

Evaluation of third countries certification bodies for EU-recognition: the example of an EA accreditation body

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On behalf of DAkkS



Contents of this presentation

- A brief introduction to DAkkS
- Approach to the assessment of certification bodies certifying products with equivalent guarantees in third countries
 - Equivalence assessment
 - Office audits
 - Witness audits
 - Reporting
- Outlook



Introduction to DAkkS



The German Accreditation Body DAkkS

- Regulation (EC) No. 765/2008 requires one accreditation body per EU member state
- Establishment of DAkkS GmbH in October, 2009
- Integration of other accreditation bodies in December, 2009
 - Shareholders:
 - 1/3 German Federal Republic
 - 1/3 German Federal States
 - 1/3 Federation of German Industries (BDI)

Organisation Chart of Deutsche Akkreditierungsstelle GmbH (DAkkS) **General Assembly** (DAkkS **Supervisory Board** Deutsche <u> Akkraditiarungs</u>stelle **Accreditation Committee Advisory Board Executive Board** Staff unit **Central Service** - Legal Adivisor and Objection Body - Budget and Finances - Information Technology - Committee Coordination and Reporting - Internal Services and Purchasing Offices - Human Resources and Organisation - Controlling / Project Management - Corporate Communications **Central Costumers Coordination Quality Management**

Division I

Construction | Transport | Materials

Departments:

- Lifts
- Construction Products
- Construction
- Portable Pressure Equipment
- Fire Protection
- Pressure Equipment
- Simple Pressure Vessels
- Renewable Energy
- Areas with potentially explosive atmospheres and storage areas for flammable liquids
- Driver's License
- Vehicles and Vehicle Parts
- Consumer Goods
- Acoustics / Vibrations
- Noise Emission
- High- Speed Rail Systems
- Marine Technology
- Materials Testing
- Measurement / Testing Technology
- Petroleum / Automotive
- Reference Material Producers
- Proficiency Test Providers
- Marine Equipment
- Safety Engineering
- Recreational Craft
- Hot- Water Boilers
- Anti Doping Laboratory (WADA)

Division II

Product and Installation Safety | Telecommunication | EMC

Departments:

- Mechanical Engineering
- Electromagnetic Compatibility (EMC)
- Explosives for Civil Use
- Precision Engineering
- Gas Appliances
- Information Technology
- Machinery Safety
- Electrical Engineering
- Low Voltage Equipment
- Optics
- Personal Protective Equipment
- Products / Consumer Products
- Pyrotechnic Articles
- Toys
- Telecommunications

Division III

Health | Forensics

Departments:

- Active Implantable Medical Devices
- Medical Devices
- Pharmaceuticals and Ingredients.
- Pharmacy
- Forensic Medicine, Toxicology, Biology
- Gene Diagnostics
- Health Care
- Hygiene
- In-vitro-Diagnostic
- Forensic Science
- Laboratory Diagnostics

- Occupational Medicine
- Point of Care Tests
- (POCT)
- Care
- Reproductive Medicine
- Veterinary medicine

Division IV

Consumer Protection | Agriculture | Chemistry | Environment

Departments:

- Waste
- Soil / Contaminated Soils
- Chemical Products
- Dangerous Goods
- Consumer Health Protection incl. Food Safety
- Immission Control
- Food, Commodities and Animal Feed
- Organic Farming
- Pathology
- Sampling of Environmental Area
- Regional Certification Programs of food
- Beef Labeling
- Social and Sustainability
- Certification Standards
- Drinking Water Monitoring
- Food Industry and Agriculture Certification Systems
- Veterinary

Division V

Metrology

Departments:

- Chemical Quantities
- **Dimensional Quantities**
- **Electrical Quantities**
- High Frequency and Radiation
- Mechanical Quantities
- Medical Quantities
- Measuring Instruments (MID, NAWI)
- Thermo- dynamic Quantities

Division VI

Certification of Management Systems and Persons

Departments:

- Occupational Health and Safety Assessment Series (OHSAS)
- Auditors
- Training
- Joining Technology /
- Non- Destructive Testing /
- Corrosion prevention
- Health Care
- Real Estate
- Food
- Aviation - Quality Management
- Safety- Certificate-Contractors (SCC)
- Safety/IT
- Environmental Management / Energy
- Transport / Motor Vehicle Assessor



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Approach to the assessment of certification bodies certifying products with equivalent guarantees in third countries

(Art. 33 (3) Reg. (EC) No. 834/2007)



Accreditation process (EN 45011)

Initial assessment



max. 6 month

Initial accreditation



12 month

Surveillance 1



12 month

Surveillance 2



12 month

Surveillance 3



12 month

Assessment for re-accreditation

max. 5 years



Equivalence assessment

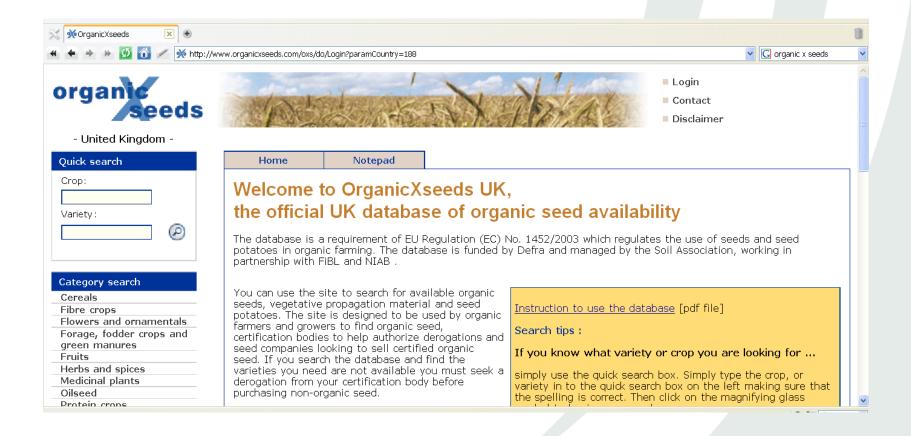


Equivalency

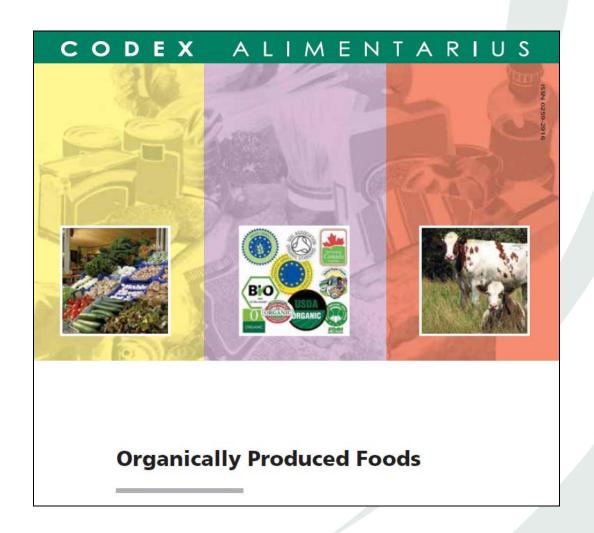




Equivalency





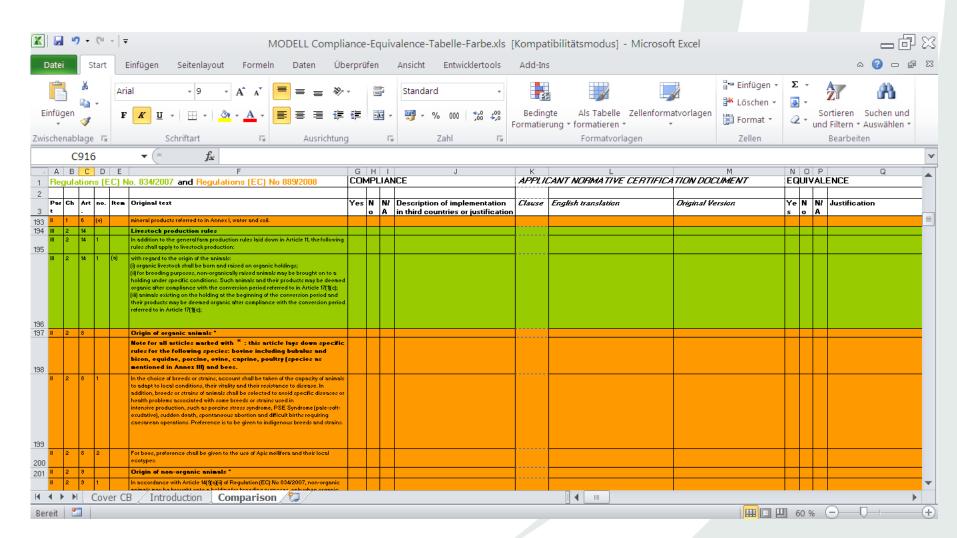




Organic standards applied in third countries

- Simple, understandable, transparent and equivalent to the EU-legislation on Organic Farming
- Line by line comparison, Excel table
- First step: Internal judgement of deviations by the third countries CB
- Second step: Assessment of equivalence by a DAkkS technical assessor and decision on equivalence







Office audits



Office audits

Integration of specific EU information requests

- Structure including critical locations
- Sampling policy
- Unannounced and follow-up visits
- Information exchange with other certification bodies and authorities
- Handling of nonconformities and complaints etc.



Witness audits in third countries



Witness audits

Integration to the accreditation / surveillance process

• Representative operators in third countries



Reporting



Reporting

Use of

- Regular assessment reports
- Supplementary assessment reports



Outlook



Outlook

- An improved information flow between EU-Commission and accreditation bodies is required.
- The DAkkS accreditation and surveillance procedure for certification bodies certifying in third countries has changed already according to the new EU information requirements.
 Specific trainings for the technical assessors involved are offered.



Outlook

- The Federal Ministry for agriculture and consumer protection wants DAkkS to play an active role in the international cooperation between accreditation bodies to support an effective surveillance of certification bodies active in third countries.
- DAkkS is willing to co-operate with other accreditation bodies to draw up a code of good practice to ensure a harmonized approach.