Annex 1

PROJECT DOCUMENT

Proposal for New Work on Foods Derived from Plants with "Stacked" Genes

Prepared by: Japan

1. The purposes and the scope of the proposed work.

To develop a guideline for safety assessment of the foods derived from **plants with "stacked" genes**, as an appendix to the Guideline for the Conduct of Food Safety Assessment of Foods Derived from Recombinant-DNA Plants, on the basis of scientific evidence, risk analysis and having regard, where appropriate, to other legitimate factors relevant to the health of consumers and promotion of fair trade practices. It is important to keep the scope of the work science-based in order to facilitate achieving useful outputs.

2. Its relevance and timeliness.

Ad Hoc Codex Intergovernmental Task Force on Food Derived from Biotechnology (2000 – 2003) produced Principles for the Risk Analysis of Foods Derived from Modern Biotechnology and Guidelines for the Conduct of Food Safety Assessment of Foods Derived from Recombinant-DNA Plants and of Foods Produced Using Recombinant-DNA Microorganisms. The last session of the Task Force in March 2003 and the 26th Session of the Codex Alimentarius Commission noted the opinions expressed by many delegations that the Codex should continue the discussion on foods derived from modern biotechnology, and the 27th Session of the Codex Alimentarius Commission agreed to establish a new Ad Hoc Intergovernmental Task Force on Foods derived from Biotechnology. In view of the proposals and views expressed in the Task Force and the Commission, it is relevant and timely to produce new Codex texts on foods derived from **plants with "stacked" genes** that would further support and complement the above Principles and Guidelines.

3. The main aspects to be covered.

Additional safety assessment for foods derived from **plants with "stacked" genes**

4. An assessment against the criteria for the establishment of work priorities.

As modern biotechnology can be significant powerful tools for the production of food, the safety of foods derived from modern biotechnology must be ensured as much as possible. The safety of foods derived from **plants with "stacked" genes**, its potential risks to consumer health and promotion of its fair trade must be fully considered.

This proposal is consistent with:

(a) Consumer protection from the point of view of health and fraudulent practices

(b) Diversification of national legislations and apparent resultant or potential impediments to international trade.

(d) Work already undertaken by other international organizations in this field.

There is no other international organization that has undertaken international standard setting activities for the foods derived from **plants with "stacked" genes**.

5. Relevance to the Codex strategic objectives.

The new work contributes to the safety of human health and fair trade of foods derived from modern biotechnology by satisfying the following objectives the "Strategic objectives and priorities" (CAC Strategic Framework 2003 - 2007).

Objective 1: Promoting sound regulatory frameworks

Objective 2: Promoting widest and consistent application of scientific principles and risk analysis

Objective 4: Enhancing capacity to respond effectively and expeditiously to new issues, concerns and developments in the food sector

Objective 6: promoting maximum application of Codex standards

6. Information on the relation between the proposal and other existing Codex documents.

The previous Task Force produced the following documents which are related with the other existing Codex documents especially in conjunction with the Working Principles for the Risk Analysis for Application in the Framework of the Codex Alimentarius. The text on the Assessment of Possible Allergenicity was developed as an appendix to the Guideline for the Conduct of Food Safety Assessment of Foods Derived from Recombinant-DNA Plants and the text on **plants with "stacked" genes** can be developed in a similar manner.

- Principles for the Risk Analysis of Foods Derived from Modern Biotechnology
- Guideline for the Conduct of Food Safety Assessment of Foods Derived from Recombinant-DNA Plants
- Guideline for the Conduct of Food Safety Assessment of Foods Produced Using Recombinant-DNA Microorganisms

7. Identification of any requirement for and availability of expert scientific advice.

- In which combination of parental plants should safety assessment be conducted for individual plants with "stacked" genes. How to select comparator.

- How to ascertain gene stability of plants with "stacked" genes

8. Identification of any need for technical input to the Task Force from external bodies so that this can be planned for.

Necessary, if available.

9. The proposed time-line for completion of the new work, including the start date, the proposed date for adoption at Step 5 and the proposed date for adoption by the Commission; the time frame for developing a standard should not normally exceed five years.

The time frame for the Task Force is four years. Therefore, if the new work is approved by the Commission in 2006, adoptions at Step 5 and at Step 8 will be at the latest in 2008 and in 2009, respectively.

Annex 2

PROJECT DOCUMENT

Proposal for New Work on Foods Derived from "nutritionally-enhanced" Plants

Prepared by: Japan

1. The purposes and the scope of the proposed work.

To develop a guideline for safety assessment of the foods derived from **"nutritionally-enhanced" plants**, as an appendix to the Guideline for the Conduct of Food Safety Assessment of Foods Derived from Recombinant-DNA Plants, on the basis of scientific evidence, risk analysis and having regard, where appropriate, to other legitimate factors relevant to the health of consumers and promotion of fair trade practices. It is important to keep the scope of the work science-based in order to facilitate achieving useful outputs.

2. Its relevance and timeliness.

Ad Hoc Codex Intergovernmental Task Force on Food Derived from Biotechnology (2000 – 2003) produced Principles for the Risk Analysis of Foods Derived from Modern Biotechnology and Guidelines for the Conduct of Food Safety Assessment of Foods Derived from Recombinant-DNA Plants and of Foods Produced Using Recombinant-DNA Microorganisms. The last session of the Task Force in March 2003 and the 26th Session of the Codex Alimentarius Commission noted the opinions expressed by many delegations that the Codex should continue the discussion on foods derived from modern biotechnology, and the 27th Session of the Codex Alimentarius Commission agreed to establish a new Ad Hoc Intergovernmental Task Force on Foods derived from Biotechnology. In view of the proposals and views expressed in the Task Force and the Commission, it is relevant and timely to produce new Codex texts on foods derived from **"nutritionally-enhanced" plants** that would further support and complement the above Principles and Guidelines.

3. The main aspects to be covered.

Additional safety assessment for foods derived from **"nutritionally-enhanced" plants**

4. An assessment against the criteria for the establishment of work priorities.

As modern biotechnology can be significant powerful tools for the production of food, the safety of foods derived from modern biotechnology must be ensured as much as possible. The safety of foods derived from **"nutritionally-enhanced" plants**, its potential risks to consumer health and promotion of its fair trade must be fully considered.

This proposal is consistent with:

(a) Consumer protection from the point of view of health and fraudulent practices

(b) Diversification of national legislations and apparent resultant or potential impediments to international trade.

(d) Work already undertaken by other international organizations in this field.

There is no other international organization that has undertaken international standard setting activities for the foods derived from **"nutritionally-enhanced" plants**.

5. Relevance to the Codex strategic objectives.

The new work contributes to the safety of human health and fair trade of foods derived from modern biotechnology by satisfying the following objectives the "Strategic objectives and priorities" (CAC Strategic Framework 2003 - 2007).

Objective 1: Promoting sound regulatory frameworks

Objective 2: Promoting widest and consistent application of scientific principles and risk analysis

Objective 4: Enhancing capacity to respond effectively and expeditiously to new issues, concerns and developments in the food sector

Objective 6: promoting maximum application of Codex standards

6. Information on the relation between the proposal and other existing Codex documents.

The previous Task Force produced the following documents which are related with the other existing Codex documents especially in conjunction with the Working Principles for the Risk Analysis for Application in the Framework of the Codex Alimentarius. The text on the Assessment of Possible Allergenicity was developed as an appendix to the Guideline for the Conduct of Food Safety Assessment of Foods Derived from Recombinant-DNA Plants and the text on **"nutritionally-enhanced" plants** can be developed in a similar manner.

- Principles for the Risk Analysis of Foods Derived from Modern Biotechnology
- Guideline for the Conduct of Food Safety Assessment of Foods Derived from Recombinant-DNA Plants
- Guideline for the Conduct of Food Safety Assessment of Foods Produced Using Recombinant-DNA Microorganisms

7. Identification of any requirement for and availability of expert scientific advice.

- Can the profiling techniques be applied to "nutritionally-enhanced" plants? If yes, how?

8. Identification of any need for technical input to the Task Force from external bodies so that this can be planned for.

Necessary, if available.

9. The proposed time-line for completion of the new work, including the start date, the proposed date for adoption at Step 5 and the proposed date for adoption by the Commission; the time frame for developing a standard should not normally exceed five years.

The time frame for the Task Force is four years. Therefore, if the new work is approved by the Commission in 2006, adoptions at Step 5 and at Step 8 will be at the latest in 2008 and in 2009, respectively.

Annex 3

PROJECT DOCUMENT

Proposal for New Work on Foods Derived from Recombinant-DNA Fish

Prepared by: Japan

1. The purposes and the scope of the proposed work.

To develop a guideline for safety assessment of the foods derived from **recombinant-DNA fish**, on the basis of scientific evidence, risk analysis and having regard, where appropriate, to other legitimate factors relevant to the health of consumers and promotion of fair trade practices. It is important to keep the scope of the work science-based in order to facilitate achieving useful outputs.

2. Its relevance and timeliness.

Ad Hoc Codex Intergovernmental Task Force on Food Derived from Biotechnology (2000 – 2003) produced Principles for the Risk Analysis of Foods Derived from Modern Biotechnology and Guidelines for the Conduct of Food Safety Assessment of Foods Derived from Recombinant-DNA Plants and of Foods Produced Using Recombinant-DNA Microorganisms. The last session of the Task Force in March 2003 and the 26th Session of the Codex Alimentarius Commission noted the opinions expressed by many delegations that the Codex should continue the discussion on foods derived from modern biotechnology, and the 27th Session of the Codex Alimentarius Commission agreed to establish a new Ad Hoc Intergovernmental Task Force on Foods derived from Biotechnology. In view of the proposals and views expressed in the Task Force and the Commission, it is relevant and timely to produce new Codex texts on foods derived from **recombinant-DNA fish** that would further support the Principles for the Risk Analysis of Foods Derived from Modern Biotechnology.

3. The main aspects to be covered.

Safety assessment for foods derived from **recombinant-DNA fish**

4. An assessment against the criteria for the establishment of work priorities.

As modern biotechnology can be significant powerful tools for the production of food, the safety of foods derived from modern biotechnology must be ensured as much as possible. The safety of foods derived from **recombinant-DNA fish**, its potential risks to consumer health and promotion of its fair trade must be fully considered.

This proposal is consistent with:

(a) Consumer protection from the point of view of health and fraudulent practices

(b) Diversification of national legislations and apparent resultant or potential impediments to international trade.

(d) Work already undertaken by other international organizations in this field.

There is no other international organization that has undertaken international standard setting activities for the foods derived from **recombinant-DNA fish**.

5. Relevance to the Codex strategic objectives.

The new work contributes to the safety of human health and fair trade of foods derived from modern biotechnology by satisfying the following objectives the "Strategic objectives and priorities" (CAC Strategic Framework 2003 - 2007).

Objective 1: Promoting sound regulatory frameworks

Objective 2: Promoting widest and consistent application of scientific principles and risk analysis

Objective 4: Enhancing capacity to respond effectively and expeditiously to new issues, concerns and developments in the food sector

Objective 6: promoting maximum application of Codex standards

6. Information on the relation between the proposal and other existing Codex documents.

The previous Task Force produced the following documents which are related with the other existing Codex documents especially in conjunction with the Working Principles for the Risk Analysis for Application in the Framework of the Codex Alimentarius. The previous Task Force left the area of foods derived from recombinant-DNA animals, including fish.

- Principles for the Risk Analysis of Foods Derived from Modern Biotechnology
- Guideline for the Conduct of Food Safety Assessment of Foods Derived from Recombinant-DNA Plants
- Guideline for the Conduct of Food Safety Assessment of Foods Produced Using Recombinant-DNA Microorganisms
- Draft Code of Practice for Fish and Fishery Products (Aquaculture) (Step 8)

7. Identification of any requirement for and availability of expert scientific advice.

- How to choose conventional counterpart taking into account breeding partner, life stages, etc?
- How offspring of recombinant-DNA fish should be assessed for safety as food
- Availability of sufficient compositional analysis data for assessment of recombinant-DNA fish

8. Identification of any need for technical input to the Task Force from external bodies so that this can be planned for.

Necessary, if available.

9. The proposed time-line for completion of the new work, including the start date, the proposed date for adoption at Step 5 and the proposed date for adoption by the Commission; the time frame for developing a standard should not normally exceed five years.

The time frame for the Task Force is four years. Therefore, if the new work is approved by the Commission in 2006, adoptions at Step 5 and at Step 8 will be at the latest in 2008 and in 2009, respectively.

Annex 4

PROJECT DOCUMENT

Codex Ad Hoc Intergovernmental Task Force on Foods Derived from Biotechnology: United States Proposal for New Work: Food Safety Issues Specific to Staple Food Crops for Developing Countries (Food Composition).

Prepared by : The United States of America

1. Purpose and scope of the proposed work

To identify information that can assist countries, especially developing countries, in conducting food composition analyses of foods derived from recombinant-DNA plants to facilitate food safety assessments. This work, to be developed as an Annex to the existing *Guideline for the Conduct of Food Safety Assessment of Foods Derived from Recombinant-DNA Plants,* will identify key nutrients, anti-nutrients, toxicants, and other substances that are critical to the safety assessment of foods derived from recombinant-DNA plants for staple foods derived from recombinant-DNA plants in developing countries.

2. Its relevance and timeliness

This work is intended to supplement the Codex *Guideline for the Conduct of Food Safety Assessment of Foods Derived from Recombinant-DNA Plants* (CAC/GL 45-2003; the plant guideline) to provide countries with guidance on addressing comparative food composition analyses as part of the safety assessment for staple foods derived from recombinant-DNA plants. Research is progressing in several countries to produce food derived from recombinant-DNA plants. For example, modern biotechnology is being used to develop new varieties of staple crops such as cassava, plantain, sweet potato. Countries will need to conduct food safety assessments for foods derived from these crops prior to commercial distribution. Food composition analyses are an important element of the safety assessment and are specific to each crop. Guidance from Codex would benefit countries that conduct food safety assessments for staple foods derived from modern biotechnology.

3. The main aspects to be covered

a) Identify staple food crops in developing countries in which new varieties are under development using modern biotechnology.
b) Identify and compile information on such substances as key nutrients, anti-nutrients, toxicants for each crop, including data on the range of concentration reported for each component in food.
c) Develop an annex to the plant Guidelines to provide information to countries on food composition analyses

4. An assessment against the *criteria applicable to general subjects* as contained in the *Criteria for the Establishment of Work Priorities*

a) *Consumer protection from the point of view of health and fraudulent practices:* This new work proposal is consistent with this criterion as it provides additional scientific data with which to undertake scientific safety assessments of food derived from modern biotechnology, thus helping to ensure consumer protection.
b) *Diversification of national legislations and apparent resultant or potential impediments to international trade:* This new work proposal is consistent with this criterion as it will provide scientific data which countries may utilize to establish their own individual standards or guidance, and which, when applied internationally may assist in providing an harmonized approach that can facilitate trade.
c) *Scope of work and establishment of priorities between the various section of work:* This new work proposal meets this criterion as it has a clearly defined and achievable scope of work and provides a clear and understandable sequence of what needs to carried-out.

d) *Work already undertaken by other organizations in this field:* This new work proposal meets this criterion as it supplements, but does not duplicate, work undertaken by other international organizations.

5. Relevance to Codex Strategic Objectives
This new work proposal is consistent with:

a) Promoting sound regulatory frameworks.
b) Promoting widest and consistent application of scientific principles and risk analysis.

6. Information on the relation between the proposal and other existing Codex documents.
This proposal would support but not duplicate the Codex *Guideline for the Conduct of Food Safety Assessment of Foods Derived from Recombinant-DNA Plants* (CAC/GL 45-2003).

7. Identification of any requirement for and availability of expert scientific advice.
None identified, though the Task Force will need data and information on recombinant-DNA plants under development in developing countries and data and information on key components for foods derived from such crops.

8. Identification of any need for technical input to the standard from external bodies so that this can be planned for.
None identified.

9. The proposed timeline for completion of the new work, including the start date, the proposed date for adoption at Step 5 and the proposed date for adoption by the Commission; the timeframe for developing a standard should not normally exceed 5 years.
If agreed to by the Task Force at its first meeting, a draft would be presented to the Task Force at its second meeting (2006) for consideration at Step 3. It is expected that the work can be completed within the four-year timeframe for the Task Force.

Annex 5

PROJECT DOCUMENT

Codex Ad Hoc Intergovernmental Task Force on Foods Derived from Biotechnology: United States Proposal for New Work: Low-level presence in food of plant material derived from recombinant-DNA plants.

Prepared by: The United States of America

1. Purpose and scope of the proposed work

To identify food safety issues in Codex *Guideline for the Conduct of Food Safety Assessment of Foods Derived from Recombinant-DNA Plants* (CAC/GL 45-2003) related to the presence in foods of low levels of material derived from recombinant-DNA plants. The scope of this proposed work would be limited to recombinant-DNA plants developed for food use.

2. Its relevance and timeliness

The focus of this work would be the examination of the existing safety assessment approach in the Codex *Guideline for the Conduct of Food Safety Assessment of Foods Derived from Recombinant-DNA Plants* (CAC/GL 45-2003) to determine which issues in this guideline are appropriate to establish the food safety of low levels of material derived from recombinant-DNA plants. This work is intended to supplement CAC/GL 45-2003 and to provide countries with guidance on addressing food safety issues that pertain to low level presence in foods of material derived from recombinant-DNA plants. This work could be considered as an annex to the Plant Guideline.

Countries will likely be increasingly faced with different circumstances in which they will need to assess the food safety of low levels of recombinant-DNA plant material in food. At various stages in a plant variety's development and production cycle material from that plant variety might be present in the food supply at very low levels. Increasing numbers of new varieties of recombinant-DNA plants are in the research and development stage and are being tested in the field in a growing number of countries. Additionally, as new recombinant-DNA plant varieties leave research and development and enter commerce, older varieties are coming off the market. Even though a plant variety is no longer used commercially, material from it will continue to be present in the food supply, albeit at low levels. Using the existing Codex Guideline on recombinant-DNA plants for identifying the relevant food safety considerations pertaining to such low level presence of recombinant-DNA plant material will aid in the determination of the safety of food in these situations. National governments would use this guidance within the context of their own regulatory frameworks. The document could help guide appropriate risk assessment and risk management decisions made within the contexts of those frameworks.

3. The main aspects to be covered

Develop an annex to the plant Guidelines to identify food safety issues associated with low level presence of recombinant-DNA plant material in food.

4. An assessment against the *criteria applicable to general subjects* as contained in the *Criteria for the Establishment of Work Priorities*

a. *Consumer protection from the point of view of health and fraudulent practices:* This new work proposal is consistent with this criterion as it provides additional guidance with which to undertake scientific safety assessments of food derived from modern biotechnology, thus helping to ensure consumer protection.

b. *Diversification of national legislations and apparent resultant or potential impediments to international trade:* This new work proposal is consistent with this criterion as it will provide scientific guidance which countries may utilize to establish their own individual standards or guidance.

c. *Scope of work and establishment of priorities between the various section of work:* While the precise scope of this work proposal will need to be defined by the Task Force, this proposal provides sufficient guidance to indicate the general scope and nature of the intended work to permit the Task Force to discuss and determine the final scope of the project.
d. *Work already undertaken by other organizations in this field:* This new work proposal meets this criterion as it does not duplicate work undertaken by other international organizations.

5. Relevance to Codex Strategic Objectives
This new work proposal is consistent with:

a) Promoting sound regulatory frameworks.
b) Promoting widest and consistent application of scientific principles and risk analysis.

6. Information on the relation between the proposal and other existing Codex documents.
This proposal would support but not duplicate the Codex *Guideline for the Conduct of Food Safety Assessment of Foods Derived from Recombinant-DNA Plants* (CAC/GL 45-2003).

7. Identification of any requirement for and availability of expert scientific advice.
None identified.

8. Identification of any need for technical input to the standard from external bodies so that this can be planned for.
None identified.

9. The proposed timeline for completion of the new work, including the start date, the proposed date for adoption at Step 5 and the proposed date for adoption by the Commission; the timeframe for developing a standard should not normally exceed 5 years.
If agreed to by the Task Force at its first meeting, a draft would be presented to the Task Force at its second meeting (2006) for consideration at Step 3. It is expected that the work can be completed within the four-year timeframe for the Task Force.

Annex 6

PROJECT DOCUMENT

Codex Ad Hoc Intergovernmental Task Force on Foods Derived from Biotechnology: Consumers International Proposal for New Work: Food safety guidelines for food derived from recombinant-DNA animals.

Prepared by: Consumers International

1. Purpose and scope of the proposed work

To develop a guideline for the conduct of food safety assessment of foods derived from Recombinant-DNA animals. The guideline would take as a model, the Codex Guideline for the Conduct of Food Safety Assessment of Foods Derived from Recombinant-DNA Plants (CAC/GL 45-2003), taking into account differences between plants and animals.

However an extremely important difference between plants and animals is the greater relevance of "other legitimate factors" to animals. Therefore more attention must be given to this area, and guidance should be developed on assessing and integrating other legitimate factors, including environmental impact on public health, animal welfare, and religious and ethical concerns, into the food safety assessment.

2. Its relevance and timeliness

This work would fulfill the recommendation of the first session of the Task Force of March 2000 (ALINORM 01/34, para. 28) that a guideline be developed on safety of foods of animal origin derived from biotechnology, as a third priority after guidelines on "foods of plant origin, followed by micro-organisms used directly in foods." Genetically engineered/genetically modified (recombinant-DNA) animals are being developed in a number of countries around the world and having international guidelines developed would greatly aid countries in assessing the safety of foods derived from such animals.

3. The main aspects to be covered

Using a step-wise approach, develop a guideline for food safety assessment of foods derived from recombinant-DNA animals, taking into account the comparative approach and other concepts from the Principles for Risk Analysis for Foods Derived from Modern Biotechnology and from the Guidelines adopted by Codex for foods derived recombinant-DNA plants and microorganisms.

The guideline should also be developed taking into account the WHO/FAO Expert Consultation on the Safety Assessment of Foods Derived from Genetically Modified Animals, including Fish, held in Rome, Italy on 17-21 November, 2003.

Integration of consideration of "other legitimate factors" should be explicitly addressed.

4. An assessment against the criteria applicable to general subjects as contained in the Criteria for the Establishment of Work Priorities

a. Consumer protection from the point of view of health and fraudulent practices: This new work proposal will provide additional guidance with which to undertake scientific safety assessments of food derived from modern biotechnology, thus helping to ensure consumer protection. The safety assessment, by considering environmental and ethical aspects that can affect food safety would help to ensure consumer protection and also ensure fair and non-fraudulent practices in the food trade. For

example, GM animals could potentially enter the food supply via the environment by escape. Thus, escaped GM fish and shellfish, or their descendants, could be harvested without being detected and subsequently eaten by people. Similar mechanisms could apply for poultry such as ducks and quail that are subject to sport or subsistence harvest. The live transport and sale of GM fish and poultry poses another route for escape of GM animals and their entry into the environment. In all such cases, theses escaped GM animals and their descendents could be eaten by people.

b. Diversification of national legislations and apparent resultant or potential impediments to international trade: This new work proposal will provide scientific guidance which countries may utilize to establish their own individual standards or guidance, and which, when applied internationally, may assist in providing a harmonized approach that can facilitate fair practices in food trade.

c. Scope of work and establishment of priorities between the various section of work: See (1.) above.

d. Work already undertaken by other organizations in this field: This new work does not duplicate work undertaken by other international organizations.

5. Relevance to Codex Strategic Objectives

This new work proposal is consistent with promoting sound regulatory frameworks.

6. Information on the relation between the proposal and other existing Codex documents.

This new work proposal would be consistent with the Principles for the Risk Analysis of Food Derived from Modern Biotechnology (CAC/GL 44-2003) and would complement the Guideline for the Conduct of Food Safety Assessment of Foods Derived from Recombinant-DNA Plants (CAC/GL 45-2003) and the Guideline for the Conduct of Food Safety Assessment of Foods Produced Using Recombinant-DNA Microorganisms (CAC/GL 46-2003).

7. Identification of any requirement for and availability of expert scientific advice.

This new work proposal would need expert scientific advice on the proper elements of a safety assessment of GE/GM animal-derived foods. FAO and WHO held an Expert Consultation on the Safety Assessment of Foods Derived from Genetically Modified Animals, including Fish, held in Rome, Italy on 17-21 November, 2003, which should be used in preparation of this new document.

8. Identification of any need for technical input to the standard from external bodies so that this can be planned for.

Technical input already exists. See answer to 7.

9. The proposed timeline for the completion of the new work, including the start date, the proposed date for adoption at Step 5 and the proposed date for adoption by the Commission; the timeframe for developing a standard should not normally exceed 5 years.

If agreed to by the Task Force at its first meeting, a draft would be presented to the Task Force at its second meeting in 2006 for consideration at Step 3. It is expected that the work can be completed within the four-year timeframe for the Task Force.