GMOのトレーサビリティに関するディスカッションペーパー
（フランス提案の概要　CX/FBT 01/6）

定義

GMOへの適用

・目的

①人体へのリスクが解明された場合の（市場からの）撤去

②人体への意図せざる、長期的な影響の確認とモニタリング

③表示制度の支援

④特定製品のIP（分別流通）の促進

実施

①手段

手段としては、添付文書と登録による記録

②対象

すべてのGMO及びその応用食品を対象とすべき。

③種子から最初の加工までの段階では、それぞれのGMOの特性（transformation even
ts）を明らかにすべきであるが、その後から最終製品にかけては、必ずしもGMOの特
性（transformation events）ではなく、GMO応用食品の存在を確認することが目的。

④具体的に求められる情報

・GMO及びGMO応用製品の存在を適切な様式で明確に示した文書

・未加工品の場合、存在するGMOの名称

・関連する供給者と顧客の名前及び詳細

管理

主に文書による。

コスト及び実行可能性

コストについてはあまり知られていない。トレーサビリティはGMOの存在の文書による伝達、保存が基本であり、分別や分析試験が必要でないことから、IPのような分別流通も行わず、既存の物流に付随する文書にGMOの存在を追加するための費用だけではそれほどかからないものと予想される。一方、トレーサビリティがない場合には、（GMOの悪影響が判明したような場合）トレーサビリティによって文書等を用いた部分回収の費用と比べて、製品回収の費用は膨大なものとなる。

途上国

企業の規模や途上国の経済的能力を考慮すべき。

提案

以下をバイオテクノロジー応用食品のリスクアナリシスの原則に追加することを提案する。

リスクマネージメントは以下のことを目的としてトレーサビリティを含みうる。

・人体へのリスクが解明された場合の（市場からの）撤去
・適切であれば、人体への意図せざる、長期的な影響の確認とモニタリング
・表示制度の支援
・特定製品のIP（分別流通）の促進

管理者（種子生産者、農家、加工者、流通者）は、適切な情報の継続的な流れを保証するシステムをバイオテクノロジー応用食品の市場のすべての段階で実施するものとする。

トレーサビリティの手順は、以下の情報を貿易及び輸送の文書に記載する義務に基づく。

・GMO又はGMO応用製品の存在を適切な様式で表現する言葉
・未加工品の場合、存在するGMO（又はGMO複合物）の名前
・関連する供給者と顧客の名前及び詳細

加えて、上述されたことが記載された場合、それぞれの管理者は交換又は加工したGMO又はその由来品の出入りの記録をつけなければならない。

交換される情報の性質及び様式は国際的に調和されたものとする。

codex alimentarius commission

FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS

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Agenda Item 6

JOINT FAO/WHO FOOD STANDARD PROGRAMME

CODEX AD HOC INTERGOVERNMENTAL TASK FORCE ON FOODS DERIVED FROM BIOTECHNOLOGY

Second Session

Chiba, Japan, 25-29 March 2001

DISCUSSION PAPER ON TRACEABILITY

INTRODUCTION

1. At the 1st Session of the Codex *Ad Hoc* Intergovernmental Task Force on Foods Derived from Biotechnology (CTFBT), the issue of traceability was raised by several delegations. The Task Force noted that a better understanding of this concept and its implications was required before it could be included definitively in the text (a set of broad general principles for risk analysis) to be developed. The Task Force therefore agreed that the discussion papers should be prepared on this issue as soon as possible. In the mean time, any reference to the[se] issue[s] in the main text[s] under development would remain in square brackets (ALINORM 01/34, paras.27 and 31).

2. CTFBT agreed to establish an *Ad Hoc* Working Group to develop a set of broad general principles for risk analysis of foods derived from biotechnology (ALINORM 01/34, para.35). It was understood that the Working Group, to be chaired by Japan, would also review the discussion paper on traceability if it became available in time (ALINORM 01/34, para.35).

3. The *Ad Hoc* Working Group met twice in Tokyo, Japan, from 5-7 July and from 30 October to 1 November 2000. The First Meeting of the Working Group reviewed a draft discussion paper on traceability of genetically modified organisms, introduced by the Delegation of France. In view of a number of points of clarification put forward by many delegations, it was agreed to request France to revise the draft discussion document by giving considerations to the issues raised.

4. The Second Meeting of the Working Group also held a discussion session on traceability. While a proposal was made to insert a specific wording on traceability in the risk management section of the proposed draft Principles, it was agreed to include a short, square-bracketed reference to traceability, in expectation of further discussion to take place at the 2nd Session of CTFBT, based a revised information document on traceability to be submitted by France.

5. The present document incorporates the revised discussion paper prepared by France.

Discussion paper on the traceability of GMOs

(Prepared by France)

Background

1. France was asked by the Working Group (Tokyo, 5-7 July and 30 October-1 November 2000) to review its discussion paper on traceability on the basis of the questions of the delegations in order to prepare the second session of the Task Force in Chiba (March 2001). Australia, Canada, Norway and Sweden proposed to contribute to this revised document.

2. France is very grateful to those delegations who submitted comments.

Context

3. The application of modern biotechnology to food and plants is currently the focus of intense public and political debate with particular reference to the issue of food safety. All GMOs have to undergo a comprehensive scientific assessment of risks to human health before being placed on the market. To date there have been no peer-reviewed scientific articles reporting adverse effects on human health from GMOs.

4. However, the public is concerned about their potential implications for human health and foods derived from biotechnology face a lack of confidence of consumers.

5. Consumers have the right of choice. Consequently, suppliers are seeking to meet the demand from consumers or purchasers, for information on the presence of GMOs or derivatives of GMOs in products.

6. Increasingly, producers and traders are having to meet emerging mandatory GMO-labelling requirements in certain countries, in particular the European Union, but also in Switzerland, Australia, New Zealand, Japan, Norway, etc...

7. Operators can be faced with the following factors :

- The tolerance levels for labelling may differ among countries or still have to be decided.
- The set of GMOs approved in different countries is not the same.
- The existence of products of different destination on the same industrial structure.

Definition

8. Traceability is defined in standard ISO 8402 in general terms as being "*the ability for the retrieval of the history and use or location of an article or an activity through a registered identification*".

9. Traceability in the food system provides mechanisms of continuous flow of relevant information that allow the retrieval of the history and of the origin of a product at any point in the food chain. Traceability aims at limiting discontinuity of the information throughout the food supply chain.

10. This means a system of record keeping and documentation by operators that enables a retroactive tracking of the movement of a product or ingredient through the chain. Record keeping and documentation are linked to commercial transactions between operators.

11. Elements to ensure traceability include that:

- operators ensure, at each stage of the placing on the market, that relevant information is provided in the form of labelling or accompanying documentation;
- operators transmit and retain the relevant information at each stage of the placing on the market.

12. Traceability should be applicable to all food. Verifiable documentation is important since analytical tests can only be used to confirm documentation where detectable material is present. Traceability system enables to carry any kind of information which can be related to specific uses.

Uses of traceability for GMOs

13. The concept of traceability is currently applied in most countries, often by commercial operators (e.g., the labelling of country of origin). Existing traceability systems are based on paper or computerized documentation and/or analytical detection methods when appropriate. The transmission and retention of relevant information for a product at each stage of the placing on the market allows its identity, history and source to be traced.

14. Regarding GMOs, traceability aims at providing each agro-food business operator - from seed production to the finished product - with reliable information on the nature and genetically modified origin of the products he is delivered.

15. The system should allow all the sector operators to rely on information from the previous operator(s). In general, the following reasons for the establishment of a traceability system for GMOs can be identified:

- to possibly withdraw products if a risk to human health is established;
- to facilitate the identification and monitoring of unintended and long-term effects on human health, where appropriate;
- to assist the control of labelling;
- to facilitate the preservation of the identity of specific products.

16. Basic reasons for the establishment of such a traceability system for GMOs is food safety. However, this improvement in the fairness and transparency of transactions will facilitate the task of operators who must comply with certain regulatory or commercial requirements on the part of their customers (labelling of finished products, restrictive list of authorised GMOs, etc.).

Traceability and withdrawal of products

17. Traceability is firstly required for products derived from GMOs for the purpose of withdrawing products in the event of an unforeseen problem arising from consumption of material from GMO origin.

18. Secondly, even if pre-market approval of products derived from GMOs would normally provide for necessary safety assurance, their utilisation or purposes of use can be of different types and may be incompatible. It might appear that there is a necessity of recall measures in the event of mixture of products of different destinations.

19. Thirdly, traceability enables for targeted withdrawal based on the ability to trace back the origin or trace forward the destination. This ability limits the range of products concerned and, consequently, the scale of recall measures.

Traceability and post market monitoring

20. One of the objectives of traceability would be to facilitate monitoring of possible long-term and unintended health effects associated with particular foodstuffs. However, it is widely recognized that

little is known about the long-term effects of any food, making the identification of health effects that might be unique to GM foods problematical. Post-market monitoring does not automatically prove a direct causal relationship between the occurrence of an adverse human health effect and the consumption of a particular food.

21. During the pre-market risk assessment of a food derived from GMOs, the need for post-market monitoring is normally examined on a case-by-case basis. It is generally recognized that such measures would be most useful in monitoring effects of genetically modified foods that are significantly different from their conventional counterpart.

22. In this context, traceability can be an essential component to facilitate the follow up and the vigilance that should be exercised after these products are marketed.

Traceability and labelling

23. The primary objective of food labelling is to provide relevant information to purchasers and consumers. In particular, labelling aims at facilitating consumer choice, and at protecting consumers against misleading or deceiving practices.

24. Even if traceability and labelling have different objectives they can be linked to complement one another. As an example, a traceability system could carry information to be used for labelling or in the other way, traceability for products derived from GMOs may facilitate control of labelling of such products.

25. However, it is not necessary to establish the detailed history and origin of individual GMOs to provide for a comprehensive labelling scheme. For the purpose of providing information to the final consumer it is sufficient that operators can document whether authorized GMOs have been used or not.

Traceability and Identity preservation

26. Identity preservation (IP) is an active process where actions are taken to preserve the identity of a higher value product as it moves through the chain to a specific end market. IP systems are determined by the end user who has a particular requirement that can only be met by a system that relates the identity of the final ingredient back to some earlier stage of the chain.

27. IP systems are not applied for safety reasons, or to provide safety guarantees. Their focus is to preserve a certain specification based on an agreement between a supplier and a customer. Keeping apart or segregating raw materials is one of the consequences of applying an IP system.

28. Consumer demand for non-GM or GM free food provides an economic incentive for farmers, processors and distributors to supply such products, which require IP to be accepted by the consumer.

29. By comparison, traceability does not imply segregation while traceability does not exclude the possibility of combining several GMOs or combining GMOs and conventional products, but allows the qualitative composition of the combination to be known. In this context, traceability could facilitate the implementation of IP systems.

Implementation of traceability for GMOs

30. As expressed earlier in the document, regarding GMOs, traceability aims at providing each operator - from seed production to the finished product - with reliable information on the nature and genetically modified origin of the products he is delivered.

31. The physical support of traceability is accompanying documentation - preferably existing documentation. The "memory" of the traceability as a way to retain information is registers - preferably existing registers.

32. On this base, traceability should apply to all GMOs and foods derived from GMOs, this means:

- to products composed entirely or partly of GMOs, whatever their use, because the choice of the use, particularly regarding plant products, is not always determined beforehand;
- to GMO derivatives intended for human and animal consumption.

33. Traceability should make it possible to find each GMO (transformation event) during the phase from the seed to the first processing. Then, from the first processing to the finished product, the aim is to follow the presence of GMO derivatives without necessarily identifying each transformation event.

34. The following information are needed, in trade and transport documents for a practical traceability systems for GMOs:

- a clear statement indicating the presence of genetically modified organisms or of products derived from GMOs through appropriate formulations;
- the name of each GMO present (or of the GMO combination) when non-processed products are concerned;
- the names and particulars of the supplier and of the customer depending on the case.

35. In addition, each operator must keep an entry and exit register of GMOs or their derivatives that he has exchanged or processed, where the same statements as those mentioned above are noted.

36. The nature and form of exchanged information should be harmonised internationally.

Controls

37. Official services or operators themselves can be led to check the fairness of transaction and thus control documentation as well as reliability of the information on the documentation and the content of the product.

Documentary controls are the main controls.

38. Official control must be based on official control principles as defined in the document CAC/GL 20-1995 (Principles for Food Import and Export Inspection and Certification).

39. Where necessary analysis can be carried out to check the presence of GMOs or to identify a specific GMO, to confirm the reliability of information. This requires unambiguous physical detection of individual GMOs and unique DNA or protein sequences that arise as a result of the modification process. Appropriate methodology has been developed for the detection of unique DNA and protein sequences from material containing GMO but this supposes the availability of materials (primer sequences allowing identification and samples) and of harmonised analysis methods.

Cost and feasibility

40. Traceability must be based on realistic feasibility regarding its implementation procedures and cost. Little is known on the actual cost of a traceability system for GMOs as described earlier. As a contrary more information is available as it relates to the cost of IP systems or to the consequences of a non traced system in the case of recall of product.

41. As traceability has less constraints than IP systems, notably because it doesn't require segregation neither impose any obligation of analytical tests, its cost is intended to be less than the cost of IP systems.

42. Because traceability aims at reducing the scale of recall measures, its cost has also to be compared to known costs of the consequences of non targeted recall measures.

Cost of IP

43. Identity preservation (IP) systems require extra care to ensure the identity of the material from farm to end-user. The cost of an IP system is relative to the complexity and number of actors in the chain. For a product produced and sold locally costs are minimal, but with increasing product complexity, involving many suppliers and geographical origins costs of IP systems increase rapidly.

44. Any IP system reduces the flexibility an operator has in purchasing raw materials. That increases prices and the need for additional analysis on purchased goods. But there must be willingness among consumers to pay for the specific product quality associated with the IP element.

45. For that reason IP systems in practice are limited to characteristic ingredients that are « recognizable » to the consumer or a critical part of the product's identity. It must however be kept in mind that the price flexibility of most processed food products is limited.

46. An important element to establish IP systems is the technical possibility to test samples for the preserved identity (e.g. its physical or chemical contents). Random or regular tests can be carried out for the final product delivered to the consumer or the processor. To enhance the performance, control mechanisms might be applied not only to the final product but also at different stages of production and transportation.

47. Ensuring absolute purity of a food product would be prohibitively expensive in practical processing and handling chains. The principle of fixing a tolerance level (threshold) in purity standards is therefore a long-established feature for IP systems throughout the food industry. The costs of an IP system can be expected to increase with a reduction of the tolerance level.

48. Identity preservation often involves advance contracts with farmers who commit themselves to keep the crop separate during harvesting or to produce only under certain rules (quality labels, organic farming). Furthermore, seed varieties, growing specifications, chemical treatments or handling and storage requirements may be subject to specific contracts.

Cost of non traceability

49. In the case where scientific evidence highlights unforeseen effects to human health of a product, or in case of mixture of product of different destination there is an absolute need of efficient and total withdrawal of this product. In such a situation, non-traced systems for GMOs imply long, heavy and expensive analytical tests for operators and for official services. At the contrary traceability requires only to check available documentation and registers.

50. Consumer can hardly recover its confidence if the system allow only for partial withdrawal.

51. Non traced systems doesn't allow for a targeted withdrawal, and a significant part of the wide range of products concerned by the recall measures are not those products that present a risk.

52. Non traced systems impose expensive and systematic analytical tests to determine the presence of GMOs for operators who must comply with certain regulatory requirements on labelling of finished products.

Cost of traceability

53. Traceability for GMOs is based upon the transmission and retention of documentation to provide information as to the identity of individual GMOs or as to the content of product thereof.

54. Documentation accompanies already the majority of transactions to provide information with respect to the supplier, customer and transaction date as well as the nature, source, contents and amount of the product. On this basis, the costs of placing additional information in such documentation, as a mean to identify individual GMOs contained in the product or specify the presence of material derived from GMOs are expected not to be significant.

55. Incorporating additional record-keeping requirements for GMOs in the existing systems for food materials should not imply significant extra costs either, unless regular testing is required. Indeed, systematic analytical detection is expensive and has its limits. Documented follow-up within a company and upon each commercial transaction is the most informative and least expensive solution.

56. As this traceability system does not rely on a segregation system with difference to the IP system there should not be extra cost related to the dedication of industrial process structure or storage.

57. *In fine*, targeted withdrawal is economically more effective for operators and official services than non targeted withdrawal that apply to a very wide range of products not necessarily concerned.

Developing countries

58. An adequate modulation in the implementation of traceability should take into account the size of the enterprise and the financial capability of the developing countries with respect to the record keeping.

Proposal

59. It is proposed to insert the following text in the Principles for risk analysis of foods derived from modern biotechnology:

"19. Risk management may include traceability for the purpose of:

- possibly withdrawing products if a risk to human health is established;
- facilitating the identification and monitoring of unintended and long-term effects on human health, where appropriate;
- assisting the control of labelling,
- facilitating the preservation of the identity of specific products.

Operators (seed producers, farmers, processor, distributor) should implement a system which guaranty a continuous flow of appropriate information at all the stages of placing on the market of foods derived from modern biotechnology.

Traceability procedures are based on the obligation to state the following information in trade and transport documents:

- wording stating the presence of genetically modified organisms or of products derived from GMOs through appropriate formulations;
- the name of each GMO present (or of the GMO combination) when non-processed products are concerned;
- the names and particulars of the supplier and of the customer depending on the case.

In addition each operator must keep an entry and exit register of GMOs or their derivatives that he has exchanged or processed, where the same statements as those mentioned above are noted.

The nature and form of exchanged information should be harmonised internationally."