



Brexit - The Implications for Accreditation

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Webinar Overview

- What we know now
- Accreditation in Europe
- Implications - Accreditation & Regulations
- Implications – INAB accredited clients
- Implications - INAB
- Useful Resources



What we know now

UK decision to leave the European Union

Transition period ends on 31/12/20, giving effect

Northern Ireland (NI) Protocol exists

- With a trade deal
- With no trade deal

Getting Ireland Brexit Ready

Commission notices



Accreditation in Europe

Accreditation in Europe

ILAC/IAF – worldwide associations of accreditation bodies

Multi-lateral agreements – tested/inspected/certified
once, accepted everywhere

EA – European association of accreditation bodies



Accreditation in Europe

Regulation 765/2008 establishes legal framework for accreditation in Europe

One national accreditation body per Member State

- INAB, Ireland
- UKAS, UK
- Both EA members



<https://european-accreditation.org/publications/ea-inf-05/>

Accreditation in Europe

From 1st January 2021

- ❑ UKAS is no longer an accreditation body as defined in Regulation 765/2008

'national accreditation body' shall mean the sole body in a Member State that performs accreditation with authority derived from the State'

- ❑ EA to 2022 and expected to continue

- ❑ UKAS a member of ILAC and IAF

<https://european-accreditation.org/ea-and-the-impact-of-brexit/>

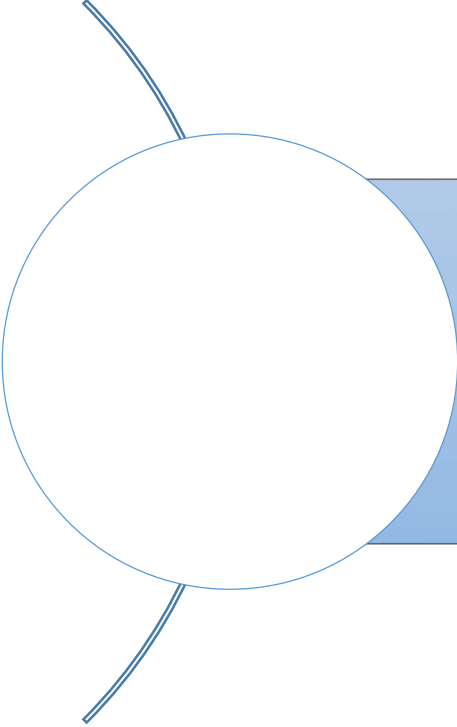
Accreditation in Europe

Regulatory

- **During** the transition period - UKAS accreditation recognition continued
- At the **end** of the transition period - the European Commission will no longer recognise UKAS accredited certificates **where EU legislation requires conformity assessment to be awarded by a national accreditation body of a Member State.**

Multi-lateral Agreements (MLA)

- UKAS is a current member of EA/ILAC/IAF
- An agreement between members - **recognize and accept the equivalence of the accreditation systems** operated by the signing members, and also the **reliability of the conformity assessment results** provided by Conformity Assessment Bodies (CABs) accredited by the signing members



Implications – Accreditation & Regulations

Accreditation & the Regulated Sector

Notified bodies

Environment

Greenhouse gas emissions

EMAS verifiers

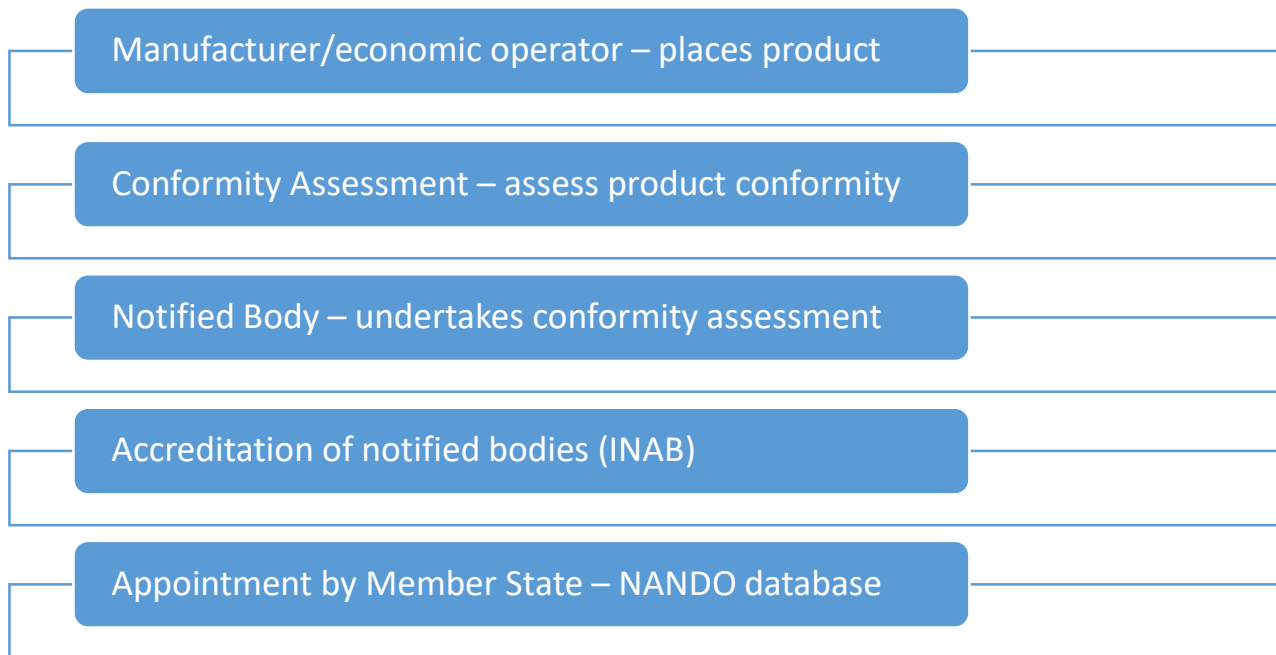
Food

Official controls

Organic produce

Good laboratory practice (GLP)

Accreditation & the Regulated Sector – Notified Bodies



Accreditation & the Regulated Sector – Notified Bodies

From January 1st 2021:

UK notified bodies lose status as an EU notified body

UKAS accreditation not accepted

Economic operators must use an EU-27 notified body

- CE mark
- Place on European market

Commission notice March 2020

Accreditation & the Regulated Sector – Notified Bodies

- ❑ Large database of EU notified bodies (NANDO)
 - ❑ By country
 - ❑ By product legislation

- ❑ 17 notified bodies now established in Ireland and accredited by INAB
 - ❑ PPE, CPR, Machinery, TPED, EMC.....

Accreditation & the Regulated Sector – Notified Bodies

The IE/NI Protocol certain provisions of EU law applicable also to and in the United Kingdom in respect of Northern Ireland, provides for:

- ❑ Conformity Assessment Bodies established in NI to certify products
- ❑ UK(NI) mark – valid in NI only, not EU
- ❑ Accreditation

Accreditation & the Regulated Sector – Notified Bodies

UK Conformity Assessment Scheme

- UK approved bodies
- UKAS accredited
- Certify products to place on UK market
- UK(CA) mark

Accreditation & the Regulated Sector – Environment

Eco-Audit & Management Scheme (EMAS) – Regulation 1221/2009

- ❑ EMAS environmental verifiers accredited by UKAS according to Articles 20 and 21 of the EMAS Regulation will lose their status and will not be in the position to carry out the tasks described in the EMAS Regulation
- ❑ EMAS verifiers shall be accredited by the national accreditation body of a Member State
- ❑ EMAS registrations
- ❑ Commission Notice July 2020, notice does not reference IE/NI Protocol

Accreditation & the Regulated Sector – Environment

Emissions Trading (greenhouse gas)

- Verifiers accredited by an accreditation body in the United Kingdom cannot draw up verification reports for submission according to Articles 14 and 15 of Directive 2003/87/EC
- Verifiers accredited by the national accreditation body of a Member State
- Commission Notice July 2020
- Notice references IE/NI Protocol

Accreditation & the Regulated Sector – Food

Official Controls – Regulation

625/2017

- Laboratories designated by Member State
- Accredited by national accreditation body of a Member State
- Appears UKAS accredited laboratories no longer accepted
- No Commission notice as yet

Organic Produce – Regulation

834/2007 and 2018/848

- Official Control bodies (OCBs)
- Accredited, 3 Irish OCBs
- Approved by national competent authority
- Validity of UK OCB certificates for import to EU
- Commission notice March 2020

Good Laboratory Practice

- INAB is the national Monitoring Authority
- Pre-clinical trials required under GLP
- 2 facilities in INAB programme
- UK Monitoring Authority is MHRA
- Mutual acceptance of data
 - Under the OECD MAD system – Yes
 - Under the EU mutual system - No
- Commission notice, June 2020, updated for NI protocol



Implications – Accredited Clients

INAB Accredited Clients – Possible Implications

Supply chains

- Access to consumables
- Security of proficiency test supply / access to inter-lab comparisons
- Access to calibration, maintenance and other technical services
- Possible increased costs, delays
- Distribution of products
- Access to subcontractors
- Any customs considerations?

UK sites of INAB accredited clients

INAB Accredited Clients – Possible Solutions

- ❑ Supply chains
 - ❑ Analyse supply chains, distribution routes and ensure continuity of supply & access to services
 - ❑ Investigate alternate to proficiency test supplier, www.eptis.com
 - ❑ INAB can accredit proficiency test providers and reference material producers, based in Ireland

INAB Accredited Clients – Possible Solutions

- Is there an INAB accredited calibration supplier?
- Consider expansion of accredited scope



Implications – INAB

Implications for INAB

- Expand the accreditation programme
 - Notified bodies
 - Greenhouse Gas Emissions, ISO 14065 (1)
 - Certification of Persons, ISO 17024 (5)
- Expand the accreditation programme
 - Proficiency test providers, ISO 17043 (any demand?)
 - Reference material producer, ISO 17034 (2, any more?)
 - Extensions to scope for new business opportunities
- UK based assessors, continue

Implications for INAB

- Clarity on accredited conformity assessment
- Response to Brexit related queries
- Promotion of INAB accreditation
- New staff



Useful Resources

Useful Resources

- ❑ <https://ec.europa.eu/growth/tools-databases/nando/>
- ❑ <https://european-accreditation.org/>
- ❑ <https://www.gov.uk/guidance/using-the-ukca-mark-from-1-january-2021>
- ❑ <https://www.hsa.ie/eng/Topics/Brexit/>
- ❑ www.inab.ie
- ❑ https://ec.europa.eu/info/european-union-and-united-kingdom-forging-new-partnership/future-partnership/getting-ready-end-transition-period_en
- ❑ <https://www.ukas.com/download/brochures/UKAS-Brexit-Leaflet-final.pdf>
- ❑ <https://ec.europa.eu/growth/tools-databases/nando/>

HSA Webinar Series

7th October

- Brexit – the implications for industrial products, 10am
- Brexit – the implications for transportable pressure equipment, 2pm

15th October

- Brexit – what you need to do if you source chemical products from the UK, 10am

Please register at

https://www.hsa.ie/eng/news_events_media/events/hsa_webinars/

Thank You – Q&A

**INAB – 35 years providing accreditation in
Ireland**

