RELACS

IMPROVING INPUTS FOR ORGANIC FARMING

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1. Executive summary

The plant and animal health care strategy in organic farming strengthens agro-biodiversity, protects the environment as well as animal and human health. In addition to fully exploiting preventive options, the use of external inputs such as plant protection products, fertilisers or veterinary medicinal products is allowed to prevent inacceptable losses in productivity or animal suffering. However, external inputs need to comply with organic standards as well as European legislation and are therefore carefully evaluated before any decision on acceptance is taken. Organic farming systems should aim at reducing dependency on off-farm fertilisers to the lowest feasable level to ensure closed nutrient cycles and avoid nutrient leakage and contamination.

This policy brief explains the underlying principles and the procedures for evaluation of inputs, focusing on plant protection products, fertilisers, feed additives and veterinary medicinal products used in organic farming under European legislation. The case study in Annex I on plant protection products provides a full picture on the processes and criteria for authorisation, the assessment of new inputs according to the suitability in organic farming, the history of utilised substances and possible trade-offs and concerns.

2. Introduction

The use of chemical-synthetic pesticides and fertilisers is growing in Europe and throughout the world. The excessive use of synthetic inputs causes contamination, nutrient leakage, residues and drift-off leading to high direct and indirect costs for the ecosystem, biodiversity and non-targeted organisms.[1] A reduction of synthetic inputs needs to be well prepared and alternative approaches, such as organic farming, can lead the way towards an agri-food system free from synthetic inputs. Research projects such as RELACS are one important step to ensure a smooth transition towards the use of less inputs.

Organic agriculture is a farming system that sustains the health of soils, plants, animals, ecosystems and people whilst contributing to long-term food security. It is built on ecological processes and closed nutrient cycles adapted to local conditions. Organic livestock husbandry is based on the harmonious relationship between land, plants, animals and humans, respect for the physiological and behavioural needs of livestock and the feeding of good quality organically grown feedstuffs. The organic system is often further described by standards, which govern labelling and claims for organic products.[2]

External inputs acceptable in organic farming are selected based on a strict set of criteria, with the aim to exclude any inputs that may cause issues related to environmental, human and animal toxicity, or may be in contradiction to the traditions of the sector and/or expectations by organic farmers and consumers. As a result, only the small number of substances which are listed in technical annexes (e.g. Annex I – Fertilisers, Annex II - Pesticides) of the Organic Regulation (EC) No 889/2008 can be used in the organic food and farming sector.

Organic farming constantly evolves, and new inputs are proposed to replace contentious inputs traditionally used or to tackle yet unsolved production obstacles as well as climate change. Whenever new options are proposed the precautionary principle is strictly applied, and principles of organic farming are followed. This implies that unpredictable risks, from newly designed, synthetic molecules and organisms are rejected.

[1] INRA 2018: Towards chemical pesticide-free agriculture.

[2] The IFOAM OI Norms for Organic Production and Processing. Version 2014.

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3. Principles of organic farming

The dynamic development of the organic sector in the past years was possible because of a smart combination of tradition, innovation and science whereby the organic principles of health, ecology, fairness and care represent the underlying basis.[3]

The **principle of health** aims at sustaining and enhancing the health of soil, plant, animal, human and planet as one and indivisible. Plant health is based on preventive and indirect management measures and plant nutrition done by feeding the soil and enhancing soil quality rather than the plant directly. Livestock health and welfare depends on a combination of factors such as the appropriate feeding and housing, social behaviour, environment and general management and husbandry activities. The use of fertilisers, pesticides, veterinary medicinal products and feed additives that may have adverse health effects should be avoided.

The **principle of ecology** expresses that organic agriculture should be based on living ecological systems and cycles, work with them, imitate them and help sustain them. The appropriate design and management of biological processes and natural resources which are internal to the agroecosystem aim to create resilient agricultural systems. These management practices must be adapted to local conditions, ecology, culture and scale. Decreasing the use of external inputs like non-renewable, mined fertilisers, synthetic pesticides or feed additives usually happens in parallel with increasing other inputs. These inputs can be bought or produced on the farm (such as manure), others come in the form of knowledge and measures taken (e.g. timing of planting or a wide crop rotation).

The **principle of fairness** should build on relationships that ensure fairness regarding the common environment and life opportunities. This implies socio-economic conditions where the development, production and use of natural inputs is made feasible from an economic as well as a regulatory point of view. The availability of natural substances needs to be ensured to preserve substances with a long history of safe use in farming. SMEs developing such substances need to have access to the market in order to tackle the strong monopolisation of the sector. Natural inputs used in organic farming should be produced and managed in a resilient way that is socially and ecologically just in order to make them available also for future generations.

The **principle of care** lays down that organic agriculture should enhance productivity and efficiency in a precautionary and responsible manner to protect the health and well-being of current and future generations and the environment. Farmers' knowledge of pest–crop interactions, about the natural enemies of pests and parasites, natural animal behaviour, local conditions and traditional practices in combination with latest research findings and technology developments are of key importance in the success of organic agriculture. Organic agriculture should prevent significant risks by only adopting appropriate technologies and rejecting unpredictable ones. Decisions about the suitability of an input for organic farming should reflect the values and needs of all stakeholders through transparent and participatory processes.

4. Strategic approach towards inputs

To reach agro-ecosystem health in organic farming, three sets of measures are combined and implemented in parallel which ensures highly efficient **plant and animal health care strategies**:

4.1 Working with functional agro-biodiversity, not against it
4.2 Management measures: preventive instead of intervening approach
4.3 External inputs in form of natural substances or energy[4]

[3] Principles of Organic Agriculture Preambel. IFOAM Organics International

[4] Kienzle, J. (2017): Gesunderhaltung der Kulturpflanzen im Ökologischen Apfelanbau. FÖKO Weinsberg.

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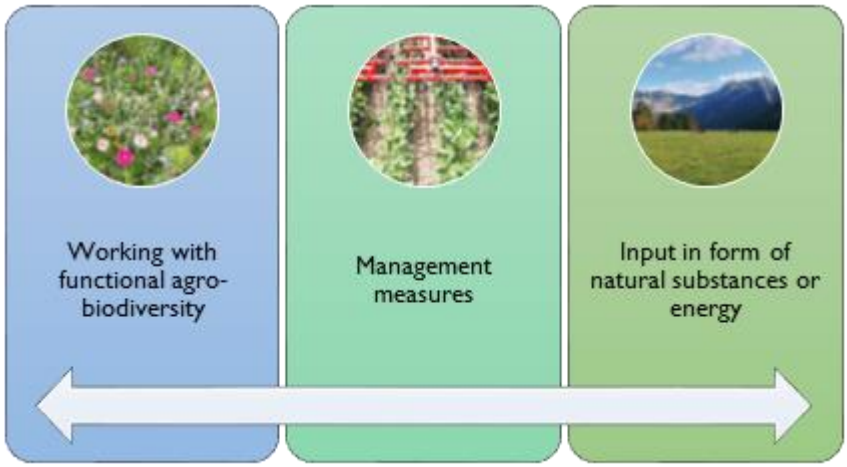

The full exploitation of the preventive potential of management measures and systematic usage of agro-biodiversity stands at the core of sustainable farming practices.

4.1 Functional agrobiodiversity

The availability of appropriate, resilient and nutrient-efficient species and varieties is the key factor on which productivity and quality depend on. Organic plant breeders and small, local seed suppliers aim for broader genetic diversity as it is essential for the adaptability of plants to local farming conditions and changes in weather patterns, and the basis for natural disease and pest resistance. Furthermore, a high level of biodiversity is vital for healthy and resilient organic farming systems. Conservation and improvement of natural landscape features such as hedgerows and ponds, flowering stripes or the planting of cover and catch crops enhance species diversity as they present a refuge for beneficial insects. A main driver against pests and diseases is to make the habitat unsuitable by a limitation of resources, competition, parasitism and predation. Faunal and floral diversities play a crucial role in this regard. A wide crop rotation provides for example an obstacle to pest life cycles by removing host plants. Furthermore, a higher abundance of beneficial insects leads to natural predation and pest suppression.

In livestock production, the use of breeds adapted to organic farming with increased disease resistance and longevity, health and quality traits is essential. Locally adapted breeding strategies and breeding traits also allow to adapt to the diverse feeding strategies and outdoor conditions.

4.2 Management measures

Preventive measures may include protecting crops by netting or coverage or herbicide-free weed control by ploughing, mechanic weeding, solarisation, mowing, and tillage regime. Minimal dependency from off-farm fertiliser inputs is achieved by year-round covering of soils, the use of legumes and application of farm manure in mixed farming systems based on farmgate balance calculations. The development of new technologies such as drones for aerial spraying of pesticides or smartphone apps for nutrient balance calculation and weather monitoring could potentially be big opportunities for the organic sector.

In livestock production, preventive herd/flock health management aims at optimizing factors such as adequate living conditions of animals, including allowance of species-specific social behaviour in an appropriate environment, an appropriate nutrition, and, from a more long-term viewpoint, breeding of resilient and local adapted breeds.
Putting in place animal health and welfare planning and monitoring tools such as protocols, high hygiene standards and high-quality feedstuff underpin this strategy. All organic animals have access to outdoor areas and thus benefit from daylight, natural climate, physical exercise, a variety of feedstuffs and other factors contributing to environmental and nutritional enrichment. Traditional forage species and species rich natural meadows and pastures

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may have lower yields, but they often foster animal health and well-being due to their bioactive compounds, and they are therefore increasingly used as feedstuffs for organic animals. Diets and feeding systems are adapted to the animals' digestive system and species-specific natural feeding behaviour. The availability of breeds adapted to organic farming with increased disease resistance and longevity, health and quality traits is essential. Locally adapted and even farm-specific breeding strategies and breeding traits also allow to adapt to the diverse feeding strategies and outdoor conditions.

4.3 External natural inputs

Inputs used in organic farming are in line with the above-mentioned (part 3) general principles of organic farming and are evaluated against criteria based on the precautionary principle. Inputs are limited to substances that are "natural or naturally derived substances" as stated in the Organic Regulation (EC) No 834/2007, Art. 4. The criteria for acceptance of external inputs depend on the intended use. Organic farming **rejects the unpredictable risks** coming from the release of artificially designed molecules into the environment. Several substances used in organic plant health are "multi-functional", meaning they perform a number of roles like for example fertilising, enhancement of crop quality, plant strengthening or direct plant protection.

4.3.1 Plant Protection Products

Active substances allowed for the use in organic farming are categorised in substances derived from plant and animal origin, microorganisms or mineral compounds. The biggest category of inputs used for plant protection in organic farming are microorganisms followed by natural substances of plant, animal, microbial or mineral origin and pheromones. In terms of use the number of fungicides and insecticides is the strongest growing type of application. Herbicides are generally not allowed in organic farming. Arboriculture, such as orchards, represents the sector which uses most external inputs, while cereals have the smallest number of applied substances.[5] Questionable cases of inputs currently still used as plant protection include substances with a long history of use (i.e. copper, paraffin oils) and substances causing residues (e.g. phosphoric acid).

4.3.2 Fertilisers

Nutrient availability is primarily dependent on the activity of soil organisms therefore fertilisation in organic farming focuses on feeding the soil life. Fertilisation in organic farming focuses on biological processes like nitrogen fixation by legumes, complemented by recycling of nutrients, green manure crops and crop residues. It is dependent on the efficient recycling of nutrients within the farm and from the cities, on the characteristics of the nutrient sources, on their subsequent treatment and the nutrient losses during the treatment. Therefore, the implementation of efficient nutrient recycling systems combined with low nutrient losses during manure management are of high importance in organic farming. Several easy soluble mineral fertilisers are not allowed (e.g. mineral N fertilizers), instead fertiliser material of microbial, plant or animal origin such as livestock manure or organic residues from the cities and food industry are used. Questionable cases for future evaluation include e.g. recycled materials from sewage and new fertiliser treatment and nutrient recovery technologies as well as the use of manure from non-organic farms.

4.3.3 Feed additives

Organic livestock are primarily supplied by organically produced feed and ruminants are mainly fed forages. Animals may be fed vitamins, supplements and trace elements from natural sources as well as pure herbal feed additives. The organic sector has been active to diversify the supply of feed additives and research efforts are ongoing. Questionable cases include synthesised, nature-identical vitamins and non-organic produced herbs rich in bioactive substances.

[5] Robin, D, Marchand, P. (2018): Evolution of the biocontrol active substances in the framework of the European Pesticide Regulation (EC) No. 1107/2009. 10.1002/ps.5199.

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4.3.4 Veterinary treatments

Organic farming practices promote animal health and well-being through adequate nutrient supply, stress-free living conditions and selection of breeds which are resilient to diseases, parasites and infections. If animals become sick or injured despite these measures, they need to be treated timely and adequately in order to guarantee animal welfare. Preference should be given to natural medicines (such as medicinal plants) and to vaccinations of non-GM origin. Chemically synthesised veterinary medicinal products and antimicrobials are to be reduced to a minimum and any form of prophylactic treatment with such allelopathic veterinary medicinal products is not allowed. Numbers of allopathic veterinary treatments per animal are limited and prolonged withdrawal periods apply. Questionable cases for future evaluation include e. g. the use of vaccines produced based on recombinant microorganism if no non-GM vaccines are available.

5. Registration and legislative background of inputs

Inputs used in organic farming have to comply with two sets of regulations: the input first needs to be registered in the corresponding horizontal legislation (e.g. for pesticides (1107/2009), fertilisers (2003/2003), feed (68/2013 and 2017/2017), feed additives (1831/2003), veterinary medicinal products (2019/6 and 37/2010)) in order to be added into the annexes of the regulation for organic production (EC) No 889/2008. The need for inclusion of novel inputs in the organic regulation causes a time lag between the introduction of an input in general agriculture and the legal use in certified organic farming. The time lag caused by the assessment and approval process has reached in some cases more than four years (e.g. in the case of Laminarine for plant protection, Struvite as fertiliser). Furthermore, inputs may be regarded as controversial within the organic sector and in such cases, no decisions may be reached. Both, time and conformity aspects, are considered as obstacles for the development of novel solutions since the financial risks for the producers are substantial. Additionally, there are many national regulations in place which make the availability of certain inputs very different from country to country. The number of plant protection products available for the use in organic farming varies for example from 11 in Lithuania to 576 in Italy.[6]

5.1 Legal background – Horizontal EU legislation

Plant protection is subject to the EU-legislation on plant protection products (EC) No 1107/2009 covered by DG SANTE (Directorate General Health and Food Safety). The implementing regulation No 540/2011 (Annex I) contains a list of all active substances allowed for plant protection purposes in Europe. The European pesticide database contains all approved active substances as well as the Maximum Residue Level (MRL). Under current EU rules, **it takes 2.5 to 3.5 years**[7] from the date of admissibility of the application to the approval of a new active substance. This time varies depending on how complex the application is, and deadlines cannot always be met. Only if the final product containing the active substance is authorised in the respective country for the specific use and the given crop it may be also used in organic farming. The lengthy legal approval process for the use of substances in certified organic farming in the EU is described in the subsequent chapter.

The recently revised **Fertiliser Regulation (EC) No 2003/2003** falls under the responsibility of DG GROW (Internal Market, Industry, Entrepreneurship and SMEs) and still applies until June 2022. With the new Regulation (EU) No 2019/1009 on Fertiliser Products already in force, materials covered by the Regulation include for the first time organic and organo-mineral products, liming materials, soil improvers, growing media, agronomic additives and plant biostimulants. In the moment of writing this paper the detailed secondary legislation (implementing and delegated acts) is still under development, therefore a three years transition period until the new regulation applies has been agreed. The new regulation will offer optional harmonisation: a fertiliser must meet the requirements of the new regulation in order to be traded within the EU (CE marked). Member States still have the possibility to set

[6] Matyjaszczyk, E. (2017): Plant protection means used in organic farming throughout the European Union. Pest Manag Sci 2018; 74: 505-510.

[7] Source: https://ec.europa.eu/food/plant/pesticides/approval_active_substances_en

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specific rules for their internal market. Furthermore, mutual recognition between Member States of products will still be possible.

With regard to **animal feed** material the regulations (EC) No 68/2013 and (EC) 2017/2017 describe (a) partly on "part of a plant species"-base (e.g. soy-beans) and (b) partly on a very overall base ("grass-, herbs and legumes", "bark" or "flower" - allowed feed-ingredients as a positive list. While most of the mentioned feed materials are dominated by main nutritional components like carbohydrates, fat or protein, some others can also represent high (and mainly) contents of bioactive substances (e.g. garlic, fennel).

Regulation (EC) No 1831/2003 lays down the use of **additives in animal nutrition** while Regulation (EC) No 429/2008 details the rules for implementation. Authorisation is granted for specific animal species or categories and for specific conditions of use. All authorised products are listed in the European Commission's (DG SANTE[8]) Register for Feed Additives. Again, several extracts of plants rich in bioactive components are registered as feed additive – mainly as flavouring substance. However, nearly all of these extracts are only provisionally registered.

The current legal framework for the market authorisation, distribution and use of **veterinary medicinal products** is set out in Regulation (EU) 2019/6 and, more specific with regard to active substances for livestock, in Regulation (EU) No 37/2010. Whereas homeopathy itself seems to be well embedded within this new Regulation (EU) 2019/6, veterinary phytotherapy or herbal medicine is only mentioned in the preamble with the sentences: "There is insufficient information to date on traditional herbal products used to treat animals in order to allow the setting up of a simplified system. Therefore, the possibility of introducing such a simplified system should be examined by the Commission based on the information provided by the Member States on the use of such products on their territory". However, about 40 medicinal plants are registered as active substances without withdrawal periods in Regulation (EU) No 37/2010.

5.2 Legal background – Organic Regulation

The new Organic Regulation (EU) No 2018/848 will apply from 1 January 2021 repealing Council Regulation (EC) 834/2007. The Regulation defines organic farming as a sustainable systems approach. Only where the necessity of use of external inputs is duly justified, inputs can be used. Eligible inputs are limited to natural or nature-identical substances, low solubility mineral fertilisers and veterinary drugs including antibiotics where necessary to avoid animal suffering. In terms of current organic legislation, implementing regulation (EC) No 889/2008 contains annexes with a list of all inputs which may be used in organic production. The organic regulation falls under the responsibility of the Unit 'Organics' of DG AGRI[9]. In order to add an input on any of the Annexes, the European Commission asks for advice from the independent expert group for technical advice on organic production (EGTOP). The European Commission generally follows the opinion of the group. Major authorisation criteria used for the analysis of new inputs are in line with the IFOAM International standards for organic production and include:

- **Necessity and alternatives:** Any input used is necessary for sustainable production, is essential to maintain the quantity and quality of the product and is the best available technology.
- **Source and manufacturing process:** Organic production is based on the use of natural, biological, and renewable resources.
- **Environment:** Organic production and processing is sustainable for the environment.
- **Human health:** Organic techniques promote human health and food safety.
- **Quality:** Organic methods improve or maintain product quality.
- **Social, Economic, and Ethical:** Inputs used in organic production meet consumer perceptions and expectations without resistance or opposition. Organic production is socially just, and economically sustainable,

[8] Directorate General for Health and Food Safety

[9] Directorate General for Agriculture and Rural Development

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and organic methods respect cultural diversity and protect animal welfare (The IFOAM Norms for Organic Production and Processing, Version 2014).

There is no indication on how to deal with trade-offs or how to weight one criterion over another, but the approach is rather to take a holistic perspective and decide on a case-by-case basis. In the past, this set of criteria proved to be a useful tool for input evaluation and facilitated a participatory, science-based discussion of the EGTOP and the European Commission. Proposals for amendments of regulation (EC) No 889/2008 are then presented in a transparent format to the Committee on Organic Production (COP), comprising representatives of all EU countries, which votes on the possible approval of an input into the annexes.

For credibility and wide acceptance, this involvement of different independent experts from the organic sector is very important. However, the current system of EGTOP, the European Commission and Member States (COP) is slow and cumbersome and needs to be improved in order to equip farmers with the necessary tools in a feasible timeframe.

6. Policy implications and recommendations

Organic farming is making a very important positive contribution to the reduction of the dependency on chemical inputs of today's agri-food system and the risks derived from the use of these substances. In order to facilitate a smooth transition towards organic farming and the adoption of agroecological practices, coming along with the phasing out of contentious inputs, following recommendations are presented:

6.1 Better adapt regulatory framework to specific characteristics of natural substances

- **Introduce a definition and a separate category for natural substances** in horizontal legislations: The current EU regulatory framework for inputs is primarily designed to evaluate chemical (mono-constituent) substances, well defined on single molecular level. There are technical difficulties to adapt the registration criteria to usually highly complex, natural substances. The requirements for data, risk assessment and exposure modelling have been designed for highly efficient, single molecules, whereas for example, plants rich in secondary metabolites contain often more than 100 different single compounds. Furthermore, very different terminologies like 'biological', 'natural' 'naturally-occurring' or 'nature -identical' substances are used in different legislations[10] without in-depth description nor uniform definition.

- **Expand knowledge of experts in Member States and EU authorities about natural substances.** The harmonisation of the evaluation process in the Member States as well as expert coordination of different fields (like plant protection or animal health and welfare) could help to streamline procedures for substance authorisation and reduce workload and delays of applications and facilitate mutual recognition**.**

- **Public money for natural substances of public interest:** Many natural substances have a long history of safe use, but the market segment is small and often it is not possible to obtain intellectual property rights. Since the registration process is very costly and time consuming, there is only very limited return on investment for SMEs producing natural substances. In consequence, these substances will no longer be available for farmers because of simple economic reasons.

[10] Compare for example the terminologies used in the REACH Regulation EC No 1907/2006 'substances which occur in nature' and the Plant Protection Regulation EC No 1107/2009 talking about 'plant protection product of biological origin'

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6.2 Coherence of horizontal and organic regulation and acceleration of approval process:

- It is crucial to reduce the current time lag of up to several years from the approval in the horizontal regulation to the inclusion in the annexes of the organic regulation. Furthermore, the predictability for acceptance for novel inputs in the organic sector needs to be improved.

- Introduce a non-binding, ex ante assessment procedure to predict compatibility of inputs with the organic standard. The assessment can for example be carried out by the EGTOP. This would give security to companies to invest in new products and therefore facilitate innovation and at the same time speed up the whole authorisation process.

- In order to speed up the process the EGTOP needs to be further professionalised in terms of funding and procedures. Professional experts need to be remunerated adequately and a clear and binding timeframe from the request to the final opinion on the suitability for organic farming should be introduced.

6.3 Specific recommendations per type of input

6.3.1 Appropriate regulation for bioprotectants of plants: [11]

- Establish a specialised working group for the authorisation of natural substances on EU level. Currently there are three different working groups that cover many natural substances (working groups on biopesticides, low-risk products and basic substances). The further harmonisation of the evaluation process would help to streamline procedures for active substance authorisation and reduce workload and delays of applications and facilitate mutual recognition.

- In order to speed up the authorisation process of low-risk natural substances applicants should have free-of-charge pre-submission meetings with the authorising body. Furthermore, in case of a high number of applications, authorising bodies could give priority in first assessing applications for low-risk natural substances.

- There are some types of uses of plant protection products (e.g. in greenhouses, products to be applied in storage areas, post-harvest treatments, seed treatments) where the same assessment will apply across the whole EU. It means that an application for the authorisation is only filed once in one Member State instead of an application in every Member State, which is currently the common procedure. If a substance has been approved to be in line with the organic principles, this system of only having one assessment could also apply for the type of use in organic production. This would lead to equal conditions, fairness and the highest degree of harmonisation of product authorisation in the organic sector in the EU.

- Increased knowledge of Member State experts on natural substances in order to improve the functioning of the zonal system and mutual recognition

6.3.2 Appropriate regulation for fertilisers and biostimulants:

The European Commission's Circular Economy Package, and in particular the new Fertiliser Regulation, is a welcomed step towards further closing nutrient cycles. When finalising the technical details of the new regulation it is important that the specific needs of the organic sector are considered:

- Actively promote non-commercial use of animal manure and compost: The use of animal manure and farm-produced compost not labelled with the CE mark remains outside the scope of the new EU fertiliser legislation.

[11] Recommendations build on the position paper of IFOAM EU 2016: Plant health care in organic farming. https://www.ifoam-eu.org/sites/default/files/ifoameu_policy_position_paper_plant_health_201604.pdf

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Nevertheless, it is important to ensure that recycling of farm residues is not being hindered by disproportionate administrative burdens and quality control.

- Nutrient recovery and reuse especially of nitrogen and phosphorous from waste streams should become a bigger priority. This would reduce the dependency on non-renewable nutrients and manure from conventional farming and reduce pressures on the environment and human health. Alternatives such as meat and bone meal, struvite from municipal wastewater treatment or treated organic waste from commercial origin (catering / retail) need to be considered, developed and carefully evaluated.

- The registration procedure for biostimulants should not repeat the situation of the plant protection legislation (EC) No 1107/2009 where the process is designed for synthetic molecules (see also point 1) presenting many difficulties for naturally occurring substances which have an existing natural background presence. Furthermore, the process should be proportional to the potential risks of such substances and consider a potential long history of safe use.

- Today the terms 'organic*', 'biological', 'ecological', or abbreviations such as 'bio' or 'eco', 'eko' etc. are recognised as synonymous to organic*[12] production depending on the nationally used terminology. As a result, the use of such terms can mislead organic* farmers because they suggest a fertiliser is suitable for organic* farming. All CE fertiliser products compatible with organic* farming should be explicitly labelled as "allowed in organic* farming in accordance with the Regulation (EC) No 834/2007".

6.3.3 Appropriate regulation for natural substances in animal health and welfare:

- A better coordination and cooperation between Member States and different regulatory bodies (feed including feed additives (EFSA), veterinary medicinal products (EMA), biocides) to help streamlining procedures for active substance authorisation, reducing workload and delays of applications and facilitating mutual recognition

- Defining and implementing a new category "herbal and natural substances based bioactive feed additives" in the regulation (EC) No 1831/2003 including a simplified registration process

- Implementing in accordance with the aims of the "European One Health Action Plan against Antimicrobial Resistance" (in particular with chapter 3.2 "develop new therapeutics and alternatives") a simplified registration process for herbal veterinary medicinal products including traditional herbal products.

- Defining, in this context, the word "traditional" in a more open way as for human medicinal products: in contrast to human medicine only a few herbal veterinary medicinal products have been preserved

- Develop herbal monographs for veterinary use following the already existing HMPC-monographs for human medicine funded with public money

6.4 Long term EU policies for organic farming and agroecological methods:

- This includes a more supportive and coordinated agricultural policy environment to stimulate the uptake of organic and agro-ecological practices such as good soil management, crop rotation, the breeding of robust varieties and animal breeds and biological pest control.

[12] In this bullet point, **organic*** means allowed in organic farming according to the Regulation (EC) No 834/2007 and does not mean **organic** as category of fertilisers which contain mainly organic matter, not mineral components. In the first case the term is marked by an asterisk (*).

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- Incentivise the uptake of agroecological practices and prioritise the development of organic farming under the new delivery model of the Common Agricultural Policy, including knowledge transfer and innovation as well as market development.

- Natural substances with their specific characteristics can play a vital role in meeting the goals set in the Sustainable Pesticide Use Directive (SUD, 2009/128/EC), and other environmental policies, and should therefore be prioritised and supported in the National Action Plans of the Directive[13].

- Development of solid Harmonised Risk Indicators (HRI) to measure the implementation of the Sustainable Pesticide Use Directive (SUD): Member States must be obliged to not only gather data on the sale of plant protection products but also on the application rate. Appropriate risk indicators are needed for plant protection products use that do not discriminate against sustainable solutions and therefore need to be weighted according the product category / use of substance.

- Introduction of a green value-added tax (VAT) on synthetic inputs with revenues used to fund applied research on organic and agroecological approaches

- Prioritisation of research, innovation and knowledge transfer for organic farming and agroecological approaches in Horizon Europe[14]

- The development of digital tools and technologies such as drones, sensors, or decision support tools based on big data could potentially lead to further reduction of the use of inputs. However, a strong regulatory framework is needed to protect farmers from exploitation and data theft and to guarantee the safe, environmental-friendly and socially sound use.

- Ensuring that traditional and heterogeneous plant material and animal breeds with a broad genetic spectrum have access to the market.

- More and better data: for a more precise assessment of natural inputs, policy makers, farmers and companies require better data than currently available. This implies better standardised definitions, monitoring and analysis of the flows of the relevant inputs in the EU and beyond.

[13] Like the EU strategy for a non-toxic environment, the Water Framework Directive (WFD; Directive 2000/60/EC), the Groundwater Directive (Directive 2006/118/EC), the Habitats Directive (Council Directive 92/43/EEC) and the General Food Law (GFL; Regulation (EC) No 178/2002).

[14] See full position paper: TPorganics (2017): Research & Innovation for Sustainable Food and Farming.

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7. Appendix

Evaluation of plant protection products in organic farming

Excerpt of: Speiser, Bernhard; Schärer, Hans-Jakob and Tamm, Lucius (2018) Direct plant protection in organic farming. In: Köpke, Ulrich (Ed.) Improving organic crop cultivation. Burleigh Dodds Science Publishing, Cambridge, UK, pp. 1-21.

Legal background (European Union legislation)

Plant protection on organic farms is subject to the legislation on organic production as well as the legislation on plant protection. Only substances and practices which comply with both legislations may be used. In the following, this is described for the European Union (EU).

In the context of plant protection legislation, the EU-Regulation No 540/2011 (Annex I) contains a list of all substances which may be used as constituents of plant protection products (so-called active substances). In any given plant protection situation, however, only those plant protection products which are registered in the specific country for the specific use on a given crop may be applied. Pesticide registration also specifies details of use such as the dosage, the number and timing of applications and the pre-harvest interval. Pesticide legislation applies to all pesticides, regardless whether they are used in conventional or organic agriculture, and it covers also plant extracts (e.g. azadirachtin), pheromones and microbial biocontrol agents (e.g. *Bacillus thuringiensis*). Since a few years, the EU pesticide legislation recognizes 'basic substances' as a separate category; for more explanations, see section on "Substances exempt from individual authorization" further below.

In the context of organic legislation, Regulation No 889/2008 (Annex II) contains a list of all active substances which may be used in EU organic production. Only a small proportion of all the pesticides authorized for general agriculture are permitted for use in organic farming. The following sections give an overview over the authorized substances/organisms.

Invertebrate biocontrol agents

Predatory and parasitic insects, predatory mites and entomopathogenic nematodes are commercially available and are widely used for plant protection. Such organisms are collectively referred to as 'invertebrate biocontrol agents', and sometimes also as 'beneficials'. Examples of predatory insects include *Aphidoletes aphidimyza* (Diptera, Cecidomyiidae), *Adalia bipunctata* (Coleoptera, Coccinellidae) and *Chrysoperla carnea* (Neuroptera, Chrysopidae). Examples of parasitic insects include *Trichogramma brassicae* (Hymenoptera, Trichogrammatidae). Examples of predatory mites include *Amblyseius swirskii* (Gamasida, Phytoseiidae). Examples of entomopathogenic nematodes include *Steinernema carpocapsae*.

The use of invertebrate biocontrol agents is one of the preferred methods of plant protection in organic farming (Speiser *et al.*, 2006). Under EU legislation, they are not considered to be plant protection products and are therefore not listed in Annex II of Reg. 889/2008. Nevertheless, they may be used in EU organic farming. National regulations concerning the import and release of invertebrate biocontrol agents are not harmonized across Europe at the moment (Hunt *et al.*, 2011).

Microbial biocontrol agents

Microbial biocontrol agents include bacteria (e.g. *Bacillus thuringiensis, B. subtilis*), fungi (e.g. *Beauveria brognartii, Metarhizium anisopliae, Aureobasidium pullulans*) and viruses (e.g. *Cydia pomonella* granulosis virus). The longest-known and most used microbial biocontrol agent is *B. thuringiensis*. Some strains can be used to control lepidoptera, while others may be used to control diptera (mainly aquatic disease vectors) or coleoptera such as the potato beetle (*Leptinotarsa decemlineata*) (Bravo *et al.*, 2011). Genes from *B. thuringiensis* are often used to develop insect-resistant transgenic crops (soy, maize, rape, cotton), but transgenic crops may not be used in organic production.

Micro-organisms are generally authorised for organic production, provided that they are not GMOs. In the EU, microbial preparations are regarded as plant protection products, and only registered products may be used.

Substances of plant origin

Substances of plant origin have traditionally been used for plant protection in organic farming. All plant oils are authorised (e.g. rapeseed or sesame oil as insecticide, fennel oil as fungicide and caraway or mint oil as sprouting

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inhibitors; for a discussion see section on "Substances exempt from individual authorization" further below). The following substances are also authorised: azadirachtin, laminarin, pyrethrins and *Quassia* extract. Since 2016, substances of plant or animal origin which are approved as 'basic substances' (see section on "Substances exempt from individual authorization") and which are food may also be used. This group comprises lecithins, sucrose, fructose, vinegar and horsetail extract. Nicotin extract and rotenone were authorised earlier but are not authorised any more due to toxicological concerns.

Substances of animal origin

Substances of animal origin have traditionally been used for plant protection in organic farming. All pheromones are authorised (use for mating disruption or mass-trapping). Beeswax is used as a pruning agent, sheep fat as a repellent for game animals, hydrolysed proteins as attractants for pest insects and whey and chitosan hydrochloride to stimulate plants' natural defences.

Substances of microbial origin

At the moment, spinosad is the only substance of microbial origin which may be used for plant protection in organic farming. It is an insecticide with well-known effectivity, and it is also widely used in conventional production. When Spinosad was approved for EU organic farming, the experts clarified that microbial products are not automatically approved as a group but need to be evaluated and authorised individually (Forster *et al.*, 2008). Derivatives of microbial products (e.g. strobilurines) are not authorised for organic farming.

Other substances

The group of 'other substances' is a heterogeneous assemblage of substances, many of which have traditionally been used in organic farming. Some substances are directly obtained from nature as minerals (aluminium silicate, kieselgur, quartz sand). Paraffin oil is a natural constituent of petroleum but undergoes substantial purification. Other substances occur in nature but are obtained with chemical processes for practical reasons (often to ensure the necessary purity). This group includes carbon dioxide, ethylene, copper compounds, ferric phosphate, sulphur, lime sulphur and potassium hydrogen carbonate. Calcium hydroxide and soft soap are obtained with 'simple chemical processes' but have traditionally been used.

Why authorised substances are unavailable in some countries

As explained above, only those plant protection products which are registered in a specific country for a specific use on a specific crop may be applied. If this is not the case, the product may not be used. There are marked differences between EU member states in which products are registered, leading to very heterogeneous availability of products. Because only few substances are authorized for organic farming, the non-availability of one substance can often not be compensated, because no other substance with a comparable effect is authorised. In some countries, the non-availability of substances at national level has been an important bottleneck for production. In 2004, the situation was described by Speiser and Schmid (2004). Although this report is outdated in terms of individual substances, countries and uses, it illustrates the general pattern and the mechanisms behind it. The following paragraphs briefly discuss the main reasons why plant protection products are not always registered for all uses which are technically possible.

Distributors of plant protection products are private companies which consider registration as an investment to open new business opportunities. Before engaging in the registration procedure, they will estimate registration costs and potential payback from product sales. If estimated registration costs and financial risks outweigh the potential gains, they will not attempt registration. Such economic mechanisms have greatly limited the availability of plant protection products for organic farmers in many European countries (Ehlers, 2011).

Registration costs include costs for dossier preparation and registration fees. For complex mixtures of substances such as plant extracts, it may be very costly to determine which substance(s) contribute to the pesticidal effect and to carry out all toxicological studies for each component of potential toxicological concern. For pheromones acting by mating disruption, the main challenge lies in establishing efficacy trials, because they act on large surfaces. An EU-funded project has elaborated proposals how pesticide registration could be improved in the case of baculoviruses (Hauschild, 2011), bacteria and fungi (Strauch *et al.*, 2011), plant extracts (Tamm *et al.*, 2011a) and pheromones (Speiser *et al.*, 2011).

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In the past, registration of plant extracts and micro-organisms in the EU has sometimes taken very long (Ehlers, 2011). This is another obstacle to registration, because it increases the time-span between investment (costs for product development and registration) and payback (product sales).
The investments for registration must be proportionate to the market volume. The market volume depends on the surface of the crop in a given country, on the importance of the pest or disease which is controlled, on the efficacy of the pesticide and on the presence or absence of competitor products in the country. Organic fields usually make up only a small percentage of the total surface of a crop grown in a given country, and thus organic farmers are only a small target market. In recent years, however, the demand for biocontrol agents and pheromones has greatly risen due to the fact that non-organic farmers are under pressure to reduce the levels of pesticide residues. This growing demand has stimulated a more rapid development of such products, which benefits also organic farmers.

Grey zones in legislation

Plant health is the result of complex interactions between plants and their environment. Substances which are used for direct control of pests and diseases and which are therefore legally classified as pesticides have been discussed above. In addition, however, a number of disinfectants, fertilisers, trace elements, micro-organisms, 'plant strengtheners' or other products also have the potential to influence plant health indirectly (Tamm *et al.*, 2011b). In many cases, the mode of action is unknown, and reports on efficacy are controversial. European countries have taken different regulatory approaches to the use of such products (Speiser and Schmid, 2004). Thus, there is a grey zone where several legislations (national and EU) interact. The final decision whether such a product is allowed for organic farming depends on the individual constellation, and may vary between different countries. This is illustrated with a few examples below.
Herbal decoctions have traditionally been used for the maintenance of plant health. As soon as a plant protection claim is made (i.e. control of a specific pest or disease is mentioned on the product label), such a product has to be registered as a pesticide, which is a long and costly process (see above). If no plant protection claim is made, however, such products may be marketed without pesticide registration.
All trace elements which are authorized for conventional production may be used in organic farming. The EU fertilisers' legislation recognizes also substances such as 'copper salt', copper hydroxide and copper oxychloride as trace element fertilisers. The foliar application of such fertilisers is an obvious overlap with copper fungicides. Again, the key is whether or not a plant protection claim is made.
Disinfectants also have a role in maintaining plant health. This applies in particular to the disinfection of greenhouse equipment and equipment for growing mushrooms. Also, the disinfection of cutting tools is important to prevent the spread of bacterial diseases, (such as fire blight). At the time of writing, the use of disinfectants in EU organic plant production is not yet regulated. According to a proposal by the Expert Group for Technical Advice for Organic Production (see section on "Authorization process"), similar substances should be authorized as in organic animal husbandry (EGTOP, 2016a).

Dynamics of authorization of materials in the EU

The list of authorised pesticides is constantly evolving, as illustrated below. Examples for the authorisation history of individual substances (including reasons for listing or de-listing) can be found in Speiser *et al.* (2014) or Tamm *et al.* (2015).

Developments in the last 25 years

When the European 'Organic Regulation' was first published in 1991 (EC, 1991), it contained 19 entries of individual substances or groups of substances which were authorised for plant protection. In 2016, the organic regulation contained 26 entries of authorised substances. A quantitative comparison of the two lists is not possible, because some items were split up, while others were pooled. Instead, the development is qualitatively described below.
Among those items which were cancelled, the majority had to be de-listed for reasons not related to organic production or organic principles (mainly alignment with pesticide legislation). Only few substances were de-listed because they were considered not to be suitable for organic farming any more.

Traditional substances still in use today

Pyrethrins, extract of *Quassia amara*, sulphur, soft soap, pheromones and paraffin oil were continuously authorised from 1991 – 2016. Diatomaceous earth was authorised in 1991, then de-listed and finally re-introduced in 2016.

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Sodium bicarbonate was authorised in 1991 and later de-listed. In 2016, EGTOP has recommended its re-introduction, but by the time of writing, this has not yet taken place. However, the similar substance potassium bicarbonate was authorised. Among the microbial biocontrol agents, only *Bacillus thuringiensis* and granulosis viruses were mentioned in 1991, while all micro-organisms were later authorised. Microbial biocontrol agents were always considered as acceptable for organic farming, and the difference merely reflects the poor availability of such products in 1991. Copper fungicides were also authorised continuously, but not the same substances were allowed. In 1991, Bordeaux mixture (a mixture of copper sulphate and slaked lime) and Burgundy mixture (a mixture of copper sulphate and sodium carbonate) were authorised. In 2016, Bordeaux mixture is still authorised together with copper hydroxide, oxychloride, oxide and sulphate, while Burgundy mixture is not authorised any more. Stone meal was generically authorised in 1991. In 2016, this is not the case anymore. Instead, kaolin and quartz sand are listed as two separate items in Annex II. In 1991, plant and animal oils were authorised. In 2016, the entry has been reduced to 'plant oils'. As there are no pesticides based on animal oils, these are not mentioned any more.

Historically used substances not in use any more

Propolis and sodium silicate were mentioned in 1991, but not any more in 2016. These substances were de-listed, because they are not considered to be pesticides under EU legislation. Extract of *Ryania speciosa* was mentioned in 1991, but not any more in 2016, because it is no longer registered as a pesticide in general agriculture as a result of the re-evaluation of pesticides under pesticide legislation. Extract of *Derris elliptica* (also known as rotenone) was also mentioned in 1991, but not any more in 2016. This substance was authorised as a pesticide in general agriculture, but the registration was not prolonged due to human health concerns. In all these cases, the substances were de-listed from the organic regulation due to factors outside the control of the organic sector.

Among the molluscicides, metaldehyde was authorised in 1991. In 2016, this substance is not authorised for organic production any more, but ferric phosphate is authorised instead. Metaldehyde is a synthetic substance, but it was traditionally authorised, because slugs can cause severe damage and there were no alternatives available for their control. Ferric phosphate is an example of a substance which occurs in nature but is chemically manufactured for practical reasons. When ferric phosphate became available, it was judged to be more acceptable than metaldehyde.

New substances not yet in use in 1991

Several new substances are novel pesticides which were not yet developed in 1991. This group includes azadirachtin, spinosad, laminarin and sheep fat, as well as some of the basic substances authorised today.

Other substances were not authorised in 1991, but had to be authorised later because of urgent need. The first example is ethylene. Ethylene is mainly used for degreening bananas after transport from Central or South America to the final market in Europe. This use was considered as essential, and therefore authorised. Later, selected other uses were also authorised (kiwis, kakis, citrus, pineapple, potatoes and onions). In 2016, all restrictions of the use of ethylene were deleted. This was done for legal considerations, and not because further uses were considered as essential. The second example are the pyrethroids deltamethrin and lambda-cyhalothrin. These two substances had to be authorised for the control of the olive fruit fly (*Bactrocera oleae*) and the Mediterranean fruit fly (*Ceratitis capitata*). Because these two substances are not well in line with the principles of organic plant protection (see below), their use was limited to these two pests, and to the use inside traps (no spray applications). Also, the organic sector discusses whether they could be further restricted or phased out again (EGTOP, 2011).

Finally, there is a group of substances which were not explicitly authorised in 1991, because they were not considered as pesticides at that time. These may seem to be 'new' substances, while in reality they have been traditionally used. Examples are horsetail extract (used for strengthening plants), lime sulphur (used against apple scab) and beeswax (used as pruning agent). For calcium hydroxide (used as trunc paint), hydrolysed proteins (used as attractants in traps) and carbon dioxide (conservation of food from storage pests), there is little evidence about their status in 1991, but we assume that they also belong to this group.

Authorisation process

This chapter describes the process for authorisation of a new substances in EU organic farming. The process for de-listing of an existing substance or for changing the conditions for its use follows the same pattern. This section is specific for the situation in the EU at the time of writing, while the processes under other legal or private standards

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may be very different. In the EU, the authorisation process is governed by Article 16 of Regulation 834/2007. Three main steps can be identified: request; discussion and decision; implementation.

Request

At EU level, the process officially starts with a request from an EU member state. However, national administrations usually make such a request only if the organic sector clearly expresses a need for that substance (for a discussion of necessity see below). Thus, the request is usually preceded by lobbying activities. How this is done depends on the organisation of the organic sector and its connections with the administration, and may vary from country to country and from case to case. The organic sector and the manufacturers may support the administration by providing data on the substance or draft texts for the request.

Discussion and decision

Discussion of the requests requires a high degree of specialist knowledge in several disciplines such as organic practices, crop protection, chemistry and environmental sciences. The EU Commission has therefore decided to seek technical advice from independent experts. In 2009, the European commission created the Expert Group for Technical Advice for Organic Production (EGTOP). Since then, requests for the authorization of new substances were usually subjected to a technical evaluation by EGTOP. EGTOP is consulted for different subjects related to plant production, animal husbandry and food processing. Until now, it has produced three reports concerned with plant protection products. All EGTOP reports are public. They are published on the EU commission's website[15]. When the technical evaluation by EGTOP is available, the EU commission discusses the request with the member state delegates, and then takes a formal decision.

Implementation

Whenever a change of the current policy has been decided, an amendment of Annex II of Reg. 889/2008 is necessary. This is done with a separate Commission Regulation. This process takes several months. It is not specific for organic farming but follows the general pattern for changes in European legislation. It is therefore not described in detail here.

Duration of the process

The entire process from the preparation of a dossier to the authorisation of a new substance may take several years. Input manufacturers as well as organic farmers are often frustrated by this duration, and have repeatedly proposed to establish a 'fast-track' procedure. However, there is a risk that with such a procedure, substances which are controversial within the organic sector or which might compromise the reputation of organic farming could be authorised inadvertently. Therefore, no fast-track procedure was established until now. However, the general authorisation of basic substances of plant or animal origin which are food was decided as a compromise.

Authorisation criteria

This section describes the major requirements which a new substance has to fulfil. The quintessence of these requirements is very similar for all organic farming standards, but the precise wording differs from one standard to another.

What are 'natural' and 'synthetic' substances?

It is intuitively clear that only 'natural' substances are eligible for use in organic farming, but what does this mean precisely? Substances produced by plants (e.g. pyrethrine), animals (e.g. beeswax) or microorganisms (e.g. spinosad) are eligible for organic production. Naturally occurring mineral substances such as quartz sand or kaolin (a clay mineral) are also eligible. By contrast, synthetic molecules which do not occur in nature (so-called 'synthetic pesticides') are not eligible.

In certain cases, the naturally occurring materials cannot be used for plant protection, because they are not available in sufficient quantities or in appropriate quality. In such cases, the substances may be obtained by chemical synthesis

[15] Reports can be found here.

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(so-called 'nature-identical' materials). This exception applies for example to pheromones, sulphur and bicarbonate. Nature-identical substances may be used for plant protection, but not as fertilisers. There are sufficient naturally occurring materials which may be used as fertilisers, therefore there is no need to authorise also nature-identical materials for fertilisation.
It could be argued that all materials are ultimately derived from nature, by more or less complex processes. At the moment, the EU organic legislation does not explicitly specify which processing steps are allowed and which are not. However, the general understanding is that 'chemical processes' (i.e. processes which change the chemical structure) are prohibited, while 'physical processes' such as drying, milling, extraction with water are allowed.

Major authorisation criteria

The EU organic legislation defines the following authorisation criteria:

- Substances must be of plant, animal, microbial or mineral origin. This means that they must be natural in the sense discussed above.
- Organisms must not be GMOs, and substances must not be of GMO origin. In the context of plant protection, this concerns mainly microbial biocontrol agents, rapeseed oil and lecithin.
- Substances must not have inacceptable effects on the environment, and they must be harmless for human health. In the EU, effects on human health and the environment are assessed during pesticide registration, and the organic sector should not duplicate these efforts. In exceptional cases, however, the organic sector has a stricter view than general agriculture about which environmental effects are acceptable.
- The substances and their use must be necessary. The use of a plant protection product can be considered necessary (i) if it controls pests or diseases at least partially, (ii) if there are no authorized alternative methods or products, or at least none which are practical and economic, and (iii) if the pest or disease it controls has some relevance for organic farming.
- The substances and their use must comply with the traditions and principles of organic farming and with consumer expectancies. This point covers any additional aspects which might occur with certain substances or uses. Examples include aspects of animal welfare, food quality and/or authenticity, social effects, vegan nutrition etc.

The above criteria are evaluated as a whole. For example, limited negative side-effects may be tolerated, if a product is highly necessary (e.g. side-effects of Spinosad on certain non-target organisms). These criteria apply for the authorisation of new substances. For substances which have traditionally been used in organic farming, there is no formal requirement that they must also fulfil these criteria, but most of them do. Those few substances which do not fulfil the criteria are closely observed, and if possible, replaced by new substances which comply better with the criteria.

Substances which are exempt from individual authorisation in EU organic farming

When a new substance for plant protection is developed, it first has to be approved under pesticide legislation. Once this has been achieved, it may be used in conventional agriculture, but not in organic farming. Use in organic farming is only possible after it has also passed the authorisation process described above and is included in Annex II of Reg. 889/2008. However, four entries in Annex II refer to entire groups of substances (with some restrictions). These are:

- 'micro-organisms (not from GMO origin)'
- 'pheromones (only in traps and dispensers)'
- 'plant oils (all uses authorized, except herbicide)'
- 'basic substances (only those which meet the definition of 'foodstuff' and have plant or animal origin)'

Thus, any new micro-organism which has been approved for use in general farming may be applied in organic production (as long as it is not a GMO). The same applies for any new pheromone or plant oil.
The entry of 'basic substances' requires some explanations. The category of 'basic substances' has been introduced in EU pesticides legislation a few years ago. It describes substances which may be used for plant protection but have a predominant use for another purpose. Registration of basic substances is easier, cheaper and faster than for ordinary pesticides, but does not offer any exclusivity of commercialisation to the applicant. Typically, requests for basic substances are made by non-profit organisations such as growers' associations or public-funded research

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institutes, while commercial companies prefer ordinary pesticide approval. Examples of substances approved as basic substances in the EU include calcium hydroxide, lecithin, sucrose and vinegar (please note that rapeseed oil and garlic oil also have a predominant use outside plant protection, but are not categorised as basic substances, because this was not requested by the applicants). Basic substances are automatically approved for organic farming only (i) if they meet the definition of 'foodstuff' and (ii) if they have plant or animal origin. An example of such automatic approval is lecithin, which is a basic substance, and which is also food and of plant origin. By contrast, calcium hydroxide is a basic substance and food, but not of plant or animal origin. Calcium hydroxide is therefore not automatically authorized under the entry of basic substances. It may nevertheless be used in organic farming, because it is separately mentioned in Annex II.

Authorisation of commercial products

Pesticides are not used in the form of active substances, but as formulated products sold under a trade name. For older active substances without patent protection, there are numerous commercial products. As a practical guide for organic farmers, there are so-called 'input lists' in many countries, which list all authorized products, often together with the authorized uses. Inputs lists may be prepared by organic certifiers, authorities or by specialized institutes.

As a minimum requirement, input lists must ensure that products comply with national pesticide legislation, that they contain only active substances mentioned in Annex II of Reg. 889/2008 and that these substances are not obtained from GMOs (e.g. rapeseed oil). Other input lists (e.g. the inputs list for Switzerland) are based on criteria which go further and include not only the active substances but also all co-formulants. For example, insecticides based on pyrethrin often contain piperonyl butoxide as a 'synergist'. In many countries, such insecticides have traditionally been allowed, because synergists are not part of the evaluation criteria. By contrast, the Swiss inputs list was always opposed to piperonyl butoxide, and manufacturers replaced it by other synergists such as sesame oil or rapeseed oil already in 1997 – 98. In 2014, the EGTOP has recommended to phase out the use of piperonyl butoxide in EU organic farming (EGTOP, 2014b).

8. References

Bravo, A., Likitvivatanavong, S., Gill, S. S. and Soberón, M., 2011. Bacillus thuringiensis: A story of a successful bioinsecticide. *Insect Biochemistry and Molecular Biology* 41, 423–31.

EC, 1991. Council regulation No 2092/91 of June 24, 1991 on organic production of agricultural products and indications referring thereto on agricultural products and foodstuffs. *Official Journal of the European Communities* L198, 1–15.

EGTOP, 2011. *Final Report on Plant Protection Products*. European Commission, Directorate-General for Agriculture and Rural Development, B.4 Organics. https://ec.europa.eu/agriculture/organic/sites/orgfarming/files/docs/body/final_report_egtop_on_plant_protection_products_en.pdf.

EGTOP, 2014a. *Final Report Feed Mandate II*. European Commission, Directorate-General for Agriculture and Rural Development, B.4 Organics. https://ec.europa.eu/agriculture/organic/sites/orgfarming/files/docs/body/egtop-final-report-feed-ii_en.pdf.

EGTOP, 2014b. *Final Report on Plant Protection Products (II)*. European Commission, Directorate- General for Agriculture and Rural Development, B.4 Organics. http://ec.europa.eu/agriculture/organic/eu-policy/expert-advice/documents/final-reports/egtop-final-report-on-ppp-ii_en.pdf.

EGTOP, 2016a. *Final Report on Cleaning and Disinfection*. European Commission, Directorate-General for Agriculture and Rural Development, B.4 Organics.

https://ec.europa.eu/agriculture/organic/sites/orgfarming/files/docs/body/final_report_egtop_on_cleaning_disinfection_en.pdf.

EGTOP, 2016b. *Final report on Plant Protection (III)*. European Commission, Directorate-General for Agriculture and Rural Development, B.4 Organics. https://ec.europa.eu/agriculture/organic/sites/orgfarming/files/egtop_plant_protection_iii-2016-10-26-definitive_version.pdf.

Ehlers, R. U., 2011. Cost-benefit, risk and trade-off analysis of regulation. In: Ehlers, R. U. (Ed.), *Regulation of Biological Control Agents, first edition*. Springer Science+Business Media B.V., Dordrecht, Heidelberg, London, New York, pp. 139–53.

Forster, R., Micheloni, C., Regouin, E., Speiser, B. and Viñuela, E., 2008. *Report of the Ad-hoc Expert Group on Pesticides in Organic Food Production*. Meeting on 22–23 January 2008. European Commission, Directorate F.5. Organic Farming, Brussels.

Hauschild, R., 2011. Facilitations in the regulation of plant protection products containing baculoviruses. In: Ehlers, R. U. (Ed.), *Regulation of Biological Control Agents*. Springer Science+Business Media B.V., pp. 259–66.

Hunt, E. J., Loomans, A. J. M. and Kuhlmann, U., 2011. An international comparison of invertebrate biological control agent regulation: what can Europe learn? In: Ehlers, R. U. (Ed.), *Regulation of Biological Control Agents, first edition*. Springer, Dordrecht, Heidelberg, pp. 79–112.

Speiser, B., Glen, D., Piggott, S., Ester, A., Davies, K., Castillejo, J. and Coupland, J., 2001. *Slug Damage and Control of Slugs in Horticultural Crops*. FiBL, Frick. https://core.ac.uk/download/pdf/10919097.pdf.

Speiser, B., Mieves, E. and Tamm, L., 2015. Kupfereinsatz von Schweizer Biobauern in verschiedenen Kulturen. *Agrarforschung Schweiz* 6, 160–5.

Speiser, B. and Schmid, O., 2004. Current evaluation procedures for plant protection products used in organic agriculture. In: *Proceedings of a Workshop Held 25–26 September 2003 in Frick, Switzerland*. FiBL, Frick, Switzerland.

Speiser, B., Tamm, L. and Mattock, S., 2011. Proposals for regulation of semiochemicals. In: Ehlers, R.U. (Ed.), *Regulation of Biological Control Agents, first edition*. Springer Science+Business Media B.V., Dordrecht, Heidelberg, London, New York, pp. 305–21.

Speiser, B., Tamm, L. and Weibel, F. P., 2014. Regulatory framework for plant protection in organic farming. In: Bellon, S., Penvern, S. (Eds), *Organic Farming, Prototype for Sustainable Agricultures*. Springer Netherlands, the Netherlands, pp. 65–82.

Speiser, B., Wyss, E. and Maurer, V., 2006. Biological control in organic production: First choice or last option? In: Eilenberg, J. and Hokkanen, H. (Eds), *An Ecological and Societal Approach to Biological Control*. Springer, Dordrecht, The Netherlands, pp. 27–46.

Strauch, O., Strasser, H., Hauschild, R. and Ehlers, R. U., 2011. Proposals for bacterial and fungal biocontrol agents. In: Ehlers, R. U. (Ed.), *Regulation of Biological Control Agents, first edition*. Springer Science+Business Media B.V., Dordrecht, Heidelberg, London, New York, pp. 267–88.

Tamm, L., Speiser, B. and Holb, I., 2015. Direct control of airborne diseases. In: Finckh, M. R., van_Bruggen, A. H. C. and Tamm, L. (Eds), *Plant Diseases and their Management in Organic Agriculture*. APS Press, St. Paul, Minnesota, pp. 205–16.

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Tamm, L., Speiser, B. and Mercier, T., 2011a. Proposals for regulation of botanicals. In: Ehlers, R. U.(Ed.), *Regulation of Biological Control Agents, first edition*. Springer Science+Business Media B.V., Dordrecht, Heidelberg, London, New York, pp. 289–304.

Tamm, L., Thürig, B., Fliessbach, A., Goltlieb, A. E., Karavani, S. and Cohen, Y., 2011b. Elicitors and soil management to induce resistance against fungal plant diseases. *NJAS – Wageningen Journal of Life Sciences* 58, 131–7.