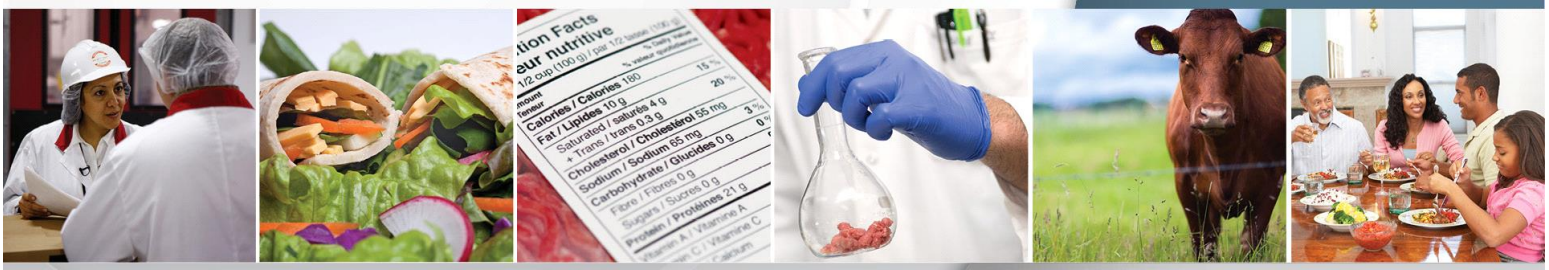
SAFE FOOD FOR CANADIANS ACTION PLAN



Strengthening Canada's World-Class Food Safety System

Incorporation by Reference: Discussion Document

Canadian Food Inspection Agency
Agence canadienne d'inspection des aliments

Canada

Executive Summary

Incorporation of documents by reference is a drafting technique that brings the content of a document into a regulation, without the need to reproduce the document in the regulation itself. This can be particularly valuable in having the regulations reflect modern science and new innovations. The Canadian Food Inspection Agency is considering guiding principles in its approach for choosing the documents to be recommended for incorporation by reference, specifically under the new *Safe Food for Canadians Act*, which provides an explicit authority for the incorporation of any document, regardless of its source, into the regulations. This set of principles will guide how the CFIA chooses what documents it will recommend as appropriate to incorporate in the regulations, as well as how those documents are maintained and kept up-to-date, including providing stakeholders with notice of upcoming changes and the ability to comment. This discussion document outlines the set of principles, and is being released for public consultation on the CFIA's proposed approach.

Introduction

The Canadian Food Inspection Agency (CFIA) has embarked on a change agenda designed to strengthen how food commodities are regulated in Canada. Change initiatives include the new *Safe Food for Canadians Act* (SFCA), regulations from the Act, and the Improved Food Inspection Model (IFIM). As a result of these initiatives, the landscape for how food is regulated will change from commodity-specific to food as a whole. In addition, the CFIA is undertaking a broad review of all of its regulations for food safety, plant and animal health to improve consistency, reduce their complexity and strengthen consumer protection. Modernized regulations will reduce unnecessary regulatory burden; provide clarity and flexibility in regulations; and support innovation and changes in science and technology.

One of the regulatory tools that the CFIA may pursue in developing the SFCA regulations is the incorporation by reference of documents into the regulations that are externally or internally generated, and that may change over time. This explicit authority was included in the SFCA. This discussion paper seeks to outline the general principles, policy and processes that the CFIA will follow when identifying, using and applying incorporated documents both under the SFCA and under other Acts administered by the CFIA, and the process the CFIA will follow in respect of any changes to those documents.

Scope

The express authority to incorporate documents in regulations exists in the SFCA, and so it is available, where appropriate, for the regulations that are made under that Act (i.e. that regulate food commodities).The relevant authority is found in section 52 (not yet in force):

A regulation made under subsection 51(1) may incorporate by reference any document, regardless of its source, either as it exists on a particular date or as it is amended from time to time.

What is Incorporation by Reference?

Incorporation by reference is a term used to describe a means to allow a document, not in the body of the regulation, to be made part of the regulation. Such documents could be technical or non-technical standards, methods and guidelines.

The legal effect of incorporation by reference is to write the words of the incorporated document into the regulation as if it had actually been reproduced word for word. Documents incorporated by reference therefore have the force of law.

The use of appropriately incorporated documents could make the food safety regulatory system more responsive, and can help with the speed of regulatory change. For example, instead of needing to amend a regulation to revise a list, a list developed by the CFIA and able to be incorporated by reference could be revised by the CFIA, usually following consultations, without amending the regulation itself. In addition, international or 3rd party standards incorporated into the regulations, if appropriate, could be used rather than reproducing the standard in the regulation itself.

Types of Incorporated Documents

"Static" or "Closed" Incorporation by Reference
"Static" or "closed" documents means that the document is incorporated as it exists at the time it is made part of the regulation.

If the document is amended after it is incorporated, the amendment will not be automatically incorporated, and the regulation continues to make reference to the past version. The regulation would need to be amended to adopt a subsequent amendment to the incorporated document.

"Open" or "Ambulatory" Incorporation by Reference

In the case of an "open", "ambulatory" or "rolling" document, an enabling provision would give the regulation-making authority the power to incorporate by reference future amendments to a document "as amended from time to time". Section 52 of the *Safe Food for Canadians Act* provides such power.

Once material is incorporated "as amended from time to time" any change to that material will automatically become part of the regulation

What other Regulations use Incorporation by Reference?

Many current regulations across the Government make use of incorporation by reference to varying degrees, and incorporate documents such as rates, standards, technical guidelines, and provincial legislation. Notable examples include the *Canada Occupational Health and Safety Regulations*, the *Food and Drug Regulations*, and the *Income Tax Regulations*. In the previous Parliamentary session, the Government advanced a Bill that would have set a baseline for the use of incorporation by reference - Bill S-12. The Bill has been reintroduced in the Senate as Bill S-2. Of special note,

provisions in the *Food and Drugs Act* also contain a very similar authority to that in the SFCA that permits the incorporation of documents by reference, including, where appropriate, technical and non-technical standards, methods, guidelines or any other documents relating to food and marketing authorizations. The documents can be incorporated, regardless of their source, into the *Food and Drug Regulations*, including documents developed by Health Canada.

Health Canada is currently using the incorporation by reference authority in the *Food and Drugs Act* in relation to marketing authorizations for additives. The CFIA is working closely with Health Canada on their experience, both in using the incorporation power, and how to effectively manage changes to the documents after incorporation.

How Does It Work?

In order to incorporate a document by reference, there must be a valid reason for its use and the document must be properly identified in the applicable regulation to be prescribed by the Governor in Council. The regulatory reference is usually made by naming the title of the document and other identifiers (for example, author and date) in the text of the regulation.

Other Acts and Regulations that use Incorporation by Reference

Incorporation of documents by reference is used under various Acts and regulations of the Government of Canada. Depending on the specific authority provided and purpose of the incorporation, the document could be either internally or externally generated including, where appropriate, matters pertaining to lists, standards, grades, or financial rates

The *Meat Inspection Regulations* , for example, currently incorporate the Meat Hygiene Manual of Procedures and the Food Safety Enhancement Program Implementation Manual for Processing Establishments and Shell Egg Grading Stations which are both detailed documents outlining the requirements for operational implementation of regulatory provisions as found in the *Meat Inspection Act* and *Meat Inspection Regulations* that are necessary for, among other things, the safe and hygienic operation of meat establishments. These manuals may need to be revised quickly, to address emerging issues and to maintain safety.

As part of the regulatory process, the Department of Justice will review and provide legal input in respect of the document that is proposed to be incorporated by reference, including an assessment of whether the document is appropriate for being incorporated. Additionally, the public and stakeholders will be notified of the regulatory proposal and given the opportunity to share their comments or concerns. Notification of the regulatory proposal and the opportunity to comment would occur via the *Canada Gazette* process. The Treasury Board must approve the regulatory proposal, and Canada's international obligations would need to be shown to be met.

An example of the incorporation of a third party document in a regulation on an ambulatory basis can be found in section B.01.045 of the *Food and Drug Regulations*:

> B.01.045. A food additive shall,
> …

(b) where no specifications are set out in this Part for that additive but specifications are set out for it in the Food Chemicals Codex, Fourth Edition, 1996, published by the National Academy of Sciences, Washington, D.C., United States, as amended from time to time, meet those specifications;

An example of the incorporation of a static, internal document in a regulation can be found in the *Health of Animals Regulations*, in the definitions in section 10:

> "import reference document" means the document prepared by the Agency and entitled Import Reference Document, bearing the date January 25, 2007 and policy number AHPD-DSAE-IE-2002-3-4.

Benefits

Incorporation of documents by reference in the regulations is an important tool that can benefit industry, stakeholders, and the government by providing a regulatory environment that can respond to new science and technology. An example of the benefit of incorporation by reference in the food context for consumers and the food industry is the ability of the Minister of Health under the authority of the *Food and Drugs Act* to update (i.e., expand or remove items), on an ambulatory basis, a document containing the list of acceptable food additives that had been incorporated into the regulations, after scientific and safety reviews are complete, without further delays inherent in a full regulatory process.

Currently, adding a new item directly into a regulation takes, at a minimum, 12 to 18 months after the scientific, policy and/or safety reviews are complete. By incorporating into the regulation an ambulatory document setting out a list, the time between completion of the review, and addition or deletion of an item to the list would be substantially reduced. Other types of documents that could be considered for incorporation, allowing for quicker updating, might include lists of ingredients, standards for foods, etc. provided a valid reason for using incorporation by reference is identified.

Some other benefits of the use of validly incorporated documents are the reduction in the amount of legislative text that is required to be published, the promotion of harmonization with laws and standards of other jurisdictions or international bodies and the use of documents that are already familiar for regulated parties.

Potential Concerns

While the use of incorporation by reference can provide benefits for regulated parties and the government, it may present concerns that the law is fragmented between different texts – both the regulation and the incorporated document would apply for

compliance purposes. Where a document is maintained by a third party, the government will have less direct control over the content and any future changes, if the document is incorporated on an ambulatory basis, which can lead to issues related to the ability of government to amend its laws on a timely basis. Where the legislative provision allowing for incorporation by reference is not clear, there may also be concerns relating to delegation of authority away from the regulation-making authority (such as the Governor in Council).

In certain situations, particularly those involving third party documents, the incorporated material may be subject to copyright, and may be difficult to obtain. For these reasons, and others, the document to be selected must be thoroughly examined as to whether there is appropriate authority to incorporate the document in question by reference and, if so, whether it is the right legislative tool. In all cases, incorporation by reference cannot be used to circumvent the normal regulatory process, and stakeholders should continue to have the ability to comment and review requirements set out in incorporated documents including any changes to those requirements before the change is made (subject to certain exceptions relating to minor administrative changes or revisions made to address urgent health and safety concerns). Incorporation by reference of ambulatory documents may also create situations where it is problematic to meet international obligations surrounding notification, for example.

How Will the CFIA Determine an Appropriate Document for Incorporation?

The decision to incorporate a document by reference in a regulation is just one possible instrument choice in addressing a policy need. While the other instrument choice with the same legal effect would be to embed the rules directly in a regulation, other possible means to address the policy objective would be to make a legislative change or to promote the policy through use of administrative means and guidance to regulated parties.

The rationale for choosing to use incorporation by reference as a tool, and whether it is an internal or external document, and whether it is to be incorporated on a static or ambulatory basis, will be set out by the CFIA in the Regulatory Impact Analysis Statement (RIAS) related to the applicable regulation. The RIAS is reviewed by Treasury Board, and then made available for consultation with stakeholders, and would include the rationale for the incorporation and the regulation, as well as cost-benefit analysis. The Department of Justice will also play a key role in determining if a document is suitable for incorporation, on either an ambulatory or static basis.

Some of the factors that would be considered, and included in the RIAS, as to whether the incorporation of a document is appropriate are:

- source of the document;

- the document's intended purpose;
- how often the document may change;
- should the information in the document properly be in a regulation, or does it help clarify or provide details to a regulatory provision;
- what the rationale is for an ambulatory reference, instead of static;
- is the document written in appropriate language (i.e. language that could be enforced);
- how accessible is the document (including cost and language);
- who is responsible for maintaining the document;
- how easily understandable and widely accepted is the content of the document;
- whether the document is subject to copyright;
- what are the international trade implications of incorporating the document;
- the rigour (scientific, technical, other) with which the third party document was developed (if it is an external document);
- the relevance of the third-party document to the Canadian context; and the extent of the CFIA's participation and involvement in development and future revisions of the document.

How the Regulations Stay Up-to-Date

From time to time, documents that have been incorporated by reference will be revised; for instance, in response to new science or an emerging health risk. Changes to CFIA documents that have been incorporated by reference are managed internally by the Agency, while changes to third party documents that have been incorporated by reference are managed by the authors of the document. With respect to incorporated third party documents, if a document from an international standards organization incorporated by reference on an ambulatory basis, subsequent changes to that standard would be made by the third party, and would take effect immediately on the date the change becomes effective. A proposed pathway for CFIA incorporating changes to ambulatory documents controlled by the CFIA, or controlled by a third-party, is set out in detail in Annex A. It should be noted that, in all cases, the CFIA is committed to transparency in its notification to stakeholders, as set out in the Guiding Principles section of this document.

Changes to documents controlled by the CFIA will only be made following a thorough assessment, and approval of the change by the appropriate level within the CFIA. Domestic and international stakeholders will be notified of all proposed modifications and provided with an opportunity to comment. Changes to third-party documents are managed by the external authority – however, the CFIA will work with the authority so that the CFIA is aware of any upcoming changes, and then can provide an opportunity for stakeholders to comment. The CFIA would then endeavour to communicate those changes to stakeholders prior to them being made. Note, though, that changes to

incorporated documents do not travel through the *Canada Gazette* process, but may, if required, be subject to the WTO Notification process.

Guiding Principles

The CFIA will follow these guiding principles in its use of the incorporation by reference power: **accessibility**, **transparency**, **consistency**, **reasonableness** and **clarity**. Of particular note is the principle of accessibility, which is specifically set out in the *Safe Food for Canadians Act* as a requirement. These guiding principles are consistent with the CFIA's *Statement of Rights and Service for Producers, Consumers and Other Stakeholders*, which reinforces its commitment to transparency, fairness, responsiveness, and accessibility.

- The CFIA **will only recommend incorporating documents** from third parties where the CFIA has a reasonable expectation that notice and a reasonable period to comment will be given by the third party of changes to its documents, and that the incorporation will allow Canada to meet its international obligations.

- Documents that may be incorporated will be **assessed for their clarity in language**, so that regulated parties can have a clear understanding of their requirements. The CFIA will follow a consistent and transparent approach in determining what documents it will recommend for incorporation in regulations (the assessment will be part of the rationale contained in the Regulatory Impact Analysis Statement, which will set out the factors for why a document is appropriate to incorporate).

- When any change is being considered, either to a CFIA document or a third-party document, the **potential for additional administrative burden** and **the cost-benefit analysis** will be considered by the CFIA. This would weigh into the determination of whether the change should be made, or whether, in the case of a third-party document, the regulations should be amended so as to maintain the incorporation of the document to the earlier version or take some other measure.

- To support transparency, **notifications of proposed changes** to incorporated documents will be sent to the public and stakeholders via a notice posted on the CFIA external website, and where appropriate, through the WTO Notification process. Such notifications would clearly indicate the period to provide comments on the proposed changes and a contact person to whom comments may be sent. Consideration could be given to an extension of the comment period for documents that the CFIA controls.

- CFIA **will post all changes to internal documents** on its external website for comment; it will also endeavour to post forthcoming changes to third party incorporated documents prior to their change, to seek comments from stakeholders.

- After the completion of the notification period, the CFIA would confirm that the comment period has ended, indicate if comments were received and **post a summary** of the comments made during the notification period. CFIA will also issue a notification as to whether it is proceeding with the changes (if it is not a third party document). This summary will be posted on the CFIA external website.

- **Incorporated internal documents will be posted in both official languages on the CFIA external website**. Previous versions will be archived along with a summary of the changes.

- **Incorporated third party documents will be available for access on the CFIA external website** with full consideration to both official languages if necessary. Previous versions will be archived along with a summary of the changes.

- **A transition period** - where appropriate - may apply before a modification to an incorporated document can formally take effect.

- The CFIA will take a **consistent approach** to incorporation by reference and verify that any obligations in law related to incorporation by reference, such as accessibility, have been satisfied.

Review of the CFIA incorporation process

Concerns from regulated parties about whether a document should be incorporated or not can be submitted as a comment during the *Canada Gazette* process, where the comments will be reviewed and assessed by the CFIA.

If a regulated party feels that the CFIA has not been diligent in following its guiding principles in relation to the incorporation or change or revision to an incorporated document, they may address their concerns to the CFIA's Complaints and Appeals Office.

Questions for Consideration and Next Steps

This discussion document is intended to signal to stakeholders how the CFIA will choose documents to be recommended for incorporation by reference in regulations.

Some of the questions that should be considered:

- Do the approaches proposed with respect to choosing the appropriate documents for incorporation seem appropriate?
- Do the guiding principles proposed for keeping both internal and external documents up-to-date manage to strike an appropriate balance between flexibility and responsiveness, and ability for stakeholders to provide input?

If you wish to submit a comment on anything proposed in the document, please send it to CFIA-Modernisation-ACIA@inspection.gc.ca.

After this discussion document has been presented to stakeholders, and feedback received and considered, the CFIA – working closely with Health Canada - will develop and release a joint policy statement on Incorporation by Reference.

Annex A
Process for Revising Ambulatory Incorporated documents

DOCUMENTS CREATED BY THE CFIA OR OTHER FEDERAL GOVERNMENT DEPARTMENTS

If a document developed by the CFIA or other Government of Canada department or agency is chosen as appropriate for ambulatory incorporation, this process will be followed when the incorporated document is updated or changed.

Step 1 – Review and Final Approval

Following the completion of the policy and/or scientific assessment and any related consultations, proposals to modify a document incorporated by reference must be considered and approved by the Executive Director of the relevant program area. A determination of the potential administrative burden change would be completed at this time. In some instances, depending on the incorporated document, approval of the proposed change from the President of the CFIA or the Minister responsible will be required.

Step 2 – Domestic and International Notification

Once approved within the CFIA, the Canadian public, domestic stakeholders, and international trading partners and other foreign governments will be notified of the proposals and given the opportunity to provide any comments or concerns they may have. The duration of the comment period will be specified in the notice and varies depending on the nature of the change. International notification may not always be required.

Notification will be sent to the public and domestic stakeholders through the CFIA external website. For international partners, notification will be sent to the World Trade Organization (WTO) through established processes and channels, as appropriate.

Note on Proposed Changes due to Immediate Risks to Health

In instances where a change to an incorporated document is being proposed to address an immediate risk to health and safety, the CFIA may forgo the comment period and proceed immediately with modifying the document incorporated by reference at the time of domestic and international notification.

Note on Minor Administrative Changes

In instances where minor administrative changes (e.g. correcting spelling, correcting grammar, etc.) are required to documents incorporated by reference, the CFIA may also forgo the comment period and proceed immediately with modifying the document incorporated by reference at the time of domestic and international notification.

These changes would be limited to those of a "house-keeping" nature that have no impact on health and safety or the industry's ability to market their food commodities in Canada.

Step 3 – Analysis of Comments

The CFIA will undertake an analysis of all comments received during the notification period, take them under consideration, and determine whether any revisions to the proposal are required.

Step 4 – Summary of Comments

Upon completion of the notification period, the CFIA will confirm that the comment period has ended, indicate if comments were received and post a summary of the comments made during the notification period. The CFIA will also state whether or not it intends to proceed with the proposed change or if a re-assessment will be required due to the comments received. This information will be published on its external website, and, if applicable, be notified internationally.

Step 5 – Final Publication of Modified Document

Once the notification period has ended and no significant concerns which would require a revision to the proposal have been identified, the French and English versions of the document incorporated by reference will be modified accordingly. If there are significant issues raised in the comment period, revisions would be made, and the process would return to step 2.

The previous French and English versions of the document will be archived online along with a short summary of the change(s) for referencing purposes. The modification to the incorporated document takes effect the day on which it is indicated, but not earlier than put on the external website.

Note on Transition Periods

A transition period may be required before a modification to an incorporated document can formally take effect to provide domestic and international

stakeholders with sufficient time to modify their products or practices in order to come into compliance. The requirement for and length of any such period will be determined on a case-by-case basis and/or based on any applicable legislative, regulatory or other formal requirements (e.g. international agreements). The public and WTO notices will specify if there is a transition period. A transition period is generally used in those instances where the proposed modification will impact the industry's ability to market a food commodity in Canada.

DOCUMENTS CREATED BY THIRD-PARTIES

The CFIA will only recommend the incorporation of documents from third-parties where the CFIA has a reasonable expectation that notification of upcoming revisions will be given. Where a third party document has been incorporated and CFIA is aware that the third party is making a revision, the CFIA will identify to stakeholders that the document will be changed, and invite comments on the appropriateness of that change. These comments will be assessed by the CFIA, and, where relevant, communicated to the author of the third-party document, though there is no assurance that the third party will address the comments.

Step 1 – Domestic and International Notification

When a third party identifies that a document that has been incorporated will be revised, the CFIA will endeavour to notify the Canadian public, domestic stakeholders, and international partners of the proposal, and provide an opportunity for comments. The comment period will be specified in the notice and varies depending on the nature of the change.

Notification will be sent to the public and domestic stakeholders through the CFIA external website. For international partners, notification will be sent to the World Trade Organization (WTO) through established processes and channels, when appropriate.

Step 2 – Analysis of Comments

The CFIA will undertake an analysis of all comments received during the notification period to determine whether any revisions to the proposal will be suggested to the third party. The CFIA will develop a strategy for addressing the situation where the third party does not accept any changes proposed. After analysis of the change, including any comments received, if the change is not one that the CFIA wishes to have incorporated, the CFIA can initiate a regulatory amendment to the regulations that incorporated the document, such that it will no longer be an ambulatory document, but instead reference the earlier version of the document or take some other measure, such as provide for a specific regulation.

Step 3 – Summary of Comments

Upon completion of the notification period, the CFIA will confirm that the comment period has ended, indicate if any comments were received, and post a summary of the comments made during the notification period. This information will be published on the CFIA external website, and communicated directly to the third party who maintains the document.

Step 4 – Final Publication of Modified Document

Once the third-party modifies and publishes its document, if the change is considered acceptable to the CFIA, the CFIA will provide access to the revised document through its external website with an indication of when the change takes effect, along with the previous versions of the document.

If the CFIA determined that the change was not acceptable, then a regulatory process would be considered to change or remove the reference to the document in the regulations (either to remove it entirely, revise it to be a static reference to a past version of the document, or reproduce the relevant text in the regulation itself), or take some other appropriate measure.