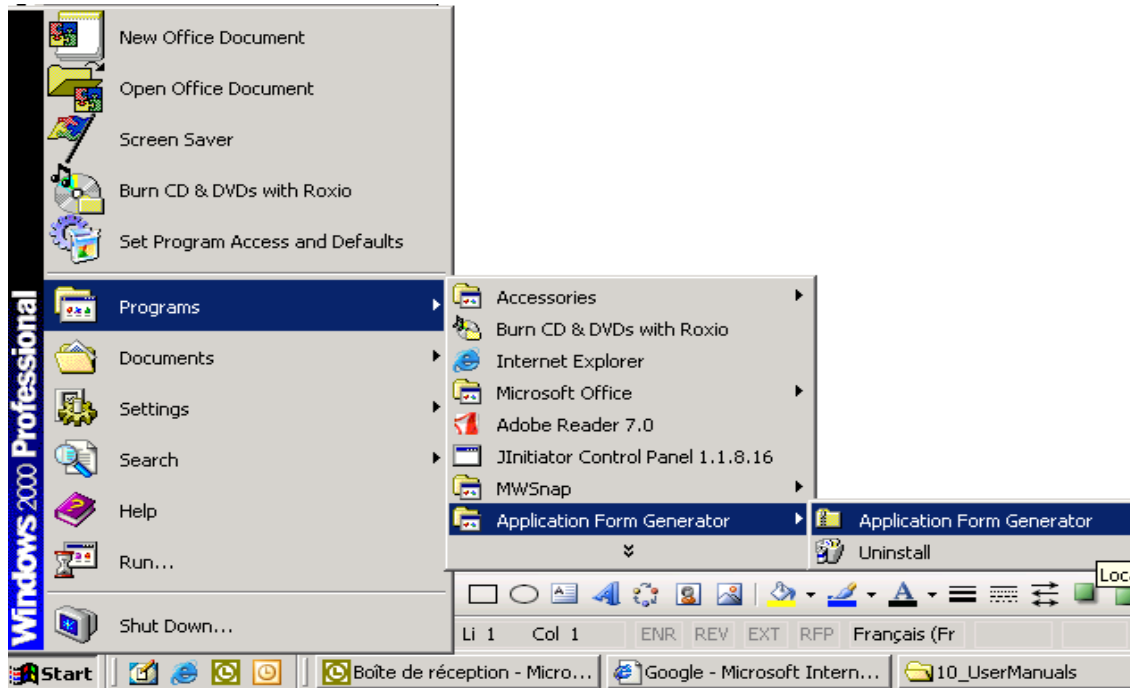
The program opens two different screens; the black screen must stay "OPEN". For more convenience, you may restore down the black screen and maximize the other one. (See arrow-pointer below)

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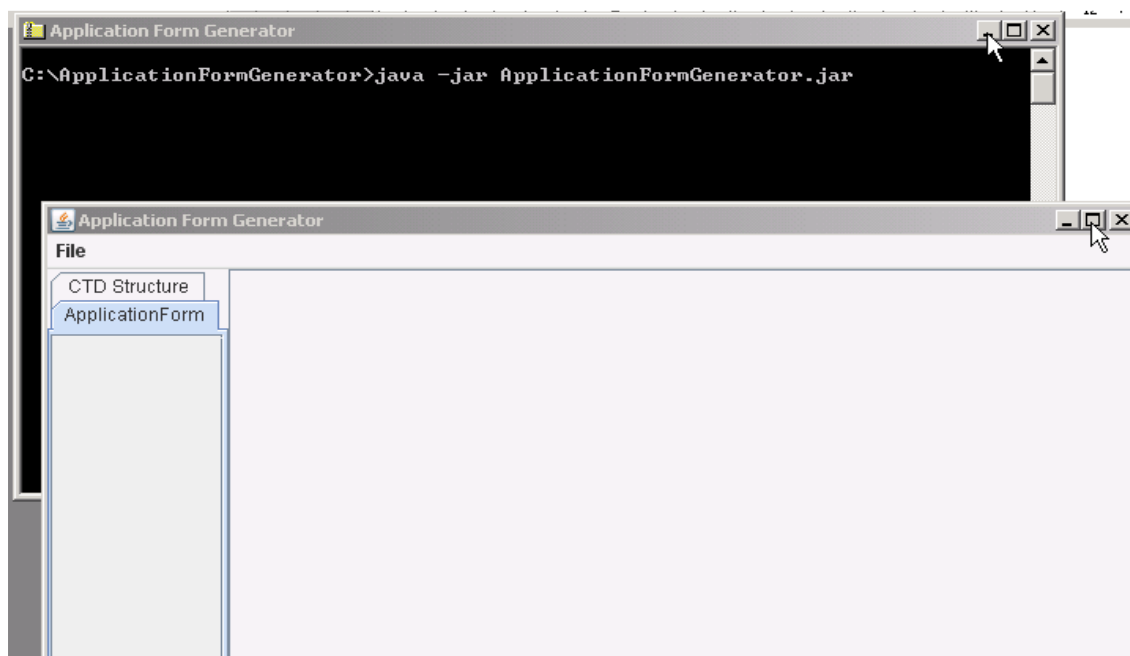
2) When the program is open, click on « file » and then « new »;
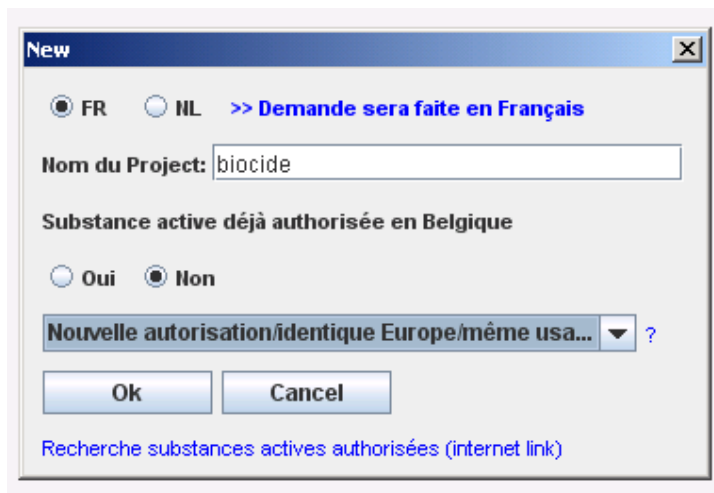
3) In the window that appears, (see below)

a) Choose the language of the application that will be submitted (French or Dutch). The language choice for the application is important because the chosen language will be used in all mail addressed to applicant as well as in the authorisation for the concerned product;
b) Enter the name of the project, e.g. the trade name of the product for which an application for authorisation is submitted;
c) Check if the active substance(s) in the submitted product is (are) already authorised in a biocidal product in Belgium. You can check this through the following link "recherche substances actives autorisées" (search authorized active substances). **!!Caution!!:** You cannot search these substances if you are not connected to the internet.
d) If the active substance(s) is (are) already authorised in Belgium, click **"Oui" (yes)**. If the active substance(s) is (are) not yet authorised in Belgium, click **"Non"** "**no"**);
e) Choose the type of file to be submitted in the scroll menu. If you want more details on the possible choices, click on the question mark (?);

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f) Click **OK** to generate the electronic form and begin completing the spaces on the form
    and adding the required files.
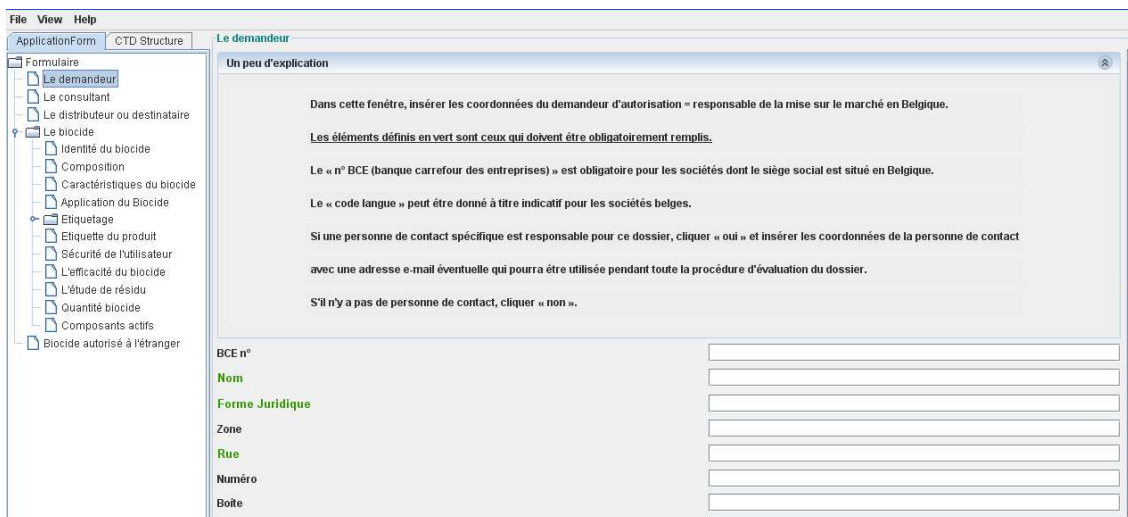
The above screen is the one where you will start entering the information required for your application
for authorisation.
As you can see, you have to complete different headings!
According to the application type (see window below), some of those headings do not appear in the
electronic application form as they are not necessary for that kind of application.

Please note that the **green** zones are <u>mandatory</u> in each form.

You can make the file structure disappear at any moment under Application Form. To make those files disappear, you have to use the Hide Tree option in the menu. That option is useful if you cannot see the complete form on one screen. If the file structure disappears, there is more space for the form.
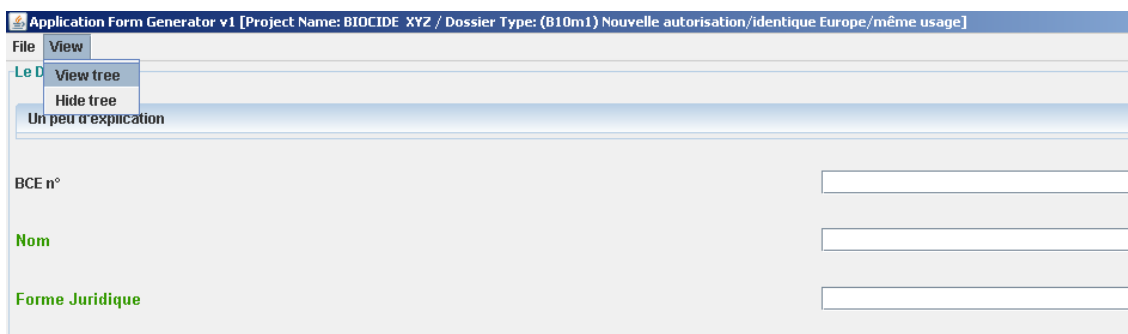
To make the file structure reappear, use View Tree option.

You can save the zones that have already been filled in at any moment by clicking on "**file"** and then **"save**".

When all form zones have been filled in, you must check that all those zones have been filled in correctly by clicking on "**file, complete**".
If some zones have not been filled in correctly, error messages will appear on your screen.

Example of an error message: 'Completion Error List'
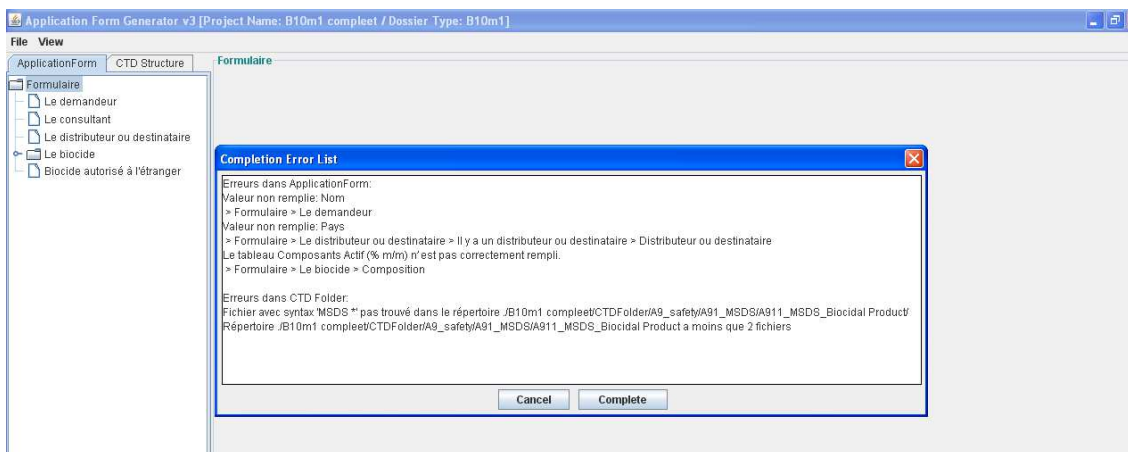
This example contains the following errors:

The errors in the ApplicationForm correspond with the errors made in the form:

- The value for the zone 'Nom' (name) has not been not filled in.
  The place where this zone is situated is mentioned in the next line.
  In this example, the compulsory zone 'Name' has not been filled in under "Formulaire > le demandeur".
- The table 'Composants actifs (% m/m)' has not been filled in correctly.
  This table can be found under: "Formulaire > le biocide > Composition". You will receive this message if one or several columns of a compulsory table have not been filled in correctly.

The errors in the « CTD Folder » correspond with errors regarding the files that are missing or the files that do not start with the name that is required.

- The files of which the names start with MSDS have not been found in directory CTDFolder/A9_Safety/A91_MSDS/A911_MSDS_Biocidal   Product.
  This directory must contain at least two of those files.
  The product's MSDS files are asked for in heading "Sécurité de l'utilisateur" (User safety).
  They must be added in both languages, that is in French **and** in Dutch.

It is not necessary to close the list of errors; you can move it on your screen and solve the problems one by one. When all problems have been solved, you have to click on 'Complete' until the message 'Complete successful' appears.

You can also close the list of errors and afterwards click on "**file→complete**".
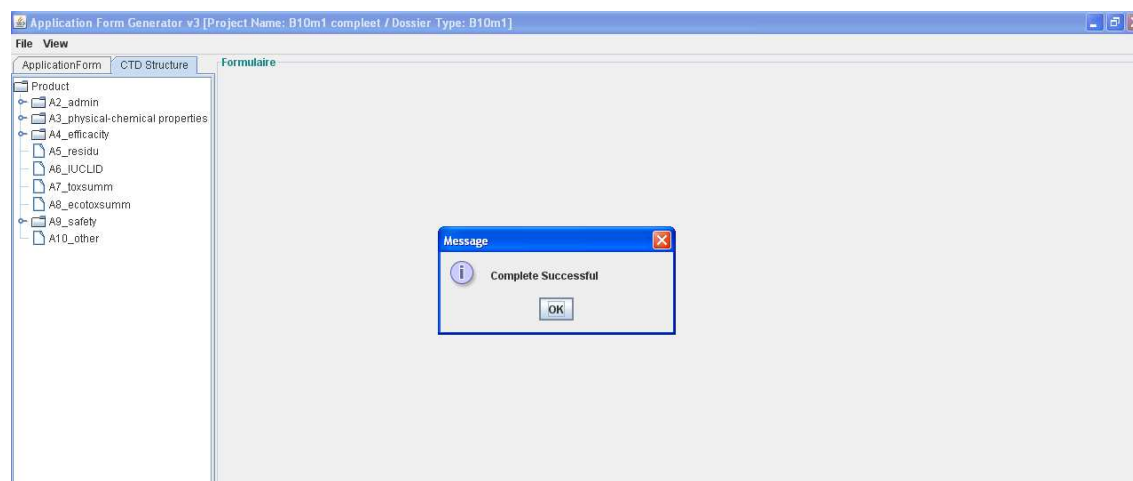
Once again, « green » zones are mandatory!!

At some stages, you have to add files. You can add those files by clicking on the window with a computer icon.

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Through that window, you have access to the different documents saved on your PC.
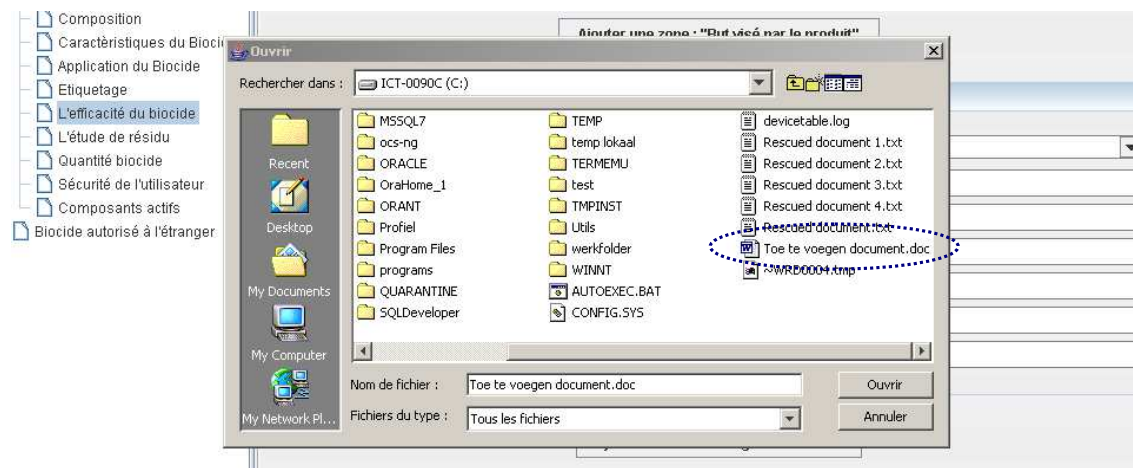
Click on the right file and then click on « Open » to add the file at the right place.

Caution! **File name has to correspond exactly (correct capital letters and small letters are important!) to the defined norms. You can see those names in the "educational" help windows at every place you have to add files.**

Note: **only the beginning of file names, as mentioned in the help panels, is controlled. You can choose the end of the file names. Example: mentioning numbers by safety data sheet added, …If you have to add several sheets, you must use that method because it is impossible to add a second file with the same name in the same folder.**

! Before you begin completing the electronic form, file names to be added should be determined with the correct name on your computer to make things easier!

If you want to add several documents at a time in the same heading, you can use the « shift » or « control » buttons to select several documents at a time.

Added files do not appear in the electronic form but only via the '**CTD Structure**'.

You have to go to 'CTD Structure' to see the documents that have been added to your application. You have no access to the content of the documents in Application Form Generator.
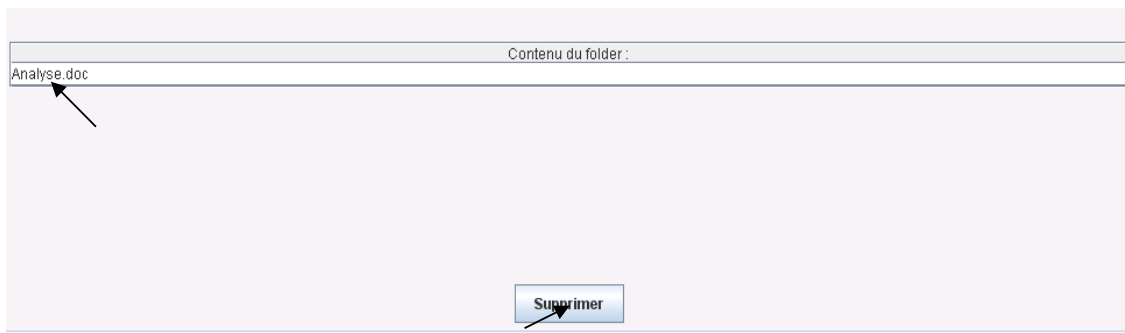
It is also there that you can delete an added file.

Here is a global view of 'CTD Structure':

Remark: if applicant wants to provide other documents that can be useful in assessing the application but that are not required in the electronic form headings, these documents must be added via 'CTD Structure' under A10_other.

4. Last steps

When the registration of your product's application for authorization is done, you can make a "zip"-file of it. Here is how you do that:

- Using 'windows explorer', go to the place where the program 'Application Form Generator' is installed.
- Select the folder with the same name as your project (as given when you opened the electronic form).
- With a right click of your mouse, open the pop-up menu and save the whole folder (CTD Folder + xml file) in "Zip" format by clicking on "Add to BiocideX.zip"
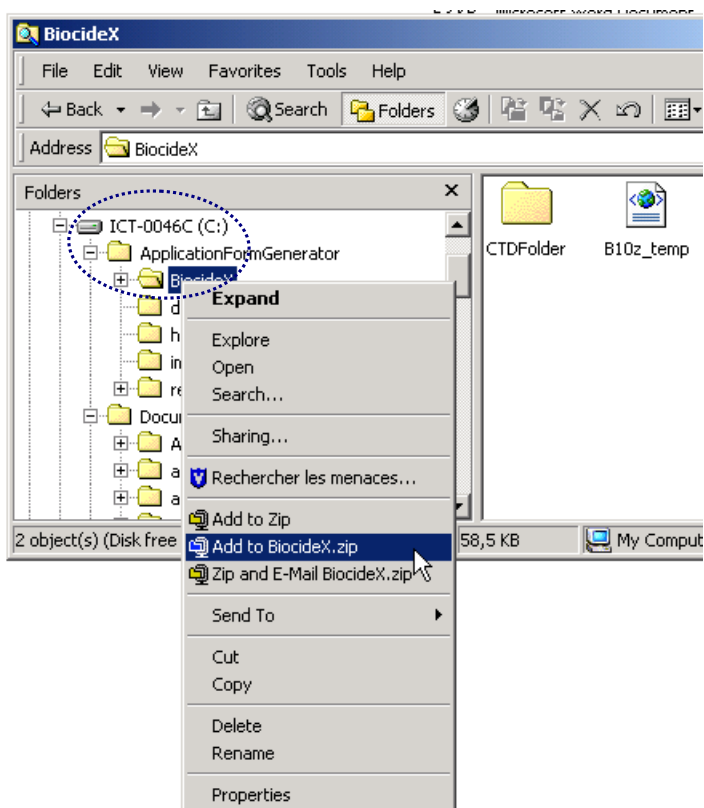
If your folder has been transformed into a zip-file, you can send it by e-mail to the following address: info.gestautor@health.fgov.be

If you prefer sending the electronic file by mail (post), you have to copy the whole folder on a CD. In that case, it is not necessary to create a zip-file!

B. COMPLETE FORM FOR ELECTRONICALLY SUBMITTING AN APPLICATION FOR AUTHORISATION FOR A BIOCIDAL PRODUCT

This part of the manual explains in detail the different headings for a new application for authorisation for a biocidal product.

For certain application types, the electronic form only contains the headings required for the chosen type of application and does not necessarily include all the headings listed below.

1. *The Applicant*

In this window, fill in the information of the authorisation applicant, which is by definition the person responsible for the putting on the market in Belgium.

The green elements are mandatory.

See screen below:

[Formulaire, Le Demandeur]

Additional explanation concerning that screen:

- « **BCE** n° » (Crossroads Bank for Enterprises number) is mandatory for enterprises with their head office in Belgium.

- « zone » may be filled in if the Belgian or foreign enterprise is installed in an industrial area.

- « **code langue** » (language code) can be filled in for information as far as Belgian enterprises are concerned.

- If a specific contact person is responsible for the application, click « **oui** » (yes) and fill in the contact person information, including an e-mail address if there is one. This address will possibly be used through the whole application assessment procedure. If there is no specific contact person for that application, click « **non** » (no) and go to the next heading.

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2. *The Consultant*

If a consulting enterprise is involved in submitting your application, click « **oui** » (yes). If there is no consulting enterprise involved, click « **non** » (no).

See screen below:

That heading should be filled in the same way as for the applicant, taking the following remarks into account:

- « n° **BCE »** (Crossroads Bank for Enterprises number) is mandatory for enterprises with head office in Belgium.

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- « **code langue** » (language code) can be filled in for information as far as Belgian enterprises are concerned.

- If a specific contact person, as a consultant, is responsible for the application, click « **oui** » (yes) and fill in the information of the contact person, as a consultant, including an e-mail address if there is one. This address will possibly be used through the whole application assessment procedure. If there is no specific contact person for that application, click « **non** » (no) and go to the next heading.

3. *The Distributor or Addressee*

This heading is **mandatory** for foreign enterprises with head offices in the European Union using one or more Belgian distributors or addressees to put their product on the market in Belgium.

This heading is **optional** for Belgian enterprises using one or more Belgian distributors or addressees to put their product on the market.

If there are one or more distributors or addressees, click « **oui** » (yes). If there is no distributor or addressee, click « **non** » (no).

See screen below:

If several distributors or addressees are involved in the putting on the market of that product in Belgium, click then on « ajouter une zone : **distributeur** ou **destinataire** » (Add a « distributor or addressee » field).

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4. The Biocide

4.1 Heading "Identité du biocide" (biocide identity)

Under "dénomination commerciale" (trade name)

In this window, fill in the trade name of the product in French, Dutch and German (if there is one). If the trade name is the same in all three languages, fill in the three fields with the same name.

The name should not contain one or several of the following characters: \ / : * ? " < > |

If the name of your product contains one of those characters, you must mention this in an annexed document. Document to be added in folder A10_other.

If the product has been given a code name and if that code is in the testing reports/documents that have been submitted, enter that code here so that the link can be made between the code and the application product.

Dénomination commerciale française	
Dénomination commerciale néerlandaise	
Dénomination commerciale allemande	
Nom de code	

Under "fabricant" (producer)

If the information concerning the producer head office is not different from the information concerning the applicant for authorisation, click « **non** » (no) next to that question. In this case, you nevertheless have to open the heading « coordonnées du siège social du fabricant différentes de celles du demandeur » (head office of producer information different from applicant information) and then enter the branch unit number ("numéro d'unité d'établissement") as defined by the Crossroad Bank for Enterprises.

If the information concerning the producer head office is different from the information concerning the applicant for authorisation, click « **oui** » (yes) and fill in the fields in the window.

Fill in the table above in the same way as the previous headings, taking the following remark into account:

- « n° **BCE »** (number in the Crossroads Bank for Enterprises) is mandatory for enterprises with head office in Belgium.
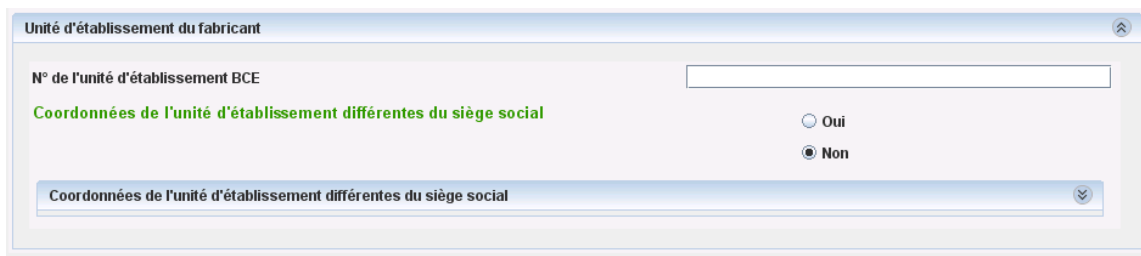
- « **code langue** » (language code) can be filled in for information as far as Belgian enterprises are concerned.

Under "Unité d'établissement du fabricant" (producer branch unit number)

As far as Belgian enterprises are concerned, enter the branch unit number of the producer as mentioned in the Crossroads Bank for Enterprises (**CBE**).

If the branch unit information is not different from the head office information, click « **non** » (no) and go to the next heading concerning the biocide « **composition** ».

If the information concerning the branch unit is different from the information concerning the head office, click « **oui** » (yes) next to that question and fill in the window below where you have to enter the information concerning the branch unit.

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Unité d'établissement du fabricant

N° de l'unité d'établissement BCE

Coordonnées de l'unité d'établissement différentes du siège social

○ Oui
○ Non

Coordonnées de l'unité d'établissement différentes du siège social

Champ	Valeur
Nom	
Zone	
Rue	
Numéro	
Boîte	
Code postal	
Commune	
Région	
Pays	▼
Téléphone	
Fax	
E-mail	
Code langue	▼

4.2 "Composition"

Under "Analyse" (analysis)

Add here the analysis report justifying the active substance(s) concentration contained in the product. The analysis must be made by an independent laboratory on the product submitted for application. The **original** analysis report must be sent by mail (post).

The name of the file that will be added must begin with: Analyse (file visible under CTD Structure, A32_comp)

Under "Composants" (substances)
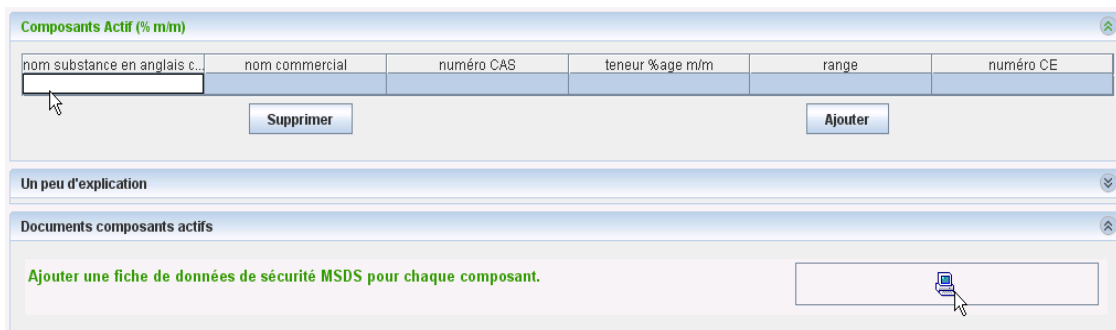
Fill in the following tables listing all substances contained in the biocidal product, i.e. active substances (predefined list), non active substances (predefined list) and, if necessary, non active substances that are not listed.

The concentration of the different ingredients must be expressed in % m/m (mass/mass).

! All ingredients of the product must be registered until the product total percentage reaches **100 %.**

Under "Composants Actifs" (active substances)

To add data to the table, you have to click on the left mouse button on the field where you want to enter a value.

Here is how you complete the table:

1. First, enter in one of the three following columns the **active substance name in English** OR its **CAS** number OR its **EC** no. Example: if you choose to fill in the active substance name, it must correspond to the notification name as registered in the European lists. You can enter the name in small letters or in capital letters. When the name is found, the system will transform the name automatically into capital letters.
When you have completed <u>one</u> of those three columns, the system will automatically search in the substance list and fill in the 2 other columns.
Check if the substance found corresponds to the right substance.
The Column ID is also filled in by the system. This ID is used to identify the substance in the Gestautor system.

2. Enter manually the **trade name** of the selected active substance.

3. In the « *Teneur %age m/m* » (content percentage m/m) column, enter the concentration of each active substance (% m/m) contained in the product.
If there is a concentration range/margin, "**pas d'application" (does not apply)** must be written in that field and the « **range** » column has to be filled in.

4. The « *range* » column only has to be filled in if there is concentration range/margin and when only one concentration value cannot be given for the active substance.
If that range does not apply to your product, write « pas d'application » in that column.

As explained above, if your product contains several active ingredients, add the needed number of rows using the "ajouter" (add) button. If you want to delete a needless row, click on "supprimer" (delete).

Important remark: Several substances on the predefined list of active substances may have the same CAS number and the same EC number but totally different notification names. In that case, you will have to search by active substance name and not by CAS number and CE number. The reason ifs that if you search by CAS number or CE number, the system will choose the first substance it finds in the list, which will not necessarily correspond to the right substance.

Under "documents composants actifs" (active substances documents), add the safety data sheets for each active substance contained in your product using the computer icon.

The file name must begin with: MSDS (substance name) (file visible under CTD Structure, A912_MSDS_Active Substances)

Under "Composants Non-Actifs" (non active substances)

Just like for active substances, the concentration of the different ingredients must be expressed in % m/m (mass/mass).

The table must be filled in like the one for active substances, except that there is an additional field:''**fonction dans le biocide**'' (function in the biocide) that you have to fill in by choosing a function in a scroll menu.

If you choose "**autre**" (other), specify the real function of that substance in the "remarque" (remark) field. But if you choose a defined function in the scroll menu, write "pas d'application" (does not apply) in the "**remark**" field.

Non active ingredients that do not appear in the predefined list must not be added here but in the table below.

Under "**documents composants non-actif**s" (non active substances documents), add the safety data sheets for each non active substance contained in your product using the computer icon.
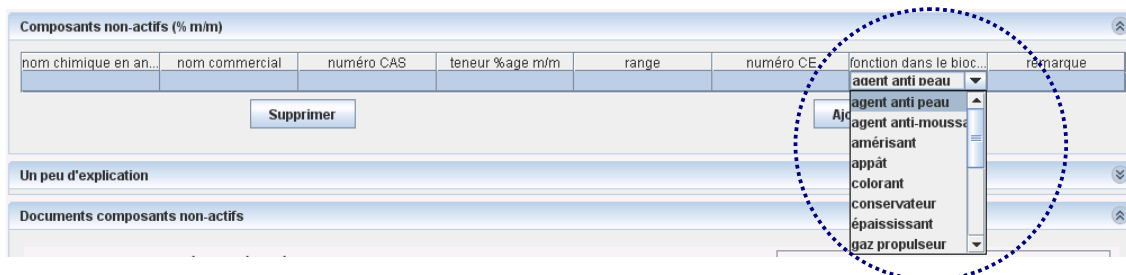
The safety data sheets that must be added here are those corresponding to the substances added under the table "Composants Non-Actifs" (non active substances) coming from a predefined list.

The name of the file must begin with: MSDS (substance name) (file visible under CTD Structure, A913_MSDS_Non_Active Substances).

Under « Composants Non-Actifs pas définis dans la liste » (= non active substances that are not in the predefined list)

The concentration of the different ingredients must be expressed in % m/m (mass/mass), just like for the « **composants actifs et non-actifs** » (active and non active substances).

The table must be filled in like the one for other ingredients. Every field in the table is mandatory. If you think that one of the fields is not necessary for a certain substance, please write "pas d'application" (does not apply) in the corresponding field.

In this particular case, you must fill in the chemical name, the **CAS** number and the **EC** number manually and there is no automatic search made by the programme, as there is no predefined list.

All substances contained in the product must be registered until the **total percentage** reaches **100 %**.

Under « Documents Composants Non-Actifs pas définis dans la liste » (= documents concerning non active substances that are not defined in the list), add the safety data sheets for each non active substance contained in your product using the computer icon. The safety data sheets that must be added here are those corresponding to the substances added under the table "Composants Non-Actifs pas définis dans la liste" (non active substances that are not defined in the list).

The file name must begin with: MSDS (substance name) (file visible under CTD Structure, A913_MSDS_Non_Active Substances).

nom chimique ou aut...	nom commercial (no...	numéro CAS	teneur %age m/m	range	numéro CE	fonction dans le bioci...	remarque

Composants Non-Actif pas définis dans la liste (% m/m)

Supprimer   Ajouter

Documents composants non-actifs

Ajouter une fiche de données de sécurité (MSDS) pour chaque composant

4.3 "Caractéristique du biocide" (biocide characteristics)

All details in this heading must be submitted.

If you cannot give one or more values for the product, complete « **pas d'application** » in the concerned field(s). In that case, join a letter for each of those missing values explaining the reasons why no value could be given. Such a letter must be added via CTD Structure, A10_other, and must begin with the name: Argumentation (biocide name).

To get a definition of the different parameters mentioned above and to know which tests are necessary to obtain the required values/data, please consult the « Technical Guidance Document in support of the Directive 98/8/EC concerning the placing of biocidal products on the market. Guidance on data requirements for active substances and biocidal products » (http://ecb.jrc.it/biocides/).

As far as the physical state of the biocide is concerned, just mention the formulation type, based on a coding system harmonised at international level which is already used for pesticides. You will find those codes in the « Manual on Development and Use of FAO Specifications for Plant Protection Products » which is based on the « Catalogue of pesticide formulations types and international coding system ».

You will find a list of the codes on http://www.fytoweb.fgov.be/FR/DOC/INLEIDING/Formuleringstype.htm . For a detailed description of the codes, please consult the following internet site http://www.insah.org/protectiondesvegetaux/csp/Annexe2.pdf.

If you cannot find any suitable code for your biocide, you can choose "autre" (other) in the scroll menu. In the "explication en cas d'autre" (explanation if "other") field, give a brief description of your product's physical appearance.

Concerning the product storage stability and its shelf-life, first indicate the shelf-life of the product (i.e. 1 year, 6 months,…) and then add one or several stability tests made on the product submitted for application , using the computer icon. Each test that is submitted has to establish the asserted shelf-life.
The name of the file must begin with: "Stabilité" or "Stabiliteit" (file visible under CTD Structure, A31_stab)

The « **caractéristique technique** » (technical characteristics) field depends on the product type that has to be examined. Some additional technical characteristics can be submitted to allow a better evaluation of certain formulation types.
(example: flowability, wettability, surface tension, suspensibility, emulsion stability, …).

If no additional technical characteristic is required for the product type submitted, indicate « **pas d'application** » (does not apply) under this heading.

The « **incompatibilité** » (incompatibility) field only has to be completed when the product cannot be mixed with specific substances or in the case of a mixture with 2 products. If this is not the case, indicate « **pas d'application** » (does not apply) under this heading.
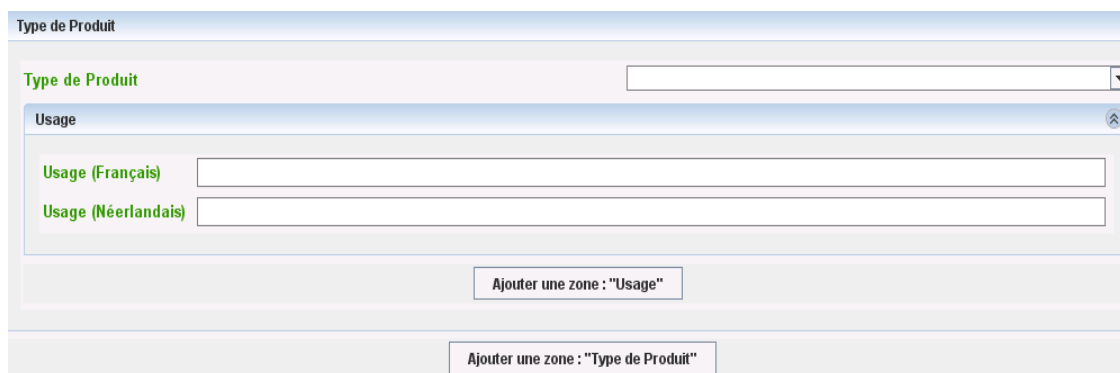
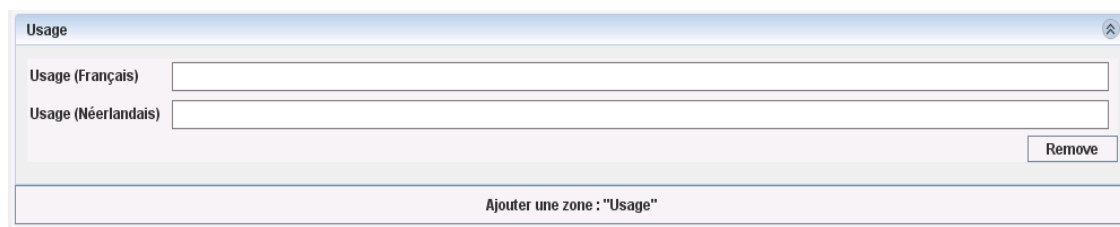Remark: if you have to fill in exponential values, please use the following form: 10 E -6 (instead of 10 $^{-6}$)

4.4 "Application du biocide" (biocide application)

Indicate in this window the product types for which the application for authorisation is submitted.

Fill in one product at a time using the scroll menu and describe in detail, for each product type selected, the desired use(s) for that product in French and Dutch.

If there are different possible uses for a selected product type, click on « **ajouter une zone 'Usage'** » (Add a 'Use' field) so that you can describe another use for that product in French and Dutch.

If there is a second product type for the concerned product, click « **ajouter une zone type de produit** » (add a 'product type' field) so that you can select the 2nd product type and describe the use(s) in French and Dutch.

Under 'Description du biocide par type d'utilisateur' (biocide description by type of user), there are two possible choices:

- Class A = product that may only be sold by registered sellers to approved or professional users

- Not classified = product sold to the general public and/or professionals without particular reseller/user registration

Attention: You must complete the classification twice: a first time using a list and a second time through indicating the class.

If the product is a « class A product », the system will automatically complete « utilisateur professionnel : **ou**i » (professional user: yes) as the product is a class A product.

Then you have to open the « utilisateur professionnel » window and fill in the following items:

- under « **emballage** » (packaging), complete table as follow, for all possible packaging of your product:

- "Unité" (unit) : choose from the proposed scroll menu (kg, g, l, ml)
- "Nombre" (number) : indicate the packaging capacity (content)
- "sorte" (type): choose from the proposed scroll menu. If nothing corresponds to the product packaging, choose « **autres** » (other) and complete the field « **emballage non standard** » (no standard packaging)
- "Emballage non standard" (no standard packaging): to be completed only if it is a special packaging that does not appear in "**sorte**".
  If it is a standard packaging, indicate in this field: "**pas d'application"** (does not apply).
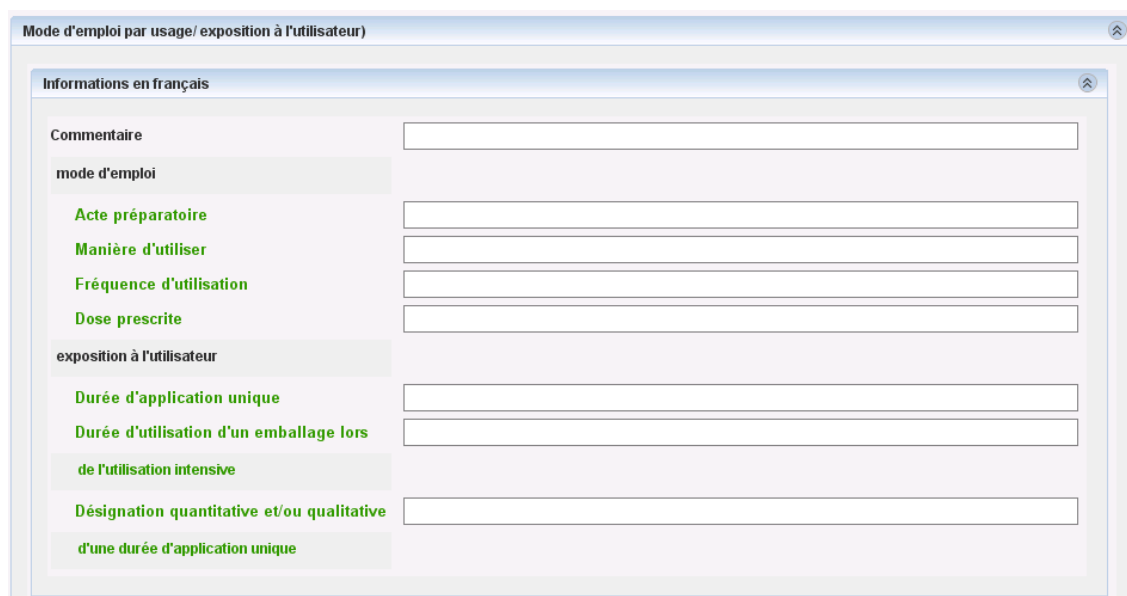
- under "**mode d'emploi par usage/exposition à l'utilisateur**" (instructions by use/exposure to user), fill in all fields under this heading in a very detailed way in French and Dutch.

Add as many « **mode d'emploi par usage/exposition à l'utilisateur** » fields as necessary.

!! It goes without saying that the number of additional fields to be added will depend on the number of (professional) uses defined at the level of the chosen product types at the top of the window.

Remark: The packaging period of use in case of intensive use has to be completed <u>for each type of packaging</u> defined in the packaging table.
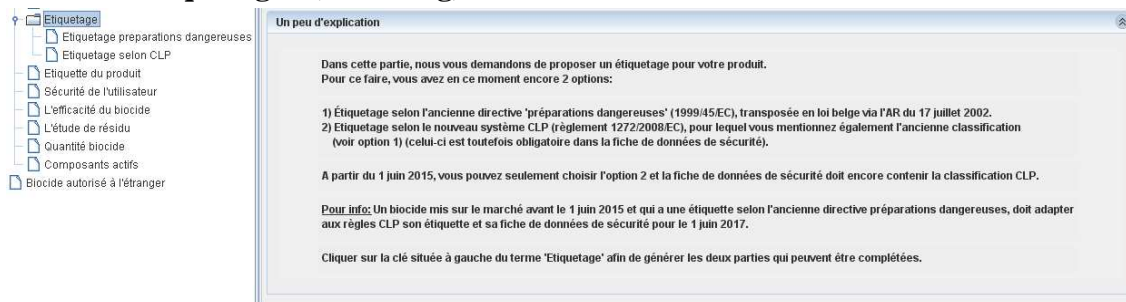

If the product is not classified ("pas classé"), choose the concerned type of user: professional user and/or general public by ticking "**oui**" (yes) or "**non**" (no) where required.

Open appropriate windows and fill in as described above for "**emballage**" (packaging) and "**mode d'emploi/exposition à l'utilisateur**" (instructions by use/exposure to user).

4.5 "Etiquetage" (Labelling)

a) "Etiquetage" (Labelling) according to the old directives 'Préparations dangereuses'
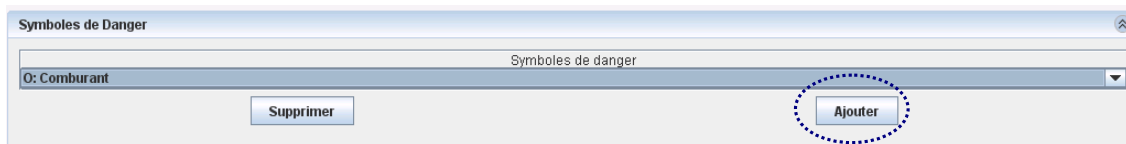
Under "symboles de danger" (danger symbols):

Indicate the danger symbol(s) to be attributed to the product using the scroll menu. Click on the line with your mouse to activate the scroll menu.

If several danger symbols correspond to the preparation, insert additional zone(s). To add zones, click "Ajouter" (Add).
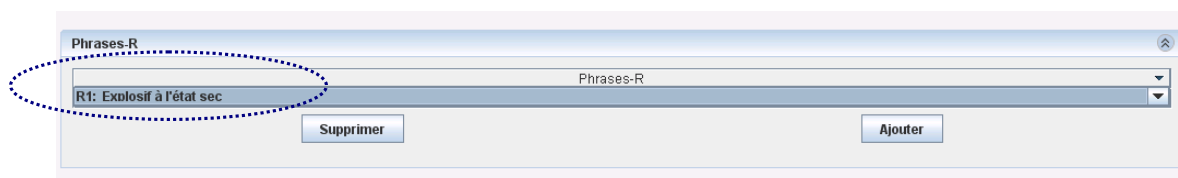

If no danger symbol applies to the submitted product, do not complete the zone.

Under "phrases R" (R phrases):

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Indicate the risk phrase(s) (R) to be attributed to the submitted product using the scroll menu.
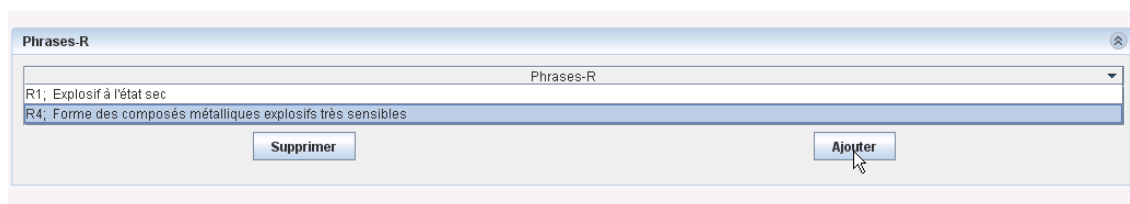
If several R-phrases apply to product, insert additional zone(s) using the "Ajouter" (Add) button.

If no R phrase applies to that product, do not complete the zone.

Under "phrases S usage professionnel" (S phrases for professional use):

If your product is meant for professional use, complete the following heading where you have to fill in the security (S) phrase(s) to be attributed to the product for its professional use.

For some S phrases the title is not complete and specifications typical of the product have to be added by the producer. As far as those phrases are concerned, add those specifications where required in French and in Dutch.

If several S phrases for professional use correspond to the product, insert one ore more additional zones using the "Ajouter" (add) button.

If no S phrase for professional use applies to that product, do not complete that field.

Under "phrases S usage grand public" (S phrases for use by the general public):

Complete the table following the same principles as for the S-phrases for professional use, but only if your product is meant to be used by the general public.

Remark: Choosing the type of user under the heading "biocide application" (professional and/or general public) automatically determines which "S-phrases" fields have to be completed under the heading "etiquette" (labelling).
Example: if you choose "professional user" for your product under "biocide application", you only have to fill in the part on "S-phrases for professional use" under the heading « étiquette » (labelling) and not the part concerning "S-phrases for use by the general public".

  b) "Etiquetage" (Labelling) according to the new CLP system

Under "Classes et catégories de danger" (Hazard Classes and Categories):

Indicate the danger classes and categories with the corresponding danger picture to be attributed to the submitted product using the scroll menu.
If several danger classes and categories apply to your product, insert additional zone(s) using the "Ajouter" (Add) button.
If no danger classe and category apply to your product, do not complete the zone.

Under "Mentions de danger et mentions d'avertissement" (H-Statements and signal words):

Indicate the H-statements and signal words to be attributed to the submitted product using the scroll menu.

If several H-statements and signal words apply to your product, insert additional zone(s) using the "Ajouter" (Add) button.
If no H-statement and signal word apply to your product, do not complete the zone.

For some H-statements and signal words the title is not complete and specifications typical of the product have to be added by the producer. As far as those phrases are concerned, add those

specifications where required in French and in Dutch. (e.g. H350… (*mentionner les voies d'exposition*)).

Under "Mentions de danger supplémentaires" (EUH-Statements):

4.6 Label of the product

Under "Projet d'étiquette" (labelling project), insert a labelling project for your product using the computer icon.
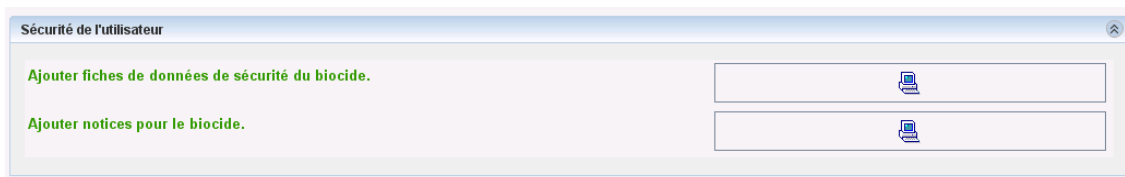
If your product is meant for professional use and for use by the general public, you have to add a labelling project for each of the concerned uses in French and in Dutch.

The names of the files must begin with: "Etiquette professionnelle", "Etiquette grand public", "Etiket groot publiek" or "Etiket professioneel" (files visibles under CTD Structure, A92_label).

Pour rappel, the labelling project must include all the elements required by Articles 39 and 40 of the Royal Decree of 22 May 2003.

4.7 "**Sécurité de l'utilisateur**" (user safety):

Under this heading, add a **safety data sheet** for the submitted biocidal product using the computer icon. The safety data sheet must be added in French and in Dutch.

The file name has to begin with: MSDS (biocide name) (files visible under CTD Structure, A911_MSDS_biocidal product)
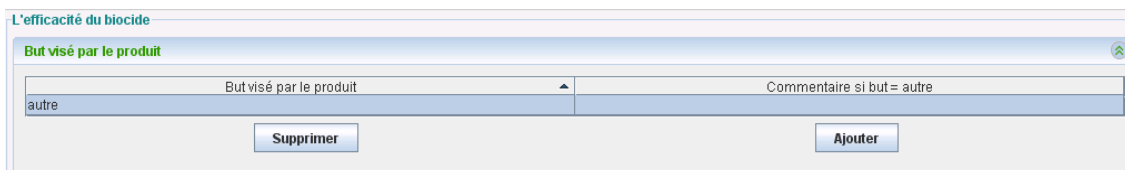
You also have to add a first aid **leaflet** in compliance with the writing instructions given by the Poison Centre ("Centre antipoison"). You can get those instructions as well as the form concerning the leaflet by following this link. You can find the first aid writing instructions below on that page (Word file) and the form concerning the leaflet (Excel file).

When you write that leaflet, it is important that you adhere to the lay-out imposed by the Poison Centre. The leaflet has to be added in French and in Dutch using the computer icon.

The file name has to begin with: « Notice » or « Bijsluiter » (files visible under CTD Structure, A93_notice)

4.8   "Efficacité du biocide" (biocide effectiveness):

Under "But visé par le produit" (product goal):

Insert in this window the product goal(s) using the scroll menu. If the product has several goals, insert additional zone(s) using the "Ajouter" (add) button.

If the product goal does not correspond to a predefined choice, select "**autre**" (other) and explain why in the comment field.

Under "organisme cible" (target organism):

Organisme cible

Organisme cible	▼
Effets sur l'organisme cible (Français)	
Effets sur l'organisme cible (Néerlandais)	
Effets secondaires indésirables ou involontaires (Français)	
Effets secondaires indésirables ou involontaires (Néerlandais)	
Commentaire si autres organismes cibles (Français)	
Commentaire si autres organismes cibles (Néerlandais)	

Ajouter une zone : "Organisme cible"

Fill in the data required under this heading. ("organisme cible visé" (targeted organism), "effets" (effects) and "effets secondaires" (secondary effects)). If an organism targeted by the product does not appear in the predefined list of target organisms, choose "autre" (other) and complete the field "commentaire si autres organismes cibles' (comment if other target organisms) in French and Dutch.
If your product is effective against several target organisms, insert an additional zone by clicking "ajouter une zone : organisme cible" (add a zone: target organism).

Under Efficacité et résistance (Potency and resistance):

L'efficacité

Ajouter les rapports de test d'efficacité.

Résistance

Ajouter les rapports de test et documentation concernant la résistance.

As far as "**efficacité**" (potency) is concerned, join all potency test reports concerning the biocidal product using the computer icon. Each target of the product has to be established by potency testing. The tests must be carried out on the submitted product and a comprehensive description of the testing method is required.

The name of the file(s) must begin with : « Efficacité » ou « Werkzaamheid » (files visible under CTD Structure, A41_eff).

As far as "**résistance**" is concerned, data concerning the product possible resistance to active substances are asked. The data may come from testing results from tests carried out on products in the same product type or from literature.

The name of the file(s) must begin with: « Résistance » ou « Resistentie » (files visible under CTD Structure, A42_resist).
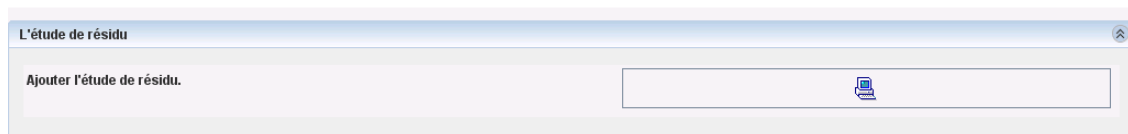
4.9 « étude de résidu » (residue study):

A residue study is mandatory for biocides when their use can lead to residue in foodstuffs, drinks or food intended for animals (e.g. products of type 3 (stall disinfectants), 4 (disinfectants used in the food sector), 8 (wood used in food transport), 18 (for insecticides used in stalls or on cattle when there is a possibility that actives substances are found in meat and/or milk and/or eggs, …).

If your product is intended for the above uses, you have to add a residue study on the submitted product to your application file, using the computer icon. If your product is not intended for the above applications, do not complete that heading.

The name of the file(s) must begin with: « Résidu » or « Résidu » (file visible under CTD Structure, A5_residu)

L'étude de résidu	
Ajouter l'étude de résidu.	🖳

Example : For type 3 and type 4 products: you have to provide a study on the residue quantities remaining on surfaces that have been in contact with the above mentioned foodstuffs after using the product.

Kind of study that you have to submit: In the residue study, different materials (like stainless steel, glass or other material used in food (-processing) industry have to be treated according to the product instructions for use. Those materials are then rinsed several times.
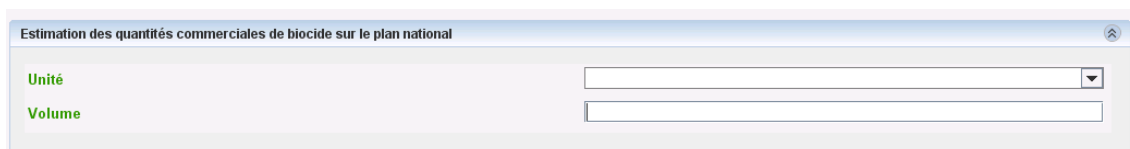
The first and second rinsing water will then be analysed to determine the quantities of remaining active and non active substances in that rinsing water.

If those quantities are small enough or under the detection limit, one can conclude that there is no risk for the consumer.

4.10 "**Quantité biocide" (biocide quantity**):

In this window, give an estimation of the commercial quantities that will yearly be put on the Belgian market for the submitted biocidal product.

Estimation des quantités commerciales de biocide sur le plan national	
Unité	▼
Volume	

Under "Unité" (unit): choose unit of measurement (ex. : l, kg, …)
Under "Quantité"(quantity): give a figure

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4.11 "**Composants actifs" (active components)**

In this window fill in the properties of each active substance present in the biocidal product. Insert the name of the first active substance contained in the product, based on the same principle as the one used to fill in the table under "Composition". Just fill in its **name** or its **CAS number** or its **CE number** and the two other values automatically appear in the table.

We remind you that the names on the list correspond to the names as they appear on the European lists of notified substances (in English, capital letters).

Composants actifs		
Un peu d'explication		
Composants actifs		
Composants Actif (% m/m)		
nom substance en anglais comme notifié	numéro CAS	numéro CE

Under "Le fabricant" (producer), fill in the required data:

If the active substance producer also is the applicant for authorisation, answer "**non**" (no) to the question. Nevertheless open the window "le fabricant est autre que le demandeur" (producer is not the applicant) and directly fill in the branch unit number ("numéro d'unité d'établissement").

If the active substance producer is not the applicant for authorisation, answer « **oui** » (yes) to the question. Open the window "le fabricant est autre que le demandeur" (producer is not the applicant) and directly fill in all the required data.

In that case, you have to add an **access letter** from the active substance producer. With this letter, the active substance producer grants access to toxicological/ecotoxicological data he owns to applicant. That access would preferably refer to the IUCLID data concerning that active substance that have been given for the notification or the European file summary submitted to the different Member States when it has been declared admissible by the reporting Member State. The **original** access letter has to be sent by post.

The file name has to begin with: "Lettre d'accès (substance name)" or "Toegangsbrief (substance name)" (file visible under CTD Structure, A26_access).

Then fill in the active substance **producer's data**, i.e. the head offices data.

The "**BCE** n°" (Crossroads Bank for Enterprises number) is mandatory for enterprises with their head offices in Belgium.

The "code langue" (language code) can be filled in for information as far as Belgian enterprises are concerned.

Under "Unité d'établissement du fabricant" (producer branch unit number), fill in – for Belgian companies – the producer branch unit number as defined in the Crossroads Bank for Enterprises (BCE).

If the branch unit data are the same as the head office data, click "**non**" (no) and go to the following heading ("caractéristiques") concerning the properties of the active substance.

If the branch unit data are different from the head office data, click "oui" (yes) and fill in the following window concerning the branch unit data. The "code langue" (language code) can be filled in for information as far as Belgian enterprises are concerned.

Under "caractéristiques" (properties):

Fill in this heading with the required values taking the units of measures into account. If you cannot give one or more active substances, complete « **pas d'application** » in the concerned field(s). In that case, join a letter for each of those missing values explaining the reasons why no value could be given. Such a letter must be added via CTD Structure, A10_other, and must begin with the name: 'Argumentation (active substance name)' or 'argumentatie (active substance name)'.

Under "fichiers ajoutés" (joined files):

As far as the active substance is concerned, choose from the files that have been added to the application:
- either the **IUCLID** file submitted at the moment of the active substance notification;

- or a **summary** from the active substance producer, which must include data on the toxicological and ecotoxicological properties of that substance;
- or **both documents -** IUCLID file + producer summary – are submitted in the application for authorisation file.

When you have made your choice, add the required document(s).

The name of the files must begin with: IUCLID (substance name), Tox résumé (substance name) or Ecotox résumé (substance name) (files visible under CTD Structure, A6_IUCLID (as far as IUCLID file is concerned) or A7_toxsumm (as far as the toxicological properties summary is concerned) or A8_ecotoxsumm (as far as the ecotoxicological properties summary is concerned).

If the product contains several active substances, click « **ajouter une zone composants actifs** » (add an active component field) and fill in the window like you did it for the previous active substance.

Important remark: If the producer - and not the applicant for authorisation - submits the physico-chemical properties of the active substance and/or the tox/ecotox summary and/or the IUCLID file, the applicant for authorisation must write in the concerned fields that those data will be provided by the producer. The applicant for authorisation must join in each case - instead of the required documents - a letter explaining that the producer will submit the IUCLID file and/or the tox/ecotox summary. The letter must bear the name of the required document.
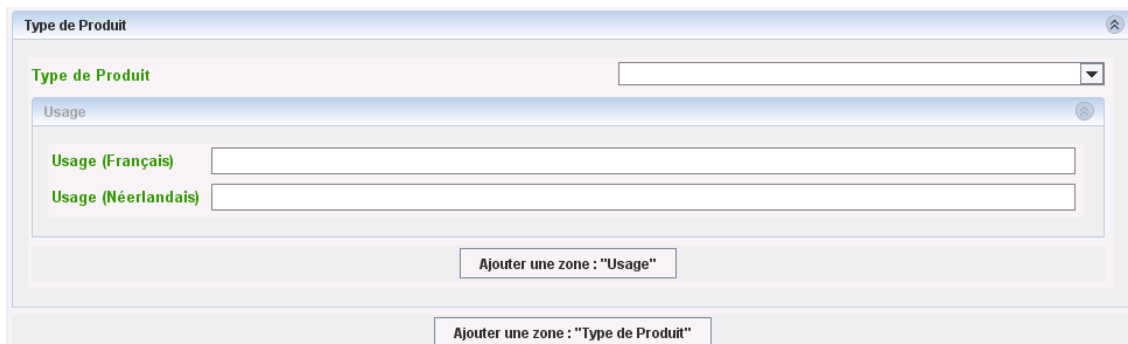
Gestautor

5. *Biocide authorised abroad:*

Fill in the trade name of the product under which it is authorised in the other Member State of the European Union.

Choose the Member State where the product has been authorised using the scroll menu.

Under "Type de produit" (product type):

Fill in the product type(s) for which the product has been authorised in the other Member State. Fill in one product type at a time using the scroll menu and describe thoroughly for each selected product type the use(s) of that product authorised in the other Member State in French and in Dutch.

If several uses have been authorised for a product type, click "**ajouter une zone: usage**" (add a "use" field) so that you can describe the other authorised use of that product in French and in Dutch.

If another product type has been authorised in the other Member State, click "**ajouter une zone: type de produit**" (add a "product type" field) so that you can select the other authorised product type and describe the authorised use(s) in French and in Dutch.

Under "**Composition"**:

You must give the product composition as authorised in the Member State.

Add in the right tables the names of active components, non active components and other non active components (only for those that do not appear yet in the list of non active components) following the instructions described above in biocide « composition ».

The concentration of the different ingredients must be expressed in % m/m (mass/mass).

! All substances of the product must be registered until the product total percentage reaches **100 %.**

Under "documents à ajouter" (documents to be added), add the required documents using the computer icon.

The following **original documents**:
the certified copy of the ORIGINAL authorisation act, an ORIGINAL statement on honour (= letter stating that the product authorised in the other Member State is identical to the biocidal product submitted for authorisation in Belgium) as well as a label APPROVED in the other Member State, must be sent **by post**
and an electronic version of these documents (with a correct name) must be added to the form as required above.

Remark: the certified translation of the authorisation act is mandatory if its original language is not French, Dutch or English.

As far as the documents to add are concerned, the file name respectively has to begin with:
- « Autorisation à l'étranger » or « Buitenlandse toelating »
  See under CTD Structure, A22_act
- « Autorisation traduction » or « Vertaling toelating »
  See under CTD Structure, A23_transl
- « Déclaration honneur » or « Verklaring erewoord »
  See under CTD Structure, A24_letter
- « Etiquette à l'étranger » or « Etiket buitenland »
  See under CTD Structure, A25_foreign label

If the product submitted for authorisation has been authorised in several Member States, click « **ajouter une zone biocide autorisé à l'étranger** » (add a "biocide authorized abroad" field). In that case, fill in the newly created field with the data concerning the authorization given in the other Member State.