参考資料１

GUIDELINE FOR THE CONDUCT OF FOOD SAFETY ASSESSMENT OF FOODS DERIVED FROM RECOMBINANT-DNA PLANTS CAC/GL 45-2003	GUIDELINE FOR THE CONDUCT OF FOOD SAFETY ASSESSMENT OF FOODS DERIVED FROM RECOMBINANT-DNA PLANTS CAC/GL 45-2003 Adopted in 2003, Annexes II and III adopted in 2008.	組換え DNA 植物由来食品の安全性評価の実施に関するガイドライン
SECTION 1 - SCOPE 1. This Guideline supports the Principles for the Risk Analysis of Foods Derived from Modern Biotechnology. It addresses safety and nutritional aspects of foods consisting of, or derived from, plants that have a history of safe use as sources of food, and that have been modified by modern biotechnology to exhibit new or altered expression of traits.	SECTION 1 - SCOPE 1. This Guideline supports the Principles for the Risk Analysis of Foods Derived from Modern Biotechnology. It addresses safety and nutritional aspects of foods consisting of, or derived from, plants that have a history of safe use as sources of food, and that have been modified by modern biotechnology to exhibit new or altered expression of traits.	セクション 1-適用範囲 1. このガイドラインは、「モダンバイオテクノロジー応用食品のリスク分析に関する原則」を支持するものである。食品として安全に使用されてきた歴史があり、かつ新規のまたは改変された形質の発現のためにモダンバイオテクノロジーを用いて組換えられた植物で構成されるか、またはそれに由来する食品の安全性と栄養的局面を扱っている。
2. This document does not address animal feed or animals fed with the feed. This document also does not address environmental risks.	2. This document does not address animal feed or animals fed with the feed. This document also does not address environmental risks.	2. 本文書は、動物飼料または当該飼料を投与した動物は対象としない。また、環境上のリスクについても扱わない。
3. The Codex principles of risk analysis, particularly those for risk assessment, are primarily intended to apply to discrete chemical entities such as food additives and pesticide residues, or a specific chemical or microbial contaminant that have identifiable hazards and risks; they are not intended to apply to whole foods as such. Indeed, few foods have been assessed scientifically in a manner that would fully characterise all risks associated	3. The Codex principles of risk analysis, particularly those for risk assessment, are primarily intended to apply to discrete chemical entities such as food additives and pesticide residues, or a specific chemical or microbial contaminant that have identifiable hazards and risks; they are not intended to apply to whole foods as such. Indeed, few foods have been assessed scientifically in a manner that would fully characterise all risks associated	3. リスク分析に関するコーデックスの原則、特にリスク評価に関する原則は主として、食品添加物や残留農薬等の化学物質、または特定の化学・微生物汚染物質等の同定可能な危害やリスクを有する物質の識別のために用いることを目的としており、丸ごとの食品に適用するものではない。実際に、食品に関わるリスクの全てを完全に明らかにする方法で科学的に評価された食品はほとんどない。さらに、多くの食品には従来の安全性検試験手法を用いた場合有害と見なされるであろう物質が含まれている。従って、食品そのものの安全性

with the food. Further, many foods contain substances that would likely be found harmful if subjected to conventional approaches to safety testing. Thus, a more focused approach is required where the safety of a whole food is being considered.	with the food. Further, many foods contain substances that would likely be found harmful if subjected to conventional approaches to safety testing. Thus, a more focused approach is required where the safety of a whole food is being considered.	を検討する場合は、焦点を絞ったアプローチが必要となる。
4. This approach is based on the principle that the safety of foods derived from new plant varieties, including recombinant-DNA plants, is assessed relative to the conventional counterpart having a history of safe use, taking into account both intended and unintended effects. Rather than trying to identify every hazard associated with a particular food, the intention is to identify new or altered hazards relative to the conventional counterpart.	4. This approach is based on the principle that the safety of foods derived from new plant varieties, including recombinant-DNA plants, is assessed relative to the conventional counterpart having a history of safe use, taking into account both intended and unintended effects. Rather than trying to identify every hazard associated with a particular food, the intention is to identify new or altered hazards relative to the conventional counterpart.	4. このアプローチは、意図的・非意図的な影響の両方を考慮して、今まで安全に食品として使用されてきた既存の対応物と関連づけて組換え DNA 植物を含む新しい植物品種由来の食品の安全性を評価するという原則に基づいている。特定食品に関わる全ての危害を同定するのではなく、既存の対応物との比較に基づいて新しいまたは改変された危害を特定することを目的としている。
5. This safety assessment approach falls within the risk assessment framework as discussed in Section 3 of the Principles for the Risk Analysis of Foods Derived from Modern Biotechnology. If a new or altered hazard, nutritional or other food safety concern is identified by the safety assessment, the risk associated with it would first be assessed to determine its relevance to human health. Following the safety assessment and if necessary further risk assessment, the food would be subjected to risk	5. This safety assessment approach falls within the risk assessment framework as discussed in Section 3 of the Principles for the Risk Analysis of Foods Derived from Modern Biotechnology. If a new or altered hazard, nutritional or other food safety concern is identified by the safety assessment, the risk associated with it would first be assessed to determine its relevance to human health. Following the safety assessment and if necessary further risk assessment, the food would be subjected to risk	5. この安全性評価手法は、「モダンバイオテクノロジー応用食品のリスク分析に関する原則」のセクション 3 で述べられたリスク評価の枠組みにはいる。安全性評価によって、新たなまたは改変された危害や、栄養学的なまたはその他の食品安全性の問題が明らかになった場合には、それに関わるリスクをまず評価してヒトの健康との関連を調べる。安全性評価、また必要に応じ追加リスク評価を行った後、食品または製造過程で用いた微生物などの食品成分は市販を検討する前に「モダンバイオテクノロジー応用食品のリスク分析に関する原則」に沿って、リスク管理に関する検

management considerations in accordance with the Principles for the Risk Analysis of Foods Derived from Modern Biotechnology before it is considered for commercial distribution.	management considerations in accordance with the Principles for the Risk Analysis of Foods Derived from Modern Biotechnology before it is considered for commercial distribution.	討が行なわれる。
6. Risk management measures such as post-market monitoring of consumer health effects may assist the risk assessment process. These are discussed in paragraph 20 of the Principles for the Risk Analysis of Foods derived from Modern Biotechnology.	6. Risk management measures such as post-market monitoring of consumer health effects may assist the risk assessment process. These are discussed in paragraph 20 of the Principles for the Risk Analysis of Foods derived from Modern Biotechnology.	6. 消費者の健康に対する影響の上市後モニタリングといったリスク管理手段が、リスク評価過程に役立つ場合がある。このことは「モダンバイオテクノロジー応用食品のリスク分析に関する原則案」のパラグラフ 20 に述べられている。
7. The Guideline describes the recommended approach to making safety assessments of foods derived from recombinant-DNA plants where a conventional counterpart exists, and identifies the data and information that are generally applicable to making such assessments. While this Guideline is designed for foods derived from recombinant-DNA plants, the approach described could, in general, be applied to foods derived from plants that have been altered by other techniques.	7. The Guideline describes the recommended approach to making safety assessments of foods derived from recombinant-DNA plants where a conventional counterpart exists, and identifies the data and information that are generally applicable to making such assessments. While this Guideline is designed for foods derived from recombinant-DNA plants, the approach described could, in general, be applied to foods derived from plants that have been altered by other techniques.	7. このガイドラインでは、既存の対応物が存在する場合は組換え DNA 植物由来食品の安全性評価の実施に関して勧告されたアプローチについて述べ、こうした評価を行なうために汎用できるデータと情報を明らかにしている。このガイドラインは組換え DNA 植物由来食品を意図したものであるが、記述されているアプローチは一般的に、他の技術によって改変された植物由来食品にも適用可能である。
SECTION 2 - DEFINITIONS	SECTION 2 - DEFINITIONS	セクション 2-定義
8. The definitions below apply to this Guideline: “Recombinant-DNA Plant” - means a plant in which the genetic material has been changed through in vitro nucleic acid techniques, including recombinant	8. The definitions below apply to this Guideline: “Recombinant-DNA Plant” - means a plant in which the genetic material has been changed through in vitro nucleic acid techniques, including recombinant	8. このガイドラインでは以下の定義を適用する。 「組換え DNA 植物」-組換えデオキシリボ核酸(DNA)及び細胞または細胞小器官への核酸の直接挿入などを含む、インビトロ核酸技術を利用して遺伝物質を変化させた植物を指す。 「既存の対応物」- 食品としての一般使用に基づ

deoxyribonucleic acid (DNA) and direct injection of nucleic acid into cells or organelles. "Conventional Counterpart" - means a related plant variety, its components and/or products for which there is experience of establishing safety based on common use as food1.	deoxyribonucleic acid (DNA) and direct injection of nucleic acid into cells or organelles. "Conventional Counterpart" - means a related plant variety, its components and/or products for which there is experience of establishing safety based on common use as food1.	き安全性が実証されている関連植物種およびその構成成分・製品を指す1。
SECTION 3 - INTRODUCTION TO FOOD SAFETY ASSESSMENT	SECTION 3 - INTRODUCTION TO FOOD SAFETY ASSESSMENT	セクション3-食品の安全性評価の説明
9. Traditionally, new varieties of food plants have not been systematically subjected to extensive chemical, toxicological, or nutritional evaluation prior to marketing, with the exception of foods for specific groups, such as infants, where the food may constitute a substantial portion of the diet. Thus, new varieties of corn, soya, potatoes and other common food plants are evaluated by breeders for agronomic and phenotypic characteristics, but generally, foods derived from such new plant varieties are not subjected to the rigorous and extensive food safety testing procedures, including studies in animals, that are typical of chemicals such as food additives or pesticide residues that may be present in food.	9. Traditionally, new varieties of food plants have not been systematically subjected to extensive chemical, toxicological, or nutritional evaluation prior to marketing, with the exception of foods for specific groups, such as infants, where the food may constitute a substantial portion of the diet. Thus, new varieties of corn, soya, potatoes and other common food plants are evaluated by breeders for agronomic and phenotypic characteristics, but generally, foods derived from such new plant varieties are not subjected to the rigorous and extensive food safety testing procedures, including studies in animals, that are typical of chemicals such as food additives or pesticide residues that may be present in food.	9. これまでは、ある食品が食事の大部分を占める可能性がある乳児などの特定集団向けの食品を除いて、新種の食用植物について詳細な化学的・毒性学的・栄養学的評価が体系的に行なわれることはなかった。従って、新種のトウモロコシ・大豆・ジャガイモその他の一般的な食用植物は、育種家たちによって作物学的なまたは表現型に係わる特徴に関し評価が行われているが、このような新種の植物由来食品は、動物試験を含め、食品添加物や残留農薬など通常の食品に含まれる可能性のある化学物質に対して一般的に行われる厳密かつ詳細な食品安全性試験を課せられてはいない。
10. The use of animal models for assessing toxicological endpoints is a major element in the risk assessment of many	10. The use of animal models for assessing toxicological endpoints is a major element in the risk assessment of many	10. 毒性学的な指標の評価において動物モデルを用いることは、農薬など多くの化合物のリスク評価において主要要素である。しかしほと

compounds such as pesticides. In most cases, however, the substance to be tested is well characterised, of known purity, of no particular nutritional value, and, human exposure to it is generally low. It is therefore relatively straightforward to feed such compounds to animals at a range of doses some several orders of magnitude greater than the expected human exposure levels, in order to identify any potential adverse health effects of importance to humans. In this way, it is possible, in most cases, to estimate levels of exposure at which adverse effects are not observed and to set safe intake levels by the application of appropriate safety factors.	compounds such as pesticides. In most cases, however, the substance to be tested is well characterised, of known purity, of no particular nutritional value, and, human exposure to it is generally low. It is therefore relatively straightforward to feed such compounds to animals at a range of doses some several orders of magnitude greater than the expected human exposure levels, in order to identify any potential adverse health effects of importance to humans. In this way, it is possible, in most cases, to estimate levels of exposure at which adverse effects are not observed and to set safe intake levels by the application of appropriate safety factors.	んどの場合、被試験物質の特徴は十分に明らかにされており、純度が既知で、特別な栄養的価値がなくそれに対するヒトの曝露は一般的に低い。従って、ヒトに対して重大な有害な健康影響を明らかにするために、こうした化合物をヒトの予想曝露量より数段階多い一定範囲内の用量で動物に投与することは比較的簡単である。この方法ではほとんどの場合、有害影響が認められない曝露量を概算し、適切な安全性係数の適用によって安全な摂取量を設定することは可能である。
11. Animal studies cannot readily be applied to testing the risks associated with whole foods, which are complex mixtures of compounds, often characterised by a wide variation in composition and nutritional value. Due to their bulk and effect on satiety, they can usually only be fed to animals at low multiples of the amounts that might be present in the human diet. In addition, a key factor to consider in conducting animal studies on foods is the nutritional value and balance of the diets used, in order to avoid the induction of adverse effects which are not related directly to the material itself. Detecting any potential	11. Animal studies cannot readily be applied to testing the risks associated with whole foods, which are complex mixtures of compounds, often characterised by a wide variation in composition and nutritional value. Due to their bulk and effect on satiety, they can usually only be fed to animals at low multiples of the amounts that might be present in the human diet. In addition, a key factor to consider in conducting animal studies on foods is the nutritional value and balance of the diets used, in order to avoid the induction of adverse effects which are not related directly to the material itself. Detecting any potential	11. 丸ごとの食品に関するリスク試験については、それが化合物の複雑な混合物であり、しばしば組成や栄養価において多様であるため、動物試験を容易に適用できない。量が多く満腹になるため、動物に与えることのできる量は通常はヒトの食事に含まれると考えられる量の数倍でしかない。さらに、食品に関する動物試験の実施に当たり、物質そのものには直接関係しない有害影響の誘発を避けるため、使用される食餌の栄養価とバランスを考慮することが重要である。従って、潜在的な有害影響を判定し、食品の個々の特性との関係を確実に示すことは非常に困難であろう。食品の特徴から徹底した安全性評価を実施するためにはデータが不十分であることが分かった場合は、丸ごとの食品を使用して、

adverse effects and relating these conclusively to an individual characteristic of the food can therefore be extremely difficult. If the characterization of the food indicates that the available data are insufficient for a thorough safety assessment, properly designed animal studies could be requested on the whole foods. Another consideration in deciding the need for animal studies is whether it is appropriate to subject experimental animals to such a study if it is unlikely to give rise to meaningful information.	adverse effects and relating these conclusively to an individual characteristic of the food can therefore be extremely difficult. If the characterization of the food indicates that the available data are insufficient for a thorough safety assessment, properly designed animal studies could be requested on the whole foods. Another consideration in deciding the need for animal studies is whether it is appropriate to subject experimental animals to such a study if it is unlikely to give rise to meaningful information.	適切に計画された動物試験が必要とされる場合もある。動物試験の必要性を判断する際に考慮すべきもう１つの事項は、有意義な情報を生み出す可能性が低い場合に、動物をこうした試験に使用することが妥当であるかどうかということである。
12. Due to the difficulties of applying traditional toxicological testing and risk assessment procedures to whole foods, a more focused approach is required for the safety assessment of foods derived from food plants, including recombinant-DNA plants. This has been addressed by the development of a multidisciplinary approach for assessing safety which takes into account both intended and unintended changes that may occur in the plant or in the foods derived from it, using the concept of substantial equivalence.	12. Due to the difficulties of applying traditional toxicological testing and risk assessment procedures to whole foods, a more focused approach is required for the safety assessment of foods derived from food plants, including recombinant-DNA plants. This has been addressed by the development of a multidisciplinary approach for assessing safety which takes into account both intended and unintended changes that may occur in the plant or in the foods derived from it, using the concept of substantial equivalence.	12. 丸ごとの食品に従来の毒性学試験およびリスク評価過程を適用することは困難であるため、組換え DNA 植物を含む食用植物由来の食品の安全性評価には的を絞ったアプローチが必要である。この問題については、実質的同等性の概念を使用して、植物あるいは植物由来食品中に生じうる意図的または非意図的変化の両方を考慮した安全性評価のための学際的アプローチを開発して対応してきた。
13. The concept of substantial equivalence is a key step in the safety assessment process. However, it is not a safety assessment in itself; rather it	13. The concept of substantial equivalence is a key step in the safety assessment process. However, it is not a safety assessment in itself; rather it	13. 実質的同等性の概念は、安全性評価過程の重要な段階である。しかしこれは安全性評価自体ではなく、むしろ既存の対応物との比較に基づいて新しい食品の安全性評価を構築する

represents the starting point which is used to structure the safety assessment of a new food relative to its conventional counterpart. This concept is used to identify similarities and differences between the new food and its conventional counterpart2. It aids in the identification of potential safety and nutritional issues and is considered the most appropriate strategy to date for safety assessment of foods derived from recombinant-DNA plants. The safety assessment carried out in this way does not imply absolute safety of the new product; rather, it focuses on assessing the safety of any identified differences so that the safety of the new product can be considered relative to its conventional counterpart.	represents the starting point which is used to structure the safety assessment of a new food relative to its conventional counterpart. This concept is used to identify similarities and differences between the new food and its conventional counterpart2. It aids in the identification of potential safety and nutritional issues and is considered the most appropriate strategy to date for safety assessment of foods derived from recombinant-DNA plants. The safety assessment carried out in this way does not imply absolute safety of the new product; rather, it focuses on assessing the safety of any identified differences so that the safety of the new product can be considered relative to its conventional counterpart.	ために用いる出発点である。この概念は、新しい食品と既存の対応物との類似性及び相違性の同定に用いる 2。これは安全性や栄養学的な問題点の特定に役立ち、現時点では組換え DNA 植物由来食品の安全性評価に最適な方法と考えられている。このようにして実施される安全性評価は新製品の絶対的安全性を示すものではなく、同定された相違の安全性を評価することに焦点を当てて新製品の安全性を既存の対応物との比較の上で検討できるようにするものである。
UNINTENDED EFFECTS	UNINTENDED EFFECTS	非意図的な影響
14. In achieving the objective of conferring a specific target trait (intended effect) to a plant by the insertion of defined DNA sequences, additional traits could, in some cases, be acquired or existing traits could be lost or modified (unintended effects). The potential occurrence of unintended effects is not restricted to the use of in vitro nucleic acid techniques. Rather, it is an inherent and general phenomenon that can also occur in conventional breeding. Unintended effects may be deleterious,	14. In achieving the objective of conferring a specific target trait (intended effect) to a plant by the insertion of defined DNA sequences, additional traits could, in some cases, be acquired or existing traits could be lost or modified (unintended effects). The potential occurrence of unintended effects is not restricted to the use of in vitro nucleic acid techniques. Rather, it is an inherent and general phenomenon that can also occur in conventional breeding. Unintended effects may be deleterious,	14. 確認済みの DNA 配列の挿入により植物に特定の形質（意図的な影響）を与えるという目的を達成するに当たって、余分な形質が得られたり、既存の形質が失われたり修飾される場合がある（非意図的な影響）。非意図的影響が発生する可能性は、インビトロ核酸技術の使用に限ったことではなく、従来の育種においても発生し得る一般的現象である。非意図的な影響は、植物の健全性または植物由来食品の安全性について有害であったり、有益であったり、またはどちらでもない可能性がある。組換え DNA 植物における非意図的な影響は、DNA 配列の挿入によって起きることもあ

beneficial, or neutral with respect to the health of the plant or the safety of foods derived from the plant. Unintended effects in recombinant-DNA plants may also arise through the insertion of DNA sequences and/or they may arise through subsequent conventional breeding of the recombinant-DNA plant. Safety assessment should include data and information to reduce the possibility that a food derived from a recombinant-DNA plant would have an unexpected, adverse effect on human health.	beneficial, or neutral with respect to the health of the plant or the safety of foods derived from the plant. Unintended effects in recombinant-DNA plants may also arise through the insertion of DNA sequences and/or they may arise through subsequent conventional breeding of the recombinant-DNA plant. Safety assessment should include data and information to reduce the possibility that a food derived from a recombinant-DNA plant would have an unexpected, adverse effect on human health.	れば、組換え後の従来の育種を通じて起きることもある。安全性評価には、組換え DNA 植物由来食品がヒトの健康に対し予期せぬ有害影響を与える可能性を最低限に抑えるためのデータ及び情報が含まれるべきである。
15. Unintended effects can result from the random insertion of DNA sequences into the plant genome which may cause disruption or silencing of existing genes, activation of silent genes, or modifications in the expression of existing genes. Unintended effects may also result in the formation of new or changed patterns of metabolites. For example, the expression of enzymes at high levels may give rise to secondary biochemical effects or changes in the regulation of metabolic pathways and/or altered levels of metabolites.	15. Unintended effects can result from the random insertion of DNA sequences into the plant genome which may cause disruption or silencing of existing genes, activation of silent genes, or modifications in the expression of existing genes. Unintended effects may also result in the formation of new or changed patterns of metabolites. For example, the expression of enzymes at high levels may give rise to secondary biochemical effects or changes in the regulation of metabolic pathways and/or altered levels of metabolites.	15. 植物ゲノムへ DNA 配列を無作為に挿入することによって非意図的な影響が生じ、既存の遺伝子の攪乱またはサイレント化（沈黙化）、サイレント遺伝子の活性化、既存の遺伝子の発現の変化などを引き起こす場合もある。非意図的な影響によって、代謝産物の構成パターンが新しく形成されたり変化したりする可能性もある。例えば、高濃度の酵素が発現すると二次的な生化学的影響が現れたり、代謝経路の調節機能が変化したり、代謝産物量が変化する可能性がある。
16. Unintended effects due to genetic modification may be subdivided into two groups: those that are "predictable" and those that are "unexpected". Many unintended effects are largely	16. Unintended effects due to genetic modification may be subdivided into two groups: those that are "predictable" and those that are "unexpected". Many unintended effects are largely	16. 遺伝子組換えによる非意図的な影響は、次の 2 種類に分けることができる。「予測可能な」影響と「予期せぬ」影響である。多くの非意図的な影響は、挿入された形質およびその代謝的な関連、または挿入部位が分かれば大部

predictable based on knowledge of the inserted trait and its metabolic connections or of the site of insertion. Due to the expanding information on plant genome and the increased specificity in terms of genetic materials introduced through recombinant-DNA techniques compared with other forms of plant breeding, it may become easier to predict unintended effects of a particular modification. Molecular biological and biochemical techniques can also be used to analyse potential changes at the level of gene transcription and message translation that could lead to unintended effects.	predictable based on knowledge of the inserted trait and its metabolic connections or of the site of insertion. Due to the expanding information on plant genome and the increased specificity in terms of genetic materials introduced through recombinant-DNA techniques compared with other forms of plant breeding, it may become easier to predict unintended effects of a particular modification. Molecular biological and biochemical techniques can also be used to analyse potential changes at the level of gene transcription and message translation that could lead to unintended effects.	分が予測可能である。植物ゲノムに関する知識が増大しており、また他の植物育種形態と比較して組換え DNA 技術によって導入された遺伝物質に関する特異性が高まっていることにより、特定の修飾による非意図的な影響の予測が容易になる可能性がある。分子生物学および生化学技術を利用して、非意図的な影響を生じる可能性のある、遺伝子転写およびメッセージ翻訳における変化を解析することができる。
17. The safety assessment of foods derived from recombinant-DNA plants involves methods to identify and detect such unintended effects and procedures to evaluate their biological relevance and potential impact on food safety. A variety of data and information are necessary to assess unintended effects because no individual test can detect all possible unintended effects or identify, with certainty, those relevant to human health. These data and information, when considered in total, provide assurance that the food is unlikely to have an adverse effect on human health. The assessment for unintended effects takes into account the agronomic/phenotypic	17. The safety assessment of foods derived from recombinant-DNA plants involves methods to identify and detect such unintended effects and procedures to evaluate their biological relevance and potential impact on food safety. A variety of data and information are necessary to assess unintended effects because no individual test can detect all possible unintended effects or identify, with certainty, those relevant to human health. These data and information, when considered in total, provide assurance that the food is unlikely to have an adverse effect on human health. The assessment for unintended effects takes into account the agronomic/phenotypic	17. 組換え DNA 植物由来食品の安全性評価には、このような非意図的な影響を同定・検出する方法と、それらの生物学的関連ならびに食品の安全性に対する影響を評価する手法が含まれる。個別の試験で、起こりうる非意図的な影響を全て検出しまたはヒトの健康に対するそれらの関性を確実に同定することはできないので、非意図的な影響の評価には多様なデータと情報が必要である。こうしたデータや情報は、総合的な検討を行うことにより、当該食品がヒトの健康に有害な影響を与える可能性が低いことを保証するものであるべきである。非意図的な影響の評価に際しては、商品化に向けての新種の選択にあたり育種家が一般的に注目している植物の作物学的・表現型特性を考慮する。育種家によるこのような注目は、非意図的な形質を示す植物に対する

characteristics of the plant that are typically observed by breeders in selecting new varieties for commercialization. These observations by breeders provide a first screen for plants that exhibit unintended traits. New varieties that pass this screen are subjected to safety assessment as described in Sections 4 and 5.

FRAMEWORK OF FOOD SAFETY ASSESSMENT

18. The safety assessment of a food derived from a recombinant-DNA plant follows a stepwise process of addressing relevant factors that include:
    A) Description of the recombinant-DNA plant;
    B) Description of the host plant and its use as food;
    C) Description of the donor organism(s);
    D) Description of the genetic modification(s);
    E) Characterization of the genetic modification(s);
    F) Safety assessment:
        a) expressed substances (non-nucleic acid substances);
        b) compositional analyses of key components;
        c) evaluation of metabolites ;
        d) food processing;
        e) nutritional modification; and
    G) Other considerations.

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FRAMEWORK OF FOOD SAFETY ASSESSMENT

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    F) Safety assessment:
        a) expressed substances (non-nucleic acid substances);
        b) compositional analyses of key components;
        c) evaluation of metabolites ;
        d) food processing;
        e) nutritional modification; and
    G) Other considerations.

予備的なスクリーニングとなる。このようなスクリーニングを通過した新種には、セクション 4 および 5 に記述した安全性評価が課せられる。

食品安全性評価の枠組み

18. 組換え DNA 植物由来食品の安全性評価は、以下を含む関連要因に対応する段階的過程に従って実施する。
    A) 組換え DNA 植物の概要
    B) 宿主植物とその食品としての使用についての概要
    C) （遺伝子）供与体の概要
    D) 遺伝子組換えの概要
    E) 遺伝子組換えの特徴の明示
    F) 安全性評価
        a) 発現物質（非核酸物質）
        b) 主要成分の組成分析
        c) 代謝産物の評価
        d) 食品加工
        e) 栄養的修飾
    G) その他の検討事項

19. In certain cases, the characteristics of the product may necessitate development of additional data and information to address issues that are unique to the product under review.	19. In certain cases, the characteristics of the product may necessitate development of additional data and information to address issues that are unique to the product under review.	19. 特定の場合には、製品の特徴によっては、検討中の製品に固有の問題点に対処するために、データ・情報を更に整備することが必要となる場合がある。
20. Experiments intended to develop data for safety assessments should be designed and conducted in accordance with sound scientific concepts and principles, as well as, where appropriate, Good Laboratory Practice. Primary data should be made available to regulatory authorities at request. Data should be obtained using sound scientific methods and analysed using appropriate statistical techniques. The sensitivity of all analytical methods should be documented.	20. Experiments intended to develop data for safety assessments should be designed and conducted in accordance with sound scientific concepts and principles, as well as, where appropriate, Good Laboratory Practice. Primary data should be made available to regulatory authorities at request. Data should be obtained using sound scientific methods and analysed using appropriate statistical techniques. The sensitivity of all analytical methods should be documented.	20. 安全性評価のためのデータの整備を目的とする試験は、科学的に信頼できる概念と原則に従うと共に、必要に応じ GLP に従って計画・実施すべきである。一次データは、要求があれば規制当局が利用できるようにすべきである。データは科学的に信頼できる方法を用いて入手し、適切な統計学的技術を用いて解析すべきである。分析方法には全て感度が示されるべきである。
21. The goal of each safety assessment is to provide assurance, in the light of the best available scientific knowledge, that the food does not cause harm when prepared, used and/or eaten according to its intended use. The expected endpoint of such an assessment will be a conclusion regarding whether the new food is as safe as the conventional counterpart taking into account dietary impact of any changes in nutritional content or value. In essence, therefore, the outcome of the safety assessment process is to define the product under	21. The goal of each safety assessment is to provide assurance, in the light of the best available scientific knowledge, that the food does not cause harm when prepared, used and/or eaten according to its intended use. The expected endpoint of such an assessment will be a conclusion regarding whether the new food is as safe as the conventional counterpart taking into account dietary impact of any changes in nutritional content or value. In essence, therefore, the outcome of the safety assessment process is to define the product under	21. 安全性評価の最終目標は、利用できる最善の科学的知識に照らして、その食品が意図する用途に従って調理・使用・摂取された場合は有害とならないことを保証することである。こうした評価において期待される指標は、栄養成分含量や栄養価の変化が食事に及ぼす影響を考慮し、新規食品が既存の対応物と同様に安全であるかどうかに関する判定である。従って本質的には、安全性評価過程の結果は、リスク管理者が何らかの措置が必要かどうかを判断することができ、必要な場合には十分な情報を与えられた上で適切な決定を下すことができる方法で、検討中の製品を定義することである。

consideration in such a way as to enable risk managers to determine whether any measures are needed and if so to make well-informed and appropriate decisions.	consideration in such a way as to enable risk managers to determine whether any measures are needed and if so to make well-informed and appropriate decisions.	
SECTION 4 - GENERAL CONSIDERATIONS DESCRIPTION OF THE RECOMBINANTDNA PLANT 22. A description of the recombinant-DNA plant being presented for safety assessment should be provided. This description should identify the crop, the transformation event(s) to be reviewed and the type and purpose of the modification. This description should be sufficient to aid in understanding the nature of the food being submitted for safety assessment.	SECTION 4 - GENERAL CONSIDERATIONS DESCRIPTION OF THE RECOMBINANT-DNA PLANT 22. A description of the recombinant-DNA plant being presented for safety assessment should be provided. This description should identify the crop, the transformation event(s) to be reviewed and the type and purpose of the modification. This description should be sufficient to aid in understanding the nature of the food being submitted for safety assessment.	セクション 4-一般的検討事項 組換え DNA 植物の概要 22. 安全性評価の対象となる組換え DNA 植物に関する概要説明が必要である。この説明では、作物、対象となる形質転換、組換えの種類と目的を明らかにすべきである。また、安全性評価の対象となる食品の特質を理解する上で役立つものあるべきである。
DESCRIPTION OF THE HOST PLANT AND ITS USE AS FOOD 23. A comprehensive description of the host plant should be provided. The necessary data and information should include, but need not be restricted to: A) common or usual name; scientific name; and, taxonomic classification; B) history of cultivation and development through breeding, in particular identifying traits that may adversely impact on human health ; C) information on the host plant's genotype and phenotype relevant to its safety, including any known toxicity or allergenicity; and	DESCRIPTION OF THE HOST PLANT AND ITS USE AS FOOD 23. A comprehensive description of the host plant should be provided. The necessary data and information should include, but need not be restricted to: A) common or usual name; scientific name; and, taxonomic classification; B) history of cultivation and development through breeding, in particular identifying traits that may adversely impact on human health ; C) information on the host plant's genotype and phenotype relevant to its safety, including any known toxicity or allergenicity; and	宿主植物とその食品としての利用に関する概要 23. 宿主植物に関する包括的概要説明が必要である。以下のデータ・情報が必要とされるが、これに限定されない。 A) 一般名または通称、学名、分類学上の分類 B) 育種を通じた栽培・開発の経緯 特に、ヒトの健康に有害影響を及ぼす可能性のある形質の特定 C) 既知の毒性またはアレルギー誘発性を含む安全性に関わる宿主植物の遺伝子型と表現型に関する情報 D) 食品として安全に消費されてきた履歴

D) history of safe use for consumption as food.	D) history of safe use for consumption as food.	
24. Relevant phenotypic information should be provided not only for the host plant, but also for related species and for plants that have made or may make a significant contribution to the genetic background of the host plant.	24. Relevant phenotypic information should be provided not only for the host plant, but also for related species and for plants that have made or may make a significant contribution to the genetic background of the host plant.	24. 宿主植物だけでなく関連種や、宿主植物の遺伝的背景に大きく寄与した、またはその可能性のある植物に関しても表現型情報を示すべきである。
25. The history of use may include information on how the plant is typically cultivated, transported and stored, whether special processing is required to make the plant safe to eat, and the plant's normal role in the diet (e.g. which part of the plant is used as a food source, whether its consumption is important in particular subgroups of the population, what important macro- or micro-nutrients it contributes to the diet).	25. The history of use may include information on how the plant is typically cultivated, transported and stored, whether special processing is required to make the plant safe to eat, and the plant's normal role in the diet (e.g. which part of the plant is used as a food source, whether its consumption is important in particular subgroups of the population, what important macro- or micro-nutrients it contributes to the diet).	25. 使用歴には、その植物が一般的にどのように栽培・輸送・保管されるのか、その植物を食料として安全なものとするために特殊な加工が必要か否か、その植物の食事における通常的な役割（例えば、植物のどの部分を食品原料として使用するか、その摂取が人口の内の特定の集団にとって重要なものか、それが食事に対してどのような重要な主要・微量栄養素を供給するか）に関する情報が含まれる場合がある。
DESCRIPTION OF THE DONORORGANISMS	DESCRIPTION OF THE DONOR ORGANISM(S)	（遺伝子）供与体についての概要
26. Information should be provided on the donor organism(s) and, when appropriate, on other related spieces. It is particularly important to determine if the donor organism(s) or other closely related members of the family naturally exhibit characteristics of pathogenicity or toxin production, or have other traits that affect human health (e.g. presence of antinutrients). The description of the	26. Information should be provided on the donor organism(s) and, when appropriate, on other related species. It is particularly important to determine if the donor organism(s) or other closely related members of the family naturally exhibit characteristics of pathogenicity or toxin production, or have other traits that affect human health (e.g. presence of anti-nutrients). The description of	26. 供与体に関する情報及び、必要に応じてその他の関連する種についての情報も示すべきである。供与体または同一科の中の密接に関係する他の生物が、自然の状態で病原性や毒産生といった特徴を示すかどうか、ヒトの健康に影響を与える何らかの形質を有するかどうか（抗栄養素の存在など）を判断することが特に重要である。供与体についての概要には以下の事項が含まれるべきである。 A) 通称または一般名

donor organism(s) should include: A) its usual or common name; B) scientific name; C) taxonomic classification; D) information about the natural history as concerns food safety; E) information on naturally occurring toxins, anti-nutrients and allergens; for microorganisms, additional information on pathogenicity and the relationship to known pathogens; and F) information on the past and present use, if any, in the food supply and exposure route(s) other than intended food use (e.g. possible presence as contaminants).	the donor organism(s) should include: A) its usual or common name; B) scientific name; C) taxonomic classification; D) information about the natural history as concerns food safety; E) information on naturally occurring toxins, anti-nutrients and allergens; for microorganisms, additional information on pathogenicity and the relationship to known pathogens; and F) information on the past and present use, if any, in the food supply and exposure route(s) other than intended food use (e.g. possible presence as contaminants).	B) 学名 C) 分類学上の分類 D) 食品の安全性に関わる自然な状態でのその植物の歴史についての情報 E) 自然に存在する毒素、抗栄養素およびアレルゲンに関する情報 微生物については、病原性に関する追加情報および既知の病原体との関係 F) 過去および現在の食品としての使用に関する情報、食用以外の曝露経路（たとえば汚染物質として存在する可能性）
DESCRIPTION OF THE GENETIC MODIFICATIONS) 27. Sufficient information should be provided on the genetic modification to allow for the identification of all genetic material potentially delivered to the host plant and to provide the necessary information for the analysis of the data supporting the characterization of the DNA inserted in the plant.	DESCRIPTION OF THE GENETIC MODIFICATION(S) 27. Sufficient information should be provided on the genetic modification to allow for the identification of all genetic material potentially delivered to the host plant and to provide the necessary information for the analysis of the data supporting the characterization of the DNA inserted in the plant.	遺伝子組換えの概要 27. 宿主植物に伝達された可能性のあるすべての遺伝物質の同定を考慮し、植物に挿入されたDNA の特徴付けを裏付けるデータを解析するために必要な情報を示すために、遺伝子組換えに関する十分な情報が提示されるべきである。
28. The description of the transformation process should include: A) information on the specific method used for the transformation (e.g. Agrobacterium-mediated transformation);	28. The description of the transformation process should include: A) information on the specific method used for the transformation (e.g. Agrobacterium-mediated transformation);	28. 形質転換過程の概要には、以下の事項が含まれるべきである。 A) 形質転換に使用した特定の方法に関する情報（たとえばアグロバクテリウム媒介転換） B) 妥当な場合は、起源（植物、微生物、ウイ

B) information, if applicable, on the DNA used to modify the plant (e.g. helper plasmids), including the source (e.g. plant, microbial, viral , synthetic), identity and expected function in the plant; and C) intermediate host organisms including the organisms (e.g. bacteria) used to produce or process DNA for transformation of the host organism;	B) information, if applicable, on the DNA used to modify the plant (e.g. helper plasmids), including the source (e.g. plant, microbial, viral, synthetic), identity and expected function in the plant; and C) intermediate host organisms including the organisms (e.g. bacteria) used to produce or process DNA for transformation of the host organism.	ルス、合成)、本質、その植物において期待される機能を等、植物の組換えに使用した DNA（たとえばヘルパープラスミドなど）に関する情報 C) 宿主生物の形質転換のための DNA の産生または加工に使用した生物（細菌など）など中間宿主生物
29. Information should be provided on the DNA to be introduced, including: A) the characterization of all the genetic components including marker genes, regulatory and other elements affecting the function of the DNA; B) the size and identity; C) the location and orientation of the sequence in the final vector/construct; and D) the function.	29. Information should be provided on the DNA to be introduced, including: A) the characterization of all the genetic components including marker genes, regulatory and other elements affecting the function of the DNA; B) the size and identity; C) the location and orientation of the sequence in the final vector/construct; and D) the function.	29. 以下をはじめとする導入 DNA に関する情報を提示すべきである。 A) マーカー遺伝子、DNA の機能に影響を及ぼす調整及びその他の要因を含み、すべての遺伝的構成成分の特徴評価 B) サイズと同定 C) 最終ベクター・構成体における配列の位置と方向 D) 機能
CHARACTERIZATION OF THE GENETIC MODIFICATIONS)	CHARACTERIZATION OF THE GENETIC MODIFICATION(S)	遺伝的組換えの特徴の明示
30. In order to provide clear understanding of the impact on the composition and safety of foods derived from recombinant-DNA plants, a comprehensive molecular and biochemical characterization of the genetic modification should be carried out.	30. In order to provide clear understanding of the impact on the composition and safety of foods derived from recombinant-DNA plants, a comprehensive molecular and biochemical characterization of the genetic modification should be carried out.	30. 組換え DNA 植物に由来する食品の組成と安全性に対する影響に関し、明確な理解に資するため、遺伝的組換えの分子的・生化学的特徴付けを包括的に行なう必要がある。
31. Information should be provided on the DNA	31. Information should be provided on the DNA	31. 植物ゲノムへの DNA 挿入に関する情報を提

insertions into the plant genome; this should include: A) the characterization and description of the inserted genetic materials; B) the number of insertion sites; C) the organisation of the inserted genetic material at each insertion site including copy number and sequence data of the inserted material and of the surrounding region, sufficient to identify any substances expressed as a consequence of the inserted material, or, where more appropriate, other information such as analysis of transcripts or expression products to identify any new substances that may be present in the food; and D) identification of any open reading frames within the inserted DNA or created by the insertions with contiguous plant genomic DNA including those that could result in fusion proteins.	insertions into the plant genome; this should include: A) the characterization and description of the inserted genetic materials; B) the number of insertion sites; C) the organisation of the inserted genetic material at each insertion site including copy number and sequence data of the inserted material and of the surrounding region, sufficient to identify any substances expressed as a consequence of the inserted material, or, where more appropriate, other information such as analysis of transcripts or expression products to identify any new substances that may be present in the food; and D) identification of any open reading frames within the inserted DNA or created by the insertions with contiguous plant genomic DNA including those that could result in fusion proteins.	供すべきであり、これには以下の事項が含まるべきである。 A) 挿入遺伝物質の特徴付けと説明 B) 挿入部位の数 C) 挿入物質および周辺領域のコピー数および配列データを含み、挿入の結果発現した物質を同定するために十分な、各挿入場所での挿入遺伝物質の構成。更に適切な場合は、食品に含まれる可能性のある新物質を同定するために、適宜転写や発現産物の解析などの情報も示す。 D) 挿入 DNA 内にあるか、融合タンパク質を生じる可能性のあるものを含めて隣接する植物ゲノム DNA の挿入によって生成したオープンリーディングフレーム（open reading frame）の同定
32. Information should be provided on any expressed substances in the recombinant-DNA plant; this should include: A) the gene product(s) (e.g. a protein or an untranslated RNA); B) the gene product(s)' function; C) the phenotypic description of the new trait(s); D) the level and site of expression in	32. Information should be provided on any expressed substances in the recombinant-DNA plant; this should include: A) the gene product(s) (e.g. a protein or an untranslated RNA); B) the gene product(s)' function; C) the phenotypic description of the new trait(s); D) the level and site of expression in	32. 組換え DNA 植物において発現した物質に関する情報は全て示すべきである。これには次の事項が含まれるべきである。 A) 遺伝子産物（タンパク質や非翻訳 RNA など） B) 遺伝子産物の機能 C) 新しい形質の表現型の説明 D) 植物中の発現遺伝子産物の発現量と部位、植物特に食用部位における代謝産物の量

the plant of the expressed gene product(s), and the levels of its metabolites in the plant, particularly in the edible portions; and E) where possible, the amount of the target gene product(s) if the function of the expressed sequence(s)/gene(s) is to alter the accumulation of a specific endogenous mRNA or protein.	the plant of the expressed gene product(s), and the levels of its metabolites in the plant, particularly in the edible portions; and E) where possible, the amount of the target gene product(s) if the function of the expressed sequence(s)/gene(s) is to alter the accumulation of a specific endogenous mRNA or protein.	E) 発現配列・遺伝子の機能が、特定の内在性の mRNA あるいはタンパク質の蓄積を変化させるものである場合、可能な範囲で標的遺伝子産物の量
33. In addition, information should be provided: A) to demonstrate whether the arrangement of the genetic material used for insertion has been conserved or whether significant rearrangements have occurred upon integration; B) to demonstrate whether deliberate modifications made to the amino acid sequence of the expressed protein result in changes in its post-translational modification or affect sites critical for its structure or function; C) to demonstrate whether the intended effect of the modification has been achieved and that all expressed traits are expressed and inherited in a manner that is stable through several generations consistent with laws of inheritance. It may be necessary to examine the inheritance	33. In addition, information should be provided: A) to demonstrate whether the arrangement of the genetic material used for insertion has been conserved or whether significant rearrangements have occurred upon integration; B) to demonstrate whether deliberate modifications made to the amino acid sequence of the expressed protein result in changes in its post-translational modification or affect sites critical for its structure or function; C) to demonstrate whether the intended effect of the modification has been achieved and that all expressed traits are expressed and inherited in a manner that is stable through several generations consistent with laws of inheritance. It may be necessary to examine the inheritance	33. さらに、以下を目的として情報を提供すべきである。 A) 挿入に使用された遺伝物質の配列が保持されているかどうか、あるいは組み込みによって大幅な配列の転換が生じたか否かを示す。 B) 発現タンパク質のアミノ酸配列を意図的に修飾することによって、翻訳後の修飾に変化が生じたり、構造・機能に不可欠な部位に影響を与えるかどうかを示す。 C) 組換えによって意図された効果が達成されたかどうか、または全ての発現形質が発現され遺伝の法則に従って何世代かに渡って安定した状態で受け継がれていることを示す。表現型の特徴が直接計測できない場合は、挿入 DNA そのものの継承あるいは対応する RNA 発現について調べる必要がある場合もある。 D) 新たに発現した形質が、対応する遺伝子の発現を促進する関連した調節配列に一致した方法および量において、しかるべき組織内で期待通りに発現しているかどう

of the DNA insert itself or the expression of the corresponding RNA if the phenotypic characteristics cannot be measured directly; D) to demonstrate whether the newly expressed trait(s) are expressed as expected in the appropriate tissues in a manner and at levels that are consistent with the associated regulatory sequences driving the expression of the corresponding gene; E) to indicate whether there is any evidence to suggest that one or several genes in the host plant has been affected by the transformation process; and F) to confirm the identity and expression pattern of any new fusion proteins.	of the DNA insert itself or the expression of the corresponding RNA if the phenotypic characteristics cannot be measured directly; D) to demonstrate whether the newly expressed trait(s) are expressed as expected in the appropriate tissues in a manner and at levels that are consistent with the associated regulatory sequences driving the expression of the corresponding gene; E) to indicate whether there is any evidence to suggest that one or several genes in the host plant has been affected by the transformation process; and F) to confirm the identity and expression pattern of any new fusion proteins.	かを示す。 E) 宿主植物内の１つまたは複数の遺伝子が、形質転換過程の影響を受けたことを示唆する根拠があるかどうかを示す。 F) 新規の融合タンパク質の本質および発現パターンを確認する。
SAFETY ASSESSMENT Expressed Substances (non-nucleic acid substances) Assessment of possible toxicity	SAFETY ASSESSMENT Expressed Substances (non-nucleic acid substances) Assessment of possible toxicity	安全性評価 発現物質（非核酸物質） 毒性評価
34. In vitro nucleic acid techniques enable the introduction of DNA that can result in the synthesis of new substances in plants. The new substances can be conventional components of plant foods such as proteins, fats, carbohydrates, vitamins which are novel in the context of that recombinant-DNA plant. New substances might also include new metabolites resulting from the activity	34. In vitro nucleic acid techniques enable the introduction of DNA that can result in the synthesis of new substances in plants. The new substances can be conventional components of plant foods such as proteins, fats, carbohydrates, vitamins which are novel in the context of that recombinant-DNA plant. New substances might also include new metabolites resulting from the activity	34. インビトロ核酸技術によって DNA の導入が可能になり、植物内で新規物質を合成することができるようになる。新物質は、組換え DNA 植物においては新規物質でも、タンパク質・脂肪・炭水化物・ビタミンなど食用植物の通常成分である場合もある。新物質には、導入 DNA の発現により生成した酵素の活性に由来する新代謝産物も含まれる場合がある。

of enzymes generated by the expression of the introduced DNA.	of enzymes generated by the expression of the introduced DNA.	
35. The safety assessment should take into account the chemical nature and function of the newly expressed substance and identify the concentration of the substance in the edible parts of the recombinant-DNA plant, including variations and mean values. Current dietary exposure and possible effects on population sub-groups should also be considered.	35. The safety assessment should take into account the chemical nature and function of the newly expressed substance and identify the concentration of the substance in the edible parts of the recombinant-DNA plant, including variations and mean values. Current dietary exposure and possible effects on population sub-groups should also be considered.	35. 安全性評価では、新発現物質の化学的性質や機能を考慮に入れ、組換え DNA 植物の可食部分における物質濃度を変動や平均値を含めて特定すべきである。現在の、母集団中の小グループに対する食事由来の曝露とその影響を検討すべきである。
36. Information should be provided to ensure that genes coding for known toxins or anti-nutrients present in the donor organisms are not transferred to recombinant-DNA plants that do not normally express those toxic or anti-nutritious characteristics. This assurance is particularly important in cases where a recombinant-DNA plant is processed differently from a donor plant, since conventional food processing techniques associated with the donor organisms may deactivate, degrade or eliminate anti-nutrients or toxicants.	36. Information should be provided to ensure that genes coding for known toxins or anti-nutrients present in the donor organisms are not transferred to recombinant-DNA plants that do not normally express those toxic or anti-nutritious characteristics. This assurance is particularly important in cases where a recombinant-DNA plant is processed differently from a donor plant, since conventional food processing techniques associated with the donor organisms may deactivate, degrade or eliminate anti-nutrients or toxicants.	36. 供与体に存在する既知の毒素または抗栄養素を合成するコードを指定する遺伝子が、通常はそうした毒性または抗栄養的特性を発現しない組換え DNA 植物に伝達されていないことを立証する情報を示すべきである。供与体に関わる従来の食品加工技術は、抗栄養素または毒素を不活性化し、劣化させまたは排除する可能性があるため、組換え DNA 植物に供与植物とは異なる加工を施す場合は特に、これを保証することが重要である。
37. For the reasons described in Section 3, conventional toxicology studies may not be considered necessary where the substance or a closely related substance has, taking into account its function and	37. For the reasons described in Section 3, conventional toxicology studies may not be considered necessary where the substance or a closely related substance has, taking into account its function and	37. セクション 3 に示した理由により、当該物質または密接に関連する物質が機能と曝露に基づき食品において安全に消費されている場合は、従来の毒性学試験は必要ない場合がある。その他の場合は、新物質について適切な従来

exposure, been consumed safely in food. In other cases, the use of appropriate conventional toxicology or other studies on the new substance may be necessary.	exposure, been consumed safely in food. In other cases, the use of appropriate conventional toxicology or other studies on the new substance may be necessary.	の毒性学またはその他の試験が必要な場合もある。
38. In the case of proteins, the assessment of potential toxicity should focus on amino acid sequence similarity between the protein and known protein toxins and anti-nutrients (e.g. protease inhibitors, lectins) as well as stability to heat or processing and to degradation in appropriate representative gastric and intestinal model systems. Appropriate oral toxicity studies3 may need to be carried out in cases where the protein present in the food is not similar to proteins that have previously been consumed safely in food, and taking into account its biological function in the plant where known.	38. In the case of proteins, the assessment of potential toxicity should focus on amino acid sequence similarity between the protein and known protein toxins and anti-nutrients (e.g. protease inhibitors, lectins) as well as stability to heat or processing and to degradation in appropriate representative gastric and intestinal model systems. Appropriate oral toxicity studies3 may need to be carried out in cases where the protein present in the food is not similar to proteins that have previously been consumed safely in food, and taking into account its biological function in the plant where known.	38. タンパク質の場合、潜在的な毒性に関する評価では、当該タンパク質と既知のタンパク質毒素や抗栄養素（プロテアーゼ阻害因子、レクチンなど）におけるアミノ酸配列類似性ならびに熱・加工安定性や適切な代表的な消化系モデルにおける分解に対する安定性に注目すべきである。食品に含まれるタンパク質がこれまで食品において安全に消費されてきたタンパク質と類似ではない場合は、分かっている範囲で植物の生物学的機能を考慮に入れて、適切な経口毒性試験 3 を実施する必要がある場合もある。
39. Potential toxicity of non-protein substances that have not been safely consumed in food should be assessed on a case-by-case basis depending on the identity and biological function in the plant of the substance and dietary exposure. The type of studies to be performed may include studies on metabolism, toxicokinetics, sub-chronic toxicity, chronic toxicity/carcinogenicity, reproduction and development toxicity according to the	39. Potential toxicity of non-protein substances that have not been safely consumed in food should be assessed on a case-by-case basis depending on the identity and biological function in the plant of the substance and dietary exposure. The type of studies to be performed may include studies on metabolism, toxicokinetics, sub-chronic toxicity, chronic toxicity/carcinogenicity, reproduction and development toxicity according to the	39. これまで食品において安全に消費されたことがない非タンパク物質の毒性は、植物中での当該物質の本質と生物学的機能および食事由来の曝露に基づき個別に評価すべきである。実施すべき試験の種類には、従来の毒性学的手法に従い、代謝物、毒性動態、亜慢性毒性、慢性毒性、発癌性、生殖・発生毒性に関する試験などが含まれる。

traditional toxicological approach.	traditional toxicological approach.	
40. This may require the isolation of the new substance from the recombinant-DNA plant, or the synthesis or production of the substance from an alternative source, in which case, the material should be shown to be biochemically, structurally, and functionally equivalent to that produced in the recombinant-DNA plant.	40. This may require the isolation of the new substance from the recombinant-DNA plant, or the synthesis or production of the substance from an alternative source, in which case, the material should be shown to be biochemically, structurally, and functionally equivalent to that produced in the recombinant-DNA plant.	40. 安全性評価では、組換え DNA 植物に由来する新物質の分離または起源が異なる物質の合成や生成が必要な場合もあり、その際は物質が生化学的・構造的・機能的に組換え DNA 植物で生成されたものと同じであることを証明すべきである。
Assessment of possible allergenicity (proteins)	Assessment of possible allergenicity (proteins)	アレルギー誘発性の評価（タンパク質）
41. When the protein(s) resulting from the inserted gene is present in the food, it should be assessed for potential allergenicity in all cases. An integrated, stepwise, case-by-case approach used in the assessment of the potential allergenicity of the newly-expressed protein(s) should rely upon various criteria used in combination (since no single criterion is sufficiently predictive on either allergenicity or non-allergenicity). As noted in paragraph 20, the data should be obtained using sound scientific methods. A detailed presentation of issues to be considered can be found in the Annex to this document. 4	41. When the protein(s) resulting from the inserted gene is present in the food, it should be assessed for potential allergenicity in all cases. An integrated, stepwise, case-by-case approach used in the assessment of the potential allergenicity of the newly-expressed protein(s) should rely upon various criteria used in combination (since no single criterion is sufficiently predictive on either allergenicity or non-allergenicity). As noted in paragraph 20, the data should be obtained using sound scientific methods. A detailed presentation of issues to be considered can be found in Annex 1 to this document4.	41. 挿入遺伝子に起因するタンパク質が食品に含まれる場合、いかなる場合もアレルギー誘発性を評価すべきである。新規発現タンパク質のアレルギー誘発性評価で用いる総合的かつ段階的な個別手法は、様々な基準を組み合わせて用いるべきである（1 つの基準ではアレルギー誘発性の有無を十分に判断できないため）。パラグラフ 20 に示したように、データは科学的に信頼できる方法を用いて入手すべきである。検討すべき問題の詳細は本文書の添付資料に示した 4。
42. The newly expressed proteins in foods derived from recombinant-DNA plants should be evaluated for any possible role	42. The newly expressed proteins in foods derived from recombinant-DNA plants should be evaluated for any possible role	42. 導入遺伝物質が小麦・ライ麦・大麦・オート麦その他の穀物に由来する場合は、組換え DNA 植物に由来する食品中に新たに発現した

in the elicitation of gluten-sensitive enteropathy, if the introduced genetic material is obtained from wheat, rye, barley, oats, or related cereal grains.	in the elicitation of gluten-sensitive enteropathy, if the introduced genetic material is obtained from wheat, rye, barley, oats, or related cereal grains.	タンパク質に関して、グルテン過敏症腸疾患の誘出における役割について評価すべきである。
43. The transfer of genes from commonly allergenic foods and from foods known to elicit gluten-sensitive enteropathy in sensitive individuals should be avoided unless it is documented that the transferred gene does not code for an allergen or for a protein involved in gluten-sensitive enteropathy.	43. The transfer of genes from commonly allergenic foods and from foods known to elicit gluten-sensitive enteropathy in sensitive individuals should be avoided unless it is documented that the transferred gene does not code for an allergen or for a protein involved in gluten-sensitive enteropathy.	43. 一般に、アレルギー誘発性食品または過敏な個人に対してグルテン過敏性腸疾患を誘発することが明らかな食品からの遺伝子の伝達は、伝達された遺伝子がアレルゲンまたはグルテン過敏性腸疾患に関与するタンパク質を合成するコードを指定していないことが明記されていない限り避けるべきである。
Compositional Analyses of Key Components	Compositional Analyses of Key Components	主要成分の組成分析
44. Analyses of concentrations of key components5 of the recombinant-DNA plant and, especially those typical of the food, should be compared with an equivalent analysis of a conventional counterpart grown and harvested under the same conditions. In some cases, a further comparison with the recombinant-DNA plant grown under its expected agronomic conditions may need to be considered (e.g. application of an herbicide). The statistical significance of any observed differences should be assessed in the context of the range of natural variations for that parameter to determine its biological significance. The comparator(s) used in this assessment should ideally be the near isogenic parental line. In practice, this may not	44. Analyses of concentrations of key components5 of the recombinant-DNA plant and, especially those typical of the food, should be compared with an equivalent analysis of a conventional counterpart grown and harvested under the same conditions. In some cases, a further comparison with the recombinant-DNA plant grown under its expected agronomic conditions may need to be considered (e.g. application of an herbicide). The statistical significance of any observed differences should be assessed in the context of the range of natural variations for that parameter to determine its biological significance. The comparator(s) used in this assessment should ideally be the near isogenic parental line. In practice, this may not	44. 組換え DNA 植物の主要成分 5、特にその食品の代表的成分の濃度分析は、同じ条件下で栽培し収穫した既存の対応物に関する同等の分析と比較すべきである。期待された栽培条件下で成育した組換え DNA 植物との更なる比較を検討する必要がある場合もある（除草剤の利用など）。生物学的意義を判定するために、観察されるあらゆる相違点の統計学的有意性をパラメータの自然の変動範囲内で評価すべきである。この評価で使用する比較対象は、理想的には、ほぼ同一遺伝系親種であるべきである。実際には、それが常に実現可能であるわけではない。その場合はできる限り近い系統を選択すべきである。曝露評価も併せてこのような比較を必要に応じて行なう目的は、栄養学的に重要であるか、または食品の安全性に影響を与える可能性がある物質が、ヒトの健康に有害影響を及ぼすような方法で改変されていないことを実証するためで

be feasible at all times, in which case a line as close as possible should be chosen. The purpose of this comparison, in conjunction with an exposure assessment as necessary, is to establish that substances that are nutritionally important or that can affect the safety of the food have not been altered in a manner that would have an adverse impact on human health.	be feasible at all times, in which case a line as close as possible should be chosen. The purpose of this comparison, in conjunction with an exposure assessment as necessary, is to establish that substances that are nutritionally important or that can affect the safety of the food have not been altered in a manner that would have an adverse impact on human health.	ある。
45. The location of trial sites should be representative of the range of environmental conditions under which the plant varieties would be expected to be grown. The number of trial sites should be sufficient to allow accurate assessment of compositional characteristics over this range. Similarly, trials should be conducted over a sufficient number of generations to allow adequate exposure to the variety of conditions met in nature. To minimise environmental effects, and to reduce any effect from naturally occurring genotypic variation within a crop variety, each trial site should be replicated. An adequate number of plants should be sampled and the methods of analysis should be sufficiently sensitive and specific to detect variations in key components.	45. The location of trial sites should be representative of the range of environmental conditions under which the plant varieties would be expected to be grown. The number of trial sites should be sufficient to allow accurate assessment of compositional characteristics over this range. Similarly, trials should be conducted over a sufficient number of generations to allow adequate exposure to the variety of conditions met in nature. To minimise environmental effects, and to reduce any effect from naturally occurring genotypic variation within a crop variety, each trial site should be replicated. An adequate number of plants should be sampled and the methods of analysis should be sufficiently sensitive and specific to detect variations in key components.	45. 試験実施施設の立地条件は、多様な植物が生育すると予想されるような環境であるべきである。試験実施施設は、この範囲全体で組成の特徴を正確に評価するのに十分な数が必要である。同様に、自然において様々な条件への曝露が適切に起きるのに十分な世代数にわたって試験を実施すべきである。環境の影響を最小限に抑え、作物の品種内で自然発生的に起こる遺伝子型の変化の影響を抑制するため、各試験施設は同一とすべきある。十分な数の植物をサンプリングし、十分な感度を備え主要成分の変化を特異的に検出する分析方法を用いるべきである。
Evaluation of Metabolites	Evaluation of Metabolites	代謝産物の評価

46. Some recombinant-DNA plants may have been modified in a manner that could result in new or altered levels of various metabolites in the food. Consideration should be given to the potential for the accumulation of metabolites in the food that would adversely affect human health. Safety assessment of such plants requires investigation of residue and metabolite levels in the food and assessment of any alterations in nutrient profile. Where altered residue or metabolite levels are identified in foods, consideration should be given to the potential impacts on human health using conventional procedures for establishing the safety of such metabolites (e.g. procedures for assessing the human safety of chemicals in foods).	46. Some recombinant-DNA plants may have been modified in a manner that could result in new or altered levels of various metabolites in the food. Consideration should be given to the potential for the accumulation of metabolites in the food that would adversely affect human health. Safety assessment of such plants requires investigation of residue and metabolite levels in the food and assessment of any alterations in nutrient profile. Where altered residue or metabolite levels are identified in foods, consideration should be given to the potential impacts on human health using conventional procedures for establishing the safety of such metabolites (e.g. procedures for assessing the human safety of chemicals in foods).	46. 組換え DNA 植物の中には、修飾によって食品中に新規のまたは量の変化した様々な代謝産物が生じるものもある。ヒトの健康に有害影響を及ぼす恐れのある食品における代謝産物の蓄積の可能性を考慮すべきである。こうした植物の安全性評価では、食品中の残留物及び代謝産物の量の調査及び栄養学的変化に関する評価が必要となる。食品中で残留物または代謝産物の量の変化が認められた場合、このような代謝産物の安全性の確立のために、従来の手順を用いてヒトの健康に対する潜在的な影響を考慮すべきである（食品に含まれる化学物質のヒトに対する安全性評価手順など）。
Food Processing 47. The potential effects of food processing, including home preparation, on foods derived from recombinant-DNA plants should also be considered. For example, alterations could occur in the heat stability of an endogenous toxicant or the bioavailability of an important nutrient after processing. Information should therefore be provided describing the processing conditions used in the production of a food ingredient from the plant. For example, in the case of vegetable oil, information should be	Food Processing 47. The potential effects of food processing, including home preparation, on foods derived from recombinant-DNA plants should also be considered. For example, alterations could occur in the heat stability of an endogenous toxicant or the bioavailability of an important nutrient after processing. Information should therefore be provided describing the processing conditions used in the production of a food ingredient from the plant. For example, in the case of vegetable oil, information should be	食品加工 47. 組換え DNA 植物由来の食品については、家庭での調理を含め食品加工の潜在的影響も検討すべきである。例えば、加工後に内因性毒素の熱安定性や重要な栄養素の生体利用率に変化が起きる可能性もある。従って、植物に由来する食品成分の製造における加工条件を示す情報を提供する必要がある。植物油であれば、抽出過程やその後の精製段階に関する情報を提供する必要がある。

provided on the extraction process and any subsequent refining steps.	provided on the extraction process and any subsequent refining steps.	
Nutritional Modification	Nutritional Modification	栄養学的な修飾
48. The assessment of possible compositional changes to key nutrients, which should be conducted for all recombinant-DNA plants, has already been addressed under 'Compositional analyses of key components'. However, foods derived from recombinant-DNA plants that have undergone modification to intentionally alter nutritional quality or functionality should be subjected to additional nutritional assessment to assess the consequences of the changes and whether the nutrient intakes are likely to be altered by the introduction of such foods into the food supply.	48. The assessment of possible compositional changes to key nutrients, which should be conducted for all recombinant- DNA plants, has already been addressed under 'Compositional analyses of key components'. However, foods derived from recombinant-DNA plants that have undergone modification to intentionally alter nutritional quality or functionality should be subjected to additional nutritional assessment to assess the consequences of the changes and whether the nutrient intakes are likely to be altered by the introduction of such foods into the food supply. A detailed presentation of issues to be considered can be found in Annex 2 to this document.	48. 主要栄養素に起こりうる組成の変化に関する評価は、組換え DNA 植物すべてについて実施すべきであり、既に「主要成分の組成分析」の項で取り上げている。しかし、栄養の質や機能の意図的な改変を目的として修飾が行われた組換え DNA 植物由来食品については、変化の結果並びにこうした食品を供給することによって栄養素の摂取に変化を来す可能性があるかどうかを評価するために、更なる栄養評価を実施すべきである。その詳細については、本文書の付属書 2 に記載されている。
49. Information about the known patterns of use and consumption of a food, and its derivatives should be used to estimate the likely intake of the food derived from the recombinant-DNA plant. The expected intake of the food should be used to assess the nutritional implications of the altered nutrient profile both at customary and maximal levels of consumption. Basing the estimate on the highest likely	49. Information about the known patterns of use and consumption of a food, and its derivatives should be used to estimate the likely intake of the food derived from the recombinant-DNA plant. The expected intake of the food should be used to assess the nutritional implications of the altered nutrient profile both at customary and maximal levels of consumption. Basing the estimate on the highest likely	49. 食品およびその派生物の使用と消費についての既知のパターンに関する情報は、組換え DNA 植物に由来する食品の想定される摂取量を概算するために使用すべきである。こうした食品の予測摂取量を用いて、通常の消費量と最大消費量の両者について改変された栄養特性の栄養学的な意味を評価すべきである。最も消費する可能性の高いものについての概算を基盤とすると、望ましくない栄養学的影響のあらゆる可能性も検出されるという確証が得られる。乳児・小児・妊産婦・授乳婦・

consumption provides assurance that the potential for any undesirable nutritional effects will be detected. Attention should be paid to the particular physiological characteristics and metabolic requirements of specific population groups such as infants, children, pregnant and lactating women, the elderly and those with chronic diseases or compromised immune systems. Based on the analysis of nutritional impacts and the dietary needs of specific population subgroups, additional nutritional assessments may be necessary. It is also important to ascertain to what extent the modified nutrient is bioavailable and remains stable with time, processing and storage.	consumption provides assurance that the potential for any undesirable nutritional effects will be detected. Attention should be paid to the particular physiological characteristics and metabolic requirements of specific population groups such as infants, children, pregnant and lactating women, the elderly and those with chronic diseases or compromised immune systems. Based on the analysis of nutritional impacts and the dietary needs of specific population subgroups, additional nutritional assessments may be necessary. It is also important to ascertain to what extent the modified nutrient is bioavailable and remains stable with time, processing and storage.	高齢者・慢性疾患及び免疫系疾患を有する人など、特定の集団における生理学的特徴や代謝条件に注目すべきである。母集団中の小集団における栄養学的影響及び食事に関する必要性の解析に基づき、栄養学的評価が更に必要となる場合もある。修飾された栄養素がどの程度まで生体利用ができ、時間・加工・保存に対して安定であるかを確認することも重要である。
50. The use of plant breeding, including in vitro nucleic acid techniques, to change nutrient levels in crops can result in broad changes to the nutrient profile in two ways. The intended modification in plant constituents could change the overall nutrient profile of the plant product and this change could affect the nutritional status of individuals consuming the food. Unexpected alterations in nutrients could have the same effect. Although the recombinant-DNA plant components may be individually assessed as safe, the impact of the change on the overall nutrient profile	50. The use of plant breeding, including in vitro nucleic acid techniques, to change nutrient levels in crops can result in broad changes to the nutrient profile in two ways. The intended modification in plant constituents could change the overall nutrient profile of the plant product and this change could affect the nutritional status of individuals consuming the food. Unexpected alterations in nutrients could have the same effect. Although the recombinant-DNA plant components may be individually assessed as safe, the impact of the change on the overall nutrient profile	50. 穀物の栄養素量を変えるためにインビトロ核酸技術を含む植物育種技術が利用された場合、栄養上の側面に 2 通りの広範な変化が生じる可能性がある。植物成分に意図的に修飾を施した場合、植物製品の栄養素上の特性を全体的に変える可能性があり、この変化は食品を消費する個人の栄養状態に影響を与える可能性がある。予期しない栄養上の変化も同じ影響を及ぼす可能性がある。組換え DNA 植物成分の安全性が個別に評価された場合であっても、この変化が栄養素の全体的な特性に与える影響を検討すべきである。

should be determined.	should be determined.	
51. When the modification results in a food product, such as vegetable oil, with a composition that is significantly different from its conventional counterpart, it may be appropriate to use additional conventional foods or food components (i.e. foods or food components whose nutritional composition is closer to that of the food derived from recombinant-DNA plant) as appropriate comparators to assess the nutritional impact of the food.	51. When the modification results in a food product, such as vegetable oil, with a composition that is significantly different from its conventional counterpart, it may be appropriate to use additional conventional foods or food components (i.e. foods or food components whose nutritional composition is closer to that of the food derived from recombinant-DNA plant) as appropriate comparators to assess the nutritional impact of the food.	51. 修飾の結果、植物油などのように、既存の対応物と組成が大幅に異なる食品が生じた場合、その食品の栄養学的影響を評価するための適当な比較対象として、通常食品または食品成分（栄養組成が組換え DNA 植物に由来する食品により近い食品または食品成分）追加して用いることが適当な場合もある。
52. Because of geographical and cultural variation in food consumption patterns, nutritional changes to a specific food may have a greater impact in some geographical areas or in some cultural population than in others. Some food plants serve as the major source of a particular nutrient in some populations. The nutrient and the populations affected should be identified.	52. Because of geographical and cultural variation in food consumption patterns, nutritional changes to a specific food may have a greater impact in some geographical areas or in some cultural population than in others. Some food plants serve as the major source of a particular nutrient in some populations. The nutrient and the populations affected should be identified.	52. 食品消費パターンは地理的・文化的要因によって異なるため、特定食品の栄養学的変化がある地域や文化圏において他の場合より重大な影響をもたらす可能性がある。ある集団ではいくつかの食用植物が特定栄養素の主要摂取源となっている。栄養素とその影響を受ける集団を明らかにすべきである。
53. Some foods may require additional testing. For example, animal feeding studies may be warranted for foods derived from recombinant-DNA plants if changes in the bioavailability of nutrients are expected or if the composition is not comparable to conventional foods. Also, foods designed	53. Some foods may require additional testing. For example, animal feeding studies may be warranted for foods derived from recombinant-DNA plants if changes in the bioavailability of nutrients are expected or if the composition is not comparable to conventional foods. Also, foods designed	53. 食品によっては追加試験が必要な場合がある。例えば、栄養素の生体利用率の変化が予想される場合や、組成が従来の食品とは異なる場合は、組換え DNA 植物由来食品について動物給餌試験が当然必要となるであろう。また、健康増進を目的とする食品では、特定の栄養学的・毒性学的試験またはその他の適切な試験が必要な場合もある。食品の特徴付け

for health benefits may require specific nutritional, toxicological or other appropriate studies. If the characterization of the food indicates that the available data are insufficient for a thorough safety assessment, properly designed animal studies could be requested on the whole foods.	for health benefits may require specific nutritional, toxicological or other appropriate studies. If the characterization of the food indicates that the available data are insufficient for a thorough safety assessment, properly designed animal studies could be requested on the whole foods.	の結果、利用できるデータが総合的な安全性評価の実施には不十分であることが分かった場合は、適切に計画され、丸ごとの食品を対象とした動物試験が必要となる場合もある。
SECTION 5 - OTHER CONSIDERATIONS POTENTIAL ACCUMULATION OF SUBSTANCES SIGNIFICANT TO HUMAN HEALTH 54. Some recombinant-DNA plants may exhibit traits (e.g., herbicide tolerance) which may indirectly result in the potential for accumulation of pesticide residues, altered metabolites of such residues, toxic metabolites, contaminants, or other substances which may be relevant to human health. The safety assessment should take this potential for accumulation into account. Conventional procedures for establishing the safety of such compounds (e.g., procedures for assessing the human safety of chemicals) should be applied.	SECTION 5 - OTHER CONSIDERATIONS POTENTIAL ACCUMULATION OF SUBSTANCES SIGNIFICANT TO HUMAN HEALTH 54. Some recombinant-DNA plants may exhibit traits (e.g., herbicide tolerance) which may indirectly result in the potential for accumulation of pesticide residues, altered metabolites of such residues, toxic metabolites, contaminants, or other substances which may be relevant to human health. The safety assessment should take this potential for accumulation into account. Conventional procedures for establishing the safety of such compounds (e.g., procedures for assessing the human safety of chemicals) should be applied.	セクション 5-その他の検討事項 ヒトの健康に重大な意味を持つ物質が蓄積する可能性 54. 組換え DNA 植物が、残留農薬、改変された当該残留物質の代謝産物、毒性代謝産物、汚染物質、その他ヒトの健康に影響を与える恐れのある物質を間接的に蓄積させる可能性を生じる形質（除草剤耐性など）を示す場合もある。安全性評価ではこの蓄積の可能性を考慮すべきである。こうした化合物の安全性を確立するための従来の手順（化学物質のヒトに対する安全性の評価過程など）を適用すべきである。
USE OF ANTIBIOTIC RESISTANCE MARKER GENES 55. Alternative transformation technologies that do not result in antibiotic resistance marker genes in foods should be used in the future development of recombinant-DNA plants, where such technologies are available and demonstrated to be safe.	USE OF ANTIBIOTIC RESISTANCE MARKER GENES 55. Alternative transformation technologies that do not result in antibiotic resistance marker genes in foods should be used in the future development of recombinant-DNA plants, where such technologies are available and demonstrated to be safe.	抗生物質耐性マーカー遺伝子の使用 55. 組換え DNA 植物の今後の開発においては、食品に抗生物質耐性マーカー遺伝子を生じることのない別の形質転換技術を利用でき安全であることが分かっていれば、これを用いるべきである。

56. Gene transfer from plants and their food products to gut microorganisms or human cells is considered a rare possibility because of the many complex and unlikely events that would need to occur consecutively. Nevertheless, the possibility of such events cannot be completely discounted6.	56. Gene transfer from plants and their food products to gut microorganisms or human cells is considered a rare possibility because of the many complex and unlikely events that would need to occur consecutively. Nevertheless, the possibility of such events cannot be completely discounted6.	56. 植物やそれに由来する食品から腸内微生物やヒト細胞への遺伝子伝達は、多くの複雑で偶発的な事象が連続的に発生する必要があるため、発生の可能性はごくわずかであると考えられるが、可能性を完全に排除することはできない6。
57. In assessing safety of foods containing antibiotic resistance marker genes, the following factors should be considered: A) the clinical and veterinary use and importance of the antibiotic in question; (Certain antibiotics are the only drug available to treat some clinical conditions (e.g. vancomycin for use in treating certain staphylococcal infections). Marker genes encoding resistance to such antibiotics should not be used in recombinant-DNA plants.) B) whether the presence in food of the enzyme or protein encoded by the antibiotic resistance marker gene would compromise the therapeutic efficacy of the orally administered antibiotic; and (This assessment should provide an estimate of the amount of orally ingested antibiotic that could be degraded by the presence of the enzyme in food, taking into account factors such as	57. In assessing safety of foods containing antibiotic resistance marker genes, the following factors should be considered: A) the clinical and veterinary use and importance of the antibiotic in question; (Certain antibiotics are the only drug available to treat some clinical conditions (e.g. vancomycin for use in treating certain staphylococcal infections). Marker genes encoding resistance to such antibiotics should not be used in recombinant-DNA plants.) B) whether the presence in food of the enzyme or protein encoded by the antibiotic resistance marker gene would compromise the therapeutic efficacy of the orally administered antibiotic; and (This assessment should provide an estimate of the amount of orally ingested antibiotic that could be degraded by the presence of the enzyme in food, taking into account factors such as	57. 抗生物質耐性マーカー遺伝子を含む食品の安全性評価においては、以下の点を検討すべきである。 A) 問題の抗生物質の臨床学的および獣医学的利用とその重要性（抗生物質には、ある種の臨床状態の治療にのみ利用できるものもある（特定のブドウ球菌感染症の治療に使用するバンコマイシンなど）。このような抗生物質に対する耐性をコード化しているマーカー遺伝子を、組換え DNA 植物において使用すべきではない。） B) 抗生物質耐性マーカー遺伝子によってコード化されている酵素またはタンパク質が食品中に存在することによって、経口投与された抗生物質の治療効果が低減するか否か（この評価において、抗生物質の服用量、中性またはアルカリ性の胃の状態などの消化条件に曝された後食品中に残存する可能性のある酵素量、酵素活性に必要な酵素補因子（ATP など）の必要性、食品中の当該因子の推定濃度などを考慮に入れて、食品中の酵素の存在によって、経口投与された抗生物質量がどの程度減少する可能性があるのかを推定

dosage of the antibiotic, amount of enzyme likely to remain in food following exposure to digestive conditions, including neutral or alkaline stomach conditions and the need for enzyme cofactors (e.g. ATP) for enzymatic activity and estimated concentration of such factors in food.) C) safety of the gene product, as would be the case for any other expressed gene product.	dosage of the antibiotic, amount of enzyme likely to remain in food following exposure to digestive conditions, including neutral or alkaline stomach conditions and the need for enzyme cofactors (e.g. ATP) for enzymatic activity and estimated concentration of such factors in food.) C) safety of the gene product, as would be the case for any other expressed gene product.	すべきである） C) 他の発現遺伝子産物の場合と同様に、遺伝子産物の安全性
58. If evaluation of the data and information suggests that the presence of the antibiotic resistance marker gene or gene product presents risks to human health, the marker gene or gene product should not be present in the food. Antibiotic resistance genes used in food production that encode resistance to clinically used antibiotics should not be present in foods.	58. If evaluation of the data and information suggests that the presence of the antibiotic resistance marker gene or gene product presents risks to human health, the marker gene or gene product should not be present in the food. Antibiotic resistance genes used in food production that encode resistance to clinically used antibiotics should not be present in foods.	58. データや情報の評価の結果、抗生物質耐性マーカー遺伝子または遺伝子産物の存在がヒトの健康にリスクを呈することが示唆された場合、このマーカー遺伝子または遺伝子産物が食品中に存在すべきではない。臨床的に使用される抗生物質に対する耐性をコード化した抗生物質耐性遺伝子を食品製造で用いる場合も、これが食品中に存在すべきではない。
REVIEW OF SAFETY ASSESSMENTS 59. The goal of the safety assessment is a conclusion as to whether the new food is as safe as the conventional counterpart taking into account dietary impact of any changes in nutritional content or value. Nevertheless, the safety assessment should be reviewed in the light of new scientific information that calls into question the conclusions of the original	REVIEW OF SAFETY ASSESSMENTS 59. The goal of the safety assessment is a conclusion as to whether the new food is as safe as the conventional counterpart taking into account dietary impact of any changes in nutritional content or value. Nevertheless, the safety assessment should be reviewed in the light of new scientific information that calls into question the conclusions of the original	安全性評価の検討 59. 安全性評価の目標は、栄養量や栄養価の変化が食事に及ぼす影響を考慮に入れ、新規食品が既存の対応物と同様に安全であるかどうかを判定することである。しかし、安全性評価は元の安全性評価の判定に疑問を投じるような新たな科学的情報に照らして行なうべきである。

safety assessment.	safety assessment.	
脚注		
1 It is recognized that for the foreseeable future, foods derived from modern biotechnology will not be used as conventional counterparts.	1 It is recognized that for the foreseeable future, foods derived from modern biotechnology will not be used as conventional counterparts.	1 モダンバイオテクノロジー応用食品は当分の間は既存の対応物として使用しないことで合意が得られている。
2 The concept of substantial equivalence as described in the report of the 2000 joint FAO /WHO expert consultations (Document WHO/SDE/PHE/FOS/00.6, WHO, Geneva, 2000).	2 The concept of substantial equivalence as described in the report of the 2000 joint FAO /WHO expert consultations (Document WHO/SDE/PHE/FOS/00.6, WHO, Geneva, 2000).	2 2000 年 FAO/WHO 合同専門家会議報告書（WHO/SDE/PHE/FOS/00.6、WHO、ジュネーブ、2000 年）に示した実質的な同等性の概念
3 Guidelines for oral toxicity studies have been developed in international fora, for example, the OECD Guidelines for the Testing of Chemicals.	3 Guidelines for oral toxicity studies have been developed in international fora, for example, the OECD Guidelines for the Testing of Chemicals.	3 経口毒性試験に関するガイドラインとしては、「化学物質の試験に関する OECD ガイドライン」などが国際学会で作成されている。
4 The FAO/WHO expert consultation 2001 report , which includes reference to several decision trees, was used in developing the Annex to these guidelines.	4 The FAO/WHO expert consultation 2001 report, which includes reference to several decision trees, was used in developing Annex 1 to these guidelines.	4 2001 年 FAO/WHO 合同専門家会議報告書には、いくつかの判断樹が引用されており、このガイドラインの添付資料の作成時に使用された。
5 Key nutrients or key anti-nutrients are those components in a particular food that may have a substantial impact in the overall diet. They may be major constituents (fats, proteins, carbohydrates as nutrients or enzyme inhibitors as anti-nutrients) or minor compounds (minerals, vitamins). Key toxicants are those toxicologically significant compounds known to be	5 Key nutrients or key anti-nutrients are those components in a particular food that may have a substantial impact in the overall diet. They may be major constituents (fats, proteins, carbohydrates as nutrients or enzyme inhibitors as anti-nutrients) or minor compounds (minerals, vitamins). Key toxicants are those toxicologically significant compounds known to be	5 主要栄養素・抗栄養素は、栄養摂取全体にかなりの影響を与えうる特定食品の成分である。これらは主要成分（栄養素としては脂肪・タンパク質・炭水化物、抗栄養素としては酵素阻害因子）である場合も、非主要成分（無機質、ビタミン）である場合もある。主要毒素とは、毒性や濃度が健康に大きな影響を与えうる化合物（量が多い場合のジャガイモのソラニン、小麦のセレニウム）やアレルゲンなど植物に潜在的に含まれることがわかってい

inherently present in the plant, such as those compounds whose toxic potency and level may be significant to health (e.g. solanine in potatoes if the level is increased, selenium in wheat) and allergens.	inherently present in the plant, such as those compounds whose toxic potency and level may be significant to health (e.g. solanine in potatoes if the level is increased, selenium in wheat) and allergens.	る毒性学的に重要な化合物である。
6 In cases where there are high levels of naturally occurring bacteria which are resistant to the antibiotic, the likelihood of such bacteria transferring this resistance to other bacteria will be orders of magnitude higher than the likelihood of transfer between ingested foods and bacteria.	6 In cases where there are high levels of naturally occurring bacteria which are resistant to the antibiotic, the likelihood of such bacteria transferring this resistance to other bacteria will be orders of magnitude higher than the likelihood of transfer between ingested foods and bacteria.	6 天然に存在する細菌であって、抗生物質耐性を有するものが高濃度で存在する場合、こうした細菌がこの耐性をその他の細菌に伝達する可能性は、摂取した食品と細菌間での伝達の可能性より高い。
ANNEX: Assessment of Possible Allergenicity	ANNEX 1: ASSESSMENT OF POSSIBLE ALLERGENICITY	アレルギー誘発性評価に関する添付資料
SECTION 1 - INTRODUCTION 1. All newly expressed proteins1 in recombinant-DNA plants that could be present in the final food should be assessed for their potential to cause allergic reactions. This should include consideration of whether a newly expressed protein is one to which certain individuals may already be sensitive as well as whether a protein new to the food supply is likely to induce allergic reactions in some individuals.	SECTION 1 - INTRODUCTION 1. All newly expressed proteins7 in recombinant-DNA plants that could be present in the final food should be assessed for their potential to cause allergic reactions. This should include consideration of whether a newly expressed protein is one to which certain individuals may already be sensitive as well as whether a protein new to the food supply is likely to induce allergic reactions in some individuals.	セクション1-はじめに 1. 組換えDNA 植物で新たに発現したタンパク質1 であって最終食品に含まれる可能性があるものはいずれも、アレルギー誘発性について評価すべきである。その際、新たに発現したタンパク質は特定個人が既に感受性を持つ可能性があるかどうか、食品供給において新しいタンパク質がある個人においてアレルギー反応を引き起こす可能性が高いかどうかを考慮すべきである。
2. At present, there is no definitive test that can be relied upon to predict allergic response in humans to a newly	2. At present, there is no definitive test that can be relied upon to predict allergic response in humans to a newly	2. 現在、新たに発現したタンパク質のヒトへのアレルギー反応の予測において信頼できる決定的試験はないため、下記に示すような総合的でかつ段階的な個別の手法を用いて、新たに

expressed protein, therefore, it is recommended that an integrated, stepwise, case by case approach, as described below, be used in the assessment of possible allergenicity of newly expressed proteins. This approach takes into account the evidence derived from several types of information and data since no single criterion is sufficiently predictive.	expressed protein, therefore, it is recommended that an integrated, stepwise, case by case approach, as described below, be used in the assessment of possible allergenicity of newly expressed proteins. This approach takes into account the evidence derived from several types of information and data since no single criterion is sufficiently predictive.	発現したタンパク質のアレルギー誘発性を評価する様勧告されている。単一の判断基準では十分な予測ができないため、この手法では数種類の情報・データに由来する根拠を考慮している。
3. The endpoint of the assessment is a conclusion as to the likelihood of the protein being a food allergen.	3. The endpoint of the assessment is a conclusion as to the likelihood of the protein being a food allergen.	3. 評価指標は、タンパク質の食品アレルゲンである可能性についての判定である。
SECTION 2 - ASSESSMENT STRATEGY 4. The initial steps in assessing possible allergenicity of any newly expressed proteins are the determination of: the source of the introduced protein; any significant similarity between the amino acid sequence of the protein and that of known allergens; and its structural properties, including but not limited to, its susceptibility to enzymatic degradation, heat stability and/or, acid and enzymatic treatment.	SECTION 2 - ASSESSMENT STRATEGY 4. The initial steps in assessing possible allergenicity of any newly expressed proteins are the determination of: the source of the introduced protein; any significant similarity between the amino acid sequence of the protein and that of known allergens; and its structural properties, including but not limited to, its susceptibility to enzymatic degradation, heat stability and/or, acid and enzymatic treatment.	セクション 2-評価方法 4. 新たに発現したタンパク質のアレルギー誘発性評価における第 1 段階は、導入タンパク質の供給源、当該タンパク質と既知のアレルゲンのアミノ酸配列における有意な類似性、構造的特性を調査することである。これには酵素分解に対する感受性、熱安定性、酸・酵素処理などが含まれるが、これに限定されない。
5. As there is no single test that can predict the likely human IgE response to oral exposure, the first step to characterize newly expressed proteins should be the comparison of the amino acid sequence and certain physicochemical characteristics	5. As there is no single test that can predict the likely human IgE response to oral exposure, the first step to characterize newly expressed proteins should be the comparison of the amino acid sequence and certain physicochemical characteristics	5. 単一の試験だけでは経口曝露に対するヒト IgE 反応の可能性を予測できないため、新たに発現したタンパク質の特徴を明らかにするための第 1 段階は、新たに発現したタンパク質と既に確立されているアレルゲンにおけるアミノ酸配列及び特定の物理化学的性質につ

of the newly expressed protein with those of established allergens in a weight of evidence approach. This will require the isolation of any newly expressed proteins from the recombinant-DNA plant, or the synthesis or production of the substance from an alternative source, in which case the material should be shown to be structurally, functionally and biochemically equivalent to that produced in the recombinant-DNA plant. Particular attention should be given to the choice of the expression host, since post-translational modifications allowed by different hosts (i.e.: eukaryotic vs. prokaryotic systems) may have an impact on the allergenic potential of the protein.	of the newly expressed protein with those of established allergens in a weight of evidence approach. This will require the isolation of any newly expressed proteins from the recombinant-DNA plant, or the synthesis or production of the substance from an alternative source, in which case the material should be shown to be structurally, functionally and biochemically equivalent to that produced in the recombinant-DNA plant. Particular attention should be given to the choice of the expression host, since post-translational modifications allowed by different hosts (i.e.: eukaryotic vs. prokaryotic systems) may have an impact on the allergenic potential of the protein.	いて、根拠を重視して比較することである。このためには、新たに発現したタンパク質を組換え DNA 植物から分離しまたは別の供給源からその物質を合成･製造する必要がある。この際、対象とする物質が組換え DNA 植物で生成されるものと構造的・機能的・生化学的に同等であることを示すべきである。宿主が異なることにより起こりうる翻訳後修飾が発生し（真核系と原核系）タンパク質のアレルギー誘発性に影響を与える可能性があるため、発現宿主の選択には特に注意を払うべきである。
6. It is important to establish whether the source is known to cause allergic reactions. Genes derived from known allergenic sources should be assumed to encode an allergen unless scientific evidence demonstrates otherwise.	6. It is important to establish whether the source is known to cause allergic reactions. Genes derived from known allergenic sources should be assumed to encode an allergen unless scientific evidence demonstrates otherwise.	6. タンパク質の供給源に関してはアレルギー反応を誘発することが知られているかどうかを明らかにすることが重要である。既知のアレルギー誘発性物質に由来する遺伝子は、科学的根拠によりそうでない旨が実証されない限り、アレルゲンをコード化していると仮定すべきである。
SECTION 3 - INITIAL ASSESSMENT SECTION 3.1 SOURCE OF THE PROTEIN	SECTION 3 - INITIAL ASSESSMENT SECTION 3.1 - SOURCE OF THE PROTEIN	セクション 3-最初の評価 セクション 3.1-タンパク質の供給源
7. As part of the data supporting the safety of foods derived from recombinant-DNA plants, information should describe any reports of allergenicity associated with the donor organism. Allergenic sources of genes would be defined as those organisms	7. As part of the data supporting the safety of foods derived from recombinant-DNA plants, information should describe any reports of allergenicity associated with the donor organism. Allergenic sources of genes would be defined as those organisms	7. 組換え DNA 植物由来食品の安全性を裏付けるデータの一部として、供与体に関するアレルギー誘発性に関する情報は全て示すべきである。これにより、遺伝子のアレルギー誘発性供給源は、IgE 媒介性経口または呼吸性・接触性アレルギーの合理的根拠が入手できる供

for which reasonable evidence of IgE mediated oral, respiratory or contact allergy is available. Knowledge of the source of the introduced protein allows the identification of tools and relevant data to be considered in the allergenicity assessment. These include: the availability of sera for screening purposes; documented type, severity and frequency of allergic reactions; structural characteristics and amino acid sequence; physicochemical and immunological properties (when available) of known allergenic proteins from that source.	for which reasonable evidence of IgE mediated oral, respiratory or contact allergy is available. Knowledge of the source of the introduced protein allows the identification of tools and relevant data to be considered in the allergenicity assessment. These include: the availability of sera for screening purposes; documented type, severity and frequency of allergic reactions; structural characteristics and amino acid sequence; physicochemical and immunological properties (when available) of known allergenic proteins from that source.	与体として定義されるであろう。導入タンパク質の供給源についての情報が得られれば、アレルギー誘発性評価において考慮すべき手段や関連データが明らかになる。これには、スクリーニングを目的とする血清の利用可能性、アレルギー反応の種類・程度・頻度の記載、構造的特徴及びアミノ酸配列、その供給源に由来する既知のアレルギー誘発性タンパク質の物理化学的・免疫学的特性（適宜）が含まれる。
SECTION 3.2 - AMINO ACID SEQUENCE HOMOLOGY	SECTION 3.2 - AMINO ACID SEQUENCE HOMOLOGY	セクション3.2-アミノ酸配列相同
8. The purpose of a sequence homology comparison is to assess the extent to which a newly expressed protein is similar in structure to a known allergen. This information may suggest whether that protein has an allergenic potential. Sequence homology searches comparing the structure of all newly expressed proteins with all known allergens should be done. Searches should be conducted using various algorithms such as FASTA or BLASTP to predict overall structural similarities. Strategies such as stepwise contiguous identical amino acid segment searches may also be performed for identifying sequences that may represent linear epitopes. The size of the	8. The purpose of a sequence homology comparison is to assess the extent to which a newly expressed protein is similar in structure to a known allergen. This information may suggest whether that protein has an allergenic potential. Sequence homology searches comparing the structure of all newly expressed proteins with all known allergens should be done. Searches should be conducted using various algorithms such as FASTA or BLASTP to predict overall structural similarities. Strategies such as stepwise contiguous identical amino acid segment searches may also be performed for identifying sequences that may represent linear epitopes. The size of the	8. 配列相同比較の目的は、新たに発現したタンパク質の構造がどの程度既知のアレルゲンと似ているかを評価することである。この情報は、恐らくこのタンパク質がアレルギー誘発性を有するかどうかを示唆することになろう。配列相同の調査は、新たに発現した全てのタンパク質の構造を全ての既知のアレルゲンと比較して行う必要がある。FASTA またはBLASTPなど様々なアルゴリズム（段階的手法）を用いて検査を行い、包括的な構造的類似性を予測すべきである。直線エピトープを示す可能性のある配列を明らかにするために、段階的な連続する同一のアミノ酸部分の検査などの方法を実施する場合もある。連続アミノ酸検査の規模は、偽陰性または偽陽性結果が生じる可能性を最低限に抑えるために科学的正当性に基づくべきである 2。生物学的に意味の

contiguous amino acid search should be based on a scientifically justified rationale in order to minimize the potential for false negative or false positive results2. Validated search and evaluation procedures should be used in order to produce biologically meaningful results.	contiguous amino acid search should be based on a scientifically justified rationale in order to minimize the potential for false negative or false positive results. 8 Validated search and evaluation procedures should be used in order to produce biologically meaningful results.	ある結果を得るため、検証済みの調査・評価手法を用いるべきである。
9. IgE cross-reactivity between the newly expressed protein and a known allergen should be considered a possibility when there is more than 35% identity in a segment of 80 or more amino acids (FAO/WHO 2001) or other scientifically justified criteria. All the information resulting from the sequence homology comparison between the newly expressed protein and known allergens should be reported to allow a case-by-case scientifically based evaluation.	9. IgE cross-reactivity between the newly expressed protein and a known allergen should be considered a possibility when there is more than 35% identity in a segment of 80 or more amino acids (FAO/WHO 2001) or other scientifically justified criteria. All the information resulting from the sequence homology comparison between the newly expressed protein and known allergens should be reported to allow a case-by-case scientifically based evaluation.	9. 80 以上のアミノ酸部分で 35%以上の同一性（2001 年 FAO/WHO）が認められるか、またはその他の科学的に正当な基準がある場合は、新たに発現したタンパク質と既知のアレルゲンの間の IgE 交差反応の可能性を考慮すべきである。個別の科学的評価を可能にするため、新たに発現したタンパク質と既知のアレルゲンの間の配列相同比較から得られた情報はすべて報告すべきである。
10. Sequence homology searches have certain limitations. In particular, comparisons are limited to the sequences of known allergens in publicly available databases and the scientific literature. There are also limitations in the ability of such comparisons to detect non-contiguous epitopes capable of binding themselves specifically with IgE antibodies.	10. Sequence homology searches have certain limitations. In particular, comparisons are limited to the sequences of known allergens in publicly available databases and the scientific literature. There are also limitations in the ability of such comparisons to detect non-contiguous epitopes capable of binding themselves specifically with IgE antibodies.	10. 配列相同研究にはある種の限界がある。特に、比較においては一般に利用できるデータベースと科学文献に掲げる既知のアレルゲンの配列に限定される。IgE 抗体と特異的に結合可能な非連続エピトープの検出においてもその比較能力に限界がある。
11. A negative sequence homology result indicates that a newly expressed protein	11. A negative sequence homology result indicates that a newly expressed protein	11. 配列相同検査でマイナスの結果が出ると、新たに発現したタンパク質は既知のアレルゲン

is not a known allergen and is unlikely to be cross-reactive to known allergens. A result indicating absence of significant sequence homology should be considered along with the other data outlined under this strategy in assessing the allergenic potential of newly expressed proteins. Further studies should be conducted as appropriate (see also sections 4 and 5). A positive sequence homology result indicates that the newly expressed protein is likely to be allergenic. If the product is to be considered further, it should be assessed using serum from individuals sensitized to the identified allergenic source.	is not a known allergen and is unlikely to be cross-reactive to known allergens. A result indicating absence of significant sequence homology should be considered along with the other data outlined under this strategy in assessing the allergenic potential of newly expressed proteins. Further studies should be conducted as appropriate (see also sections 4 and 5). A positive sequence homology result indicates that the newly expressed protein is likely to be allergenic. If the product is to be considered further, it should be assessed using serum from individuals sensitized to the identified allergenic source.	ではなく、既知のアレルゲンに対する交差反応性が低いことがわかる。有意な配列相同がないことを示す結果が得られた場合は、新たに発現したタンパク質のアレルギー誘発性評価においてこの方法でまとめたその他のデータと合わせて考慮すべきである。必要に応じ、更なる研究を実施すべきである（セクション4・5 参照）。配列相同検査でプラスの結果がでた場合、新たに発現したタンパク質はアレルギー誘発性である可能性が高いことを示す。この製品をさらに検討する必要がある場合は、同定されたアレルギー誘発性供給源に対して感作された個人の血清を用いて評価すべきである。
SECTION 3.3 - PEPSIN RESISTANCE	SECTION 3.3 - PEPSIN RESISTANCE	セクション3.3-ペプシン耐性
12. Resistance to pepsin digestion has been observed in several food allergens; thus a correlation exists between resistance to digestion by pepsin and allergenic potential3. Therefore, the resistance of a protein to degradation in the presence of pepsin under appropriate conditions indicates that further analysis should be conducted to determine the likelihood of the newly expressed protein being allergenic. The establishment of a consistent and well-validated pepsin degradation protocol may enhance the utility of this method. However, it should be taken into account that a lack of resistance to pepsin does not exclude	12. Resistance to pepsin digestion has been observed in several food allergens; thus a correlation exists between resistance to digestion by pepsin and allergenic potential.9 Therefore, the resistance of a protein to degradation in the presence of pepsin under appropriate conditions indicates that further analysis should be conducted to determine the likelihood of the newly expressed protein being allergenic. The establishment of a consistent and well-validated pepsin degradation protocol may enhance the utility of this method. However, it should be taken into account that a lack of resistance to pepsin does not exclude	12. いくつかの食品アレルゲンにおいて、ペプシン消化に対する耐性が認められており、ペプシン耐性とアレルギー誘発性には相関関係がある3。従って、適切な条件下でペプシンが存在する場合に分解に対するタンパク質の耐性が認められれば、新たに発現したタンパク質がアレルギー誘発性である可能性を調べるためにさらに分析を行うべきである。整合性があり十分に検証されたペプシン分解プロトコールが確立されれば、この方法の有効性が高まる可能性がある。しかし、ペプシン耐性がない場合も新たに発現したタンパク質が関連アレルゲンである可能性を排除することにはならないことを考慮すべきである。

that the newly expressed protein can be a relevant allergen.	that the newly expressed protein can be a relevant allergen.	
13. Although the pepsin resistance protocol is strongly recommended, it is recognized that other enzyme susceptibility protocols exist. Alternative protocols may be used where adequate justification is provided4.	13. Although the pepsin resistance protocol is strongly recommended, it is recognized that other enzyme susceptibility protocols exist. Alternative protocols may be used where adequate justification is provided10.	13. ペプシン耐性プロトコールは強く推奨されるが、他の酵素感受性プロトコールがあることも認識されている。正当性が示されれば、別のプロトコールを用いてもよい4。
SECTION 4 - SPECIFIC SERUM SCREENING 14. For those proteins that originate from a source known to be allergenic, or have sequence homology with a known allergen, testing in immunological assays should be performed where sera are available. Sera from individuals with a clinically validated allergy to the source of the protein can be used to test the specific binding to IgE class antibodies of the protein in in vitro assays. A critical issue for testing will be the availability of human sera from sufficient numbers of individuals5. In addition, the quality of the sera and the assay procedure need to be standardized to produce a valid test result. For proteins from sources not known to be allergenic, and which do not exhibit sequence homology to a known allergen, targeted serum screening may be considered where such tests are available as described in paragraph 17.	SECTION 4 - SPECIFIC SERUM SCREENING 14. For those proteins that originate from a source known to be allergenic, or have sequence homology with a known allergen, testing in immunological assays should be performed where sera are available. Sera from individuals with a clinically validated allergy to the source of the protein can be used to test the specific binding to IgE class antibodies of the protein in in vitro assays. A critical issue for testing will be the availability of human sera from sufficient numbers of individuals11 In addition, the quality of the sera and the assay procedure need to be standardized to produce a valid test result. For proteins from sources not known to be allergenic, and which do not exhibit sequence homology to a known allergen, targeted serum screening may be considered where such tests are available as described in paragraph 17.	セクション4-特定血清スクリーニング 14. アレルギー誘発性である、または既知のアレルゲンとの配列相同が明らかな供給源に由来するタンパク質については、血清が利用できる場合は免疫学的検査における試験を実施すべきである。当該のタンパク質の供給源に対するアレルギーが臨床的に検証された個人の血清を用いて、インビトロアッセイにおいてタンパク質の IgE クラス抗体との特異的結合を調べることができる。この試験において重要な問題は、十分な数の個人からヒト血清が得られるかどうかである5。さらに、血清の質とアッセイ手順を標準化して有効な試験結果を出す必要がある。供給源のアレルギー誘発性が不明で、既知のアレルゲンに対する配列相同を示さないタンパク質については、パラグラフ 17 に示したように標的血清スクリーニングが利用できる場合は、これを考慮することができる。

15. In the case of a newly expressed protein derived from a known allergenic source, a negative result in in vitro immunoassays may not be considered sufficient, but should prompt additional testing, such as the possible use of skin test and ex vivo protocols6. A positive result in such tests would indicate a potential allergen.	15. In the case of a newly expressed protein derived from a known allergenic source, a negative result in in vitro immunoassays may not be considered sufficient, but should prompt additional testing, such as the possible use of skin test and ex vivo protocols.12 A positive result in such tests would indicate a potential allergen.	15. 既知のアレルギー誘発性供給源に由来する新たに発現したタンパク質の場合、インビトロの免疫学的検査における陰性結果だけでは十分ではないと考えられる場合があり、皮膚テストやエクスビボプロトコールなど補足的試験を促すべきである 6。こうした試験における陽性結果はアレルゲンの可能性を示す。
SECTION 5 - OTHER CONSIDERATIONS	SECTION 5 - OTHER CONSIDERATIONS	セクション 5-その他の検討事項
16. The absolute exposure to the newly expressed protein and the effects of relevant food processing will contribute toward an overall conclusion about the potential for human health risk. In this regard, the nature of the food product intended for consumption should be taken into consideration in determining the types of processing which would be applied and its effects on the presence of the protein in the final food product.	16. The absolute exposure to the newly expressed protein and the effects of relevant food processing will contribute toward an overall conclusion about the potential for human health risk. In this regard, the nature of the food product intended for consumption should be taken into consideration in determining the types of processing which would be applied and its effects on the presence of the protein in the final food product.	16. 新たに発現したタンパク質に対する絶対的曝露と、関連する食品加工の影響は、ヒトの健康に対するリスクの可能性に関する総合的な結論に影響を与える。このため、適用される加工の種類や最終食品中のタンパク質の存在に対する影響を判断する上で、対象食品の本質を考慮すべきである。
17. As scientific knowledge and technology evolves, other methods and tools may be considered in assessing the allergenicity potential of newly expressed proteins as part of the assessment strategy. These methods should be scientifically sound and may include targeted serum screening (i.e. the assessment of binding to IgE in sera of individuals with clinically validated allergic responses to broadly-related categories of foods); the	17. As scientific knowledge and technology evolves, other methods and tools may be considered in assessing the allergenicity potential of newly expressed proteins as part of the assessment strategy. These methods should be scientifically sound and may include targeted serum screening (i.e. the assessment of binding to IgE in sera of individuals with clinically validated allergic responses to broadly-related categories of foods); the	17. 科学的知識と技術の進歩に伴い、評価方法の一環としての新たに発現したタンパク質のアレルギー誘発性評価においてその他の方法や手段も考慮することができる。こうした方法は科学的な信頼が得られるものであるべきである。これには、標的血清スクリーニング（広範な関連領域の食品に対するアレルギー反応が臨床的に認証されている患者の血清における IgE 結合の評価）、国際血清バンクの開発、動物モデルの使用、新たに発現したタンパク質の T 細胞エピトープやアレルゲンに関わる

development of international serum banks; use of animal models; and examination of newly expressed proteins for T-cell epitopes and structural motifs associated with allergens.	development of international serum banks; use of animal models; and examination of newly expressed proteins for T-cell epitopes and structural motifs associated with allergens.	構造的モチーフの研究などが含まれる。
脚注		
1 This assessment strategy is not applicable for assessing whether newly expressed proteins are capable of inducing gluten-sensitive or other enteropathies. The issue of enteropathies is already addressed in Assessment of possible allergenicity (proteins), paragraph 42 of the Guideline for the Conduct of Food Safety Assessment of Foods Derived from Recombinant-DNA Plants. In addition, the strategy is not applicable to the evaluation of foods where gene products are down regulated for hypoallergenic purposes.	7 This assessment strategy is not applicable for assessing whether newly expressed proteins are capable of inducing glutensensitive or other enteropathies. The issue of enteropathies is already addressed in Assessment of possible allergenicity (proteins), paragraph 42 of the Guideline for the Conduct of Food Safety Assessment of Foods Derived from Recombinant-DNA Plants. In addition, the strategy is not applicable to the evaluation of foods where gene products are down regulated for hypoallergenic purposes.	7 この評価方法は、新たに発現したタンパク質にグルテン感受性またはその他の腸疾患の誘発能があるかどうかを評価するために適用することはできない。腸疾患の問題は既に、「組換え DNA 植物由来食品の安全性評価の実施に関するガイドライン案」のパラグラフ 42「アレルギー誘発性の評価（タンパク質）」で扱っている。またこの方法は、低アレルギー誘発性を目的とし遺伝子産物が抑制されている場合は食品の評価に適用することはできない。
2 It is recognized that the 2001 FAO/WHO consultation suggested moving from 8 to 6 identical amino acid segments in searches. The smaller the peptide sequence used in the stepwise comparison, the greater the likelihood of identifying false positives, inversely, the larger the peptide sequence used, the greater the likelihood of false negatives, thereby reducing the utility of the comparison.	8 It is recognized that the 2001 FAO/WHO consultation suggested moving from 8 to 6 identical amino acid segments in searches. The smaller the peptide sequence used in the stepwise comparison, the greater the likelihood of identifying false positives, inversely, the larger the peptide sequence used, the greater the likelihood of false negatives, thereby reducing the utility of the comparison.	8 2001 年 FAO/WHO 会議は検査で使用する同一アミノ酸部分を 8 から 6 に減らすことを示唆したと受け止められている。段階的比較で用いるペプチド配列が少なければ少ないほど偽陽性となる可能性が高い。逆に、用いるペプチド配列が多ければ多いほど偽陰性の可能性が高くなり、比較の有効性が下がる。
3 The method outlined in the U.S.	9 The method outlined in the U.S.	9 相関関係の確立において米薬局方（1995 年）に

Pharmacopoeia (1995) was used in the establishment of the correlation (Astwood et al. 1996).	Pharmacopoeia (1995) was used in the establishment of the correlation (Astwood et al. 1996).	概説する方法を用いた（Astwood 他、1996 年）。
4 Report of Joint FAO/WHO Expert Consultation on Allergenicity of Foods Derived from Biotechnology (2001): Section "6.4 Pepsin Resistance"	10 Report of Joint FAO/WHO Expert Consultation on Allergenicity of Foods Derived from Biotechnology (2001): Section "6.4 Pepsin Resistance".	10 バイオテクノロジー応用食品のアレルギー誘発性に関する FAO/WHO 合同専門家会議報告書（2001 年）：セクション 6.4「ペプシン耐性」。
5 According to the Joint Report of the FAO/WHO Expert Consultation on Allergenicity of Foods Derived from Biotechnology (22-25 January 2001, Rome, Italy) a minimum of 8 relevant sera is required to achieve a 99% certainty that the new protein is not an allergen in the case of a major allergen. Similarly, a minimum of 24 relevant sera is required to achieve the same level of certainty in the case of a minor allergen. It is recognized that these quantities of sera may not be available for testing purposes.	11 According to the Joint Report of the FAO/WHO Expert Consultation on Allergenicity of Foods Derived from Biotechnology (22-25 January 2001, Rome, Italy) a minimum of 8 relevant sera is required to achieve a 99% certainty that the new protein is not an allergen in the case of a major allergen. Similarly, a minimum of 24 relevant sera is required to achieve the same level of certainty in the case of a minor allergen. It is recognized that these quantities of sera may not be available for testing purposes.	11 バイオテクノロジー応用食品のアレルギー誘発性に関する FAO/WHO 合同会議（2001 年 1 月 22-25 日、イタリア・ローマ）の合同報告書によれば、主要アレルゲンの場合、新たなタンパク質がアレルゲンではないことを 99%確実にするためには最低 8 つの関連血清が必要である。同様に、非主要アレルゲンについて同じ確実性を期すためには最低 24 の関連血清が必要である。これだけの量の血清は試験のためには利用できないことが認識されている。
6 Ex vivo procedure is described as the testing for allergenicity using cells or tissue culture from allergic human subjects (Report of Joint FAO/WHO Expert Consultation on Allergenicity of Foods derived from Biotechnology)	12 Ex vivo procedure is described as the testing for allergenicity using cells or tissue culture from allergic human subjects (Report of Joint FAO/WHO Expert Consultation on Allergenicity of Foods derived from Biotechnology).	12 エクスビボ過程とは、アレルギー患者の細胞・組織培養を用いたアレルギー誘発性試験とされている（バイオテクノロジー応用食品のアレルギー誘発性に関する FAO/WHO 合同専門家会議の報告書）。

	ANNEX 2: FOOD SAFETY ASSESSMENT OF FOODS DERIVED FROM RECOMBINANT-DNA PLANTS MODIFIED FOR NUTRITIONAL OR HEALTH BENEFITS	栄養または健康上の利点のために改変された組換え DNA 植物に由来する食品の食品安全評価 （仮訳：作業中）
	SECTION 1 – INTRODUCTION 1. General guidance for the safety assessment of foods derived from recombinant-DNA plants is provided in the Codex Guideline for the Conduct of Food Safety Assessment of Foods Derived from Recombinant-DNA Plants (CAC/GL 45-2003) (Codex Plant Guideline). This Annex provides additional considerations that are specific to foods modified for nutritional or health benefits. The document does not extend beyond a safety assessment and therefore, it does not cover assessment of the benefits themselves or any corresponding health claims, or risk-management measures. 2. The following factors determine whether a recombinant-DNA plant is a recombinant-DNA Plant Modified for Nutritional or Health Benefits, and as such within the scope of this Annex: (a) the recombinant-DNA plant exhibits a particular trait in portion(s) of the plant intended for food use, and; (b) The trait is a result of i) introduction of a new nutrient(s) or related substance(s), or ii) alteration of either the quantity or bioavailability of a nutrient(s) or related substance(s), iii) removal or	セクション１ – 導入 1. 組換え DNA 植物に由来する食品の安全性評価に関する一般的なガイダンスは、「組換え DNA 植物に由来する食品の安全性評価の実施に関するコーデックス・ガイドライン」(CAC/GL 45-2003)（コーデックス植物ガイドライン）に記載されている。本付属書は、栄養または健康上の利点のために改変された食品に特有の追加的な考慮事項を提供するものである。本文書は安全性評価を超えるものではないため、有益性そのものやそれに対応する健康強調表示、またはリスク管理措置の評価は対象としていない。 2. 組換え DNA 植物が栄養上または健康上の利益のために改変された組換え DNA 植物であるかどうか、またそのような植物として本付属書の範囲内であるかどうかは、以下の要因によって決定される。 (a) 組換え DNA 植物が、食用を目的とした植物の一部に特定の形質を示していること。 (b) その形質は、ｉ）新しい栄養成分または関連物質の導入、ii）栄養成分または関連物質の量またはバイオアベイラビリティの変更、iii）好ましくない物質（例：アレルゲンや毒性物質）の除去または削減、または、iv）これらの物質の栄養または健康に関連する相互作用の変更の結果である。

	reduction of undesirable substance(s) (e.g. allergens or toxicants), or iv) alteration of the interaction(s) of nutritional or health relevance of these substances.	
	SECTION 2 - DEFINITION 3. The definition below applies to this Annex: Nutrient - means any substance normally consumed as a constituent of food: (a) which provides energy; or (b) which is needed for growth and development and maintenance of healthy life; or (c) a deficit of which will cause characteristic biochemical or physiological changes to occur.	セクション2 - 定義 3. 以下の定義は、本付属書に適用される。 栄養素」とは、通常、食品の構成要素として消費される物質を意味する。 (a) エネルギーを供給するもの。 (b) 成長・発達及び健康な生活の維持に必要なもの。 (c) 不足すると、特徴的な生化学的または生理学的変化が生じるもの。
	4. This Annex draws, where appropriate, on the definitions of key nutritional concepts to be found or to be developed in relevant Codex texts, especially those elaborated by the Codex Committee on Nutrition and Foods for Special Dietary Uses.	4. 本付属書は、必要に応じて、関連するコーデックスの文書、特にコーデックス栄養・特別食用食品委員 会が作成した文書に見られる、又は作成される主要な栄養概念の定義を参考にしている。
	SECTION 3 - FOOD SAFETY ASSESSMENT 5. The Codex General Principles for the Addition of Essential Nutrients to Foods (CAC/GL 09-1987) are generally applicable to the assessment of food derived from a plant which is modified by increasing the amount of a nutrient(s) or related	セクション 3 - 食品安全性評価 5. コーデックスの「食品への必須栄養素の添加に関する一般原則」(CAC/GL 09-1987) は、吸収及び代謝に利用可能な栄養素又は関連物質の量を増加させることによって改変された植物由来の食品の評価に一般的に適用される。コーデックス植物ガイドラインに概説されている食品安全

	substance(s) available for absorption and metabolism. The Food Safety Framework outlined within the Codex Plant Guideline applies to the overall safety assessment of a food derived from a recombinant-DNA plant modified for nutritional or health benefits. This Annex presents additional considerations regarding the food safety assessment of those foods.	の枠組みは、栄養上又は健康上の利点のために改変された組換え DNA 植物に由来する食品の総合的な安全性評価に適用される。本付属書は、これらの食品の食品安全評価に関する追加的な検討事項を示すものである。
	6. Foods derived from recombinant-DNA plants modified for nutritional or health benefits may benefit certain populations/sub populations, while other populations/sub populations may be at risk from the same food.	6. 栄養上または健康上の利益のために改変された組換え DNA 植物に由来する食品は、特定の集団／小集団に利益をもたらす一方で、他の集団／小集団が同じ食品によってリスクを負う可能性がある。
	7. Rather than trying to identify every hazard associated with a particular food, the intention of a safety assessment of food derived from recombinant-DNA plants is the identification of new or altered hazards relative to the conventional counterpart. Since recombinant-DNA plants modified for nutritional or health benefits result in food products with a composition that may be significantly different from their conventional counterparts, the choice of an appropriate comparator is of great importance for the safety assessment addressed in this Annex. Those alterations identified in a plant modified to obtain nutritional or health	7. 組換え DNA 植物に由来する食品の安全性評価の意図は、特定の食品に関連するすべての危険性を特定しようとするのではなく、従来の食品と比較して新たなまたは変化した危険性を特定することにある。栄養学的または健康上の利点のために改変された組換え DNA 植物は、従来のものとは著しく異なる組成の食品をもたらすため、適切な比較対象を選択することは、本付属書で扱う安全性評価にとって非常に重要である。栄養上または健康上の利点を得るために改変された植物で確認された変化が、本安全性評価の対象となる。

	benefits are the subject of this safety assessment.	
	8. Upper levels of intake for many nutrients that have been set out by some national, regional and international bodies may be considered, as appropriate. The basis for their derivation should also be considered in order to assess the public health implications of exceeding these levels.	8. 国、地域、国際機関が設定した多くの栄養素の上限摂取量は、必要に応じて考慮される。これらのレベルを超えた場合の公衆衛生上の影響を評価するために、その導き出しの根拠も考慮されるべきである。
	9. The safety assessment of related substances should follow a case-by-case approach taking into account upper levels as well as other values, where appropriate.	9. 関連物質の安全性評価は、必要に応じて、上限値やその他の値を考慮したケースバイケースのアプローチに従うべきである。
	10. Although it is preferable to use a scientifically-determined upper level of intake of a specific nutrient or related substance, when no such value has been determined, consideration may be given to an established history of safe use for nutrients or related substances that are consumed in the diet if the expected or foreseeable exposure would be consistent with those historical safe levels.	10. 特定の栄養素または関連物質の摂取量については、科学的に決定された上限値を使用することが望ましいが、そのような値が決定されていない場合、予想されるまたは予測される暴露がそれらの歴史的な安全レベルと一致するならば、食事で消費される栄養素または関連物質について、確立された安全使用の歴史を考慮することができる。
	11. With conventional fortification of food, typically a nutrient or a related substance is added at controlled concentrations and its chemical form is characterized. Levels of plant nutrients	11. 従来の食品の栄養強化では、通常、栄養成分や関連物質を制御された濃度で添加し、その化学的形態を特徴づける。植物の栄養素や関連物質のレベルは、従来の品種と組換え DNA 植物の両方において、生育条件により変化する可能性

	or related substances may vary in both conventionally bred and recombinant-DNA plants due to growing conditions. In addition, more than one chemical form of the nutrient might be expressed in the food as a result of the modification and these may not be characterized from a nutrition perspective. Where appropriate, information may be needed on the different chemical forms of the nutrient(s) or related substance(s) expressed in the portion of the plant intended for food use and their respective levels.	がある。さらに、改変の結果、複数の化学形態の栄養素が食品中に発現する可能性があり、これらは栄養学的観点からは特徴付けられないかもしれません。必要に応じて、食品への使用を意図した植物の一部に発現する栄養素または関連物質の異なる化学的形態およびそれらの各レベルに関する情報が必要となる場合がある。
	12. Bioavailability of the nutrient(s), related substance(s), or undesirable substance(s) in the food that were the subject of the modification in the recombinant-DNA plant should be established, where appropriate. If more than one chemical form of the nutrient(s) or related substance(s) is present, their combined bioavailability should be established, where appropriate.	12. 必要に応じて、組換え DNA 植物の改変の対象となった食品中の栄養成分、関連物質、または望ましくない物質のバイオアベイラビリティを確立するべきである。栄養素または関連物質の 2 つ以上の化学的形態が存在する場合、必要に応じてそれらの複合バイオアベイラビリティが確立されるべきである。
	13. Bioavailability will vary for different nutrients, and methods of testing for bioavailability should be relevant to the nutrient, and the food containing the nutrient, as well as the health, nutritional status and dietary practices of the specific populations consuming the food. In vitro and in vivo methods to	13. バイオアベイラビリティーは栄養素によって異なるため、バイオアベイラビリティーの試験方法は、その栄養素、その栄養素を含む食品、およびその食品を消費する特定の集団の健康状態、栄養状態、食習慣に関連したものでなければならない。バイオアベイラビリティを測定する方法には、in vitro および in vivo の方法があり、後者は動物およびヒトで実施される。In

	determine bioavailability exist, the latter conducted in animals and in humans. In vitro methods can provide information to assess extent of release of a substance from plant tissues during the digestive process. In vivo studies in animals are of limited value in assessing nutritional value or nutrient bioavailability for humans and would require careful design in order to be relevant. In vivo studies, in particular, human studies may provide more relevant information about whether and to what extent the nutrient or related substance is bioavailable.	vitro 法は、消化過程で植物組織から物質が放出される程度を評価するための情報を提供することができる。動物を用いた in vivo 試験は、人間にとっての栄養価や栄養素のバイオアベイラビリティを評価する上では価値が限られており、関連性を持たせるためには慎重な設計が必要である。in vivo 試験、特にヒトを対象とした試験では、栄養素または関連物質が生物学的に利用可能かどうか、またどの程度利用可能かについて、より適切な情報が得られる可能性がある。
	14. Guidance on dietary exposure assessment of foods derived from recombinant-DNA plants with nutritional modifications is provided in paragraph 49 of the Codex Plant Guideline. In the context of this Annex, dietary exposure assessment is the estimation of the concentration of the nutrient(s) or related substance(s) in a food, the expected or foreseeable consumption of that food, and any known factors that influence bioavailability. Exposure to a nutrient(s) or related substance(s) should be evaluated in the context of the total diet and the assessment should be carried out based on the customary dietary consumption, by the relevant population(s), of the corresponding food that is likely to be	14. 栄養学的修飾を施した遺伝子組換え植物に由来する食品の食事暴露評価に関するガイダンスは、コーデックス植物ガイドラインのパラグラフ 49 に記載されている。本付属書において、食事暴露評価とは、食品中の栄養素又は関連物質の濃度、当該食品の予想され る又は予測される消費量、及びバイオアベイラビリティに影響を与える既知の要因を推定することである。栄養素または関連物質への曝露は、食生活全体の中で評価されるべきであり、その評価は、関連する集団による、排出される可能性のある対応する食品の慣習的な食生活の消費に基づいて実施されるべきである。曝露を評価する際には、改変された食品の消費が、置き換えられることが意図されている食品の消費と比較して、栄養上の悪影響をもたらすかどうかに関する情報を考慮することが適切である。すべてではないが、暴露評価のほとんどの側面は、栄養または健康

	displaced. When evaluating the exposure, it is appropriate to consider information on whether the consumption of the modified food could lead to adverse nutritional effects as compared to consumption of the food that it is intended to replace. Most, if not all, aspects of exposure assessment are not unique to recombinant-DNA plants modified for nutritional or health benefits.	上の利点のために改変された組換え DNA 植物に特有のものではない。
	15. The first step of an exposure assessment is determining the level(s) of the substance(s) in question in the portion of the plant intended for food use. Guidance on determining changes in levels of these substances is provided in the Codex Plant Guideline.	15. 曝露評価の最初のステップは、食品への使用を意図した植物の部分における問題のある物質のレベルを決定することである。これらの物質のレベルの変化を判断するためのガイダンスは、コーデックス植物ガイドラインに記載されている。
	16. Consumption patterns will vary from country to country depending on the importance of the food in the diet(s) of a given population(s). Therefore, it is recommended that consumption estimates are based on national or regional food consumption data when available, using existing guidance on estimation of exposure in a given population(s). When national or regional food consumption data is unavailable, food availability data may provide a useful resource.	16. 消費パターンは、特定の人々の食生活における当該食品の重要性に応じて国ごとに異なる。したがって、消費量の推定は、入手可能な場合には、国または地域の食品消費データに基づき、特定の集団における暴露の推定に関する既存のガイダンスを使用することが推奨される。国または地域の食品消費データが入手できない場合は、食品入手可能性データが有用な情報源となる可能性がある。
	17. To assess the safety of a food derived from a recombinant-DNA plant modified for	17. 栄養学的または健康上の利点のために改変された組換え DNA 植物に由来する食品の安全性を

	a nutritional or health benefit, the estimated intake of the nutrient or related substance in the population(s) is compared with the nutritional or toxicological reference values, such as upper levels of intake, ADIs for that nutrient or related substance, where these values exist. This may involve assessments of different consumption scenarios against the relevant nutritional reference value, taking into account possible changes in bioavailability, or extend to probabilistic methods that characterise the distribution of exposures within the relevant population(s).	評価するために、集団における栄養素または関連物質の推定摂取量を、その栄養素または関連物質の栄養学的または毒物学的参照値（上限摂取量、ADI など）が存在する場合には、それらの値と比較する。これには、バイオアベイラビリティの可能な変化を考慮して、関連する栄養学的参照値に対する異なる消費シナリオの評価が含まれるか、あるいは関連する集団内での暴露の分布を特徴づける確率的な方法に拡張することができる。
脚注		
	13 Principles for the Risk Analysis of Foods Derived from Modern Biotechnology (CAC/GL 44-2003, paragraph 19) 14 General Principles for the Addition of Essential Nutrients to Foods (CAC/GL 09-1987) 15 Paragraphs 18-21 (Safety Framework) and 48-53 (Nutrition Modification) 16 Further guidance for susceptible and high-risk population groups is provided in paragraph 49 of the Codex Plant Guideline. 17 Codex Plant Guideline, paragraph 4	13 現代のバイオテクノロジーに由来する食品のリスク分析に関する原則（CAC/GL 44-2003, paragraph 19 14 食品への必須栄養素の添加に関する一般原則（CAC/GL 09-1987） 15 パラグラフ 18-21（安全性の枠組み）及び 48-53（栄養改質）。 16 影響を受けやすい集団及び高リスクの集団に関する更なるガイダンスは、コーデックス植物ガイドラインのパラグラフ 49 に記載されている。 17 コーデックス植物ガイドライン、パラグラフ 4

	18 Codex Plant Guideline, paragraph 51	18 コーデックス植物ガイドライン、パラグラフ 51
	19 Where such guidance is not provided by Codex, information provided by the FAO/WHO may be preferably considered.	19 コーデックスがそのようなガイダンスを提供しない場合は、FAO/WHO が提供する情報を優先的に考慮することができる。
	20 Additional applicable guidance on dietary exposure assessment of nutrients and related substances is provided in the Report of a Joint FAO/WHO Technical Workshop on Nutrient Risk Assessment. WHO Headquarters, Geneva, Switzerland, 2-6 May 2005.	20 栄養素及び関連物質の食事暴露評価に関する追加のガイダンスは、「Report of a Joint FAO/WHO Technical Workshop on Nutrient Risk Assessment」に記載されている。2005 年 5 月 2-6 日、スイス・ジュネーブの WHO 本部。
	21 Paragraphs 44 and 45	21 パラグラフ 44 および 45
	22 A Model for Establishing Upper Levels of Intake for Nutrients and Related Substances. Report of a Joint FAO/WHO Technical Workshop on Nutrient Risk Assessment. WHO Headquarters, Geneva, Switzerland, 2-6 May 2005	22 A Model for Establishing Upper Levels of Intake for Nutrients and Related Substances. 栄養素のリスクアセスメントに関する FAO/WHO 合同テクニカルワークショップ報告書。2005 年 5 月 2-6 日、スイス、ジュネーブ、WHO 本部
	23 Data on staple food products may also be supplemented by information from FAO Food Balance Sheets.	23 主食に関するデータは、FAO Food Balance Sheet からの情報で補完することもできる。

	ANNEX 3: FOOD SAFETY ASSESSMENT IN SITUATIONS OF LOW-LEVEL PRESENCE OF RECOMBINANT-DNA PLANT MATERIAL IN FOOD	食品中に組換え DNA 植物材料が低レベルで存在する場合の食品安全評価 （仮訳：作業中）
	SECTION 1 – PREAMBLE 1. An increasing number of recombinant-DNA plants are being authorized for commercialization. However, they are authorized at different rates in different countries. As a consequence of these asymmetric authorizations, low levels of recombinant DNA plant materials that have passed a food safety assessment according to the Codex Guideline for the conduct of Food Safety Assessment of Foods Derived from Recombinant-DNA Plants (CAC/GL 45-2003) (Codex Plant Guideline) in one or more countries may on occasion be present in food in importing countries in which the food safety of the relevant recombinant-DNA plants has not been determined. 2. This Annex describes the recommended approach to the food safety assessment in such situations of low-level presence of recombinant-DNA plant material or in advance preparation for such potential circumstances. 3. This Annex also describes data and information sharing mechanisms to facilitate utilization of the Annex and to determine whether it should apply.	セクション 1 – 前文 1. 組換え DNA 植物の商業化が認可されるケースが増えている。しかし、それらは国によって認可される割合が異なっている。このような非対称的な認可の結果、ある国または複数の国で「組換え DNA 植物に由来する食品の食品安全性評価の実施に関するコーデックス・ガイドライン」(CAC/GL 45-2003)（コーデックス植物ガイドライン）に基づく食品安全性評価に合格した低レベルの組換え DNA 植物材料が、当該組換え DNA 植物の食品安全性が決定されていない輸入国の食品に混入することがある。 2. 本付属書は、このような低レベルの組換え DNA 植物材料が存在する状況において、あるいはそのような潜在的な状況に事前に備えるために推奨される食品安全性評価のアプローチを説明するものである。 3. 本附属書はまた、本附属書の利用を促進し、本附属書が適用されるべきかどうかを判断するためのデータおよび情報共有のメカニズムを記述する。

	4. This Annex can be applied in two different dietary exposure situations: a. That involving commodities, such as grains, beans or oil seeds, in which exposure to food from a variety not authorized in the importing country would likely be to dilute low level amounts at any one time. This would likely be the more common situation of low-level presence of recombinant-DNA plant material. Because any food serving of grains, beans or oil seeds would almost necessarily come from multiple plants, and because of how these types of commodities generally are sourced from multiple farms, are commingled in grain elevators, are further commingled in export shipments, at import and when used in processed foods, any inadvertently commingled material derived from recombinant-DNA plant varieties would be present only at a low level in any individual serving of food. b. That involving foods that are commonly consumed whole and undiluted, such as some fruits and vegetables like potatoes, tomatoes, and papaya, in which exposure would be rare but could be to an undiluted form of the unauthorized recombinant-DNA plant material. While the likelihood of consuming material from such an unauthorized variety would be low and	4. この付属書は、2つの異なる食事暴露状況に適用することができる。 a. 穀物、豆類、油糧種子などの商品に関わるもので、輸入国で認可されていない品種の食品に接触すると、一度に低レベルの量が希釈されてしまう可能性が高い。これは、組換えDNA植物材料が低レベルで存在するという、より一般的な状況であると考えられる。穀物、豆、油糧種子の食品は、ほとんどの場合、複数の植物から供給され、これらの種類の商品は一般に複数の農場から供給され、穀物倉庫で混ざり合い、輸出貨物の中でさらに混ざり合い、輸入時に混ざり合い、加工食品に使用されるため、組換えDNA植物品種に由来する物質が不用意に混ざり合っても、個々の食品の中には低レベルでしか存在しないであろう。 b. ジャガイモ、トマト、パパイヤなどの一部の果物や野菜のように、一般的に丸ごと原液で消費される食品に関わるもので、未承認の組換えDNA植物材料の原液にさらされることは稀であるが、その可能性はある。このような未承認の品種の材料を消費する可能性は低く、繰り返し消費する可能性はさらに低くなりますが、そのような消費は未承認の果物や野菜全体を消費することになるかもしれません。

	the likelihood of repeated consumption would be much lower, any such consumption might be of an entire unauthorized fruit or vegetable.	
	5. In both cases, the dietary exposure will be significantly lower than would be considered in a food safety assessment of the recombinant-DNA plant according to the Codex Plant Guideline. As a result, only certain elements of the Codex Plant Guideline will be relevant and therefore are included in this Annex.	5. いずれの場合も、食事による暴露は、コーデックス植物ガイドラインに基づく組換え DNA 植物の食品安全性評価で考慮されるよりも大幅に低くなります。その結果、コーデックス植物ガイドラインの特定の要素のみが関連するため、本付属書に記載している。
	6. This Annex does not: ・address risk management measures; national authorities will determine when a recombinant-DNA plant material is present at a level low enough for this Annex to be appropriate; ・ preclude national authorities from conducting a safety assessment according to the Codex Plant Guideline; countries can decide when and how to use the Annex within the context of their regulatory systems; or ・eliminate the responsibility of industries, exporters and, when applicable, national competent authorities to continue to meet countries' relevant import requirements, including in relation to unauthorized recombinant-DNA plant material.	6. 本付属書は以下を目的としていない。 - 組換え DNA 植物材料が、本付属書が適切とされるほど低いレベルで存在するかどうかは、各国当局が判断する。 - 各国は、自国の規制制度の中で、いつ、どのように本附属書を使用するかを決定することができる。 - 産業界、輸出業者、及び該当する場合には国家主管庁が、未承認の組換え DNA 植物材料に関連して、各国の関連輸入要件を継続的に満たす責任を排除すること。

	SECTION 2 - GENERAL AND OTHER CONSIDERATIONS 7. For the food safety assessment in situations of low-level presence of recombinant DNA plant materials in food, sections 4 and 5 of the Codex Plant Guideline apply as amended as follows. The applicable paragraphs are specifically indicated. Those paragraphs of the Codex Plant Guidelines that are not listed can be omitted from consideration. DESCRIPTION OF THE RECOMBINANT-DNA PLANT 8. Paragraph 22 of the Codex Plant Guideline applies. DESCRIPTION OF THE HOST PLANT AND ITS USE AS A FOOD 9. Paragraphs 23, 24 and 25 of the Codex Plant Guideline apply. DESCRIPTION OF THE DONOR ORGANISM(S) 10. Information should be provided on the donor organism(s) and, when appropriate, on other related species. It is particularly important to determine if the donor organism(s) or other closely related members of the family naturally exhibit characteristics of pathogenicity or toxin production, or have other traits that affect human health. The description of the donor organism(s) should include: A. its usual or common name;	セクション2 - 一般的およびその他の考慮事項 7. 食品中に組換え DNA 植物材料が低レベルで存在する状況下での食品安全性評価には、コーデックス植物ガ イドラインのセクション 4 及び 5 を以下のように修正して適用する。なお、該当する段落を明記する。記載されていないコーデックス植物ガイドラインのパラグラフは、検討から除外することができる。 組換え DNA 植物の説明 8. コーデックス植物ガイドラインの第 22 項を適用する。 宿主植物及びその食品としての利用に関する記述 9. コーデックス植物指針の第 23、24 及び 25 項による。 提供する生物の説明 10. ドナーとなる生物に関する情報、及び必要に応じて他の近縁種に関する情報を提供すること。特に重要なのは、ドナー生物やその他の近縁種が、病原性や毒素産生の特徴を自然に示しているかどうか、あるいは人間の健康に影響を与えるその他の形質を有しているかどうかを判断することである。ドナー生物の説明には以下が含まれるべきである。 A. 通常または一般的な名称。 B. 学名 C. 分類学上の分類。

	B. scientific name; C. taxonomic classification; D. information about the natural history as concerns food safety; E. information on naturally occurring toxins and allergens; for microorganisms, additional information on pathogenicity and the relationship to known pathogens; and, F. information on past and present use, if any, in the food supply and exposure route(s) other than intended food use (e.g., possible presence as contaminants).	D. 食品の安全性に関わる自然史についての情報。 E. 自然発生する毒素およびアレルゲンに関する情報；微生物の場合は、病原性および既知の病原体との関係に関する追加情報；および。 F. 過去および現在の食品供給における使用（もしあれば)、および意図された食品使用以外の暴露経路（例：汚染物質としての存在の可能性）に関する情報。
	DESCRIPTION OF THE GENETIC MODIFICATION(S) 11. Paragraphs 27, 28 and 29 of the Codex Plant Guideline apply.	遺伝子組み換えの説明 11. コーデックス植物ガイドラインのパラグラフ27、28及び29が適用される。
	CHARACTERIZATION OF THE GENETIC MODIFICATION(S) 12. Paragraphs 30 and 31 of the Codex Plant Guideline apply.	遺伝子組換え作物の特徴 12. コーデックス植物ガイドライン第 30 項及び第31項による。
	13. Information should be provided on any expressed substances in the recombinant-DNA plant; this should include: A) the gene product(s) (e.g. a protein or an untranslated RNA); B) the gene product(s)' function; C) the phenotypic description of the new trait(s); D) the level and site of expression in the plant of the expressed gene	13. 組換えDNA植物中の発現物質に関する情報を提供すべきであり、これには以下が含まれる。 A) 遺伝子産物（例：タンパク質または非翻訳RNA)。 B) その遺伝子産物の機能。 C) 新しい形質の表現型の説明。 D) 発現した遺伝子産物の植物における発現レベルと発現部位、および植物の可食部における代謝物のレベル。 E) 可能であれば、発現された配列・遺伝子の機能が特定の内因性 mRNA またはタンパ

	product(s), and the levels of its metabolites in the edible portions of the plant; and E) where possible, the amount of the target gene product(s) if the function of the expressed sequence(s)/gene(s) is to alter the accumulation of a specific endogenous mRNA or protein.	ク質の蓄積を変化させるものである場合、標的遺伝子産物の量。
	14. Paragraph 33 of the Codex Plant Guideline applies.	14. コーデックス植物ガイドラインのパラグラフ33が適用される。
	SAFETY ASSESSMENT Expressed Substances (non-nucleic acid substances) Assessment of possible toxicity 15. The safety assessment should take into account the chemical nature and function of the newly expressed substance and identify the concentration of the substance in the edible parts of the recombinant-DNA plant, including variations and mean values.	安全性評価 発現物質（非核酸物質）の場合 想定される毒性の評価 15. 安全性評価は、新たに発現した物質の化学的性質及び機能を考慮し、組換えDNA植物の可食部における当該物質の濃度（変動及び平均値を含む）を特定するものとする。
	16. Information should be provided to ensure that genes coding for known toxins present in the donor organisms are not transferred to recombinant-DNA plants that do not normally express those toxic characteristics. This assurance is particularly important in cases where a recombinant-DNA plant is processed differently from a donor plant, since	16. ドナー生物に存在する既知の毒素をコードする遺伝子が、それらの毒性特性を通常は発現しない組換えDNA植物に移されないことを保証するための情報が提供されるべきである。この保証は、組換えDNA植物がドナー植物とは異なる方法で加工される場合に特に重要である。なぜなら、ドナー生物に関連する従来の食品加工技術は、毒性物質を不活性化、分解または除去する可能性があるからである。

	conventional food processing techniques associated with the donor organisms may deactivate, degrade or eliminate toxicants.	
	17. Paragraph 37 of the Codex Plant Guideline applies.	17. コーデックス植物ガイドラインのパラグラフ 37 が適用される。
	18. In the case of proteins, the assessment of potential toxicity should focus on amino acid sequence similarity between the protein and known protein toxins as well as stability to heat or processing and to degradation in appropriate representative gastric and intestinal model systems. Appropriate oral toxicity studies29 may need to be carried out in cases where the protein present in the food is not similar to proteins that have previously been consumed safely in food, and taking into account its biological function in the plant where known.30	18. タンパク質の場合、潜在的な毒性の評価は、タンパク質と既知のタンパク質毒素との間のアミノ酸配列の類似性に加えて、熱や加工に対する安定性、適切な代表的な胃や腸のモデルシステムでの分解に焦点を当てる必要があります。食品に含まれるタンパク質が、これまで食品として安全に摂取されてきたタンパク質と類似していない場合には、適切な経口毒性試験 29 を実施する必要があるかもしれません。
	19. Paragraphs 39 and 40 of the Codex Plant Guideline apply.	19. コーデックス植物ガイドラインのパラグラフ 39 及び 40 が適用される。
	Assessment of possible allergenicity (proteins) 20. Paragraphs 41, 42 and 43 of the Codex Plant Guideline apply.	アレルギー性の可能性の評価（タンパク質） 20. コーデックス植物ガイドラインのパラグラフ 41、42、43 が適用される。
	Analyses of Key Toxicants and Allergens 21. Analyses of key toxicants31 and allergens are important in certain cases of foods	主要な毒物及びアレルゲンの分析 21. 主要な毒性物質 31 及びアレルゲンの分析は、組換え DNA 植物由来の食品（例えば、ジ

	from recombinant-DNA plants (e.g., those that are commonly consumed whole and undiluted, such as potatoes, tomatoes, and papaya). Analyses of concentrations of key toxicants and allergens of the recombinant-DNA plant typical of the food should be compared with an equivalent analysis of a conventional counterpart grown and harvested under the same conditions. The statistical significance of any observed differences should be assessed in the context of the range of natural variations for that parameter to determine its biological significance. The comparator(s) used in this assessment should ideally be the near isogenic parental line. In practice, this may not be feasible at all times, in which case a line as close as possible should be chosen. The purpose of this comparison is to establish that substances that can affect the safety of the food have not been altered in a manner that would have an adverse impact on human health.	ャガイモ、トマト、パパイヤのように一般的に丸ごと原液で消費されるもの）の特定のケースにおいて重要である。食品の典型的な組換え DNA 植物の主要な毒性物質およびアレルゲンの濃度の分析は、同じ条件で栽培・収穫された従来の植物の同等の分析と比較されるべきである。観察された差異の統計的有意性は、そのパラメータの自然変動の範囲との関連で評価され、その生物学的有意性が判断されるべきである。この評価に用いる比較対象は、理想的には同質性の高い親系統であるべきである。実際には、これは常に実行可能とは限らないが、その場合には可能な限り近い系統を選択すべきである。この比較の目的は、食品の安全性に影響を与える可能性のある物質が、人の健康に悪影 響を与えるような方法で変化していないことを立証することである。
	22. The location of trial sites should be representative of the range of environmental conditions under which the plant varieties would be expected to be grown. The number of trial sites should be sufficient to allow accurate assessment of key toxicants and allergens over this range. Similarly, trials should be conducted over a sufficient number of	22. 試験地は、その植物品種が栽培されると予想される環境条件の範囲を代表するものでなければならない。試験地の数は、この範囲における主要な毒性物質およびアレルゲンの正確な評価を可能にするのに十分なものでなければならない。同様に、自然界の様々な条件に十分に対応できるように、十分な数の世代にわたって試験を実施する必要がある。環境の影響を最小限に抑え、作物品種内の自然発生

	generations to allow adequate exposure to the variety of conditions met in nature. To minimize environmental effects, and to reduce any effect from naturally occurring genotypic variation within a crop variety, each trial site should be replicated. An adequate number of plants should be sampled and the methods of analysis should be sufficiently sensitive and specific to detect variations in key toxicants and allergens.	的な遺伝子型の変異による影響を低減するために、各試験地は複製されるべきである。十分な数の植物をサンプリングし、分析方法は主要な毒性物質やアレルゲンの変異を検出するのに十分な感度と特異性を持つものでなければならない。
	Evaluation of Metabolites 23. Some recombinant-DNA plants may have been modified in a manner that could result in new or altered levels of various metabolites in the food. In certain cases of foods from recombinant-DNA plants (e.g., those that are commonly consumed whole and undiluted), consideration should be given to the potential for the accumulation of metabolites in the food that would adversely affect human health. Food safety assessment in situations of low level presence of recombinant-DNA material in foods from such plants requires investigation of residue and metabolite levels in the food. Where altered residue or metabolite levels are identified in foods, consideration should be given to the potential impacts on human health using conventional procedures for establishing the safety of such metabolites (e.g. procedures for	代謝物の評価 23. 組換え DNA 植物の中には、食品中の様々な代謝物のレベルを新たにあるいは変化させるような方法で改変されたものがあるかもしれない。組換え DNA 植物由来の食品の特定のケース（例えば、一般的に丸ごとかつ原液で消費されるもの）では、人の健康に悪影響を及ぼす代謝物が食品中に蓄積される可能性を考慮する必要がある。このような植物からの食品に組換え DNA 物質が低レベルで存在する場合の食品安全性評価では、食品中の残留物や代謝物のレベルを調査する必要がある。食品中に変化した残留物や代謝物のレベルが確認された場合には、そのような代謝物の安全性を確立するための従来の手順（例えば、食品中の化学物質のヒトに対する安全性を評価するための手順）を用いて、ヒトの健康への潜在的な影響を考慮する必要がある。

	assessing the human safety of chemicals in foods).	
	Food Processing 24. The potential effects of food processing, including home preparation, on foods derived from recombinant-DNA plants should also be considered. For example, alterations could occur in the heat stability of an endogenous toxicant. Information should therefore be provided describing the processing conditions used in the production of a food ingredient from the plant. For example, in the case of vegetable oil, information should be provided on the extraction process and any subsequent refining steps.	食品加工 24. 組換え DNA 植物由来の食品に対する、家庭での調理を含む食品加工の潜在的な影響も考慮する必要がある。例えば、内因性毒性物質の熱安定性に変化が生じる可能性がある。そのため、植物から食品成分を製造する際の加工条件を記載した情報を提供する必要がある。例えば、植物油の場合には、抽出工程及びその後の精製工程に関する情報を提供すべきである。
	POTENTIAL ACCUMULATION OF SUBSTANCES SIGNIFICANT TO HUMAN HEALTH 25. Some recombinant-DNA plants may exhibit traits (e.g. herbicide tolerance) which may indirectly result in the potential for accumulation of pesticide residues, altered metabolites of such residues, toxic metabolites, contaminants, or other substances which may be relevant to human health. In certain cases of foods from recombinant-DNA plants (e.g. those that are commonly consumed whole and undiluted), the risk assessment should take this potential for accumulation into account. Conventional procedures for establishing the safety of such compounds	人の健康に重大な影響を及ぼす物質の蓄積の可能性 25. 組換え DNA 植物の中には、残留農薬、その残留農薬の変化した代謝物、毒性代謝物、汚染物質、または人間の健康に関連する他の物質の蓄積の可能性を間接的にもたらす形質（例えば、除草剤耐性）を示すものがある。組換え DNA 植物由来の食品の特定のケース（例えば、一般的に丸ごとかつ原液で消費されるもの）では、リスクアセスメントはこの蓄積の可能性を考慮に入れるべきである。このような化合物の安全性を確立するための従来の手順（例：化学物質のヒトに対する安全性を評価する手順）を適用すべきである。

	(e.g. procedures for assessing the human safety of chemicals) should be applied. USE OF ANTIBIOTIC RESISTANCE MARKER GENES 26. Paragraphs 55, 56, 57 and 58 of the Codex Plant Guideline apply. SECTION 3 - GUIDANCE ON DATA AND INFORMATION SHARING 27. In order for Codex Members to use this Annex, it is essential that they have access to requisite data and information. 28. Codex Members should make available to a publicly accessible central database to be maintained by FAO information on recombinant-DNA plants authorized in accordance with the Codex Plant Guideline. This information should be presented in accordance with the following format: a. name of product applicant; b. summary of application; c. country of authorization; d. date of authorization; e. scope of authorization; f. unique identifier; g. links to the information on the same product in other databases maintained by relevant international organizations, as appropriate; h. summary of the safety assessment, which should be consistent with the framework of food safety assessment	抗生物質耐性マーカー遺伝子の使用 26. コーデックス植物ガイドラインのパラグラフ 55、56、57 及び 58 を適用する。 第 3 章 データと情報の共有に関するガイダンス 27. コーデックス加盟国が本附属書を利用するためには、必要なデータ及び情報へのアクセスが不可欠である。 28. コーデックス加盟国は、コーデックス植物ガイドラインに基づき認可された遺伝子組換え植物に関する情報を、 FAO が維持する一般にアクセス可能な中央データベースに提供するものとする。この情報は、以下の形式に沿って提示されるべきである。 a. 製品申請者の名前。 b. 申請書の概要。 c. 認可された国。 d. 認可の日付。 e. 認可の範囲。 f. 一意の識別子。 g. 必要に応じて、関連国際機関が保持する他のデータベースの同一製品に関する情報へのリンク。 h. 安全性評価の概要(コーデックス植物ガイドラインの食品安全性評価の枠組みと一致すべきであ る)。 i. 低レベルの状況に適した検出方法のプロトコル及び適切な標準物質（非生 産性、または特定の状況では生産性のあるも

	of the Codex Plant Guideline; i. where detection method protocols and appropriate reference material (non-viable, or in certain circumstances, viable) suitable for low-level situation may be obtained; and j. contact details of the competent authority(s) responsible for the safety assessment and the product applicant.	の）を入手できる場所；及び j. 安全性評価を担当する所轄官庁及び製品申請者の連絡先詳細。
	29. This process should facilitate rapid access by importing Codex Members to additional information relevant to the assessment of food safety assessment in situations of low-level presence of recombinant-DNA plant material in foods in accordance with this Annex.	29. このプロセスは、輸入コーデックス加盟国が、本付属書に従って、食品中に組換え DNA 植物材料が低レベルで存在する状況における食品安全性評価の評価に関連する追加情報への迅速なアクセスを促進すべきである。
	30. The authorizing Codex Members should make available complementary information to other Codex Members on its safety assessment in accordance with the Codex Plant Guideline, in conformity with its regulatory/legal framework.	30. 許可したコーデックス加盟国は、コーデックス植物ガイドラインに従った安全性評価に関する補完的な情報を、自国の規制・法律の枠組みに沿って、他のコーデックス加盟国に提供するべきである。
	31. The product applicant should provide further information and clarification as necessary to allow the assessment according to this Annex to proceed, as well as a validated protocol for an event-specific or trait-specific detection method suitable for low level situations and appropriate reference	31. 製品申請者は、本付属書に従った審査を進めるために必要な更なる情報及び説明を提供するとともに、低レベルの状況に適した事象特異的又は形質特異的な検出方法の有効な手順及び適切な標準物質（非生分解性、又は特定の状況下では生分解性）を提供するものとする。これは、商業及び産業情報の機密性を保護するための正当な懸念を損なうものではな

	materials (non-viable, or in certain circumstances, viable). This is without prejudice to legitimate concerns to safeguard the confidentiality of commercial and industrial information. 32. As appropriate, new scientific information relevant to the conclusions of the food safety assessment conducted in accordance with the Codex Plant Guideline by the authorizing Codex member should be made available.	い。 32. 必要に応じて、権限を有するコーデックス加盟国がコーデックス植物ガイドラインに従って実施した食品安 全性評価の結論に関連する新たな科学情報を公開するべきである。
	脚注	
	24 This guidance is not intended for a recombinant-DNA plant that was not authorized in an importing country as a result of that country's food safety assessment. 25 The text of this paragraph was adapted from paragraph 26 of the Codex Plant Guideline. 26 The text of this paragraph was adapted from paragraph 32 of the Codex Plant Guideline. 27 The text of this paragraph was adapted from paragraph 35 of the Codex Plant Guideline. 28 The text of this paragraph was adapted from paragraph 36 of the Codex Plant	24 本指針は、輸入国の食品安全評価の結果、輸入国で許可されなかった組換え DNA 植物を対象としたものではない。 25 この段落の文章は、コーデックス植物ガイドラインの段落 26 から引用したものである。 26 本項の文章は、コーデックス植物ガイドライン第 32 項からの引用である。 27 本項の文章はコーデックス植物ガイドライン第 35 項から引用したものである。 28 本項の文章はコーデックス植物ガイドライン第 36 項から引用したものである。

	Guideline.	
	29 Guidelines for oral toxicity studies have been developed in international fora, for example, the OECD Guidelines for the Testing of Chemicals.	29 経口毒性試験のガイドラインは、OECD Guidelines for the Testing of Chemicals（化学物質の試験に関する OECD ガイドライン）などの国際的な場で作成されている。
	30 The text of this paragraph was adapted from paragraph 38 of the Codex Plant Guideline.	30 この段落は、コーデックス植物ガイドラインの段落 38 から引用した。
	31 Key toxicants are those toxicologically significant compounds known to be inherently present in the plant, such as those compounds whose toxic potency and level may be significant to health (e.g. solanine in potatoes if the level is increased).	31 主要な毒性物質とは、植物に本質的に存在することが知られている毒性学的に重要な化合物のことであり、その毒性の強さやレベルが健康に重大な影響を与える可能性がある化合物などである（例：レベルが上昇した場合のジャガイモのソラニン）。
	32 The text of this paragraph was adapted from paragraph 44 of the Codex Plant Guideline.	32 このパラグラフの文章は、コーデックス植物ガイドラインのパラグラフ 44 から引用したものである。
	33 The text of this paragraph was adapted from paragraph 45 of the Codex Plant Guideline.	33 この段落の文章は、コーデックス植物ガイドライン第 45 段落からの引用である。
	34 The text of this paragraph was adapted from paragraph 46 of the Codex Plant Guideline.	34 本項の文章はコーデックス植物ガイドライン第 46 項から引用したものである。
	35 The text of this paragraph was adapted from paragraph 47 of the Codex Plant Guideline.	35 本項はコーデックス植物ガイドライン第 47 項から引用している。

	36 The text of this paragraph was adapted from paragraph 54 of the Codex Plant Guideline. 37 This information may be provided by the product applicant or in some cases by Codex members.	36 この段落の文章は、コーデックス植物ガイドライン第 54 段落から引用したものである。 37 この情報は製品申請者が提供する場合もあれば、コーデックス会員が提供する場合もある。