

A photograph of laboratory glassware, including a glass jar with a gold lid in the foreground and several glass bottles with green labels in the background, all set against a blue-tinted background.

# POSITION PAPER

A dark blue background with a decorative dotted line forming a cross shape, with small yellow squares at the intersections.

## COMPATIBILITY OF BREEDING TECHNIQUES IN ORGANIC SYSTEMS



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## COMPATIBILITY OF BREEDING TECHNIQUES<sup>1</sup> IN ORGANIC SYSTEMS

### Introduction

The rapid development of genetic engineering techniques is leading to a level of genetic disruption never experienced before. In order to safeguard organic integrity and to ensure organic food will continue to meet the highest consumer expectations in this challenging situation, IFOAM – Organics International is proposing a number of measures to be put in place to further fortify and enhance the organic sector's available genetic resources.

This position paper provides clarity and transparency on the criteria used by the organic sector as to what breeding techniques are compatible with organic systems, which techniques to exclude, and definitions on what should be considered as genetic engineering and genetically modified organisms (GMOs). We further differentiate between the criteria relevant for organic breeding as defined in the IFOAM – Organics International norms, versus the criteria for cultivars and breeds derived from non-organic breeding programs regarding their compatibility for the use in commercial organic production and processing.

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<sup>1</sup> The 2014 General Assembly in Istanbul passed Motion 62: Guidelines for New Breeding Techniques: Dependent on the financial means being available the IFOAM General Assembly urges the IFOAM World Board to define guidelines for the use of varieties derived from new breeding techniques. This implies evaluating the compliance of new plant breeding techniques using the principles of Organic Agriculture, promoting a legally bound disclosure of breeding techniques that do not comply with the principles of Organic Agriculture, and developing a strategy to prevent varieties derived from such breeding techniques from entering the organic sector. In order to achieve these goals by the next G.A. in 2017, a working group should be established.

**Note:** In its deliberations, the working group determined that, given the rapid evolution of breeding techniques across all kinds of organisms, that expansion of the scope from plants to all organisms of all biological kingdoms was feasible and warranted. The World Board approved this approach.



## SUMMARY RECOMMENDATIONS AND ADVOCACY MESSAGES

- 1. New genetic engineering technologies:** Techniques such as Oligonucleotide directed mutagenesis (ODM), Zinc finger nuclease technology, CRISPR/Cas, Meganucleases, Cisgenesis, Grafting on a transgene rootstock, Agro-infiltration, RNA-dependent DNA methylation (RdDM), Reverse Breeding, Synthetic Genomics, are genetic engineering techniques that are not compatible with organic farming and that must not be used in organic breeding or organic production. The rapid development of these new technologies should entail that clear legal definitions are in place and are regularly updated in order to accurately classify and regulate products derived from such novel techniques.
- 2. GMO regulations:** Products obtained through genetic engineering processes should not be released into the environment. In any case such releases should not take place without a prior rigorous, multistakeholder designed and agreed risk assessment protocol that includes input from the organic sector and like-minded movements, and an assessment of the possibility to prevent the presence of such products in organic products and GMO-free products.
- 3. Genetic resources:** Protection of the collective genetic heritage and of biodiversity needs urgent attention in the face of increasing development and presence of novel organisms created through genetic engineering. Responsibility for the control and release of varieties derived from genetic engineering must become a publicly transparent, government regulated activity and should encompass all forms of breeding. The public should be able to retrieve data on what technologies have been applied, to enable producers and consumers to choose varieties according to their values and to reinforce the transparency, trust and linkages between consumers and producers. Public authorities, breeders and farmers should ensure the preservation of genotypes free of genetic modification.
- 4. Preserving and maintaining acceptable genetic resources:** It is paramount that the organic sector recognizes the importance of safeguarding our ongoing seed sources and breeding material now, while new products produced using GE technology are not yet widely on the market. The organic sector must invest substantial time, effort and resources to ensure there are sufficient GMO-free and organically acceptable resources available, in order to safeguard our seed sources and breeding material now and in the future. The organic sector should put a major focus on coordinating this effort.
- 5. Transparency:** Publicly available information on all new varieties and animal breeds derived from genetic engineering should be required of all developers, and should include information about the methods used to create the new genotype, the intended new phenotypic characteristics, and if available identifiable genetic (and other) markers to enable their detection, along with indication of the analytic technologies or other information necessary for such detection/identification. Mandatory transparency and traceability should apply to all genetic engineering processes and GMOs, at all stages of the production process, up to consumers. In particular, detailed information should be available to other breeders. The public should be able to retrieve data on what technologies have been applied, to enable producers and consumers to choose varieties and breeds according to their values and to reinforce the transparency, trust and linkages between consumers and producers.
- 6. Identification of varieties and animal breeds acceptable for organic farming:** Development of varieties/breeds acceptable for organic production should follow the criteria described in this document. Techniques and varieties that qualify according to the criteria as genetic engineering should be categorized and regulated as such in accordance with relevant government regulations. In practical terms:
- 7. Self-reliance:** Greater public resources should be directed to research, development and innovation of strains and breeding techniques that align with the criteria for organic production systems. The attitude of urgency to adopt and spread varieties of unproven safety (to ecological or human health) should be resisted. The organic sector must continue to gain self-reliance concerning the availability of acceptable genetic resources, especially as certain mainstream channels on which organic producers and breeders may have relied switch to unacceptable methods of breeding.

- A. Review panel: The organic sector and other interested stakeholders should convene a review panel or committee to evaluate techniques. Each type of technology/technique should be evaluated against these criteria and categorized accordingly, such as appears in Annex 2. (For those entries in Annex 2 that do not have a definitive determination, more deliberation is needed.)
  - B. Positive list: A positive list of organic varieties and breeds should be built and maintained on an ongoing basis, with a corresponding body established for this purpose. Said body can also list acceptable varieties/breeds that have not yet been bred under organic conditions and suggest control protocols.
  - C. Seed banks and animal conservation initiatives: Seed banks and animal conservation initiatives should be supported and/or established to provide a backup and a guarantee to the continuing line of non-GE seeds and animal breeds in case of contamination or eradication of species. Such banks should be both ex-situ and in-situ, in order to keep varieties alive and adapted through in-situ conservation and production; centralized kryo-seed banks (eg Spitzbergen) alone are not sufficient.
8. **Intellectual property rights:** No patents<sup>2</sup> should be granted on genetic resources, which should remain freely exchangeable and available to breeders and farmers. In particular, no patent should be granted on genetic information and native traits, or on varieties or traits stemming from traditional/classical breeding, regardless of whether they are in older or newly bred varieties. The breeders' exemption and the farmers' right should be legally granted in perpetuity. Participatory breeding programs involving all stakeholders (producers, processors, retailers and consumers) should be promoted, with a plurality of independent breeding programs and breeders with different types of crops, animals, and other organisms to increase agricultural biodiversity.
9. **Polluter-pays-principle:** On-going costs and harms to organic and non-GMO supply chains from contamination by these new techniques, as well as those already in commercial use should be borne by the developers and/or the company that puts the product on the market. National governments and UN fora should adopt protocols for mitigation, prevention and ongoing patent-holder responsibilities regarding GMO contamination. These costs should not be borne by those who do not use those technologies.
10. **Responsibility for biodiversity and rural livelihoods:** Products of synthetic biology and other non-agricultural production systems should not displace crops and animal products and detract from farmers' livelihoods and their ability to be good stewards of biodiversity.

## BACKGROUND AND SCOPE

### A. Background

The release of GMOs into the environment was first regulated by the European Union in 1990. In 1993 IFOAM concluded that the use of GMOs was not compatible with organic farming and the EU Regulation on organic farming was amended in 1999 to prohibit the use of GMOs in the organic production process. Since then all other private organic standards and government regulations have prohibited the use of GMOs by organic producers at any stage of the production chain. Beyond the regulated organic sector, the Cartagena Protocol on Biosafety to the Convention on Biodiversity was adopted in 2000, which governs the movements of living modified organisms (LMOs) resulting from modern biotechnology from one country to another.

<sup>2</sup> Concerning specific varieties, Protection of Plant Varieties according to UPOV (1991) Convention and even license fees for propagation are considered useful, but it must be ensured that these varieties become common-benefit after the IPR has ended (20 years).

At the time all of these norms were established, commercially available GMOs were produced by transgenesis. Since then, many new techniques to produce GMOs have been created, and some products derived from these new techniques (eg herbicide-resistant canola produced using oligonucleotide-directed mutagenesis (ODM), vanilla made via synthetic biology) are already on the market in some countries. These new techniques are not yet explicitly regulated; their proponents promote the release of organisms produced with these new techniques into the environment and food chain without adequate safety measures and precautions, technical and risk assessments, or monitoring and testing protocols. They often try to convince regulators that these new processes should not be regulated as GMOs and/or instead should fall into existing exemptions. Instead, the rapid development of these new technologies should entail that clear legal definitions are in place and are regularly updated in order to accurately classify and regulate products derived from these novel technologies.

### **A new era of genetic disruption**

The rapid development and dissemination of new genetic engineering techniques in recent years brings a level of interference in the genetic make-up of the planet's biodiversity, with consequences that remain poorly understood let alone evaluated, which society has never seen before. Despite seeming to be more precise in modifying specific genomes via these new techniques, it is not possible to know the full impact of any given genetic engineering process; most of these techniques may trigger numerous off target effects at different steps of their production process (including cell preparation, cell culture, and vectorization), and risk is inherent. The increasing accessibility of new technologies makes investigation, knowledge sharing, and creation of new biological entities faster than our collective ability to control their release into the environment and monitor their impacts, alone or in combination. Newer powerful technologies such as "gene drives" provide the tools to potentially eradicate entire species, and the scientific community is debating whether there should be a framework for experiments aimed at genetically modifying the human germ line. These developments have significant implications for our planet, our health and our future.

Increasing preponderance of genetic engineering techniques further challenges the organic sector to maintain the integrity of the genetic resources it uses, address realities of potentialities of genetic contamination and pollution, and provide a realistic market guarantee that meets consumer expectations for organic goods and services. The organic sector cannot merely react to new developments in biotechnology; it needs to proactively deal with the possible phenomenon of increased dissemination of genetically engineered products into the environment and the food chain, and anticipate ways to safeguard and improve its model of production and consumption.

### **Organic principles and practices encourage innovation**

The organic sector has a history of developing new and effective techniques, such as for weed or insect control, without resorting to inappropriate or dangerous technologies. We recognize the ongoing need to develop new cultivars of crops and breeds of livestock to adapt genetics to changing demands caused by biotic and abiotic factors, climate change, as well as needs of agriculture and its value chains as regards productivity, ecological sustainability, and human health. At the same time, we maintain respect for our genetic heritage and planetary biodiversity by taking a precautionary approach to the changes we make to it. The organic sector acknowledges that innovation should be considered in all its dimensions (technical, economic, societal, cultural, and environmental), and that it can take many forms, and has positive or negative impacts in all these dimensions.

The organic sector resolves to protect itself from GMO contamination by maintaining clear and thorough standards and regulations for itself, and advocating for adequate global regulation regarding safety

assessments and environmental release. The organic sector is further dedicated to protecting, sharing, expanding and enhancing its available base of genetic resources.

## **B. Scope**

The scope of this position paper applies to the use of genetic engineering techniques on all living organisms (prokaryotes and eukaryotes), as well as biological units or molecular entities or structures that are not able to reproduce on their own but may have a technical effect on their specific biological environment, and include (but are not limited to) the following:

- Plants
- Fungi
- Animals subject to livestock husbandry and aquaculture (including clones)
- Insects and all other wild animals
- Microorganisms and their products, including viruses and bacteria
- Algae
- Genetic or other relevant material created either through synthetic biology or obtained by other means

# **PRINCIPLES, DEFINITIONS & CRITERIA**

Organic is about practices that lead to desired outcomes for people and planet: products should be of high quality and safe to consume, and production should work toward improving ecological health and vitality.

The following definitions and criteria, founded on the Principles of Organic Agriculture (Health, Ecology, Fairness, and Care) serve as the basis for decisions and activities with respect to techniques used in creating genotypes that are compatible with organic principles, practices, and products.

## **A. Principles**

The **Principle of Health** in organic agriculture is about serving the wholeness and integrity of living systems (including society) at various levels (immunity, resilience, regeneration, sustainability). The implication for breeding is that useful organisms need to be robust, dynamic, and resilient, able to benefit from interactions with the surrounding biome in which they grow, and to reproduce themselves and to produce high quality, nutritious food.

The **Principle of Ecology** in organic agriculture is about contributing to optimally functioning of a diversity of site-specific ecological production systems. This means that breeding needs to develop multilevel approaches, such as decentralized breeding for regional adaptability and enhancing genetic diversity and adapt organism to the environment instead of the environment to the organism.

The **Principle of Fairness** in organic agriculture is about serving equity, respect, justice and stewardship of the shared world. It implies the need to develop new socio-economic structures in breeding to ensure free access to genetic resources, no patents of life, breeding approaches that involve all value chain actors, equal benefit sharing among chain partners, and maintenance and accessibility of diversity for future generations.



The **Principle of Care** in organic agriculture is about enhancing efficiency and productivity in a precautionary and responsible manner. We argue that there is plenty of unexplored (and forgotten) knowledge for new multifaceted breeding strategies. It means that organic breeding refrains from breeding techniques that interfere directly at DNA level, including cell fusion and mutation breeding, and stimulates transparent and participatory/collaborative processes.

From a holistic view the organic sector embraces the partner attitude towards nature which includes that not only humans and animals but all living entities, including plants, are considered ethically relevant out of respect for the integrity of life, referring not only to an extrinsic value (usefulness for mankind) but also to a perceived intrinsic value of living organisms (worth as a living entity as such based on respect for their “otherness”, dignity, wholeness and autonomy). This respect for the integrity of life implies that intervention in nature is not absolutely prohibited in organic farming – rather that it should be used as a positive cultural enhancement.

Definitions and criteria go hand in hand and must be used together to ensure that intent and outcomes are clear. Definitions should be as precise as possible. Any minor wording variations among definitions globally should not be an excuse for confusion or subversion of intent. If substantive differences of interpretation of terms arise, these can be checked against the criteria for consistency.

## B. Definitions

The organic sector rejects the use of the term “new breeding techniques” as misleading as it implies similarity with traditional breeding techniques. The following definitions are retained by the organic sector as the most relevant ones. Special notice should be taken of the updated definition of Genetic Engineering, which is necessary in light of newer genetic manipulation techniques.

**Classical or Traditional breeding** – Breeding that relies on phenotypic selection, field based testing and statistical methods for developing varieties/breeds or identifying superior individuals from a population, rather than on techniques of genetic engineering. The steps to conduct breeding include: generation of genetic variability in populations for traits of interest through controlled crossing (or starting with genetically diverse populations), phenotypic selection among genetically variable individuals for traits of interest, and stabilization of selected lines to form a unique and recognizable cultivar/breed. Classical breeding does not exclude the use of genetic or genomic information to more accurately assess phenotypes, however the emphasis must be on whole organism selection.

**Genetic Engineering (GE)** – A set of modern biotechnology techniques that involve the application of:

- In vitro, ex vivo, in vivo nucleic acid techniques, including recombinant deoxyribonucleic acid (DNA), ribonucleic acid (RNA) and introduction of nucleic acid into cells or organelles; or
- Editing, altering, modifying, deleting or adding DNA or RNA or any molecular components affecting their micro- or macrostructure or function directly or indirectly (e.g. through epigenetic modifications of gene expression or by other means); or
- Fusion of cells; which are not techniques used in traditional breeding and selection.

The categorization of a process as genetic engineering must be undertaken on the basis of characteristics of the process. The question if the resulting new genome could have theoretically been obtained by methods of natural mating and reproduction, spontaneous mutagenesis or natural recombination is not a determining factor.

Techniques of genetic engineering include, but are not limited to: recombinant DNA and/or RNA

techniques, cell fusion, micro and macro injection, encapsulation, gene deletion and doubling. In addition, methods such as gene targeting and genome editing are classified as genetic engineering processes. These depend on homology directed repair and non-homologous end joining, and employ engineered nucleases such as meganucleases, zinc finger nucleases (ZFNs), transcription activator-like effector nucleases (TALENs) and RNA-guided engineered nucleases (such as CRISPR/Cas9). Genetically engineered organisms do not include organisms resulting from the following techniques: natural conjugation, natural transduction, natural hybridization, and marker assisted breeding.

**Genetically Modified Organism (GMO)** – A plant, animal, or other living organism, biological unit or molecular entity that is derived from genetic engineering as defined here. This term will also apply to products derived from genetically engineered sources. It is the use of a genetic engineering process that makes the organism (or its descendant) a “genetically modified organism”, irrespective of whether the modification is currently detectable or cannot be differentiated from natural mutation or traditional breeding.

**Modern biotechnology** (according to the Cartagena Protocol on Biosafety to the Convention on Biological Diversity) - “Modern biotechnology” means the application of:

- a. *In vitro* nucleic acid techniques, including recombinant deoxyribonucleic acid (DNA) and direct injection of nucleic acid into cells or organelles, or
- b. Fusion of cells beyond the taxonomic family,

that overcome natural physiological reproductive or recombination barriers and that are not techniques used in traditional breeding and selection. *Note:* This definition is included as part of the definition of Genetic Engineering above.

**Synthetic Biology** – Designing and constructing biological devices, biological systems, biological machines and biological organisms using a range of methods derived from molecular biology and biotechnology, including in virtually all cases the techniques of genetic engineering or genetic modification. Use of synthetic biology in any form is prohibited in organic systems and as part of organic breeding. This includes, but is not limited to (i) introduction of molecular components, structures or organisms created using synthetic biology to cells or organisms; ii) the use of biological organisms or products created by synthetic biology.

### **C. Criteria and Considerations for the Evaluation of Breeding Techniques and derived Varieties/Breeds for their Compatibility with Organic Systems**

#### ***Ethical aspects: Respect of genomes and cells***

The genome is respected. Technical/physical insertion, deletions, or rearrangements in the genome is refrained from (e.g. through transmission of isolated DNA, RNA, proteins or through artificial mutagenesis).

The cell is respected as an indivisible functional entity. Technical/physical invasion into an isolated cell on growth media is refrained from (e. g. digestion of the cell wall, destruction of the cell nucleus through cytoplasmic fusions).

The creation of genetic diversity takes place within the species-specific crossing barriers through fusion of egg cell and pollen or sperm. Forced hybridization of somatic cells is not done.

New genetic engineering techniques are not compliant with these aforementioned principles. *In vitro*, *ex vivo*, or *in vivo* nucleic acid techniques, as well as editing and modifying DNA, RNA, or any other molecules in the cells are considered to be invasion into the genome and cell. Induced chromosome breakages violate the integrity of the genome.

**Social aspects: Availability of genetic resources**

In organic systems, the exchange of genetic resources is encouraged. In order to ensure farmers have a legal avenue to save seed and keep breeding animals, and breeders have access to genetic material for research and developing new varieties and breeds, the application of restrictive intellectual property protection (e.g. utility patents and licensing agreements that restrict such uses) to living organisms, their metabolites, gene sequences, or breeding processes is not done.

The ability of an organism to reproduce in species-specific manner has to be maintained and genetic use restriction technologies are not used, e.g. terminator technology. (This premise does not exclude the option for farmers to use castration of animals as an on-farm management technique.)

A plant cultivar or animal breed must be usable for further breeding and propagation. This means that the breeders' exemption and the farmers' right are legally granted and patenting is refrained from, and that the crossing ability is not restricted by technical means (e.g. by using male sterility without the possibility of restoration).

In complementation to the presently widely used hybrids, breeding of non-hybrid plant varieties and animal breeds is encouraged in order to give farmers the choice to produce their own seeds (farmers' privilege) and animal breeding lines.

**Scientific aspects: Safety**

The Principle of Care mandates a precautionary approach and an assessment of the safety of any given genotype that is created through genetic engineering. Assessment of public safety should involve the health effects of consumption (of the organism itself or of its products) as well as the ecological impact that a genetically engineered organism may have. Invasiveness or reduction in biodiversity that may be triggered by overly competitive new genotypes is to be avoided. Organisms containing gene drives must be treated with extreme caution and not released into the environment.

Organic principles do not permit the introduction or amplification of known toxins or novel proteins and other molecules produced from genetic engineering into the diet or environment, either as metabolic products of the organism in question, or as may be necessarily involved in the production system of any such new organism (eg required use of herbicides or other toxins). Invasiveness or reduction in biodiversity that may be triggered by overly competitive new genotypes is to be avoided. Organisms containing gene drives must be treated with extreme caution and not released into the environment.

## ORGANIC BREEDING, VARIETIES AND ANIMAL BREEDS AND GENETIC RESOURCES

Especially in light of the possible increasing presence of genotypes not compatible with organic systems, it is more important than ever that alternatives exist for organic producers and consumers. Renewed emphasis on development and expansion of organic breeding efforts is necessary, with corresponding market-based incentives.

**A. Organic breeding:**

- supports sustainable food security, food sovereignty, secure supply of plant, animal, and other agricultural and wild products (e.g. fiber, medicine, timber), and the common welfare of society by satisfying nutritional and quality needs of animals and human beings;
- sustains and improves the genetic diversity of our products, and thus contributes to the promotion of agro-biodiversity;

- respects the reproduction system of any given species or organism as a part of its integrity;
- makes an important contribution to the development of cultivated species and their adaptation to future growing conditions;
- ensures the circulation and accessibility of genetic resources and rejects patents on life, and edited or genetically engineered forms thereof.

Breeding goals should match the respective species and the needs of the complete value chain (producers, processors, traders and consumers). They should aim at the sustainable use of natural resources and at the same time account for the dynamic equilibrium of the entire agro-ecosystem.

From the perspective of organic farming, the interaction of a plant or animal with local conditions (or animal with their typically ethologically natural environment) is a prerequisite for the development of locally adapted organisms. The environment in which selection takes place should be under organic production methods in order to account for the organism's environmental interaction, accelerate the selection gain in traits relevant to the organic sector, and benefit from possible epigenetic effects. Phenotypic selection in the field/on-farm can be supplemented by additional selection methods (e.g. analysis of natural compounds or molecular markers for diagnostic purposes).

## **B. Organic Production:**

Genotypes used in organic systems are preferably those that have been bred according to the above defined criteria specifically under organic production conditions, from source genetic material that has been selected according to optimal performance characteristics according to the specific conditions for growth, productivity, product quality, and reproduction. Genetic sources for organic production must not be ones that are incompatible with organic systems, in particular those stemming from genetic engineering. In order to maintain a freedom not to use products obtained through genetic engineering techniques and to be sure about the processes having led to an organism used in organic agriculture, the declaration of the genetic manipulation processes involved must be a precondition. Efforts of the organic sector towards the development of a declaration system are necessary.

Other acceptable sources include:

- Those derived from breeding programs with a special focus on the breeding goals or selection environments for organic agriculture, including organic seed / semen / breeding animal propagation (product-oriented breeding for organic farming, organically propagated)
- Those derived from non-organic breeding that are suitable for organic agriculture, i.e. according to the definitions and criteria elaborated in this document (traditional breeding, organically propagated, or, if necessary, non-organically propagated but untreated).

Genetic sources for organic production must not be ones that are incompatible with organic systems, in particular those stemming from genetic engineering.

The criteria set thus far by the organic sector do not fully cover every possible breeding scenario. An example is embryo rescue in plants – while such artificial conditions separate the organism from interaction with the intended commercial growing environment, and it thereby to a degree subverts natural selection, the organic sector has not to date decided unequivocally about such developmental processes.

The organic sector will continue to evaluate the compatibility of breeding techniques with the criteria described here, and assure the ongoing relevance of the criteria against the principles of organic farming. See Annex 2.

## PRESENT SITUATION

Human safety and ecological sustainability are presumed more likely when the genome and cell are respected, as reflected by the Principles of Organic Agriculture and described above.

In order to make reasonable evaluations and appropriate choices about genetic varieties of plants and animals, it is necessary for certain fundamental information to be available to breeders, farmers, policy makers, technical evaluators, and other interested parties. Specifically, for all plant cultivars, animal breeds and other strains that have been commercialized or made available, there should be a legal requirement that there are pertinent disclosures by creators, producers, and/or suppliers about the provenance of the strain in question, and if available, with identifiable markers that distinguish it from others.

Detection technology and analytical methods for newly created strains should be readily accessible to all parties who need it. It is therefore necessary to gain a better understanding of detection methods and practical logistics for enabling identification and detection of organisms produced through new forms of genetic engineering and other breeding techniques. Coordination among different organizations may be warranted in order to have an adequately robust dynamic. Newer detection methods based on faster, easier, and/or cheaper sequencing of nucleic acids, supercomputing, and/or other combinations of techniques should be monitored and studied for their usefulness. However, in some cases the result of new genetic engineering techniques may not be detectable with available detection methods. Therefore the obligation to disclose the used breeding techniques is a prerequisite to avoid that certain strains enter the organic system and to guarantee freedom of choice for farmers and consumers.

The burden of costs for analysis and detection should not however fall to organic farmers. Organic systems should remain process-based and market guarantees and claims designed accordingly. Organic producers should be able to rely on supplies of genetic stock that have been adequately segregated and identified.

The organic sector also has the possibility of creating a positive list (or regional lists) and/or searchable database of organically acceptable strains for further development and/or field production. These could primarily identify organically bred ones as well as others that do not violate the established criteria based on breeders' declaration. Furthermore, seed banks and animal conservation initiatives should be supported or established to provide a backup and a guarantee to the continuing line of non-GE seeds and animal breeds in case of contamination or eradication of species.

## ANNEX 1 – REFERENCES

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Name	Applicability: P = plant A = animal M = Microbe F = fungus O = others	Acceptable for organic breeding?	Acceptable for cultivation in organic systems?	Respects integrity of genome and/or cell?	Availability of the genetic resource?	Adequate safety assessment?	Detection currently possible?	Key considerations / questions / additional comments
Agro-infiltration	All	No	No	No	?	?	depends if only temporarily or stable integrated in genome	In vitro nucleic acids are introduced to plant leaves to be infiltrated into them. More study needed.
Apomixis	P	No	Yes	depends on technique used	difficult to create new diversity	?	only of the trait is introduced artificially, see GMO	Apomictically propagated plants cannot be used for further breeding, because the progeny is genetically identical to the parent plant. However, apomixis also occurs in nature like in dandelion or St John's Wort
Artificial insemination	A	Yes	Yes	Yes	Yes	Yes		
Bridge Crossing	P	Yes	Yes	Yes	Yes	?	By DNA comparison	Bridge crosses are obtained by cross pollination of related species
Protoplast Fusion within Family (belongs to Cell fusion)	All	No	tolerated	No	if no patent		No	Genotypes obtained by forced fusion of somatic cells not by fusion of egg cell and pollen cell. Examples potatoes fusion of dihaploid cells with different resistance genes. Some varieties produced in this way may have been in use under organic systems for some time. Detection and replacement is potentially complex for reasons of identification and socioeconomic factors. Cultivars are used in organic farming, since they have been on the market for decades and are not subject to traceability and labelling requirements.
Cisgenesis	All	No	No	No	usually patent protected	?	difficult if gene could also be introduced by cross breeding	The intact DNA of a plant is directly modified through gene transfer and the integrity of the nuclear genome is disturbed. Introduced gene is from same family
Cloned animals and offspring	A	No	No	No	?	No	No	

Name	Applicability: P = plant A = animal M = Microbe F = fungus O = others	Acceptable for organic breeding?	Acceptable for cultivation in organic systems?	Respects integrity of genome and/or cell?	Availability of the genetic resource?	Adequate safety assessment?	Detection currently possible?	Key considerations / questions / additional comments
Cloned plants via vegetative propagation	P	Yes	Yes	Yes	Yes	Yes	yes, identical to mother plant	Many crop species are vegetatively propagated like potato, apple, banana, hops, asparagus
Composite cross populations	P	Yes	Yes	Yes	Yes	Yes	identified by pedigree only	Composite cross populations are based on complex crosses between multiple parents and the offspring is multiplied as bulk in order to increase diversity within cultivar. This populations are able to adapt to environmental conditions
CRISPR/Cas: Clustered Regularly Interspaced Short Palindromic Repeats combined with nucleasis CAS	All	No	No	No	limited by patent	No	class I + II: No Class III: Yes	CRISPR-CAS is a powerful and very time efficient tool to edit the nucleus DNA, the plastid DNA, gene expression and gene silencing. Due to a guide RNA it binds at the target gene and then cuts the DNA double helix. This can introduce mutation due to mistakes of the DNA repair enzyme (Class I), it can be combined with an oligonucleotide serving as template for desired nucleotide exchange in the target gene (Class II), or it can be used to integrate one or several cis- or transgenes at the target site (Class III). Moreover it can be linked to RNAi to cause gene silencing, used to modify DNA methylation to change gene expression, or linked to gene drive, to convert a whole population resulting in single allele with 100% frequency. This will interfere with evolutionary processes.
Cytoplasmic Male Sterility or male sterility identified in nature or obtained by wide crosses	P	Yes	Yes	Yes	limited if no restorer genes	Yes	yes morphologically	For hybrid varieties whose fertility is not restored by restorer genes, no progeny can be produced, i.e. seed saving is not possible. These individuals may only be used as mother plants for further breeding. Male sterility is passed on to the progeny.



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Cytoplasmic Male Sterility introduced by cytoplasm fusion	P	No	No	No	limited by patent		Yes, PCR test for mitochondrial gene	For certain crops like Brassica vegetables male sterility is introduced by cytoplasm fusion, therefore rules for cytoplasm fusion applies. Already introduced into organic as there is no declaration needed, but according to GMO definition of IFOAM - Organics International not compatible to organic agriculture
Cytoplasm fusion (belongs to cell fusion)	All	No	No	No	limited by patent	?	Yes, PCR test for mitochondrial gene	The integrity of the cell is compromised by the forced fusion of cells from different species. Nucleus of one cell is destroyed in order to combine nucleus and organelles of different plants. Usually between different plant species which would be extremely rare to cross pollinate under natural conditions and this affects gene regulation between the nuclear genome and extra-chromosomal DNA. Natural crossing barriers are overcome.
Double Haploids obtained by pollination with inductor line and spontaneous doubling (in vivo)	P	?	Yes	Yes	Yes	Yes	No	Egg cells can be induced by cross pollination with inductor line into develop haploid embryos without fusion of the egg cell and pollen and, thus, no recombination of genes. This is a standard practice in maize breeding. The haploid embryo can spontaneously double their chromosomes to become homozygous double haploid plants. All steps are <i>in vivo</i> ; no <i>in vitro</i> culture, no application of chemicals.
Double Haploids obtained by anther, ovary, microspore or egg culture ( <i>in vitro</i> )	P	No	Yes	?	Yes	Yes	No	Anthers, ovaries or isolated pollen (microspores) or egg cells are cultivated <i>in vitro</i> and reprogrammed by phyto-hormones into haploid embryos. They are usually treated with synthetic colchicine to duplicate their chromosomes to obtain homozygous double haploid plants. There is no fusion of the egg cell and pollen and, thus,

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								no recombination of genes. This method is regularly applied in barley breeding. Synthetically produced colchicine is not compatible with organic farming. this could be replaced by colchicine producing plants.
ECO-TILLING = Targeting Induced Local Lesions in Genomes	All	Yes	Yes	Yes	Yes	Yes	No	Analysis of natural available genetic diversity (larger number of gene bank accessions and breeding materials with marker assisted selection for the target gene
Embryo Rescue in Plants	P	Yes	Yes	Yes	Yes	Yes	No	In order to improve frequency of progeny of wide crosses, the embryo is transferred to artificial media. The embryo is derived from natural fusion of egg and pollen cell. However, in wide crosses, the endosperm is often not well developed to feed the embryo. This method was used to obtain triticale ( <i>Triticum aestivum</i> x <i>Secale cereale</i> ).
Embryo transfer in animals	A	No	No	?	Yes	Yes		Embryo transfer is prohibited at farm level in organic systems. However, farmers use sperm from bulls of non-organic breeding companies that use multiple ovulation (MO) (hormone stimulation) of bull dams to obtain multiple embryos that are transferred (ET) to recipient cows. In this way they are assured that from one 'flush' they get more young bulls to choose from. Currently under organic standards there is no regulation for this indirect use of MOET bulls (or at least their offspring).
Fast track breeding by single seed descent	P	Yes	Yes	Yes	Yes	Yes	No	in order to speed up the breeding process, plants are stressed by reduced space, or water to cause fast onset seeds allowing several generations per

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								year, e.g. in wheat.
Fast track breeding by phytohormones	P	?	Yes	Yes	Yes	Yes	No	in order to speed up the breeding process, phytohormones are applied to cause fast onset of fruits or seeds allowing shorter generation cycles, e.g. in apple.
Fast track breeding by integration of transgenes during breeding process but not in the final cultivar	P	No	No	No	Yes	Yes	No	in order to speed up the breeding process, early flowering genes are transferred, which cause fast onset of fruits allowing shorter generation cycles, e.g. in apple. Here a birch flowering gene is transferred into apple breeding material. The final apple cultivar will no longer contain the early flowering gene of birch. However this genetic engineering process has been applied during the breeding process
Gene drives	All	No	No	No, needs genetic engineering techniques to introduce it into the cell	marked gene will become predominant	No	?	It is now possible to introduce new genes or to eliminate functional genes by various methods of gene editing. Combined with gene drive the target gene will be used as copy for the homologous genes and will overcome Mendelian inheritance. Within 1-3 generations a complete population can be converted to carry only this single allele. It strongly interferes with natural evolution. A quantum leap of potentially huge impacts, the reach of which is unknowable in advance of release.

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<p>Gene Editing: induced small changes of DNA in defined target gene using sequence specific nucleasis (Class I and II)</p> <p>(Zinkfinger nucleasis, CRISPR-Cas = Clustered regularly interspaced short palindromic repeats and CRISPR associated nucleasis. TALENs = Transcription activator-like effector nucleases) (Targeted genetic modification (TagMo))</p> <p>Rapid Trait Development System</p>	All	No	No	No	restricted by patent	No	No	<p>induced small changes of DNA in defined target gene</p> <p>The isolated DNA sequences are introduced into the nucleus via technical intervention and, thus, violating the integrity of the cell as a functional unit.</p>
<p>Gene Silencing – RNA interference (RNAi)</p> <p>RNA-dependent DNA methylation (RdDM)?</p>	All	No	No	No	limited by patent	No	No	<p>Genetically modified organisms are not compatible with organic farming.</p> <p>Isolated DNA or RNA sequences are brought into the nucleus via technical interventions, thus, violating the integrity of the cell as a functional unit.</p> <p>It has been observed that gene expression can also be boosted by RNAi. Since the RNA interference is involved in control pathways, the gene expression balance of other traits could also be interfered with.</p>

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Generative propagation	All	Yes	Yes	Yes	Yes	Yes	N genotypic fingerprint different from parental lines o	main mode of multiplication by fusion of cell and pollen cell
Hybrids based on mechanical emasculation	All	Yes	Yes	Yes	Yes	Yes	No	Hybrid seed produced by removal of male flower (e.g. maize). Hybrid cannot be reproduced without a decline in performance. This limits the autonomy of the farmer and promotes dependence on seed and animal breeding (chickens / broilers / pigs) companies.
Hybrids based on Self-incompatibility, genetic male sterility or CMS (without cytoplasm fusion)	P	?	Yes	Yes	limited if no restorer genes	Yes	No	Hybrids cannot be reproduced without a decline in performance. This limits the autonomy of the farmer and promotes dependence on seed companies. CMS hybrids cannot be used to breed of new fertile varieties without a restorer genes to reestablish male fertility (e. g. broccoli and cauliflower). Thus, the breeders' exemption is nullified restricting breeding progress.
Hybrids based on CMS derived from cytoplasm fusion	P	No	No	No	Limited by patent	Yes	No	The cultivation is carried out on artificial nutrient medium, usually with the addition of synthetic phytohormones. Acceptance depends on the composition of the medium, can e.g., also be done on coconut milk and natural plant hormones. In vitro meristem culture of potato is applied in organic to remove viral infestation.
In vitro selection	P, M, F	?	Yes	Yes	Yes	Yes	No	Selection takes place in an artificial environment, and cultivation on artificial nutrient medium usually involves the addition of synthetic phytohormones.  Interaction of the plant with the soil and the climate is not possible.

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Inbred lines	All	Yes	Yes	Yes	Yes	Yes	No	Inbred lines are genetically very similar and, thus, more susceptible to pests and diseases.
induced random mutagenesis by chemicals (e.g. EMS)	(All) P	No; To be phased out	so far tolerated, under discussion	Yes, if applied on whole seed or plant?	Yes	No	No	Random mutations in the whole genome. Mainly changes or mismatches of individual nucleotides (point mutations). Most chemical mutagens are currently not compatible with organic farming and should not be applied to the germline of plants (egg cell, pollen or embryo). Cultivars are used in organic farming, with no declaration, since they have been on the market for decades and are not subject to traceability and labelling requirements. (Currently not used in animal breeding.)
induced random mutagenesis by irradiation (e.g. gamma radiation)	(All) P	No; To be phased out	so far tolerated, under discussion	No	Yes	No	No	Irradiation causes random chromosome breakage, translocation, inversion, deletions, duplications in the whole genome (Chromosome mutations). Irradiation is not compatible with organic farming and should not be applied to the germline of plants (egg cell, pollen or embryo). Cultivars are used in organic agriculture, with no declaration, since they have been on the market for decades and are not subject to traceability and labelling requirements. (Currently not used in animal breeding.)
induced targeted mutagenesis by Oligonucleotids, Zink finger nucleasis, TALEN, CRISPR-Cas, also called gene editing	All	No	No	No	limited by patent	No	No	targeted changes of gene sequence by "gene editing"

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Inter-specific hybrids	All	Yes	Yes	Yes	Yes	Yes	By DNA comparison	<p>Crossing barriers between species are not clearly defined boundaries, but become stronger with increasing differentiation of the species, i.e. the chance of successful fertilization and seed formation decreases correspondingly.</p> <p>Due to technical interventions, such as <i>in vitro</i> fertilization of the egg cell and pollen or <i>in vitro</i> cultivation of the embryo shortly after fertilization, crossing barriers may be further reduced.</p>
Intragenesis	All	No	No	No	usually patent protected	?	Yes	Similar to cisgenesis but gene sequences may be re-arranged.
Marker Assisted Selection	All	Yes	Yes	Yes	Yes	Yes	No	Molecular markers are only used as diagnostic tool. They are not interfering into the germline. However some organic breeders are reluctant in the application of molecular markers, as enzymes (Taq polymerase) are usually produced from genetically modified bacteria, but there also native enzymes available to similar price. Plants are evaluated merely based on their DNA sequence. Genotype-environment interactions and epigenetic effects are neglected.
Mega nucleases	All	No	No	No	restricted by patent	No	No	See also gene editing . The isolated DNA sequences are introduced into the nucleus via technical intervention and, thus, violating the integrity of the cell as a functional unit.
Oligonucleotide directed mutagenesis (ODM)	All	No	No	No	restricted by patent	No	No	Short nucleotide sequences will be introduced into the cell to serve as template for DNA repair. See also gene editing

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								The isolated DNA sequences are introduced into the nucleus via technical intervention and, thus, violating the integrity of the cell as a functional unit.
open pollination	P, M, F	Yes	Yes	Yes	Yes	Yes	No	open pollination is standard method of plants see also generative propagation
Ovary & Embryo Culture	P, A	Yes	Yes	Yes	Yes	Yes		By using <i>in vitro</i> cultivation of the embryo after fertilization, crossing barriers may be overridden, see embryo rescue  Development of the embryo takes place under artificial, sterile conditions on synthetically prepared nutrient medium.
Plastid Transformation	P	No	No	No	limited by patent	?	Yes	Instead of modifying the nucleus DNA, the plastid DNA of chloroplasts is changed. The genetic modification will be inherited only via female parent. The integrity of the nuclear DNA is retained, but the extra-chromosomal DNA is altered which violates cell integrity.
Plus-hybrids with xenia effects	P	No	Yes	Yes	restricted by CMS	Yes		CMS F1-hybrids are cross pollinated by unrelated male fertile plant resulting in additional yield increase (Xenia effect). CMS without restorer genes are male sterile and are therefore limited in their ability to reproduce. They cannot be used as pollen donors for further breeding, but only as a seed parent with the progeny inheriting the male sterility. Thus, the breeders' exemption is nullified and breeding progress restricted.



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Polyploidisation (chemical mutagenesis)	P	?	Yes, if natural colchicine?	Yes if applied on intact seed or plants?	Yes	Yes	yes, flow cytometry	Tetraploid plants occur in nature but can also be induced by anti-mitotic drugs, e. g. colchicine or oryzalin. Tetraploid plant often show higher vigor like in red clover, tetraploid rye. The anti-mitotic drug can be obtained from plants or can be produced synthetically. Application can take place on the whole seed or on seedlings. No <i>in vitro</i> step is necessary.
Proteomics/ Metabolomics	All	Yes	Yes	Yes	Yes	Yes	No	Proteomics and Metabolomics are diagnostic tools only. They do not interfere into the germline. They analyse functions of the plant or animal genotype and its interactions with the environment. At different developmental stages or after exposure to various stresses all proteins and metabolites are analyzed to determine differential gene expression.
Protoplast Fusion within Species	All	No	No	No	if no patent	Yes	No	Genotypes obtained by forced fusion of somatic cells not by fusion of egg cell and pollen cell. Examples are potatoes fusion of dihaploid cells with different resistance genes. Some varieties produced in this way may have been in use under organic systems for some time. Detection and replacement is potentially complex for reasons of identification and socioeconomic factors.
Protoplast fusion between different species or ploidy levels	A, P	No	No	No	restricted by patent	Yes	yes	Protoplast fusion of related species beyond the crossing barrier (i.e. they cannot be crossed). The integrity of the cell is compromised by the forced fusion of two protoplasts. Organelles of different individual plants come together, which would be extremely rare under natural conditions. Thus, the gene regulation between the nuclear

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								genome and extra-chromosomal DNA can be impacted. If tetraploid fusion products out-cross with diploid plants, triploids are produced, which are sterile.
RNA interference (RNAi)  RNA-dependent DNA methylation (RdDM)  See Gene silencing	All	No	No	No	limited by patent	No	No	Genetically modified organisms are not compatible with organic farming. Isolated DNA or RNA sequences are brought into the nucleus via technical interventions, thus, violating the integrity of the cell as a functional unit. It has been observed that gene expression can also be boosted by RNAi. Since the RNA interference is involved in control pathways, the gene expression balance of other traits could also be interfered with. Up to date, there is little empirical data on possible risks.
Reverse breeding	P	No	No	No	No	?	No	Isolated DNA or RNA sequences are brought into the nucleus via technical interventions, thus violating the integrity of the cell as a functional unit. Reverse breeding interferes in the overall control of gene expression, and the self-organization of the cell is disturbed. Cross-over events during meiosis are blocked, allowing to reproduce a heterozygous plant. The variety must be recreated from each of the hereditary components. Seed saving is not possible without a decline in performance.
Sperm sexing technology	A	?	Yes	Yes	Yes	Yes	Yes	

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Synthetic biology	All	No	No	No	No	No	Yes	Genetically engineered organisms are not compatible with organic farming. The use of synthetic biology and products created by synthetic biology is prohibited in organic systems.
Targeted crossing within a species	All	Yes	Yes	Yes	Yes	Yes	No	Traditional method of plant and animal breeding to create new diversity
Targeted crossings between species  See interspecific hybrids	P / A	Yes	Yes	Yes	Yes	Yes	No	Traditional method of plant and animal breeding (triticale, mules, hinnies)
Triploid plants	P	?	Yes	No	No	No	No	Traditional method of plant and animal breeding (triticale, mules, hinnies)
TILLING = Targeting Induced Local Lesions in Genomes	All	No	Yes	?	Yes	?	No	Induced random mutagenesis by chemicals combined with marker assisted selection for the target gene Most chemical mutagens are currently not compatible with organic farming and should not be applied to the germline of plants (egg cell, pollen or embryo).
Transduction	All	No	No	No	limited by patents	?	Yes	Transduction is the process by which foreign DNA is introduced into a cell via a virus or viral vector. This occurs naturally as viral nucleotides are introduced into the host during infection. Part of that nucleotides can be integrated into the host cell. This methodology can be used to integrate foreign genes into bacteria or plant and animal cells. This is one of the mechanisms used for gene transfer.

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transformation via mini-chromosomes	All	No	No	No	limited by patents	No	Yes	Genetically modified organisms are not compatible with organic farming. The integrity of the plant genome is disrupted. The plant is degraded to purely function as a metabolic producer. There is a ready transition of this technique to synthetic biology.
Transgenesis (transfer of genes from one species to another)	All	No	No	No	limited by patents	?	Yes	Genetically modified organisms are not compatible with organic farming. The integrity of the plant genome is destroyed and crossing barriers are overcome. There is a potential risk for outcrossing to other organisms, which creates a problem for co-existence within small areas. The plant is reduced to DNA building blocks, which are almost always patented, preventing seed saving and continuation of breeding. Thus, monopoly in the seed market is supported and biological diversity decreases.
Transposons	All	if induced by physical stress	Yes	Yes	Yes	?	No	Transposons are jumping genes that occur in nature and are responsible for mutations. Transposon activity can be modified in order to increase mutation rate. This can be done by chemicals (see induced chemical mutations) or by physical stress like drought or heat.
vegetative propagation = cloned plants	P	Yes	Yes	Yes	Yes	Yes	identical to mother plant	used for potato, grapes, bananas, hops, asparagus, apples, pears, apricots etc..

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Zinc finger nucleases class I	All	No	No	No	limited by patents	No	No	Zinc-finger nucleases are naturally occurring proteins that are modified and synthetically generated for the purpose of gene editing. ZFN Class I cause a cut to the double helix at the specific target gene. Due to mistakes in the plant's repair mechanisms, small mutation (nucleotide exchange, deletion or insertion occur in the target gene. The technological use to transfer zinc-finger nucleases into the nucleus of the plant cell compromises the integrity of the cell. Zinc finger nucleases are being used to cut cell's DNA in order to alter it, which compromises the integrity of the cell as well.
Zinc finger nucleases class II	All	No	No	No	limited by patents	No	No	Zinc-finger nucleases are naturally occurring proteins that are modified and synthetically generated for the purpose of gene editing. ZFN Class II are linked to small oligonucleodites (20-100bases) and cause a cut of the double helix at the specific target gene. Now the oligonucleotides are used as template during the plant's repair mechanisms, resulting in desired nucleotide change at the target gene. The technological use to transfer zinc-finger nucleases into the nucleus of the plant cell compromises the integrity of the cell. Zinc finger nucleases are being used to cut cell's DNA in order to alter it, which compromises the integrity of the cell as well.

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Zinc finger nucleases class III	All	No	No	No	limited by patents	No	Yes	Zinc-finger nucleases are naturally occurring proteins that are modified and synthetically generated for the purpose of gene editing. ZFN Class III are linked to one or several functional genes and cause a cut of the double helix at the specific target gene. The new genes are now integrated into the plant genome with the aid of the plant's repair mechanisms, resulting in precise insertion at the target site. The technological use to transfer zinc-finger nucleases into the nucleus of the plant cell compromises the integrity of the cell. Zinc finger nucleases are being used to cut cell's DNA in order to alter it, which compromises the integrity of the cell as well.



## THE DEFINITION OF ORGANIC AGRICULTURE

Organic Agriculture is a production system that sustains the health of soils, ecosystems and people. It relies on ecological processes, biodiversity and cycles adapted to local conditions, rather than the use of inputs with adverse effects. Organic Agriculture combines tradition, innovation and science to benefit the shared environment and promote fair relationships and a good quality of life for all involved.

## THE PRINCIPLES OF ORGANIC AGRICULTURE

Organic Agriculture is based on the principles of health, ecology, fairness and care.

## THE SCOPE OF ORGANIC AGRICULTURE

IFOAM - Organics International regards any system that is based on the Principles of Organic Agriculture and uses organic methods, as 'Organic Agriculture' and any farmer practicing such a system as an 'organic farmer'. This includes various forms of certified and non-certified Organic Agriculture. Guarantee Systems may be for instance third party certification, including group certification, as well as participatory guarantee systems.

## STANDARDS & REGULATIONS

The IFOAM Family of Standards draws the line between organic and not organic. It contains all standards and regulations that have passed an equivalence assessment against a normative reference approved by membership of IFOAM - Organics International. IFOAM - Organics International encourages governments and standard users to recognize other standards in the Family as equivalent.

## POSITIONS

IFOAM - Organics International has developed positions on a range of topics. These include: Use of Nanotechnologies and Nanomaterials in Organic Agriculture; The use of Organic Seed and Plant Propagation in Organic; The Role of Smallholders in Organic Agriculture; The Full Diversity of Organic Agriculture; The Role of Organic Agriculture in Mitigating Climate Change; Smallholder Group Certification for Organic Production and Processing; Position on Genetic Engineering and Genetically Modified Organisms; Organic Agriculture and Food Security; Organic Agriculture and Biodiversity.

## POLICY BRIEFS

IFOAM - Organics International has policy briefs on 'How Governments Can Regulate Imports of Organic Products Based on the Concepts of Harmonization and Equivalence' and 'How Governments Can Support Participatory Guarantee Systems (PGS)'.

## BEST PRACTICE GUIDELINE

The Best Practice Guideline for Agriculture and Value Chains is a contribution by the organic movement to the global discussion on sustainable agriculture.