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A large, 3D-style green spiral graphic that starts from the center and expands outwards, set against a background of faint, overlapping lines in various colors (blue, purple, green).

# Requirements for the Accreditation of Agriculture Inputs, Food, Animal Health and Plant Protection Testing Laboratories

**CAN-P-1587**  
April 2008

Program Speciality Area (PSA-AFAP)



# REQUIREMENTS

## ACCREDITATION OF AGRICULTURE INPUTS, FOOD, ANIMAL HEALTH AND PLANT PROTECTION TESTING LABORATORIES

**Program Specialty Area**

**(PSA-AFAP)**

*Domaine de spécialité de programme*

*Les exigences régissant l'accréditation des laboratoires d'analyse des intrants agricoles, des aliments, de la santé des animaux, et de la défense (ou protection) des végétaux*

*(DSP-)*

**CAN-P-1587**

**April 2008**

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# TABLE OF CONTENTS

<b>FORWARD</b> .....	<b>I</b>
<b>PREFACE</b> .....	<b>II</b>
<b>1. SCOPE</b> .....	<b>1</b>
<b>2. INTRODUCTION</b> .....	<b>1</b>
2.1 <i>CFIA –SCC Agreement</i> .....	<i>1</i>
2.2 <i>Communications between CFIA and accredited laboratories</i> .....	<i>2</i>
<b>3. PRESENTATION OF THE LABORATORY SCOPE OF ACCREDITATION</b> .....	<b>2</b>
<b>4. REQUIREMENTS AND ADDITIONAL ACCREDITATION CRITERIA</b> .....	<b>2</b>
4.1 <i>General Requirements</i> .....	<i>2</i>
4.2 <i>Additional Criteria</i> .....	<i>3</i>
4.3 <i>Laboratories involved in import and export control</i> .....	<i>4</i>
<b>5. INTERPRETATION AND AMPLIFICATION OF CAN-P-4E REQUIREMENTS</b> .....	<b>4</b>
<b>6. PROFICIENCY TESTING REQUIREMENTS</b> .....	<b>7</b>
6.1 <i>Selection of Proficiency Testing Schemes</i> .....	<i>7</i>
6.2 <i>Monitoring PT</i> .....	<i>8</i>
<b>7. GENERAL CRITERIA</b> .....	<b>8</b>
<b>8. CONFIDENTIALITY AND THE CFIA</b> .....	<b>8</b>
<b>9. SERIOUS AND CRITICAL NON-CONFORMITIES AND SUSPENSIONS AND WITHDRAWALS</b> .....	<b>8</b>
<b>11. DEFINITIONS</b> .....	<b>10</b>
11.1 <i>Canada Agriculture Products Act</i> .....	<i>10</i>
11.2 <i>Feeds Act</i> .....	<i>10</i>
11.3 <i>Fertilizers Act</i> .....	<i>10</i>
11.4 <i>Fish Inspection Act</i> .....	<i>11</i>
11.5 <i>Food and Drugs Act</i> .....	<i>11</i>
11.6 <i>Meat Inspection Act</i> .....	<i>11</i>
11.7 <i>Health of Animals Act</i> .....	<i>11</i>
11.8 <i>Plant Protection Act</i> .....	<i>12</i>
11.9 <i>Seeds Act</i> .....	<i>12</i>
11.10 <i>CFIA Act</i> .....	<i>12</i>
<b>ANNEX 1: “LIST OF PRODUCTS AND SERVICES BY CLASS (PSC) CODES”</b> .....	<b>13</b>
<b>ANNEX 2: PRESENTATION OF SCOPES</b> .....	<b>14</b>

## **FORWARD**

### About the Standards Council of Canada

The Standards Council of Canada ("Council") is a crown corporation established by an Act of Parliament in 1970 to foster and promote voluntary standardization in Canada. It is independent of government in its policies and operations, although it is financed partially by Parliamentary appropriation. The SCC Governing Council consists of members from government and the private sectors.

The mandate of the Council is to promote the participation of Canadians in voluntary standards activities, promote public-private sector cooperation in relation to voluntary standardization in Canada, coordinate and oversee the efforts of the persons and organizations involved in the National Standards System, foster quality, performance and technological innovation in Canadian goods and services through standards-related activities, and develop standards-related strategies and long-term objectives.

In essence, the Council promotes efficient and effective voluntary standardization in Canada in order to advance the national economy, support sustainable development, benefit the health, safety and welfare of workers and the public, assist and protect consumers, facilitate domestic and international trade and further international cooperation in relation to standardization.

The Council serves as the government's focal point for voluntary standardization, represents Canada in international standardization activities, sets out policies and procedures for the development of National Standards of Canada, and for the accreditation of standards development organizations, product and services certification bodies, calibration and test facilities, of quality and environmental management systems certification bodies, inspection bodies and certification bodies. In addition, Council promotes and supports the principle of recognition of accreditation or equivalent systems as a means of decreasing the number of multiple assessments and audits, both in Canada and with Canada's trading partners.

This document is one of several issued by the Standards Council of Canada to define the policies, plans, and procedures established by the Council to help achieve its mandate.

Requests for clarification and recommendations for amendment of this document, or requests for additional copies should be addressed to the publisher directly.

## **PREFACE**

This Program Specialty Area (PSA) is operated and managed by the SCC through its Program for Accreditation of Laboratories – Canada (PALCAN). Accreditation under this PSA program is the formal recognition by the Standards Council of Canada of the competence of a laboratory to perform a specific list of tests in these specialty areas. It is not a guarantee that test results will conform to standards or agreements between a testing laboratory and its clients; business transactions between an accredited testing laboratory and its clients are legal matters between the two parties.

The Task Group Laboratories (TG Labs) is constituted by and reports to the Advisory Committee on Conformity Assessment (ACCA). The TG Labs is responsible for applications for accreditation from laboratories, assessments of applicant laboratories and reassessments of accredited laboratories and making recommendations, as required, to the ACCA and the Council. The CFIA employee who is the Convenor of the Working Group for this Program Specialty Area is a member of TG Labs, serving as primary contact between the SCC and the CFIA.

This document was designed to meet International Organization for Standardization (ISO)/International Electrotechnical Commission (IEC) Standard 17025 requirements. Rather than serving as a "stand alone" document, it was designed to harmonize with and complement the SCC document CAN-P-4E, "*General Requirements for the Competence of Calibration and Testing Laboratories*", which is ISO/IEC: 17025 verbatim.

Accreditation by SCC requires an on-site assessment of the laboratory to demonstrate competence with the requirements as well as prior and continued participation and satisfactory performance in appropriate proficiency testing programs for each major area of testing.

The scope of these guidelines will be evaluated periodically to respond to client, laboratory and accreditation requirements as well as improvements in the available science and technology or regulatory changes.

This Preface is not an integral part of this document.

## **SUMMARY OF CHANGES FROM MARCH 2003 VERSION**

This program specialty area has been reconstructed and modified expressly for laboratories offering testing services to industry, retailers, importers, exporters, producers, processors and other organizations which must comply with regulatory requirement.

1. The title and scope of the program speciality areas have been expanded to include agricultural inputs, and animal and plant health testing laboratories.
2. The requirements and references have been revised to include new requirements as outlined in CAN-P-4E and any CAN-P-documents new or revised since 2003. Program speciality area-specific references have been revised to include the expanded scope. General references listed in other SCC primary documents have been removed.
3. Discipline-specific interpretations of requirements have been removed from the body of the document and added as annexes.
4. Information and criteria regarding specific CFIA proficiency testing programs have been removed and added to discipline- specific annexes.
5. Information about regulatory responsibilities of CFIA technical assessors and confidentiality agreements has been added.
6. Information to address serious and critical non-conformities has been presented.



## **1. SCOPE**

This program specialty area applies to the accreditation of agriculture inputs, food, animal health and plant protection laboratories offering testing services to industry, retailers, importers, exporters, producers, processors and other organizations which must comply with regulatory requirement. The potential impact of positive test results on public, animal or plant health and the affect on trade and commerce demands this testing to be distinguished from similar laboratory testing conducted for other purposes.

Laboratories that are conducting similar testing but for other than regulatory purposes may seek accreditation under this PSA, and participate in the relevant PT programs, provided they are prepared to adhere to the requirements of the PSA.

## **2. INTRODUCTION**

Industry, Government departments and their agencies, including the Canadian Food Inspection Agency require laboratory testing for regulatory purposes. The CFIA is faced with the increasing demand to recognize the competence of the laboratories doing this testing. The objective of this PSA is to provide a framework for the thorough and balanced assessment of laboratory competence. The technical requirements are drawn from published principles, best practices and procedures and sound science activities used or promoted by national/international organizations.

The general requirements for the competence of testing and calibration laboratories are described in CAN-P-4E (ISO/IEC 17025:2005). These requirements are designed to apply to all types of calibration and objective testing and therefore may need to be interpreted with respect to specific types of testing and the techniques involved. The requirements outlined in this document are elaborations or interpretations of the general criteria and may include additional requirements applicable to a certain field of testing, testing technology, type of test or discipline. Given the complexity and magnitude of this PSA, it is expected that where no elaborations, interpretations or additional requirements are stipulated in this document for the elements of the standard, that the SCC policy documents (CAN-P-1630, CAN-P-1570, etc.) and best scientific practices in the area of testing will guide the assessment process.

This PSA document provides an amplification and/or interpretation of those requirements in CAN-P-4E that are needed to provide guidance and identifying the minimum requirements for participating laboratories. The goal is to establish a minimum standard for quality and technical competence for laboratories testing for Canadian Food Inspection Agency (CFIA).

### **2.1 CFIA –SCC Agreement**

This PSA is managed in partnership with the Canadian Food Inspection Agency (CFIA), by way of a separate agreement. CFIA specifies its requirements in general principles and SCC agree to the principles, but SCC is responsible to implement the requirements on a laboratory by laboratory basis

## The CFIA:

- recommends CFIA technical assessors or technical experts for the assessment of the participating laboratories. These technical assessors or technical experts are then approved by the SCC, provided they meet the SCC requirements.
- may provide or specify and monitor interlaboratory proficiency testing or interlaboratory comparisons when appropriate and feasible. However, as per 17011 7.15, SCC must judge the PT provider to be competent if it is to base accreditation decisions (suspension, withdrawal) on the result of that PT.

## **2.2 Communications between CFIA and accredited laboratories**

Where appropriate, CFIA will provide information to participant laboratories regarding testing for specific regulatory purposes. To this end, bulletins and notices containing such information will be issued by the SCC, on behalf of the CFIA, to all participants in this PSA. Laboratories are also reminded of the need to comply with any and all relevant statutory or legislative requirements. Requests to send out bulletins and notices will be sent from the CFIA by the responsible officer within National Laboratory Operations to the Senior Program Officer of the SCC, responsible for this PSA who is the secretary for the working group for the PSA.

Inquiries and/or comments related to the regulatory programs can be submitted to [LAAB@inspection.gc.ca](mailto:LAAB@inspection.gc.ca). All responses affecting the accreditation process will be copied to the Senior Program Officer for this PSA at the SCC.

## **3. PRESENTATION OF THE LABORATORY SCOPE OF ACCREDITATION**

Users are required to view the scope of accreditation and review specific testing requirements before employing an accredited laboratory. The SCC website ([www.scc.ca](http://www.scc.ca)) contains a search directory for laboratory scopes. See Appendix (A.2) for direction regarding presentation of scopes specific to this PSA.

## **4. REQUIREMENTS AND ADDITIONAL ACCREDITATION CRITERIA**

### **4.1 General Requirements**

For information on the accreditation process, accreditation conditions, and details on preparing an application see: CAN-P-1570 *PALCAN Handbook – Program Requirements for Applicant and Accredited Laboratories and its respective appendices*.

Laboratories must meet all the pertinent provisions of the most recent versions of the PALCAN documents, including but not limited to:

- CAN-P-4E *General Requirements for the Competence of Testing and Calibration Laboratories, (ISO/IEC 17025:2005)*; the checklist that is used to assess these requirements is the latest version of CAN-P-1510E, *Assessment Rating Guide*.
- CAN-P-15 *Accreditation Programs: Requirements and Procedures for Suspension and Withdrawal, Complaints, Appeals and Hearings*.
- CAN-P-1623 *PALCAN Interpretation and Guidance on the Estimation of Uncertainty of Measurement in Testing*
- CAN-P-1624 *PALCAN Policy on Use of Proficiency Testing as a Tool for Accreditation of Testing*
- CAN-P-1625 *PALCAN Policy on Guidelines and Procedures for Laboratories with Serious and Critical Non-conformities*
- CAN-P-1626 *PALCAN Policy on Traceability Requirements for Calibration Sources Used by Accredited Testing Laboratories*
- CAN-P-1627 *PALCAN Policy on the Selection of Physical Measurement Calibration Sources for Testing Laboratories*
- CAN-P-1628 *PALCAN Policy on the Use of Information Technology in Accredited Laboratories*
- CAN-P-1629 *PALCAN Guidance for the Validation of Test Methods*
- CAN-P-1630 *PALCAN Interpretations for Conducting Assessments of Testing and Calibration Laboratories*
- CAN-P-1631 *PALCAN Guidelines for the Use of Accreditation Body Logos and for Claims of Accreditation Status*

## 4.2 Additional Criteria

In addition to the requirements, laboratories performing analyses must also apply the best scientific practices accepted nationally or internationally for each relevant testing field or discipline,

- Chemistry: the *CITAC / EURACHEM Guide to Quality in Analytical Chemistry* Edition 2002, prepared jointly by CITAC (The Cooperation on International Traceability in Analytical Chemistry) and EURACHEM (A Focus for Analytical Chemistry in Europe) <http://www.citac.cc/>)
- Microbiology: *EA-4/10 Accreditation for Microbiological Laboratories*, Edition 2 2002, prepared jointly by EURACHEM (47A Focus for Analytical Chemistry in Europe) and EA (European Accreditation) <http://www.citac.cc/>) \*

NOTE: These documents are based on ISO/IEC 17025:1999. In case of differences between interpretations in these documents for a specific clause of ISO/IEC 17025 and, ISO/IEC 17025: 2005 (CAN-P-4E), CAN-P-4E shall prevail.

- Animal Health (Disease monitoring, surveillance, control) the OIE (Organization International Epizootic): OIE Quality Standard and Guidelines for Veterinary Laboratories: infectious diseases. (current version). [http://www.oie.int/eng/publicat/ouvrages/A\\_112.htm](http://www.oie.int/eng/publicat/ouvrages/A_112.htm)

- Seed Testing and Plant Protection (Disease monitoring, surveillance, control) North American Plant Protection Organization (NAPPO) <http://www.nappo.org>
- International Plant Protection Convention (IPPC) <https://www.ippc.int/IPP/En/default.jsp>
- International Seed Testing Association (ISTA). <http://www.seedtest.org>

### 4.3 Laboratories involved in import and export control

There may be additional requirements specified in appropriate Codex Alimentarius (Codex) or national or international standards for laboratories involved in import and export control. For example, The Codex Alimentarius (Codex) is a key reference and guideline for the CFIA as a regulator, food processors and consumers in the context international trade. See *Guidelines for the Assessment of the Competence of Testing Laboratories Involved in the Import and Export Control of Foods*. ([www.codexalimentarius.net/download/standards/355/CXG\\_027e.pdf](http://www.codexalimentarius.net/download/standards/355/CXG_027e.pdf))

## 5. INTERPRETATION AND AMPLIFICATION OF CAN-P-4E REQUIREMENTS

All the requirements of the most recent version of CAN-P-4E apply to all accredited laboratories. This section of these requirements is to be used in conjunction with the CAN-P-4E document. It provides guidance in the form of interpretation and/or amplification of some clauses of CAN-P-4E. Laboratories are also reminded that the references specified this document and annexes also supplement CAN-P-4E by providing specific guidance in their respective fields of testing.

### Management Elements:

CAN-P-4E (ISO/IEC 17025:2005) Section No:	Interpretative/ Amplification note
4.3.1 Document control	Establish and maintain procedures to control documents from external sources from which standard methods are obtained or notices which provide updates about regulatory testing requirements. See also CAN-P 1630 interpretative note.
4.4.1 c Review of requests, tenders and contracts	See also 5.4.2 Establish and maintain procedures for the review of requests, tenders and contracts to ensure that the appropriate test method for regulatory purposes is selected and is capable of meeting the customer=s requirements.

**Technical Elements:**

<p>CAN-P-4E (ISO/IEC 17025:2005) Section No:</p>	<p>Interpretative/ Amplification note</p>
<p>5.4.2 Selection of methods</p>	<p>If a method is specified by a customer for export, HACCP or other program requirements, the laboratory must follow the specified test method as written. The laboratory must pay special attention to this requirement when the testing will ultimately support the issuance of CFIA export certificates or the use of the test results for other regulatory needs by the CFIA through the direct client of the laboratory.</p> <p>The laboratory shall confirm that it can properly operate standard methods before introducing the tests or calibrations. If the standard method changes, the confirmation shall be repeated. This exercise is referred to as verification, and is not to be confused with validation. Objective evidence to demonstrate that the laboratory meets the performance criteria of the standard method as published is generated and summarized.</p> <p>The data required for verification of a standard method may be dictated by the customer.</p> <p>See also CAN-P-1630</p>
<p>5.4.3 Laboratory-developed methods</p>	<p>Laboratories involved in significant in-house test method development activities should consider adding the PSA, Test method development and evaluation and non-routine testing to its scope of accreditation.</p> <p>See CAN-P-1595</p>
<p>5.4.5.2 Validation of methods</p>	<p>If a standard method has been modified even slightly or applied outside its intended scope, i.e. applied to another matrix etc it must be validated. Non-standard methods such as ones obtained from the literature or laboratory developed methods must also be validated. The procedure used to validate the method if not specified by the customer, must be appropriate to the testing field. The results from the validation must be summarized demonstrating that the requirements specified by the customer or regulations have been met.</p> <p>See also CAN-P-1629</p>

5.4.6 Estimation of measurement uncertainty	<p>Irrespective of the type of testing, the laboratory must identify all the significant components of measurement uncertainty. Numerical estimates are expected for those tests which produce numerical results. For qualitative tests the laboratory must identify and control major sources of uncertainty.</p> <p>For some tests it may be appropriate to select and estimate uncertainty using a representative from a larger group, i.e. from among a class of analytes or matrices, provided the approach is agreed to by the customer and is accepted practice for the testing field.</p> <p>Additional guidance as to the degree of rigour or practical examples may be provided by specific programs or testing fields.</p> <p>See also CAN-P-1623</p>
5.6 Measurement traceability	<p>See CAN-P-1626</p> <p>Note 4.2 the definition for critical equipment</p>
5.6.3 Reference standards and reference materials	<p>Where possible, certified reference materials (CRMs) should be used; however, for many testing fields in this PSA there are no CRMs available. Best practices in the testing field or program will usually dictate the type of reference standards to be employed, how they are to be stored and used, and any internal checks to be done before being put into use.</p>
5.8 Handling of test and calibration items	<p>Any customer or regulatory directives to ensure sample integrity are to be followed.</p>
5.9 Assuring the quality of test and calibration result	<p>The laboratory shall maintain records of performance and monitor results from proficiency testing activities. Unsatisfactory results must be followed up with an investigation and if necessary corrective or preventive actions. See also CAN-P-1630</p>

## 6. PROFICIENCY TESTING REQUIREMENTS

### 6.1 Selection of Proficiency Testing Schemes

Guidance in the use of proficiency testing to support accreditation is provided in the International Laboratory Accreditation Cooperation document: ILAC-G22:2004, "Use of Proficiency Testing as a Tool for Accreditation in Testing" (CAN-P-1624).

Applicant and accredited laboratories are required to participate in relevant and available PT provided by organizations administering acceptable PT programs. Acceptable programs are those which comply with ILAC G13 and/or ISO Guide 43. Other programs may be acceptable, provided they are agreed upon by the SCC, CFIA and the laboratory.

As a regulatory authority, the CFIA may, when appropriate, specify a proficiency testing, inter-laboratory comparison, or blind test item for mandatory or recommended participation by applicant/accredited laboratories. The SCC will take into account this prescription when reviewing results during assessments (CAN-P-1624, 6.4).

Information about the current, CFIA- specific proficiency testing programs available to laboratories is available from the responsible officer within CFIA, National Laboratories Operations Office or via [LAAB@inspection.gc.ca](mailto:LAAB@inspection.gc.ca)

Applicant and accredited laboratories shall identify to the SCC Senior Program Officer for the PSA the specific proficiency testing schemes in which the laboratory participates for tests accredited under this PSA. The laboratory will document efforts to search for PT providers to cover their scope of testing; however, not all analytes or matrices are necessarily included in a proficiency program for multi-analyte methods. Where feasible, a laboratory will participate in more than one PT program to cover as many or all of the analytes in the multi-analyte method(s) on the scope.

- Where these are not available, then well-organized interlaboratory comparisons (ILC's) would be chosen. Internal and/or external sample exchanges or round-robins could be selected in the absence of accredited PT schemes or pertinent ILC's. As much as possible, externally derived materials shall be used. When these are not relevant to the scope of testing, internal performance-based data such as the regular use of certified reference materials and/or internal quality control activities using secondary reference materials, replicate tests using the same or different methods or correlation of results between laboratories may be appropriate, provided they are technically sound and agreed upon by the SCC, the technical assessor(s)/expert(s) and the laboratory.
- Given the wide variety of analytical demands, the proficiency testing programs of the Canadian Food Inspection Agency cannot cover all aspects of testing related to food, feed and fertilizer products. It must be regarded as being only representative of these areas of activity. Laboratories shall participate in additional proficiency testing activities for major areas of the scope of testing not covered by the CFIA programs

## 6.2 Monitoring PT

- Criteria for successful participation in available proficiency testing activity prior to receiving accreditation will be outlined in a discipline-specific annex.

Reports of PT performance are reviewed by the SCC, and they will initiate any requests for investigations. The laboratory will be subject to suspension and withdrawal procedures as documented in CAN-P-15, *Accreditation Programs: Requirements and Procedures for Suspension and Withdrawal, Complaints, Appeals and Hearings*, when the laboratory's PT testing performance does not meet specified performance criteria.

## 7. GENERAL CRITERIA

When SCC receives an application for accreditation or a scope extension under this PSA, it will forward a copy of the scope to the convenor of the WG. In addition, the convenor will direct the applicant to the appropriate proficiency testing program, if available and identify coordinators as contact persons for the laboratories to obtain detailed information on each program. The applicable CFIA programs appropriate to the scope of testing will be recommended or specified or, alternatively, the CFIA may recommend or specify mandatory proficiency testing schemes to the applicant/accredited laboratory.

## 8. CONFIDENTIALITY AND THE CFIA

The technical assessors are required by law to report to the CFIA any contravention of the Acts and Regulations they observe., As such, the CFIA TAs or TAs representing CFIA will complete a confidentiality agreement specifically for employees of CFIA conducting assessments. Additionally, the reports on laboratory assessments conducted by the SCC are copied to the WG convenor for the purposes of informing the CFIA of the laboratory's status in this accreditation program. These reports are kept confidential.

At any time during the assessment process, provided the Team Leader is advised, the CFIA technical assessors may consult CFIA colleagues with the requisite expertise for guidance and interpretation of requirements or criteria to be met by the participant laboratories.

## 9. SERIOUS AND CRITICAL NON-CONFORMITIES AND SUSPENSIONS AND WITHDRAWALS

The document, "PALCAN Policy on Guidelines and Procedures for Laboratories with Serious and Critical Non-Conformities" (CAN-P-1625, November 2006) describes serious and critical non-conformities. Typically a laboratory is given 30 days to respond to a serious non-conformity. However, in the instance of this PSA the assessment team under advisement from the Senior Program Officer of the SCC, and CFIA technical experts, specialists or officers of the National Laboratory Operations Office might request that immediate action be taken if the non-



conformities could have an impact on test results in areas related to food safety or trade. These actions include:

- Immediate suspension of a test or tests. See CAN-P-1625.
- Response to findings within a shortened time frame, that is usually 10 working days
- It is expected that for these critical non-conformities that assessors will review responses within 2 working days or the responses will be assigned to another experienced, technical expert.
- The Team Leader and/or SPO will review the responses within 2 working days or it will be assigned to another SPO.

## 10. REFERENCES/BIBLIOGRAPHY

**10.1** APLAC Guidelines for Food Testing Laboratories. APLAC 007, October 2005.  
[http://www.aplac.org/documents/web\\_docs/tc\\_007.pdf](http://www.aplac.org/documents/web_docs/tc_007.pdf)

**10.2** Harmonized Guidelines for Single-Laboratory Validation of Methods of Analysis. Pure Appl. Chem. 74 (5)835-855, 2002.  
<http://www.iupac.org/publications/pac/2002/pdf/7405x0835.pdf>

**10.3** ISO Guide 43-1:1997 Proficiency Testing by Interlaboratory Comparison - Part 1 Development and Operation of Laboratory Proficiency Testing Schemes.

**10.4** ISO Guide 43-2:1997 Proficiency Testing by Interlaboratory Comparison - Part 2 Selection and Use of Proficiency Testing Schemes by Laboratory Accreditation Bodies.

**10.5** Harmonized Guidelines for Internal Quality Control in Analytical Chemistry Laboratories. Pure Appl. Chem 67, 649-666, 1995.  
<http://www.iupac.org/publications/pac/1995/pdf/6704x0649.pdf>

**10.6** Guidelines for the Assessment of the Competence of Testing Laboratories involved in the Import and Export Control of Foods. CAC/GL27-1997  
[www.codexalimentarius.net/download/standards/355/CXG\\_027e.pdf](http://www.codexalimentarius.net/download/standards/355/CXG_027e.pdf)

**10.7** The International Harmonized Protocol for the proficiency testing of analytical chemistry laboratories (IUPAC Technical Report) Pure Appl. Chem. 78(1), 145-196, 2006  
<http://www.iupac.org/publications/pac/2006/pdf/7801x0145.pdf>

**10.8** ILAC-G22:2004: Use of Proficiency Testing as a Tool for Accreditation in Testing.  
[http://www.ilac.org/documents/ILAC\\_G22\\_2004\\_use\\_of\\_proficiency\\_testing\\_as\\_a\\_tool\\_for\\_accreditation\\_in\\_testing.pdf](http://www.ilac.org/documents/ILAC_G22_2004_use_of_proficiency_testing_as_a_tool_for_accreditation_in_testing.pdf)

**10.9** ILAC-G13:2007 Guidelines for the Requirements for the Competence of Providers of Proficiency Testing Schemes. [http://www.ilac.org/documents/ILAC\\_G13\\_08\\_2007.pdf](http://www.ilac.org/documents/ILAC_G13_08_2007.pdf)

## 11. DEFINITIONS

The relevant definitions found in the latest edition of CAN-P-4E, CITAC/EURACHEM Guide and the EA/Eurachem Guide are applicable in addition to the following supplementary terms as they relate to CFIA administered acts and regulations. (The latest definitions found under these acts are available on the CFIA website at [www.inspection.gc.ca](http://www.inspection.gc.ca).)

### 11.1 Canada Agriculture Products Act

*An Act to regulate the marketing of agricultural products in import, export and interprovincial trade and to provide for national standards and grades of agricultural products, for the registration of establishments and for standards governing establishments.*

*"agricultural product"* means

- a) an animal, a plant or an animal or plant product,
- b) a product, including any food or drink, wholly or partly derived from an animal or a plant, or
- c) a product prescribed for the purposes of this Act.

### 11.2 Feeds Act

*An Act to control and regulate the sale of feeds.*

*"feed"* means any substance or mixture of substances containing amino acids, anti-oxidants, carbohydrates, condiments, enzymes, fats, minerals, non-protein nitrogen products, proteins or vitamins, or pelletizing, colouring, foaming or flavouring agents and any other substance manufactured, sold or represented for use:

- (a) for consumption by livestock,
- (b) for providing the nutritional requirements of livestock, or
- (c) for the purpose of preventing or correcting nutritional disorders of livestock, or any substance for use in any such substance or mixture of substances.

*"livestock"* means horses, cattle, sheep, goats, swine, foxes, fish, mink, rabbits and poultry and includes such other creatures as may be designated by regulation as livestock for the purposes of this Act.

### 11.3 Fertilizers Act

*An Act to regulate agricultural fertilizers.*

*"fertilizer"* means any substance or mixture of substances, containing nitrogen, phosphorus, potassium or other plant food, manufactured, sold or represented for use as a plant nutrient.

“*supplement*” means any substance or mixture of substances, other than a fertilizer, that is manufactured, sold or represented for use in the improvement of the physical condition of soils or to aid plant growth or crop yields.

#### **11.4 Fish Inspection Act**

*An Act respecting the inspection of fish and marine plants.*

“*fish*” means any fish, including shellfish and crustaceans, and marine animals, and any parts, products or by-products thereof “*marine plant*” includes Irish moss, kelp and other salt water plants, and any products or by-products thereof.

#### **11.5 Food and Drugs Act**

*An Act respecting food, drugs, cosmetics and therapeutic devices.*

“*food*” includes any article manufactured, sold or represented for use as food or drink for human beings, chewing gum, and any ingredient that may be mixed with food for any purpose whatever.

#### **11.6 Meat Inspection Act**

*An Act respecting the import and export of and interprovincial trade in meat products, the registration of establishments, the inspection of animals and meat products in registered establishments and the standards for those establishments and for animals slaughtered and meat products prepared in those establishments.*

“*animal*” means any animal in the class of mammals or birds and includes any other animal that is prescribed for the purposes of this Act or that falls within a class of animals prescribed for those purposes.

“*meat product*” means

- a) a carcass,
- b) the blood of an animal or a product or by-product of a carcass, or a product containing anything described in paragraph (b);

#### **11.7 Health of Animals Act**

*An act respecting diseases and toxic substances that may affect animals or that may be transmitted by animals to persons, and respecting the protection of animal.*

“*animal*” includes an embryo and a fertilized egg or ovum

“*animal by-product*” includes blood or any of its components, bones, bristles, feathers, flesh, hair, hides hoofs, horns, offal, skins and wool, and any thing containing any of those things

“*animal food*” means any thing that is capable of being a nutriment for animals and includes any of the constituent elements of an animal ration

“*animal product*” includes cream, eggs, milk, non-fertilized ova and semen

“*disease*” includes:

- a) a reportable disease and any other disease that may affect an animal or that may be transmitted by an animal to a person, and
- b) the causative agent of any such disease

## **11.8 Plant Protection Act**

*An act to prevent the importation, exportation and spread of pests injurious to plants and to provide for their control and eradication and for the certification of plants and other things. The purpose of this Act is to protect plant life and the agricultural and forestry sectors of the Canadian economy by preventing the importation, exportation and spread of pests and by controlling or eradicating pests in Canada.*

“*pest*” means any thing that is injurious or potentially injurious, whether directly or indirectly, to plants or to products or by-products of plants, and includes any plant described as a pest

“*plant*” includes part of a plant

## **11.9 Seeds Act**

*An act respecting the testing, inspection, quality and sale of seeds.*

“*seed*” means any plant part of any species belonging to the plant kingdom, represented, sold or used to grow a plant

## **11.10 CFIA ACT**

An act to establish the Canadian Food Inspection Agency and to repeal and amend other Acts as a consequence; whereas, the Government of Canada wishes to enhance the effectiveness and efficiency of federal inspection and related services for food and animal and plant health by consolidating them.

## **Annex 1: “List of Products and Services by Class (PSC) Codes”**

Additional categories of tests of the “List of Products and Services by Class (PSC) Codes” (CAN-P-1570 appendix B) which fall under this PSA include: (*text in italics are additions external to the PSC Codes and are provided for further clarification of testing activities included in this PSA*).

### **List of Products and Services by Class (PSC) Codes**

#### **ANIMAL AND PLANTS (AGRICULTURE)**

##### **Foods and Edible Products: (Human and Animal Consumption)**

###### **Includes:**

- *Testing of surfaces in abattoirs, processing environments, product contact surfaces and sampling surfaces*
- *Allergens*
- *Contaminants and residues in foods and agricultural materials (pesticides, antibiotics, insect infestation, agricultural chemicals, polyhalogenated biphenyls, chlorinated dioxins and dibenzofurans, other) and medicating ingredients in feed*

###### **Plants and Plant Propagative Material:**

- *Plant pathogens- bacterial, fungal, viral, viroid, and nematode*
- *Plant and plant materials for presence of disease (pathogens: bacterial, fungal, viral, viroid, insects)*

###### **Seeds:**

*Purity*  
*Germination*  
*Sprouting*  
*Moisture, Oil content*  
*Other*

###### **Other (Specify):**

#### **CHEMICALS AND CHEMICAL PRODUCTS**

##### **Chemicals for Agricultural Industry:**

*Fertilizers*

#### **ENVIRONMENTAL AND OCCUPATIONAL HEALTH AND SAFETY**

##### **Water Quality:**

*Process Waters*

#### **MEDICAL**

##### **Veterinary: (production animals)**

*Avian, aquatic, equine, bovine, camelid, caprine, cervine, ovine, porcine*

*Diagnostic bacteriology*  
*Antibiotic susceptibility testing*  
*Immunological methods of antigen detection*

*Diagnostic mycology*  
*Diagnostic microbiology (mycoplasma, rickettsia, algae, etc)*  
*Diagnostic virology*  
*Prions (histological, immunological, bioassay)*  
*Parasitology*  
*Serology of infection (AGID, CF, ELISA, HI, IFA, etc)*  
*Clinical immunology*  
*Cytology*  
*Histopathology*

**In all cases of food, agriculture inputs, animal or plant testing relative to the Acts and Regulations administered and/or enforced by the CFIA; the following testing activities/technologies:**

- *Qualitative analysis of GMO (detection by DNA, detection by protein)*
- *Quantitative analysis of GMO (detection by DNA, detection by protein)*
- *Molecular biology techniques*
- *Bioassays*
- *Microbioassays*
- *Toxicity*
- *Immunological techniques*
- *Cell culture*

## **ANNEX 2: PRESENTATION OF SCOPES**

The laboratory is expected to present and manage its scope of accreditation in a manner which best illustrates to users/potential users the competencies assessed by the SCC in this PSA. Where it is imperative that regulatory requirements are met, it is the responsibility of the laboratory to explain the presentation of the scope, discuss the laboratory capabilities and the parameters of the test or diagnostic method and/or analyte for appropriateness and fitness for the testing purpose (such as but not limited to: limit of detection, limit of quantification, sensitivity or specificity, screening vs. confirmatory methods, etc)

### **A 2.1 FIXED SCOPE**

A laboratory undertaking routine analysis of specified test items for pre-determined and unchanging analytes of interest will be well-served by a fixed scope. Methods chosen by the laboratory will be validated or verified by the laboratory for the full range of sample items processed by the laboratory. Where a standard method is intended for a wide range of products, the laboratory must demonstrate that it has validated or verified the performance of the method for each item or product type accepted for test, within the appropriate isolation, detection and/or identification range (sensitivity, specificity, limit of detection, limit of quantification, minimum residue limits, etc.) depending on the field of test and type of test.

### **A.2.1.1 Standard Methods**

Laboratories often specialize in standard methods specified by the customers, particularly for methods stipulated or specified in regulation for various industry sectors (dairy, egg, meat, etc) or by internationally recognized authoritative bodies in the respective sectors (OIE, IPPO, Codex, ISTA, etc.). In this case, laboratories are served by a fixed scope under which the competence to perform the specified standard method is assessed.

The titles for standard methods are to be listed on scopes as they are published by the issuing authority, provided the method is applied without modification or with minor editorial modifications. See Appendix B of CAN-P-1570 for more information about acceptable scope content.

### **A. 2. 2 IN-HOUSE DEVELOPED METHODS**

Where non-routine samples are supplied by customers, the laboratory may be required to develop a new method specifically for these samples. Applying for a scope extension for this test that may never be used in the laboratory again may not be practical or not cost-effective. A laboratory involved in test method development may consider adding the Program Specialty Area, Test Method Development and Evaluation and Non-Routine Testing to its scope of accreditation. The requirements are outlined in CAN-P-1595.