

Administrative procedures and requirements concerning the Italian Input List

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I. Introduction

This document provides guidance for companies on the administrative aspects of registering products in the Italian Input List. This document can be found on the <u>website</u> of the Italian Input List. It will be updated whenever necessary. Please refer always to the most recent version, which is available on the website, and which is the only valid version.

I.I About the Italian Input List

The Italian Input List is a public online register of inputs that may legally be used by certified organic farmers in Italy. It is generated in a co-operation between FiBL and Federbio. The Italian Input List is a result of thorough evaluation of commercial products against relevant legislation and requirements. The Italian Input List is part of a series of national input lists which are united under the umbrella of the 'European Input List'. The Italian Input List, like the European Input List, is a private standard. It is based not only on the applicable legislation but also on additional requirements defined by Federbio in the name of the Italian organic sector. For further information, please visit the website of the Italian Input List.

Contact for Italian organic farmers

Italian organic farmers who have questions relating to the Italian Input List should contact Federbio. Enquiries can be made in Italian.

Address: Federbio, Piazza dei Martiri 1, 40121 Bologna. Further information and contact details can be found on the Federbio website.

Contact for companies

Input manufacturers and traders who have questions relating to the Italian Input List should consult the <u>Italian Input List website</u> or contact FiBL. Enquiries can be made in English, German or Italian.

Address: FiBL Europe, Rue de la presse 4, 1000 Brussels, Belgium. Further contact details can be found on the <u>Italian Input List website</u>.



2. Overview of the application process

2.1 Steps to the first listing

Figure 1 visualizes the main administrative steps involved in the evaluation of a product.



Figure 1: Main steps of the application process, specified in the table below and chapter 4.

The table below furthermore provides a more detailed overview of the singles steps that involved in the application and evaluation process. More detailed explanations are given in the subsequent chapters 3-6.

Steps to the first listing		Details
Step I	Company registration: The company (see 3.3) registers with FiBL by filling and sending the distributor registration form. Where appropriate, companies may additionally enter a secrecy undertaking, by filling and submitting the secrecy undertaking form.	See chapters 3.3 and 3.4
Step 2	Product application: The company submits all requested information on a product.	See chapter 4.1
Step 3	Product evaluation: FiBL evaluates the product's composition and other product related information.	See chapter 4.2
Step 3 A	Additional documents : Depending on the nature of the product and on FiBL's risk assessment, FiBL may request additional documents from the applicant. The evaluation will only be completed, when the requested documents have been received by FiBL.	See chapter 4.2
Step 4	Quality assurance	See chapter 4.4.
Step 5	Listing decision: FiBL makes a decision on the product's compliance with the relevant admission criteria.	See chapter 4.2



Steps to	Steps to the first listing Details	
Step 5 A	Listing : At the end of each evaluation round, all products which were found to be compliant with the admission criteria are included into the Italian Input List.	See chapter 4.2
Step 5 B	Rejection : In case the product was found to be non-compliant, the company will receive a letter of rejection, stating the main reasons why the product is considered non-compliant. If the company does not agree with the decision of FiBL, it can make a complaint and FiBL will review the product and provide feedback to the company. In this case, the product is re-evaluated as described in step 5. Note : If the shortcomings mentioned in the rejection letter have been eliminated by the company (or if the relevant legislation has been changed), the product may be re-submitted for evaluation.	See chapter 4.2
Step 6	Payment of fees: Once FiBL has received the application documents, it will issue an invoice for the evaluation fees.	See chapters 4.2 and 6.1

Table 1: Detailed overview on the major steps of the application and evaluation process.

2.2 Steps for prolongation of the listing

Figure 2 visualizes the main administrative steps that have to be taken to prolong the listing of a product, which is already included in the Italian Input List.



Figure 2: Main steps for prolongation.

Steps for prolongation of the listing		Details
Step I	Call for prolongation: Once per year, FiBL asks the company to confirm the listing for the following calendar year.	See chapter 5.5
Step 2	Response to the call for prolongation: Companies have to complete the prolongation form and return it to FiBL.	See chapter 5.5
Step 2A	SIAN fertilizers register: In case of fertilizers, soil improvers, biostimulants and related products, companies have to extend the listing in the SIAN fertilizers register. The confirmation of this extension must also be sent to FiBL together with the prolongation forms.	
Step 3	Quality assurance	See chapter 4.4



Steps for prolongation of the listing		Details
Step 4	When FiBL has received all documents for prolongation, it will prolong the listing for one year.	
Step 5	Payment of fees: FiBL will issue an invoice for the prolongation of the product(s).	See chapters 4.2 and 6.1

Table 2: Detailed overview on the steps of the prolongation process.

3. Relationship between companies and FiBL

3.1 Distinction between distributors and other companies

Because the Italian Input List is produced for organic farmers, the database aims at showing for each registered product where it can be purchased by the end-users (farmers, gardeners etc.). Companies selling the product to the end-users are called 'distributors' in this guideline. Also manufacturers may be considered as distributors if they are selling the product to end-users in Italy.

The following general rules apply:

- All distributors are required to register their company at FiBL, so that their product applications can be handled and included into the database.
- Companies which do not themselves sell inputs to end-users (manufacturers, authorised representatives or importers) may in general not register as distributors. FiBL may grant an exception on a case-by-case base, if the company can demonstrate a close connection to the Italian Input market or if the product can just be distinctively identified by the purchaser if the manufacturer's name is related to it (e.g. if only the manufacturer's name is printed on the product label).
- Companies, such as manufacturers, authorized representatives, which are not eligible for registration, e.g. because they are not distributing the product, may enter the correspondence FiBL to provide technical information on a product. In such cases FiBL is offering the companies to enter a <u>secrecy undertaking</u>.
- The first contact between FiBL and the manufacturing company, authorized company representative or similar, shall be established by the applicant, while any further exchange about the product details will be effected between FiBL and the manufacturing company or the authorized company representative exclusively.



Please note that companies which are not eligible for registration as distributors may nevertheless enter a secrecy undertaking with FiBL, if they have to supply technical information on a product (for details, see chapter 3.4)

In this guideline, distributors and other companies (manufacturers, authorised representatives and importers) are collectively called 'companies'. The table below provides a short overview of the roles of distributors and other companies. **Note:** If a company is at the same time manufacturer and distributor, the specifications for distributors apply.

Activities	Distributors	Manufacturers not distributing the product, authorised representatives, importers
Register as a distributor	yes	no*
Shown in Italian Input List	yes	no*
Fees charged	yes	no*
Administrative correspondence with FiBL, including annual prolongation	yes	no*
Submit product application	yes	no*
Covered by General Business contract	yes	yes
Enter secrecy undertaking	yes, if required	yes, if required
Supply confidential data on composition / manufacture	yes, if known	yes, if not known to the distributor

Table 3: Short overview of the roles of distributors and other companies. *exceptions are described in the text above.

3.2 General Business Contract

The General Business Contract specifies the rights and obligations of companies in relation to FiBL. Upon the companies' registration and/or application of a product for evaluation, the companies accept the General Business Contract FiBL has established with respect to the European Input List. The General Business Contract can be found on the website of the European Input List. Among other provisions, the general business contract specifies the following:

 For all companies, FiBL is the only contact point with respect to the Italian Input List.



- All correspondence between FiBL and the companies is done in Italian, English
 or German and all documents have to be submitted in one of the mentioned
 languages.
- Companies are obliged to provide complete and truthful information about their products. In case of severe violation of this principle, FiBL reserves the right to discontinue the collaboration with the company, and to de-list all its products.

3.3 Registration of companies (only for distributors)

As outlined above, only distributors may register for the Italian Input List. The registration of distributors is to be done as follows:

- Download the form «company registration» from the project website.
- Fill in the company details electronically.
- Print and sign it, or alternatively add the digital signature
- Scan and submit the signed form to FiBL by e-mail to the contact email address indicated on the Italian Input List website.

Note: Please do not send any posted mails. Distributors who have many points of sale (retailers, such as garden centres, agricultural cooperatives etc.) are advised to contact FiBL in advance and ask for guidance on how to register.

3.4 Secrecy undertaking (for all companies)

All companies which supply confidential information to FiBL (distributors, manufacturers, authorised representatives or importers) can enter a secrecy undertaking with FiBL. The secrecy undertaking is established between two parties, FiBL and the company providing confidential information on products. It covers the exchange of confidential information for an unlimited number of products of the company and hence does not have to be renewed for the exchange of information for new products submitted for evaluation. The secrecy undertaking mainly specifies the conditions of secrecy which will be applied by FiBL to all information covered by the secrecy undertaking in advance. In addition, FiBL will acknowledge the receipt of information for each product. Note: For certain cases FiBL may request support from an external consultant with specific technical and general knowledge about the Italian organic and input sector, hereinafter referred to as 'national expert'. Such national experts are bound to confidentiality by a secrecy undertaking entered between the national expert and FiBL, and hence has to respect the same secrecy precautions regarding the product information as FiBL outlines in its secrecy undertaking template.

A secrecy undertaking is entered as follows:

- Download the form «secrecy undertaking» from the project website.
- Fill in the company details electronically.



- Print and sign it, or alternatively add the digital signature.
- Scan and send to FiBL by e-mail.
- FiBL will countersign the agreement and return it to the company.

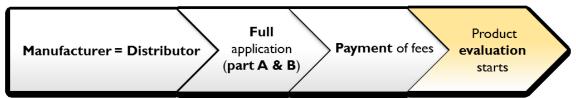
Some companies prefer to send the secrecy undertaking by posted mail, which is also possible. In this case, please send *two* filled and signed paper copies. FiBL will keep one of it and return the second copy of the countersigned agreement by posted mail. Please note that there may be delays in delivery by post.

4. Product application and evaluation

4.1 Product application

Only companies registered as distributors (see 3.3) may submit products for evaluation. Product applications from companies that have not yet registered with FiBL will not be accepted. The application procedure for companies that have knowledge on the full composition/ manufacturing process differs from the application procedure that do not know the full composition of their product. The difference is explained in sections 4.1.1. and 4.1.2 and in Fig 3.

A) applicant knows composition



B) applicant does not know composition

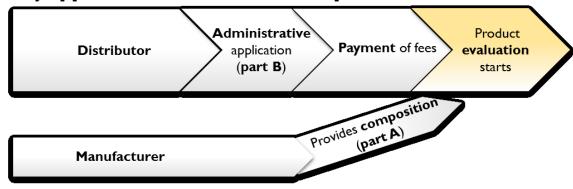


Figure 3 A & B: Procedure to be followed by companies (A) having detailed information on product composition and manufacturing (details see section 4.1.1) and (B) *not* having detailed information on product composition and manufacturing (details see section 4.1.2).



4.1.1 Procedure for companies that have knowledge on the full composition of the product.

The application procedure for **companies who have knowledge of the full product composition/ manufacturing process** is to be effected as follows:

- Download the appropriate <u>product application form</u> corresponding to the type of product category your product belongs to. There are separate forms for different product types. For more detailed information on what form you should use, please consult the document "What application form to use" (available in English only)
- Complete parts A & B of the product application form electronically.
 Documents filled in hand-writing will not be accepted. All chapters of the document need to be completed.
- Sign the filled form and convert it into a PDF. Furthermore, please prepare all *supporting documents* and information as specified in the last chapter of the application form and include them into the product application package. All documents need to be submitted as PDF.
- Send the application form together with the *supporting documents* to the <u>contact</u> <u>address</u> indicated on the website, by e-mail only.

Note: FiBL requires to know the full product composition in all cases. If the applicant does not have such knowledge, he should indicate in the form from whom FiBL will receive this information (see chapter 4.1.2).

4.1.2 Procedure for companies that do not know the full composition of the product.

The application procedure for companies who do not have knowledge of the full product composition/ manufacturing process is to be effected as follows:

- Fill in part B of the application form including all the product-related information you can provide.
- For questions, which you cannot answer, indicate the company (manufacturer, authorised representative or importer) which in a second step will supply the complete information to FiBL.
- Send the completed and signed part B of the application form (PDF) to FiBL.
- Ask the company which has knowledge of the full composition to complete
 part A of the application form and to send it directly to FiBL. That company
 may enter a separate secrecy undertaking with FiBL for this purpose, as
 outlined in chapter 3.4. It is the responsibility of the applicant to take the
 necessary steps so that FiBL receives all information required for evaluation.

Note: In this procedure, FiBL will not disclose any confidential information, which it has received from third parties, to the applicant.



4.2 The product evaluation process

Payment of fees

When FiBL has received the application form, it will start the product evaluation. Once the evaluation has been concluded and the listing decision has been taken, FiBL will issue an invoice for the evaluation fee. The evaluation fee is due also in case a product has been rejected.

Evaluation process

The product evaluation is carried out according to

- the basic admission criteria of the European Input List and
- the supplemental admission criteria of the Italian Input List.

In case the information provided by the company is not considered sufficient, FiBL may contact the company and ask for more detailed information on the product. When FiBL has received all required information, it will take a **decision whether the product complies with the relevant admission criteria**.

4.2.1 Inclusion of compliant products into the Italian Input List

Products which were found to comply with the admission criteria are included in the Italian Input List. The inclusion takes place in clusters (see 'evaluation cycle' below). In general, compliant products will also be included in the *European* Input List. For technical reasons, inclusion in the European Input List is not always synchronous with the inclusion in the Italian Input List.

4.2.2 Rejection

Communication of the reasons for rejection

In the case of rejection, FiBL will send a letter to the applicant that outlines the arguments for rejection. Where applicable, this letter will also include an indication whether the product would be acceptable, if additional data were provided by the applicant.



Possibility for making a complaint in case of rejection

If the applicant does not agree with the rejection of a product, it may submit a complaint to FiBL. When submitting a complaint the following points should be considered:

- A complaint should precisely refer to the reasons given in the rejection letter, and it should maintain a logical and structured argumentation line, elaborating why these reasons are not considered correct.
- Where appropriate, information supporting the argumentation (e.g. descriptions of manufacturing methods, analyses) should be included as annexes to the complaint.
- Complaints will only be considered if the applicant has paid the applicable evaluation fee.

Once FiBL has received a complaint, it will review the argumentation within the Italian Input List team. Where necessary, the complaint will also be discussed with the advisory board of the Italian Input List. Then, FiBL will re-evaluate the product in the light of the new information provided with the complaint, and will take a final decision on inclusion or rejection. The applicant will be informed accordingly.

4.2.3 Product re-evaluations due to altered admission criteria

The product admission criteria will evolve over time, for example due to revisions of the relevant EU or national legislation. In certain cases, such changes may necessitate a reevaluation of certain product categories. Such changes may make the listing of a previously non-compliant product possible, or it may lead to retroactive de-listing of previously compliant products. Such situations will be discussed individually between FiBL and Federbio, and possibly also with the advisory board. The aim is to find an individually tailored solution which is legally correct and has minimal impact on Italian organic farming. Stakeholders will be informed at the earliest convenience. The information policy will be decided case by case.

4.3 The evaluation cycle

FiBL is working in so-called evaluation rounds. This means that

- Product applications can be submitted continuously.
- At certain 'evaluation dates' (communicated on the project website), all product dossiers which are ready for decision-making will be considered in one cluster.
 All compliant products of the cluster will be included simultaneously.
- Product applications which were submitted too late, or for which the
 documentation is incomplete at the evaluation date, will automatically be
 postponed for the next evaluation round by FiBL.



Each evaluation phase ends with the update of the Italian Input List. At this moment all compliant products are published <u>online</u>. Figure 4 visualizes the evaluation cycle. Relevant dates for companies are published in the Italian Input List website.

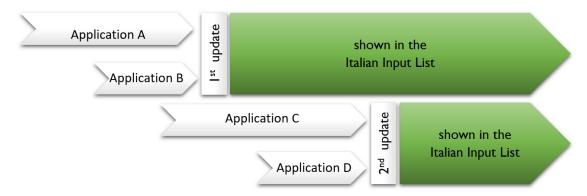


Figure 4: Overview of the evaluation cycle.

4.4 Quality assurance

Supplementary investigations

As part of the quality assurance procedures, a number of selected products from the Italian Input List will be submitted to supplementary investigations. In this context FiBL may perform a detailed follow-up, throughout which it may request additional information on a product, its composition, manufacturing process, its use. For certain products FiBL, may request analysis reports for specified parameters. If the analytical examination of a raw material used in a formulated product becomes necessary, the company must take responsibility to effect these analyses and provide the results to FiBL. FiBL may also request the re-submission of updated information on a specified product at any time. The company must react within due time as specified in the written request of FiBL.

Analytical spot-checking

As a complementation of the companies' efforts for quality control, FiBL will submit a certain number of products to analytical spot-checking. Product samples may be obtained on the market, or requested from the companies by FiBL. Analytical spot-checking is one central pillar of the quality assurance procedures.

Follow-up

If the quality assurance procedures should reveal any irregularities, FiBL will assess the situation on a case-by-case basis, optionally also involving the national expert and/or the advisory board. The applicant will be informed about the irregularity and asked to



explain it. Depending on the situation, FiBL may provisionally de-list products until it has received sufficient information to explain the irregularities.

When all information is available, FiBL will take a decision whether the product can still be considered to be compliant with the admission criteria. FiBL will inform the company about its decision. The company may make a complaint against this decision, as described in 4.4.

4.5 How to proceed when product characteristics change

All changes with relevance for the Italian Input List have to be communicated to FiBL by the applicant at the earliest convenience. For this purpose, the form <u>'Changes of an existing entry'</u> (available in English only) has to be completed and sent to FiBL. Changes of a purely administrative nature are handled differently from changes in product composition, manufacturing or use:

4.5.1 Changes of purely administrative nature

This category comprises changes, such as changes in

- product name, company name, contact person and contact details
- address, website information, legal structure etc.

The applicant is obliged to notify FiBL about such changes in time. Through the notification form 'Changes of an existing entry', the company must confirm that any change does not affect the composition of the product, and that the product still complies with the relevant EU and Italian legislation. For products which are subject to mandatory registration, any change of product or company name must be communicated also to the competent authority responsible for registration. FiBL will document such changes and modify the entry in the Italian Input List accordingly. In cases where such modifications might cause uncertainties among farmers, inspectors or other users the old trade and/or company name will be indicated next to the new trade and/or company name on the Italian Input List for a limited transition period (e.g. 'product y, formerly called x').

4.5.2 Changes in product composition, manufacturing process or compliance with relevant legislation

This category comprises changes, which are **relevant for product evaluation**. They are therefore handled analogous to new product applications, as follows:

- The company submits the updated information, as described for new products (see 4.1) using the latest version of the <u>application form</u> provided on the Italian Input List website.
- Information, which remains unchanged, has to be clearly marked. Supporting
 documents only need to be re-submitted, if the information changed, compared
 to the documents handed in throughout the first application.



• FiBL will evaluate the changes and take the final decision about the inclusion to the Italian Input List, following the procedures outlined in chapter 4.2.

5. Validity of evaluation and duration of listing

5.1 Timelines

- Company registrations and secrecy undertakings can be made any time of the year.
- **Product applications** can be made any time. However, they will be grouped by FiBL in clusters according to the evaluation rounds (see chapter 4.3).
- **Inclusion in the Italian Input List** occurs in clusters, at specific dates communicated on the project website.
- Complaints have to be submitted within 6 weeks after the company has
 received the official rejection letter from FiBL. The processing time for
 complaints may vary from case to case, depending on the complexity of the
 individual case.

5.2 Validity of the first listing

The positive evaluation of a product implies the subsequent inclusion of the product (first listing) into the Italian Input List. Inclusions of new products occur at the end of each evaluation phase. The validity of the first listing is adjusted in a way that allows all products to enter into an annual cycle of prolongation.

- If a product is included into the Italian Input List in the first half of the year, the first listing will be valid until the end of the *current* calendar year.
- If a product is included in the list in the second half of the year, the first listing will be valid until the end of the *following* calendar year.

The validity of the first listing is indicated in the listing entry which can be accessed through the <u>online search</u> of the Italian Input List.

5.3 Details of the listing layout

It is the intension of the Italian Input List team, to establish a level playing field for all products listed in the Italian Input List. For this purpose, all products are listed with the first letter in capital and the following letters in lowercase. The spelling of entire words in capital letters is not accepted (for abbreviations, the Italian Input List team may grant exceptions on a case-by-case basis). The use of special characters is limited. It is not possible to highlight trade names or other product related information (italics, underscores, bold type, colours etc.). Decisions about textual layout are in the sole responsibility of the Italian Input List team and may not be challenged by applicants.



5.4 Prolongation of existing entries

For all products included in the Italian Input List, FiBL will contact the applicants to ask whether they wish to prolong the entry. If the company confirms that request, FiBL prolongs the existing listing entry for another year. Prolongations requests are effected in written form and are to be returned to FiBL in due time. If an applicant does not respond to the call for prolongation, the listing of his products will expire. For prolongation, the following documents need to be returned to FiBL:

- completed prolongation forms
- In case of fertilizers, soil improvers, biostimulants and related products: confirmation of this extension or registration with the <u>SIAN fertilizers register</u>.

5.5 Withdrawal of the listing entry by the company

Withdrawal of the listing entry at the end of a calendar year

As outlined in 5.5, FiBL will ask the companies once a year whether they want to continue the listing of their products on the Italian Input List. If companies do not want to continue their listing and hence wish to withdraw the listing entry, they should follow the **standard procedure**:

• Notify FiBL that the product should not be prolonged for another calendar year in the course of the prolongation process outlined in 5.5.

Withdrawal of a listing entry during the year

It is usually not possible to withdraw a listing entry apart from the prolongation process, as farmers may have already used the product and may face some obstacles during the certification process if a certain product suddenly disappears from the Italian Input List. FiBL may exceptionally grant an extracurricular withdrawal of an existing listing entry if the company can bring up plausible and conclusive arguments.

Note: In case products which are on the Italian Input List are discontinued or not anymore available on the market the listing entry in the Italian Input List will be kept upright until the end of the current calendar year. However, FiBL may add a comment, indicating that the concerned products are not any more available. This is to make sure that organic farmers who have the concerned products on stock on their farm, may use them without problems (see 5.7).



Transitional period (grace period) for organic farmers

When a product is removed from the Italian Input List, FiBL may communicate a transitional period ('grace period'), during which Italian organic farmers may still use the product. Whether or not such a transitional period is established depends on the reasons for de-listing and will be determined by FiBL on a case-by-case basis.

6. Fees

The fees applicable for the evaluation and listing of products on the Italian Input List are published on the <u>project website</u>.

6.1 Evaluation fee

Companies are charged an evaluation fee for the evaluation of products against the admission criteria for the Italian Input List. The evaluation fee applicable to product applications for the Italian Input List must be paid right after the invoice has been sent to the company.

The following general rules apply:

- The evaluation fee is due both, in case of listing and in case of rejection of the product.
- The evaluation fee covers the first listing (see chapter 6.2). The evaluation fee is a fixed amount and covers the expenses related to product evaluation and includes the correspondence with the companies, examination of the documentation, background research etc.
- If a product is rejected and hence not included into the Italian Input List, the evaluation fee needs to be paid all the same.
- If a product is rejected and hence not included into the Italian Input List, the company may re-submit the product for re-evaluation, if they can show that any shortcomings have been corrected. FiBL will charge the full evaluation fee for re-submitted products.
- If a product has to be re-evaluated because the product characteristics have changed, the evaluation fee is also charged.



6.2 Listing fee

Once the prolongation of a product for another calendar year has been confirmed by the company, FiBL will charge a *listing fee* to the company:

- The listing fee covers those expenses related to the prolongation of the listing entry of the product, in particular the correspondence with the company.
- Quality control measures such as analytical spot-checking and all subsequent correspondence and inquiries are free of charge for the company.

6.3 No fees charged

In the following situations, no fees are charged:

- Complaints: There is no fee for complaints.
- Purely administrative modifications of the listing, such as name changes and similar administrative modifications, are handled free of charge.
- Withdrawal of a listing entry: No fees will be charged for the withdrawal of a listing entry/ de-listing. However, if a product is withdrawn by the company or de-listed by FiBL during the year, the listing fee that has been paid for the ongoing calendar year will not be refunded.

