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Perceived and Potential Human Health Risks Associated with Consumption of Genetically Modified Animals

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evidence review

Summary

- Numerous varieties of genetically modified (GM) crops have been approved in Canada, and processed foods containing GM ingredients can be found on grocery store shelves. In contrast, there are currently no GM animals or products derived from GM animals approved for human consumption in Canada.
- According to the principle of substantial equivalence, which is used to evaluate the safety of GM foods, the genetically modified product must be at least as safe as its unmodified counterpart. Common types of health effects include protein allergenicity, anti-nutrient properties and toxicity.
- This evidence review summarizes the potential health effects associated with consumption of two GM animal products (GM Atlantic salmon and pork) that are currently undergoing food safety review in North America.
- The GM AquAdvantage® Salmon produces excess growth hormone, allowing it to reach market size more rapidly. Due to the lack of animal feeding studies, long-term effects of consuming GM Atlantic salmon are unclear.
- The GM Enviropig™ produces an enzyme that enables phosphate absorption and utilization, thus reducing phosphate content of manure and environmental effects associated with excess phosphate. No adverse effects resulting from consumption of this enzyme have been reported.
- To date, there is little evidence that GM animals pose a significantly greater risk to human health than their unmodified counterparts in terms of allergenicity, anti-nutrient effects or acute toxicity. However, there is some uncertainty regarding long-term health effects.

Introduction

Genetically modified products have a growing presence in the Canadian and international food market, with over 60 varieties of genetically altered plants approved for safe consumption in Canada.[1] This does not include fruits and vegetables whose genetic composition has been modified using conventional methods such as breeding and selection. Organisms that are bioengineered to possess a particular trait through insertion of a specific gene and its required components for expression of a functional gene product are termed transgenic or genetically modified (GM).

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Often, the insertion of a particular gene conveys a desirable trait that may enhance the nutritional value of the food, or give the transgenic variety a survival advantage compared to the unmodified species. Examples include enhanced growth rate; tolerance to a particular herbicide, insect or virus; and ability to tolerate a certain environmental condition (i.e., drought). Novel cellular functions that convey desirable traits are achieved through insertion of a foreign gene (i.e., that originated from a different species), whereas enhancement of existing functions can be realized through insertion of additional copies of host genes. Some crops have also been genetically modified to suppress undesirable traits, such as the production of proteins that cause allergic reactions in humans.

The process to make transgenic organisms involves: (1) creation of a construct, which is the genetic material to be inserted; (2) transfer of the construct into a single-cell fertilized egg; (3) incorporation of the genetic material into the host genome; and (4) selection for successful incorporation of the construct into the host genome. Incorporation into the host genome enables the inserted gene to be passed down from generation to generation. Bacterial and viral vectors have been used in the creation of transgenic plants such as corn[2,3] and rice.[4] By comparison, most transgenic animals have been created using microinjection to introduce construct DNA into the embryo.[5,6] Opting not to use viruses or transposable elements (i.e., DNA that can cut and paste itself at different locations in the genome) in the creation of the transgenic animal reduces the potential for unintended movement of genetic material within the genome, which is an important safety consideration if the animal or its products are intended for human consumption. Another aspect to consider is public perception of risks associated with consumption of GM animal food products.

While several transgenic animals intended for human consumption are in an advanced stage of development, to date none have received safety approval for market sale from the United States Food and Drug Administration (FDA) or Canadian regulatory agencies. In Canada, regulatory approval for transgenic foods is obtained through Health Canada, and these foods are subject to the Novel Foods Regulation, under Division 28 of the Food and Drug Regulations.[7] Applications for approval of transgenic animals for food safety are currently treated as “new animal drugs.” Two transgenic animals in the development pipeline are the Enviropig™ (Ontario Pork, ON) and AquAdvantage™ Salmon (AquaBounty Technologies, Inc., MA).

This evidence review describes the elements required to assess safety of genetically modified animals and addresses the following questions: (1) What types of human health risks are associated with consumption of genetically modified foods, in general? (2) What are the general attitudes among Canadian consumers toward genetically modified animals intended for human consumption? (3) What are some of the health concerns associated with consumption of transgenic animals that are currently undergoing food safety review?

Methods

The Web of Knowledge Database was used to search for relevant peer-reviewed articles. The search strategy used combinations of the key words [“transgenic” OR “genetically modified” OR “GM”] AND [“health effects” OR “human health” OR “safety”]. Articles referring to genetically modified plants were excluded, as were those describing genetic modifications to animals for the purpose of vaccine or drug production. Grey literature, such as consumer reports, government websites and GM animal safety assessment reports, was also used.

Assessment of Novel Food Safety

Principles of the Codex Alimentarius are used internationally to guide the risk assessment process for novel foods.[8] The process to evaluate the risk of GM food products is based on the concept of substantial equivalence. That is, the genetically modified product must be at least as safe as its unmodified counterpart, and it is desirable for the GM food to be at least as nutritious. Given the unique nature of each genetic modification performed, the specific parameters required to evaluate the biological impacts of the new gene will vary on a case-by-case basis.

The risk assessment process requires an extensive analysis of complex molecules that indicate nutritional value (i.e., omega-3 fatty acids, trans fats), vitamins and minerals, and molecules with biological roles that may be impacted by the newly introduced gene. A weight-of-evidence approach that considers the outcomes generated from all comparative tests is then used to determine whether there is a substantial difference in the risk of consuming the transgenic food.

Potential Health Risks Associated with Genetically Modified Foods

Proteins administered via the oral exposure route generally pose a low risk because ingested proteins have low potential to be biologically active in the bloodstream. Proteinaceous material in GM and non-GM foods undergoes degradation to amino acids in the human stomach and intestine, and intact protein is unlikely to enter the bloodstream since large molecules cannot be absorbed by the gut. High temperatures from cooking also contribute to protein denaturation.

One study that seemingly contradicted this paradigm reported that recombinant protein produced in GM maize was found in human blood.[9] However, one of the main limitations of this study is that the commercial antibody-based assay used to quantify the protein is intended for use to analyze plant seeds and leaves, and has been shown to perform poorly for blood analyses.[10] There may be proteins in blood that cause a false-positive test result and the study did not contain negative controls (i.e., serum from individuals who had not been exposed to the recombinant protein) to investigate this possibility. Furthermore, other studies investigating the fate of the same protein (Cry1Ab) in cattle that were fed GM corn did not detect fragments of the protein in blood, milk or urine samples.[11]

Adverse human health effects associated with genetically modified foods can be categorized as (1) allergenicity to the protein encoded by the newly introduced gene, (2) anti-nutrient effects and (3) toxicity.

Allergenicity

Approximately 4% of Canadians have a food allergy.[12] Proteins in food products can cause an acute inflammatory response of the skin, mouth or digestive tract in some individuals. These reactions can range from mild inflammation to severe anaphylactic shock. The potential for the protein product of the newly introduced gene to cause an allergic reaction is a key safety consideration.

An approach to evaluate allergenicity was developed by the International Food Biotechnology Council and the International Life Sciences Allergy and Immunology Institute. The principles of this approach involve first determining whether the gene is derived from, or also present in, an organism known to cause hypersensitivity reactions. The nine foods that account for the vast majority of allergic reactions include peanuts, tree nuts, sesame seeds, eggs, milk, wheat, soybeans, seafood and sulphites.[13] If the newly inserted gene is derived from one of these foods, this should alert regulators that the transgenic food poses a greater risk for hypersensitive individuals compared to the non-GM counterpart.[14] This is illustrated in a case where a gene from the Brazil nut that encodes the protein 2S albumin was inserted into a soybean.[15] The purpose of the modification was to improve nutritional quality; however, one of the unintended effects of the transgenic soybean was its enhanced allergenic potential, affecting individuals with hypersensitivity to Brazil nuts.[15]

The second step may involve comparative analysis to determine amino acid sequence and/or structural similarity between the novel protein and proteins that are known allergens.[16] In vitro testing of purified protein (encoded by the gene of interest) using immunoassays, and in vivo testing to assess tolerance using animal models, will also indicate allergenicity potential of the protein. Animal models that are considered appropriate for assessment of allergenicity include mice and rats (i.e., Brown Norway rat, BALB/c mouse), dogs and pigs.[14] Proteins evaluated using in vivo models may be administered orally or by subcutaneous injection to achieve greater sensitivity. Allergenicity studies conducted using piglets are considered a very good approximation of the response that can be expected in humans.[14]

Lastly, skin-prick tests using human subjects can provide an indication of whether the protein raises an IgE-mediated inflammatory response. Transgenic food containing proteins found to be allergens would require that it be labelled accordingly to alert consumers.

Anti-Nutrient Effects

In some cases, a newly introduced gene can encode a protein that negatively affects the uptake and/or utilization of a particular nutrient. For example, compounds found in soybeans decrease the enzymatic activity of trypsin, thereby interfering with protein digestion and uptake of essential amino acids.[17] Each food has a unique profile of nutrients, anti-nutrients and toxins. All of these key compounds require analysis in both the GM and the unmodified counterpart to determine the impacts of the introduced gene on food composition.

An additional consideration is the impacts of food processing on nutrients, anti-nutrients and toxins, as these may alter levels of available nutrients or create

undesirable compounds in the finished product. Proteinaceous anti-nutrients denature at high temperatures, which may affect biological function and nutrient availability. Fermentation may reduce levels of certain compounds such as phytic acid, which chelates with zinc and other minerals.[18] Thus, fermentation can increase the bioavailable levels of some minerals.

For transgenic animals intended for human consumption, this analysis should be conducted for both raw and cooked sections of all parts of the animal that may be consumed.

Toxicity

No reports of acute toxic effects in humans or animals as a result of consuming GM plants have been reported. Toxicity studies are usually conducted for a 90-day period to assess acute health effects. While some differences between groups of animals fed GM and non-GM diets have been observed in this period,[19,20] the physiological significance of these observations is unclear. Long-term studies where subjects are fed GM diets for at least two years are required to provide evidence that the changes observed in the first 90 days are signs of toxicity that will progress to chronic disease, and to adequately monitor tumour incidence and progression.

Several long-term feeding studies have been conducted to assess the safety of animal feed containing GM corn that produces *Bacillus thuringiensis* or Bt toxin, which is lethal to some types of insects. Dairy cows fed GM corn for 25 months had slightly lower body weights than those in the control group.[21] Diet had no effect on milk yield, but minor differences in milk composition were observed. Flachowsky et al (2005) found no meaningful differences between quails fed a diet supplemented with GM corn and quails fed an isogenic variety of corn.[22]

A recent life-long study of rats was conducted to evaluate long-term effects associated with consumption of herbicide-resistant corn (NK603).[23] It included a group of rats fed a diet supplemented with Roundup-tolerant corn that had not been sprayed with Roundup herbicide. One limitation of this study was the small number of rats (10) used per gender-controlled treatment group. A high proportion of control and GM-fed female rats developed mammary tumours. Mortality frequency of the male control group was slightly greater than that of male GM-fed groups at some dietary doses, while mortality frequency of the female control group was lower than that of all female GM-fed groups. Replication of this study is required to determine whether differences in mortality rates and tumour incidence are greater than would be expected due to chance.

Another issue is whether toxic effects may result from consumption of herbicide-resistant plants that contain residual chemical herbicide. Residues of herbicides used on GM crops have been detected in human blood, but the levels are well below those that are considered harmful.[10]

Perceived Risks and Attitudes about GM Animals

Studies have indicated that consumer acceptance of GM foods varies in different countries.[24,25,26,27] The success of any GM product is highly dependent upon consumer preferences, which are shaped in part by attitudes about genetically modified organisms and the perceived risks and benefits of the product.

While GM foods can provide benefits to the consumer including enhanced nutritional value, price advantage, improved shelf life and better taste, these benefits may be insufficient to outweigh the consumer's perception of risks about GM products. Negative attitudes about GM food can be related to (1) concerns about perceived human health risks; (2) a lack of trust in institutions responsible for ensuring food safety and (3) unintended environmental consequences of GM food production such as antibiotic resistance, gene transfer and threats to biodiversity such as through interbreeding between GM and non-GM animals.

GM produce and processed foods containing GM ingredients can be found on grocery store shelves around the world, but transgenic meat products have not yet received market approval in any country to date. Consumers are generally less accepting of genetic modifications to animals compared to plants.[24] In Canada, transgenic animal products intended for human consumption are a subject of controversy. Anti-GM messages from public interest groups and organizations such as the Canadian Biotechnology Action Network and negative publicity from media, describing GM salmon as "Frankenfish,"[28,29] have contributed to the stigmatization of GM animal products.

A survey of 1,300 Canadians in 2005 indicated that many consumers had negative predispositions towards transgenic animals.[30] Some of the concerns about transgenic animals intended for human consumption that were expressed by survey respondents included potential side effects resulting from the increased

hormone levels, unknown long-term consequences and increased risk of cancer. Further, the study found that disclosure of product risks and benefits did not have a negative effect on their perceptions of transgenic animal products or intent to purchase them in the future. In order for consumers to make informed decisions about the products they purchase, it is paramount for manufacturers to not only clearly communicate the benefits of GM products, but also to label GM products accordingly.

It is not uncommon for processed foods in North America to contain genetically modified ingredients, since many corn and soybean crops are transgenic varieties. A consumer report's study conducted in 1999 confirmed that genetically modified ingredients from crops were present in grocery store foods such as infant formulas, veggie burgers, tortilla chips and muffin mix.[31] In North America, these products do not require labels indicating that they contain GM ingredients.

Canada and the United States have adopted a voluntary labelling policy. Manufacturers are not required to label foods containing GM ingredients. Foods can be labelled "GM-free" if less than 5% of the total ingredients by weight are GM.[32] In comparison, Europe, Australia and Japan have a mandatory GM food labelling policy.[33] Products that contain a percentage of GM ingredients that is greater than the threshold prescribed by national regulators must have a GM label. In Europe and Australia, foods require a label if more than 1% of any ingredient by weight is genetically modified.

GM Animals in Advanced Stages of Development

GM animals and GM animal-derived products intended for human consumption that are currently under development, but not yet approved for market sale by regulatory bodies, are summarized in Table 1. The risks and benefits associated with two GM animals intended for human consumption, the AquAdvantage™ Salmon and the Enviropig™, are discussed in more detail.

Table 1. Transgenic animals and animal-derived products intended for human consumption that are in development

Transgenic animal	Protein encoded by new gene	Gene source	Benefit	Reference
Animals intended for human consumption				
Yorkshire Pig (Enviropig™)	Phytase	*Escherichia coli*	Enables utilization of phosphorus in phytic acid Reduces need to feed pigs phosphorus supplements Reduced phosphorus in manure and environment	[34]
Pig	Growth hormone	Porcine	Enhanced growth rate	[35]
Pig	Humanized n-3 fatty acid desaturase	*Caenorhabditis elegans*	Enhanced nutritional value by increasing omega-3 fatty acid content	[36]
Atlantic salmon (AquAdvantage™)	Growth hormone	Chinook salmon	Enhanced growth rate	[37]
Amago salmon	Growth hormone	Sockeye salmon	Enhanced growth rate	[38]
Chicken	Recombinant Mx	Mouse	Enhanced ability for chickens to resist viral infection	[38]
Cow	Mammalianized n-3 fatty acid desaturase	*Caenorhabditis elegans*	Enhanced nutritional value by increasing omega-3 fatty acid content	[40]

Transgenic animal	Protein encoded by new gene	Gene source	Benefit	Reference
Animal-derived products intended for human consumption				
Goat	Lysozyme	Human	Enhanced antimicrobial properties in milk	[41]
Cow	Recombinant Lysozyme	Human	Enhanced antimicrobial properties in milk	[42]
Cow	β-casein, κ-casein	Bovine	Enhanced nutritional value and characteristics for processing	[43]

AquAdvantage™ Salmon

In the 1990s, a transgenic Atlantic salmon was developed that differed from its unmodified counterpart in two keys ways. Firstly, the transgenic salmon contained genetic material that encodes a Chinook salmon growth hormone. Expression of the gene encoding the growth hormone (GH) enabled fish to grow at an accelerated rate, up to six times greater than that of non-transgenic fish.[37] The increase in growth rate reduced the time required for the fish to be harvested. Secondly, the transgenic salmon were engineered to be female and triploid (i.e., have three sets of chromosomes), rendering them incapable of successfully reproducing. Thus, in the unlikely event that these salmon were released into the wild, they would pose no long-term threat to native fish species.

The transgenic salmon was named the AquAdvantage™ Salmon and is being taken to market by AquaBounty Technologies, Inc. Proposals to the FDA and Health Canada for food safety approval have been under review since 2010. The document submitted to the FDA contained comparative data from the transgenic and wild Atlantic salmon to evaluate potential human health risks associated with the transgenic variety.[44] The conclusions in the report stated that no biologically relevant differences between transgenic AquAdvantage™ Salmon and its non-transgenic counterpart were found, and that AquAdvantage™ Salmon posed no threat to the environment. Recently the FDA also concluded that transgenic salmon would have no significant environmental impact in the United States. However, the report lacked discussion on potential short- and long-term human health impacts.

Potential Human Health Effects Related to Consumption of AquAdvantage™ Salmon

One major human health concern with AquAdvantage™ Salmon relates to the uncertainty associated with consumption of a food that contains elevated levels of hormones. The hormones responsible for accelerated growth in the transgenic fish are GH and insulin-like growth factor-I (IGF-I), and it is unknown whether the amounts present in the fish are sufficient to cause undesirable long-term effects in humans. IGF-I is a signaling molecule that plays a key role in bone and muscle growth. At the cellular level, it promotes cell proliferation and differentiation. GH acts primarily through stimulation of liver cells to produce IGF-I. Levels of GH are controlled by a negative feedback system where high levels of IGF-I cause suppression of GH, and thereby IGF-I. Thus, the biological effects of consuming food containing elevated levels of GH and IGF-I require investigation.

The potential for GH and IGF-I in fish tissue to exert effects on humans who consume the fish depends on several factors including level of exposure (i.e., how much fish is consumed), duration of exposure (i.e., how frequently fish are consumed), and how much of the functional protein is absorbed and reaches the target site before being degraded by proteases. Despite the fact that proteins administered orally are likely to undergo degradation from digestive enzymes, no animal feeding studies have been conducted to evaluate the effects of consuming transgenic fish containing elevated levels of GH. Such studies should be required as part of a rigorous investigation of potential health effects, especially for compounds such as hormones.

Few studies have compared concentrations of growth hormone in plasma/tissues of transgenic and non-GM Atlantic salmon. Studies showing no significant difference between plasma concentrations of growth hormone in GM verses non-GM species had inadequate sample sizes (i.e., 5 to 7 fish per group).[37,44] Concentrations of growth hormone in tissues from GM and non-GM salmon have been below the quantification limit of the method used.[44]

Another issue is the species-specificity of fish GH and whether fish GH has biological activity in humans. Fish and human GH proteins are

biologically different, sharing only 33% amino acid sequence similarity. No in vitro or in vivo studies to evaluate biological activity of fish GH on human GH receptors have been conducted. However, early fish transgenic experiments performed using human GH in fish showed that transgenic fish grew more rapidly and were larger than non-GM fish, indicating that cross-species interactions between human GH and fish GH-receptors may occur.[45]

High levels of IGF-I and GH have been found to be associated with higher risk of developing some types of cancers and increased aggression of existing tumours in humans.[46] Acromegalic patients having excess secretion of GH from the pituitary gland were shown to have a higher prevalence of risk factors (i.e., hypertension and diabetes) for cardiovascular disease, which is the leading cause of their mortality.[47] Heart abnormalities were observed among some of the GM salmon in previous studies, indicating that this area of research may warrant further attention.[44]

A sequence similarity assessment between salmon GH and a database of allergens was performed to assess allergenicity potential.[44] Salmon GH did not share amino acid sequence homology with any of the allergens in the database. Homology was defined as having a minimum of 35% identity in a contiguous sequence of 80 amino acids. Although in vitro testing was not performed to compare the levels of proteins that are known allergens in GM and non-GM Atlantic salmon, a similar transgenic salmon was evaluated in vitro using proteins from GM and non-GM fish (n=3 per group), and in vivo using sera from patients with fish allergies.[40] They found that levels of known fish allergens were not significantly different in GM compared to non-GM fish.

No anti-nutrients or toxic substances in the transgenic salmon have been identified. While it may be unlikely that consumption of AquAdvantage™ Salmon has unforeseen anti-nutrient or toxic effects, no animal feeding studies using diets supplemented with AquAdvantage™ Salmon have been conducted, to our knowledge, to confirm this.

Enviropig™

The Enviropig™ was developed in the 1990s by scientists at the University of Guelph to address a pressing environmental issue. Phosphorus is often a growth-limiting nutrient in aquatic environments and agricultural run-off containing high levels of phosphorus can harm aquatic ecosystems. Phosphorus-rich inputs to lakes and rivers can cause oxygen depletion, fish kills and/or algal blooms. Enviropigs™ excrete up to 60% less phosphorus than non-transgenic pigs, and the amount of land required to spread manure is reduced by approximately one-third.[34]

Pigs are typically fed phosphorus supplements to meet their dietary need, since pigs are unable to digest phytic acid, the storage form of phosphorus in grains. Thus, pig feces contain high levels of indigestible phosphorus. Alternatives to phosphorus supplements include feeding the animals digestive enzymes or diets that are high in digestible forms of phosphorus and low in phytic acid, or genetically engineering pigs to produce a greater repertoire of digestive enzymes.

Enviropigs™ were developed using microinjection technology to express a gene encoding the enzyme phytase, which is not normally produced by mammals. Phytase catalyzes the hydrolysis of phytic acid into inorganic phosphorus that can be absorbed in the small intestine. Phytic acid has anti-nutrient properties that are remedied by phytase. Phytic acid is a negatively-charged molecule that chelates with monovalent (i.e., K^+) and divalent cations (i.e., Ca^{2+}, Zn^{2+}, Mg^{2+}), making these nutrients unavailable for absorption in the intestine. Phytases are produced naturally by a wide range of bacteria, fungi and plants.[48] The phytase enzyme from *Escherichia coli* was used to create the Enviropig™. Genes encoding phytase enzymes have also been used in the creation of transgenic rice, wheat, sugarcane, soybean, canola and potato to enhance nutrient and mineral bioavailability.[49]

Since the initial development of the Enviropig™, other technologies have been developed to address the issue of excess nutrients in livestock manure. These include processing slurries to extract phosphate in a crystallized form (struvite), which can be used as a fertilizer.[50] Alternatively, feeding pigs digestive enzymes has been shown to reduce phosphorus in feces by 30 to 40%.[51,52]

Ontario Pork was a great supporter of Enviropig™ research and development for several years, and holds the trademark, but stopped backing the transgenic pig in 2012. Commercialization opportunities for the Enviropig™ are being explored.

Potential Human Health Effects Related to Consumption of Enviropig™

Some scientists argue that phytase has a range of health benefits in humans.[49] However, these human health benefits would be the result of consuming raw foods that naturally contain phytase. Phytase protein denatures when it is heated, thus cooked pork would not be a significant source of enzymatically active phytase.

In terms of allergen potential, phytase in powder form can cause respiratory problems such as asthma when inhaled in an occupational setting.[53,54] However, no adverse immunological effects as a result of phytase consumption have been reported.

No toxic effects resulting from phytase consumption have been reported in animal feeding studies. One feeding study by Zhang et al. (2000) compared the health effects of administering different forms of phytase to pigs.[52] One group of pigs was given phytase in the form of a commercial feed enzyme and members of the other group were fed transgenic canola that contained a gene encoding phytase. Histological and macroscopic analysis of organ tissues of pigs that were fed diets supplemented with phytase in either form did not reveal any toxic effects.[52]

Knowledge Gaps

- Additional research on potential long-term effects of consuming genetically modified foods is required. These long-term studies (two years or more) will shed light on whether some of the metabolic differences observed in short-term (90 day) animal feeding studies are pathologically relevant and will monitor effects that occur at later stages such as tumours.
- Animal feeding trials to study the effects of consuming cooked transgenic fish or pork are needed.
- Additional experiments with adequate sample sizes are needed to verify that there is no biologically significant difference between levels of hormones such as GH and IGF-I in transgenic and non-transgenic salmon tissues.
- The most recent consumer opinion survey in Canada on attitudes toward transgenic animals was conducted in 2005. It would be interesting to re-evaluate consumer attitudes in light of new information that has since emerged regarding transgenic organisms.

Conclusions

The AquAdvantage™ Salmon and Enviropig™ are among the first genetically modified animal products that were developed to address food security and environmental issues. These transgenic animals have yet to receive safety approval from any regulatory body in the world, and many consumers are not convinced that transgenic food products, especially those derived from animals, are completely safe. The safety of novel foods is currently assessed using the concept of substantial equivalence, where potential risks of the transgenic and non-transgenic product are compared. To date, evidence indicates that AquAdvantage™ Salmon and Enviropig™ are not different from their unmodified counterparts in terms of their nutritional value, allergenicity, toxicity and anti-nutrient effects. One limitation, however, is that long-term risks have not been thoroughly assessed and additional animal feeding trials are needed. Genetically modified animal products will likely remain off grocery store shelves until the uncertainty surrounding potential long-term health effects is reduced. Looking forward, the benefits of GM animal products need to be clearly communicated to consumers if the GM product is to succeed in today's competitive food market.

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