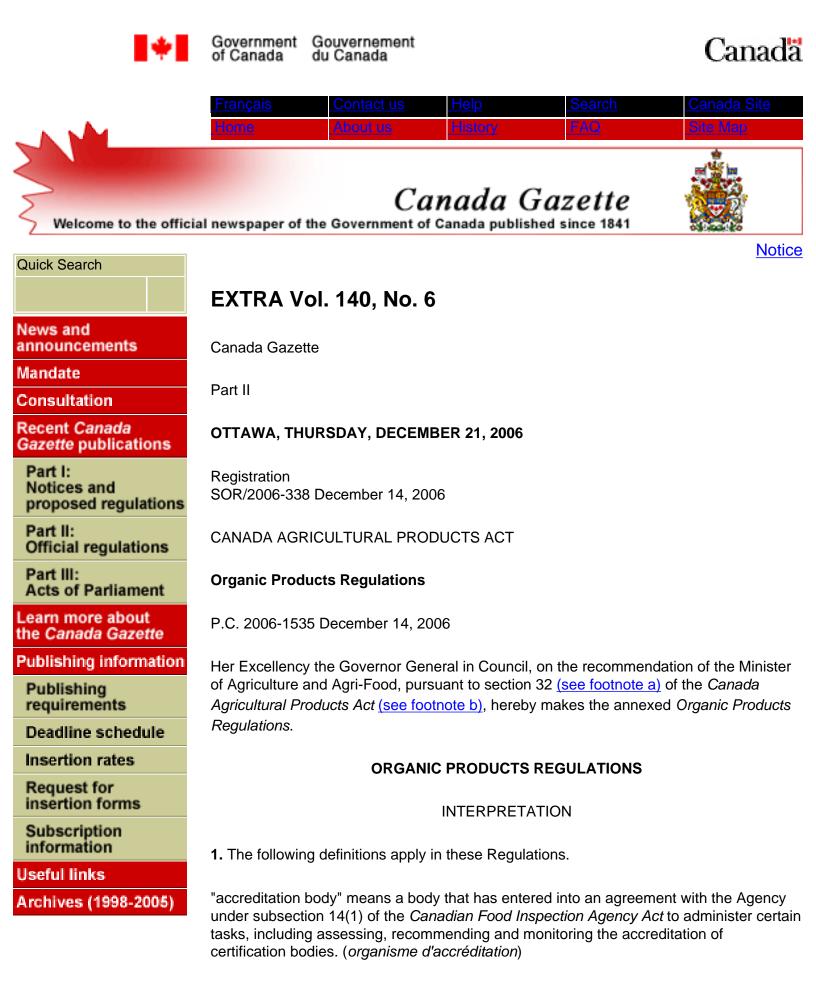
Canada Gazette



"Act" means the Canada Agricultural Products Act. (Loi)

"Agency" means the Canadian Food Inspection Agency established by section 3 of the *Canadian Food Inspection Agency Act.* (*Agence*)

"certification body" means a body that is accredited as a certification body in accordance with section 5. (*organisme de certification*)

"multi-ingredient product" means a type of agricultural product composed of two or more agricultural products. (*produit multi-ingrédients*)

"organic product" means an agricultural product that has been certified as organic in accordance with these Regulations or in respect of which an attestation referred to in section 10 has been obtained. (*produit biologique*)

ORGANIC PRODUCTS

2. (1) Only multi-ingredient products the contents of which are at least 95% organic products, and organic products other than multi-ingredient products, may bear the logo set out in the schedule or the designations "Canada Organic" and "Biologique Canada".

(2) Only organic products as defined in these Regulations may be marketed in interprovincial or international trade.

3. The logo set out in the schedule and the designations "Canada Organic" and "Biologique Canada" are agricultural product legends.

CERTIFICATION BODIES

APPLICATION FOR ACCREDITATION

4. A person who wishes to be accredited as a certification body shall apply for the accreditation in writing to an accreditation body and shall undergo an evaluation approved by the Agency that tests their knowledge of the principles and practices respecting organic certification.

ACCREDITATION

5. On the recommendation of an accreditation body, the Agency shall accredit the applicant as a certification body and provide the applicant with an accreditation number.

6. If the accreditation body refuses to recommend the accreditation of the applicant, the accreditation body shall send a notice to the applicant, by registered mail, stating the reasons for the decision and advising the applicant of their right to request that the Agency review the decision. The accreditation body shall also send a copy of the notice, including the reasons, to the Agency.

SUSPENSION AND CANCELLATION

7. (1) Subject to subsection (2), on the recommendation of the accreditation body or on the Agency's own decision, the Agency shall suspend the accreditation of a certification body if the certification body has not complied with any provision of the Act or these Regulations.

(2) No accreditation may be suspended unless the Agency has

(a) notified the certification body that there are grounds for suspension;

(*b*) provided the certification body with a copy of a report that specifies the grounds for suspension, the required corrective measures and the period within which those measures must be implemented to avoid suspension; and

(c) sent a notice of the suspension to the certification body.

(3) The suspension remains in effect until the required corrective measures have been implemented and verified.

(4) On the recommendation of the accreditation body or on the Agency's own decision, the Agency shall cancel the accreditation if

(a) the certification body has not implemented the required corrective measures within the specified period or within a longer period allowed under subsection (5); or

(b) the application made under section 4 contains false or misleading information.

(5) If the certification body has not implemented the required corrective measures, or their implementation is not possible, within the specified period, the certification body may obtain from the Agency a longer period within which to implement those measures.

(6) No accreditation may be cancelled unless the Agency has

(a) given the certification body an opportunity to be heard in respect of the cancellation, either orally or in writing; and

(b) sent a notice of the cancellation to the certification body.

ORGANIC CERTIFICATION

APPLICATION FOR ORGANIC CERTIFICATION

8. (1) A person who wishes to have an agricultural product certified as an organic product shall apply in writing to a certification body for a certicate confirming that the product is an organic product.

(2) The application shall contain

(a) the name of the agricultural product;

(*b*) in the case of a multi-ingredient product, a statement setting out the percentage of each of the organic products it contains;

(c) a statement naming the substances used in the production of the agricultural product and describing the manner in which those substances are used; and

(*d*) a report setting out in detail the methods of production used in the production of the agricultural product and the control mechanisms in place to ensure that those methods comply at all times with the standards set out in the most recent edition of CAN/CGSB 32.310, entitled *Organic Production Systems* — *General Principles and Management Standards*.

INTERNATIONAL MARKETING

9. (1) A person who wishes to market an organic product in export trade shall apply in writing to a certification body for a certificate confirming that the product is an organic product.

(2) The application shall include evidence that the product has been certified as an organic product.

(3) The certification body shall issue the certificate if it receives evidence that the product in respect of which the application was made is an organic product.

10. A person who wishes to market an organic product in import trade shall apply in writing to the competent authority of the country of origin for an attestation confirming that the product meets the requirements of these Regulations.

PROCEDURE FOR ORGANIC CERTIFICATION AND CERTIFICATE

11. (1) A certification body shall certify an agricultural product as an organic product if it determines, after evaluation, that

(a) in the case of a multi-ingredient product, at least 70% of its contents are organic products;

(*b*) the substances used in the production of the agricultural product are those set out in, and used in the manner described in, the most recent edition of CAN/CGSB 32.311, entitled *Organic Production Systems* — *Permitted Substances List*; and

(c) the methods of production used and the control mechanisms in place comply with the requirements set out in the most recent edition of CAN/CGSB 32.310, entitled *Organic Production Systems* — *General Principles and Management Standards*, and with the general principles respecting organic production set out in those standards.

(2) The organic certification remains in effect for a period of one year beginning on the

day on which it is granted.

REQUIRED IMPORTATION DOCUMENTS

12. Every imported product identified as organic shall be accompanied at the time of its importation into Canada by the attestation required under section 10.

SUSPENSION AND CANCELLATION

13. (1) Subject to subsection (2), the certification body or the Agency shall suspend an organic certification under section 11 if

(a) its holder has not complied with any provision of the Act or these Regulations;

(*b*) in the case of a multi-ingredient product, less than 70% of its contents are organic products;

(*c*) the substances used by the holder in the production of the agricultural product are not those set out in, and used in the manner described in, the most recent edition of CAN/CGSB 32.311, entitled *Organic Production Systems — Permitted Substances List*, and

(*d*) the methods used by the holder in the production of the agricultural product do not comply with the requirements set out in the most recent edition of CAN/CGSB 32.310, entitled *Organic Production Systems* — *General Principles and Management Standards,* and with the general principles respecting organic production set out in those standards.

(2) No organic certification may be suspended unless the certification body or the Agency, as the case may be, has

(a) notified its holder that there are grounds for suspension;

(*b*) provided the holder with a copy of a report that specifies the grounds for suspension, the required corrective measures and the period within which those measures must be implemented to avoid suspension; and

(c) sent a notice of suspension to the holder and, in the case of the certification body, sent a copy of it to the Agency.

(3) A suspension of an organic certification remains in effect until the required corrective measures are implemented and verified.

(4) The certification body or the Agency shall cancel the certification if

(a) its holder has not implemented the required corrective measures within the specified period or within a longer period allowed under subsection (5); or

(b) the application made under section 8 contains false or misleading information.

(5) If the holder has not implemented the required corrective measures, or their implementation is not possible, within the specified period, the holder may obtain from the Agency a longer period to implement those measures.

(6) No certification may be cancelled unless the certification body or the Agency, as the case may be, has

(a) given its holder an opportunity to be heard in respect of the cancellation, either orally or in writing; and

(*b*) sent a notice of the cancellation to the holder and, in the case of the certification body, sent a copy of it to the Agency.

LABELLING AND ADVERTISING

GENERAL REQUIREMENTS

14. In addition to the requirements under section 15, every organic product shall meet the labelling and advertising requirements of the *Food and Drugs Act* and the *Consumer Packaging and Labelling Act* and their regulations.

SPECIFIC REQUIREMENTS

15. (1) The label of or, if applicable, the advertisement for an organic product shall contain

(a) the name of the certification body that has certified the product as an organic product or, in the case of an imported product, the name of the organization that has certified the product;

(*b*) in the case of a multi-ingredient product whose contents are more than 70% and less than 95% organic products, the statement "% organic products", immediately following the percentage number rounded down to the nearest whole number; and

(c) in the case of an imported product for which the logo set out in the schedule or the designations "Canada Organic" and "Biologique Canada" are used on the label, the statement "Product of" immediately preceding the name of the country of origin or the statement "Imported", in close proximity to the logo or the designations.

(2) The statement "% organic products" referred to in paragraph (1)(*b*) shall appear on the principal display panel in accordance with subsection 14(2) of the *Consumer Packaging and Labelling Regulations*.

(3) In respect of a multi-ingredient product that contains one or more organic products but that is not certified as an organic product under these Regulations, neither its label nor any advertisement for it may state that it is an organic product. Any organic product contained in it may, however, be identified as an organic product in its list of ingredients.

COMING INTO FORCE

16. (1) These Regulations, except section 3 come into force two years after the day on which they are registered.

(2) Section 3 comes into force on the day on which these Regulations are registered.

REGULATORY IMPACT ANALYSIS STATEMENT

(This statement is not part of the Regulations.)

Description

Introduction

The purpose of the Regulations is to establish a system by which the CFIA as competent authority will regulate the use of the "Canada Organic" agricultural product legend (Legend). This national organic regime (Regime) will facilitate international market access, provide protection to consumers against deceptive and misleading labelling practices and support further development of the domestic market. The need for a federal regulatory regime has been identified and supported by the Canadian organic industry. These objectives will be met by incorporating the current voluntary system into a federally regulated framework, building upon SMART regulation principles.

The Organic Products Regulations (Regulations) are designed to restrict the use of the Legend to those products which adhere to these principles. Organic agricultural production is a management system designed to produce crops and livestock in an ecologically stable way. Soil fertility is maintained, animals are raised in a manner appropriate to their behavioural requirements and synthetic fertilizers and pesticides are not used.

In Canada, the organic industry has been growing at a rate of 15 to 20 percent annually for the past decade with approximately 3,670 certified organic farms in 2004 and is producing products whose retail value is estimated at \$986 million. This industry represents a growing sector of the global food industry and is largely consumer driven.

Several of Canada's trading partners have developed mandatory regulations prescribing requirements for products traded as organic. The European Union (EU) currently has a mandatory organic standard and a certification system for organic agricultural products. As of December 1, 2006, under the current European regulations, the EU requires that all countries exporting organic food be on an approved third-country equivalency list by December 31, 2006.

The United States Department of Agriculture's (USDA) National Organic Program (NOP), currently accredits Canadian certification bodies to certify Canadian organic producers for export to the United States. Producers currently shipping to the US may continue to do so once these Regulations come into force. Furthermore, Canada intends on negotiating with the US in order to seek recognition for the Regime.

Currently, the provinces of British Columbia and Quebec have regulations in place governing organic production systems. For the remaining provinces, voluntary systems are relied upon. Under the Regime, British Columbia and Quebec will be able to apply to the CFIA for recognition as accreditation bodies and as such be integrated into the Canada Organic Regime (COR). All provinces retain jurisdiction over intraprovincial trade. The *Food and Drugs Act* and the *Consumer Packaging and Labelling Act* and their regulations will provide additional options for the enforcement of labelling provisions.

Currently, multiple organic standards are used to certify products as organic in Canada. As a result, organic producers frequently pay multiple fees for several different certification systems. In order to further expand market share abroad and also as a result of the desire for a single national standard, the Canadian organic industry has requested a federal regulatory system to support the continued development of the industry.

Regulatory Framework

The Regime will build on the existing system of domestic accreditation and certification bodies to provide credibility and a basis for evaluation. The CFIA has established criteria modelled on internationally accepted guidelines, which will be used for the assessment and recognition of these organizations.

The Canada Agricultural Products Act (CAPA) is the enabling legislation under which these Regulations have been developed. Organic products must continue to meet the requirements set out in the Consumer Packaging and Labelling Act, the Food and Drugs Act, and all other applicable legislation.

The Organic Production Systems General Principles and Management Standards (Standard) and Organic Production Systems Permitted Substances Lists (PSL) developed by the Canadian General Standards Board (CGSB) will form the basis of the Regime. The COR is designed such that the Government of Canada will provide oversight of the Regime with the CFIA acting as the competent authority, and will integrate existing accreditation and certification bodies into the system, provided they meet the prescribed requirements.

The CFIA will permit the use of the Legend on products which have been certified as 95 percent or more organic to meet the requirements of these Regulations. When assessing organic products for certification as organic, certification bodies are determining and certifying in part that the Standard and the PSL have been complied with. The CFIA will verify compliance with and enforce the Regulations.

An early principle used in establishing the COR was that it would be cost recoverable. While industry is already covering a significant component of the costs associated with organic certification through fees to accreditation and certification bodies, resources are required to manage the national program, to interface with certification and accreditation bodies, and to verify compliance and take enforcement action when necessary. Fees may be applied in the future. Should the application of these fees be necessary this would be done in strict adherence to the *User Fees Act*, a key principle of which is broad consultation with stakeholders and provincial/territorial partners.

Shipments of imported organic products must be accompanied by an attestation issued by the recognized competent authority of the country of origin. This requirement is consistent with other regulatory provisions and is similar to the requirements of many of Canada's major trading partners such as the US and the EU.

Organic regulation is forecast to have a high degree of acceptance among consumers, producers, processors, provincial/ territorial governments and other stakeholders in the organic sector. Feedback at public meetings has been mostly positive and supportive, and the organic industry has requested the Government of Canada to develop organic regulations.

Alternatives

In the development of these Regulations the following three options were considered:

Option One — the Status Quo:

This option maintains the current system where producers, processors and handlers are self-governed through a network of accreditation and certification bodies.

International recognition for Canadian organic exports may be curtailed due to the lack of government oversight, or a competent authority. One of the key assumptions affecting the viability of this option is that foreign markets may be lost to Canadian exporters. The loss of export markets would create a surplus of products normally destined for export, resulting in significant downward pressure on prices and net reduction in revenue for Canadian producers.

This option is not recommended as it would not address issues associated with trading partner requirements, deceptive and misleading labelling practices, and variations in standards. In addition, it would result in economic loss to the Canadian economy.

Option Two — Federal Regulation with Accreditation and Certification Delivered by a Third Party — Recommended:

A single Canadian standard would be adopted, international recognition would be attained allowing continued access to export markets and consumers would be protected from deceptive and misleading labelling practices through regulatory controls.

Existing Canadian certification bodies and accreditation bodies that meet prescribed criteria would deliver certification and accreditation services, rather than the federal government delivering such services. The CFIA would provide oversight, administration and enforcement of the Regulations. The Standard and PSL would be referenced in regulation.

This option is recommended since it builds upon the existing voluntary system, provides the best value for resources and is the option preferred by industry stakeholders and provincial and territorial partners. In addition this option is expected to be accepted by trading partners.

Option Three — Federal Regulation with Accreditation and Certification Delivered by the Government of Canada:

Only those products certified by the Government of Canada would have the right to make organic claims in interprovincial or international trade. The major implication is the replacement of existing accreditation bodies and certification bodies by federal government staff. It is anticipated that approximately 30 businesses would close and 80 private sector jobs would be lost if this option was adopted. The adoption of this option would also result in the loss of goodwill with stakeholders. This option is not recommended due to the high cost of government delivery of this service, as well as increased costs to private industry.

Conclusion

Option two, Federal Regulation with Accreditation and Certification Delivered by a Third Party is the recommended option. This will allow for effective regulatory control, for protecting consumers from deceptive and misleading labelling practices and will facilitate international trade of organic agricultural products.

Environmental Impact Analysis

The organic industry may produce some positive environmental impacts through organic soil management practices. The Canadian public may experience an environmental benefit if organic acreage continues to increase. Increased organic acreage may result in reduction of the use of synthetic agricultural chemicals. No negative environmental impacts are foreseen.

Consultation

Between January and April 2004, the Organic Task Force comprised of members from the CFIA, AAFC and DFAIT, conducted consultation sessions across Canada to assess the need for organic regulations. Participants included representatives from provincial and territorial partners, producers, processors, retailers, import/exporters and other members of the organic sector. Initial consultations determined that there is consensus among stakeholders for regulations.

In response to the findings of these initial meetings, further consultation sessions were held to aid in the development of an organic standard and certification system. From November 2004 through November 2005, consultation meetings with stakeholders were held throughout Canada. Provincial and territorial partners also participated in consultation meetings held concerning the proposed regulatory regime between 2004 and 2005.

The majority of persons consulted agreed that a revised Standard was required. This revised Standard would then serve as the foundation of the COR. It was also agreed that: the Regime would include producers, processors, importers and distributors; the CFIA would act as the competent authority; existing accreditation and certification bodies that meet the CFIA criteria would be integrated into the COR; the requirements would apply to domestic and imported product, organic labelling would be permitted on products that meet the requirements of the regulations and an organic logo would be used on certified organic products.

The majority of those consulted were supportive of Option two which is federal regulation

with accreditation and certification by a third party, and supported the development of the proposed Regulations.

Pre-publication Results

On September 2, 2006 the CFIA pre-published the proposed Regulations in the *Canada Gazette*, Part I, for a 75-day public comment period. During the pre-publication period the CFIA received 91 submissions. The CFIA has reviewed and considered these comments as part of its revision of the Regulations. Many of the comments received did not relate specifically to the Regulations but more generally to the Regime. These comments will be responded to on an individual and timely basis by the Agency. Specific regulatory comments will also be responded to by the Agency. However, this "Pre-publication Results" section has been added to the RIAS in an effort to improve understanding of the Regulations.

Comments Specific to the Regulatory Text

The Regulations will govern the use of the Legend on products certified to meet the requirements of these Regulations including the processes and principles outlined in the Standard and the PSL. It is product rather than the process which is certified. The Regulations have been designed to build upon the existing functions of the accreditation and certification bodies. The Organic Policies and Procedures Manual (Manual) has been drafted to outline the structure and administrative procedures relating to the Regime. A draft of the Manual was made available upon request. The intent of this document is to facilitate consistent application of the Regime throughout Canada. This living document will continue to evolve as the Regime is implemented.

Comments received fell into four key categories:

- 1. Administration;
- 2. Labelling and the Use of the Legend;
- 3. Trade; and
- 4. Transition.

1. Administration

Several requests were made to add additional definitions to the Regulations. These requests were assessed and determined to be either covered under other Canadian legislation or more appropriately included in the Manual.

Comments were received which questioned the definition of accreditation body as it did not reflect the role of accreditation bodies under the current voluntary system. The definition was maintained as it does accurately reflect the role of accreditation bodies in the new Regime. A suggestion was also made that accreditation bodies must have an office in Canada. This was not done so as it would be contrary to the North American Free Trade Agreement (NAFTA). Additionally, comments received requested that the scope of the Regulations be defined. Submissions requested that the scope include aquaculture, cosmetics, natural health products, pet food and textiles. The definition of "agricultural product" in CAPA is broad. Aquaculture would be subject to these Regulations and as a result, following the transition period marketing restrictions on the term organic will apply until such time as it is included in the Regime. Other products may also be subject to marketing restrictions as a result of these Regulations. Specific national standards must first be developed prior to their inclusion into the Regime. Future suggestions for amendments should be forwarded directly to the CGSB.

Comments were received objecting to the Agency's issuance of an accreditation number to the certification body. This provision is required for administrative purposes, traceability and enforcement. The number assigned to the certification body will be unique and constant but will not be required to appear on the product label.

Comments were received which stated labelling requirements had been confused with certification criteria. To clarify, section 11 of the Regulations sets out the criteria which a certification body must evaluate prior to certifying an agricultural product as organic. The certification body must determine, prior to certification, that the product is made of at least 70 percent organic content, that the substances used in production are those included in the PSL, and that the methods of production and control mechanisms used are those set out in the Standard and with the general principles respecting organic production as set out in the Standard. The certification body will not be required to evaluate labels.

The Agency received requests for clarification of subsection 11(2) of the Regulations. This subsection requires that organic certification be renewed on an annual basis. The certification will remain valid for one year from the date of grant. It is the responsibility of the applicant and the certification body to ensure certification is renewed in a timely fashion. Annual renewal of this certification is required to verify that the criteria set out in subsection 11(1) of the Regulations continue to be met by the holder of the certification. This practice is in keeping with international certification requirements.

It was stated that the phrase "at all times" in section 8 of the Regulations, is confusing and should be deleted. The phrase "at all times" means the product must always be in compliance with the Regulations including following certification and is considered important to the integrity of the system.

A number of comments were received which requested that referenced sections of the Standard be included directly in the Regulations. By referencing the substances of the PSL and the control mechanisms and methods of production of the Standard all relevant provisions are incorporated by reference into the Regulation and it is therefore at this time unnecessary to transcribe them directly into the text of the Regulation.

Several comments were received which related to the role of the Agency as it relates to accreditation and certification. Given the federal oversight role of the CFIA in the Regime, it also has a role to play as it relates to these two activities.

The CFIA received requests for clarification of the evaluation procedures for accreditation bodies. These procedures are outlined in the Manual and are available upon request. Pursuant to the Regulations, accreditation bodies will be required to enter into an

agreement with the Agency which will specify the conditions under which they must operate. This agreement will build upon the existing activities of the accreditation bodies.

The CFIA received comments regarding the accreditation process for certification bodies. Some were concerned that the Agency was duplicating the work of accreditation bodies by overseeing the application process. The role of the accreditation bodies as an assessor and evaluator will continue to be similar as it was within the voluntary system, however, a necessary level of federal oversight has now been added.

Several individuals requested that the Agency be required to receive a copy of each certification body's application for accreditation. Pursuant to section 5 of the Regulations, the accreditation body will forward all applications that receive a recommendation for accreditation. Also, pursuant to section 6 of the Regulations, an application that does not receive a recommendation for accreditation will also be forwarded to the Agency for evaluation.

The Agency received comments regarding the requirement that the Agency review all refusals to recommend accreditation. Section 6 of the Regulations does not require that the CFIA review all refusals to recommend accreditation. However, it requires that all such recommendations be submitted to the CFIA. The CFIA will only conduct a review when requested to do so by the applicant.

Comments were received which questioned the Agency's role in cases of suspension and cancellation. Pursuant to the *Canadian Food Inspection Agency Act* it is the legal obligation and responsibility of the Agency to administer and enforce CAPA and its regulations including these Regulations. In the case of a suspension, the accreditation body may verify that corrective actions have been taken by the certification body and will forward its findings to the Agency.

The Agency received requests to clarify how disputes regarding suspension and cancellation will be resolved. Pursuant to subsection 7(6) of the Regulations, the Agency shall not cancel an accreditation without first providing notice of cancellation and the opportunity for the certification body to be heard either orally or in writing. Information is provided within the Manual regarding specific procedures for suspension and cancellation.

The CFIA received comments requesting clarity as to the procedures for suspension and cancellation of a person's certification. Since, under these Regulations, it is the product that is being certified as organic, it is this certification which may be suspended or canceled. Both the CFIA and the certification body have the power to suspend or cancel. The procedure to be followed is set out in section 13 of the Regulations.

Comments were received requesting that the Regulations be amended to require that a notification of suspension or cancellation be sent to the holder prior to a suspension or cancellation being issued. Subsection 13(2) and subsection 13(6) of the Regulations, specify that such notice must be sent to the holder before a suspension or cancellation may take place.

The Agency received comments regarding the requirement that a statement setting out the percentage of each organic ingredient contained in a certified multi-ingredient product be provided to the certification body and the Agency. This information is required in order for the certifier to verify the organic content of the product. Subject to the requirements of the *Access to Information Act* and the *Privacy Act* it is the Agency's intent to treat this information as confidential. Furthermore, it is the certification body's responsibility to protect this information to the extent required by law. The revised Regulations do not require that this information appear on the label or in any other document of public record. Finally, in response to comments, this paragraph has been modified to clarify that the Regulations refer to a multi-ingredient product.

The CFIA received concerns regarding the CGSB standard development process. The CGSB is an internationally recognized and accredited standards development organization. The CGSB manages a consensus-building process through its Organic Committee which is comprised of stakeholders from all sectors of the organic industry. Any one wishing to participate in the CGSB process may do so. The use of the CGSB standard was a key component of the Regime during consultations. Any amendments must go through a stakeholder voting process prior to adoption. Amendments to the Standard can be submitted to the CGSB to be considered by the Committee. The Agency will forward comments received respecting the Standard and PSL for their review. Future suggestions for amendments should be forwarded directly to the CGSB.

Several individuals requested that a list of accredited certification bodies be published by the Agency. Subject to the *Access to Information Act* and the *Privacy Act,* it is the Agency's intention to publish such a list.

Several individuals requested that International Standard ISO/ IEC17011:2004 (E) criteria (Conformity assessment - General requirements for accreditation bodies accrediting conformity assessment bodies) (ISO 17011) and International Standard ISO/ IEC 65:1996 (E) requirements (General requirements for bodies Operating Product Certification Systems)(65) be referenced in section 5 of these Regulations. Criteria for certification and accreditation were developed using internationally accepted standards as a model and were further adapted to meet Canadian requirements through consultations with members of the Canadian organic sector. It is these criteria which have been used in the development of the Manual.

The Agency will enforce these Regulations as well as the requirements of the *Food and Drugs Act* and the *Consumer Packaging and Labelling Act* and their Regulations. Additionally, organic products certified to be in compliance with these Regulations must continue to comply with the requirements of all other applicable legislation.

2. Labelling and Use of the Legend

Comments were received requesting that section 10 of the Standard which relates to labelling requirements, be transcribed directly into the Regulation. Direct transcription is not feasible for a number of reasons, including that the manner in which section 10 of the Standard is written is not consistent with regulatory drafting requirements. It was noted that some of the specific labelling requirements contained in the Standard were absent from the pre-published version of the Regulation. It is the Agency's desire that the labelling principles of the Standard be included in the Regulation whenever possible and as a result of comments received, section 15 of the Regulations, has been amended to include certain provisions of section 10 of the Standard.

The Agency received comments on the requirement that the accreditation number of the

certification body appear on the label. This has been revised so that the accreditation number need not appear on the label. Products certified under this Regulation will still be required to bear the name of the certification body on the label. In the case of imported products, the name of the certifying organization must appear on the label.

Clarification was requested as to whether the Regulations covered both single and multiingredient products. The Regulations apply to both type of products. A definition for "multiingredient product" has been added to the interpretation section of the Regulations to clarify that the use of the Legend is restricted to products of at least 95 percent organic content. Products which are made with 95 percent or more certified organic products are permitted to bear the claim organic and may also bear the Legend. Multi-ingredient products which are made with 70 to less than 95 percent certified organic products are also permitted to bear the claim organic, but not the Legend. However, certified multiingredient products of less than 95 percent organic content must also specify "X% of organic products" on their label. A formula for calculating the percentage of organic products in multi-ingredients organic products consistent with that outlined in the Standard has been set out in the Manual.

Subsection 15(3) of the Regulations has been added to require that products which are not certified as organic may not bear reference to organic content beyond the ingredient list.

Comments were received by the Agency which requested that the required percentage for certified organic products be increased to 100 percent after a period of five years. This is not consistent with either the Standard or international requirements and has, therefore, not been included.

Concerns were raised that the current definition of "organic product" would not adequately protect the use of the term organic and requests were made to enshrine the word "organic" in the Regulations. Only organic products meeting the requirements of these Regulations may use the Legend and subsection 2(2) of the Regulations provides that only organic agricultural products as defined in these Regulations may be marketed in interprovincial or international trade. In addition, existing provisions of the *Food and Drugs Act* and the *Consumer Packaging and Labelling Act* may be used to prohibit false and misleading claims. This is seen as having the same outcome.

The Agency received comments regarding the use of the Legend on imported products. These comments were equally distributed between both those supporting the use of the Legend on imported products and those against the use of the Legend on imported products. In the interests of international trade, the Agency has taken the position that the Legend may be used on imported products which is consistent with the practices of major trading partners. To avoid consumer confusion labelling requirements have been added specifying that the name of the country of origin or the statement "imported" appear in close proximity to the Legend.

Under section 15 of CAPA, the Legend is a national trade-mark and the exclusive property of Her Majesty in right of Canada. Following the transition period, agricultural products certified as organic under these Regulations and containing at least 95 percent certified organic products may bear the Legend. During the transition period, individuals wishing to use the Legend must apply to the Agency for a licence to do so.

Comments were received requesting clarification with respect to the requirements for type height on the label of certified organic products. Subsection 15(2) of the Regulations has been added to incorporate the size of type requirements of the *Consumer Packaging and Labelling Regulations*.

Comments were received requesting clarification on advertising requirements. Sections 14 and 15 of the Regulations have been amended to include advertising as well as labelling requirements. Organic products must be advertised in a manner which is consistent with the requirements set out in these sections.

3. Trade

A number of comments were received pertaining to issues of international trade. The Agency will continue to work with Canada's trading partners to develop recognition agreements to facilitate fair and equitable trade.

The Agency received several comments requesting clarity on the wording and purpose of section 9 of the Regulations. All products being exported from Canada must meet the requirements of these Regulations. The intent of the Agency is to allow for a certificate to be produced when required by an importing country. Anticipated recognition agreements with our international trading partners, may make this requirement less applicable.

Section 10 of the Regulations has been amended to more clearly demonstrate the Agency's intent that imported products must meet Canadian requirements for organic products. The required attestation is not intended to replace existing import certificates, bills of lading, or other documents. It is intended to be a separate document issued by a competent authority. The "competent authority" described in this section may be the foreign government of the country of export or a foreign certifying organization.

Several recommendations were received to exempt importers from certification. Imported agricultural products must be accompanied by an attestation. The attestation must attest, in a manner acceptable to the Agency, that the product is an organic product under these Regulations. This attestation is in effect assuring that the product in question is in compliance with the Regulations and must be provided with every shipment. This attestation is intended to facilitate access to the Canadian market and to provide protection to consumers against deceptive and misleading labelling practices, thereby supporting further development of the domestic market. Importers may be required to have the products certified as organic after importation in certain circumstances, such as where the products are further processed or handled in a way which may affect their organic integrity or nature.

Comments were received which requested that in the case of an imported product, the bill of lading should contain information similar to that required in the attestation, while other comments submitted that the bill of lading should replace the attestation. It is essential for the integrity of the Regime that an attestation be issued by the competent authority by which a bill of lading is not.

Many submissions requested clarification as to how trade in organic products will be regulated intraprovincially. Persons trading intraprovincially who wish to apply the Legend will be subject to these Regulations. Any person trading solely intraprovincially without using the Legend, are not subject to these Regulations, however, they will be subject to

applicable provincial legislation. Additionally, subsection 5(1) of the *Food and Drugs Act* and subsection 7(1) of the *Consumer Packaging and Labelling Act* provide additional enforcement options.

4. Transition

In response to comments requesting a transition period, a two-year period has been added to the Regulation, with the exception of section 3 which will come into force on the day on which the Regulations are registered. Section 3 will establish the Legend as a trade-mark of Canada and allow the Agency to authorize its use where appropriate. During the transition period, individuals wishing to use the Legend must apply to the Agency for a licence to do so.

Benefits and Costs

The Agency conducted a detailed cost-benefit analysis of the Regulations. The study, *Cost-Benefit Analysis of the Effects of Federal Regulation for Organic Products*, was conducted from January - May 2005 with stakeholder input. It examined the economic impacts and the full range of social and economic effects of regulation on Canadian society. The study considered the costs and benefits to growers and producers, the sectors that support the organic industry (processors, wholesalers, retailers, exporters, accreditation bodies, certification bodies), consumers, the Canadian public at large, and the federal and provincial governments. The full document is available on our website at http://www.inspection.gc.ca/english/fssa/orgbio/coana/coanae.shtml or at http://

In order to assess the impacts (i.e. the benefits and the costs) of the Regulations, the following three options were considered:

1. maintaining the status quo whereby organic producers are self-regulated through the existing network of independent certification bodies;

2. establishing a mandatory regulatory system implemented through third party service delivery in conjunction with the private sector and provincial governments; and

3. establishing a mandatory regulatory system with full delivery by the Government of Canada whereby the CFIA would take on all activities including certification, licensing, audit and inspection.

Costs and benefits were modelled in detail over a 10-year period with a calculation for long term effects. The study found that the status quo (option 1), if maintained, would result in a cumulative loss of \$490.2 million (in 2005 dollars) from the Canadian economy. This would occur primarily due to a loss to the export market and reduced revenues as producers and exporters sell what would be an oversupply of organic products in Canada. Canadian consumers would benefit under this option as oversupply would cause prices to fall. Overall, this option has a negative impact on the economy in that for every \$1 of costs there is only \$0.53 of benefits.

Mandatory regulation with third party delivery system (option 2) and the government full delivery system (option 3) both result in improvements to the Canadian economy

cumulatively of \$1,257.6 million and \$1,244 million (in 2005 dollars) respectively when compared to the status quo. This is a result of maintaining export markets, increasing domestic demand and overall growth in the organic industry. Both of these options would provide a positive impact on the economy as every \$1 of costs produces \$1.25 and \$1.24 of benefits respectively.

The study concluded that option 2, a mandatory regulatory system implemented through third party service delivery provides the greatest benefits to the Canadian economy over time.

Impact on Stakeholders - Option 2

The study examined the impact on each key stakeholder group in terms of benefits and costs. For comparison, the following table provides the net present value (benefits minus costs) in 2005 dollars for each group under options 1 and 2.

Stakeholders	Net Present Value of Benefits (-Costs)	
	Status Quo: Self- regulation (\$ millions)	Third-party delivery system (\$ millions)
Growers and Producers	-752.3	112.5
Processors	4.1	11.3
Wholesale Services	2.7	7.1
Exporter / Buying Services	-28.3	8.2
Import Services	0	155.8
Retailers	6.9	284.8
Accreditation Agencies	-0.1	.001
Certification Bodies	-12	0.1
Consumers/General Public	288.7	214.8
Governments	0	-27.3
Incremental Benefit (Cost)	-490.3 M	767.3 M
Cumulative Benefit over Status Quo		\$1,257.6M

Source: Cost-Benefit Analysis of the Effects of Federal Regulation for Organic Products, TDV Global Inc, May, 2005

A brief explanation of the impacts on each stakeholder group for option 2 is presented below. Further details for all options are contained in the full report.

Growers and Producers

This option brings benefits to Canadian growers and producers of organic food products due to the implementation of a Legend requirement resulting in an increase in domestic consumer demand. Growers and producers would also benefit by no longer requiring multiple certifications, realizing cost savings. As production increases, farms would also incur additional operational costs.

Processors

Processors would also earn benefits because of increasing domestic consumption. In addition, processors would see cost savings from a reduced need for multiple certifications.

Wholesale Services

Wholesale companies would benefit from wholesale service margins on the increase in domestic consumption of organic products.

Export/Buying Services

Many exporters and buyers also maintain more than one certification, depending on the countries to which they sell and federal regulation would reduce the need for multiple certifications, reducing costs.

Import Services

Imports make up a significant portion of organic food products consumed by Canadians. Increased domestic consumption of organic products would also have a positive impact on importers of organic food products.

Retailers

With the introduction of the Legend requirement, confidence in products marketed as organic would increase and organic products would also gain visibility, resulting in increased Canadian consumption. The retail sector would incur some additional operating costs. No impact on prices was assumed in the study.

Certification Bodies

Revenue increases would be experienced by certification bodies due to additional certification activities. It is assumed that there would be sufficient certification bodies in operation to maintain price competition. Incremental operating costs would be incurred, however it was assumed significant expansion costs would not be required.

Accreditation Bodies

Accreditation Bodies would earn additional revenue as certification bodies increase their activities. Additional operational costs have been estimated in the analysis.

Society/Consumers

Increased consumption of organic products would bring additional environmental benefits

to Canadian society. As Canadian organic production expands, more hectares would be required. Domestic organic farming has been assumed to provide an environmental benefit.

Governments

The establishment of this option does require incremental government expenditures. These expenditures would include increases in the personnel of the CFIA, incremental and ongoing expenditures for market access activities and various expenses incurred by provincial governments with respect to their accreditation bodies. The study did not attempt to measure net benefits to governments.

Compliance and Enforcement

The Agency will verify compliance and enforce these Regulations in accordance with its statutory authorities including those found in CAPA. Compliance and enforcement activities will include, inspections of accreditation and certification bodies for compliance with CFIA and regulatory requirements; label reviews; testing of organic products; and responding to consumer complaints via onsite inspections where required.

Contact

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Footnote a

S.C. 2001, c. 4, s. 64

Footnote b

R.S., c. 20 (4th Supp.)

NOTICE:

The format of the electronic version of this issue of the *Canada Gazette* was modified in order to be compatible with hypertext language (HTML). Its content is very similar except for the footnotes, the symbols and the tables.



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