Disclaimer: unless otherwise agreed by the Council of UPOV, only documents that have been adopted by the Council of UPOV and that have not been superseded can represent UPOV policies or guidance.

This document has been scanned from a paper copy and may have some discrepancies from the original document.

———

Avertissement: sauf si le Conseil de l'UPOV en décide autrement, seuls les documents adoptés par le Conseil de l'UPOV n'ayant pas été remplacés peuvent représenter les principes ou les orientations de l'UPOV.

Ce document a été numérisé à partir d'une copie papier et peut contenir des différences avec le document original.

———

Allgemeiner Haftungsausschluß: Sofern nicht anders vom Rat der UPOV vereinbart, geben nur Dokumente, die vom Rat der UPOV angenommen und nicht ersetzt wurden, Grundsätze oder eine Anleitung der UPOV wieder.

Dieses Dokument wurde von einer Papierkopie gescannt und könnte Abweichungen vom Originaldokument aufweisen.

———

Descargo de responsabilidad: salvo que el Consejo de la UPOV decida de otro modo, solo se considerarán documentos de políticas u orientaciones de la UPOV los que hayan sido aprobados por el Consejo de la UPOV y no hayan sido reemplazados.

Este documento ha sido escaneado a partir de una copia en papel y puede que existan divergencias en relación con el documento original.

UPOV

TWA/20/9
ORIGINAL: English
DATE: September 13, 1991

INTERNATIONAL UNION FOR THE PROTECTION OF NEW VARIETIES OF PLANTS

GENEVA

TECHNICAL WORKING PARTY FOR AGRICULTURAL CROPS

Twentieth Session

Beltsville, United States of America, May 13 to 17, 1991

REPORT

adopted by the Technical Working Party for Agricultural Crops

Opening of the Session

1. The twentieth session of the Technical Working Party for Agricultural Crops (hereinafter referred to as "the Working Party") was held in Beltsville, Maryland, United States of America, from May 13 to 17, 1991. The list of participants is reproduced in Annex I to this report.

2. Dr. K.C. Clayton, Deputy Administrator, Marketing Programs, AMS, USDA, at Beltsville, Maryland, welcomed the participants to the facilities of the U.S. Department of Agriculture. The session was opened by Dr. M.S. Camlin (United Kingdom), Chairman of the Working Party.

Adoption of the Agenda

3. The Working Party adopted the agenda of its twentieth session, as reproduced in document TWA/20/1, after having agreed to insert a new item reading: "Report on the Results of the Diplomatic Conference for the Revision of the UPOV Convention."

Important Decisions Taken During the Twenty-sixth session of the Technical Committee

4. Dr. M.-H. Thiele-Wittig gave a brief report on the important decisions taken during the previous session of the Technical Committee, referring to the full report on the session reproduced in document TC/26/5 for further information. He also brought to the Working Party's attention document TC/26/6 reproducing the amended UPOV Variety Description Form and the UPOV Standard Technical Questionnaire, and document TC/26/4 Rev. on the Harmonization of States of Expression and Notes of Characteristics recommended to be followed when establishing or revising Test Guidelines.

5. Similar Variety. The Working Party noted that with the Technical Questionnaire the applicant would have a different understanding of a similar variety, indicating what made his variety novel, informing the public what his variety was like, choosing a variety similar in use (e.g. the variety with which he would have to compete) or a genetically similar variety.

6. The Working Party agreed with the Technical Committee's interpretation that the indication of a similar variety in the variety description was primarily meant to be helpful in the testing of varieties and that the Working Party would select similar varieties from within the same group on the basis of grouping characteristics. The Working Party agreed to indicate generally either a similar variety or, if there was no similar variety, the new feature or group of the variety. The few exceptions where no similar variety was indicated referred to cases in which there existed no grouping in a small species or cases where the variety represented the first application in a given species.

7. Quantity of Plant Material to be Supplied by the Applicant. The Working Party noted paragraph 43 of document TC/26/5 on the differences in the indication in the Test Guidelines of the quantity of plant material to be supplied by the applicant. It agreed that whatever wording was used, it would have to ensure that the first submission would constitute the reference sample which had to be used to identify the variety and test homogeneity. The Working Party preferred an indication of the total amount of seed or plant material needed for testing and for the reference sample. For agricultural crops, one single seed submission would normally be required, but the situation could change according to the species dealt with. In future, the Working Party would be more specific in the Test Guidelines, fixing species by species whether only one or several seed submissions would be recommended.

Report on the Results of the Diplomatic Conference for the Revision of the UPOV Convention

8. Mr. Greengrass informed the Working Party of the main results of the Diplomatic Conference for the Revision of the UPOV Convention, which had taken place from March 4 to 19, 1991, and which, on March 19, 1991, unanimously adopted a new text for the UPOV Convention. He highlighted the definition of variety, the increased scope of protection, the application, after certain periods, to all plant genera and species, the incluson of an option for States to exclude farmer plant-back of harvested material from the scope of the breeder's right, the possibility for organizations which have their own plant breeders' rights system to become members, and the introduction of the system of essentially derived varieties. He concluded by commenting that, during the Diplomatic Conference, a resolution had been adopted requesting the Secretary-General of UPOV to begin work on guidelines on "essentially derived varieties."

9. The Working Party recalled that during its previous session it had discussed the question of "essential derivation" on the basis of document TWA/XIX/8 Rev. and had asked members to continue studying the document at the national level in preparation for the introduction of the new system in the revised Convention.

10. On the basis of the above information and document TWA/XIX/8 Rev., the Working Party had a general discussion on what should be understood by "essentially derived variety."

New Methods, Techniques and Equipment in the Examination of Varieties

11. Discussions took place on the electrophoresis method in connection with the revision of the Test Guidelines for Wheat, Barley, Oats and Maize, and they are mentioned under those headings. The Working Party considered that at present it had no other new methods to discuss. During its coming session it would also discuss the measuring of colors.

Access to Data Bases of UPOV Member States

12. The Working Party recalled the discussions that had taken place during its previous session on the possibility of access to data held by other member States, as contained in document TWA/XIX/9, paragraph 5, as well as the discussions of the Technical Committee reproduced in document TC/26/5, paragraph 20. It noted that the Technical Committee had asked the Technical Working Party on Automation and Computer Programs to study, as a first step, the possibilities of exchanging published information among member States in electronic form via diskettes. It emphasized that, in its area, it would be interested in the possibility of exchanging lists of varieties under test, since they contained very useful information that would not raise problems for the authorities. It would also be of interest to put all published information into one single data base, together with a sorting mechanism that would allow access to information on a given crop provided by all member States. It therefore asked the Technical Working Party on Automation and Computer Programs to devote special attention to such an exchange or to a centralized data base.

Statistical Methods

13. Testing of Homogeneity of Self-fertilized and Vegetatively Propagated Species. The Working Party noted document TC/XXV/8 containing tables for the maximum number of off-types and the corresponding sample size for different combinations of population standards and acceptance probability. It finally agreed to use these tables when revising Test Guidelines or establishing new ones. It asked the Technical Working Party on Automation and Computer Programs to study the question of the rule of doubling the number of off-types from Table 11 in the case of mainly self-pollinated varieties, according to the rules set out in the General Introduction to the Test Guidelines (see paragraph 29) in comparison with possible use of Table 10 or the possibility of also indicating in Table 11 sample sizes for intermediate figures of k (1.5; 2.5; 3.5 etc.), which could then be doubled for the above cases.

14. Testing of Homogeneity in Cross-fertilized Plants with the Combined Over-Years Uniformity (COU) Criterion. The Working Party noted paragraphs 19 and 20 of Annex I to document TC/26/3 as well as Annex II to document TC/26/3 Add., which explained the combined over-years uniformity (COU) method in detail. It furthermore noted that, at its previous session held in October 1990, the Technical Committee had in principle approved the introduction of that criterion, in the first instance for grasses, but possibly also for other cross-pollinated agricultural species. The only question left open was that of fixing the significance level for the acceptance and rejection of varieties. The Working Party agreed to study the criterion and apply it as soon as the significance level had been fixed.

15. Minimum Distances Between Varieties. The Working Party took note of document TWC/VIII/9 Rev., which the Technical Working Party on Automation and Computer Programs had asked should be studied by the Technical Working Parties and comments thereon submitted to it. The Working Party furthermore took note of document TWC/VIII/14 explaining the relation between Least Significant Difference and minimum distance. The Working Party had some difficulty in understanding the documents, particularly with regard to the separation between minimum distance and LSD, as well as apparently discrepant statements in the documents in respect of cases in which the minimum distance was smaller than the unit of measurement.

Cooperation with Breeders in the Testing of Varieties

16. Examination in the United States of America. The Working Party noted document TWA/20/7, prepared by the experts from the United States of America, which explained the system applied in the United States of America, as well as explanations on the following subjects:

(i) History of the Plant Variety Protection Office, by Dr. K. Evans, Commissioner;

(ii) How an Application is Processed, by Dr. A.A. Atchley, Examiner,

(iii) Data Collection and Storage, by Mrs. J.M. Strachan, Examiner,

(iv) Information Resources, by Mr. E.E. Taylor, Examiner,

(v) Search and Examination of Crops, by Dr. T.A. Salt, Examiner, and

(vi) Statistics for Handling Gene/Environment Interactions, by Dr. J.L. Strachan, Examiner.

A summary of the explanations is reproduced in Annex V to this report.

17. Examination of Maize Varieties in France. The Working Party noted document TWA/20/6 prepared by the experts from France on the French system with respect to maize. Under this system the applicant was asked to supply the results of one year's test and GEVES carried out another year's test, comparing its own data with those supplied by the applicant. Mr. Guiard (France) explained that the system's aim was to obtain from the breeder a predescription of the variety that allowed the Office to take a decision on the variety after only one year of official tests in two different locations. The decision on the variety would be based on the data from the official test alone. At the outcome of one year's experience, the system looked very promising. It was, however, restricted to maize lines only and extension to other species was not planned at present.

18. Examination in New Zealand. The Working Party noted a report from the expert from New Zealand on the change in his country from a government growing test system to a breeders' growing test system with respect to agricultural and vegetable species. A summary of the report is reproduced in Annex II to this report. The expert concluded that the change had not been an easy one as in the beginning breeders had not been able to describe varieties so that procedures, test guidelines and training courses had had to be prepared to make the system work but within three years after the change, it was working satisfactorily. One other difficulty had been the non-existence of any descriptions of the varieties of common knowledge. For rye-grass, the Office had had to go back to official growing tests. Thus, in general, New Zealand had a mixed system comprising both official growing tests and breeders' growing tests.

19. Examination in Canada. The Working Party also noted a report from the expert from Canada on Canada's intention to build up a system of breeders' growing tests comparable to that already applicable in Australia, where the examiner would look at the plants in the premises of the breeder. A summary of that report is reproduced in Annex III to this report. As the system would be completely new in Canada, one difficulty would be the setting up of a test of varieties of common knowledge and the selection of similar varieties with which a candidate variety would have to be compared.

20. In the discussions that followed the above-mentioned reports, the Working Party noted that the member States at present applying solely a government growing test system would also have to consider partial acceptance of a breeders' growing test system, especially in view of the planned opening of the protection system to the whole plant kingdom. The higher cost of testing and the covering of cost increasingly demanded by governments would also lead to greater involvement of the breeder in the testing. Among the different examples noted, there was, however, a large range of different possibilities for breeders' growing tests, ranging from cases where the breeder received detailed instructions on how to execute the tests and establish the test report and the variety description to very liberal cases leaving details of how to execute tests and establish the description entirely to the responsibility of the breeder.

Report from the Subgroup for Electrophoresis in Cereals on the Test Guidelines for Wheat, Barley and Oats

21. The Working Party noted an explanation given by Dr. Cooke (GB) of Circular U 1674 containing a report on the Subgroup meeting on Electrophoresis which took place in Surgères, France, on October 16 and 17, 1990, as well as the documents TWA/20/2, TWA/20/3 and TWA/20/4 containing the updated versions of new Test Guidelines for Wheat, Barley and Oats, and paragraphs 45 and 46 of document TC/26/5.

22. Electrophoresis for Oats. Dr. Cooke (GB) explained the provisions of Circular U 1674 and the Working Party noted with respect to oats that the Subgroup had agreed on a method, on the list of bands to be considered and on a list of example varieties. Each absence or presence of one band would form a characteristic on its own.

23. Electrophoresis for Wheat. The Working Party noted that for wheat two groups were being studied: glutenins and gliadins, and within the glutenins two subgroups, those with high molecular weight (HMW) and those with low molecular weight (LMW). The Subgroup's study was most advanced in respect of HMW glutenins, where a method, a list of bands and a list of reference varieties had been agreed upon. Some further study was necessary with respect to LMW glutenins and even more with respect to gliadins, especially concerning the high number of bands, which resulted in them being closer to each other. The Subgroup needed further work on the calibration of the scale, the identification of the bands and the comparison of varieties.

24. Electrophoresis for Barley. The Working Party noted that for barley a Subgroup had, and still is having, enormous problems in establishing an agreed method, especially because two different methods (SDS-Page and Acid-Page) have already been used on a larger scale. The comparison of these methods will require further study.

25. The Working Party had a general discussion on the introduction of new characteristics in the Test Guidelines. It agreed that a characteristic could only be introduced on the basis of an existing useful method which would allow the breeder to maintain his variety homogeneous in the normal maintenance. Otherwise, the characteristic should not be accepted. When introducing a new characteristic as a routine from that date on:

(i) all new varieties had to be homogeneous in that characteristic;

(ii) all old heterogeneous varieties would be allowed to remain heterogeneous.

There was no agreement on the requirements with respect to old varieties being already homogeneous in that characteristic. Some experts took the position that they had to remain homogeneous while others claimed that, for old varieties only, the characteristics examined at the time of granting a right should be applicable. A change in another characteristic should have no effect on the right granted. The Working Party could not, therefore, solve either the question of what the effect would be if, after grant of a right to a candidate variety, the other older variety, from which it was distinguished by that characteristic alone, became heterogeneous in that distinguishing characteristic.

26. The Working Party stressed that in the acceptance of electrophoretic characteristics it was very important to agree on avoiding the use of different techniques and to adopt one single standardized method. That method should be strictly applied and it should be ensured that everybody used the same material of the example varieties, if possible by setting up a centralized bank with seed samples of those varieties. The acceptance of the use of bands should be made in common, either all member States would use a given band for distinction purposes or they would all reject it. The Working Party was aware that other bands could be observed, especially in using other methods, but these should only be accepted by common agreement among all member States and not individually by one member State. The uniformity requirements would apply not only to the band needed for distinctness vis-à-vis another variety, but the whole diagram of accepted bands needed to be homogeneous.

27. The Working Party had lengthy discussions on the principle of the introduction of characteristics of electrophoresis and on the possible consequences of such an introduction on the notion of distinctness. The introduction of electrophoresis might be the opening to accept any further new methods of DNA technology which could lead to accepting finally any difference between two varieties. The problems of minimum distance might thus be moved to the notion of essential derivation and left to the courts to decide. A further difficulty existed in that so far only little knowledge on the genetics and the relation of given bands to certain features was available. The possible consequences on the distinctness criterion would therefore have to be studied further during the next session on the basis of a document to be prepared by the expert from France.

28. Starting from the position taken during its previous session to use electrophoretic characteristics only as non-routine characteristics and as a last resort if other characteristics failed to establish distinctness, the Working Party took the following intermediate position:

(i) electrophoretic characteristics should be included in the Table of Characteristics and not in an Annex to the Test Guidelines;

(ii) the characteristics should not have an asterisk;

(iii) it had to be studied further whether the characteristics could be used alone or only in combination with another traditional characteristic and whether a difference in one band alone would be sufficient to establish distinctness. The following possible combinations could be considered:

(a) combination of several bands,
(b) combination of several proteins,
(c) combination with traditional characteristics.

The Working Party considered that, as long as the above points had not been solved within UPOV, an electrophoretic characteristic alone should not be used to establish distinctness.

29. The Subgroup on Electrophoresis in cereals would have to meet on October 8 and 9, 1991, in Hanover, Germany, to study the points remaining open. All UPOV member States should receive an invitation specifying that, besides experts in electrophoresis, experts with full knowledge of the UPOV system should also participate. The Subgroup would have the following tasks:

(i) to complete the technical work;

(ii) to involve other laboratories in examining new material;

(iii) to agree on one single acceptable method for each species;

(iv) to agree on acceptable bands; and

(v) to advise the Working Party on whether to use single bands, multiple bands or patterns.

30. The Working Party approved documents TWA/20/2, TWA/20/3 and TWA/20/4 and decided that they should remain pending until the decision on the inclusion of electrophoretic characteristics had been taken and the wording of those characteristics had been agreed upon. The Working Party further noted that, in conjunction with the Technical Working Party on Automation and Computer Programs, an exercise for the selection of example varieties for wheat was taking place.

31. Common Data Structure for Electrophoretic Data. The Working Party noted document TWC/VIII/3, as well as the fact that that document had already been presented to the Subgroup on Electrophoresis for Cereals at its last session. It asked the Subgroup to consider the document once it had solved the other more urgent tasks given to it.

Variety Denomination Classes for Brassica

32. The Working Party noted Circular U 1681 containing proposals for grouping of species of Brassica for purposes of variety denomination, prepared on the basis of a proposal made in the Technical Working Party for Vegetables. The Working Party also noted Circular U 1725 containing objections to that proposed change. It finally decided that it could not endorse the proposal of the Technical Working Party for Vegetables to combine the Brassica species of the present classes 5 and 6 in one class, with the exception of Sinapis in another class since this would create other problems in the naming of varieties. In addition, it pointed out that the agricultural varieties and the vegetable varieties were split into different markets and, in the present situation, no big risks of confusion existed. It therefore proposed to keep the present classes as mentioned in Annex 1 to the UPOV Recommendations on Variety Denominations (document UPOV/INF/12).

Final Discussion on Draft Test Guidelines for Peas

33. The Working Party noted that the expert from the United Kingdom was at present amending the draft Test Guidelines for Peas according to the decisions of the Technical Committee and also adding resistance characteristics and additional example varieties. Should the Technical Working Party for Vegetables approve the new draft Test Guidelines for Peas during its next session for presentation to the professional organization, the Working Party could agree to that presentation and would formulate any proposals for amendments at the same time as the professional organizations.

Discussion on Working Papers on Test Guidelines

Test Guidelines for Maize (Revision)

34. The expert from France introduced document TWA/20/8 containing proposals for revised draft Test Guidelines for Maize and also a proposal for the inclusion of characteristics obtained with the help of electrophoresis in the draft Test Guidelines for Maize. The Working Party did not enter into details regarding the Table of Characteristics and finally agreed on the following:

35. Table of Characteristics. The expert from France would prepare a list of the characteristics deleted from the present Test Guidelines and of the new characteristics to be included, stating the reasons for either the deletion or inclusion. The list would be circulated for comments, which should be sent to Mr. Guiard, and later discussed in a Subgroup. Mr. Guiard would also prepare Technical Notes and include therein the explanation of the new French system for establishing distinctness. The Subgroup would also consider the statement of the maize subcommittee of the American Seed Trade Association (ASTA) on minimum distances.

36. Electrophoretic Characteristics. The Working Party noted the explanation given by the expert from France. It also noted that the use of electrophoresis for Maize was under study in Germany and Spain. For the time being it was too early to take a decision in principle on the use of electrophoresis, therefore, the Working Party could only agree that it would work towards the incorporation of electrophoresis in the Test Guidelines for Maize.

37. Classification of Characteristics for Maize. Mr. Guiard explained the system of classification of characteristics of maize applied in France. He would prepare a paper on that classification, including a definition of hybrid variety, and distribute it before the next session of the Technical Committee so that advice could be obtained from the Technical Committee. The basic principle of that classification was that the characteristics were separated into three groups depending on their genetic determination and reliability, and were then given different weights for the determination of distinctness. Group 1 consisted of polygenic characteristics (e.g. earliness, height of plant, attitude of panicle) which were very useful and not difficult to assess. This was the most important group and a clear difference in one characteristic was enough to establish distinctness. Group 2 consisted of monogenic characteristics (e.g. color of silk, color of cob) in which differences could be seen easily but which were due to only one gene. For distinctness purposes, a clear difference in at least two of these characteristics was required. Group 3 consisted of other characteristics which were difficult to assess with precision or which showed large fluctuations. A clear difference in three of these characteristics was needed to establish distinctness.

38. Definition of Hybrid Variety. Mr. Guiard (France) explained the system of testing of maize hybrids in France where, in the first instance, the lines and the formula of the hybrid were studied. The lines would be checked by automatic comparison by computer. If one line in the formula was different, it could be assumed that the hybrid variety would also be different. If two lines were too close, the hybrid varieties would be compared with each other. With this procedure, 90% of the hybrid varieties could be distinguished on the basis of their lines. Mr. Guiard considered that the large number of 300 to 400 applications of hybrid varieties did not leave the office any other choice. The experts from Germany and Spain reported that, in contrast to France, in their countries the decision on distinctness was based on the comparison of the hybrid varieties themselves. There was indeed a large probability that, in the case of a difference in the lines, the hybrid variety would also be different, but exceptions were also possible and so far they had not wished to take that risk since for them it was too high. The risk, however, might be smaller in electrophoretic characteristics.

39. Letter of the Maize Section of ASSINSEL. The Working Party noted a letter dated May 15, 1991, from ASSINSEL containing comments from the Maize Section of ASSINSEL on minimum distances and hierarchical determination of characteristics. In view of the above agreed procedure, it was too early to enter into detail regarding those comments which will, however, be reflected by the above Subgroup.

40. Subgroup on Maize. The Working Party agreed to set up a Subgroup on Maize which would meet at La Minière, France, from February 18 to 20, 1992. Government experts and breeders should be invited to the meeting in order to

ensure good discussion and useful results. The bases for discussion during the meeting should be documents TWA/20/6 and TWA/20/8, the methods for electrophoresis on maize prepared by experts from France, the list of deleted and newly-included characteristics and the comments received thereon, and the comments of the Maize Section of ASSINSEL.

Test Guidelines for Rape (Revision)

41. The expert from Germany reported on the outcome of the meeting of the Subgroup on Rape which had met two weeks previously. The Subgroup had distinguished the following three groups of varieties:

(i) line varieties and narrowed populations resulting from the same progenies but differing by two generations;

(ii) hybrid varieties (to be available in about three years from controlled cross-pollination);

(iii) synthetic varieties (constituted from defined components and a fixed number of multiplications).

42. The Subgroup had not been able to solve the question of how to test homogeneity and whether to require unthreshed plants. It had been agreed that each member State would indicate its procedure and the tolerances for homogeneity. In addition, a ring test was foreseen with material of three varieties at present under application in several countries. In this ring test, varieties would be tested under two systems: (i) as line varieties with unthreshed plants and (ii) as allogamous varieties (with relative homogeneity).

43. The Subgroup agreed to observe glucosinolate only on seed harvested from the plots as the content might otherwise be open to manipulation by the breeder. It was planned to hold the next meeting in France in October. At that meeting, the Subgroup would have to study the data collected on the assessment of homogeneity, try to find a solution for synthetic varieties, go through the Table of Characteristics and study the uniformity requirements for hybrid varieties, which might have to be twice those for self-pollinated varieties.

Test Guidelines for Flax (Revision)

44. The Working Party noted document TWA/20/5 containing a draft for revised Test Guidelines for Flax prepared by the experts from France and made the following main changes thereto:

(i) Material required. The miminum quantity of seed to be supplied in one sample only.

(ii) Methods and Observation. The number of aberrant plants in paragraph 2 to be 5 in 2,000, in paragraph 3 to be 2 in 80.

(iii) Grouping of Varieties. Subparagraphs (i) and (ii) in paragraph 2 to read:

(i) Types, with the groups: Linseed, Flax;

(ii) Petal: color (characteristic 5, but with the states "white, blue, pink, violet" only.

(iv) Table of Characteristics:

Characteristics

1a to be deleted

1,2 the example varieties of the two groups to be checked; the characteristic might have to be split for the two groups

2 to have the bracketed addition "when fully extended"

5 to have the example variety "Royale" replaced

5a to be checked

7 to read: "Stamen: color of top of filament (at opening of flower)" with the example variety "Blue Chip" to be checked

8 to have the bracketed content read: "as for 7"

9 to have the brackets removed and a new bracketed part added reading: "as for 7"

14,15 to have the indication of Notes checked

15 to be placed at the beginning of the Table of Characteristics

(v) Literature. The French expert to indicate example varieties.

(vi) Technical Questionnaire. The two groups linseed and flax were added in paragraph 1 and deleted in paragraph 5.

Test Guidelines for Fodderbeet

45. The Working Party noted that the expert from Denmark, after having started to prepare draft Test Guidelines for Fodderbeet, had been informed that Belgium was interested in offering testing facilities for fodderbeet. After preliminary contacts, the expert from Belgium had offered to prepare a first draft of the above Test Guidelines. Unfortunately, the draft only reached the Office of UPOV after the session. The expert from Denmark would therefore again contact the Belgian expert with a view to preparing a common document.

Obsolete Varieties

46. The Working Party discussed the question of how to proceed with older varieties for which seed was no longer available on the market, where no maintainer existed and a seed sample might only be available in a gene bank or another seed collection. The Working Party questioned whether such a variety should still form part of the varieties of common knowledge and be compared to each new candidate variety. When setting up its reference collection, a State normally took a practical approach and only included those varieties likely to be grown or have a market in its area. It never attempted to collect all varieties from all over the globe, thus running a small risk of overlooking a variety existing in a remote country or area. The Working Party therefore took the position that this balance between the risk taken in not considering

a possible existing variety on one side and unjustified efforts to avoid it on the other would, as long as national law would allow, also have to apply to varieties for which seed was no longer available. The situation would however have to be decided species by species. A decision for vegetatively propagated species, for example, roses, would be completely different to that for wheat or other agricultural seed propagated species.

Status of Test Guidelines

47. The Working Party agreed to rediscuss the revision of the Test Guidelines for Maize (Revision), Rape (Revision), Flax (Revision) and Fodderbeet at its next session. It also agreed to rediscuss the draft Test Guidelines for Wheat (Revision), Barley (Revision) and Oats (Revision) at its next session if the inclusion of electrophoresis characteristics had been completed.

Future Program, Date and Place of Next Session

48. At the invitation of the expert from Denmark, the Working Party agreed to hold its twenty-first session in Menstrup Kro, Denmark, from June 16 to 19 (noon), 1992. The Working Party planned to discuss or rediscuss the following items at that session:

(i) Important decisions taken during the twenty-seventh session of the Technical Committee;

(ii) General discussion on the use of electrophoresis in the examination of varieties (FR to prepare a document);

(iii) Color measurements (GB to prepare a document);

(iv) Statistical methods;

(v) Cooperation with breeders in the testing of varieties;

(vi) Report from the Subgroup on Electrophoresis in Cereals on the Test Guidelines for

- Wheat (TWA/20/2)
- Barley (TWA/20/3)
- Oats (TWA/20/4);

(vii) Discussion on working papers on Test Guidelines for:

- Peas (Revision) (GB to prepare a document)

- Maize (Revision) (FR to prepare a document)

- Rape (Revision) (TG/36/3, TWA/XIX/2 Rev.)

- Flax (Revision) (TG/57/3 and TWA/20/5)

- Fodderbeet (DK to prepare a working paper)

- Soybean (USA to prepare a working paper).

49. The Working Party agreed that the Subgroups should meet as follows:

(i) Subgroup on Electrophoresis in Cereals, at Hanover, Germany, on October 8 and 9, 1991;

(ii) Subgroup on Rape, in France in October 1991 [La Minière, October 23 and 24, 1991];

(iii) Subgroup on Maize, at La Minière, France, from February 18 to 20, 1992.

50. The Working Party already noted the invitation to hold its 1993 session in Christchurch, New Zealand, in the course of November. The session may be combined with visits to be hosted by the Australian Plant Variety Rights Office.

Visits

51. On the afternoon of May 15, 1991, the Working Party visited the Beltsville Agricultural Research Center and the Federal Seed Testing Station and heard a report by Dr. P. Cregan, research analyst in the Soybean and Alfalfa Research Laboratory, on the testing of soybeans with the help of RFLPs, as well as a presentation given by Dr. Sally L. McCammon, Senior Plant Pathologist and International Coordinator, on certification for the planned field introduction into the environment of transgenic plants (for a summary of the latter presentation see Annex IV to this report), in the Biotechnology, Biologics and Environmental Protection Section of the Animal and Plant Health Inspection Service (APHIS). Immediately following the closure of the meeting, the experts of the Working Party had the opportunity of visiting turfgrass trials at the Beltsville Research Center and grass breeding research at Rutgers University.

52. This report has been adopted by correspondence.

[5 annexes follow]

ANNEX I

LIST OF PARTICIPANTS AT THE TWENTIETH SESSION OF THE TECHNICAL WORKING PARTY FOR AGRICULTURAL CROPS BELTSVILLE, MARYLAND, UNITED STATES OF AMERICA MAY 13 TO 17, 1991

I. MEMBER STATES

CANADA

Ms. V. SISSON, Plant Breeders Rights Office, Seed Division, K.W. Neatby Building, 960 Carling Avenue, Ottawa, Ontario, K1A OC6, (tel. (613) 995-7900, fax (613) 992-5219)

DENMARK

Mrs. J. RASMUSSEN, Director, Department of Variety Testing, Statens forsoegsstation, Teglvaerksvej 10, Tystofte, 4230 Skaelskoer (tel. 53-596141, fax 53-590166)

FRANCE

Mr. J. GUIARD, GEVES, La Minière, 78285 Guyancourt Cedex (tel. 30.83.35.80, fax 30.83.36.29)

GERMANY

Dr. G. FUCHS, Bundessortenamt, Osterfelddamm 80, 3000 Hannover 61 (tel. 0511-57041, tx. 9 21 109 bsaha d, fax (0511) 56 33 62)

NETHERLANDS

Mr. H.C.H. GHIJSEN, Head of DUS Department, C.P.R.O., P.O. Box 32, 6700 AA Wageningen (tel. 08370-76800, fax 08370-22994)

NEW ZEALAND

Mr. G.A. SPARKS, Plant Variety Rights Office, Canterbury Agricultural and Science Centre, Ellesmere Junction Road, Lincoln, P.O. Box 24, Lincoln (tel. (03) 253-011, fax (03) 252-946))

SOUTH AFRICA

Dr. S. VISSER, Agricultural Counsellor, South African Embassy, 59, Quai d'Orsay, 75007 Paris, France (tel. 01-45 55 92 37)

SPAIN

Mr. L. SALAICES SANCHEZ, Instituto Nacional de Semillas y Plantas de Vivero, Carretera de La Coruña, Km. 7,5, 28040 Madrid (tel. (1)307 9442 or 307 9443, tx. 48226 INSM, fax 4428264 or 3070777)

UNITED KINGDOM

Dr. M.S. CAMLIN, Department of Agriculture for Northern Ireland, Plant Testing Station, 50 Houston Road, Crossnacreevy, Belfast BT6 9SH (tel. 0232 448121/2/3, fax 0232 448353)

Dr. R.J. COOKE, National Institute of Agricultural Botany, Huntingdon Road, Cambridge CB3 0LE (tel. 0223 276381, fax 0223 277602)

UNITED STATES OF AMERICA

Dr. K.C. CLAYTON, Deputy Administrator Marketing Programs, U.S. Department of Agriculture, Agricultural Marketing Service, Room 3069, South Agriculture Building (1400 Independence Avenue, SW), Washington, DC 20005 (tel. 202-447-4276)

Mr. W.J. FRANKS, Jr., Deputy Director Science Division, U.S. Department of Agriculture, Agricultural Marketing Service, Room 3064, South Agriculture Building (1400 Independence Avenue, SW), Washington, DC 20005 (tel. 202-447-3075)

Dr. K.H. EVANS, Commissioner, Plant Variety Protection Office, NAL Building, Room 500, 10301 Baltimore Blvd., Beltsville, MD 20705-2351 (tel. 301-344-3485, fax 301-344-5472)

Mr. E.E. TAYLOR, Examiner, Plant Variety Protection Office, NAL Building, Room 500, 10301 Baltimore Blvd., Beltsville, MD 20705-2351 (tel. 301-344-3487)

Dr. T.A. SALT, Examiner, Plant Variety Protection Office, NAL Building, Room 500, 10301 Baltimore Blvd., Beltsville, MD 20705-2351 (tel. 301-344-2518)

Dr. J.L. STRACHAN, Examiner, Plant Variety Protection Office, NAL Building, Room 500, 10301 Baltimore Blvd., Beltsville, MD 20705-2351 (tel. 301-344-3489)

Mrs. J. STRACHAN, Examiner, Plant Variety Protection Office, NAL Building, Room 500, 10301 Baltimore Blvd., Beltsville, MD 20705-2351 (tel. 301-344-3495, fax 301-344-5472)

Dr. A.A. ATCHLEY, Examiner, Plant Variety Protection Office, NAL Building, Room 500, 10301 Baltimore Blvd., Beltsville, MD 20705-2351 (tel. 301-344-3494)

Mrs. K.K. WAIN, Examiner, Plant Variety Protection Office, NAL Building, Room 500, 10301 Baltimore Blvd., Beltsville, MD 20705-2351 (tel. 301-344-6082)

Mr. C.F. WARREN, Deputy Director, Group 180 Biotechnology, U.S. Department of Commerce, Patent and Trademarks Office, Washington, DC 20231 (tel. 703-308-1123, fax 703-308-3718/3721)

Ms. E.C. WEIMAR, Supervisory Primary Examiner, Art Unit 184, Group 180, U.S. Department of Commerce, Patent and Trademarks Office, Washington, DC 20231 (tel. 703-308-0254, fax 703-308-4227)

Dr. G. BENZION, Patent Examiner, Group 180 Biotechnology and Genetic Engineering, U.S. Department of Commerce, Patent and Trademarks Office, Washington, DC 20231 (tel. 703-308-1119)

Dr. P. RHOADES, Patent Examiner, Group 180 Biotechnology and Genetic Engineering, U.S. Department of Commerce, Patent and Trademarks Office, Washington, DC 20231 (tel. 703-308-1119)

Dr. P. CREGAN, Research Geneticist (Plants), Soybean and Alfalfa Research Laboratory, Building 011, Room HH16, BARC-West, Beltsville, MD 02705-2351 (tel. 301-344-3070)

Dr. S. McCAMMON, Senior Plant Pathologist, Room 848, Biotechnology, Biologies and Environmental Protection, Animals and Plant Health Inspection Service, APHIS, USDA, 6505 Belcrest Road, Hyattsville, MD 20782 (tel. 301-436-7601, fax 301-436-8669)

Dr. R. PAYNE, Chief, Federal Seed Branch, Bldg. 306, Room 216, BARC-East, Beltsville, MD 20705 (tel. 301-344-2089)

II. TECHNICAL EXPERTS

Mr. J.A. CAVANAGH, Pioneer Hi-Bred International Inc., 6800 Pioneer Parkway, P.O. Box 316, Johnston, IA 50131 (fax (515) 270 3106)

Dr. S. SMITH, Pioneer Hi-Bred International Inc., 7250 NW 62nd Ave, P.O. Box 1004, Johnston, IA 50131 (tel. (515) 270 3353 fax (515) 270 4312)

Dr. A. FORREST TROYER, Ph. D., Vice President, Research and Development, Dekalb-Pfizer Genetics, 3100 Sycamore Road, De Kalb, Illinois 60115

III. OFFICER

Dr. M.S. CAMLIN, Chairman

IV. OFFICE OF UPOV

Mr. B. GREENGRASS, Vice Secretary-General, 34, chemin des Colombettes, 1121 Geneva 20, Switzerland (tel. 022 7309155, tx. 412 912 ompi ch, fax (41-22)7335428)

Dr. M.-H. THIELE-WITTIG, Senior Counsellor, 34, chemin des Colombettes, 1211 Geneva 20, Switzerland (tel. 022 7309152, tx. 412 912 ompi ch, fax. (041-22)7335428)

[Annex II follows]

Plant Variety Rights in New Zealand and the Examiner's Role

by G.A. Sparks

The New Zealand Plant Variety Rights Scheme came into operation in 1975 under the provisions of the Plant Variety Rights Act 1973. In 1975 the Plant Variety Rights Office's (PVRO) staff numbers were low with a part-time commissioner and one examiner who was based at Lincoln, Canterbury. The first species to come into force in New Zealand were: Roses, Barley, Wheat, Oats, Peas, Potatoes and Alfalfa.

Originally the DUS testing was developed on the official testing or the European testing system. New Zealand PVRO staff soon discovered that breeders had not adequately described the varieties of common knowledge in New Zealand. The examiner then had the task of describing all the New Zealand varieties at the same time of DUS testing the new candidate varieties. There was also much pressure from breeders to include new species under the scheme, but this would incur more costs to the Government. In 1980 the New Zealand breeders invited a contingent of USA delegates representing the Plant Varieties Protection Office and the American Seed Trade to New Zealand to explain and discuss the advantages of their breeder testing system. New Zealand breeders wanted a breeder testing system and advised the PVRO that they had the expertise to describe their varieties, that they knew their varieties, and that with their maintenance programmes they already were conducting DUS trials. PVRO staff were not very optimistic about changing testing systems, but to expand the scheme and to keep costs down the breeder testing system was the only alternative. After the breeder testing system was implemented, it soon became very obvious that New Zealand breeders could not describe their varieties to the level required to enable the examiner to make a paper examination. Much time was then spent producing trial procedures/ guidelines for breeders to follow, and several training courses were run to standardise breeders interpretation of characteristics. Time was spent with breeders to show them how their trial data should be presented.

The breeder testing system for agricultural and vegetable varieties including Ryegrass is now working satisfactorily in New Zealand after this initial transition period. Ornamental, fruit and miscellaneous trees are tested mostly officially. In any plant variety protection system it is essential to define what are the varieties of common knowledge. The New Zealand PVRO with the breeders have a practical working policy in regards to what is a variety of common knowledge. New Zealand is very fortunate that the list of varieties of common knowledge is not exhaustive, for example:

Barley	12 varieties
Wheat	35 varieties
Oats	11 varieties
Potatoes	43 varieties
Peas	38 varieties
Ryegrass	28 varieties

Success of any breeder testing system is the contact between the breeders and the Plant Variety Rights Office

How does the DUS breeder testing system work in New Zealand? This is an example of a cereal variety:

(i) The Breeder brings a description or head samples to the PVRO examiner.

(ii) The examiner checks out the breeder's description or assists him in describing the new variety.

(iii) The examiner uses UPOV grouping characteristics or any other important characters to define the most similar varieties. At this stage the examiner may guide the breeder as to any obvious distinguishing features of the new variety.

(iv) The breeder establishes a side by side comparative trial with the similar varieties.

(v) The breeder describes the new variety fully and observes the differences between the varieties.

(vi) When the breeder believes there are differences between the varieties and that these distinguishing features are at the optimum time for inspection, they contact the PVRO examiner.

(vii) The PVRO examiner visits these comparative trials and observes these distinguishing features. At this stage the examiner also observes the uniformity. Generally trial data from breeders is collected/collated from a minimum of two growing seasons.

(viii) After the breeders have completed the comparative trials they submit to the PVRO: the completed objective description, a distinctness statement, a uniformity and stability statement, an origin and breeding history and a reference seed sample with 50 heads. The examiner encourages breeders to submit photographs of the distinguishing features, mounted specimens on cards or any other material which will help substantiate his distinctness claims.

(ix) The examiner can then proceed to examine the breeders data. He may require the breeders to supply further information or he may, if satisfied, make the recommendation to the commissioner to grant plant variety protection.

The agricultural and vegetable examiner in New Zealand spends 40% of his time on plant variety protection and 60% with seed certification. He has the responsibility at the technical training of the MAF Seed Certification Field Inspectors and is a field inspector himself. These crop inspections allow him to see the uniformity of the PVR protected varieties. Another responsibility of his is the OECD Stability Control Plots. These plots indicate if the protected varieties have any genetic shift and are often used as a training resource for MAF Field Inspectors and Breeders.

New Zealand joined UPOV in 1981. For an agricultural crop it costs NZ $ 1,650 plus tax. The PVRO recoups approximately 60% of its total running costs. The New Zealand breeder testing system is a hybrid between the European and the USA Plant Variety Protection Office schemes. Our system certainly caters for our needs, it works extremely well as we are a small country, which enables this close contact between the PVRO staff and breeders.

Thank you for enabling New Zealand to contribute to this worthwhile session on the cooperation with breeders in the testing of varieties.

[Annex III follows]

PLANT BREEDERS' RIGHTS IN CANADA

The Plant Breeders' Rights Act received Royal Assent on June 19, 1990 and came into force on August 1, 1990. Within Seed Division, Agriculture Canada, the Plant Breeders' Rights Office was set up and Mr. Wilf Bradnock was appointed Commissioner. In addition to the Commissioner, there are six staff members.

The Plant Breeders Rights Advisory Committee was appointed and is composed of the representatives from the agricultural and horticultural sectors, plant breeders and producers. They have met twice and established the criteria for determining the priority of introducing regulations for the various species and have recommended the first six species to be covered (rapeseed/canola, chrysanthemum, potatoes, roses, soybeans and wheat). Regulations are expected to be in effect by early fall and then applications will be accepted for varieties of the first six species. Regulations for additional species will be introduced as soon as possible.

The Committee also recommended that any variety of any kind released on the market in Canada after August 1, 1990 should be eligible to be considered for rights. In other countries, sales will be allowed of varieties of potatoes after August 1, 1970; of varieties of vines, forest trees, fruit trees and ornamental trees and their rootstocks after August 1, 1984; and of varieties of all other kinds after August 1, 1986. Application for rights must be made within one year of regulations coming into effect for the respective species. This means that any variety released that meets the dates set out above will be eligible for consideration for rights for one year after the regulations are in place for a specific species. After one year, the only varieties eligible will be varieties never sold before in Canada and not sold more than 4 or 6 years in other countries.

The Canadian system will be based on breeder testing. Breeders will be required to submit a description of the new variety in comparison to varieties they feel are the most similar. Descriptions will be published in the Plant Varieties Journal and a 6 month objection period will be allowed. If no objections are received, a right will be granted and may last up to 18 years.

[Annex IV follows]

ANNEX IV

Certification for the Planned Field Introduction into the Environment of Transgenic Plants

Sally L. McCammon, Ph.D.
Senior Plant Pathologist and International Coordinator

Biotechnology, Biologics, and Environmental Protection, Animal and Plant Health Inspection Service, United States Department of Agriculture, 6505 Belcrest Road, Hyattsville, Maryland 20782

The review process of the United States Department of Agriculture (USDA), Animal and Plant Health Inspection Service (APHIS), for field testing of genetically engineered plants and microorganisms, certifies that there is no significant plant pest risk even if the organism being released is derived from a plant pest. In addition, this process assures that there is no significant risk to the environment. In issuing a permit for release, APHIS certifies that there is no plant pest risk even though the organism released into the field may have used genetic material from a plant pest at some point in its development and that an environmental evaluation has been done.

APHIS issued 145 permits for field testing of genetically engineered plants and microorganisms as of May 17, 1991. At this time there were also 31 pending applications for a permit. Most of these were for plants and were issued to 23 industrial institutions and 12 academic institutions. The flow of sophisticated applications from academic institutions is increasing in the same manner as did applications from private industry two years ago. These field tests have occurred in 33 states and Puerto Rico at almost 300 field test sites.

Among the first generation of field tests permitted by APHIS, primarily the 21 tests that occurred in 1988, about half of the tests were for herbicide tolerance in tomato and tobacco. The remaining half were nearly all for insect and disease resistance, also in tomato and tobacco. In 1989, a much greater range of plants was used for experimentation, including alfalfa, cotton, cucumber, poplar, potato, and soybean, as well as tomato and tobacco. This range was extended in 1990 to include two major monocotyledon crops, corn and rice, as well as cantaloupe, squash, and walnuts. In 1991, rapeseed, sunflower, and chrysanthemum also will be field tested.

Apart possibly from a few "pharmaceutical genes", the genes that are being introduced into plants using the techniques of molecular biology are the same kinds of genes that classical plant breeding techniques have sought to introduce. These include genes for insect resistance, disease resistance, increased resistance to stress, and improved nutritional qualities. The range of sources for acquisition of these genes has been extended using these techniques, however. As an example, a gene from the bacterium Bacillus thuringiensis coding

for an insect toxin has been cloned into cotton for resistance to the cotton boll worm.

The range of characteristics tested includes slowed fruit ripening, heavy metal sequestration, and increased nutritional composition, reporter genes and pharmaceutical products. Many plants are being tested for various virus resistances through the use of coat protein genes. At least twelve different viral coat protein genes have been tested and these kinds of tests form the greatest number, above insect resistance and herbicide tolerance.

Technology Transfer and the Regulation of Transgenic Plants

Development of new technology brings with it decisions regarding regulation for technology transfer. Regulations when properly drafted and administered can be a catalyst, not a barrier, for technology transfer. Effective regulation integrates the various forces in society and facilitates the relationship between government, industry, the research community, and public interest groups. Traditionally, development of regulations which neither over-regulate or under-regulate has been one of the most formidable tasks for the Federal Government (1 C.F.R. § 305.89-7). However, if the technological advances that are an outgrowth of tremendous public and private investment, are to be of the greatest benefit, the efforts to develop the appropriate effective regulatory framework are more than justified and positive public perception is a necessity. Thus, regulations provide for the transfer of the technology as well as assuring its safety.

The U.S. Federal agencies that share a major responsibility for regulating plants and plant products produced through biotechnology are the Environmental Protection Agency (EPA), the Food and Drug Administration (FDA), and USDA. For a more detailed description of the responsibilities and policies of the different agencies see the Coordinated Framework for Regulation of Biotechnology (51 Fed. Reg. 23302 (1986)).

The USDA has major responsibilities for both research in agricultural biotechnology, and for regulation of genetically engineered organisms and products. Within U.S. agencies, the research and regulatory activities are generally separated administratively. A delegation of authority by the Secretary of Agriculture published on July 19, 1985 (50 Fed. Reg. 29367 (1985)) assigned responsibility for USDA biotechnology research activities to the Assistant Secretary for Science and Education, and responsibility for Departmental regulation of biotechnology to the Assistant Secretary for Marketing and Inspection Services. This is similar to the Department of Health and Human Services delegating research responsibilities to the National Institutes of Health (NIH) and regulatory responsibilities to FDA. The USDA regulatory agencies directly concerned with biotechnology

regulation are the APHIS and the Food Safety and Inspection Service (FSIS).

Jurisdiction for regulation of field testing of plants produced through biotechnology overlaps between USDA and EPA in some instances (51 Fed. Reg. 23318; 23329; 23358-59 (1986)). APHIS and EPA coordinate reviews of proposed field releases when jurisdiction is shared. For example, APHIS sends copies of permit applications to EPA for transgenic plants that EPA considers to have pesticidal properties, such as those containing the Bacillus thuringiensis endotoxin. Such products are regulated jointly by USDA under the Federal Plant Pest Act (FPPA), May 23, 1957, as amended (7 U.S.C. § 150aa-150jj), and the Plant Quarantine Act (PQA) of August 20, 1912, as amended (7 U.S.C. § 151-164a, 166-167) and by EPA under the Federal Insectide, Fungicide, and Rodenticide Act (FIFRA) (7 U.S.C. § 136-136y). EPA and USDA perform simultaneous, coordinated, but independent reviews to ensure that data requests from the applicant are not duplicated.

APHIS also works closely with FDA in regulatory efforts involving the food products of biotechnology. This coordination will enable the U.S. Federal agencies to anticipate any potential safety concerns with the range of bioengineered food products currently under development.

Plant and Field Test Evaluation

The procedures developed at APHIS for issuing permits are to assure the environmental safety and elimination of plant pest risk in the introduction of transgenic plants into the environment for field testing. The process and requirements for obtaining a permit for release into the environment of a R-DNA-derived organism are contained in the Federal Register document entitled "Plant Pests; Introduction of Genetically Engineered Organisms or Products; Final Rule" (52 Fed. Reg. 22892 (1987)). These regulations provide that an organism or product altered or produced through genetic engineering would be a "regulated article" if the donor organism, recipient organism, or vector or vector agent used to produce this organism belongs to a group designated in the list in 340.2 of the regulations, and meets the APHIS definition of "plant pest," or is an unclassified organism and is being imported, moved interstate, or released into the environment. The organism being considered for release will be a "regulated article" if it is a plant pest or if it contains nucleic acid sequences derived from a plant pest and these sequences have been introduced into the "regulated article" via recombinant DNA technology. Thus, even if the gene donor and recipient are not plant pathogens, if the vector used to transfer that gene contains sequences from a plant pathogen, the organism is a regulated article.

A User's Guide has been developed by APHIS that goes through a

sample permit application showing the questions asked under APHIS regulations and giving answers for a hypothetical field test.

In essence, in issuing a permit for release APHIS certifies that there is no plant pest risk even though the organism released into the field may have used genetic material from a plant pest at some point in its development. The regulation of plant pests or potential plant pests and the mandatory requirements for permits occurs with traditional agricultural products. The definition of "plant pest", taken from the FPPA is: "Any living stage (including active and dormant forms) of insects, mites, nematodes, slugs, snails, protozoa, or other invertebrate animals, bacteria, fungi; other parasitic plants or reproductive parts thereof; viruses, or any organisms similar to or allied with any of the foregoing; or any infectious agents or substances, which can directly or indirectly injure or cause disease or damage in or to any plants or parts thereof, or any processed, manufactured, or other products of plants."

Environmental Assessments (EA) are prepared for each permit application for field a test. When the EA results in a Finding of No Significant Impact (FONSI), the permit is issued, and notice of the action and the availability of the EA and FONSI is published in the Federal Register. These environmental analyses are conducted in accordance with the provisions of the National Environmental Policy Act (NEPA) of 1969 (42 U.S.C. § 4332 (1970)). Under NEPA, there is a requirement for the production of an assessment of the risk to human health and the environment before approval is granted (50 Fed. Reg. 16636, April 16, 1985). Such assessments examine the alternatives to a given action and evaluate data on the potential risks accompanying each of the favored alternatives. APHIS is stating, with the granting of the permit, that there is no significant risk to the environment that could be ascertained in the release of the organism into the environment for the field test.

APHIS verifies that the pathogenic potential contained in the construction of the organism or performance of the field test has been removed or will be contained. This is done through an evaluation of the biology of the donor and recipient organisms and the molecular biology of the gene which has been taken from the donor organism and genetically engineered into the recipient to be field tested. Analysis of the molecular biology includes an analysis of all newly acquired sequences including promoters, polyadenylation and termination signal sequences, engineered genes, marker or antibiotic resistance genes, and other non-coding sequences.

An evaluation of the biological effects of these modifications looks at the gene expression of the inserted gene as well as gene expression compared with the non-modified organism, plant pathogenic genes remaining in the system, mechanism of gene

transferral, and the potential for gene transfer by reversal of the method for gene introduction. Evaluation of morphological or structural characteristics, physiological processes, products and secretions, growth characteristics, and the number of copies and location of inserted material may be done. Additionally, the origin of the vector or vector agent which was used to transfer this gene from the donor to the recipient is also scrutinized.

The environmental assessment evaluates not only the molecular biology and biology of the plant but also the environmental consequences, environmental aspects, safeguards, and other factors. For instance, safeguards to prevent introduction into the environment, if necessary, can be biological, temporal, or physical. Examples of biological safeguards to prevent gene transfer and dissemination include prevention of flowering, use of self-compatible varieties, and the use of male sterile varieties. Temporal safeguards include manipulation of time of planting or time of flowering.

Developmental Field Testing and Exemption from APHIS Review
In the first few years of field testing, small scale tests were done primarily to see if the technology worked and, in addition, to see if there were any unpredictable consequences. The determination of biosafety of these small scale tests has revolved around the ability to contain or eliminate the plants from the field test sites. Containment has primarily meant the prevention of pollen dispersal and/or seed dissemination and the destruction of plant material at the end of the test. Evaluations have been case-by-case and have included an analysis of the organism, field test site (including the surrounding environment), and the agricultural and experimental practices employed.

Field testing is now proceeding into the developmental stage on the way to commercialization. The field trials that have been permitted have proceeded unimpeded after the permits were issued. Second and third generation trials with particular plants have commenced. Field tests proposed by industry are now often larger in scale and occur at multiple sites in multiple states.

As small scale field tests give way to developmental research, evaluation of the same components and the same issues will occur. However, the emphasis of the evaluation will shift from issues of containment to those of environmental consequences. Thus, the potential for weediness and probability of its occurrence will become a major criterion as it will be more difficult to assure containment. The nature and stability of the inserted gene, the probability of gene transfer, and the consequences of gene transfer into wild species, into weedy species, or into related crop varieties will be important evaluation factors. Unless some kind of significant detrimental effect to the environment can be ascertained, containment will not be a concern for transgenic

plants. The evaluations of these applications will focus specifically on environmental issues that may be present with the widespread use in the United States of such transgenic staple crop plants that can be wind or insect pollinated. Examples of these include rapeseed, corn, wheat, and rice. The USDA is now developing its approach and framework for these evaluations. The scientific issues being considered for their potential for risk will be considered on a crop-by-crop and/or case-by-case basis.

As part of the commercialization process, APHIS expects to receive, within the next several years requests for exemption from the USDA regulatory review process and from the requirement for a permit for field testing or introduction into the environment of the transgenic plant. This will be based on data and experience accumulated from field tests providing evidence that plant pest potential has been removed and that potential detrimental impacts to the environment have been minimized. Some of the data requirements will include the genetic stability of new genes, a detailed description of vector systems, the nature of the gene or donor organism, and potential to effect weediness characteristics, if present. APHIS is preparing for the commercialization of transgenic plants through setting up procedures for exemption from USDA review through the petition process and regulations, preparing notification and renewal systems for routine field testing, and international harmonization efforts.

International Harmonization

The purpose of the APHIS international harmonization efforts for the plant products of biotechnology are to promote the use of scientific principles as the basis for the evaluation of biotechnology products; to coordinate the approaches used by different nations to regulate the products of biotechnology; and to coordinate internationally the regulations for the products of biotechnology. We are actively pursuing regulatory coordination with Canada (Agriculture Canada and Environment Canada) and Mexico (Sanidad Vegetal) through in depth meetings and exchange of information. We have participated in an on-going manner in the Group of National Experts in Safety of Biotechnology in the Organization for Economic Cooperation and Development (OECD). Projects with the OECD have included: Good Developmental Principles: Guidance for the Design of Small-Scale Field Research with Genetically Modified Plants and Micro-organisms; Good Industrial Large Scale Practices; Monitoring of Genetically Modified Organisms Introduced into the Environment: Findings and Suggestions; A Discussion Paper on Performance Evaluations for the Development of Plant Cultivars; and Food Safety.

In addition to bilaterals in several arenas with the European Community, other organizations in which we are contributing both personnel and time are the Andean Corporation for Development, International Service for National Agricultural Research (ISNAR),

Certification for Transgenic Plants

Inter-American Institute for Cooperation in Agriculture (IICA), the North American Plant Protection Organization, several United Nations (UN) agencies, World Bank, and the Consultative Group on International Agricultural Research (CGIAR). Countries with which we have exchanged philosophy and regulatory policy with official agricultural representatives include Canada, China, Germany, India, Israel, Italy, Japan, Mexico, and the Philippines.

APHIS is participating in the United Nations efforts to develop guidelines for facilitating the introduction of different biotechnology products and technologies into developing countries. We have encouraged developing countries to evaluate biotechnology products under their existing statuatory authorities such as their plant quarantine statutes.

Ultimately, the overall purpose of developing new technologies, cultivars and appropriate regulation is to provide choices for the future. The world has many problems, primary among them is that 75,000 people die daily from starvation and malnutrition. Progressive and positive approaches to agricultural production can eventually solve these problems.

Selected References

McCammon, S. L., and Medley, T. L. 1990. Certification for the Planned Introduction of Transgenic Plants into the Environment, in The Molecular and Cellular Biology of the Potato. ed. Vayda, M. E. and Park, W. D., CAB International, Wallingford. pp. 233-250.

McCammon, S. L., and Medley, T. L. 1991. Certification for the Planned Introduction into the Environment of Transgenic Plants and Microorganisms, in The Biosafety Results of Field of Genetically Modified Plants and Microorganisms. ed. Mackenzie, D. R., and Henry, S. C., Agricultural Research Institute, Bethesda. pp. 107-118.

Medley, T. L. 1990. APHIS Seeks to Aid Tech Transfer While Ensuring Environmental Safety. Genetic Engineering News 10(8):14-15.

National Academy of Sciences. 1989. Field Testing Genetically Modified Organisms: Framework for Decisions. National Academy Press, Washington.

Office of Technology Assessment. 1988. New Developments in Biotechnology Field-Testing Engineered Organisms: Genetic and Ecological Issues. OTA-BA-350. Government Printing Office, Washington.

[Annex V follows]

ANNEX V

HISTORY OF THE U.S. PLANT VARIETY PROTECTION SYSTEM

Three United States laws grant intellectual property rights on plant material: the 1930 Townshend-Purnell amendment to the Patent Act, the 1970 Plant Variety Protection Act, and the utility patent statute. Two government departments administer these laws. Plant patents and utility patents are granted through the Department of Commerce, while the Department of Agriculture issues Plant Variety Protection Certificates. Some companies receive both PVP certification and patent protection on the same variety. This is not prohibited by the laws.

The Patent Act grants ownership rights on man's new inventions. The 1930 Townshend-Purnell Act amended the Patent Act to provide patent rights to breeders of asexually-reproduced varieties. This amendment is commonly referred to as the Plant Patent Act. Sexually-reproduced varieties were not included in the patent amendment because they were not believed to be sufficiently identifiable, uniform, and stable to be protected. However, by 1961 it was evident that sexually-reproduced varieties could be produced with uniform and stable recognizable traits. With this knowledge and a desire to provide rights to breeders of sexually-reproduced varieties, American seed interests considered possible methods of protection. A proposal to extend the Plant Patent Act to cover sexually-reproduced varieties was considered, but the proposal was opposed by the Patent Office and failed.

Having failed at amending the Patent Act to include sexually-reproduced varieties, the American seed interests proposed a bill based on the Patent Act and the European breeder's rights laws. The basic principles of the proposed bill were (a) participation should be voluntary, (b) rights should be based only on novelty, (c) no performance tests should be required, (d) protection should not interfere with germplasm distribution, and (e) enforcement of rights should be the responsibility of the owner. Based on these premises, the Plant Variety Protection Act (PVPA) was passed December 24, 1970. It established a Plant Variety Protection Office (PVPO) in the Department of Agriculture to administer the PVPA. In addition, the PVPA provides for an advisory board (Board) made up of members representing the seed trade, the public sector, and farm interests. The Board advises the Secretary of Agriculture on administration of the act and on appeals from examiners. As passed, the PVPA (1) included an exemption for farmers to save seed for their own use and to sell some seed to their neighbors, and (2) provided that the applicant could request that the certificate require that the variety be sold by variety name only as a class of certified seed. F1 hybrids are not protectable under the PVPA.

The third system for protecting plants is the utility patent statute. To be granted a utility patent, the invention must have novelty, utility, and non-obviousness. Up to 1985, utility patents were issued only to F1 hybrids. Since that time, the Patent Office has been issuing utility patents for all plants. Cultivars, genera, species, and plant parts that have some patentable character may be granted plant patents.

The examination system used to grant plant breeders' rights in the United States is based on the PVPA, which was written to include the use of breeder testing, rather than government testing. Breeder testing puts the burden of proof on the breeder during the processing of the application and in enforcing their rights once the certificate is granted. This system is preferred by the seed industry,

since they can test and describe their varieties better and cheaper than it could be done by the government. The government did not want to hinder commerce in seeds as long as the information furnished was truthful. Since the application is a legal document, the applicant certifies the truthfulness of all information presented when he signs the application.

The type of information that the Office receives is affected by the use of breeder testing. For example, the description and supporting information in an application may come from several locations. The testing locations used in one application may differ from the locations in other applications. Also the testing sites for public varieties may differ from locations used to test application varieties. As a result of the many environmental conditions found at these different locations, comparisons between varieties are limited to the most stable characteristics in most cases.

In many cases, all varieties in a species can not be adequately tested in a single location. The area to which a crop is adapted can be wide. For example, wheat can be grown in many areas of the United States under many climatic conditions. Some varieties are better adapted to a hot and dry climate, while others are better adapted to a cool and moist climate. To adequately describe all wheat varieties, several testing locations would be necessary, considerably raising the cost of any government testing program that might be contemplated. Another example is the testing of winter survival in alfalfa, or lucern. Winter survival varies considerably due to temperature, moisture, and disease. A single location would not provide a range of conditions in which to exam winter survival reaction. Two or more locations are needed to more adequately test each variety.

Although centralized testing is preferred for measuring some characteristics, the use of breeder testing has some advantages. The costs and efforts involved in conducting grow-out trials are not duplicated by both breeders and government officials. The reaction of the variety to differing climatic conditions can be tested in one year, reducing the length of the trial period. Finally, if all testing has been done prior to the filing of the application for protection, the granting of breeders' rights can be completed in a short time.

PROCEDURES FOR PROCESSING PLANT VARIETY PROTECTION APPLICATIONS

Filing an Application

Upon receiving the Application in the Office, the receiving secretary or clerk (a) stamps on the back of the Application the date and time of receipt, and (b) enters certain information from the Application into an administrative database called PVACNT. This information includes the crop kind, variety name, applicant's name and address, fee information, certified seed option, if chosen, and the assigned examiner. The Application is placed in a file folder and forwarded to the assigned examiner for a recommendation on acceptance.

Upon receiving the Application for approval to file, the examiner verifies (a) that the application form has been signed and fees have been paid, (b) that exhibits A, B, C, and E have been received (exhibit D is optional) and that information in PVACNT is correct, and (c) that a seed sample has been received. The Application and the exhibits must be in the English language and be legibly written, typed, or printed. Any interlineations, erasures, cancellations, or alterations in the Application or the Exhibits must be clearly initialed and dated by the applicant. If all things are in order, the examiner recommends the application be accepted for filing and returns the file to the secretary for a letter of acceptance. Once accepted by the examiner, an application number is assigned and entered into PVACNT. All exhibits and related materials are stamped with the application number. A letter acknowledging receipt of the Application, filing fee and seed sample, and giving the effective filing date is sent. The folder is returned to the assigned examiner.

Examination of Application

Upon receiving the filed application the examiner determines that the variety is NOT one of the following: (1) a hybrid, (2) a species consisting of fungi or bacteria, (3) a variety which is not sexually reproduced, (4) an application from an ineligible applicant, or (5) that commercializing limits have not been exceeded. There is a one year limitation for commercializing in the United States, and a four year (herbaceous plants) or six year (woody plants) limitation for commercializing in a foreign country. If any of these bars to protection are present, then the applicant is informed that the variety is ineligible for protection and that the search fee will be credited to their account or refunded. If none of these bars are present, then the Examiner handles each assigned Application through to the final issuance or denial of the certificate, except under exceptional circumstances agreed to by the Commissioner.

For all eligible Applications the Examiner checks the Application to determine whether all necessary information has been provided by the applicant. The variety name need not be given at the time of application, but must be given before a certificate is issued. It should be acceptable under the Federal Seed Act and Regulations. Exhibits A, B, C, D, and E should be attached as separate documents and each should include the information required in the instructions on the back of the Application. If the Exhibits are not in the proper format, the applicant is requested to resubmit the exhibits in the proper format.

If the Application is not sufficiently complete to permit a search for novelty, then the applicant is requested to supply the information that is needed.

Information requested by the examiner may include a specimen of the flower, fruit, or seed that would clearly demonstrate novelty; photographs or drawings which disclose the distinctive characteristics of the variety; or additional data gathered from field trials of the variety. In the first request for information, all incomplete or unclear items that have been noticed are called to the attention of the applicant. The applicant will have 6 months after this letter to supply the information before the Application is considered abandoned. Extensions of time may be requested if necessary to obtain the information.

Issuance of Certificate

Upon completion of the search procedure, the examiner prepares a summary of the search findings. If the applicant appears to be entitled to a certificate of protection, the examiner recommends that a certificate of protection be issued. The Commissioner reviews the application and the search summary. If his review agrees with the examiner's findings, then a Notice of Allowance and a request for certificate fee is sent to the applicant. If 3 months elapse from the date of the Notice of Allowance without a reply, then the Application will be considered "abandoned", unless the fee for delayed payment and the requested original fee are submitted within 9 months thereafter.

When all of the requirements have been met by the applicant, a certificate of protection is prepared, with a covering letter signed by the Commissioner. The certificate is mailed by certified mail to the owner or to their attorney or agent. A press release describing varieties which have been newly protected is issued. Statements of the novel characteristics of newly protected varieties are published quarterly in the Official Journal.

Maintaining Confidentiality

In any pending Application or proceeding, only the applicant, or attorneys or agents specified in writing by the applicant, shall be allowed to inspect papers or to take action of any kind on behalf of an applicant. All correspondence between the Office and the applicant shall be only through the designated attorney or agent, if any.

All pending Application file folders and associated materials are kept in locked drawers whenever the room is not occupied. Unless the applicant sends written authority, no one in the PVP Office may discuss or reveal to anyone outside the Office or Department any information concerning a pending Application, except for (a) the number of the Application, (b) the kind of crop involved, (c) the variety name or temporary designation assigned, (d) the name of the applicant, or (e) whether the variety is to be sold by variety name only as a class of certified seed. These facts are the only information published in the Official Journal. With respect to confidentiality, abandoned Applications are treated the same as pending Applications.

After a certificate of protection is issued, the contents of the certificate folder become publicly available, with some small exceptions. Upon approval by the Commissioner, the public may examine records that are open to them in the Office during regular business hours.

Abandoned and Withdrawn Applications

Applications shall not be considered abandoned if the applicant (a) has made a bona fide attempt to advance the Application, and (b) is in substantial compliance with the Examiner's request for action, but has inadvertently failed to comply with some procedural requirement. An opportunity to comply with procedural requirements shall be given to the applicant before classifying an Application as abandoned. Compliance with procedural requirements may be required in a shortened period, but not less than 30 days. An abandoned Application may be revived as a pending Application after receiving an applicant's request accompanied by the appropriate fee and a written statement showing (a) the reason for not responding to a request by the Office for action, and (b) a response to the last request for action. Also the Commissioner must determine that the failure to respond was inadvertent or unavoidable and without fraudulent intent.

The applicant may voluntarily withdraw or abandon the Application by written request signed by themselves or their agent or assignee. The Office shall return the voluntarily withdrawn Application to the applicant or assignee. The applicant may revive a voluntary abandonment within 3 months by (a) paying the prescribed fee, and (b) showing that abandonment occurred without fraudulent intent.

Miscellaneous Procedures

An Application for plant variety protection may require individualized handling that may not have been covered in the above discussion. Procedures have been developed for amending applications, amending certificates, recording assignments, appealing Office decisions, and other activities associated with processing plant variety protection applications. The Examiner of the application and the Commissioner will be able to answer questions concerning Office procedures should the need arise.

DATA COLLECTION AND STORAGE

During this portion of our presentation, I will describe the way in which we gather data on application varieties, and the computer system we use to store and analyze the data. Applicants for plant variety protection in the United States must gather and report data that objectively describes their variety. This data may be obtained from several sources, including grow-out trials conducted by the applicant, by a university, or by a State or Federal agency. The data are included in the Application for Plant Variety Protection as Exhibit C, Objective Description of the Variety.

The U.S. Plant Variety Protection Office has developed crop-specific Objective Description forms for use by applicants. The forms are developed by the examiner responsible for the crop. Breeders are asked for comments and suggestions before the form is finalized, but the examiner decides the contents of the finalized form. At this time, there are 77 forms which are considered to be finalized. Copies of Objective Description forms can be obtained by writing to the U.S. Plant Variety Protection Office and naming the specific crop or crops for which forms are desired.

The U.S. Objective Description forms are similar to UPOV Test Guidelines in several ways. First, the characteristic states are arranged from least to greatest for convenience in coding. Example varieties are listed to help code the application variety correctly. The developmental stage at which the characteristic should be evaluated is indicated. Finally, the characteristics included on both forms are those which are useful in describing and differentiating varieties.

There are two major differences between the U.S. Objective Description forms and the UPOV Test Guidelines. First, measurements are required on the U.S. form for many continuous variables, such as plant height, maturity date, and seed weight. The examiner performs a computer search for varietal distinctness by defining an appropriately wide range of values around the reported value. The appropriate range is determined by the examiner, and varies from characteristic to characteristic.

The second major difference is that disease and insect resistance data can be reported on the U.S. form. In the past, applicants were limited to reporting only resistance or susceptibility. As forms are updated, this scale is being changed to reflect the actual ratings gathered during the tests. Applicants will be able to report intermediate resistance to a disease or insect pest. Appropriate example varieties will aid breeders in coding the expression of resistance and susceptibility.

After the data on the Objective Description form is received in the Plant Variety Protection Office, it is entered into our computer system. For the last ten years, we have used an Alpha Micro System 1072. The operating system is called AMOS, an acronym for Alpha Micro Operating System. There are three main software packages that are used on the Alpha Micro. The first is AlphaVUE, or VUE, which is a text editor that allows editing of simple text files. SuperVUE, a word processing program that performs more advanced text editing commands, is the second software program. The third program is STAR, which allows the user to manipulate data by defining "databases".

The computer has 119.5 megabytes of memory allocated to STAR databases, and 86.22 megabytes are in use. This amount of memory holds 283 database definitions and data. Currently 80 crop databases are defined, containing data on between 6 and 3000 varieties per database. The remaining 203 defined databases are reference databases, administrative databases, databases used by the Federal Seed Laboratory and Seed Branch, or "views" of these databases. A view is a subset of a database that restricts access to certain characteristics by a second user, or that rearranges the characteristics for special input needs.

Some of the main features of STAR can be seen on the partial variety description of maize inbred Mo17Ht, which is attached. (The complete description of Mo17Ht is five pages long.) Mo17Ht is frequently used as a comparison variety in grow-out trials, so some characteristics have been described at different locations and in different years. STAR allows the user to enter multiple occurrences of a single characteristic. This was done with several characteristics of Mo17Ht, including Days to 50% Silk and Plant Height.

Each occurrence can be marked with a subfield that gives a code for the source of each measurement. In the maize database, each reference code begins with "lr". The reference codes are defined either within the variety description or in a separate reference database, depending on the preference of the examiner.

All data entered into the database is treated as text by the indexing and retrieval functions of the STAR program. Some small computations can be performed, but the results are treated as text. Text used within notes, variety names, and reference citations need not be in fixed-field format. Data, however, should be entered in a fixed-field format so it can be indexed and retrieved properly. The Ear Height of Mo17Ht demonstrates this by having measurements less than 100 cm entered with a leading zero. If this is not done, incorrect retrieval of data may result. For example, if an Ear Height of 79 cm had been entered as "79" rather than "079", the computer would index the data, and retreive it, as if it were an Ear Height of 790 cm.

STAR has an on-screen search function which shows the number of variety records retrieved as soon as the search is complete. By using STAR to retrieve data in our main administrative database, some facts on office performance are available. For example, there are currently 2347 U.S. Plant Variety Protection Certificates in force. Of those, 1108 certificates (47%) were processed (from application date to certification date) in less than 13 months. An additional 724 certificates (31%) were processed in 13 to 24 months. The crops in which the greatest number of certificates have been issued are soybean (522 certificates), wheat (235), pea (197), bean (187), cotton (183), and corn (171).

Within the last eight months, two advisory groups have recommended that we update both hardware and software to take advantage of new technology and to improve the Office's efficiency. Research into purchasing a new computer system has begun, but there is no time table for completing the research and switching to a new system.

STAR Record No.	667
PV Number	8310001
Crop Kind	CORN
Variety Name	MO17HT
Originator	Missouri AES
Kernel Type	DNT|r 0020
Ploidy Level	DIP|r 0020
Best Region	MO|r 0020
Days to 50% Silk	65|r 0020
	88|r 5008
	73|r 5007
	87|r 5006
	89|r 5004
	70|r 5009
	83|r 5010
Heat to 50% Silk	1428|r 0020
	1510|r 5007
	1593|r 5006
	1617|r 5004
	1527|r 5009
	1591|r 5010
Days to 25% Mois	68|r 5004
	54|r 5009
	67|r 5010
Heat to 25% Mois	1067|r 5004
	1355|r 5009
	1161|r 5010
Plant Height	216|r 0020
	226|r 5007
	238|r 5004
	206|r 5009
	230|r 5010
	200|r 5058
Ear Height	079|r 0020
	097|r 5005
	102|r 5004
	101|r 5007
	085|r 5009
	101|r 5010
Internode Length	16|r 5004
	15|r 5009
	14|r 5010
No. of Tillers	ABS|r 0020
No. of Ears	001|r 0020
	SL2|r 5009
	001|r 5010
Cytoplasm Type	N|r 0020
Leaf Color	MEGN|r 0020
	DRGN|r 5007
	MEGN|r 5004
	MEGN|r 5009
	MEGN|r 5010

INFORMATION RESOURCES OF THE PLANT VARIETY PROTECTION OFFICE

Since the U.S. Plant Variety Protection Office (PVPO) does not conduct grow-out trials to compare application varieties with previous or currently existing varieties, the data to make these comparisons must be obtained from the world agricultural literature. The PVPO is located in the National Agricultural Library (NAL) Building at Beltsville, Maryland, and has ready access to the vast collection and services of that library. The NAL is one of the largest collections of agricultural literature in the world with more than 2 million volumes and 27,000 current journal subscriptions from all over the world. Besides the collection itself, employees of the PVPO routinely make use of the Current Awareness Literature Service (CALS) of NAL, a computer-based literature system designed to keep researchers and others posted on current literature in their fields. Through CALS and from CD-ROM (Compact Disc - Read Only Memory) sources available from NAL, examiners in the PVPO conduct literature searches on the AGRICOLA database (which contains NAL and additional holdings), Biological Abstracts, and the full CAB (Commonwealth Agricultural Bureaux) files. Other databases frequently consulted are the Current Research Information System (CRIS) database of the Cooperative State Research Service, USDA, and the Germplasm Resources Information Network (GRIN) database maintained by the Agricultural Research Service of USDA. In addition, the PVPO subscribes to, or receives, a limited number of publications and professional journals relating to the seed trade, breeder's rights, or variety information, and maintains them in the PVPO library. Publications containing useful variety information from the USDA and other sources, especially public sources, are becoming more difficult to obtain because of budget restrictions resulting in reassigned research, testing and reporting priorities, and because of an increased tendency toward secrecy in releasing varietal or germplasm information as a result of licensing agreements.

EXAMPLES OF A SEARCH FOR NOVELTY

Searches can be performed by describing what the variety is (a positive search) or what the variety is not (a negative search). Both methods are used by examiners in the PVP Office, although some examiners prefer one method over another. In this section of the presentation, examples of negative searches are presented for cotton and for onion.

Cotton

Cotton is a crop that has grow-out trials performed under many different watering and fertilizing conditions in different years. Each characteristic that has such information has many occurrence lines in the PVCOTT database. Each line has the average value for the characteristic at that watering and fertilizing regime; the LSD, if available, in a separate subfield; and a reference number in a separate subfield. The reference numbers match the literature references given at the bottom of the variety description, and indicate the treatment under which the measurement was taken. An example of this is given for one variety's lint percent on the attached sheet. The location and year that the data was gathered is indicated beside each group.

On the Search screen within STAR, the examiner defines the application variety and the varieties that would be most similar to it. In a negative search this is done by indicating what the variety is not. For example, on the attached search, the growth habit of the application variety is not intermediate or compact. In a positive search, the growth habit would be defined as spreading or undefined. Both methods include the undefined or missing information so that possible matches are not missed due to lack of information.

After each line is entered on the Search screen and the return key is pressed, STAR finds all variety records that match the given criteria. The number of matches to each piece of information are given below the code terms. Boolean logic is applied to these matches and the result is displayed in the second column of the screen. As the variety is more completely defined, fewer records agree with the description of the application variety, and the number in the second column of the screen becomes smaller. The most stable characteristics for the crop are used in the search. When numeric data is used, as in the last two lines of this particular search, an appropriate range around the median value is used, rather than a single value.

After using the computer to find the most similar varieties to the application variety, the examiner prints all varieties that match the computer search criteria. Of the 11 varieties that remain in this example search, 3 are duplicate records that can be combined with the main records when conducting the hand searching that is now required. Preferably, measurements that were taken during the same grow-out trial, or character states that are very stable, are used to separate the remaining varieties. Only one clear difference is needed to establish novelty according to the the Plant Variety Protection Act. On the attached printout, each of the eight varieties listed can be separated by one or more characteristics. Differences between varieties are circled to aid your understanding.

Onion

Onions differ from cotton in that few grow-out trials are conducted to provide additional information on the varieties. Most of the data comes from that supplied by the applicants within applications for plant variety protection. The example search provided for onion is also a negative search. At the end of the computer search, five varieties remain. When they are printed to conduct a hand search, many of the varieties have missing data for most of the characteristics. Since the burden of proof is the responsibility of the applicant, the applicant is asked to provide additional information to distinguish his variety from other varieties. Preferably this information comes from grow-out trials in which both varieties are present. On the attached printout, additional information that was supplied by the applicant is marked with an asterisk. The applicant also supplied a photograph (indicated by a percent sign) to document interior color differences.

Other information that aids in distinguishing the applicant variety from other varieties may come from descriptions of varieties in other applications. Descriptions from other applications may be for that application variety, or for other varieties that were similar to the application variety. Since all applicants certify the truthfulness of the information within their applications by signing the application forms, use of this information is appropriate. Without using this information, the applicant would be required to grow all varieties to determine differences between them. Information from seed catalogs has limited usefulness in distinguishing between varieties.

Using the information gathered from these various sources, each variety can be separated from the application variety. Differences are circled on the attached sheet.

Multiple Occurrences of Lint Percent in PVCOTT

LINT PERCENT

33.9

34.7 Id LSD .05 1.2 Ir 98
39.8 Id LSD .05 1.1 Ir 98a
37.5 Id LSD .05 1.1 Ir 98b
38.0 Id LSD .05 1.2 Ir 98e
37.2 Id LSD .05 1.1 Ir 98i
40.6 Id LSD .05 1.1 Ir 98j
38.0 Id LSD .05 0.9 Ir 98k
} TEXAS 1986

37.2 Id LSD .05 1.2 Ir 111
38.4 Id LSD .05 1.0 Ir 111d
36.7 Id LSD .05 1.2 Ir 111f
36.4 Id LSD .05 1.1 Ir 111p
39.6 Id LSD .05 0.9 Ir 111q
37.8 Id LSD .05 1.2 Ir 111r
} TEXAS 1987

37.0 Id LSD .05 1.2 Ir 112
43.0 Id LSD .05 0.9 Ir 112a
40.0 Id LSD .05 1.1 Ir 112b
40.0 Id LSD .05 1.2 Ir 112c
39.0 Id LSD .05 1.1 Ir 112d
41.0 Id LSD .05 1.2 Ir 112e
37.0 Id LSD .05 0.8 Ir 112f
40.0 Id LSD .05 1.0 Ir 112g
42.0 Id LSD .05 1.1 Ir 112h
40.0 Id LSD .05 0.9 Ir 112i
} ALABAMA 1989

38.9 Id LSD .05 1.1 Ir 113
37.9 Id LSD .05 1.0 Ir 113a
38.1 Id LSD .05 0.9 Ir 113b
38.3 Id LSD .05 1.3 Ir 113c
37.7 Id LSD .05 1.1 Ir 113d
37.4 Id LSD .05 1.1 Ir 113e
38.7 Id LSD .05 1.2 Ir 113f
39.6 Id LSD .05 0.9 Ir 113g
37.6 Id LSD .05 1.3 Ir 113h
38.8 Id LSD .05 1.1 Ir 113i
41.8 Id LSD .05 0.8 Ir 113j
} MISSISSIPPI 1989

37.7 Id LSD .05 1.1 Ir 136
41.4 Id LSD .05 0.9 Ir 136b
39.9 Id LSD .05 1.3 Ir 136d
36.0 Id LSD .05 1.1 Ir 136f
39.3 Id LSD .05 1.0 Ir 136n
39.2 Id LSD .05 1.2 Ir 136p
36.4 Id LSD .05 0.8 Ir 136r
} TEXAS 1988

40.1 Id LSD .05 1.1 Ir 163
40.7 Id LSD .05 1.2 Ir 163a
41.4 Id LSD .05 1.4 Ir 163b
42.7 Id LSD .05 0.9 Ir 163c
42.6 Id LSD .05 1.1 Ir 163d
42.1 Id LSD .05 1.3 Ir 163e
} GEORGIA 1990

42.0 Id LSD .01 1.2 Ir 164
41.0 Id LSD .01 1.1 Ir 164a
40.0 Id LSD .01 1.2 Ir 164b
40.0 Id LSD .01 0.8 Ir 164c
41.0 Id LSD .01 1.0 Ir 164d
40.0 Id LSD .01 1.1 Ir 164e
41.0 Id LSD .01 1.2 Ir 164f
39.0 Id LSD .01 1.4 Ir 164g
41.0 Id LSD .01 0.9 Ir 164h
41.0 Id LSD .01 1.1 Ir 164i
} ALABAMA 1990

42.3 Id LSD .05 1.3 Ir 504
40.9 Id LSD .05 1.4 Ir 505
42.2 Id LSD .05 1.4 Ir 506
39.4 Id LSD .05 1.6 Ir 507
41.1 Id LSD .05 1.8 Ir 508
} GEORGIA 1989

39.9 Id LSD .05 1.2 Ir 509

37.0 Id LSD .10 1.7 Ir 516
39.2 Id LSD .10 1.1 Ir 516a
37.4 Id LSD .10 2.8 Ir 516b
40.1 Id LSD .10 1.9 Ir 516c
} SOUTH CAROLINA 1990

39.8 Id LSD .05 1.4 Ir 523
39.2 Id LSD .05 2.4 Ir 524

Search for Novelty of a Cotton Variety

STAR Search Database: PVCOTT Search Name:

Srch#	Count	Enter your searches:	
S1	589	KIND=COTT AND SPEC=HIRS AND INSUF NOT 1 ^1610 ^1591 ^1015	
S2	231	S1 AND HAB NOT (INT OR COM) ^589 ^253 ^123	Growth habit not intermediate or compact
S3	223	S2 AND STM NOT (LAX OR ASC) ^231 ^13 ^71	Stem growth not lax or ascending
S4	217	S3 AND TYPE NOT (OKRA OR SPOK) ^223 ^13 ^4	Leaf type not okra or super okra
S5	211	S4 AND NEC NOT ABS ^217 ^32	Nectaries not absent
S6	177	S5 AND FBT NOT (CLS OR SHT) ^211 ^8 ^172	Fruiting branch not clustered or short
S7	171	S6 AND POL NOT YEL ^177 ^53	Pollen not yellow
S8	103	S7 AND BTYP NOT (STMR OR STMP) ^171 ^210 ^146	Boll type not storm resistant or storm proof
S9	94	S8 AND TTH NOT FIN ^103 ^130	Bracteole teeth not fine
S10	94	S9 AND SPUB NOT (SGLA OR SHVP) ^94 ^8 ^1	Stem pubescence not glabrous or heavy
S11	92	S10 AND LPUB NOT (GLAB OR HYPB) ^94 ^28 ^8	Leaf pubescence not glabrous or heavy
S12	84	S11 AND LCOL NOT (GRYL OR LTGN) ^92 ^3 ^182	Leaf color not greenish yellow or light green
S13	83	S12 AND GLND NOT (NOGL OR HIGL) ^84 ^55 ^4	Glands not none or high density
S14	83	S13 AND GOS NOT (NON OR HGH) ^83 ^6 ^6	Gossypol content not none or high
S15	80	S14 AND FUZ NOT (SPR OR HVY OR TUF) ^83 ^19 ^48 ^4	Seed fuzz not sparse, heavy or tufted
S16	66	S15 AND VWL NOT (VWL3 OR VWL4) ^80 ^216 ^28	Verticillium wilt not moderate to highly resistant
S17	33	S16 AND FUWL NOT FUWL1 ^66 ^183	Fusarium wilt not very susceptible
S18	31	S17 AND MCL NOT (MLT OR LTE) ^33 ^9 ^53	Maturity not medium late or late
S19	14	S18 AND STIR=(21.0:28.0 OR "") ^31 ^778 ^387	Stelometer range between 21.0 and 28.0 or blank
S20	11	S19 AND MICR=(3.6:4.6 OR "") ^14 ^1126 ^138	Micronaire range between 3.6 and 4.6 or blank

Command:
Help DAtabase Recall Save
Options Display Print Write Index ENTER GLOBAL MENU

Hand Search of Eight Cotton Varieties

Variety Name	Appl	Var 1	Var 2	Var 3	Var 4	Var 5	Var 6	Var 7	Var 8
Experimental etc	S-171			CBX 1207		S-478	PD 6520		
Days earlier	06DP61					06DPL61			
Maturity same as	PM383					PM383			
ref 521	MER								
Height class									
ref 521	MDTL								
Plant height cm									
ref 526	074			058					
ref 526a	071			084					
ref 526b	071			071					
Height same as	MN220					DES119			
Cm. taller	10DP50								
Plant habit	SPR				SPR	SPR			
Foliage density	ME				(DN)	ME			
Stem lodging	ERE					ERE			
Cm. 1st fruit br	11					14			
Nds 1st fruit br	06					06			
Stem pubescence	SPSS					SPSS			
Leaf width (cm)	20					21			
Leaf type	NORM				NORM	NORM	NORM		NORM
Leaf pubescence	PBST				PBST	PBST			
Leaf color	DKGN				DKGN	DKGN			
Leaf nectaries	PRE					PRE			
Fruit brnch type	NOR		NOR		NOR	NOR	NOR		
Fruit brnch grow	INT	(IND)	(IND)		INT	INT			
Glands	MDGL				MDGL	MDGL	MDGL		MDGL
Bud gossypol	MED					MED			
Flower bracts	NOR					NOR	NOR		
Flower nectaries	PRE				PRE	PRE	PRE		PRE
Petal color	CRM					CRM			
Pollen color	CRM		CRM			CRM			
Seed index	11.3	13.0			10.3	11.2	12.0		13.1
Lint index	6.41					6.45			
Seed fuzz	MOD					MOD			
Lint percent	36.3	36.4	39.1		36.5	36.6	37.0		33.8
ref 516b	37.7								
ref 516c	38.4								
ref 521	35.0								
ref 526	35.9			(38.0					
ref 526a	37.4			39.7					
ref 526b	36.6			38.8)					
Lint % less than	01.9S213					01.7S213			
Lint % more than	00.5DP50					00.7DP50			
No. seeds/boll	36					36			
Boll size class					MED				
ref 521	MDL								
Gms Seed Cot/bol	5.27	(7.77)	(5.96)		(6.50)	(5.79)	5.62		(6.39)
Grs. same as	MN220								
Grs. more than	0.33DP50					0.53DP50			
Locules/boll	4-5					4-5			
Boll pitting	Fine					Fine			
Boll type	Open	Open	Open		Open	Open	Open		Open
ref 521	Open								
Boll diameter mm	33					33			
Boll breadth	BRMD					BRMD			
Boll shape	L)W					L)W			

Hand Search (contin.) Page 2

Variety Name	Appl	Var 1	Var 2	Var 3	Var 4	Var 5	Var 6	Var 7	Var 8
Bracteole bredth	L)W					L)W			
Bracteole teeth	CRS					CRS			
No. teeth	05-07					05-07			
Staple length 32	35	36	34		34	35			33
ref 521	37								
ref 526	36			35					
ref 526a	35			36					
ref 526b	36			36					
2.5% spn lght in	1.17	1.18	1.10			1.13	1.13		1.07
2.5% Ins same as	DP50					DP20			
50% span length	0.57	(0.95)				0.54	0.55		0.48
Uniformity index	49				45	48	44		47
ST1 fb stg g/tex	24.6	21.0	22.7		23.0	22.8	22.0		24.6
ref 521	29.0								
ref 526	27.3			27.7					
ref 526a	28.0			31.3					
ref 526b	27.6			29.5					
Micronaire	4.10	4.10	(4.51)		3.75	(4.40)	4.00		(3.66)
ref 521	4.60								
ref 526	3.30			3.53					
ref 526a	3.83			3.83					
ref 526b	3.56			3.68					
Yarn strgt 22psi	163	(140)				(136)	(114)		
Verticillium wil	SUS	SUS			MS	SUS			SUS
Fusarium wilt	RES		MR		MR	RES	MR	MR	
ref 519	MR					MR			
ref 521	MR								
Bacterial blt R-1	SUS	MR	SUS		SUS	SUS			MR
Seed available		NO	NO	(New Not released)				(New variety Not released)	NO

Search for Novelty of a Onion Variety

```
 STAR Search          Database: PVONIO          Search Name:
-------------------------------------------------------------------------------
Srch# Count  Enter your searches:

S1      199  KIND=ONIO AND INSUF NOT 1 AND HYBRD NOT 5
                  ^1149              ^578             ^467
S2      178  S1 AND TP NOT BH
             ^199          ^51
S3      100  S2 AND TYP NOT LND
             ^178           ^180
S4       66  S3 AND HAB NOT (INT OR FLO)
             ^100            ^30    ^14
S5       61  S4 AND COLR NOT (LTGN OR MEGN OR GRAY)
             ^66              ^32     ^24     ^5
S6       37  S5 AND SZ NOT (ML OR LG OR VL)
             ^61            ^20   ^146  ^16
S7       13  S6 AND BULB NOT (TPSH OR DEFT OR THFT OR FLAT OR ELONG OR TORP)
             ^37              ^39     ^17     ^40     ^30     ^2       ^5
S8        7  S7 AND SKIN NOT (BRWN OR BRYL OR DPYL OR MEYL OR PLYL OR WHIT)
             ^13              ^75     ^112    ^26     ^52     ^157    ^119
S9        5  S8 AND SKIN NOT (LMYL OR LTBZ OR SVWH)
             ^7               ^2      ^8      ^2
-------------------------------------------------------------------------------
Command:
Help DAtabase Recall Save
Options Display Print Write Index ENTER GLOBAL MENU
```

Hand Search of Five Onion Varieties

Name of variety	Appl	MSV	Var 1	Var 2	Var 3	Var 4
Year released	89				87	
Type	BB	BB	BB	BB	BB	
Day length type	SHD	SHD	SHD	SHD		SHD
Degrees latitude	06-20	24-28				
Maturity class	ME		ME#	VL@		
ref 528		EA		LA	ML	
Days to Harvest	110	108*	125#	130@		
ref 528		110				125
Plant height cm	35	34*	34			
Cm shorter than	05RDCRL					
Plant habit	ERE	ERE*	INT#			
Leaf length cm	28	27*	26#			
Leaf width mm	12	11*	12#			
Leaf thickness mm	08	08*				
Leaf color	BLGN	BLGN*	BLGN			
Sheath col length mm	74	70*				
Sheath col dia. mm	12	11*				
Scape height cm	88	79*				
Scape diameter mm	14	13*				
Inf max no/plant	3	3*				
Inf min no/plant	1	1*				
Inf ave no/plant	2	2*				
Inflores dia. mm	50	48*				
Inflor compactns	COM	COM*	COM#			
Spate	SHBK	SHBK*				
Flower color	WHI	WHI*	WHI#			
Anther length mm	6	7*				
Anther color	DRGN	DRGN*				
Pollen viability	FTL	FTL*				
Sepal shape	LNPT	LNPT*				
bulb no/meter	20	18*	18#			
Bulb size	SM	LG*		ML@		
ref 528		LG	ME	ME		ME
Bulb shape	FTGL	FTGL*	DEGL#	GLOB@		
ref 528		THFL	DEGL	GLOB	FTGL	
Bulb height cm	5.0	4.9*				
Bulb diameter cm	7.0	6.8*	7.0			
Bulb index	0.71					
Evagination	EVA	EVA*	EVA#			
Skin color	LTPRRD	RED*	RED#			
ref 528		BFRD	BFRD	PRRD	PRRD	
Interior color	PRRD	LTRD*	LTRD#	WHIT@		
ref 528		Pink			Red	
Photograph	PRRD%				Red%	Red%
Scale number	MED	MED*				
Scale thickness	MED	MED*			THK	
Scale retention	GD	GD*	VG			
Pungence	SG	SG*	SG	MD		
Bulb storage	G			P	G	

528. Seed catalogues.
* Breeder's description of similar variety.
# Competitor Company description of variety in another application.
@ Competitor Company description of variety in another application.
% Photograph

[End of annex and of document