



**DIRECTORATE FOR FOOD, AGRICULTURE AND FISHERIES
COMMITTEE FOR AGRICULTURE**

OECD Schemes for the Varietal Certification of Seed Moving in International Trade

**DRAFT SUMMARY RECORD OF THE 2ND MEETING
OF THE WORKING GROUP ON GENETICALLY MODIFIED SEED ISSUES**

Begnins/Geneva, Switzerland on 19-20 October 2000

As a follow-up to the 1st Meeting of the Working Group on GM Seed Issues held in San Antonio, Texas, USA last August, a 2nd Meeting took place in Switzerland with a view to preparing an Extraordinary Meeting of the National Designated Authorities, as requested by the National Designated Authorities on 4-6 July in Celle.

The present document was prepared by the Co-ordinating Centre and the Secretariat. It is circulated to Delegations and the Members of the Working Group for COMMENTS by 10 January 2001.

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held in Begnins, Geneva, Switzerland on 19 – 20 October 2000

1. Opening statement by the Chairman and the Secretariat

Mr. Miauton welcomed meeting participants to Begnins and introduced Mr. Staübli, Director of the Federal Research Station for Plant Production at Changins (RAC), near Nyon. Mr. Staübli gave a general presentation of the six Federal Research Stations of Switzerland and elaborated on the RAC activities. The Changins central station co-ordinates three satellite stations and five experimental sites, all of which are located in the Southern and the Western parts of the country. RAC has national responsibility for arable crops (including transgenic plant breeding), pastoral systems, viticulture and oenology, medicinal and aromatic species, berries, greenhouse cropping. In addition RAC deals with regional aspects of grassland management and agro-ecology in the Italian and French speaking regions. Collaboration has also developed with other Federal Stations concerning arboriculture, vegetable production in open fields, plant protection and registration of phytosanitary products.

Mr Debois explained that the next meeting of the Committee for Agriculture would be held on 28-29 November. Therefore, if an experiment was to start in the near future, the National Designated Authorities would need to approve documents quite quickly in order to submit them to Committee for Agriculture (for endorsement and transmission to the Council with a view to adoption).

2. Adoption of the Draft Agenda AGR/CA/S/A(2000)6

The draft agenda was adopted. Mr Dagallier confirmed that the documents referred to in it should have been numbered AGR/CA/S(2000)27 and 28, not ..S(99)27 and S(99)28.

3. Comments on the draft Summary Record of the San Antonio Meeting

It was agreed to delay receiving comments on the draft Summary Record of the 1st Working Group Meeting [AGR/CA/S/M(2000)7] held in San Antonio, Texas, USA, until the beginning of the Annual Meeting scheduled for the following day.

4. General Discussion of Document AGR/CA/S(2000)27

Mr Debois introduced the document briefly and reminded the meeting that the Working Group in San Antonio had been unable to agree on thresholds in the proposal for an experiment. The Advisory Group had met straight after the San Antonio meeting and had proposed thresholds in AGR/CA/S(2000)27. Mr Miauton asked representatives to indicate what were the main concerns to them in this document.

Mr Valvassori (EU) indicated the support of the EU for an experiment, in which the important elements were the implications for importing and exporting seed, identifying standards, the difference between authorised and non-authorised events and the inclusion of flexibility on previous cropping and isolation requirements. However, he stressed that participation in the experiment should not be interpreted as a permit to market seed in importing countries if it did not meet their domestic regulations.

Mr Le Buanec (FIS) indicated that the seed industry felt that a legal framework was necessary. In relation to thresholds the FIS view was that nil presence of adventitious GM material was impossible to achieve, and that a 0.5% level would require seed companies to discard a significant amount of seed, whereas a 1% level was attainable.

There was support from Canada and the USA for a single threshold, set at 1% initially. In particular, Canada felt that the main value of the experiment was not as a basis for free marketing but as a way to validate seed production processes and GM testing methods.

Canada also felt that once the testing methods had been validated it was quite possible that it would be shown that the current varietal purity standards were not being achieved in practice.

Mr. Le Buanec stressed that the morphological tools used for assessing varietal purity were quite different from the biomolecular tools needed for validating thresholds. A good deal of contingency was attached to the latter. Both "purities" had to be examined in parallel. Anticipation of final results of the experiment was unwarranted.

Mrs. Harries (Argentina) saw the practical solution of the nil threshold issue as one of sample size determination, given that completely pure lots could not be guaranteed in the absolute.

Mr. Scheffel concurred. A nil threshold was a matter of sample size and test systems equivalence.

Mr. Fernandez drew attention to the difference between test methodologies and rule making: One should not lose sight of the whole purpose of the exercise which was to evaluate production practices, not to reach an absolute zero. Other delegates agreed with him that appropriate sample sizes and detection levels should be found.

Mr Valvassori did not consider that potential trade disruption, as alleged by FIS, should underpin the experiment and that trade repercussions would be as considerable as FIS was suggesting. The document should rather make clear that no country was obligated to import seed that did not meet its own legal requirements for GMO's.

Mr Miauton summarised the main points that required detailed discussion:

- 1) The legal framework of the experiment;
- 2) The difficulty of a nil threshold;
- 3) The cost implications of different thresholds;
- 4) The existing rules for varietal purity, adherence to them and their relationship with threshold levels for adventitious presence of genetically modified seed.

Mr. Debois read the New Zealand statement he had received from Mr Johnston on national requirements pertaining to all the above mentioned issues.

Mr Leist (ISTA) indicated that methodologies based on PCR technology were being developed in some ISTA laboratories. The most reliable results were likely to be obtained by using event specific primers which companies possessed rather than promoters which could lead to false positives. Agreements with companies were being sought.

Mr. Kastrissios raised the issue of knowing which testing methodology applies in exporting countries. It might not be accepted in the importing country.

Mr Martin (FIS) indicated that an agreed threshold was needed to enable testing methods to be developed. PCR testing relied upon knowing the threshold in order that the size of sample that had to be ground up could be determined. A pre-ring test was being conducted to validate quantitative testing methodology. Mr Martin emphasised that companies would not licence any technology in the presence of a nil threshold because it was not possible to test every seed present in the seed lot.

Mr. Girsch pointed out that in San Antonio all delegations understood that the statistical meaning of each threshold would be defined during the experiment. He saw the issues of appropriate sample size and statistical interpretation of results linked up with those of thresholds and standards. All of these points could be dealt with by the Technical Committee and the outcome should be reported to the Working Group and Annual Meeting. Interpreting a nil threshold as an impurity level inferior to a detection threshold could be an option.

Mr Miauton considered that it was not necessary to test every seed to establish a nil threshold if a confidence level was applied.

Mr Valvassori (EU) stated that nil thresholds were possible, using as examples nil standards prescribed in seeds legislation for certain weeds and noxious seeds. That said, the EU would be happy to co-operate on all methodological issues.

Mrs. Dahlberg (Sweden) emphasised the need for organic farmers to have access to non-GM seed, that is seed without any GM seed.

The same point was made by Turkey: companies must have the choice between GM and non-GM seed. To this remark, Mr. Le Buanec replied that the discussion was about adventitious presence, not voluntary presence of GM seed in the form of a genetically modified variety.

Before considering paper AGR/CA/S(2000)27, Mr. Le Buanec understood that the experiment should not have any trade implications; furthermore, no unauthorised transgenic event would be accepted. He stood with the fact that multiple thresholds would *de facto* be reduced to the lowest one but this was in contradiction with the 1 per cent the industry was advocating as the only practicable level.

5. Detailed Discussion of Document AGR/CA/S(2000)27

Mr Miauton suggested that a detailed discussion of the clauses proposed in the document would help to resolve the difficulties.

Mr. Dagallier reminded that the "Note" by the Secretariat appearing at the beginning of each document was prepared only for summarising the rationale and the context of the paper. The Note by the Secretariat was purely informative and not intended for pre-commitments.

Mr. Rego (Portugal) reported that the EU Member States had set up a special meeting at the request of France, current holder of the Council Presidency, to agree on a common position for the present meeting.

5.1 Note by the Secretariat

Mr Valvassori (EU) expressed the wish to start with the Note by the Secretariat.

⇒ **Paragraph 1**

Paragraph 1 says that "changes have been agreed" in San Antonio. In his opinion all matters had not been agreed because he had expressed a general reservation.

⇒ **Paragraph 2**

No changes requested. In line 5, he wished the word "*considered*" substituted for "*agreed*". This was accepted as a more open statement.

⇒ **Paragraph 3**

The wording of Paragraph 3 of the Note was amended at Mr. Valvassori's request to read "*For the time being it proposes neither to amend the current OECD Seed Schemes nor to derogate from them*".

⇒ **Paragraph 4**

Mr Valvassori (EU) asked for the removal of the final sentence of Paragraph 4, which made reference to FIS' purpose of avoiding the disruption of international seed trade due to the adventitious presence of GM's in non-GM seed. There was a lengthy discussion on the question of the retention of this sentence, and the meeting was reminded that it had been reported as a statement ascribed to FIS, not as a value judgement by OECD at an early meeting which the EU attended.

This was not agreed but would be omitted in the next version.

⇒ **Paragraph 5**

Mr Valvassori (EU) was content with the wording of Paragraph 5.

⇒ **Paragraph 6**

Mr Valvassori was not content with the first part of Paragraph 6 because there was no agreed legal framework for the experiment and he wanted the first two sentences deleted. Reference to the "*Management*" of the experiment should be included in the final sentence of the Paragraph.

The first sentence would be redrafted with a reference to the accreditation experiment, the omission of the term "*regulatory*", and the substitution of "*management*" for "*policy*" would be made in the last sentence.

Mr. Debois felt it necessary to put the paragraph 6 in perspective (no OECD pre-commitment). The paragraph described the procedure and requirements if there was to be an experiment. That being said, rewording of some points remained obviously possible. This would be tried, in order to reflect the EU concern .

⇒ **Paragraph 7**

It was agreed first that the beginning of the second sentence (3rd line) should read "*The issue of the detection of adventitious...* "

Mr Valvassori (EU) was concerned that Paragraph 7 required science based experimentation, it would be better, he felt, to make reference to experimentation based on established experiences and knowledge. The science of testing for the presence of GM adventitious contamination was a new science.

Mr Mathon (France) supported this view and stated that it would take time before the French and other research programmes yielded readily applicable information.

Mr Fernandez (USA) couldn't see why the EU was objecting because the experiment was science based.

It was finally agreed that the end of the second sentence would read as follows: "*deserves experimentation based on established experiences and knowledge*".

Mr Valvassori (EU) also wanted the sentence which reads "*The movement of such seed, like any seed, should yield itself to existing regulations, without excluding new rules and information as demanded by consumers whose collective or individual choices may vary due to uncertainty*", deleted. This was rejected.

⇒ **Paragraph 8**

Mr Valvassori (EU) indicated that the text should be amended to make specific reference to the identification of GM adventitious contamination as varietal impurities.

To render the statement even more factual, the Co-ordinating Centre suggested amending the last two sentences as below:

"Current rules have no specific provisions requiring the identity of each varietal impurity to be specified. However, in the case of GM adventitious presence, several countries think this may become necessary, using appropriate testing technologies."

This was agreed.

⇒ **Paragraph 9**

It was agreed that the word "*facilitate*" should be replaced by "*in*" in the third sentence and the last sentence should be deleted.

Mr Debois explained that the meaning of the paragraph was to avoid forbidding that some importing and exporting countries use, on a voluntary basis, the framework of the experiment when trading seed which had been certified according to OECD Rules and Standards if their legislation so permitted.

Mr Scheffel (Canada) said that there was an urgent need for valid tests, and that the results of the validated test methods might well allow countries to use them, to facilitate trade, in the future.

5.2 Main body of the document

The discussion turned to the main body of document 27. It was agreed that the wording of the proposal should itself be discussed in detail.

Mr Valvassori (EU) indicated that the European Commission wished to insert two new opening paragraphs:

⇒ ***The new paragraph (1) should be titled: Adoption of the experiment***

The wording of this paragraph would read as follows: "*The experiment shall be adopted by the Council*".

This was agreed.

⇒ ***The new paragraph 2 should be titled: Member States' GM Legislation***

Since the Proposal related to countries participating in the OECD Seed Schemes, not just EU Member States, Mr Debois noted that a more appropriate title should be "*Participating Countries' GM Legislation*".

Furthermore, both Argentina and the USA stated that they had rules for food safety and rules on environmental releases, and preferred the word "*rules*" to "*legislation*". Canada suggested that the wording be amended to read: "*Participating Countries' relevant domestic rules on GM's*".

Mr Valvassori (EU) wanted the paragraph to read "*No country shall be led to import seeds not conforming with its domestic GM legislation*".

It was eventually agreed that the wording be amended to read: "*No country shall be led to import seed not conforming with its relevant domestic rules with respect to GM's*".

⇒ ***New Paragraph 3, Old Paragraph 1:***

Time period of the experiment. It was agreed that the Annual Meeting may propose "*to the Council*" to extend the experiment beyond 2003. This addition was agreed.

⇒ ***New Paragraph 4, Old Paragraph 2***

Mr Valvassori (EU) wished to add to this paragraph the words "*it will begin with maize, soya bean, cotton and oilseed rape.*" This was agreed, but FIS felt that other species could be important.

⇒ ***New paragraph 5, Old Paragraph 3***

Mr Valvassori (EU) wished to expand the text of this paragraph as follows: "*...include a list of events that were authorised for release for the placing on the market in their countries. The inclusion in the experiment of events non-authorised in the importing country should not be interpreted as a permit to market in the importing country, seeds containing this kind of events.*"

Mr Le Buanec (FIS) considered that the final sentence was not necessary, because non-authorised events were being included in the experiment.

Both USA and Canada confirmed that they did not authorise events for release for the placing on the market, and it was suggested by Mr Fernandez (USA) that the wording should read "*and include a list of events that have successfully completed the necessary regulatory requirements that would allow commercialisation in their countries*". Mr Valvassori (EU) accepted the proposal made by USA but suggested that this matter might be better dealt with as a footnote. Mr Debois agreed to redraft the text in the form of a footnote.

This was agreed.

⇒ ***New Paragraph 6, Old Paragraph 4***

The wording was agreed without amendment.

⇒ ***New Paragraph 7, Old Paragraph 5***

Mr Valvassori (EU) wished to see clearly defined rules and terms of reference for the three ISNI Committees included in the proposal. This was agreed and Mr Debois would transfer this information from paper 28 to the present paper 27 which was the legal proposal

There was a short debate on the respective roles of ISTA and AOSA. It was agreed that the Technical Committee would be chaired by ISTA/AOSA.

⇒ ***New Paragraph 8, Old Paragraph 6***

Mr Valvassori (EU) wished to delete the reference to “*those countries taking part in the experiment*” because he felt it important to make the whole information available to all countries that participated in OECD Seed Schemes.

Mr Le Buanec (FIS) felt that only the participating countries should have the report in the first instance because they might have comments to make. The Annual Meeting would receive the report of the participating countries anyway.

Mr Miauton reminded the meeting that, as with previous experiments, all countries could be represented on the present Working Group, even if they did not participate in the experiment.

Mr. Debois reminded also that reporting to the Annual Meeting, that is to all countries, by countries in the experiment was the following step required by the procedure.

⇒ ***New Paragraph 9, Old Paragraph 7***

The wording was agreed without amendment.

⇒ ***New Paragraph 10, Old Paragraph 8***

Mr Valvassori (EU) considered that it was necessary to specify the identity of the GM adventitious contamination. He also wished to add a further sentence to the paragraph to the effect that “*The thresholds of 1% or 0.5% should not be interpreted as a permit to market in the importing country seed satisfying such thresholds*”.

Mr Le Buanec (FIS) reminded the meeting that no agreement had been reached on the wording of this paragraph during the San Antonio meeting.

He made three points:

- 1) The words “*adventitious contamination*” should be replaced by the words “*adventitious presence*”
- 2) If a seed lot was found to have an adventitious presence of GM seed of less than 0.5%, of an approved event, would the EU block it?
- 3) FIS, however, maintained its position that the experiment should work on a 1% threshold only, to start with.

Mr Miauton informed the meeting that the Advisory Group had held a meeting earlier that morning and had looked at the possibility of adjusting the wording of this paragraph.

Mr Wray (Co-ordinating Centre) confirmed that a better form of wording might be “*Detection levels which meet everybody’s needs*”.

Mr Valvassori (EU) responded by stating that, in his view, contamination is presence. He felt that it should be possible to identify the contamination. The EU supported 1%, 0.5% and Nil thresholds in the OECD experiment.

Mr Miauton asked Mr Valvassori what the last sentence he wished added to the paragraph (see above), actually meant, other than expressing in different words contents of paragraphs 2 and 5.

Mr Valvassori replied that this sentence contributed to the transparency of the experiment.

Mr Fernandez (USA) indicated that the USA was totally opposed to the including of the identity of the GM adventitious contamination and that a single threshold value of 1% was the most sensible and appropriate value. The USA was, however, prepared to consider the concept of not defining a number threshold in the text.

Mr Le Buanec (FIS) agreed with the USA delegation. Identifying the GM contamination was an extremely complex matter and there was a need for trust by all parties. It was understood that the EU had not as yet finally decided on threshold levels, but he knew that seed would be transported during the coming months into the EU and many problems could arise as a result of this.

Mr Miauton asked the FIS delegation to draft a counter proposal which it agreed to do, and the FIS delegation left the meeting.

Mr Le Buanec returned to the meeting with the FIS proposed text, which read as follows:

“An experiment shall be established to evaluate production practices and validate testing methodology. The experiment will be designed to test seed lots at a purity level greater than or equal to 99% at a confidence level of 95%. It is noted that other purity levels could be assessed with the defined methodology by testing additional seed samples”.

Mr Valvassori (EU) confirmed that the European Union was not in a position at this time to accept this text because there was only a 1% threshold included in the proposal. Two or three experimental thresholds should have been included. Mr Valvassori was also concerned about the confidence level of 95%, he preferred the Secretariat's phrase reading *“with associated confidence levels”*.

Mr Miauton asked FIS to explain what their proposal did permit.

Mr Le Buanec explained that the FIS proposal was very open, and he himself was well aware that FIS' proposal no longer made it possible to market the seed under the terms of the experiment, because the revised proposals excluded marketing threshold levels. The starting purity level of 99% was experimental and a method had to be established at 99%. There was no reason to suppose that this level could not be changed by increasing the number of samples tested, but this would lead to much more work and would be very expensive. It was important to introduce an experiment which all laboratories could carry out. The appropriate confidence levels could be worked out by the Technical Committee.

Mr Miauton considered that the proposal was valid and he invited more comments.

Mr Scheffel (Canada) was happy to accept the proposal, but the reference to a purity level was in fact a reference to a varietal purity level.

Mr Fernandez (USA), Mrs Harries (Argentina) and Mrs Messina (Chile) all supported the FIS proposal.

Mr Girsch (Austria) asked for an explanation of the meaning of the terms “production practices” and “purity level”; in the FIS counter proposal, greater than or equal to 99% could be interpreted as a system with multiple thresholds based on varietal purity levels such as 99.5% or 99.7% or 99.9%.

Mr Le Buanec (FIS) agreed that the word varietal should be added before purity. He stated that other confidence levels could be studied and FIS already had knowledge on measuring the adventitious presence of GM seed in seed lots, testing had already commenced in 3 laboratories in Europe, 1 in South America and 3 in USA.

Mr Miauton concluded that the FIS proposal had raised considerable interest, although no agreement was reached on this paragraph; USA, Canada, Argentina and Chile expressed their willingness to introduce the OECD papers for a joint experiment.

Mr Valvassori (EU) confirmed that at the present time the EU could not support the FIS proposal because of the 99% varietal purity level which was equivalent to a 1% contamination level. He drew attention to the revisions made to the paper by the EU on 3 October, which had been circulated to the meeting, which confirmed the remarks he had been making on the papers AGR/CA/S(2000)27 and AGR/CA/S(2000)28 which he thought would be useful for further negotiations.

The EU representatives expressed their strong support for the OECD experiment based on the Advisory Group proposal introduced in item 8 of OECD paper AGR/CA/S(2000)27.

Mr Le Buanec (FIS) confirmed again the reasons why FIS could not support the OECD proposal originally made by the Advisory Group as stated in old paragraph 8.

Companies and laboratories were essentially concerned about the costs of carrying out the work, it would be very expensive to test to threshold levels lower than 1%.

Having established a method at a threshold level which was reasonable, the method could be developed for other thresholds. Apart from Switzerland, no other country had defined specific threshold levels.

No agreement was reached on the matter of paragraph 8 but Argentina, Canada, Chile and USA expressed their willingness to use the OECD papers for a joint experiment.

There was no time available to discuss the final paragraphs 9 and 10 of the proposal.

Conclusions

Before concluding the meeting, future steps were agreed on as follows:

- Papers AGR/CA/S(2000)27 and 28 would be rewritten as a result of the present meeting;
- Argentina, Canada, Chile and USA informed the meeting that they would undertake a technical experiment between themselves along the lines of the OECD documents and using a 1% threshold as a starting point with associated confidence levels. AOSCA offered to help with this experiment. It would be the subject of a report to the Working Group on Genetically Modified Seed Issues and the 2001 Annual Meeting.
- FIS and ISTA agreed to co-operate with this initiative and appoint experts for an interim technical committee.
- Special attention would be paid to sample size and the number of samples in respect of any threshold; It was reminded that the Schemes already permitted on some conditions voluntary additional statements on the OECD labels. The meaning of traditional varietal purity standards would be examined with respect to genetic modification-linked molecular varietal purity levels.
- The EU representatives expressed support for the OECD experiment, based on the Advisory Committee proposal included as Item 8 of the OECD document AGR/CA/S(2000)27. The substantial room document circulated by the EU Commission indicated the willingness of the Commission and EU Member States to continue to discuss the important issues that were still unresolved.
- The Advisory Group would meet to take stock of the problems and to advise for the best way to pursue discussions and the best use of experimental results as they became available.
- In lieu of a proposal for endorsement of an OECD Scheme-wide experiment by the Committee for Agriculture, the Secretariat would report the current situation to the Committee for information and comments.

ANNEX I

**LIST OF PARTICIPANTS
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(Begnins, Switzerland, 19-20 October 2000)**

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