

A framework for the animal health risk analysis of biotechnology-derived animals: a Canadian perspective

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Summary

This paper describes the framework used by the Canadian Food Inspection Agency to assess the risks to animal health associated with biotechnology-derived animals and their products. In Canada the risks to animal health associated with biotechnology-derived animals are one consideration among several other regulatory concerns (e.g. human health, the environment). The risk analysis process begins with hazard identification, includes a risk assessment for each hazard, and concludes with risk management and risk communication.

Keywords

Animal – Animal health – Biotechnology – Clone – Genetically modified – Hazard – Risk – Transgene.

Introduction

‘The assessment of risk for many genetically engineered organisms may be dauntingly complex, combining as it does the micro-scale of molecular biology, biochemistry and physiology with the macro-scale complexity of ecology, population genetics, behaviour, biogeography, and evolutionary biology.’ (20).

Advances in biotechnology continue to emerge at an accelerating pace, enhancing the potential for its application in fields such as human health, animal health, agriculture and the environment. It is anticipated that commercial use of farm animals genetically engineered for novel traits (enhanced productivity and disease resistance, improved product quality, reduction or elimination of undesirable by-products, biomedical and biopharmaceutical applications and xenotransplantation) will soon be a reality. However, such rapidly emerging technologies rarely come without unknown hazards and uncertainty regarding their potential impact. It is conceivable that genetic modifications may cause deliberate or accidental anatomic, physical or behavioral changes in animals that may have adverse effects on their

wellness and thriftiness, or could lead to adverse impacts on other animals, human health and the environment.

Within the Canadian federal government, the Animal Health and Production Division (AHPD) of the Canadian Food Inspection Agency (CFIA) is responsible for the health of livestock and poultry populations that are derived from genetic engineering or from conventional breeding. It is now accepted by regulatory authorities that prior to the release of genetically modified livestock animals into the commercial agricultural sector, the impact of the genetic modification on the wellness of the animal must be assessed within the context of the end-user environment (6). For the public to have confidence in regulations designed to protect animal health, regulatory assessments must be based on scientific knowledge and assessment procedures that are thoughtful, practical and transparent (14).

Historically, risk assessment considerations pertaining to animal health have focussed on infectious pathogens. However, advances in technology and the continued globalisation of agriculture have broadened the risk assessment considerations for animal health in the area of biotechnology-derived animals (hereafter referred to as

‘B-D animals’) to include a wider range of potential risks. A document entitled ‘Animal health risk analysis framework for biotechnology-derived animals’ (4), prepared by the Animal Health Risk Analysis Unit (AHRA) of the CFIA, provides guidance to AHRA staff (and others) when performing risk assessments pertaining to B-D animals.

This article introduces the processes employed by the CFIA to assess the animal health-related risks posed by B-D animals. An overview of the institutional structure within the Canadian government and the application of the precautionary principle are also provided for a better understanding of the context in which risk assessment is conducted. The CFIA and several other government departments, reflecting their respective regulatory mandates (animal health, human health, environmental impact, etc.), are involved in the assessment of any given B-D animal or its products. Dr H. Kochhar of the CFIA discusses the legislative framework for the regulation of B-D animals elsewhere in this volume. Human health and environmental impacts related to B-D animals are assessed by the federal departments of Health Canada and Environment Canada, respectively, and will not be addressed in this paper. However, before the sale of B-D animals, or their release into the environment, risk assessments conducted by those departments will need to be taken into consideration. Transgenic fish are the responsibility of the Department of Fisheries and Oceans and will also not be discussed in this paper.

Definitions

Animal

For the purposes of risk analyses of B-D animals, the term ‘animal’ ‘includes an embryo and a fertilised egg or ovum’ (11).

Biotechnology

Biotechnology is defined as ‘the application of science and engineering to the direct or indirect use of living organisms or parts or products of living organisms in their natural or modified forms’ (12).

Modern biotechnology is defined in Article 3 of the ‘Cartagena Protocol’ under the Convention on Biological Diversity as:

‘The application of:

a) *in vitro* nucleic acid techniques, including recombinant deoxyribonucleic acid (DNA) and direct injection of nucleic acid into cells or organelles, or

b) fusion of cells beyond the taxonomic family, that overcome natural physiological reproductive or recombination barriers and that are not techniques used in traditional breeding and selection’ (21).

Biotechnology-derived animals

The term ‘biotechnology-derived animals’ refers to animals that have been produced through biotechnological methods. This term may include, but is not limited to, the following categories of animals (1):

- genetically engineered or modified animals, in which genetic material has been added, deleted, silenced or altered to influence the expression of genes and traits
- cloned animals derived by nuclear transfer from embryonic or somatic cells
- chimeric animals
- interspecies hybrids
- animals derived from *in vitro* cultivation, such as oocyte maturation or manipulation of embryos.

Hazard

A hazard is defined as an element or event that poses potential harm, i.e. an element that may cause an adverse event or may result in an adverse outcome. A hazard is identified by describing what might go wrong and how that might happen (2). Covello and Merkhofer (10) define a hazard as a source of risk that does not necessarily produce risk (i.e. a source with the potential to produce risk). A hazard produces risk only if an exposure pathway exists and if exposure creates the possibility of adverse consequences.

Risk

Risk is the likelihood of the occurrence and the magnitude of the consequences of an adverse event: a measure of the probability of harm and the severity of the impact of a hazard. Objective measurement and scientific repeatability are key features of risk evaluation. In risk studies it is common, especially in oral communication, to use the term ‘risk’ synonymously with the likelihood (probability or frequency) of the occurrence of a hazardous event. In such instances the magnitude of the event is assumed to be significant (2, 3).

Risk analysis

Risk analysis is the process that includes risk assessment, risk management and risk communication (3, 10).

Risk assessment

Risk assessment is the process of identifying a hazard and evaluating the risk of a specific hazard in absolute or relative terms. The risk assessment process involves four interrelated steps:

- release assessment
- exposure assessment
- consequence assessment
- risk estimation.

It includes estimates of uncertainty in the assessment process and is an objective, repeatable, scientific process. Quantitative risk assessment characterises the risk in numerical representations (2, 3). Qualitative risk assessment characterises the likelihood of the outcome or the magnitude of the consequences in qualitative terms such as 'high', 'medium', 'low' or 'negligible' (17).

Institutional context

In Canada the CFIA has the federal mandate for safeguarding Canada's food supply, protecting plants and maintaining animal health. To fulfil this mandate the CFIA sets strategic goals that support the broader priorities of the Government of Canada, which include protecting public health, contributing to economic growth, protecting the environment, contributing to public security and promoting good governance (8, 14).

Within the CFIA different divisions share responsibilities and carry out the mandate of the Agency by regulating and assessing the safety of agricultural products derived from biotechnology (including plants, biofertilizers, animal feeds and veterinary biologics). Through various assessment processes, these agricultural products are evaluated by the CFIA (often in conjunction with other regulatory authorities) for their safety and efficacy in animals, possible effects on the environment, and for effects on humans exposed to these materials. The Plant Biosafety Office is responsible for the assessment of plants with novel traits, the Plant Production Division is responsible for assessing the safety of fertilizers, and the Feed Section and the Veterinary Biologics Section of the AHPD are responsible for the assessment of animal feeds and veterinary biologics, respectively. The Animal Biotechnology Unit (ABU) of the CFIA is consulted by Environment Canada (the federal department that has the legislative authority on genetically modified animals under the 'Canadian Environmental Protection Act') regarding animal health matters related to B-D animals.

The Royal Society of Canada has identified independence, objectivity and transparency of risk assessment procedures

as major issues (19). The CFIA is committed to operating with transparency (9, 14): consultations with stakeholders on issues related to biotechnology have been held on many occasions, and protocols and procedures used to conduct risk assessments are available to the public, as are final risk assessment documents. The CFIA organisational structure separates the task of risk assessment from risk management decision-making to ensure that risk assessments are not influenced by prior regulatory conclusions (14). The AHRA Unit of the Science Branch conducts risk assessments at the request of the AHPD of the Program Branch and risk assessment documents are made available on the Internet. Reviews by experts external to the Canadian government may also be conducted.

Risk analysis procedures for biotechnology-derived animals

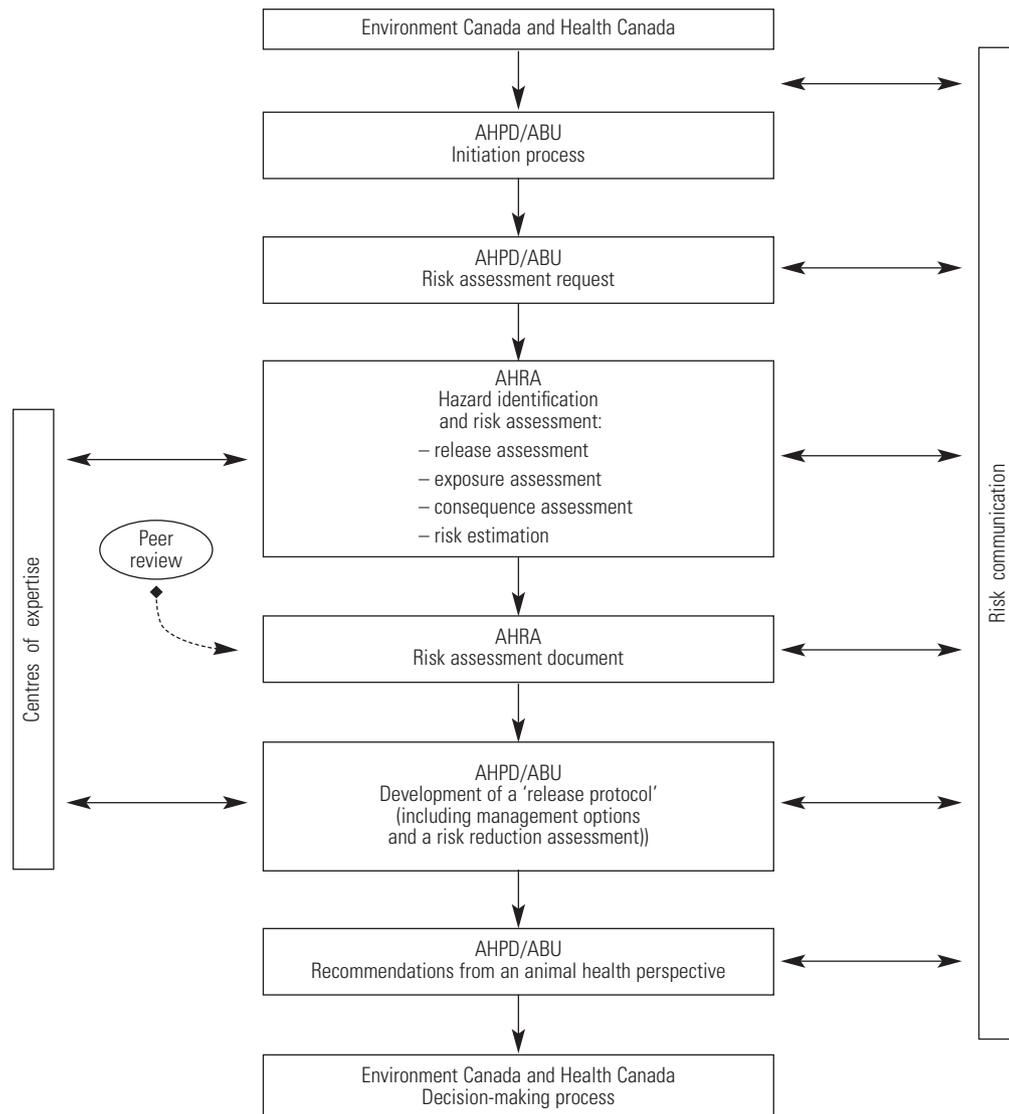
The general process of conducting a risk analysis

Risk analysis is the process of identifying hazards, analysing the likelihood of the occurrence of an adverse event, determining the significance of the potential impact, devising methods for hazard management and communicating this assessment to applicants and stakeholders (16, 17).

Initiation of the process

The process of risk analysis is initiated by Environment Canada and/or Health Canada following a request made by a notifier to release a B-D animal or its products into the environment. The notifier must provide detailed information as required under the New Substances Notification Regulations of the 'Canadian Environmental Protection Act, 1999' (13). Depending on the end use, the CFIA may be asked to collaborate by conducting a risk analysis and to provide an expert opinion from the animal health perspective as to whether or not to authorise the release of an animal or its derived products. The process for approving a commodity remains constant regardless of whether the request is for single, multiple or continuous release of B-D animals or their derived products. Figure 1 describes the steps of the risk analysis procedure used by the CFIA beginning with the initiation of a request and concluding with the CFIA recommendations to Environment Canada and Health Canada.

The information supplied under the New Substances Notification Regulations and a form requesting that a risk assessment be conducted is sent to AHRA by ABU of the AHPD. The request form requires information such as the



ABU: Animal Biotechnology Unit
 AHPD: Animal Health and Production Division
 AHRA: Animal Health Risk Analysis Unit

Fig.1

Risk analysis procedure for biotechnology-derived animals in Canada

history, background and description of the commodity, including production protocols, and the volume, quantity, frequency and time-frame of the proposed release. Additional information may be required from the applicant in order to conduct a risk assessment, as described in Table I.

Risk assessment process

The risk assessment process begins with the identification and characterisation of animal health disease risks or biological hazards, and follows with an estimation of the likelihood of their occurrence and the magnitude of the consequences (17). Because B-D animals could potentially present new hazards not usually encountered in more routine animal health risk assessments, the task of

performing risk assessments on the animal health of B-D animals is more complex. In addition, as each genetic modification on B-D animals presents a different set of circumstances and potential risks, assessments must be performed on a case-by-case basis. This is consistent with the recommendations of the Royal Society of Canada (19), the Food and Agriculture Organization and the World Health Organization (15). This process is warranted because of the large number of variables involved, such as:

- the species
- the health status of herds/flocks and individual animals
- the techniques and materials employed in production
- the transgene used

Table I
Information required from the applicant when submitting
a request to the Canadian authorities to release a biotechnology-derived animal into the environment (4)

All sections of the document must be completed by the applicant. If an applicant considers a section not to be applicable, the rationale must be stated in the document

<ol style="list-style-type: none"> 1. Summary description of animal or product 2. Reason for production 3. Details of production <ol style="list-style-type: none"> 3.1 Source of genetic material <ul style="list-style-type: none"> – gene product information (physiological function, biological effects, toxicity, etc.) 3.2 Source of donor animals <ul style="list-style-type: none"> – species, breeds/strains, origin (domestic, foreign) – other relevant information 3.3 Health status of donor animals <ul style="list-style-type: none"> – serology and other laboratory reports – health status of herd of origin – clinical disease 3.4 Source of recipient animals <ul style="list-style-type: none"> – species, breeds/strains, origin (domestic, foreign) – other relevant information 3.5 Health status of recipient animals <ul style="list-style-type: none"> – serology and other laboratory reports – health status of herd of origin – clinical disease history 4. Cloned/transgenic animal production <ol style="list-style-type: none"> 4.1 Sources and quality control of reagents 4.2 Detailed description of techniques employed <ul style="list-style-type: none"> – methods and steps taken to make the modifications – methods of accomplishing genetic modifications – numbers of embryos/animals used 5. Characterisation of cloned/transgenic animals <ol style="list-style-type: none"> 5.1 Health evaluation of founder animals and subsequent generations <ul style="list-style-type: none"> – species, breed, origin – clinical examination – clinical biochemistry – haematology – specific serological examination – others (e.g. immune function tests, etc.) 	<div style="text-align: center; margin-bottom: 10px;"> </div> <ol style="list-style-type: none"> 5.2 Genetic characterisation <ul style="list-style-type: none"> – karyotyping – microsatellite deoxyribonucleic acid (DNA) analysis – mitochondrial DNA analysis – characterisation of transgene – copy number – sequence – genomic location – gene expression: messenger ribonucleic acid (mRNA) detection and levels – information concerning the shedding of the transgene from the organism – information concerning the stability of the transgene – information on the transmission and expression of the transgene through subsequent generations (homozygous versus heterozygous, transmission via germplasm) – a description of methods that can be used to distinguish and detect the modified organism 5.3 Transgene product <ul style="list-style-type: none"> – sites of production – levels of production – shedding of product – leaking of product into non-target tissues 5.4 Biological and ecological characteristics <ul style="list-style-type: none"> – life cycle – reproductive biology – adverse ecological effects (pathogenicity, toxicity and invasiveness) – geographical description and habitat – potential for dispersal of traits by gene transfer – locations and situations where organism has caused ecological effects – involvement in biogeochemical cycling – involvement with other organisms in the environment – conditions required for survival, growth, reproduction and overwintering – capability of the organism to act as a vector for harmful agents (pathogens, toxins) – mechanisms of dispersal of the organism and modes of interaction with any dispersal agents <div style="text-align: center; margin-top: 10px;"> </div>
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- the potential for exposure to the environment (biological and ecological characteristics of the animal)
- the end use of the animal or its products.

exposure of susceptible animals or humans to these hazards. This process occurs through the collection of evidence found in the literature and includes consultation with experts within Canada and internationally.

Hazard identification

Hazard identification is a categorisation step that identifies biological agents, and genotypic and phenotypic changes, as potential hazards that could be introduced with a commodity or activity and for which pathways exist for

In contrast to conventional import risk assessments, assessments of B-D animals include consideration not only of hazards associated with infectious pathogens (3), but also hazards related to the impact of the genetic modification, e.g. the effects on animal health and welfare of any changes in diversity and sustainability that result from the genetic modifications. Criteria to identify

infectious hazards are described in the Animal Health and Production Risk Analysis Framework (3).

Table II lists potential hazards related to the techniques and methods used to produce B-D animals. Because of the rapid pace of advancement in the field of animal biotechnology, genotypic and phenotypic hazards have not been completely identified and characterised. This list of hazards represents a snapshot in time and will be updated to keep pace with the technology as it develops and evolves.

The production of B-D animals is a sequential series of events that cannot be viewed in isolation. In the case of transgenic animals, the series begins with the generation of transgenic founder animals and ends with the production of a group of transgenic animals exhibiting the desired trait. Risk must be evaluated throughout this process (including during the production of subsequent generations) and should include consideration of whether or not the transgene is present in a heterozygous or homozygous state. Similarly, cloned animals must be evaluated from the generation of the initial cloned animal to the production of progeny.

Risk assessment steps

Release assessment

A release assessment describes and quantifies the potential of a risk source (the animal or animal products) to release or introduce a hazard into an environment accessible to animal and human populations, and includes the risk to the B-D animals themselves and subsequent generations.

Release assessment involves consideration of the prevalence of the hazard, the point at which the hazard can be detected and the methods used to detect the hazard. The release assessment typically describes the type, amount, timing, and probability of the release of the hazard. In addition, the release assessment will include consideration of how these factors may change as a result of various actions, events or measures outlined in the release protocol. The various types of hazards – infectious, genotypic and phenotypic – dictate the variety of measures that need to be considered in the release assessment. In addition, all release assessments of B-D animals and their derived products must include consideration of the effects of animal waste products.

Exposure assessment

An exposure assessment describes and quantifies the relevant conditions and characteristics associated with potential exposure to hazards produced or released by a

Table II
Hazards related to the techniques and methods used in the production of biotechnology-derived animals (4)

1. Technique or process-based hazards
1.1 Adventitious infectious agent transfer
– viral, bacterial, fungal, prion
– vector virus crossing species barrier
1.2 Endogenous retroviral activation
– activation associated with infection and/or neoplastic agent
1.3 Heteroplasmy of mitochondria
– metabolic disorders
1.4 Embryo manipulation/use of cell culture
– large-offspring syndrome and metabolic diseases
– pregnancy loss
– neonatal mortality
– young animal morbidity/mortality associated with congenital and developmental defects
2. Transgene or product-based hazards
Transgene expression
– altered reproductive physiology (lack of libido, female anestrus)
– growth disturbances in the transgenic animal
– altered metabolic pathways with concentration of toxin in tissues
– excess transgene expression/production of product or its metabolite
– pleiotropic effects of transgene expression
– ectopic expression of transgene/production of product or its metabolite
3. Insertional mutagenesis/mutation-based hazards
Insertional mutagenesis/mutation
– disruption of endogenous gene function causing immune suppression and infectious diseases
– altered metabolic pathways due to toxin production
– lethal congenital/developmental defects
4. Other hazards
4.1 Transfer of antibiotic resistance genes from cells of transgene (TG) animals to the environment
– transfer of antibiotic resistance gene to the environment
4.2 Transfer of TG-bearing deoxyribonucleic acid (DNA) through the digestive tract
– passage and persistence of transgene-bearing DNA in the digestive tract
4.3 Transfer of TG to domestic animal populations, wildlife populations and ecosystems
– spread of transgene into indigenous domestic animals or wildlife
5. Hazards associated with interspecies hybrid animals produced by <i>in vitro</i> techniques
– disproportionate size and shape of offspring associated with hybrid genetics

given risk source. The exposure assessment typically describes the amount, timing, frequency, and routes of exposure, as well as the number, species and characteristics of the animal populations that might be exposed. For B-D animals this may include exposure of the B-D animal itself or other animal populations.

Consequence assessment

A consequence assessment describes and quantifies the consequences of exposure to a specified hazard. A situation must exist in which the exposure produces adverse animal health or environmental consequences. The consequence assessment typically specifies the impact on animal health sustained under given exposure scenarios. In conventional import, related risk assessments consequences are related to infectious pathogens and may include:

- animal mortality and morbidity
- production losses (e.g. decreased reproductive efficiency, feed conversion, etc.)
- costs associated with disease control (e.g. veterinary fees, vaccination, antibiotics, depopulation, decontamination, etc.)
- restricted market sales (e.g. domestic or export, live animals or animal products)
- human health implications (e.g. zoonotic disease).

Such consequences also apply with respect to B-D animals. In addition, other consequences related to unique genotypic and phenotypic hazards, such as the following, should be considered:

- perinatal mortality and morbidity
- costs associated with genotypic and phenotypic changes in B-D animals (e.g. immune function effects)
- loss of genetic diversity
- costs associated with tracing B-D animals and their products
- impacts on commercial market sales related to consumer acceptance
- welfare concerns (e.g. repetitive invasive procedures, animal handling and restraint)
- adverse consequences to the environment, including the disruption of ecosystems and the extinction of native species (4, 22).

Risk estimation

Depending on the B-D animal or product involved, it may be difficult or inappropriate to conduct a quantitative risk estimation due to a high level of uncertainty and lack of

information. Therefore, a qualitative or semi-quantitative risk estimation may be more appropriate, at this point in time, when assessing risks to animal health associated with B-D animals or their products. As more information becomes available, quantitative risk assessments may be feasible.

Risk estimation integrates the results from the release, exposure and consequence assessments to produce an overall measure of risk. The results of this process are estimates of the magnitude of the potential adverse health or environmental consequences, and include the probabilities, uncertainties and, if available, the degree of confidence associated with these estimates. Therefore, risk estimation takes into account the whole of the risk pathway from hazard identification to the potential consequences of exposure. It is thus an analysis of the summation of the findings of the release, exposure and consequence assessments (17).

At this stage a peer review process may be appropriate to validate the approach and the results obtained based on the available information. The importance of peer review, particularly for risk assessments related to biotechnology, has been highlighted in several reports and studies (5, 19).

Risk management and communication

The remaining steps in the risk analysis process include risk management and risk communication. Risk management is the responsibility of the Director of the AHPD and the ABU. Based on the tolerability of the estimated risk, the ABU develops a 'release protocol' authorising the use of the animal or its derived products, and proposes mitigation measures and evaluates the efficacy of these measures in reducing the identified risk. Efficacy is the degree by which a proposed measure reduces the likelihood and magnitude of adverse biological and economic consequences. Evaluating the efficacy is an iterative process that involves the incorporation of proposed risk mitigation measures into the initial risk assessment, which is then re-evaluated to determine the degree of risk reduction.

Risk mitigation measures incorporated in the release protocol may include, but are not limited to:

- biocontainment requirements for the animal or product
- breeding restrictions
- requirements for labelling
- requirements for traceability
- monitoring requirements (gene stability, health effects, gene expression, etc.)
- disposal and decontamination procedures.

Based on the animal health risk analysis, the CFIA makes a recommendation to Environment Canada and Health Canada to accept (or decline) the release of the animal or its derived products into the environment. This recommendation is utilized with other assessments made by these departments examining environmental and human health concerns in order to make a final decision regarding the release of the B-D animal or its products.

The precautionary principle

The Canadian government has an obligation to ensure that these new technologies are implemented without undue risk to animal health, human health or the environment. Perhaps the greatest challenge faced by those performing the risk assessment is the relative newness of and rapid progress in the technologies involved, and the paucity of data needed to answer some of the questions. While ‘the assessment of risk for many genetically engineered organisms may be dauntingly complex’ (20), there are, fortunately, tools available to assist the analyst faced with this challenge.

The Canadian government recognises the utility of the ‘precautionary principle’ in risk analysis and has produced guidelines for its application (18). The application of the precautionary principle is based on three tenets: ‘the need for a decision, a risk of serious or irreversible harm, and a lack of full scientific certainty’. Although application of the precautionary principle is primarily associated with risk management, its use must be based upon a ‘scientifically sound or credible scientific basis’, which in this model is derived largely from the risk assessment. The risk assessment is also important in identifying what types of follow-up activities may be warranted following the release of a B-D animal or its products, which is an important component of the precautionary principle.

Conclusion

With respect to the regulation of B-D animals and their products, the principal responsibility of the CFIA is to protect Canada’s livestock and maintain a sustainable animal resource base. The CFIA also has roles in

promoting science-based regulation, maintaining an effective regulatory framework, and protecting consumers and the market place from unfair practices. By meeting these objectives the CFIA provides a fair and effective environment in which commodities, including B-D animals and their products, can be regulated.

Animal biotechnology presents new challenges for regulatory risk analysts and risk managers, and also for laboratory staff, field operational staff and others involved in supporting and implementing policy. Risk analysts and managers, at this early stage in the production of B-D animals, make judgments based upon data extrapolated from related studies using other types of genetic modifications or different species, often utilising material supplied by the companies marketing their products. In this context, the CFIA intends to maintain a high level of public trust by ensuring the impartiality, integrity and transparency of all its decision making processes that are related to B-D animals and their products.

Research scientists involved in regulatory work have an important role to play in the risk assessment process by providing expert opinions to the risk analyst, performing research to answer certain questions and performing testing to assist in ‘tracking’ genetic modifications. Ideally, there needs to be an ongoing exchange between risk analysts, risk managers and research scientists on these issues.

It is perhaps reasonable to believe that in the coming years the analysis of the risks associated with B-D animals will become routine as it has for the import of conventional animals and animal products. Ongoing improvements in the techniques of B-D animal production will probably reduce the incidence of animal health problems now recognised. The continued growth of the body of knowledge will reduce the uncertainties that now exist, and new techniques and further experience will improve methods of risk management. Conversely, future research and new techniques will perhaps identify additional problems for the risk analyst to deal with – as old issues become resolved, new ones will emerge. It is safe to assume that the challenges presented by animal biotechnology for the risk analyst and other regulatory staff will continue for some time to come.



Un cadre pour l'analyse du risque zoonitaire lié aux animaux issus de la biotechnologie : une perspective canadienne

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Résumé

Le présent article décrit le cadre utilisé par l'Agence canadienne d'inspection des aliments pour évaluer les risques zoonitaires liés aux animaux issus de la biotechnologie et à leurs produits. Au Canada, les risques pour la santé animale liés aux animaux issus des biotechnologies représentent un des aspects réglementaires parmi d'autres (par exemple, santé humaine, environnement). La procédure d'analyse du risque commence par l'identification des dangers, comporte une évaluation du risque pour chaque danger identifié et s'achève avec la gestion du risque et la communication sur les risques.

Mots clés

Animal – Biotechnologie – Clone – Danger – Génétiquement modifié – Risque – Santé animale – Transgène.



Sistema de análisis de los riesgos zoonitarios ligados a los animales obtenidos por biotecnología: el punto de vista de Canadá

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Resumen

Los autores describen el sistema utilizado por la Agencia Canadiense de Inspección de Alimentos para determinar los riesgos zoonitarios que puedan entrañar los animales obtenidos por biotecnología y sus derivados. Estos riesgos son uno de los varios aspectos que, desde el punto de vista reglamentario, preocupan en Canadá (otros son, por ejemplo, la salud humana o el medio ambiente). El proceso de análisis de riesgos empieza con la identificación de los peligros, sigue con una determinación de riesgos para cada uno de esos peligros y termina con la gestión y el proceso de comunicación de los riesgos existentes.

Palabras clave

Animal – Biotecnología – Clon – Genéticamente modificado – Peligro – Riesgo – Sanidad animal – Transgén.



References

1. Adlakha-Hutcheon G. (2001). – Transgenic animal safety assessments: transgenic avian species. Internal report, Animal Biotechnology Unit, Animal Health and Production Division, Canadian Food Inspection Agency, Ottawa, 27 pp.
2. Ahl A.S., Acree J.A., Gipson P.S., McDowell R.M., Miller L. & McElvaine M.D. (1993). – Standardisation of nomenclature for animal health risk analysis. *In* Risk analysis, animal health and trade (R.S. Morley, ed.). *Rev. sci. tech. Off. int. Epiz.*, **12** (4), 1045-1053.
3. Animal Health Risk Analysis Unit (2004). – Animal health and production risk analysis framework. Science Strategies Directorate, Canadian Food Inspection Agency, Ottawa, 48 pp.
4. Animal Health Risk Analysis Unit (2004). – Animal health risk analysis framework for biotechnology-derived animals. Science Strategies Directorate, Canadian Food Inspection Agency, Ottawa, 66 pp.
5. Canadian Biotechnology Advisory Committee (2002). – Improving the regulation of genetically modified foods and other novel foods in Canada. Report to the Government of Canada, Biotechnology Ministerial Coordinating Committee. Website: <http://cbac-cccb.ca/epic/internet/incbac-cccb.nsf/vwGeneratedInterE/ah00186e.html#sum> (accessed on 15/09/2004).
6. Canadian Food Inspection Agency (CFIA) (1999). – Consultation on regulating livestock animals and fish derived from biotechnology. Session report, April 1999, CFIA, Science Branch, Office of Biotechnology. Website: <http://www.inspection.gc.ca/english/sci/biotech/tech/aniconsulte.shtml#little> (accessed on 15/09/2004).
7. Canadian Food Inspection Agency (CFIA) (2001). – Risk communication and government: theory and application for the CFIA. CFIA Public and Regulatory Affairs Branch, Website: <http://www.inspection.gc.ca/english/corpaffr/publications/riscomm/riscomm.shtml> (accessed on 28/09/2004).
8. Canadian Food Inspection Agency (CFIA) (2003). – CFIA, Corporate Business Plan 2003-2008. Website: <http://www.inspection.gc.ca/english/corpaffr/busplan/2003-2008/plan02e.shtml#1> (accessed on 30/09/2004).
9. Canadian Food Inspection Agency (CFIA) (2004). – Transparency. Office of Biotechnology, Science Branch, CFIA. Website: <http://www.inspection.gc.ca/english/sci/biotech/trans/trans.shtml> (accessed on 10/10/2004).
10. Covello V.T. & Merkhofer M.W. (1993). – Risk assessment methods: approaches for assessing health and environmental risks. Plenum Press, New York, 319 pp.
11. Department of Justice Canada (1990). – Health of Animals Act c. 21: interpretation, section 2(1). Website: <http://laws.justice.gc.ca/en/H-3.3/64369.html#rid-64378> (accessed on 23 March 2005).
12. Department of Justice Canada (1990). – Health of Animals Regulations of the Health of Animals Act c. 296: interpretation, section 2. Website: <http://laws.justice.gc.ca/en/H-3.3/C.R.C.-c.296/131364.html#rid-131372> (accessed on 23 March 2005).
13. Environment Canada (2001). – Guidelines for the notification and testing of new substances: organisms, 150pp. Website: <http://www.ec.gc.ca/substances/nsb/download/Bioe1201.PDF> (accessed on 10/10/2004).
14. Evans B.R., Doering R.L., Clarke R.C. & Ranger C. (2003). – The organisation of federal Veterinary Services in Canada: the Canadian Food Inspection Agency. *In* Veterinary Services: organisation, quality assurance, evaluation (E. Correa Melo & F. Gerster, eds). *Rev. sci. tech. Off. int. Epiz.*, **22** (2), 409-421.
15. Food and Agriculture Organization of the United Nations (FAO)/World Health Organization (WHO) (2003). – FAO/WHO expert consultation on the safety assessment of foods derived from GM animals, including fish, 17-21 November. FAO/WHO, Rome, 36 pp.
16. MacDiarmid S.C. & Pharo H.J. (2003). – Risk analysis: assessment, management and communication. *In* Veterinary Services: organisation, quality assurance, evaluation (E. Correa Melo & F. Gerster, eds). *Rev. sci. tech. Off. int. Epiz.*, **22** (2), 397-408.
17. OIE (World Organisation for Animal Health) (2004). – Terrestrial Animal Health Code. Section 1.3: Risk Analysis. Chapter 1.3.1: General Considerations, 21-23. Website: http://www.oie.int/eng/normes/mcode/en_chapitre_1.3.1.htm (accessed on 20/10/2004).
18. Privy Council Office (2003). – A framework for the application of precaution in science-based decision making about risk. Government of Canada, Ottawa, 14 pp.
19. Royal Society of Canada (2001). – Elements of precaution: recommendations for the regulation of food biotechnology in Canada. An expert panel report on the future of food biotechnology. Royal Society of Canada, January 2001, Ottawa, 245 pp.
20. Scientist's Working Group on Biosafety (1998). – Manual for assessing ecological and human health effects of genetically engineered organisms. The Edmonds Institute, Washington, DC. Website: <http://www.edmonds-institute.org/manplos.pdf> (accessed on 25/10/2004).
21. Secretariat of the Convention on Biological Diversity (SCBD) (2000). – Cartagena protocol on biosafety to the convention on biological diversity: text and annexes. SCBD, Montreal, 30 pp.
22. United States National Academy of Sciences (2002). – Animal biotechnology: science-based concerns, chapter 6. National Academy Press, Washington, DC, 93-107.