RESOLUTION OIV/VITI 355/2009

OIV PROTOCOL FOR THE EVALUATION OF GRAPEVINES OBTAINED BY GENETIC TRANSFORMATION

THE GENERAL ASSEMBLY,

ON THE PROPOSAL of the Viticulture Commission I,

TAKING NOTE of the work developed by the « GENETIC RESOURCES AND VINE SELECTION» (GENET) expert group, focused on harmonising evaluation systems for new vine varieties obtained by using genetic transformation techniques,

CONSIDERING the recommendations of Resolution Viti 1/2006 on « Vine genomes and genetically modified varieties », particularly the recommendation that « compared to the initial variety/clone any change in characteristics due to a genetic modification should be clearly described (through transcriptomic, proteomic and metabolomic studies, in addition to all new appropriate methods which will be developed.) »,

DECIDES to adopt guidelines of the OIV Protocol for the evaluation of grapevines obtained by genetic transformation »,

RECOMMENDS Member states to adopt and integrate the guidelines in “the OIV protocol for the evaluation of grapevines obtained by genetic transformation”, in accordance with their regulatory scheme.

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A. PREAMBLE

Research work aiming at an improvement of existing grapevine cultivars by transgenic approaches is carried out in several countries resulting in genetically modified vines (GM-vines).

Genetic modifications applied may have various objectives, e.g.:

- improvement of resistance against pest and diseases such as fungus diseases of the berry, foliage and wood (e.g. downy mildew, powdery mildew, eutypa dieback, esca), viruses and their vectors (in particular nematodes), bacteria, phytoplasms and insects (e.g. grape moths);

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- tolerance to the abiotic stresses, in particular to thermal stress, draught, salinity of the soil and freezing;
- tolerance to certain inputs (herbicides);
- modification of the physiological and phenological characteristics (seedlessness, early ripening) and quality traits (product composition of berry components and their relations);

Non-applied scientific purposes may exist.

B. FUNDAMENTALS AND GENERAL OBJECTIVES OF THE EVALUATION

In addition to the usual criteria taken into consideration in the selection of new varieties, the development and use of GM-vines or products thereof implies that it is necessary to assess and evaluate risks and benefits.

To evaluate potential risks and benefits of cultivating a GM vine, the following issues should be taken into account:

- the nature of the genetic modification
- the gene construct (target gene, marker gene)
- the species, variety and clone of vines subjected to transformation
- the growing conditions and the ecosystem
- the application, for food or industrial purposes

Based on these factors, the GM-vines should be evaluated according to the following items:

- health effects for consumers (e.g. toxic and allergenic potential)
- effects on the grape's composition
- environmental effects;
- potential commercial value

Socio-economic aspects could also be taken into consideration

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Finally the evaluation procedure should clearly point out the potential risks as well as the potential benefits of a GM-vine.

All evaluation procedures should be based on scientifically sound hypotheses. Scientific knowledge coming from other genetically modified crops should likewise be taken into account. The evaluation protocol for the GM-vines must be flexible. Thus, for example, depending on the modified characteristics (e.g. qualitative, resistance, or phenological characteristics) the priorities of the evaluation procedures should be performed on a case by case basis.

In spite of the preferential autogamous fertilization of hermaphrodite vine flowers, the pollination of non GM-vines by the pollen of GM-vines located in the vicinity can not be excluded. Within the Vitis genus, the risk of uncontrolled spreading of genes incorporated in other varieties is very low due to the asexual commercial propagation of varieties and clones. However the possible risk of introgression of the incorporated genes into wild populations of Vitis genus depends on the continent and the geographic region. There is no risk in grape-growing areas without any wild vines like Australia, South America and most parts of Africa. Risk is very limited in Europe where the only one wild grape, Vitis vinifera subsp. sylvestris, is rarely found and the existing habitats are usually located far away from commercial vine-growing areas.

C. GENERAL FRAMWORKS FOR THE EVALUATION OF TRANSGENIC VINES

1. Evaluation procedure control institution

Each country appoints a control institution in charge of supervising the different evaluation procedures described according to point 2.1-2.6 which reacts in due respect to criteria established in its respective country. This control institution can be, for example, a corresponding research centre, a technical institute, a university, particularly those institutions qualified to carry out studies and surveys on genomes. The control institution may appoint other organizations and/or laboratories qualified for executing certain special subtasks. The control institution periodically checks corresponding field trials, collects all corresponding data and assesses the results of all the experiments and draws up annual reports and provides a summary in a final report.

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2. Evaluation procedures

For each new GM vine obtained the laboratories that have operated, as well as all the in vitro multiplication procedures, acclimatisation steps and propagation and multiplication interventions should be described and drawn up in a document in accordance with recommendations of resolution VITI 1/2006.

2.1. Phenotypic evaluation

a. Requirements on field trials

The designing of field trials may vary depending on the usage of GM vines (wine, table grape, raisin, rootstock) and from the modified characteristics(s). In any case, these trials should be in a way which leads to reliable results. As a minimum requirement, these field trials should be carried out, at different periods and in distinctly different sites (different climatic regions) with a number of plants and repetitions in accordance to the analysis, for at least three harvesting periods. Furthermore, original untransformed cultivar/clone should be used as a control test.

During the trial period of genetically modified vines, the established conditions (for example instructions for handling the pruning material, the defoliation, the gathering) should be fulfilled.

b. Evaluation of the target characteristic(s)

Based on the field trials and eventually on other available data, the influence of the modification on target characteristic(s) should be precisely described. This (e.g. modification of resistance level to diseases and pests, modification in sugar or acid content, qualitative and/or quantitative modification of anthocyanins or aroma compounds, etc.). The description should be made through transcriptomic, proteomic and metabolomic studies, in addition to all new appropriate methods which will be developed. In any case, analytical evaluations of the final product (wine, table grape, raisin) should be carried out and completed by organoleptic tests.

In the case of root stock, the compatibility with grafts should be checked.

c. Evaluation of other characteristics beside the target characteristic(s)

It has to be verified whether other important viticultural characteristics beside the

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target characteristic(s) are influenced by the genetic modification. If so, the relevant features as well as the degree of alterations compared to the original untransformed cultivar/clone has to be described in detail.

The ampelographic and ampelometric characteristics of GM vines should be evaluated and compared to appropriate data from the original untransformed cultivar/clone. This has to be done using scientifically appropriate and internationally accepted methods and/or descriptors (i.e. OIV, UPOV). Any significant alterations should be reported.

d. Stability of phenotype

The stability of the transformed gene has to be proved over several propagation cycles by asexual propagation. It should be confirmed that adult plants, after repeated multiplications, show no other significant alteration than the sought and identified in preliminary tests.

2.2. Genotypic evaluation

The genetic transformation itself should be confirmed by adequate molecular techniques (e.g. PCR, border sequencing, ...). Furthermore, the number of copies, as well as the number of insertion locations should be investigated (e.g. Southern Blot). For studies on traceability (refer to point 2.3.) it is necessary to establish appropriate molecular tools (e.g. SCAR-markers).

2.3. Final product traceability of genetic modification

It should be verified whether the incorporated gene construct(s), parts of the gene construct(s), new metabolites due to the incorporated gene(s) are traceable in the final product (for example wine, table grape, raisin, oil from seed). This data is of special importance with regard to labelling in the case of later commercial use of genetically modified vines. In certain cases, it may be particularly interesting to investigate in the course of the production process that the incorporated genes or the corresponding metabolites are traceable (ex.: wine production: fresh grapes -> must -> during fermentation -> several steps after fermentation up until bottling). This should be done by using appropriate analytical tools which are registered and made available to the control institution.

2.4. Evaluations of possible interactions of transgenic vines on ecosystem

Depending on the kind of modification (case by case basis) reliable results of

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monitoring investigations on the influence of the ecosystem should be presented (for example possible occurrence of horizontal and/or vertical gene transfer, effects on flora and/or fauna, qualitative and/or quantitative changes in metabolism and their possible effects). The methods for evaluating these parameters should be based on scientifically international accepted protocols.

2.5. Evaluations of possible effects of transgenic vines on the health of consumers

In the case that the genetic transformation leads to qualitative and/or quantitative changes of the metabolites in the final product, possible influence on human health should be checked.

2.6. Evaluations of possible effects of transgenic vines on technological aspects

It has to be evaluated whether the genetic modification leads to an impact on technological parameters (e.g. influence on the fermentation process).

A. COMMERCIAL USE OF A GENETICALLY MODIFIED VINE

1. Registration of a genetically modified grapevine

Based on the data revealed by the investigations described in the aforementioned section C and certified by the control institution, the official institution in charge of reviewing the genetically modified vines will be able to make a decision by:

a. accepting an application without obligations,

b. accepting an application with specific obligation(s)

c. rejecting an application

In case of a) it will be possible to propagate and disseminate the new genetically modified grapevine. In case of b) it may be possible, with some restrictions and recommendations, to propagate and disseminate the new genetically modified grapevine.
In both cases the further propagation and dissemination can be stopped if further research results (carried out for example with newly developed, formerly unknown research techniques) gives evidence of some kind of possible “danger”. GMO matter

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should be indicated as such on the label.

2. Phytosanitary status

As for existing varieties and clones, a genetically modified grapevine – when introduced to the market – should fulfill all the existing obligations in the individual Member countries of OIV concerning the phytosanitary status of the propagation material.

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