（参考２－３）

トレーサビリティーに関するディスカッションペーパーへのコメント
（米国コメントの概要　ＣＲＤ３）

ＩＳＯの定義では、トレーサビリティーは、製品の品質を確保するための製品同定のためのシステムと関連づけられている。米国は、食品の安全の観点から製品を回収する「トレースバック」というシステムを持っている。製品同定と食品の安全確保は峻別して考える必要があり、米国は「トレースバック」という用語を用いることを提唱する。

ディスカッションペーパーの要点について
（１）「人体へのリスクが解明された場合の（市場からの）撤去」について
→　遺伝子組換え食品の安全性確保のためにトレースバックが必要との意見は疑問。なぜなら、①遺伝子組換え食品が本質的に危険なわけではない、②遺伝子組換え食品は事前に安全性評価を受けている、③製品回収は稀に起こるのみである
（２）「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」について
→　トレーサビリティーとモニタリングは無関係。モニタリングは個々別々に行うべき。
　コストがかかる面倒なトレーサビリティーを全ての製品に義務付けることは不適当。製品回収は極めて稀であり、コスト的に割に合わない。
（３）「表示制度の支援」について
→　表示の目的のためだけのトレーサビリティーに反対。ディスカッションペーパーの根底には、遺伝子組換えは本質的に他の食品より安全でないとの仮定があるように見受けられるが、公衆の健康という明白な根拠がない限りコストのかかるトレーサビリティーの義務付けは正当化されない。コストは結局消費者に転嫁される。
（４）「特定製品のＩＰ（分別流通）の促進」について
→　ＩＰシステムは、純粋に民間取引に関係するものであり、トレーサビリティーの義務付けの根拠とはならない。

米国としては、トレースバックを義務付ける合理的必要性について各国は十分検討すべきであると考えている。公衆の健康の理由以外でトレースバックが必要であるとするならば、それは市場の力によって行われるべきである。産業界は、消費者のニーズに対応して任意のトレースバックメカニズムを導入し、そのコストは消費者に転嫁されるのである。

遺伝子組換え食品の安全性評価については、本特別部会で既に検討されている。遺

伝子組換え食品が安全でない場合は稀なケースであり、そのためにコストのかかるトレーサビリティーを義務付けることには反対である。

その他のコメント

・定義については更に検討が必要。米国は、登録システムの使用は支持しない
・しばしば「分別流通を意図しているわけではない」としているが、遺伝子組換え食品の表示義務付けを意図していると考えられ、そのためには結局、遺伝子組換え食品の分別流通が必要となる。
・「分別や分析試験が不要なので、ＩＰシステムよりコストが安くなる」としているが、上記の理由から、米国はこの結論に同意しない。更に、ＩＰの議論とトレーサビリティーの議論は無関係である。
・「既存の物流に書類が付随しているので、追加的なコストはさほどのものではない」としているが、現行の物流の書類では遺伝子組換えの有無を明示することが必要とされておらず、米国はこの見解に同意しない。
・更に、トレーサビリティーの必要性と実行コストの観点から厳密なコスト分析が行われるまで、コストについて言及するのは不適当である。
・「トレーサビリティーは全ての遺伝子組換え食品に適用されるべきである」とする見解には、米国は上記の理由から同意しない。
・途上国に関するパラグラフが良く分からない。仮に、消費者の保護の観点からトレーサビリティーが不可欠なのであれば、全ての国に対して義務付けるべきである。

上述のごとく、米国は、提案のような追加を行うことを支持できない。

米国は、公衆の健康に直接関係している限りにおいて、トレースバックの概念を入れることを支持しうる。

トレースバック／トレーサビリティーの概念は、遺伝子組換え食品よりも幅広い文脈で、コーデックスの他の部会で提起されている。米国は、もっと一般的な議論を支持し、食品輸出入検査・証明システム部会で議論することが最も適当であると考えている。

codex alimentarius commission

FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS

WORLD HEALTH ORGANIZATION

JOINT OFFICE: Viale delle Terme di Caracalla 00100 ROME Tel: +39(06)5701 Telex: 625825-625853 FAO I Email: Codex@fao.org Facsimile: +39(06)5705.4593

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JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX INTERGOVERNMENTAL TASK FORCE ON FOODS DERIVED FROM BIOTECHNOLOGY

Second Session

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COMMENTS RELATING TO THE DISCUSSION PAPER ON TRACEABILITY

Comments provided by the United States

The United States expresses it thanks to France for preparing the *Discussion Paper on Traceability of GMOs* that presents one view regarding the concept of traceability.

The United States, however, has many concerns regarding the concept of traceability.

The United States believes it is important to note the distinction between traceability and traceback. "Traceability" according to definitions of the International Standards Organization (ISO) pertains to systems for product identification in order to assure product quality. Traceability is not specifically designed to assure safety nor is it necessarily a prerequisite for assuring food safety. For food safety, the United States employs a system of "traceback" which directly addresses recall of products for food safety reasons. We believe it is important to distinguish product identification from assurances of food safety in order to avoid developing a false sense of security that food is safe just because it is labeled and traceable. For these reasons the United States prefers the use of the term traceback rather than traceability because of the term's historical usage and the public health understanding and meaning that is associated with the term.

The United believes that it is important to clearly articulate the reason for implementing a traceability program.

The United States recognizes that there is a clear role for traceback when there are public health concerns about the safety of food and note that the concept is applicable in contexts that are broader than foods derived from biotechnology. The purpose for traceback is to locate and, as necessary, remove a food or food ingredient from the marketplace when a specific public health problem has been identified. The United States does not support traceability programs that have no basis in food safety or public health protection for the reasons noted below.

The United States notes that the Discussion Paper outlines three reasons for a traceability/traceback program.

- First, " to possibly withdraw products if a risk to human health is established". The United States concurs with public health as a reason, but questions the need for traceback of safe bioengineered foods because:

  1. Foods derived from modern biotechnology are not inherently unsafe.
  2. A complete and appropriate safety assessment is performed for all foods and food ingredients derived from modern biotechnology before they are marketed.
  3. Recall of product will be the rare exception for products that were reviewed for safety before marketing.

- Second, "to facilitate the identification and monitoring of unintended and long-term effects on human health, where appropriate". The United States does not support the linkage of traceability to monitoring. If monitoring is to be done, it should be determined on a case-by-case basis and should be employed only in special and exceptional cases related to human health concerns, including monitoring changes in nutrient levels. A plan for monitoring should be determined based on the specific concern associated with a particular product. It is inappropriate to require a costly and onerous traceability program for all products when the need for traceability is limited to exceptional situations and when traceability would not routinely be necessary even when some form of monitoring may be appropriate. The United States believes that a full and proper safety assessment will avoid such situations, that the occurrence of such a situation will be extremely rare and that implementing a mandatory traceability program to cover such a possibility is not cost beneficial.

- Third, "to assist in the control of labeling". The United States strongly opposes traceability merely for the purposes of labeling. The United States believes that labeling should provide important information required by the consumer. The assumption underlying the Discussion Paper's proposal appears to be that foods derived from biotechnology are inherently less safe than other foods, therefore the consumer must be informed of this fact. Such is not the case. Foods derived from biotechnology are not inherently less safe. The United States believes that setting up a costly traceability system is not justified unless there is a clear public health justification. Establishment of mandatory traceability systems "to assist in the control of labeling" of foods derived from biotechnology is not justified. The United States believes that consumer needs for information can be met by policies that permit truthful, non-misleading statements to appear on labels without imposing mandatory traceability systems with the attendant costs (which in turn will be passed on to consumers) and practical problems of implementation.

- Fourth, "to facilitate the preservation of the identity of specific products." This is simply alternative wording for "identity preserved" or IP product. While the United States believes that IP systems are appropriate in certain circumstances, the United States believes that such systems relate entirely to private buyer-seller relationships and that Codex should not use this rationale as the basis for recommending mandatory traceability systems.

The United States believes that governments, particularly, should carefully examine the rationale for mandatory traceback-requirements. The United States recognizes that there is a clear role for traceback when there are public health concerns. United States food safety agencies have historically used traceback as a tool within the existing food safety regulatory system to aid in the retrieving of product that may be injurious to health or is unfit for human consumption. Traceback is applied to food and feed products that are in the market place and to unsafe ingredients of these adulterated products. In the view of the United States, the need for traceback for other than public health reasons should be driven by market forces. Industry will respond to consumer interest for the need for such traceback programs resulting in the implementation of voluntary traceback mechanisms. Costs for these programs will be passed on to the consumers wishing to pay for such a service. Governments should exercise great care in mandating programs that do not clearly justify themselves with respect to the protection of the consumer.

The United States notes that Paragraph 16 of the Discussion Paper says that "the basic reasons for the establishment of such a traceability system for GMOs is food safety". The United States agrees, as noted immediately above, that traceback for food safety reasons, is justified. It is important however, to put this rationale into the proper perspective for foods derived from biotechnology. Properly conducted safety assessments, as currently being proposed in other documents under consideration by this Task Force should assure the safety of foods derived from biotechnology. As noted above, the occurrence of an unsafe food product derived from modern biotechnology should be the rare exception, not the rule. Consequently, imposing a costly mandatory traceability program as outlined in this document is, in the United States unnecessary and certainly not cost beneficial. The proposal outlined in this document essentially imposes on consumers a mandatory IP program.

The United States believes it is important to understand and be clear about how regulatory systems work to ensure a safe food supple. It is essential to ensure that food products and their ingredients are safe *before* they are placed on the market. Appropriate food safety assessment systems should be in place to accomplish this objective. Recall and traceback should be the rare exception and be required only when a significant food safety concern exists, for example the presence in a food of a bacterial pathogen at levels that can cause illness. In certain infrequent situations, monitoring systems may be appropriate to verify the scientific conclusions made in regards to the approval of a food or food ingredient and to ensure that no long term chronic adverse health effects are arising.

In regards to a number of other statements and points raised in this document.

- Paragraph 8 presents a definition for the term traceability. The United States believes this definition needs further discussion. The United States does not support the use of a registered identification system.

- The statement is made in various places in the document that traceability does not imply segregation. While this may, in some cases be true, the United States does not agree that it is true as presented in the context of this document. This document implies mandatory labeling for foods derived from biotechnology and states that all trade and transport documents should provide detailed information on the food product derived from modern biotechnology. In the United States judgment, the only way to assure that such labeling and documentation is correct is to segregate foods/food ingredients derived from biotechnology from those that are not derived from biotechnology.

  Paragraph 41 states that the costs of traceability programs as proposed in this Discussion Paper are intended to be "less than those for IP systems" since product segregation and analytical tests would not be required. For the reasons noted above, the United States does not agree with this conclusion. Additionally, The United States believes that the discussion on IP product is not germane for a discussion on traceability within the Codex context since it is purely a buyer/seller relationship and therefore need not appear in this document.

- The statement is made that "the costs of placing additional information...as a means to identify individual GMOs contained in a product or specify the presence of material derived from GMOs are not expected to be significant" since documentation already accompanies the product with respect to supplier, customer, transaction date as well as the nature, source, contents and amount of the product. The United States disagrees with this statement. Current shipping documentation clearly does not include the special needs required to show that the food or food ingredients are derived from modern biotechnology, particularly with respect to event specific requirements.

- Further on this point, the United States believes that it is inappropriate to make any statement regarding the costs of traceability programs, particularly a statement that costs of traceability are "not expected to be significant" until a thorough and careful cost analysis is carried out of: a) the requirements for traceability as outlined in paragraphs 34 and 35 and, b) the costs of implementation

enforcement, including the availability and costs of implementing appropriate analysis as gested in paragraph 39.

paragraph, 32, the statement is made that "traceability should apply to all GMOs and foods rived from GMOs. For reasons noted above, the United States does not agree with this statement.

he United States is not clear as to the intent of paragraph 58 that relates to developing countries. If, is stated in this document, that it is important for consumers to be aware of the presence of foods and food ingredients derived from biotechnology, it would seem that this should apply to all consumers, irrespective of the country in which they are located or in which the food is produced. If food importing countries believed that traceability were necessary for consumer protection, they would require it of all exporting countries. The United States believes that the burdens and costs of establishing the kind of traceability programs envisaged in the paper would be particularly difficult for developing countries. Developing countries would also be particularly vulnerable to the adverse effects of rising food prices that would result from implementing such programs domestically or in countries that export food to them

The United States notes that paragraph 59 proposes language that would include the use of traceability in the Principles document for the purposes presented in paragraph 15, that is for: 1) withdrawing products if a risk to human health is established; 2) facilitating the identification and monitoring of unintended and long-term effects on human health, where appropriate; 3) assisting in the control of labeling; and 4) facilitating the preservation of the identity of specific products. The United States cannot support the inclusion of this language for the reasons given above.

The United States can support the inclusion of the concept of traceback in the paper so long as it related directly to public health.

The United States notes further that the concept of traceback/traceability is being raised in other Codex venues in a context that is broader than foods derived from biotechnology. The United States can be supportive of this more general discussion on traceback/traceability within Codex and believes this discussion most appropriately can be done within the Codex Committee on Food Import and Export Inspection and Certification Systems.

e United States believes that it is important for Codex, and for the Task Force, to carefully and broadly evaluate the concept of traceback/traceability, before moving forward with its inclusion the Principles document, or other Codex documents.