IFOAM – Organics International position paper

Compatibility of Breeding Techniques[1] in Organic Systems

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.

I. 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

[1] 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.

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:
    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
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.

8. **Intellectual property rights:** No patents[2] 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. 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 patent-holders 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.

II. 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.

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

[2] 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).

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

III. 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 breeding 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 cytoplast 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.

IV. 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, processers, 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.

V. System transparency and ongoing review

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 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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