Evaluating inputs for organic farming – a new system

Proposals of the ORGANIC INPUTS EVALUATION project

Authors
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1 Foreword

This volume contains proposals for criteria for evaluation of plant protection products, fertilisers and soil conditioners\(^1\) to be used in organic agriculture. These ideas were developed in the course of the European Union (EU) Concerted Action project ‘ORGANIC INPUTS EVALUATION’ (QLK5-CT-2002-02565). For more information on this project see the end of this volume or visit the project website www.organicinputs.org. The documents in this volume are proposals elaborated by the project consortium and external experts. They were discussed with a broader audience at a public conference held in Brussels on October 13, 2005, and have been amended accordingly.

Our proposals also include a “criteria matrix”, which is in Microsoft Excel format, and therefore stands as a separate file. The criteria matrix is discussed in section 5, but we strongly recommend that you consult the original document. To illustrate the use of the matrix, we have further prepared two case studies, which are also separate Excel files. All of these files are contained on the CD, and can also be downloaded from the project website.

Currently, Regulation 2092/91 is under revision. We hope that our ideas can be incorporated into the regulation during this revision! In addition, we strongly encourage national institutions to make use of our proposals at the national level.

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\(^1\) In the industry, ‘soil conditioners’ are sometimes also referred to as ‘soil improvers’.
2 Introduction

2.1 Regulatory framework for inputs

Regulation 2092/91 EEC establishes the regulatory framework for organic farming in every Member State of the European Union. Annex II A of this regulation lists the products which are allowed for use as fertilisers and soil conditioners (F&SC), while Annex II B lists the products which are allowed for use as plant protection products (PPP). In this publication, F&SC and PPP are collectively called ‘inputs’. For an explanation of the term ‘products’ in this context see section 2.5.3.

Regulation 2092/91 EEC is currently under revision. During this revision, the numbering of Articles and Annexes referred to in this document is likely to change. Our proposals refer to the present numbering.

The range of available inputs strongly affects quantitative yield, yield security, quality of produce and profitability of the crops. It may also affect the environment and has an influence on the public perception of organic and non-organic farming systems. Thus, the use or non-use of inputs is an important element of agricultural production systems from the point of view of farmers, consumers and policymakers. Organic farming is characterised by a strict regulation of inputs, which precludes the use of the vast majority of all available products.

Despite the common regulatory framework of Reg. 2092/91, the range of products which may be used by organic farmers differs greatly among EU Member States, and also between EU Member States and other states. These differences are further explored in section 2.2.

2.2 Causes of major differences between countries

This section describes the most frequently observed causes of differences between countries. The collection is based on two inventories of the current situation which were made in the course of the ORGANIC INPUTS EVALUATION project\(^2\), \(^3\). This collection is not intended as an exhaustive list, but rather as an illustration of the problems with the current situation. Although we list a number of disparities here, we would like to emphasise that for many products the inventories also revealed a high degree of homogeneity between countries.

2.2.1 PPP legislation

In all countries, there is a legal requirement that PPP must be registered for use. The registration procedures are independent of organic farming regulations, and apply to use in conventional as well as in organic farming.


Generally, registration of PPP is expensive and time consuming. Registrants (manufacturers and/or distributors) expect a return on their investment, and most PPP manufacturers have been reluctant to invest in PPP directed mainly for use in organic production, because of the organic sector’s small market share and because of many organic farmers’ sparing use of PPP, which is consistent with the principles of organic farming. PPP are only registered upon request by a registrant.

Whether a product is registered in a given country depends on many factors. In the present context, the most important are:

- The expected **market share**, which depends on the pests and diseases which can be controlled, on the crops on which the product can be used and on the number of organic farmers growing these crops. These factors vary greatly across Europe, mainly for climatic reasons.

- Whether there are **companies** in that country which are interested in this market segment. Particularly for the large, multinational agribusinesses, organic farming is too small a segment to be addressed profitably. In addition, most of the products used in organic farming are old and enjoy no patent protection.

- The exact requirements, procedures and fees of the **registration process**, which vary greatly between countries. The most obvious differences are found in the requirements concerning **efficacy** and in those concerning **safety and human health**. The duration of the registration procedure and fees also vary considerably.

- Some countries have established **simplified procedures** for certain product categories. These are addressed in section 2.2.3.

Where the combination of factors listed above is unfavourable, PPP will not be registered and therefore not available for use.

To harmonise PPP registration within the EU, the Council of the European Union established a Directive regarding the marketing and regulation of plant protection products (91/414/EEC). The directive intended to establish a Community-wide list for active substances used in plant protection. The intent was to protect the environment and human health by establishing the safety of different substances, and to harmonise the regulations already in force in the different Member States.

To this end, all existing products have to be re-evaluated or else will be withdrawn from the market. The evaluation proceeds in four stages, and most of the PPP used in organic farming are subject to the fourth stage, which is scheduled to be completed in 2008. This stage is currently in progress, and its outcome is difficult to predict. Products which complete this re-evaluation successfully should be more homogeneously available afterwards. However, there is also a risk that many products will not complete this re-evaluation, mainly for financial reasons (see comments on returns above). This risk has been identified by the Commission, but at present it is not clear what could be done to resolve this problem.

### 2.2.2 F&SC legislation and availability

The fertilisers with greatest importance for organic farming are animal excreta. Manure should come from organic livestock production (Reg. 2092/91, Annex I A, subparagraph 2.1). If this is not possible, manure from “extensive animal husbandry” and not from “factory farming” may be used (Annex I A, subparagraph 2.2 and Annex II A). The interpretation of these terms, however,
varies from country to country. Given this restriction, stockless farms and farms with low stocking rates may experience difficulties to obtain such fertilisers. This is most pronounced in southern European countries, where vegetative growth is long, nutrient uptake high and organic matter metabolism fast.

Many countries have established quantitative limits on the use of \textbf{N fertilisers} to prevent nitrate leaching. These vary considerably between countries due to a mix of national and EU regulations and their interpretations.

In most countries, there is a legal requirement that F&SC must be notified or registered for use. These procedures are independent of organic farming regulations, and apply to the use in conventional as well as organic farming. Often, notification or registration is required only for certain product categories. Compared to PPP registration, the process requires considerably less documentation, takes less time and is far less expensive. Thus, the notification or registration process rarely limits the availability of F&SC.

Another important difference between countries with practical implications are the regulations on \textbf{slaughterhouse residues}. Since the BSE crisis, some countries have imposed major restrictions on these, or completely prohibit their use, while they can be used freely in other countries.

\subsection*{2.2.3 Simplified registration procedures}

Several countries have established simplified registration procedures for low-risk products, for which normal pesticide registration is neither appropriate nor economically viable. These procedures were not established primarily with organic farming in mind, but some of them affect organic farming regulations (though not all in the same way). Some simplified registration procedures are described below.

- **Plant strengtheners (Germany)**: At present, Germany is the only country within the EU where a category of ‘plant strengtheners’ (Pflanzenstärkungsmittel) is legally defined. A number of low-risk substances which were traditionally used in organic farming and which are listed in Annex II are registered as plant strengtheners in Germany (e.g. commercial products based on plant/algae extracts, etheric (ethereal) oils, fatty acids, homeopathic preparations). Because Reg. 2092/91 does not mention plant strengtheners, they are considered to be generally allowed. This becomes problematic in the case of products which are not listed in Annex II, but registered as plant strengtheners, such as potassium phosphonate. According to a recent amendment of the Austrian fertiliser regulation, products registered in Germany as plant strengtheners are considered soil conditioners in Austria. In some other Member States (e.g. Italy, France), there is a public discussion about introducing a category of plant strengtheners at national level. At the level of Reg. 2092/91, plant strengtheners and other products used in crop production could be dealt with in Annex II F, which is currently empty.

- **RUB (The Netherlands)**: Low risk PPP can be registered with a simplified procedure called ‘Regeling Uitzondering Bestrijdingsmiddelen’ (RUB). Examples are milk (viricide, fungicide), sugar (fungicide) and several plant oils. Such products are nevertheless considered PPP, and they must be listed in Annex II B in order to be used in organic farming.

- **Presidential Decree 290 (Italy)**: Presidential Decree 290, dated April 23\textsuperscript{rd} 2001, Article 38, establishes simplified registration procedures for certain PPP traditionally used in organic or biodynamic farming (e.g. oils, lecithine, herbs, Quassia). However, products registered ac-
According to this procedure may be sold only under their chemical name and not under a brand name. At present, the decree is under discussion again because the Commission does not agree with the concept of “simplified registration”, unless it is agreed within Dir. 91/414.

- **Partial efficacy (Switzerland)**: Switzerland requires all PPP to complete the ordinary registration procedure. However, products with lower efficacy than the standard (often conventional) PPP can be registered with the restriction that they have “partial efficacy” (in German: “Teilwirkung”). This has facilitated registration of PPP used in organic farming considerably.

- **Homemade products (also ‘on-farm’ or ‘self-cooked’ products)**: Organic farmers have traditionally relied upon preparations made on the farm. They were considered to be beneficial for crops, often without a clear distinction between PPP, F&SC, plant strengtheners or other products. Germany has a legally defined “self-cooking list” (Selbstkocherliste), where a few products are exempt from registration requirements, if they are home made. Such products are nevertheless considered PPP, and they must be listed in Annex II B in order to be used in organic farming. The situation is more complex in tropical countries, where products can be home made which are commercial PPP in the EU (e.g. neem extract). Other, traditionally home made plant extracts are not commercialised in the EU, and therefore not included in Annex II.

### 2.2.4 National regulations and private guidelines for organic farming

In some EU Member States, national legislation on organic farming may restrict the use and application of certain inputs beyond the limits set by 2092/91, but these cases are rare. As far as it was covered by the inventories, the organic legislation of non-EU countries was found to be very similar to Reg. 2092/91, and is thus responsible for only few of the national differences. The most obvious exception are microbial products, none of which are currently listed in Annex II B, but which are allowed in the Swiss Organic Farming Ordinance \(^4\) and the US National Organic Program \(^5\), as well as the Codex Alimentarius norms \(^6\) and the IFOAM (International Federation of Organic Agriculture Movements) Basic Standards \(^7\). One microbial product which regularly causes discussions is spinosad. We therefore selected this product for a case study (see annex).

More frequently, private standards restrict the range of products beyond what is legally allowed. This is particularly the case for PPP and slaughterhouse residues. For examples see the standards of the Soil Association (United Kingdom), Bioland (Germany) or BIO SUISSE (Switzerland), and some of the country reports in Speiser and Schmid (2004) \(^8\).

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\(^5\) National Organic Program, 7 CFR, part 205


\(^7\) IFOAM Basic Standards. See [http://www.ifoam.org](http://www.ifoam.org)

Imports from non-EU countries: Organic foods imported from non-EU countries must have been produced according to the rules of production laid down in Reg. 2092/91 or according to national legislation in the case of ‘recognised third countries’. An example of the latter case is the ‘Organic Farming Ordinance’ of Switzerland⁹. Although the Organic Farming Ordinance is very similar to Reg. 2092/91, it is not identical, but equivalent. This means that there may be differences in certain aspects (including inputs), but that these were judged acceptable by the Commission. The above-mentioned example of spinosad (allowed in Switzerland, but not in the EU) is such a case. Imports from countries which are not recognised as third countries must be authorised on a case by case basis.

2.2.5 Implementation of the organic regulation

Annex II of Reg. 2092/91 lists only active ingredients of PPP and the components of F&SC, but most of the end-users use commercial products. Within the EU, accredited inspection bodies for organic farming conduct most of the evaluation of commercial products. In some countries, official bodies evaluate products for compliance with organic standards. The requirements for evaluation vary between different institutions. In some cases, disclosure and/or participation in evaluation is mandatory; in others it is voluntary. The major differences can be found in the following areas:

- **Branded products**: In the evaluation of branded PPP, most institutions evaluate only the active ingredients that appear on the label; others evaluate both the claimed active ingredients and all other substances. By contrast, the full composition must be evaluated in branded F&SC. Most F&SC contain no inert ingredients, so their full composition appears on the label.

- **Factory farming**: Reg. 2092/91 requires that fertilisers based on animal excreta should come from “extensive husbandry” / not come from “factory farming”. However, there is no EU-wide definition of either term. Guideline EEC 5684/VI/95, Rev. 5 provides some guidance, but delegates competence to national authorities. As a result, there may be some variability between countries in the interpretation of this requirement, but the degree of variability is not known.

2.2.6 Flexible response to varying need

Climate, soil, geology, cropping systems, pest and disease pressure and socio-economic conditions vary across Europe, and even to some degree within Member States. These variations may create different needs and use patterns for a given product. In order to take such differences into account, many products are listed in Annex II with the restriction "need recognised by the inspection body or inspection authority". The "need recognised" restriction is made with the intention to stimulate flexible implementation of Annex II, adapted to regional or local conditions, or exceptional conditions (e.g. exceptional meteorological conditions).

This restriction may be handled in different ways. Typical cases are: (i) the product is not allowed; (ii) farmers have to apply for authorisation before use in every single case; (iii) farmers may use the product, but only if they can demonstrate the need for it during inspection (e.g. with a soil analysis); (iv) the inspection authority generally recognises the need for a product (either for a specific crop or generally) for the whole country and every year.

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At the project’s final conference, concern and criticism of the “need recognised” restriction and/or its present implementation were expressed. Preliminary suggestions for improvements can be found in section 6.4.

2.2.7 Conclusions

In conclusion, most of the disparity between countries is due to factors other than the organic regulation 2092/91, and thus outside the scope of the ORGANIC INPUTS EVALUATION project. Nevertheless, the project may provide solutions for some of the problems, particularly those described in section 2.2.3 and 2.2.5.

2.3 Current procedures for amendments to Annex II

The inputs currently allowed for use in organic farming are listed in Annex II of the organic regulation 2092/91. When new PPP and F&SC become available, they are evaluated according to the criteria given in Article 7 of the organic regulation. However, while Annex II is very detailed, Art. 7 is rather rudimentary. In addition, it contains a “non-contact clause” which states that new products may only be included if “the conditions for their use preclude any direct contact with the seed, the crop, crop products [...]” (see section 3.1). This is a major obstacle to the inclusion of most new products.

Thus, amendments to Annex II are often impossible, and if they are possible consume a lot of time and resources. As a consequence, not all of the recently developed PPP and F&SC are available to European organic farmers, even if they comply with established principles of organic farming, such as the IFOAM Basic Standards. The proposals of the ORGANIC INPUTS EVALUATION project will improve this aspect of the current situation considerably.

2.4 Improved procedures for amendments to Annex II

To improve the current situation, the ORGANIC INPUTS EVALUATION project proposes a number of changes. Our proposals are designed as one package which should be implemented together. We hope that the Commission can take our proposals into account during the current revision of regulation 2092/91. We propose the following:

- To change Article 7 of the organic regulation, as described in section 3. The changes will establish better evaluation criteria and facilitate the listing of new products, while safeguarding the principles of organic farming.
- To establish better evaluation procedures, as described in section 4. The procedures involve assistance by an expert panel, and aim at a more straightforward and transparent process.
- To utilise a criteria matrix as a tool in the proposed procedures, which puts the criteria of Article 7 into practice, as described in section 5. The matrix provides detailed guidance for all steps of the procedure, and ensures transparency and consistency.
We propose that new products should be evaluated in this way, and if a Member State or the Commission finds that any of the products already in Annex II should be re-evaluated (with the aim to change its specifications or to withdraw it), the same procedure may be applied. However, we do not suggest that all currently allowed products should automatically be re-evaluated. An approval of a new product may also be coupled with the decision to withdraw another product which is already on Annex II and is less compliant with the criteria. This has been the case with metaldehyde molluscicides, when iron (III) orthophosphate was listed\(^{10}\).

2.5 Frequently asked questions (FAQ)

2.5.1 Is the suggested evaluation of inputs a scientific or a political process?

The final decision about the inclusion of new products in Annex II, and removal of products, is taken by the Commission, assisted by the Standing Committee on Organic Farming set up by Art. 14 of Reg. 2092/91. Thus, it is always a political process ultimately. However, the process has both scientific and political components, and scientific reasoning should support and facilitate political argumentation.

With the proposed procedures and criteria, the final decision will continue to be a political outcome. However, the process leading to the final decision will be much better structured, and there should be a clear distinction between aspects which are evaluated on a scientific basis and those which are decided politically.

Given the political nature of the process, it is important that all stakeholders are involved in the process. To address this, we propose to give considerable weight to the Member States during evaluation, and suggest that the Member States consult the stakeholders within their countries.

2.5.2 What is the difference between the proposed criteria, when applied to PPP, and evaluation under Dir. 91/414?

PPP have to comply with the requirements of Dir. 91/414 and they have to be registered, regardless whether they are used in organic or in conventional agriculture. If they are to be used in organic agriculture, they have to be listed in Reg. 2092/91, Annex II B. The major differences are as follows:

- PPP registration under 91/414 covers certain aspects in great detail, especially efficacy, environmental impact, human health, metabolism, breakdown and residues, and can thus be considered ‘safe’. It is therefore unnecessary to duplicate these efforts. Nevertheless, these criteria are still part of organic evaluation, in case that organic farming desires to set stricter limits than conventional farming.
- However, organic evaluation is much broader than registration under 91/414, and extends into economy, socio-economy and ethics. The two processes therefore require different expertise.
- PPP registration under 91/414 is a scientific process, where a product which meets all criteria has the right to be included into Annex 1. By contrast, product evaluation for organic farming is a political process, in which the desirability of a product is judged. The answers to some of

\(^{10}\) see COMMISSION REGULATION (EC) No 473/2002 of 15 March 2002
the questions reflect opinions rather than facts. There is no guarantee that a product judged favourably on scientific grounds will be included in Annex II B.

- In the case of PPP, organic evaluation applies only to active ingredients, but not to commercial (branded) products. Consequently it does not apply to inert ingredients. Whether a certain commercial product may be used, and under which conditions, is determined by pesticide registration. However, Reg. 2092/91 may set further restrictions.

### 2.5.3 What is the meaning of the term “product”?

In the context of Reg. 2092/91, the term “product” means all items which are listed in the Annexes. Depending on the Annex (II A, B, C, D or E), these may be products of different legal categories (in Annex II B, for example, the active ingredients of plant protection products are listed). Sometimes, this is compounded with “commercial product” or “branded product”, but Reg. 2092/91 does not deal with these.

### 2.5.4 Is there a “comparative assessment” for products?

“Comparative assessment” means that products are not evaluated on their own, but in comparison to other products. As a consequence, products may not be registered, or have to be withdrawn, if products with better properties are available. Currently, there is no comparative assessment under the pesticide directive 91/414 (although this is discussed), but there is under the biocidal products directive 98/8.

In our opinion, organic farming is a production system for highest demands and should only use the best possible practices (including the use of the best inputs, if this is necessary). Therefore, a comparative assessment is clearly appropriate. For the inclusion of new products, we suggest a comparative assessment, in which the product is not only compared with other products, but also with plant breeding alternatives and management practices.

An example of comparative assessment is the previously mentioned case of metaldehyde molluscicides, which were ruled to phase out by March 2006 when iron (III) orthophosphate was listed.

### 2.5.5 Some questions are difficult to answer, particularly those on public perception

While doing the case studies, we were told that ‘some questions are difficult to answer’. Indeed, questions such as those on public perception or on economic effects require expertise which is substantially different from the expertise needed for conventional registration of pesticides or other products, and even some members of the SCOF might not be familiar with such evaluation criteria. Nevertheless, other stakeholders are more familiar with such criteria and experience little difficulty with them. For this reason, we suggest an expert panel which covers all the expertise needed. During evaluation by Member States, the broad inclusion of stakeholders at national level may also help to resolve this problem.

The answers to some questions reflect opinions or trends, the truth of which is difficult to measure. In a political process, this is common and poses no problems, as long as these an-

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11 see COMMISSION REGULATION (EC) No 473/2002 of 15 March 2002
swers reflect the opinions of the major stakeholder groups, and not of individuals. The major stakeholder groups are (i) consumers; (ii) the farmer community (organic and conventional); (iii) environmentalists; (iv) groups concerned about animal welfare; (v) groups concerned about social issues, particularly fair trade. Each of these stakeholder groups has specific topics of interest. In the evaluation matrix, we distinguish between the interests of group (i) (question A & E 8.01), group (ii) (question A & E 8.02) and groups (iii) to (v) (question A & E 8.03).

In practice, many consumers will care not only about issues related to consumption, but also about other issues, e.g. animal welfare, and the same is true for all other stakeholders. Therefore, we decided not to ask for opinions of individuals, but for opinions of stakeholder groups with defined interests. For example, we do not ask for the public perception of “the consumer”, but for public perceptions relating to the process of consumption (regardless of who expresses them). In this way, the logical structure and predictability of this section is improved.

2.5.6 How does input evaluation relate to organic farming principles?

We believe that input evaluation must reflect the principles of organic farming. Recently, the General Assembly of IFOAM approved the explicit description of four principles upon which organic agriculture is based12:

- **The Principle of Health.** Organic Agriculture should sustain and enhance the health of soil, plant, animal and human as one and indivisible.

- **The Principle of Ecology.** Organic Agriculture should be based on living ecological systems and cycles, work with them, emulate them and help sustain them.

- **The Principle of Fairness.** Organic Agriculture should build on relationships that ensure fairness with regard to the common environment and life opportunities.

- **The Principle of Care.** Organic Agriculture should be managed in a precautionary and responsible manner to protect the health and well being of current and future generations and the environment.

Due to their very general nature, the above principles are not directly applicable for the purpose of input evaluation. Instead, we have used the more specific “principles for inputs evaluation” of the IFOAM Basic Standards (edition 2002, Appendix 3), which are presented here in shortened form.

- **Necessity.** Each input must be necessary.

- **Nature and Mode of Production.** The origin of the input should usually be (in order of preference): (i) Organic - vegetative, animal, microbial; (ii) Mineral. The ingredients of the inputs may undergo the following processes: (i) Mechanical; (ii) Physical; (iii) Enzymatic; (iv) Action of micro-organisms; (v) Chemical (as an exception and restricted).

- **Environment.** The input shall not be harmful or have a lasting negative impact on the environment.

- **Human Health.** Inputs shall not be harmful to human health.

- **Ethical Aspects - Animal Welfare.** Inputs shall not have a negative influence on the natural behaviour or physical functioning of animals kept at the farm.

- **Socio Economic Aspects.** Inputs should not meet resistance or opposition of consumers of organic products.

For the purpose of this project, we have made the following changes to these principles:

- There are additional criteria to make sure that the product applied for is **clearly identifiable**, and that its **use is legal**.

- The requirements on “nature and mode of production” were split up into two separate criteria: “**origin**” and “**manufacturing**”.

To remind evaluators of the broader perspective behind individual questions, we make reference to the above mentioned “principles” in the section headings on the Evaluation Form of the criteria matrix. In the future, Reg. 2092/91 is likely to define the principles of organic farming at the European level. Proposals are currently being elaborated by the EU-funded project “Organic Revision”. It is evident that the principles defined by Reg. 2092/91 have to be considered with priority, but they are likely to be similar to those mentioned above, which make up the basis for our proposals.

### 2.5.7 How many products should Annex II ideally contain?

During the project’s final conference, there was a discussion about how many products should ideally be listed in Annex II. There were voices saying that the Annexes should contain **as few products as possible**, to demonstrate that organic farming attempts to solve problems through the systems approach, and uses inputs only as a last resort. Also, a short list of inputs could distinguish organic farming clearly from conventional farming.

On the other hand, there were also voices arguing that the Annexes should contain **as many products as possible**, to allow organic farmers to select those inputs which are best adapted to the individual situation and have minimal side-effects in that specific situation.

This question is closely connected with the desired direction in which organic farming should evolve in the future. Individual persons have different views on this aspect, and there is no official position. We recognise that one’s position in this question will influence input evaluation to some extent. However, the structured approach of the proposed procedure (with criteria matrix, Member State involvement, expert panel etc.) should minimise this influence, ensure stakeholder involvement and make the final decision transparent.

### 2.5.8 How strict should organic inputs evaluation be?

During the project’s final conference, there was also a discussion about how strict the evaluation of organic inputs should be. Similar questions can be asked for all organic farming regulations, and the answer will always be the same: strict regulations lead to higher credibility of organic farming, while liberal regulations lead to more organic farms, which will result in lower prices of organic products. These two aspects must be balanced carefully. There is no general agreement on how strict organic regulations should be. This is clearly a political decision which should not be decided by the expert panel, but by the Member States and the Commission. In
any case, the strictness applied in input evaluation should be **consistent** with the strictness in other aspects of organic regulations. To ensure this, the expert panel should comprise members with a knowledge of all organic farming regulations, and it will have to follow the policy set by the SCOF and the Commission.
3 Proposed changes to Article 7

3.1 Changes to the text of the regulation

The consortium proposes the following changes to Article 7 of Regulation 2092/91. The changes are presented as follows:

- normal font: text of the present version to be retained
- strike out: text of the present version to be deleted
- underlined, green: new text
- red numbers on right margin: numbered comments, see section 3.2

1. Products not authorised at the date of adoption of this Regulation for a purpose indicated in Article 6(1)(b) may be included in Annex II, provided that the following conditions are satisfied:

   (a) if they are used for the purpose of plant pest or disease control or for cleaning and disinfecting livestock buildings and installations:
       - they are essential for the control of a harmful organism or a particular disease for which other biological, cultural, physical or breeding alternatives are not available, and
       - the conditions for their use preclude any direct contact with the seed, the crop, crop products or livestock and livestock products; however, in the case of perennial crops, direct contact may take place, but only outside the growing season of the edible parts (fruits) provided that such application does not indirectly result in the presence of residues of the product in the edible parts, and
       - their use does not result in, or contribute to, unacceptable effects on, or contamination of, the environment;

   (b) if they are used for fertilisation or soil-conditioning purposes:
       - they are essential for specific nutrition requirements of crops or specific soil-conditioning purposes which cannot be satisfied by the practices mentioned in Annex I, and
       - their use does not result in unacceptable effects on the environment or contribute to the contamination thereof.

1a. The conditions provided for in paragraph 1 shall not apply to products which were in common use before the adoption of this Regulation according to the codes of practice on organic farming followed in the Community.
Evaluating inputs for organic farming – a new system

(a) for all products:
   - they are of plant, animal, microbial (only from micro-organisms which are not GMOs) or mineral origin; if products from such sources are not available in sufficient quantities or qualities, additional sources for these products may exceptionally be included provided that they are in the same form, and
   - they may only undergo the following processes: physical treatments such as milling, heating and purification; microbial and enzymatic treatments such as fermentation, composting or hydrolysis (providing that no GMOs and products derived from GMOs are used); exceptionally they may also undergo simple chemical treatment, and
   - manufacture, use and disposal of the substance do not result in, or contribute to, harmful effects on the environment, and
   - they have the lowest negative impact on human or animal health and quality of life, and
   - their use has no negative social impacts such as economic effects, effects on rural development or unfavourable public perception, and
   - their use is consistent with the principles of organic farming;

(b) besides, if they are used for fertilisation or soil-conditioning purposes, they are essential for specific nutrition requirements of crops or specific soil-conditioning purposes which cannot be satisfied by the practices mentioned in Annex I;

(c) besides, if they are used for the purpose of plant pest or disease control, for animal nutrition or cleaning and disinfecting livestock buildings and installations or for other purposes related to crop production, they are essential for the control of a harmful organism or a particular disease, or to achieve the intended purpose for which breeding alternatives or management practices are not available or less effective, and alternative substances are not included in Annex II.

(d) Products obtained by chemical processes and not identical to their natural form may be authorised only if their conditions for use preclude any direct contact with the edible parts of the crop.

(e) With regard to minerals and trace elements used in animal nutrition, additional sources for these products may be included in Annex II provided that they are of natural origin or failing that, synthetic in the same form as natural products.
2. If need be, the following may be specified for any product included in Annex II:

- the detailed description of the product, its origin, its composition or other relevant characteristics,
- the conditions of its use and compositional and/or solubility requirements, with regard in particular to the need to ensure for these products a minimal presence of residues on edible parts of the crop and on edible crop products as well as a minimum effect on the environment, particularly restrictions concerning the crop, the amount applied or crop growth stage,
- particular labelling requirements for products referred to in Article 1 where such products are obtained with the aid of certain products referred to in Annex II.

3. Amendments to Annex II, concerning either inclusion or cancelling withdrawal of products as referred to in paragraph 1 or inclusion or amendments of specifications as referred to in paragraph 2, shall be adopted by the Commission in accordance with the procedure laid down in Article 14.

4. Where a Member State considers that a product should be added to or withdrawn from Annex II or that amendments should be made thereto, it shall ensure that a dossier request for amendment giving the reasons for the inclusion or the amendments, all relevant information on the product and its intended use to demonstrate it is fulfilling / failing to fulfil the criteria for inclusion or for the amendment is sent officially to the other Member States and the Commission, which shall introduce it to the committee referred to in Article 14.

3.2 Comments on the changes

1 The present criteria in section 1. (a) and 1. (b) shall be deleted and replaced by new criteria.

2 The “traditional use clause” shall be deleted. With the adoption of better criteria, it should not be necessary any more to give such great importance to this aspect. Instead, traditional use will be considered in the evaluation procedure, as one aspect in the criteria matrix. Note: if the new criteria and wording of Article 7 are not implemented, the traditional use clause should not be deleted!

3-8 The proposed new criteria are now in section 1. (a) to (c). A new product must conform with all criteria to be eligible for inclusion in Annex II.

3 Bullet point no 1 is a new criterion specifying the origin. This criterion is consistent with the Codex Alimentarius (GL 32 – 1999, Rev. 1 – 2001) and the IFOAM Basic Standards. Products from microbial origin are explicitly mentioned as eligible for inclusion. Note that currently Annex II A and B do not contain such products.

4 Bullet point no 2 is a new criterion specifying the processing steps. The IFOAM Basic Standards contain a similar criterion and also mention chemical processing “as an exception and restricted”. “Simple chemical treatment” is not an officially recognised term. Here, we use it to describe: (i) treatment with inorganic acids or bases (e.g. change of pH, hydrolysis) and (ii) treatment with other substances, provided that there is a high degree of consensus.
among the evaluators that this is acceptable. Simple chemical treatment is included to ensure consistency of the evaluation criteria with the products currently listed in Annex II (i.e. to ensure that these currently listed products could remain listed, if their re-evaluation was requested). A number of products currently listed undergo “simple chemical treatments” (e.g. seaweed products from acid/alkaline extraction; leather meal; copper fungicides; ethylene; lime sulphur) but to our knowledge their listing has never been questioned because of this. Part (ii) of this description needs to be interpreted very carefully, because it could potentially open the door for products which are generally considered unsuitable for organic farming. However, we believe that the proposed procedures ensure a high standard of evaluation and thus can prevent the inclusion of undesirable products. As a guideline, but without obligation, the processing steps involved in the manufacture of products presently on Annex II A or B should be considered acceptable.

5 Bullet point no 3 specifies environmental impact. It is a slightly modified version of a criterion in Codex Alimentarius (GL 32 – 1999, Rev. 1 – 2001).

6 Bullet point no 4 is a new criterion specifying human and animal health. The present formulation is taken from Codex Alimentarius (GL 32 – 1999, Rev. 1 – 2001).

7 Bullet point no 5 is a new criterion specifying social effects. In our opinion, this criterion is necessary for proper evaluation of inputs, and is an important safeguard to ensure the positive public perception of organic farming. In the case studies, several participants experienced difficulties with these questions. For a brief discussion, see section 2.5.5.

8 Bullet point no 6 is a new criterion specifying consistency with principles of organic farming. It is a slightly modified version of a criterion in Codex Alimentarius (GL 32 – 1999, Rev. 1 – 2001).

9 In our opinion, all products should be essential for their intended use. The present requirements on essentiality apply to products which are listed in Annex II A, B and E. The new wording “animal nutrition or” expands the scope to Annex II C and D, while the wording “or for other purposes related to crop production” expands the scope to Annex II F.

In our opinion, Annex II F should be used for products which are generally known as “plant strengtheners”. At present, there is no EU regulation on plant strengtheners, and such a category is not recognised under Dir. 91/414. Therefore, we think that it is most appropriate to list them for “other purposes”. At present, plant strengtheners are not regulated by Reg. 2092/91, therefore all recognised plant strengtheners may be used in organic farming. Although many plant strengtheners are consistent with organic farming principles and some have been traditionally used in organic farming, we prefer an explicit listing to a “carte blanche” for all plant strengtheners. In addition, Germany is the only Member State which officially recognises plant strengtheners. This leads to unequal opportunities for organic farmers in Germany versus those in all other Member States.

Note 1: In section 6.5, we describe a variant of section (c) which also covers stored product pests.

Note 2: The ORGANIC INPUTS EVALUATION project is concerned only with crop production aids, i.e. products listed in Annex II A, B and possibly F, and our proposals have been elaborated with these products in mind. However, we believe that they are sufficiently general to also be applicable to animal husbandry. In any case, we recommend verifying their
applicability for products to be listed in Annex II C to E (i.e. feed materials; feed additives, certain substances used in animal nutrition and processing aids used in feedingstuffs; products authorised for cleaning and disinfection of livestock buildings and installations).

10 The requirements for essentiality of plant protection products have been expanded.

11 In the present version of the regulation, there is a “non-contact clause” for all plant protection products, which was meant as a safeguard against the inclusion of undesirable products. With the adoption of more detailed criteria (see above), there is no longer a need for such a safeguard. It is therefore suggested to restrict the “non-contact clause” to products obtained by chemical processes and not identical to their natural form.

12 Several changes to section 2. are suggested which should result in a more logical structure (bullet point no 1 relating to the product, no 2 to its use and no 3 to labelling requirements) and provide more flexibility.

13 For consistency in language with other EU regulations, it is proposed to replace “cancelling” by “withdrawal”.

14 To ensure consistency with section 3., withdrawal must be mentioned here, too.

15 We propose to replace “dossier” by “request for amendment”, because the term “dossier” is used in the context of pesticide registration. This may cause confusion about the nature of the document to be provided.

16 This change makes clear that the applicant (a Member State) should bear the burden of proof (i.e. all information necessary for the evaluation must be provided by the applicant).

3.3 Summary of proposed changes

The proposed changes will result in the following major innovations:

- The present evaluation criteria, section 1 (a) and (b), will be replaced by a set of criteria covering all aspects relevant for organic farming; the new section 1 (a) to (e). Some of these criteria are new in Reg. 2092/91, but consistent with other standards such as the IFOAM Basic Standards or the Codex Alimentarius norms.

- The present “non-contact clause” (section 1 (a), second bullet point) which precludes the listing of new PPP which come into contact with the crop is restricted to synthetic products; see new section 1 (d).

- Products of microbial origin are explicitly admitted for evaluation, such products are currently not included in Annex II B. Both the IFOAM Basic Standards and the Codex Alimentarius norms consider products of microbial origin eligible for organic farming. To avoid misunderstandings: Such products will not automatically be allowed, but only if they fulfill the entire set of criteria, and each product will need to be listed individually in Annex II.

- The criteria will be applicable not only to PPP and F&SC, but also to products which are used for other purposes related to crop production. This will help to close gaps and prevent disparities which may be caused by differing procedures for approval at national level, particularly relating to the use of plant strengtheners. Plant strengtheners should be listed in Annex II F.

- The present “traditional use clause” (section 1a) is deleted. However, traditional use will be considered in the evaluation procedure, as one aspect in the criteria matrix.
4 Proposed procedures and structures

4.1 Background concerning input evaluation

- Fertiliser and pest control inputs are one of organic farming’s most complex and controversial aspects. At the heart of organic farming are closed cycles and the natural balance of healthy ecosystems but external inputs, whilst being minimised, are sometimes necessary to correct deficiencies and imbalances.

- Deciding which inputs are and are not allowed is critical. It requires not only an understanding of organic farming principles and aims, but also sound technical and scientific knowledge, and in addition an awareness of consumer perceptions and political considerations.

- Organic food and farming cover all sectors of agriculture and food processing, which means that the technical and other expertise needed to address the breadth of its standards and systems are extremely wide.

- The unit dealing with organic farming in the European Commission is small and has an increasing workload.

- In other areas, scientific panels and/or expert working groups support the Commission where specified and technical know-how is needed. It is proposed that a similar structure be introduced for the purposes of the ongoing review of Regulation 2092/91, in particular with reference to Annex II.

- Action 11 of the EU Organic Action Plan, published on 10 June 2004, recommends the setting up of “an independent expert panel for technical advice”. The Commission Working Document on the Action Plan expects that this project could provide the basis for setting up this panel.

- The Commission Working Document on the Action Plan stipulates more than just the evaluation of inputs in the context of the expert panel. The present paper recognises this wider brief whilst nevertheless concentrating on inputs evaluation.

- The proposed structure outlined here is aimed at the EU level but it could be used as the blueprint for similar consultation groups at the national level. Member states generally have to draw up requests for submission and these groups could assist with this and also review proposals tabled by other Member States at the SCOF. International and private standard-setting organisations such as Codex Alimentarius, IFOAM or national organic farmers’ associations might also find a similar approach useful.

4.2 Objectives of the new procedures

- To provide the Commission Directorates and the Standing Committee on Organic Farming with independent, excellent and transparent advice on the evaluation of input materials in the context of Regulation 2092/91 and other relevant legislation.

- To ensure the advice is based on agreed criteria and follows clear procedures, taking into account existing Community policy objectives as well as organic farming principles and consumer expectations.
To ensure that the reviewing of inputs is consistent with other regulations on organic farming.

To work towards consistency with other international organic food standards developments and utilising the expertise of the organic farming and food sector.

4.3 Existing structure for input evaluation

- Decisions on inputs are made by the Commission, assisted by the SCOF according to the procedures laid down in Article 14 of regulation 2092/91. The Commission tables requests for amendments to Annex II. These are normally submitted by Member States who have to set out the case for their request. Currently these vary in length and level of detail from a few paragraphs to many pages. The Commission may also table proposals.

- The request may be considered in a working group before a final opinion is sought from the SCOF. The working groups of the SCOF generally consist of up to five Member State representatives with, increasingly, one or more invited experts from the organic farming sector. Usually the IFOAM EU Group has provided these. The Commission may withdraw a request if it considers there is insufficient support for it.

- Each Member State representative is responsible for consulting with the stakeholders from the organic food and farming sector in their country and representing their national view in the SCOF.

- A further method of consultation involves the recently revised advisory group structure of which the Advisory Group on Organic Farming is a part. This is a more general and political advisory body comprising representatives from a wide cross-section of stakeholders and is therefore not expected or equipped to provide specific technical expertise.

- A final, less formal, method of consultation is with the IFOAM EU Group through its board consisting of elected representatives from each EU and EFTA country. The IFOAM EU Group aims to present a consensus position to the Commission and takes as its reference point the IFOAM Basic Standards.

4.4 Proposed structure for input evaluation

- The expert panel proposed here is, or is part of, the “independent expert panel for technical advice” cited in action 11 of the EU Action Plan for Organic Food and Farming. Formally, it could be set up either as a working group of the SCOF, or as an independent working group.

- The primary responsibility of the expert panel will be to review the requests for amendments on the instructions of the Commission. Thus, they should take the major load of the technical evaluation of inputs, while the SCOF can concentrate on advising the Commission on the political aspects.

- Membership of the expert panel should be made up of:
  - Chair, appointed by the Commission or elected by the group
  - 6 organic farming experts with expertise covering animal and crop husbandry including viticulture, horticulture and sheltered production, and having a broad geographical /climatic /farming systems spread
Expert on organic marketing, policies and standards and expectations of consumers and other stakeholders
- Organic inspection and certification expert
- Soil science expert
- Biochemistry or inorganic/organic chemistry expert
- Eco-toxicology expert
- Ecology expert
- Human health expert
- Plant protection expert
- Plant nutrition expert

Note 1: In its final composition, the expert panel may also have to cover the fields of animal production, nutrition and behaviour. However, these aspects are outside the scope of the ORGANIC INPUTS EVALUATION project (see section 32, comment no 9).

Note 2: The panel could consist of all permanent members or a combination of permanent members and ad-hoc invited experts, if it was felt that there was a need for wider expertise than could be incorporated in a permanent group.

- The panel members should act in the public interest, and not in national or commercial interests. Whenever a panel member has a national or commercial interest in a product, he should declare this when the panel discusses it.

- The evaluation criteria, methodology and procedures used should be based on those proposed by this ORGANIC INPUTS EVALUATION project. The criteria and methodology also provide a framework for the SCOF.

- The panel should have the power to:
  - request additional information if a request for amendment is considered incomplete
  - seek more expertise and invite additional experts where it feels that this is necessary
  - comment on any aspect of the application
  - contact the applicant and try to reach consensus on application statements
  - comment on any aspect of the Member State evaluations, particularly on differences between countries in evaluation or perception
  - make a final recommendation to accept or refuse the application, with or without conditions or restrictions.

- The aim should be to co-ordinate with, or at least know the positions of, other organic standards setting authorities (e.g. Codex Alimentarius, IFOAM standards committee, US National Organic Programme).

- The budget for the panel should be sufficient for:
  - organising and administering the meetings;
  - remuneration for the members to prepare for and attend meetings;
  - background research work and consultation with relevant experts;
  - inviting additional experts to the meetings (who may reside outside the EU);
  - the possibility that the handling of a request may need more than one round of evaluation.

- As requests are generally made by the Member States, it is important that the criteria and procedures they use to develop the requests for amendments are consistent with those out-
lined in this project. The precise nature of national structures is outside the scope of this project, but the principles established here could serve as blueprints for them. At the least, the Member States should consult with their organic stakeholders in order to bring up requests that have already gained a wide consensus in that Member State.

- Bearing in mind the global influence of the EU regulation, there should be the possibility for third countries to submit requests for amendments and to be consulted where requests may have an impact on their organic sectors.

- Bearing in mind the innovative nature of organic farming, there should be the possibility for requests for amendments to be submitted for products that are not (yet) registered as a plant protection product (or fertiliser or soil conditioner).

### 4.5 Proposed procedures for input evaluation

- **Application:** The Commission tables requests for the inclusion of a product in Annex II or an amendment of specifications for, or withdrawal of, an existing product. A request is generally submitted by a Member State (hereafter called ‘applicant’) which needs to provide all information required to evaluate the application, using the criteria matrix proposed by the organic inputs evaluation project (see section 5). It is recommended that the Member State discusses the request with its national consultation group before application. The Commission Services screen the application for completeness and may request additional information if any is deemed missing. Commission Services table the completed application and forward it to the expert panel.

- **Review:** The expert panel reviews the application for correctness. The panel may request additional information from the applicant and may seek further expert advice from elsewhere. In case of major disagreement with the applicant, it should discuss the issue with the applicant. The aim is to reach a high degree of consensus regarding the facts underlying the application. Whenever an application is likely to meet strong opposition during Member State evaluation, the expert panel should consider whether appropriate specifications/restrictions might alleviate the opposition. If this is the case, it should discuss the possibility of including these specifications/restrictions into the application, with the aim of avoiding multiple rounds of review and evaluation at the Member State level. When the application is reviewed, the expert panel makes a provisional evaluation. The Commission Services forward the reviewed application together with the provisional evaluation to Member States for national evaluation.

- **Evaluation:** Member States evaluate the reviewed application, using such national consultation and expertise as they think fit. The Commission collates the evaluated applications and forwards them to the expert panel. It seems unlikely that reviewed applications will be translated into all languages used in the EU, which will present an obstacle in the national evaluation. To alleviate this, we propose a numerical scoring during the evaluation. Thus, national experts may identify all key issues by the numerical scores, and need only translate selected statements.

- There may need to be more than one round of review and evaluation in order to reach sufficient agreement on the application, particularly for applications with unclear specifications/restrictions.
- **Final recommendation**: The expert panel reviews all Member States’ evaluations with special emphasis on key areas of difference. In the event of a wide discrepancy of national evaluations, the Commission may decide to return the summarised evaluations to all Member States for their further evaluation, with the aim of arriving at more consistent national evaluations. Based on the national evaluations, the expert panel makes a final recommendation to the Commission.

- **Final Decision**: The Commission Services table the request for amendment with the expert panel’s final recommendation at the SCOF. The SCOF assists the Commission in making a final decision.

- **Time limits**: We suggest that the whole evaluation process, from application to final decision, should aim to be completed within 18 months. If a request is not completed after 18 months, the SCOF shall discuss the reasons and suggest suitable measures to ensure that the request is rapidly concluded.
5 Criteria matrix as a guidance document

5.1 What is the criteria matrix?

The proposed changes to Article 7 provide the general principles for evaluation of products. To complement this with more detailed instructions and guidance, the consortium has also prepared a “criteria matrix”, which is in Microsoft Excel format and therefore supplied as a separate file. The consortium recommends that the criteria matrix is adopted by the Commission as a guidance document.

The proposed criteria matrix is available at the project website www.organicinputs.org; the final documents will also be available on CD. Here, its main features are briefly discussed.

5.2 How to use the criteria matrix

Instructions for use are given in the criteria matrix, and are therefore only briefly described here. The criteria matrix contains the following worksheets:

- **READ ME FIRST**: Provides some general information on the matrix, and refers the reader to this document for further information.

- **Application Form**: This form provides guidance on the application and requests specific data, which should be entered as 'applicant statement'. The applicant must fill in the entire Application Form; the expert panel may provide additional information as ‘Experts’ comments’ as they consider appropriate. In case of major disagreement between the applicant and the expert panel, the panel should discuss the issue with the applicant, with the aim to obtain an application with unambiguous information. If the applicant and the expert panel cannot reach consensus, both of their statements will be left in the application sheet.

- **Quick Screening**: The Quick Screening is a simple tool which provides an indication (without obligation) of the product's chances of passing a full application/evaluation procedure. Please note that the Quick Screening is neither part of the full application/evaluation procedure, nor does it anticipate the outcome of the final evaluation. Individuals, institutions or Member States who are uncertain whether or not to engage in an application procedure may consult the Quick Screening as a decision-making aid. The Quick Screening is a combination of selected questions from the Application and the Evaluation Form. If a full application and evaluation is to be done, the Quick Screening need not be done.

- **Evaluation Form**: This form provides guidance on the evaluation of applications, and asks for evaluation in the form of statements and additionally as scores. The intention of the scoring is mainly to highlight the key issues, which were evaluated either as very positive or as very negative. The statements explain the reasons for each evaluation. The scores provide a semi-quantitative indication whether an aspect is judged as favourable or unfavourable, and to what extent. They also facilitate comprehension among Member States with different languages, but they are not intended to be added or used for other mathematical/statistic data analysis, because they are non-commensurate. As a final step in the evaluation, a recommendation A, B, C or D has to be made concerning inclusion in Annex II (A: include without restrictions; B: include with restrictions; C: require further information before recommendation can be made;
D: do not include/withdraw). The Evaluation Form is to be filled in by the expert panel (for provisional evaluation) and the Member States (for national evaluation).

- **Comparison**: This form provides an overview of the evaluations made in different Member States, again highlighting the key issues. It is to be filled in by the Commission and the expert panel. In the event of a wide discrepancy of national evaluations, the Commission may decide to return the summarised evaluations to all Member States for their further evaluation, with the aim of arriving at more consistent national evaluations. Based on the national evaluations, the expert panel makes a final recommendation to the Commission, which it enters at the bottom of the Comparison sheet (include with or without restrictions, or do not include/withdraw). The Commission Services then table the request for amendment at the SCOF, using the completed criteria matrix as a basis for discussion.

- **Abbreviations and Definitions**: This worksheet provides explanations of abbreviations, and definitions of terms used in the matrix.

- **Case studies**: Two case studies have been prepared to illustrate the use of the criteria matrix. These are available as separate files at the project website www.organicinputs.org. For more information see the Appendix.
6 Further research and actions needed

The ORGANIC INPUTS EVALUATION project has identified a number of problems (see sections 2.2 and 2.3). Some of these problems might be solved or at least alleviated with the criteria and procedures proposed here (see sections 2.4 – 5), while others are outside the scope of this project and need to be addressed elsewhere. Here, we briefly describe some of the latter.

6.1 General regulatory framework

General (non-organic) legislation may have a significant impact on the availability of inputs. In particular, products which are not allowed for use throughout the Union will have to be withdrawn from Annex II without even being evaluated. At present, the fourth stage of PPP re-evaluation is likely to have the greatest impact on the availability of inputs for organic farming (see section 2.2.1). F&SC legislation may also have a significant impact (see section 2.2.2). Simplified registration procedures may also have a great impact, but these are highly variable and so is their likely effect (see section 2.2.3).

In all these cases, we encourage intensive communication and close co-operation between organic stakeholders and the authorities involved in such legislation.

6.2 Evaluation of commercial products

Annex II of Reg. 2092/91 lists only active ingredients of PPP and the components of F&SC, but most products are supplied to the end-users as commercial products (see section 2.2.5). At present, most of the institutions which evaluate commercial products evaluate only the active ingredients that appear on the label. However, stakeholders from several countries are dissatisfied with this practice and expressed the opinion that all ingredients of inputs should be evaluated. Where evaluation is restricted to active ingredients, there are two main reasons:

- The full composition of inputs is often confidential, and manufacturers are reluctant to disclose it to the evaluators, and/or
- Reg. 2092/91 provides no guidance on how to evaluate inert ingredients.

We are aware of two more or less well-documented cases in which the full composition of inputs is evaluated. (i) The US National Organic Program lays down transparent criteria for input evaluation, which are implemented by the Organic Materials Review Institute (OMRI). (ii) In Switzerland, the private label organisation BIO SUISSE and the Research Institute of Organic

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Agriculture (FiBL) have established evaluation criteria, which are implemented by FiBL and are compulsory for all BIO SUISSSE and Migros-Bio producers\(^\text{15}\).

We recognise that a full evaluation of commercial products is desirable. However, given the present state of the art in plant protection, criteria for evaluation of inert ingredients will have to be different from those for active ingredients. Thus such a procedure seems ambitious and can only be achieved in the long term. At the project workshops, it was not rated as a high priority at present.

The final goal of such activities is the replacement of synthetic inert ingredients by natural ones. To achieve this goal, not only appropriate evaluation criteria are required, but also considerable research efforts.

### 6.3 Communication of decisions

Many of the various inspection bodies and officials communicate their decisions internally to the farmers, inspectors, and reviewers. However, prior to starting the ORGANIC INPUTS EVALUATION project, there was no formal, organised structure to communicate decisions regarding inputs between the various bodies and Member States.

While many F&SC are marketed within a Member State, PPP are often sold in several Member States. Thus, improved information and communication would enable experts and officials to carry out their evaluation work in a more consistent way, and to detect and resolve possible differences between institutions or Member States. Some variations are likely to continue to exist for the reasons mentioned in section 2, but there is a potential to minimise them.

We recommend to improve communication of decisions concerning inputs between organic stakeholders. Communications should be documented and made public by a database, preferably accessible by internet. The documentation should also contain the argumentations and justification, in order that the decisions are understood by the public. In case of detected differences, there should be a discussion forum which clarifies the reasons for the differences and attempts to resolve them.

### 6.4 Improvement of the “need recognised” restriction

At present, a large proportion of products in Annex II are listed with the specification “need recognised by the inspection body or inspection authority”. At the project’s final conference, there were voices asking for improvements of this restriction. The major criticism was that there is a lack of transparency regarding the way in which this restriction is implemented in different countries and/or by different inspection bodies. It was suspected that the restriction is not implemented equally in different countries and/or by different inspection bodies.

The following products are listed with the “need recognised” restriction: F&SC: Farmyard manure; Dried farmyard manure and dehydrated poultry manure; Composted animal excrements, including poultry manure and composted farmyard manure; Liquid animal excrements (slurry,

urine, etc.); Composted or fermented household waste; Guano; Composted or fermented mixture of vegetable matter; Products or by-products of animal origin: blood meal, hoof meal, horn meal, bone meal or degelatinised bone meal, fish meal, meat meal, feather, hair and ‘chiquette’ meal, wool, fur, hair, dairy products; Seaweeds and seaweed products; Basic slag; Crude potassium salt (for instance: kainit, sylvinite, etc.); Potassium sulphate, possibly containing magnesium salt; Magnesium and calcium carbonate of natural origin (for instance: magnesian chalk, ground magnesium limestone, etc.); Industrial lime from sugar production; Industrial lime from vacuum salt production; Calcium chloride solution; Elemental sulphur; Trace elements; Sodium chloride. **PPP:** Azadirachtin extracted from Azadirachta indica (Neem tree); Pyrethrins extracted from Chrysanthemum cinerariaefolium; Rotenone extracted from Derris spp., Lonchocarpus spp. and Terphrosia spp.; Pyrethroids (only deltamethrin or lambdacyhalothrin); Copper in the form of copper hydroxide, copper oxychloride, (tribasic) copper sulphate, cuprous oxide; Ethylene; Lime sulphur (calcium polysulphide); Mineral oils.

The “need recognised” restriction should ensure that inputs are only used if they are necessary or “needed” at the farm level, i.e. if a production problem cannot be solved with methods other than the use of the input. This intention is a fundamental principle of organic farming and was not questioned. However, the present implementation of this restriction is not satisfying. The in-depth elaboration of improvements is out of scope of the ORGANIC INPUTS EVALUATION project, but some general principles and practical suggestions have emerged from the discussions of this issue.

### 6.4.1 Improvements at the agronomic level

Whether or not a product is needed often depends on whether alternative methods or alternative inputs are available. Therefore, need should not be evaluated for individual products, but rather for “functional groups”. In addition to products, these groups may also contain alternative methods. Then, the order of preference of the products and methods should be established within each functional group (but not across the groups). In many cases, it will be more adequate to divide them into high and low priority than to establish a full order of preference. One aim of the restriction is to promote the use of products/methods with high preference within their functional group, and to prevent the use of products with low preference. Another aim is to prevent “unnecessary” use of inputs, and to stimulate locally adapted production strategies which serve this aim. In practice, this may cause conflicts because a farmer will consider all the inputs he uses “necessary”. Therefore, some guidance is needed. In the following, we discuss some cases; please note that these ideas are preliminary drafts.

Within the nitrogen-rich fertilisers, products and by-products of animal origin are most controversial, because factory farming origin often cannot be excluded (see case study on hydrolised proteins). Also, some steps of the manufacturing processes give rise to concerns. On the other hand, the use of farm-derived fertilisers such as manure, slurry or composted materials is particularly well in line with organic farming principles. Therefore, a possible restriction for products and by-products of animal origin could be: “only to be used if nutrient requirements cannot be satisfied through crop rotation, use of green manure and animal excreta or plant derived fertilisers”. Within the products and by-products of animal origin, it seems unnecessary to establish an order of preference for those products where there are concerns about possible factory farming origin. Fish meal and wool might be considered higher priority, because there are no concerns about factory farming origin.
In the case of deficiencies, the use of trace elements may be necessary. In the absence of deficiencies, however, the use of trace elements is usually unnecessary. Therefore, a possible **restriction for trace elements** could be: “only to be used in the case of documented deficiencies”. The regional or national concept for implementation would then have to specify whether soil analyses and/or leaf analyses and/or symptoms of deficiency are accepted as “documentation of deficiencies”\(^{16}\). Similar restrictions could be applied to **fertilisers rich in calcium, magnesium or potassium**.

Within the products and methods for the control of crop pests, there is a steep hierarchy of preference. Ideally, such problems should be prevented with cultural practices such as the choice of crops and varieties that fit to the specific farm environment, the use of tolerant varieties or habitat management for the promotion of natural enemies. The release of predatory insects or mites and the application of microbial control agents are also methods of high preference, because of their minimal impact on the environment and on non-target organisms. By contrast, insecticides such as azadirachtin, pyrethrins, rotenone, mineral oils or spinosad are the last choice, because they may also affect non-target insects\(^{17}\). Therefore, a possible **restriction for these insecticides** could be: “only to be used against pests which cannot be controlled with cultural practices or biological control agents under the specific circumstances”. The “specific circumstances” may be specific regions (e.g. northern Italy for the leak fly) or exceptional climatic situations.

There is no obvious reason why in general the use of a new insecticide (e.g. spinosad) should only be allowed against pests which cannot be controlled with one of the already listed insecticides. Of course, in specific cases the full evaluation may reveal preference for one of the two products – either the new or the existing one.

Within the products and methods for the control of crop diseases, the situation is similar as for pests. Ideally, such problems should be prevented with cultural practices, while the copper based fungicides and lime sulphur are the last choice. Therefore, a possible **restriction for these fungicides** could be: “only to be used against plant diseases which cannot be controlled with cultural practices or biological control agents under the specific circumstances”.

The listing in Annex II might also specify for which commodity an input shall be used (i.e. horticulture, fruit trees, grapevines, arable crops, fodder crops etc.). By contrast, specification at lower levels such as individual crops seems too detailed for the Regulation.

### 6.4.2 Improvements at the administrative level

The decision whether an input is necessary on a given farm cannot be left to the farmer alone (although he carries a large proportion of it), but it also cannot be regulated at EU level, because this exceeds the desirable level of detail for Regulation 2092/91. Thus, the decision should be taken at an intermediate level (currently, this is the level of the inspection body or inspection authority). In our opinion, however, only **public authorities** (and not inspection bod-

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ies) should have the power to recognise the need for a product. With (private) inspection bodies, there are potential conflicts with commercial interests.

As a link between Reg. 2092/91 and the individual organic farms, the “intermediate level” (see below) should provide concepts of implementation which contain clear decision-making rules to be applied at the farm level. The decision-making rules may vary for different countries, but they should be based on the same principles. To ensure transparency, the concepts of implementation should be publicly available. Note that many national authorities, private label organisations and certifiers already have standards and regulations which cover certain aspects of these concepts of implementation, but that these are neither harmonised nor transparent. Examples of such decision-making rules could be:

- “soil analysis must demonstrate levels below…” (e.g. for trace elements)
- “only against insect pests in fruit trees, vegetables and ornamentals”
- “only against the rosy apple aphid and (etc.)”
- “use only during the growth stage…”
- “only with prior written license by …”

The units of the “intermediate level” could be either the Member States or larger climatic zones (e.g. north, centre, south\(^{18}\)). As a practical approach which takes into account the limited resources in some countries, we recommend that the Commission and SCOF, possibly aided by the expert panel, prepare concepts of implementation for these three climatic zones. The Member States can either implement the concept for their climatic zone, or develop a national concept, using the concept for its zone as a blueprint.

Note: In the case studies, we have attempted to evaluate hydrolised proteins and spinosad consistently with existing products and concluded that both should be allowed with the “need recognised” restriction. In the case of hydrolised proteins, this ensures consistency mainly with “products or by-products of animal origin”; in the case of spinosad, with the insecticides azadirachtin, pyrethrins and rotenone. More specific restrictions would be possible for these products, too. In the case of hydrolised proteins, the need was only claimed by the applicant for horticultural crops and cereals. During the discussions, need was mainly claimed by southern countries, while central European countries seem to have a smaller need and northern countries hardly any need. For spinosad, need was mainly claimed by southern and central countries, but hardly by northern countries. Spinosad can be used against a wide variety of pests in a wide array of commodities, and registrations for many additional crops is likely in the future. Many of these pests cause significant economic damage. Whether spinosad is “necessary” depends mainly on whether other insecticides are registered for use against the same pest. However, even if alternative products are available, resistance management may require the alternating use of different insecticides and thus create a need for spinosad. Because of this complex situation, restrictions on need are difficult at the EU level, but should be made in the concepts of implementation at the “intermediate level”.

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\(^{18}\) In a draft working document, DG SANCO distinguished three zones in the EU as follows: **North** (Denmark, Estonia, Latvia, Lithuania, Finland, Sweden), **Centre** (Austria, Belgium, Czech Republic, Germany, Hungary, Ireland, Luxemburg, The Netherlands, Poland, Slovakia, Slovenia, United Kingdom) and **South** (Cyprus, France, Greece, Italy, Malta, Portugal, Spain).
6.5 Control of stored product pests

A participant in the project’s final conference suggested better regulations concerning stored product pests. Most storage of organic foodstuffs is not part of agricultural production. Thus, the legal implications of regulations in this sector are complex. Regulations in this area should follow the principles outlined here.

- Consumers expect that foods labelled as “organic” are not only produced according to organic farming principles, but also that their post-harvest treatment follows the same principles. In particular, residues from synthetic pesticides applied post-harvest must be avoided.

- Organic farming principles establish a clear hierarchy of preference for the control methods: Preventive measures such as blocking pathways for pest immigration and regular turnover of foodstuffs have the highest priority and preference. Physical and mechanical control methods such as seed cleaning, heat and cold treatment are also highly preferable. This category contains also methods which prevent oxygen supply for the pests like vacuum package and/or replacement of air by inert gases such as carbon dioxide.

- The control of pests in grains with diatomaceous earth (kieselgur) is also acceptable. Diatomaceous earth has been listed in Annex II B but has been withdrawn because of “lack of use”. We suspect that the argument “lack of use” referred to use in agricultural production, and not in storage. Diatomaceous earth acts on pest insects by abrasion of chitinised articulations and desiccation, but it has no physiological, toxic effects. Therefore, it should be considered a physical method rather than a pesticide. Its registration status is unclear at the moment. Diatomaceous earth was notified during the “render-4” call. In June 2005, the notification was withdrawn with the argument that diatomaceous earth acts by physical means and is therefore not a pesticide. This argument has not been questioned by the Rapporteur Member State to date. However, some national registration authorities still consider diatomaceous earth a pesticide.

- The use of pesticides is highly controversial. The products listed in Annex II B are generally not registered for use on stored products (with some exceptions for pyrethrum), and the use of synthetic pesticides meets low public acceptability (see first bullet point). In our opinion, the minimum restriction is: if synthetic pesticides are allowed at all, they must be restricted to the absolute minimum and limited to cases where other methods are not successful and when there is a threat of severe damage.

To also cover stored product pests, section (c) of Article 7 could be changed as follows (the deviation from the version given in section 3.1 is shown in red):

\[(a)(c)\] Besides, if they are used for the purpose of plant pest or disease control, for animal nutrition or cleaning and disinfecting livestock buildings and installations or for other purposes related to crop production and storage of foods, they are essential for the control of a harmful organism or a particular disease, or to achieve the intended purpose for which breeding alternatives or management practices are not available or less effective, and alternative substances are not included in Annex II;
6.6 Review of existing inputs

At the project’s final conference, there were voices suggesting that all inputs currently listed in Annex II should be re-evaluated. The experience with the two case studies elaborated in this project shows that this would be a very laborious task, and it is unclear who would carry the burden of work. We consider it sufficient to review those products which are controversial. Our proposals explicitly mention the possibility for “applicants” to request the withdrawal of existing products. In our opinion, the initiative should be left to Member States which consider a listed input unacceptable, and therefore do not recommend any actions to be taken at EU level.

6.7 Labelling of inputs

Many inputs are currently sold with trade names carrying the words “organic”, “biological” or “ecological”. This may give consumers the impression (i) that the input is derived from raw materials of organic agriculture origin (particularly in composts and fertilisers) and/or (ii) that the input is allowed for use in organic agriculture. However, there is no guarantee that either of these impressions reflects the truth, because there is no legal protection of the terms “organic”, “biological” and “ecological” in the context of input labelling.

In our opinion, this is a gap in legislation which facilitates misleading consumer information in a sensitive area. We consider the topic important and recommend that the terms “organic”, “biological” and “ecological” should also be legally protected in the context of input labelling. However, because this topic is outside the scope of the ORGANIC INPUTS EVALUATION project, we have not elaborated further suggestions.

6.8 On-farm trials

On-farm trials are a key element for the further development of organic farming. The testing of new inputs in on-farm trials is regulated in Reg. 2092/91, Annex I, section 1.4 (b). We recommend that Member States develop a policy of implementation which facilitates on-farm trials through simple authorisation procedures, while safeguarding the integrity of organic products. In this process, it will be necessary to make a preliminary assessment whether the input to be tested has any chances to be allowed for organic farming in the future. We recommend that the Quick Screening page of the criteria matrix is used for this purpose.
7 Appendix: case studies

As case studies, hydrolised animal proteins (nitrogen fertilisers) and spinosad (an insecticide) were evaluated by two working groups. The results are available from the project website in the form of a completed evaluation matrix for each case. Here, we only report some of the experiences encountered during these case studies.

The case studies may be consulted as examples on how to fill in the matrix. In addition, they are interesting because there is a public debate on both of these products concerning whether they should be allowed in organic farming. However, it must be emphasised that this is not an official evaluation of these products.

Both working groups felt that the completed matrix gave an adequate and complete picture of the key issues associated with the products. It can work out precisely what the controversial issues are, but it cannot help to solve controversies. This is ultimately a political discussion to take place in the SCOF.

As every input is unique, there is no single, logical solution to fill in the matrix. For example, we had to deviate from the scoring instructions in two cases (E 5.01 for hydrolised proteins; E 2.01 for spinosad). We believe that this poses no problems, as long as it is explicitly mentioned and therefore transparent to all stakeholders.

7.1 Case study 1: hydrolised proteins

- When the experts first evaluated the application, they expressed reservations on several aspects, and desired to obtain more information concerning these. With subsequent amendments by the applicant, some reservations were given up. We believe that this pattern will be the rule rather than the exception, and we would like to stress the need for communication between applicant and expert panel. Although some time may be lost in the short term, the resulting improvements of the request will save effort in national evaluation, reduce the potential for misunderstandings and may ultimately speed up the evaluation process.

- Some partners questioned the need for such products, because they are not needed for the crops grown in their countries. In such a case, it is important for experts to be aware that conditions may be different elsewhere and we suggest that the expert panel covers a wide geographical range. How the needs of individual countries or individual crop groups are weighed is a political decision, which is beyond the authority of the expert panel.

- The different ways of manufacture (enzymatic, thermal or chemical hydrolysis) were judged differently. This made it necessary to give a multiple evaluation with different scores for different ways of manufacture. This was not originally foreseen when the matrix was made, but it poses no problems, other than slightly reducing the legibility.

- Some partners expressed strong concerns about the raw materials, for which factory farming origin cannot be excluded. On the other hand, several other products of similar origin are currently listed in Annex II A (e.g. blood, horn and meat meal). There is a case to argue that the Annexes should be consistent and based on a general policy. In other words: as long as blood, horn and meat meal are allowed, hydrolised proteins should not be rejected because of the origin of the raw materials. For other experts, the factory farming origin is unacceptable to
such an extent that the precedent of blood, horn and meat meal did not convince them. We think that it is the experts panel’s task to work out such conflicts, but that the final decision should be left to the SCOF.

- The application contains specific information about the chromium contents of hydrolysed proteins derived from the tannery industry (if materials are obtained post-tanning). Nevertheless, the experts disagreed whether such levels are acceptable or not. Again, we think that it is the experts panel’s task to work out such conflicts, but that the final decision should be left to the SCOF.

- Some experts considered the recycling of animal wastes (instead of disposal) desirable. Other experts argued that organic farming should not recycle wastes from factory farming, because this could be seen as indirect support for such systems. Once more, the final decision must be left to the SCOF.

- The widest disagreement occurred in the field of public perception. It was quite clear which issues are relevant for public perception, but the significance of the issues was judged very differently.

The case of hydrolysed animal proteins raises several, highly controversial issues and this is reflected in our case study. It must be emphasised that it is not the expert panel’s task to take political decisions. Its task is to provide a structured collection of arguments in favour and against the product, which may provide a basis for the political decisions to be taken by the SCOF.

### 7.2 Case study 2: spinosad

- Some of the partners were uncertain about the relationship between organic evaluation and pesticide registration, and wondered about the differing degree of detail required, or about the different kind of questions asked. Therefore, we have addressed this as a “frequently asked question” under 2.5.2.

- Occasionally, it was assumed that if spinosad was allowed, other microbial products with unwanted side-effects such as antibiotics would also be allowed automatically. This is a misunderstanding of the criteria. Products must fulfill all criteria listed in Art. 7, and these cover also environmental impact and human health.

- The possible use of spinosad in organic farming has been discussed by various stakeholders for a prolonged period, and we considered it important to address the major arguments which have been expressed in these discussions. Therefore, we also discuss arguments which we consider invalid, simply because they are frequently heard. For example, chemical mutants are sometimes judged similarly as GMOs, but we think that they must be judged differently.

- This group of experts has agreed on a single evaluation statement and score for each evaluation question. Once more, we emphasise that this is only a case study and not a final evaluation, and that other experts might judge some aspects differently.

- There has been a discussion to what extent the evaluation should be based on hazards, and to what extent on risks. For example, spinosad is potentially hazardous in water. However, risk management practices are specified during PPP registration with the aim to minimise these risks (example from the product label of “Tracer”: “DO NOT ALLOW DIRECT SPRAY
from broadcast air-assisted sprayers to fall within 40 metres of the top of the bank of a static or flowing waterbody, unless a Local Environmental Risk Assessment for Pesticides (LERAP) permits a narrower buffer zone, or within 5 metres of the top of a ditch which is dry at the time of application. Aim spray away from water”). Similar restrictions also manage the risks to bees and to the health of farm workers. For the purpose of evaluation, it must be assumed that the restrictions are followed, resulting in relatively low risks and a scoring of -1 seems adequate. In the sections on environment and on human health, the risks should be evaluated. However, some participants in the project’s final conference were irritated about the potential use of a product with such hazards in organic farming. This illustrates that hazards should be evaluated in the section on public perception.

- The need for spinosad in the case of the codling moth is particularly interesting. In organic farming in Southern Germany, this pest has been controlled with granulosis virus exclusively, which has led to resistance in the codling moth and failing codling moth control. If the evaluation was carried out in a very narrow sense, it would state that granulosis virus is an alternative control method with lesser side-effects on non-target organisms. However, sustainable pest management requires the alternative use of different products. In this sense, there is a need for spinosad to enable sustainable control of the codling moth with granulosis virus.

- At the project’s final conference, there was a discussion about the possible use of GMOs in the culture broth used for manufacture of spinosad, which is relevant for the evaluation of many microbial products. According to the generally accepted “ALOG definition” applying to organic products, the last reproducing organism must not be a GMO. In the case of spinosad, this is the bacterium Saccharomyces spinosad. For the broth used to culture this bacterium, the presence of GMO materials cannot be excluded. However, spinosad is a highly purified product and it can be excluded that GMO traces from the broth would be detectable in spinosad based insecticides. The situation could be further complicated by the following argument: the ALOG definition applies to organic products and not to inputs (inputs cannot be labelled as organic, see section 6.7). According to this argumentation, the last reproducing organism is the crop and not the bacterium. In the case of spinosad, GMO origin is not a problem. In other products, however, it might be problematic. Like at other levels, co-existence of organic farming and GMOs proves to be very problematic.
About the ‘ORGANIC INPUTS EVALUATION’ project

The ‘ORGANIC INPUTS EVALUATION’ project is an EU Concerted Action project carried out under the Quality of Life Work Programme, 5th Framework Programme. It is funded by the Commission of the European Communities (QLK5-CT-2002-02565; full title: Harmonised and Standardised procedures for evaluation of plant protection products, fertilisers and soil conditioners for use in organic agriculture) and co-funded by the Swiss Federal Office for Education and Science (BBW 02.0113). The project lasts from January 2003 until December 2005.

The objective of this Concerted Action project is to develop recommendations for harmonised and standardised procedures for the evaluation of plant protection products, as well as for fertilisers and soil conditioners authorised for use in organic agriculture according to Council Regulation 2092/91. The project proceeds in three phases:

• Inventories of current evaluation procedures in the participating countries (separately for plant protection products and fertilisers and soil conditioners).
• Elaboration of standardised evaluation procedures.
• Recommendations for evaluation procedures and identification of research needs.

The following institutions participate in this project:

• Danish Agricultural Research Centre for Organic Food and Farming – Danish Institute of Agricultural Sciences (DARCOF-DIAS), Denmark
• Research Institute of Organic Agriculture (FiBL), Switzerland
• EcoS Consultancy, United Kingdom
• Consiglio per la Ricerca e la Sperimentatione in Agricoltura (CRA) - Istituto Sperimentale per la Nutrizione delle Piante (ISNP), Italy
• Associazione Italiana per l’Agricoltura Biologica (AIAB), Italy
• Louis Bolk Instituut (LBI), The Netherlands
• Soil Association, United Kingdom
• Ludwig Boltzmann Institut for Biological Agriculture, Austria
• Austria Bio Garantie / InfoXgen, Austria
• Associação Portuguesa de Agricultura Biologica (Agrobio), Portugal
• University of Kassel, Germany
• Danish Ministry of Agriculture, Foods and Fisheries, Plant Directorate, Denmark

For more information on this project, visit the project website www.organicinputs.org.
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