

**National Organic Standards Board
GMO ad hoc Subcommittee**18th March 2013**Feedback of FiBL Switzerland to the US Department of Agriculture National Organic Standards Board Discussion Document on “Excluded Methods Terminology” from 6th February 2013*****Discussion Questions:******1. Does the definition of "excluded methods" in the Organic Rule need to be revised? Please provide reasoning for either a "yes" or a "no" answer.***

Yes, it should be revised as the techniques of molecular genetics have advanced and new techniques are introduced meanwhile that might not be compatible with organic agriculture and which are not covered by the present definition of excluded methods. Also the definition of the mentioned “excluded methods” might not be unique and have lots of space for interpretation.

2. On what general principle(s) should practical and consistent distinctions be made between “excluded” and permitted methods of breeding that could apply to plants, animals and micro-organisms? Under such general principles should we further define or replace terms such as "natural conditions" and "traditional breeding"?**Ethical Criteria:**

- The genome is respected as an indivisible entity and technical/physical invasion into the plant genome is refrained from (e.g. through transmission of isolated DNA, RNA, or proteins).
- The cell is respected as an indivisible functional entity and 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 cytoplasm fusions).
- The ability of a variety to reproduce in species-specific manner has to be maintained and technologies that restrict the germination capacity of seed-propagated crops are refrained from (e.g. Terminator technology).

- A variety must be usable for further crop improvement by other breeders. This means on one hand that the breeders' exemption is legally granted and patenting is refrained from, and on the other hand that the crossing ability is not restricted by technical means (e.g. by using male sterility without the possibility of restoration).
- The use of genetic diversity takes place within the plant specific crossing barriers through fusion of egg cell and pollen. Forced hybridization of somatic cells (e.g. through cell fusions) is refrained from.

3. Are there other terms beyond those discussed here that should be addressed in the context of excluded methods?

New techniques need to be included that are invasive methods that are interfering with the functional entity of a cell, like

- Cis genetics
- Plastid transformation
- gene silencing via RNAi and DNA methylation
- site directed mutagenesis via oligonucleotides, meganuclease, zink finger nuclease
- reverse breeding
- agro-infiltration
- mini chromosomes
- cloning of animals
- sperma sexing of animals
- embryo transfer of animals

4. Of the terms and practices discussed here, which ones should be in the definition of excluded methods and which not excluded? Why?

Method	Excluded Method	Why
Cell fusion including protoplast fusion, cytoplasm fusion and somatic hybridization	YES	It violates the functional integrity of the cell. Only gametic cells fuse without artificial induction to an embryo, while somatic cells need to be triggered to force somatic fusion
Micro and Macro encapsulation	YES	This technique is used to incorporate organic or synthetic material into the cell. It is a technical invasion and violates the integrity of the cell
Recombinant DNA	??	Definition is not clear.
Gene deletion	YES, if artificially introduced	If caused by invasive methods into the genome or into the cell
Genetic engineering including DNA or RNA constructs	YES	DNA or RNA sequences are designed outside of the organism and incorporated into the genome or plastom by various methods, disturbs integrity of genome or cell
Recombinant DNA techniques	??	Definition is not clear
Mutagenesis	YES, if artificially introduced	Mutation occurs naturally, however induced mutation that use techniques like irradiation or toxic substances that harm the DNA or chromosome structure are not compatible with organic agriculture

Conjunction	No	Is a natural phenomenon
Fermentation	No	No breeding technique
Genetic Hybridisation	No	Many different definitions available
Hybrid	No	Different definitions available
Nuclear Acid Hybridization	No	Is a natural phenomenon
In situ Hybridization	No	No Breeding technique but a diagnostic tool
In vitro fertilization	No /YES in animals	Plants: Fusion of gametic cells to embryo is not disturbing the integrity of the cell Animals: Fertilization of the egg cells takes place outside of the animal body in an artificial culture medium. This raises concerns about possible damage. Selection can be determined by the technology. Danger of gene pool narrowing.
Tissue culture techniques, Cell culture techniques Primary Cell Culture Batch Cell Culture	No	Functional entities of cells are maintained, no genetic changes during normal tissue culture, only allowed substances should be used
Silencing including RNAi or DNA Methylation, Histone reorganisation, etc..	YES	Gene silencing is interfering with the regulation of the gene expression and thus affects the functionality of a cell. It is a higher hierarchy intervention, which is not well understood until now.
Embryo rescue	No / YES in animals	Plants: Embryo is maintained on artificial media, but no genetic changes occur. Animals: Embryo transfer on organic farms is rejected, therefore also embryo rescue
Microinjection	YES	Invasive technique that violates integrity of a cell
Biolistic device	YES	Invasive technique that violates integrity of a cell
Somaclonal variation	YES, if artificially introduced	Somaclonal variation results from mutation and is identified during in vitro culture, but might not necessarily be introduced by the tissue culture, see mutagenesis
Transposons	Yes if artificially introduced	Transposons are a regulatory element influencing gene silencing and mutation rate. Transposons can be artificially introduced by genetic engineering, see genetic engineering
Transduction	No	Is a natural phenomenon

5. How far back into the development or manufacture of a substance, or in the development of vaccines, or in the lineage of a breeding line, should the excluded methods prohibition apply? How far back is practical and verifiable?

Cultivars exposed to genetic engineering shall not be used as a parental line for further breeding. For several techniques like cytoplasm fusion there is no mandatory declaration. To avoid cultivars that are derived from such breeding processes the organic sector relies on voluntary declaration of the breeding companies. For practical reasons it was discussed that organisms that were exposed to such techniques before the definition of allowed or excluded methods can be used for

further plant breeding. For example, most of the barley cultivars are derived from a progenitor that was exposed to induced mutation. Excluding all these genotypes, only limited genetic diversity will be available for breeding.

Many of the new breeding techniques might not be traceable any more. There is strong lobbying to evaluate the derived cultivars on product basis instead of process based consideration. The organic sector needs to make clear statements about their process based assessment and the defined criteria that apply for the evaluation of such breeding techniques.

In animals the use of embryo transfer on farm is rejected, but the use of semen from sires, issued by embryo transfer can be allowed (different depending on organisation; some organisations allow only ET-grandfathers of animals on organic farms).

FiBL has accompanied a process to find a minimal consensus among different stakeholders in Germany and Switzerland about general criteria for the evaluation of breeding techniques in plants (see Annex 1) and in animals (see Annex 2).