#### Frequently Asked Questions

#### **FAQ FOODSUP**

We highly advise you to read both the user manual and the FAQ carefully before contacting us.

If you want to contact us, please specify the product-related information (company's name and number, file number, product name).

#### How do I register to FoodSup?

The registration occurs in two stages. You first need to register the e-mail address of the responsible in accordance with the instructions as provided for in Section 4.1 of the User Manual. The second stage consists of sending us the signed Annex 1 (local admin) by post.

#### I work as consultant and I have to notify products for my clients.

Consultants are asked to register following the same procedure as for company responsibles, stating that it is a consultancy firm. Companies which give a delegation to a consultant have to send the signed Annex 3, specifying the name of the consultant. Annexes 3 signed by the consultant will not be accepted.

If the company wishes to give a delegation for one or several products already notified, the table at the bottom of the annex must be filled in.

Please note that a list of consultants is available in FoodSup. The inclusion on the list of consultants is not a recognition of expertise or experience and does not engage the responsibility of the FPS of Health.

### I cannot have access to FoodSup. I use Internet Explorer 10 or 11.

The FoodSup application has been developed to be used with Internet Explorer 7 to 9 but does not currently work with Internet Explorer 10 and further versions. However, you can change the compatibility settings of those versions back to the earlier version (9).

FoodSup works with other browsers (such as Mozilla and Firefox) but application stability cannot be guaranteed.

#### When I log in, I get a blank page and cannot have access to my file.

After login, the application will open a pop-up box. Therefore it will be necessary to configure your web browser to allow pop-up windows.

## I cannot have access to FoodSup as I did not receive my password.

We do not send any password. When you register (see User Manual, Section 4.1), you have to choose a password. If you lost or forgot it, you can ask for a new one (see Section 4.3.1).

## My account has been blocked...

When the user encodes three times the wrong password, the account will be blocked. After half an hour the account will be unblocked and a new password can be asked through the lost password module (see Section 4.3.1).

#### I have created a shortcut and now I cannot log in.

The module to log in uses a few redirects, check if the right url (www.health.belgium.be/foodsup) was saved (click right -> properties).

#### I cannot log in to FoodSup with my token or e-ID.

Access is gained only by means of an email address (see envelope icon on the login page).

## I am a local admin and I wish to give access to my colleagues. Do I have to send Annex 1 for each of them?

There can be only one Annex 1 per company (= 1 local admin). The local admin can give access to other users by following the procedure outlined in Section 8 of the User Manual. You can request a modification of local admin by using Annex 2.

## The composition of my product is confidential and my manufacturer does not want to give me the information required for the notification. What can I do?

The information we receive is treated confidentially. The qualitative and quantitative composition must be mentioned in the notification file. Sometimes manufacturers do not want to provide such information straight to their customers; in such cases, they can send the information to us instead of to their customers. In that respect, the responsible notifies the product and clearly stipulates that the information will be forwarded directly by the manufacturer. The field "Ingredients and composition will be provided by a third party for reasons of confidentiality" has to be flagged. We will encode the information in FoodSup so as to make it available to the competent bodies but without making it visible for the responsible.

Please note that if you flag the field mentioned above, the responsible will be <u>forever</u> denied access to ingredient quantities.

#### I do not find an ingredient among those listed in FoodSup. Do I have to create a new one?

Before creating a new ingredient, you have to check if it does not already exist in the list by using our search engine and by typing in pieces of words to search for. Please make sure you spell the word correctly and use the right accents. Searching by E number is recommended as far as additives are concerned.

If the ingredient cannot be found, please read Section 6.2.4 of the User Manual.

### Can I put symbols like \* or % for searches?

No.

#### If I find an ingredient in the list, does it mean that the use of that ingredient is permitted?

The list of ingredients in FoodSup is neither a positive nor a negative list. It contains all ingredients listed in the present or former food legislation, as well as ingredients reported by operators. Please click "view" to the right of the ingredient as we may have put potentially useful information.

## Why are there no warnings for ingredients/nutrients/active substances/... that are overdosed but only technical validations when a notification is submitted?

This is a very deliberate decision made during the analysis before FOODSUP was developed. The main elements that have led to this decision are:

- the way limits are expressed in the legislation: some limits are expressed per daily portion, others by kg, l, ... of the product, some limits are applicable on the product as such, other on the product after preparation following the instructions of the responsible, ...

- the way data are encoded: in order to implement a check on the composition of a product, FOODSUP would need much more structured and mandatory fields than it is the case now.

#### When and how do I pay the notification fee?

If you have submitted your file through FoodSup, you will receive the invoice by email indicating the deadline for payment. The invoice can also be found in the annexes to the file, under "invoice". A series of 12 numbers starting with 117 will be specified on the invoice and must be communicated in the payment transfer request. Please do not mention any other information or symbols (no "/") here.

We advise you to pay the fee as quickly as possible instead of waiting until the payment deadline, otherwise the processing of your file might be delayed.

Regarding files submitted by email or by post, payment must be made in advance with mention of the following: "FP/117/company name/product name". Evidence of payment must be attached to the file (e.g. a sealed proof of payment or a copy of bank account statement).

I have mentioned the wrong name (company or consultant) on the invoice. Can you put it right? No, we cannot.

The product name, the name of the responsible or the address is incorrect. Can you correct the invoice and/or the file that have been generated?

No, we cannot. The system does not allow us to make such corrections.

You will have to modify your file to correct the mistake by yourself. However, invoices can never be corrected.

#### I cannot submit my file as I am being told that some ingredients are inactive.

Such warning can be found mainly in files submitted to us before starting to use FoodSup. As a result of legislative changes, inactive ingredients are no longer accepted. Most of them are ingredients for which the indication "chemical form undetermined" is stated, and plant names ending with "*spp*". If you receive such message, you have to replace the inactive ingredients by ingredients provided for in the law. If you cannot find the inactive ingredients of your product, please contact us and mention the file references.

#### What should I do with pack products?

"Pack" means one product (packaging) that consists of more than one product, for example capsules for the morning and capsules for the evening. As every list of ingredients has to be encoded separately, those products have to be encoded as two separate products and a difference needs to be made in the name of the product. For example: XXX [pack 1/2: day/yellow capsule] and XXX [pack 2/2: night/white tablet]. Both products will therefore have a different notification number (which was not the case before). If the products are never going to be sold separately, only one invoice should be paid.

If the product has been notified before FoodSup is in use, you have to split the pack in as many files as there are components. Don't forget to change the name of the file.

#### I cannot find the reply you sent to me.

For all files processed in FoodSup (since October 2012), a copy of the reply is available in the annexes to the file.

## My files are not up-to-date (different names, compositions, labelling, products no longer placed on the market). What should I do?

The file must reflect what has been put on the market. Therefore the responsible is required to check if his/her files are in compliance. If a product is not brought on the market anymore, you can indicate it by clicking "Withdraw from market" (see Section 6.6 of the User Manual). You do not need to make a file modification to provide us with this information.

## I wish to submit my file, but I get an error message showing a triangle with an exclamation mark inside.

As explained in Section 6.3.1 of the Manual, such information applies to "gentile warnings". You then can submit your file even if some information is missing. Please note that the missing information can be mentioned in our reply.

#### I cannot submit my notification because of error messages.

See Section 6.3.1 of the User Manual.

#### Why can I not download or open a document after uploading it?

The error message "An error was encountered while downloading. Please retry later." can appear if immediately after uploading, the user tries to download that document. Usually this happens because FoodSup and the document management system behind have not finished archiving the document. Waiting for a few minutes should solve the problem.

#### I am a consultant and I wish to have a copy of the reply.

Consultants receive a copy of the reply by email if they have submitted the file through the on-line portal. In any other case, they have to contact the company that hires them.

### I still have not received an answer concerning my file in draft.

If the state of your file is "in draft", it means that it has not been submitted to our Department. You have to click "Submit". A file that has been submitted and for which there has been no answer yet can be found under "products waiting for decision".

# I want to be sure that my file is complete or will be approved. May I send it in advance by email for agreement?

No. We do not preprocess files. Please consider sending your file early enough so that potential problems can be solved before the product is placed on the market.

### Which products are visible in the WWW-module?

The WWW-module only shows products for which a notification number has been granted. However, products for which it has been indicated that they are withdrawn from the market are not visible.

The WWW-module only shows the name of the product, the name of the responsible and the notification number. The WWW-module is update in real-time.

#### I made a mistake in a submitted file, can I delete it?

A notification that has been submitted cannot be removed neither by the responsible nor by our Department. Be very attentive before sending files. If you still find an error after submitting, please submit a modification.

#### **FAQ FOOD SUPPLEMENTS**

#### For which files should the notification fee be paid?

The notification fee has to be paid only when new dossiers for food supplements are submitted. It does not have to be paid for any modification of existing files or for notification files relating to fortified foods.

#### Should samples be submitted?

No. We only check administrative files. The Belgian Federal Agency for the Safety of the Food Chain is responsible for performing controls on the product market.

#### Should sweets "for sucking" be considered as "predosed forms"?

No. Such products should generally not be regarded as predosed forms. Sweets "for sucking" to which nutrients have been added are fortified foods that should be notified in accordance with the Belgian Nutrient Decree.

#### Which bodies are competent for monitoring food supplements?

The FPS of Health is competent for checking pre-market notification files and modifications.

The Federal Agency for the Safety of the Food Chain is competent for monitoring products placed on the market. The Federal Agency for Medicines and Health Products has been delegated the task to ensure inspection and control activities in pharmacies.

#### Who is liable for selling non-compliant products?

The manufacturer, the distributor, the wholesaler or the seller can be held accountable, depending on the situation that will be assessed on a case-by-case basis. In most cases, the (Belgian) manufacturer or importer is held accountable and can possibly be fined. Shopkeepers can also be caught in breach of the law in case of direct import or distribution, if the distributor cannot be identified (if there is no invoice e.g.) or if the shopkeeper him/herself is in breach (e.g. selling non authorized product or poor standards of hygiene).

## Regarding plant (preparation) products, which (active or toxic) substances or markers should be mentioned in the notification file?

Manufacturers and distributors are supposed to be able to determine themselves which substances should be mentioned (together with their concentrations). Relevant information can be obtained in the literature or from specialists. Both the identification and the quantity of relevant components must be stated. In the case of plants for which maximum levels of active substances and markers are determined in Column 4 of the list in Annex 3 to the Plant Decree, the levels of those substances must be expressed in terms of daily doses in the file. If the extracts used are not standardized, the minimum and maximum levels of active substances/markers can be indicated in the notification file. The maximum value must be mentioned in the field "Quantity active substance" in the Plant tab (see Section 6.2.6 of the User Manual). Additional information should be indicated in the Comment box. We can ask for additional information if we think the data submitted are not sufficient.

#### <u>Should Bach flower essences or floral elixirs be notified?</u>

Products called Bach flower essences can fall under different laws. If you wish to know under which law your product should be classified, please see the guideline of the Mixed Commission relating to

the classification of Bach flower essences (<u>www.fagg-afmps.be</u> > human medicines > grey area) (only in French or Dutch).

Products for internal use which do not fall under the medicines legislation must comply with the food legislation and particularly the Belgian Royal Decree of 29 August 1997 on the production and marketing of foods composed of plants or containing plant preparations (arrêté royal du 29 août 1997 relatif à la fabrication et au commerce de denrées alimentaires composées ou contenant des plantes ou préparations de plantes). In the notification file you submit to the FPS of Health, please mention the name and quantity of marker or active substance for each plant used.

The quantity of marker or active substance can be obtained by means of analysis and is an integral part of the product quality control system. The quantities measured are mostly low but can be detected. Nevertheless, if the quantities are too low to be detected, such information should be mentioned in the notification file by means of an analysis certificate stating the name of the plant, the marker searched for, the analysis method used and the detection limit of the measuring equipment. Statements without analysis certificate will not be accepted.

#### In which languages should plant names be indicated in the product labelling?

For all plants, the full scientific name must be mentioned, as well as the name, if any, in the language(s) of the region where the product will be sold.

#### Should plant parts also be mentioned?

The indication of plant parts in the labelling is not required but can be useful. Plant parts must however be mentioned in the notification file as they can be a cause of toxicity or activity.

#### Which maximum amount of caffeine may be used in food supplements?

Pursuant to Article 7 (precautionary principle) and Article 14 (food safety) of Regulation (EC) No 178/2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety, the FPS of Health relies on the limit values published in the advisory report No 8689 by the Belgian Superior Health Council which states that the amount of caffeine provided by any caffeine-containing food supplement should not exceed 80 mg per daily serving. Furthermore, caffeine-containing food supplements should carry a message warning that the product "contains caffeine and is not suitable for children, pregnant and lactating women", in the same field of vision as the name of the food, followed by the caffeine content in parentheses, expressed per portion as recommended for daily consumption on the labelling.

## May predosed forms be marketed with the same formulation but with different names (brand names)?

Yes, provided that it is stated in the notification files submitted. As a result, the same notification number can also be attributed to products with different brand names but with the same formulation (e.g. notified by the manufacturer for each of the brands put on the market).

### May predosed, non-prepacked products be supplied by wholesalers to retailers or packers?

Predosed products supplied to the final consumer must be prepacked. Manufacturers or wholesalers are allowed to supply products in bulk insofar as the notification file shows that those same products will not be supplied in bulk to the consumer. The notification file must include the labelling of the product as placed on the market.

#### I want to change the composition of my product. Do I have to notify it as a new product?

Decisions are made on a case-by-case basis. If the difference is minor from a qualitative, quantitative, nutritional or functional point of view, the product can be considered as a product

modification. If not, the change will be considered to be significant and must be notified in a new file.

Please note that a modification can never be the first version of a file.

### My product has several tastes. May I send only one file?

If the products only differ in their natural or artificial flavours, you are allowed to send only one file, with indication of all flavours in the title of the file and all labelling of the products available. If the difference consists of using a plant (chocolate, banana, etc.) or means adding, removing or modifying the quantity of an ingredient, the products have to be notified in separate files.

### My file is a priority. Can you process it before other files?

No. Files are processed according to the date of receipt.