

RESPONSIBILITY LINKED TO THE IMPORTATION OF PRODUCTS FROM COUNTRIES OUTSIDE OF EUROPE: RISK PREVENTION

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WHEN YOU NEED TO BE SURE



ACCREDITATION : A VIABLE TOOL FOR IMPORT SAFETY



- Use of competent testing inspection and product certification bodies to ensure product quality at supply sources
 - Most effective means of reducing the risk of importing defective products
 - Product compliance with standards and regulations need testing

- Accreditation is the tool for ensuring and providing confidence in the
 - Accuracy
 - Reliability of testing results

- Accreditation must be recognized internationally
 - Ex : ILAC (International Laboratory Accreditation Cooperation)
ILAC member accreditation bodies (e.g. COFRAC in France) have been recognized internationally as competent through rigorous peer evaluation to accredit testing and inspection organisations. The bodies must meet with the requirements of ISO 17011.

ACCREDITATION : A VIABLE TOOL FOR IMPORT SAFETY

- Under ILAC and MRA (Mutual Recognition Arrangement):
 - Competent laboratories and inspection bodies have been recognised globally to facilitate acceptance of testing and inspection results accompanying goods across international borders

- Laboratories must be accredited to a specific scope of accreditation
 - Thus it is very clear which tests they have been found competent to perform
 - The scope of accreditation transparently describes the limits of a laboratory's competences.
 - » e.g. toys: paint lead testing, tested wheels cannot be removed

- Industry and government rely on accreditation as one tool of product quality assurance
 - China has an ILAC recognised accreditation body that can accredit laboratories
 - The available competent testing need to be more effectively present in the early stages of the supply chain
 - Once the product enters the market place and is found to be defective it is too late:
 - Recalls are never 100% effective, and they are a tremendous waste and nuisance
 - Cost associated with accreditation of laboratory is far less than the costs and public scrutiny associated with the recalls



ACCREDITATION

- A credential:
 - It shows a qualification to provide the services in the fields in which it is accredited
 - Product compliance with standards and regulations need testing

- International recognition of the accredited lab who has an MRA recognition by ILAC.

- Significant discounts in liability insurance premiums

- Users of laboratory and inspection services are beneficiaries of accreditation:
 - They have confidence that accreditation is used at a regulatory level

- Like government regulators, specifiers have come to appreciate the importance of accreditation programs. With restricted budgets many governments can no longer do all by themselves
 - They must rely on third party organisations to support their regulatory efforts
 - They need a fair and meaningful basis for identifying qualified partners.
 - Accreditation will provide just that.
 - Accreditation bodies (as COFRAC) work with the regulators and specifiers to establish any specific technical laboratory requirements to be applied to the ISO 17025.



STANDARDS FOR COMPETENCE : ISO 17025 REQUIREMENTS

- **CAPABILITY:**
 - People with the required skills and knowledge
 - Procedures to ensure consistency of test
 - Quality control
 - Required facilities, equipments and instruments

- **RESPONSIBILITY:**
 - People demonstrate accountability for their results

- **SCIENTIFIC APPROACH:**
 - Accepted scientific principles are carried on

- **OBJECTIVITY:**
 - Results are produced based upon measurable quantities

GROWING NEED FOR ACCREDITATION

- The high tendency to resort to accredited bodies has become more important since the European regulation of July 9, 2008 was issued. This regulation (765/2008) deals with the accreditation and market surveillance.

- Accreditation is developing in the regulatory field, it is now required by public authorities as pre-requisite to any future agreement. Accreditation is necessary when it comes to national or European regulation.
 - Few examples:
 - ILAC
 - IAF
 - EA
 - APLAC
 - IAAC
 - ...



- Procedure of notification of organisms
- Regulation requirements to which notified organisms must comply
- Purpose of accreditation
 - Structure of accredited bodies is reinforced by the evaluation and notification of organisms
 - Ensure technical competency required by the regulations
- International activities
 - MRA: notified organisms can accelerate their business deals internationally
- Ministerial agreements based on accreditation
 - Directive 765/2008 dealing with accreditation and market surveillance

CODEX ALIMENTARIUS: FOOD IMPORT & EXPORT INSPECTION

- Appropriate level of protection (ALOP):
 - level of protection deemed appropriate by the country establishing a sanitary measure to protect human life or health within its territory

- Official accreditation
 - procedure by which a government agency having jurisdiction formally recognises the competence of an inspection & certification body to provide its services

- Where the competent authorities of an importing country use third party providers as officially recognised to implement controls, such arrangements should be conducted in the manner discussed in the official accreditation

CODEX ALIMENTARIUS: FOOD IMPORT & EXPORT INSPECTION



- Function that can be conducted by such providers may include:
 - Sampling
 - Analysis of sample
 - Compliance evaluation

- Legislation should provide the competent authority with the ability to:
 - Recognise accredited laboratories, or to accredit laboratories

- Frequency of inspection & testing of imported food
 - Nature and frequency should be based on the risk to human health and safety presented by the product

CODEX ALIMENTARIUS: FOOD IMPORT & EXPORT INSPECTION

- Sampling & analysis
 - Based on codex or scientifically based sampling plans
 - Internationally validated standard methods of analysis
 - Analysis should be conducted in an accredited laboratory

- Recognition of export controls
 - The importing country should establish mechanisms to accept control system in an exporting country
 - MRA
 - COFRAC ISO 17025
 - ILAC

Assessment and accreditation of food import and export inspection and certification system.



- **EXAMPLE OF CPSIA (Consumer Product Safety Improvement Act of 2008)** which was signed into US law by the Consumer Product Safety Commission (CPSC)
 - Comprehensive overhaul of consumer product safety rules
 - Impact for all children’s products entering the US market, with more stringent criteria and new requirements
 - CPSIA mandates that children’ products be tested by CPSC recognised laboratories
 - To date, CPSC recognition requires laboratories to have ISO 17025 accreditation for the specific tests
 - Accreditation from an accreditation body who is signatory to ILAC / MRA (Mutual Recognition Arrangement)

- **ISO 17025**
 - General requirements for the competence of testing and calibration laboratories

REGULATORY FRAME – EXAMPLE OF FDA

- MY PRODUCT IS DETAINED WHAT DOES THAT MEAN
 - FDA has made an initial determination that the product appears to violate requirement
 - It is subject to refusal of admission into the USA

- WHAT CAN I DO IF FDA DETAINS MY PRODUCT
 - FDA will not analyse your product for you
 - Hiring a private laboratory
 - Introducing evidence to support the release of your product

- WHAT FDA STANDARDS SHOULD A LABORATORY MEET?
 - Sample collection report representative sample from the actual goods offered for import
 - It is in your interest to work with private lab that has experience with offering analytical testimony to FDA
 - Guidance for providing analytical results
 - Regulatory procedures manual

- FDA METHODOLOGIES & ANALYTICAL PRACTICES
 - Accreditation under ISO 17025: laboratory adhere to official methodologies as independent testing laboratory



SAFETY OBLIGATION FOR RAW MATERIALS & FINISHED PRODUCTS

- RSTS?
- RoH(s)?
- REACH?
- CODEX ALIMENTARIUS compliance (food)
- S.V.H.C. (health & environment)
 - e.g. 38 substances target in article



SGS MULTILAB ROUEN
**OUR APPROVALS, RECOGNITIONS &
ACCREDITATIONS**

WHEN YOU NEED TO BE SURE





- 20 accreditations from COFRAC (ISO 17025)
- Government Approvals (Ministry for agriculture, Ministry for Economy and Finance Labour Ministry, Ministry of Environment, Fraud Prevention Department)
- International Approvals: FOSFA, GAFTA
- GLP recognition of EOCD

SGS MULTILAB ROUEN AND THE ENVIRONMENT



- ACCREDITATIONS COFRAC programs:
 - 100-1 Physico-chemical analyses of water
 - Biological analyses of water
 - 94 (occupational air quality)
 - 134 (Soils)
 - 156 (Sewage and Sediments)
 - Waste program
 - 135 (Radionucleides- environmental matrices)
 - 99-2 / 99-3 / 99-4 (Pesticides/Heavy metals/ Radionucleides in foodstuff /pollution markers)
 - COFRAC accreditation for development of new analytical methods

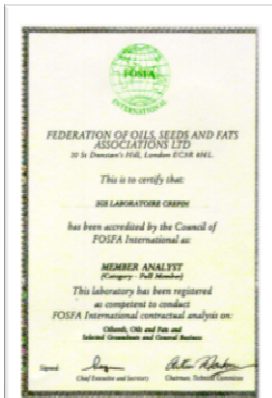


SGS MULTILAB ROUEN AND THE ENVIRONMENT

- Approved by the Ministry of environment and sustainable development (micropollutants in water and sediments) for the following: 01, 02, 03, 04, 05, 09, 10 and 13
- Approved by the Ministry of Health and Environment for the measurement of radioactivity in the environment
- Approved by the Ministry of Labour for the measurement and control of lead in the work place atmosphere
- Approved by the French national standards committee (AFNOR) to conduct tests of conformity for eco-labels on detergents, textiles, soils and cultivating land
- Approved by the Ministry of Health, Youth and Sports to sample and perform sanitary control on water

SGS MULTILAB ROUEN AND AGRICULTURE AND FOODSTUFF

THE LABORATORY



- COFRAC accreditation for physico-chemical programs:
 - 60 (Analysis of dietary food and analysis for nutritional food labelling)
 - 61 (Dairy products)
 - 81 (Analysis of animal feed)
 - 82 (Analysis of fat products and oil seeds)
 - 118 (Sugar)
 - 119 (Analysis of soft wheat, flour and other milling products)



- COFRAC accreditation programs for alimentary security:
 - 99-1 (Mycotoxins)
 - 99-2 (Pesticides)
 - 99-3 (Heavy metals)
 - 99-4 (Radionucleides)
 - 99-6 (Veterinary residues)

- COFRAC accreditation on vitamins, antibiotics, mycotoxins, pesticides, acrylamides, heavy metals and minerals

APPROVALS FOR AGRICULTURE AND FOODSTUFF

THE LABORATORY



- Approved by the Ministry of Economy and Finance **D.G.C.C.R.F.** (Fraud Prevention Department), to deliver certificates of analysis. Our Expertise leads to the following approvals: V, VI, VII, VIII, XII a, b, c, XIII a, b, c, d, and other competencies: XI, XII b, c, XIII b (finished 06/10/1997-JORF)
- Approved by the **GAFTA** (Grain and Feed Trade Association)
- Approved by the **London F.O.S.F.A.** (Federation of Oils, Seeds and Fats Association)
- Approved by the **MATIF** (French financial futures market for milled wheat)
- Approved by **ONIC** (contaminants on cereals)
- Approved by **Japan and KFDA** (Korean authorities) to deliver certificates for merchandise export

SGS MULTILAB ROUEN AND THE CHEMICAL FIELD



■ COFRAC Accreditations

- COFRAC accreditation programs:
- 95 (Phytopharmaceutical Products)
- 108 (Fertilising matter and culture support)
- COFRAC accreditation for chemical formulations

■ Approvals

- Approved for the analysis of chemical formulations by the U.S. Agency for International Development
- Approved by the French national standards committee (AFNOR) to conduct tests of conformity for European eco-labels on: detergents, textiles, soils and cultivation fields

■ ENTITLEMENTS

- Entitled by the **Department for the Prevention of Fraud** to deliver
 - analysis and purity certificates for foodstuffs and agricultural
 - products for export
- Entitled by the **D.G.C.C.R.F.** (Head Office for Competition, Consumption and Fraud Prevention) according to the terms of the decrees dated 1.8.1988 and 2.11.1988
- Entitled by **O.N.I.C.** (French National Inter-professional Office for Cereals) for milled wheat analysis

■ ACKNOWLEDGEMENTS

- Acknowledged for Good Laboratory Practises (**G.L.P.**) by the Interministerial Group for Chemical Products since December 3rd 1993



WELCOME TO THE FUTURE

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