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REVIEW DOCUMENT ON DEBATE ON BIOTECHNOLOGY IN VITIVINICULTURE WITHIN OIV

May 2015

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Sommaire

Purpose

The purpose of this document is to recall and assemble in a single document some important elements of guidance from the OIV activities related to biotechnology in vitiviniculture

The OIV has chosen to undertake this study to establish a vast body of knowledge that Member States, international standardization bodies and other stakeholders may draw on the application of modern biotechnology in the production of wine and its evaluation. This study does not attempt to cover in detail all the issues and facts, but rather to contextualize the overall potential impact of the application of biotechnology in the wine sector. Its purpose is to provide a factual basis for potential discussion.

Considerations

Different approaches regarding vitiviniculture products derived from modern biotechnology are expressed. Any approach implemented should be consistent with other texts already adopted by different intergovernmental organisations.

Definitions adopted by other intergovernmental organisations

Codex Alimentarius

"**Recombinant-DNA Plant**" - means a plant in which the genetic material has been changed through in vitro nucleic acid techniques, including recombinant deoxyribonucleic acid (DNA) and direct injection of nucleic acid into cells or organelles.. http://www.codexalimentarius.net/download/standards/10021/CXG_045f.pdf

"Modern Biotechnology" means the application of:

(i) In vitro nucleic acid techniques, including recombinant deoxyribonucleic acid (DNA) and direct injection of nucleic acid into cells or organelles,

or

(ii) Fusion of cells beyond the taxonomic family, that overcome natural physiological reproductive or recombinant barriers and that are not techniques used in traditional breeding and selection
http://www.codexalimentarius.net/download/standards/10007/CXG_044f.pdf [1]

"Recombinant-DNA Microorganism" - means bacteria, yeasts or filamentous fungi in which the genetic material has been changed through in vitro nucleic acid techniques including recombinant deoxyribonucleic acid (DNA) and direct injection of nucleic acid into cells or organelles.
http://www.codexalimentarius.net/download/standards/10025/CXG_046f.pdf

Cartagena protocol on biosafety to the convention on biological diversity[2]

The Cartagena Protocol on Biosafety to the Convention on Biological Diversity is an international treaty governing the movements of living modified organisms (LMOs) resulting from modern biotechnology from one country to another. It was adopted on 29 January 2000 as a supplementary agreement to the Convention on Biological Diversity and entered into force on 11 September 2003.

Use of terms

For the purposes of this Protocol:

(g) "**Living modified organism**" means any living organism that possesses a novel combination of genetic material obtained through the use of modern biotechnology;

(h) "**Living organism**" means any biological entity capable of transferring or replicating genetic material, including sterile organisms, viruses and viroids;

(i) "**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;

[1] This definition is taken from the Cartagena Protocol on Biosafety to the Convention on Biological Diversity.
[2] http://bch.cbd.int/protocol/text/

Discussion on GMO in vitiviniculture within the OIV

In October 2008, a synthetic note on GMO has been presented to the CST and COMEX. This note was intended to place the vitivinicultures in the fields of biotechnologies

This memo outlined the various areas in which biotechnology could play a role in viticulture

The use of innovative biotechnologies in vitiviniculture is centred on three main areas:

Genetic modification of the vine

The genetic modification of the vine can either be carried out on the rootstock or the scion. Each of the modifications shares the goal of improving resistance to problems resulting from biotic or abiotic factors, or improving the vine qualitatively.

More specifically, the following motives figure among the sought objectives of genetic modifications to the vine:

a) *Improvement of vine resistance* to diseases and pests. Researchers foresee the introduction of one or several genes which would increase resistance against:

- fungal (e.g. mildew, powdery mildew, eutypa dieback), viral (e.g. fanleaf), bacterial or phytoplasmic diseases;
- insects harmful to the vine (e.g. grape moth);
- viral vectors (e.g. nematodes);
- certain production factors (herbicides)

A resistant gene could be introduced in the rootstock or the scion.

b) Tolerance to the various abiotic stresses. Faced with a marked and continuous change of climatic conditions the world over, wine growers foresee a break-out of problems associated with abiotic stress, such as drought, thermal stress, soil salinity and freezing. Genetic transformation would seek to develop varieties which better tolerate these types of stress.

c) *Modification of physiological and phenological characteristics* (seedlessness, early ripening) and *qualitative characteristics* (enrichment of sugar or other grape components such as colour or vine resveratrol).

Genetic modification of yeasts

Over the course of the last 20 years, alcoholic fermentation via selected strains gradually supplanted fermentation carried out using endogenous yeasts. However, over the past few years, new genetic tools have made the construction of genetically modified yeast strains a major challenge.

Five main targets have been identified for the direct genetic improvement of yeasts in oenology, all related to the improvement of the winemaking process and wine quality:

1. increasing the efficiency of the fermentation process: the optimisation of fermentation yeast performance. Inversely, the search for low-yield yeast enabling the production of wines of low alcoholic strength is under experimentation.
2. wine treatment: improving clarification by the elimination of certain components, tolerance to ethanol in order to reduce stuck fermentation, assimilation of nitrogen by the yeasts, and adjusting acidity.
3. food safety issues: reducing the formation of ethyl carbamate or biogenic amines.
4. sensory quality: many prospects for the future exist in this domain, either by limiting the production of some compounds (volatile acidity, thiols) or conversely by stimulating the production of others (glycerol or flavour precursors).
5. microbiological control

Canadian authorities have approved the use of two genetically modified yeasts . In 2003, the United States Food and Drug Administration (FDA) designated the GM yeast as GRAS (Generally Recognized As Safe). Taking into account this designation and in agreement with the USA regulation it is possible to use this GM yeast in the wine making process. Today, these genetically modified yeasts are already available for commercial use and can be used in particular countries like USA, and Canada;,

Another genetically modified yeast which was engineered to reduce the risk of the production during fermentation of ethyl carbamate is also available.

Enzymes produced by GMM

Enzymes produced by GMM are simple proteins and therefore are not genetically modifiable,. They are generally produced by micro-organisms, often fungi or bacteria with an easily manipulable genetic makeup.
The purpose of developing these enzymes from GMMs is to make them pure, precise and in this way to reduce or even terminate the ancillary activities of enzymatic preparations.
The food and agriculture sector already uses enzymes produced by genetically modified micro-organisms such as proteases for cheeses and amylases for beer and bread.

Issues related to the use of GMOs in vitiviniculture

Definition of GM vine and products originating from a GM plant

Today, there is no harmonised, international definition of a genetically modified vine. What is meant by the term "genetically modified vine"? It is clear that several types of genetic modification are possible, and therefore that at a minimum, the following cases must be elaborated upon:

a) Introduction of one or more genes into the scion
- Introduction of one or more genes of the same species (*Vitis vinifera*) and/or variety
- Introduction of one or more genes of another species

b) Introduction of one or more genes into the rootstock
- Introduction of one or more genes of the same genus (Vitis)
- Introduction of one or more genes of another genus

c) Influence of techniques implemented in the genetic modification in question

Once the above definitions have been established, the question of defining products originating from GM vines should be solved. Are the grapes produced by varieties grafted on genetically modified rootstocks considered GM products? Answers to such questions are a prerequisite to solving other problems related to product naming and labelling.

Definition of viticultural products produced with the assistance of a GM micro-organism

As for the genetically modified vines, it is important to work out precise criteria for determining whether or not a micro-organism is genetically modified.
Likewise, what status should be given to additives or processing aids produced from the use of genetically modified microorganisms"?
Indeed, what status should be given to products originating from genetically modified micro-organisms such as enzymes and vitamins? These products, because of the treatment they have undergone, cannot reproduce or transmit genetic material.
In all the case, is it important to know the fate of proteins or DNA material coming from the MMG in the final product.
Lastly, what happens to final products, such as wine, obtained using genetically modified processing aids or additives derived from GMOs, which are often present in the final composition of the product?

Labelling

Labelling is highly important in the wine industry, since it is in large part responsible for consumer attitudes towards the product (origin name, geographic status, varieties, etc.).
The labelling of wine products produced from GM plants or using GM micro-organisms may require an additional specific indication regarding the use of innovative biotechnologies, which will be adapted to the specificities of the sector, such as:
- Indication of the variety of scion when the rootstock was genetically modified (Is there a gene transfer between the rootstock and the scion?)
- Use of GMO derived additives (sugar, caramel, agricultural alcohol…)
- Consideration of whether there is retained GM protein or DNA material itself in final product; this may differ between wines, grape juice, fresh grapes or raisins .
- Effect on the wine blend

Also, additives that are produced with the help of genetically modified microorganisms do not require labelling because GMOs are not directly associated with the final product. Because the final product is carefully purified and does not contain any genetically modified organisms, vitamins and additives made in this way are not subjected to special regulations or labelling requirements.

In some cases, amino acids and enzymes are not legally considered foods. Rather, they are known as processing aids. This is why there is no legal requirement to declare these additives on the list of ingredients.

Environmental impact

The Cartagena Protocol provides a scientific assessment of the possible adverse effects of living modified organisms on the conservation and sustainable use of biological diversity. In many countries, an environmental risk assessment is carried out before the placing on the market of GMOs. In Europe, for example, Directive 2001/18/CE establishes the principles and the methodology applying to the environmental risk assessment.

Studies on risks and environmental impact must be carried out before clearing the path for marketing genetically modified vine. The risks and impact of an uncontrolled and undesired dissemination of all vitivinicultural products genetically modified organisms in the environment must be also studied.

Socio-economic aspects

The introduction of genetically modified organisms in vitiviniculture will have an influence on several aspects of the industry and it will be necessary to study at least the implications for:

a) the structure of the sector, in particular that of the nursery operators,
b) product production costs,
c) the influence on the product production process,
d) the attitude of the consumer towards these products.

Food safety

On the international level, in 2003 the Codex Alimentarius[3] adopted general principles for the analysis (evaluation, management and communication) of the health risks of foods derived from biotechnologies, whether plants or micro-organisms, which rely heavily upon on FAO/WHO consultation of international experts.

This common framework lays down guidelines for managing food risks and monitoring marketed products.

A great number of countries have also set up evaluation protocols. In Canada, for example, the food safety evaluation of genetically modified yeasts was carried out in accordance with Canadian guidelines for novel food safety.

[3] Foods derived from modern biotechnology
ftp://ftp.fao.org/codex/publications/Booklets/Biotech/Biotech_2009e.pdf

In Europe, in order to market or industrially transform for human consumption food or food ingredients composed of GMOs or originating from GMOs, a technical file must be drafted allowing the evaluation of public health risks in accordance with regulation (EC) no. 1829/2003.

The application of these protocols specifically in vitiviniculture in order to analyse the implications for human health of the use of the genetically modified organisms in vitiviniculture could be necessary.

OIV recommandations and actions concerning GMOs

OIV activities

OIV activities related to GMOs in vitiviniculture will focus on several topics.

In November 1998, a first draft resolution was drawn up concerning the use of genetically modified organisms in oenology. A wide-ranging debate carried on from this point until October 2003, when the resolution was removed for a lack of a clear consensus.

In June 2003, during the 83rd General Assembly of the International Vine and Wine Office which took place in Paris from June 16-17, the Viticulture, Oenology and Wine Economy commissions presented about thirty papers concerning "Vitiviniculture and biotechnologies: prospects, issues and risk assessment".

These documents enabled the organisation to take stock of the latest knowledge and scientific research, as well as the perception of this issue by consumers.

The conclusions of scientists at that time made clear the need for continuing research in all fields, including vine genomics. In addition, an emphasis was put on the assessment of human health and environmental risks. Lastly, the installation of traceability and consumer information systems was proposed.

The 2005-2008 Strategic Plan, approved by the Extraordinary General Assembly of the OIV on October 14, 2005, specifies the subjects to be studied on the key theme of GMOs in vitiviniculture in point A.7., "INNOVATIVE BIOTECHNOLOGIES".

Similarly, in the groups "Genetic resources and vine selection" and "Law and consumer information", experts were working on the definitions and denominations of GM vines and resulting products. In addition, a resolution project on the “Environmental impact of transgenic vines” was under discussion by the expert group "Genetic resources and vine selection", aiming to assemble all the scientific data acquired on the subject and thus, facilitate the risk assessment of the use of transgenic vines.

The 2009-2012 Strategic Plan furthers the emphasis put on GMOs by proposing a more concrete methodological approach.

The new OIV strategic plan 2015-2019 precises specific action to Evaluate innovative technologies in particular to define products issued from biotechnologies in the vine and wine sector and participate to the evaluation of their consequences with other International Organisation

Adopted resolution

Resolution viti 1/97: TRANSGENIC VINES

This resolutions proposes that research in the field of genetic transformation of the vine be pursued, notably in the field of disease and ravage control, that the evaluation of risk related to genetic transformation and the dissemination of transgenic vines be taken into account by researchers and those engaged in experiments and that the cultivation and organoleptic qualities of transgenic vines be evaluated on a vigorous experimental basis, with an international viticultural and oenological protocol.

Resolution Viti 1/2006: VINE GENOME AND GENETICALLY MODIFIED VARIETIES.

This resolution proposes that all Member States form coordinating bodies to assess risks and monitor genetically modified material, given the significant controlled research undertaken on GMOs.

Resolution Viti 355/2009: OIV PROTOCOL FOR THE EVALUATION OF GRAPEVINES OBTAINED BY GENETIC TRANSFORMATION

The 7th General Assembly approved a resolution related to an evaluation protocol of vines obtained through genetic engineering. The research works, carried out in several countries, are focused on improving existing vine varieties using genetic engineering techniques and are in the process of producing genetically modified vines (« GM vines »). This resolution recommends that the member states adapt, and where relevant, integrate the guidelines found in this protocol in accordance with their respective regulatory regimes. This protocol integrates the general bases and objectives for the evaluation of genetically modified vines in addition to the commercial use of genetically modified vines.

BIOTEC Ad Hoc group activities

In accordance with the guidelines laid down in the Strategic Plan of the OIV, at its meeting on 24 March 2009 the CST proposed to set up an interdisciplinary working group on GMOs in the vitivinicultural industry. The proposal was approved by the Comex.

At its meeting held on 21 October 2009, the CST requested that the experts liable to join the working group be confirmed by the Committee chairs by or before November 30, 2009, and that the latter ensure prominent scientists on the subject be included.

This working group, backed by the skills of the Secretariat of the OIV, is mandated to:

- Draft (cf. Item H10 of the 2009-2012 Strategic Plan) an overview of the international regulations and a scientific situation report on the subject,
- Draw up (item H6 of the 2009-2012 Strategic Plan) the proposals for definitions of GMO vines and genetically modified micro-organisms, in order to discuss them in March 2010,
- Draft (items H7 and H8 of the 2009-2012 Strategic Plan) a definition of a genetically modified grape, and of a viticultural product containing GMOs,
- Appraise (item H9 of the 2009-2012 Strategic Plan) the various assumptions concerning consumer information, and as needed, formulate proposals for updates of the labelling standard.

Discussion on definition of genetic engineering in vitivinicultural sector

At this stage, the group has undertaken a thorough legal research on existing definitions both on international and national levels. As working methodology, it was decided to take the definitions of “modern biotechnology”, “Recombinant DNA plant” and “Recombinant DNA microorganism” (as defined in Cartagena protocol) as a basis and to adapt them to the particularities of the vitivinicultural sector.

For this definition, two points were fiercely debated between the experts:

(i) the list of exceptions for genetic engineering techniques, and the definition of genetic engineering techniques.

On the first point, the following techniques was proposed by all experts for not to be considered as genetic engineering neither for microorganisms nor for vines..

Not considered techniques of genetic engineering are:

a1. In vitro fertilization;
a2. Natural processes such as union, transduction,
a3. Polyploidy induction.

a4. The selection of variants or natural mutants;
a5. The selection of mutants brought about by physical or chemical methods;
a6. The crossbreeding, hybridisation using natural sexuality

The discussion concerned the genetic engineering, "cell and protoplast fusion". Since the natural barrier is the critical point that separates genetic engineering techniques from those that are not, It has been mentioned that **"cell and protoplast fusion in vines not belonging to the same genus"** overcame natural barriers in the vine, and must therefore be considered as a genetic engineering technique.

The qualification of cell and protoplast fusion techniques was also keenly debated. With regards the **techniques used for microorganisms**, after discussion and consideration of the arguments of the relevant experts' groups regarding the fact that this type of fusion can take place naturally at the level of organisms belonging to the same family in microorganisms, it has been proposed to keep the current barrier as "family".

Two points were addressed:

1. the taxonomic affiliation of young vines along with the taxonomic affiliation limits for young vines

2. for the qualification of cell and protoplast fusion techniques as genetic engineering or not.

With regards the first issue, after clarification, the group agreed to say that young vines all belong to the "*Vitis*" genus.

For the second point, some experts highlighted that cell and protoplast fusion techniques can create a new plant from a limited number of cells and for this reason, it is important to qualify these techniques as genetic engineering for operations involving taxonomically distant organisms.

The group decided to ask the opinion of the group of experts "genetic resources and vine selection" on the issue of whether or not the **in vitro hybridisation technique should be considered as a genetic engineering technique**.

The group of experts on genetic resources and vine selection indicated that this technique seems to be unknown in the vine and wine sector and that it can therefore be removed from the definition, unless it makes sense for microbiologists.

However, the concern about the mismatch with the definition of "modern biotechnology" adopted in 2000 by the United Nations within the framework of the Cartagena Protocol and adopted by the *Codex Alimentarius* in the various standards on analysing risks related to the use of genetic engineering techniques in food is raised. Some experts specified that the *Codex Alimentarius* standards are used as a reference in the Marrakesh Agreement establishing the WTO. In the event of a dispute between two countries, the Codex standards are used as a reference base.

In addition the lack of a common definition of GMOs settled in a broader international community lead to some difficulties for recognizing the above consideration. Some experts have mentioned that international definition of GMO is not absolutely necessary. National food law of every country has the role to protect consumers. Meanwhile, continuing the research and collection of information on the consequences of GMO utilisation on the quality of products, on environment and human health can be considered of primary importance for an organisation like OIV.

At this stage, due to the controversial positions, an identification of the Genetic engineering techniques in the vitivinicultural sector cannot be proposed as a final text

Techniques of Genetic engineering in the vitivinicultural sector

In reference to the Cartagena protocol, the OIV understands as genetic engineering all the techniques aimed at modifying artificially the genetic material of an organism by overcoming the natural barriers of the physiology of reproduction or recombination, more particularly by application of:

I. *techniques of manipulation in vitro, including the recombination or the direct introduction of the nucleic acids (RNA/DNA) in cells or organelles;*

II. *or the cellular fusion and fusion of protoplasts:*

- for micro-organisms, not belonging to the same taxonomic family, and
- for vine plants of genus Vitis belonging to the species which can not be crossed naturally
Not considered techniques of genetic engineering are:

a7. Natural processes such as union, transduction,
a8. Polyploidy induction.
A3. The selection of variants or natural mutants;
A4. The selection of mutants brought about by physical or chemical methods;
A5. The crossbreeding, hybridisation using natural sexuality
The resolution is subject for compulsory automatic review in regular intervals

Discussion on definition of GM vine

This definition on Genetic modified vines caused a debate about the proposal to introduce two scenarios for the taxonomic limits for the *cis* and *trans* classification for genetically engineered vines. The current classification of *cis* for plants of the same genus and trans between plants of different genus was criticised on two aspects.

Firstly, the vines belong to a single genus, *Vitis*, consequently the definition should be clarified on the use of the word "vine". Some delegation requested that greater clarity was introduced into the terms used and proposed replacing the definitions "cis genetically engineered plants" and "trans genetically engineered plants" by "intra-genetically engineered plants and inter-genetically engineered plants" respectively.

Secondly, another delegation indicated that the cis/trans classification for genetically engineered plants is often used in international scientific literature for *cis*: for the application of genetic engineering techniques between plants of the same species or between inter-fertile species; and for *trans*: for the application of genetic engineering

techniques between plants belonging to different species of the same genus. It has been also specify that results comparable to those obtained on cis-genetically engineered plants can be obtained by traditional selection techniques.

A discussion took place on the definition of "ancestor". After the intervention of the Italian expert, the group did not object to the fact that only individuals from **vegetative reproduction** must be considered under the term "descendant". The group did not see the need to introduce a limit in the number of generations from the ancestor that had been subject to a genetic modification for the descendant no longer to be considered as genetically engineered.

The graft-rootstock relationship was discussed in the case of a genetic modification made at rootstock level. It has been proposed a case by case evaluation for defining the entire plant as genetically engineered. Some delegations agreed that there is no modified DNA from the rootstock present in the graft's products. The experts from Italy and Spain insisted that there was an exchange of proteins between the rootstock and the graft and consequently the entire plant had to be considered as genetically engineered, in accordance with the principle of precaution.

The group decided to refer to the GENET group for greater clarification regarding:

- the possible exchanges that take place between the graft and the rootstock (ref. question asked within the scope of resolution CST 10-473)
- the consistency of the cis/trans classification for genetic modifications
- the objective of differentiating between *cis/trans* for genetically engineered vines in the definition of the GMO vine.

Concerning the definitions of cis- and trans- genetically modified. Several speeches were made, particularly by experts on the relevance of both classifications, without however resulting in a common position. Since the cis/trans classification does not change the meaning of the definition of the genetically engineered vine, the Group decided not to keep this classification in the discussion.

Another discussion takes place on how should be considered the vine for which only the rootstock or only the scion have been genetically modified.

Some expert underlines that a vine plant must have roots and leaves, in case a part of the plant is modified, the whole organism should be considered as genetically modified. The question of the existence of transfer of genes and/or metabolites between the rootstock and the scion is actively debated. Expert mentioned that for the moment there are no solid evidences of transport of genetically modified material between the rootstock and the scion. However, another opinions indicate that even there are no transfers of genetically modified material; the whole plant has been in a certain measure improved.

In absence of consensus, the experts proposed to apply the **principle of precaution** for the question of eventual transfer of genetically modified material between the rootstock and the scion. In 1992 in Principle 15 of the Rio Declaration, **principle of precaution** is defined in the following terms: "Where there are threats of serious or irreversible damage, lack of full scientific certainty shall not be used as a reason for postponing cost-

effective measures to prevent environmental degradation.". The principle of precaution is also reasserted in the preamble of the Cartagena Protocol

Major questions raised in all four resolutions under discussion:

- The relation between rootstock and the scion:
- Should the product obtained from a plant with GM rootstock be considered as obtained from GMO?
- Should a vine obtained vegetatively from a non GM scion grafted on the GM rootstock be considered as a GM vine?
- In general, should a vine for which one of the ascendants was a GM vine be considered as GM vine (should there be a generational limit?)

At this stage, due to the controversial positions, a definition as follow for Genetically modified vine cannot be proposed as a final text

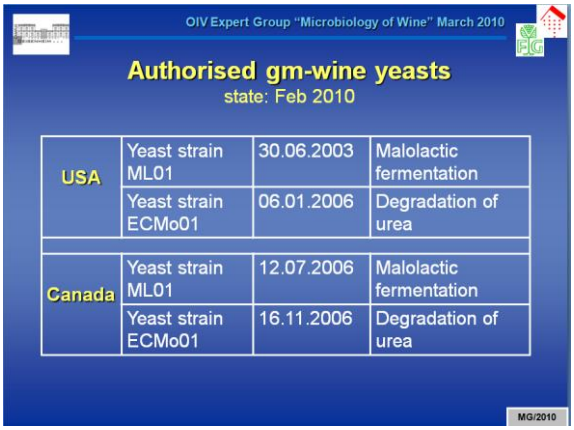
Genetically modified vine

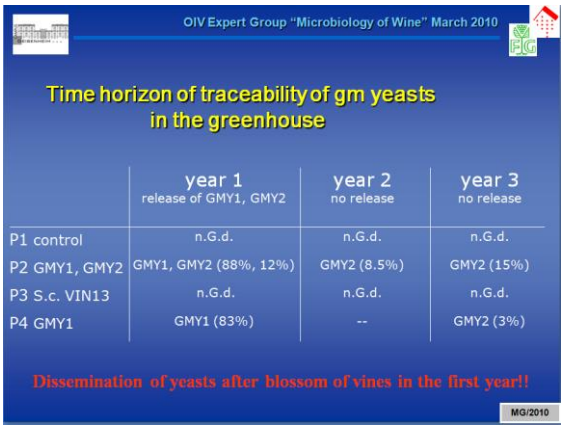
A genetically modified vine is a vine of which the genetic material of scion or rootstock has been modified by means of techniques of genetic engineering, as identified by the OIV [OIV resolution CST 10-470]

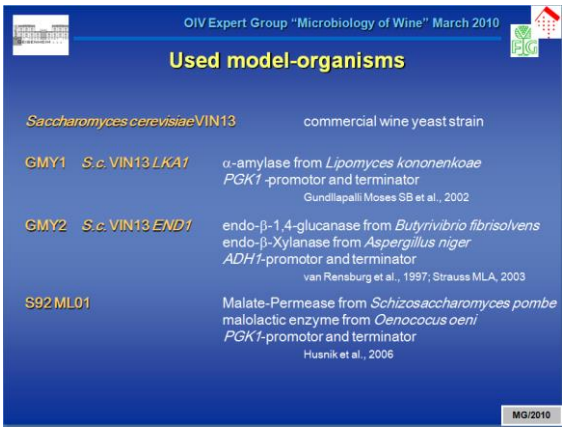
Discussion on definition of GMM

This regulatory framework should encompass all possible situations that could potentially occur without entering the debate on the appropriateness of genetic modification itself. In particular, it seems urgent to work on the MMG bearing in mind that some yeasts are already commercially available and potentially used in the wine making process.

The Group president of the group of experts “Microbiology” informed that it is important to bear in mind that from a technical perspective the presence of GMMs can only be certified if the mutation/modification of the microorganism is known.







At this stage, due to the controversial positions, a definition as follow for Genetically modified microorganisms cannot be proposed as a final text

Genetically modified microorganisms (GMM) in the vitivinicultural sector

Genetically modified microorganism in the vitivinicultural sector is a microorganism obtained by application of techniques of genetic engineering as identified by the OIV [OIV resolution CST 10-470].

Discussion on definition of products

Based on the discussion of the Commission “Safety and Health”, a summary of the current situation on food additives and processing aids, as they appear in the various regulations (worldwide and European) has been presented. A focus on enzymes has been made including tables extracted from FAO meetings where a series of enzymes arising from GM microorganisms could be seen. Finally, a reference to the DG SANCO portal has been also made where the labelling of products containing GMOs or produced from GMOs, among other things, must be labelled in accordance with (EC) regulation No. 1829/2003 http://ec.europa.eu/food/food/biotechnology/etiquetage/index_en.htm.

Therefore, it is proposed that the status of a vine produced using additives or processing aids produced from GMOs or GMMs should be evaluated on a "case-by-case" basis, according to the decision tree for evaluation of GMOs which will be specifically developped

Following a question from the president of the Commission CI, a discussion began on whether "biological equivalence" exists between GM vines and the wine produced using additives or processing aids produced from GMOs or GMMs. The majority of experts were in favour of the non-existence of such an equivalence, because the reasoning is different in both cases.

The group held lively discussions about the exchange of materials (genetic or protein) that may take place between the rootstock and the graft, the presence of material from the vine that may have been genetically engineered in the grape and the wine, the presence of residues from genetically engineered microorganisms in the final product and the existence of techniques that would make it possible to detect these materials in the products. The experts did not have sufficient information to reach a consensus on these issues.

The Group of experts Genetic responded that there is currently no standard method for determining that modified DNA or proteins resulting from the modification of the genome are present in grapes and consequently it is impossible to give a single answer that would cover all scenarios. The decision would have to be made on a case-by-case basis.

Another issue concerns the reliable methods for determining the presence of genetically engineered microorganisms in wine. The group of experts “Microbiology” specified that the presence of GMMs can only be certified if the mutation/modification of the microorganism is known.

Additionally, some expert reported another application of GMOs in the vitivinicultural sector about the use of GM microorganisms as biocides. It has been proposed to take into consideration the treatment of vine or grape with genetically modified microorganisms.

At this stage, due to controversial positions, a definition as follow for vine based products which are produced from or with the assistance of GMOs cannot be proposed as a final text

Vine based products which are produced from or with the assistance of GMOs

These products are:

1- Grapes from a GM vine as defined by the [proposed] OIV draft resolution 10-471;
2- Grape juice and must which is produced from grapes from a GM vine as defined by the OIV;
3- Wine and special wine (as defined in the Chapters 3 and 4 in the Part I of the International Code of Oenological practices) which is produced from grapes from a GM vine or grape must from a GM vine as defined by the OIV;
4- Wine and special wine (as defined in the Chapters 3 and 4 in the Part I of the International Code of Oenological practices), which is produced using genetically modified microorganisms as defined by the OIV,
5- Wine vinegar and spirituous beverage (as defined in the chapters 6 and 7 in the Part I of the International Code of oenological practices) elaborated from products mentioned in point 3, 4, 5 and 7.
6- grapes or other vine products issued from vines which were treated using genetically modified microorganisms, as defined by the resolution CST 10-472 of the OIV
7- by-products obtained during the production of vitivinicultural products as mentioned in the points 2, 3, 4, 5 and 6

Status of wine which is produced with additive(s)[4] or processing aid(s)[5] deriving from GMO or GMM, will be considered on the case by case basis,.

The resolution is subject for compulsory automatic review in regular intervals

Some information stay to be clarified on this issue

- Information research on the existing research in the field of GM vine varieties and GM yeast starters:
- information research on the economic and commercial importance of GM vines and GM yeast starters and their derived products
- Information and compilation of methods for detection of GMO residues and metabolites in vinicultural products.

4 ***Food Additive*** *means any substance not normally consumed as a food in itself and not normally used as a typical ingredient in food, whether or not it has nutritive value, the intentional addition of which to food for a technological (including organoleptic) purpose in the manufacture, processing, preparation, treatment, packing, packaging, transport or storage of such food results, or may be reasonably expected to result, (directly or indirectly) in it or its by-products becoming a component of or otherwise affecting the characteristics of such foods. The term does not include contaminants or substances added to food for maintaining or improving nutritional qualities. (Codex Alimentarius Procedural Manual*)

5 ***Processing aid*** *means a substance or material, not including apparatus or utensils, which is not consumed as a food ingredient in itself, but is intentionally used in the processing of raw materials, food or its ingredients, to fulfil a given technological purpose during treatment or processing and which may result in the non-intentional but unavoidable presence of residues or their by-products in the final product. (Codex Alimentarius Procedural Manual*)

Information on existing labelling regulation for products containing GMOs

2nd Session (October 2010)

During this session, discussion on the hypotheses relative to consumer information and the labelling of the GM products of those containing GMOs were engaged. A report from Italian expert was discussed about the legal framework for the use of GMOs[6].

In this report the issues relating to the use of yeast, bacteria and by-products in the winemaking techniques could be compared to the relationship between GMOs and food.

In general, positions can be attributed to two main lines, which schematically refer to two major organizational principles:

1.A) the principle of equivalence, and

1.B) the precautionary principle.

1.A) jurisdiction, namely the direct management responsibility for the company, which launched the product, communicating it to the supervisory authority, attaching the equivalence of the final product for the production of which has been used a GMO, compared to that obtained with traditional techniques, but assuming directly the responsibility to ensure that food ingredients are safe, and are in compliance with all legal and regulatory requirements .

1.B) The administration, a procedure is engaged by the authorities prior authorization, otherwise the product cannot be used or sold. In this case there is a public register of authorized products containing limitations of use which they are subjected.

These two models are variously combined and declined in different jurisdictions.

In some regulations (Australia, New Zealand….) GM foods, ingredients, additives, or processing aids that contain novel DNA or protein must be labelled with specific words. Novel DNA or protein is defined as DNA or a protein which, as a result of the use of gene technology, is different in chemical sequence or structure from DNA or protein present in counterpart food, which has not been produced using gene technology.

Labelling is also required when genetic modification results in an altered characteristic in a food, with changed nutritional characteristics.

6 Insight into the legal framework for the use and experiments using GMOs: Ferdinando Albisinni March 2010

GM labelling is not about safety. It is about helping consumers make an informed choice about the food they buy.

In these jurisdictions, all GM foods and ingredients must undergo a safety assessment and be approved before they can be sold.

Some Exemptions for GM labeling exist. GM foods that do not contain any novel DNA or protein or altered characteristics do not require labeling (Australia NZ…). A decision not to label these foods was made because the composition and characteristics of these foods is exactly the same as the non-GM food. These foods are typically highly refined foods, such as sugars and oils, where processing has removed DNA and protein from the food, including novel DNA and novel protein.

In some jurisdiction, food Labeling is also not required when there is no more than a specific % (1% Australia, New Zealand[7], 0.9% UE[8]) (per ingredient) of an approved GM food unintentionally present as an ingredient or processing aid in a non-GM food. This means labelling is not required when a manufacturer genuinely orders non-GM ingredients but finds that up to the specific % of an approved GM ingredient is accidentally mixed in non-GM ingredient.[add reference of regulations]

Some other jurisdictions (eg USA, Canada …) have developed different general principles to:

- require mandatory labelling if there is a health or safety concern, i.e., from allergens or a significant nutrient or compositional change (these decisions will be made by Health Canada), in order to inform consumers of the allergen or change,
- ensure labelling is understandable, truthful and not misleading,
- permit voluntary positive labelling on the condition that the claim is not misleading or deceptive and the claim itself is factual, and;
- permit voluntary negative labelling on the condition that the claim is not misleading or deceptive and the claim itself is factual.

Mandatory labelling for foods, including genetically engineered foods, can be required where there are health or safety concerns that could be mitigated through labelling, or to highlight a significant nutritional or compositional change.

In some case, voluntary labelling is permitted in order to provide consumers with information that is not related to the safety of the product. To facilitate the use of such voluntary labelling, the Canadian government supported the development of a national standard to provide guidance on the voluntary labelling of products of genetic engineering.

[7] http://www.foodstandards.gov.au/consumer/gmfood/labelling/Pages/default.aspx
[8] http://ec.europa.eu/food/food/animalnutrition/labelling/Reg_1829_2003_en.pdf

Since 1992, the U.S. Food and Drug Administration (FDA) has required labeling of GM foods only if the food has a nutritional or food safety property that is significantly different from what consumers would expect of that food. For example, if a new GM food includes a protein that may be an allergen not expected to be present, then it would have to be labeled. Otherwise, the FDA has not considered the methods used to produce new plant varieties to present systematic differences in nutritional properties or safety concerns compared to standard methods of traditional plant breeding. Early in 2001, the FDA proposed voluntary guidelines for companies that choose to label foods as to whether they do or do not contain GM ingredients if they see sufficient market opportunities for doing so.

3rd Session (March 2011)

The group coordinator presented a legal article on the labelling of genetically modified products[9]. This paper aims to discuss about the force of the GM crops law. It is not possible to reduce this law to an accumulation of fixed rules because they reflect evolving policy guidelines that make it fragile even if they are part of a seemingly solid law system. As it is based on specific principles and methods, but is under strong social pressure, the GM crops law is caught between structural solidity and fragility of the rule.

5th Session (March 2012)

The coordinator gave a short presentation on the CAC/GL 76-2011 standard in the CODEX Alimentarius, which compiles in a single document, the important elements of guidance from Codex texts applicable to the labelling of foods derived from modern biotechnology. The negotiations for adopting this text on the labelling of products containing GMOs have lasted almost twenty years and the final text is not a summary document. This situation demonstrates the diversity of labelling policies for products containing GMOs across the world and the difficulty in reaching a consensus.

The coordinator of the group then presented an overview of labelling policies for products containing GMOs and their distribution across the world. The coordinator specified that the information presented came from various scientific articles.

Research shows that countries with a strict and compulsory labelling policy are mostly developed countries that are not dependent on agriculture. Countries that produce and export products containing GMOs generally adopt more flexible labelling policies.

In view of the BIOTEC group's mandate and particularly the action to "Assess the various hypotheses regarding consumer information and as required, formulate proposals for changes to the labelling standard", the coordinator discussed the potential difficulty in drafting the OIV guidelines on the labelling of vitivinicultural products containing GMOs and the need to consider this within the BIOTEC group and Commission III with an open document that could respond to the sensitivities of each Member State

[9] *Les cultures génétiquement modifiées: anges ou démons ? Réflexions sur l'extraordinaire fragilité du droit - Luc Bodiguel*

7th session (March 2013)

The coordinator informed the experts about the results and conclusions of a five-year research programme by Switzerland, conducted following the five-year moratorium on GMOs voted by the population in 2005 and extended by three years in 2010. The research programme budget was 15M Swiss Francs and the programme was made up of 19 projects.

The report on the results of the programme's work was published in September 2012. According to these results, genetic engineering does not lead to more dangers than the "natural crossing" of commercially used plants. In some cases, it would seem that this type of technology may have positive health benefits.

Nevertheless, despite the report's conclusions, on 26th September 2012, the National Council voted by an overwhelming majority (112 votes against 62) to adopt a decision to extend the moratorium by another 4 years.

It is hoped that the DROCON group will participate directly in discussions relating to labelling and information for the consumer.

Update to the bibliographic note on regulatory monitoring of GMOs

Since 2008 the Secretariat General of the OIV established a report on the progress of the bibliographic note on regulatory monitoring of GMOs to the experts. Bibliographic monitoring began in 2008 with the aim of facilitating the OIV's work in the field of definitions related to modern biotechnology techniques. The note focuses on three topics: a directory of the regulations in force in the different countries, the adapted definitions and the rules relating to the labelling of products containing GMOs or which consist of GMOs.

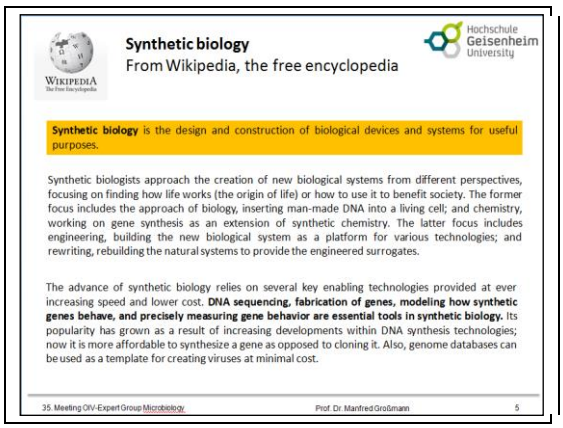
The update of the regulatory note consists in extending it to new countries as well as updating the information already contained in the document. New countries have been included according to two criteria: the importance of the country for the OIV (hence, the OIV Secretariat has started work on Indian and Chinese legislation) and recent regulatory changes (the Secretariat worked on the basis of recent notifications given by countries to the WTO).

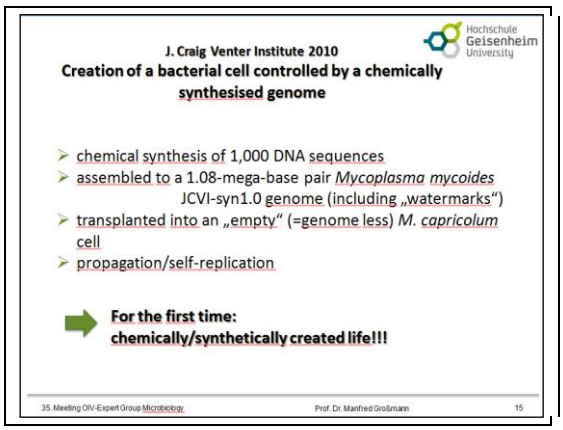
Synthetic biology

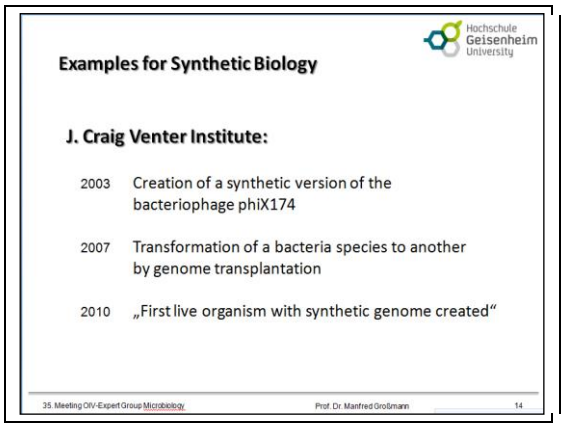
At the 3rd and 4th session, a report on synthetic biology was presented and the question of whether or not to continue works in this field was raised. Some experts proposed continuing the works, and mentioned the existence of an almost complete platform on this area on the internet. It has been proposed to continue the investigation on Synthetic biology in order to provide all relevant information for future discussion.

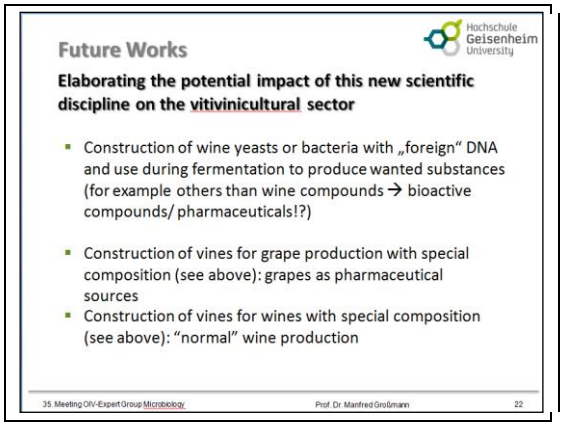
Synthetic biologists approach the creation of new biological systems from different perspectives, focusing on finding how life works (the origin of life) or how to use it to benefit society. The former focus includes the approach of biology, inserting man-made DNA into a living cell; and chemistry, working on gene synthesis as an extension of synthetic chemistry

Some elements on synthetic biology have been presented during the group of experts "Microbiology" in 2014 and are reproduced below:









Recommendations

In addition to specific questions mentioned in the different part above, general question listed below should be analysed when the application of biotechnology to the vitivinicultural sector is approached.

1. Question regarding coherence, including any difference in wording, between OIV proposed definitions and definitions of Codex Alimentarius (CAC/GL 44-2003) and the Cartagena Biosafety Protocol under the Convention on Biological Diversity .

2. Question regarding the proposed definition of what constitutes a genetically modified or derived organism since it is not settled in the broader international community, with strong and opposing views held within the scientific community and between governments

3. Questions regarding the transfer of genetic material from rootstock to the scion for the denomination of
   - Vine level
   - the vine based products which are produced from or with the assistance of GMOs or are produced from GMOs

4. Need for further research and information with regard to knowledge gaps and uncertainties identified :
   a. transfer of genetic material from rootstock to the scion,
   b. information on research on GM yeast in the vitivinicultural sector
   c. detection methods for determining the presence of GM microorganisms in wine