



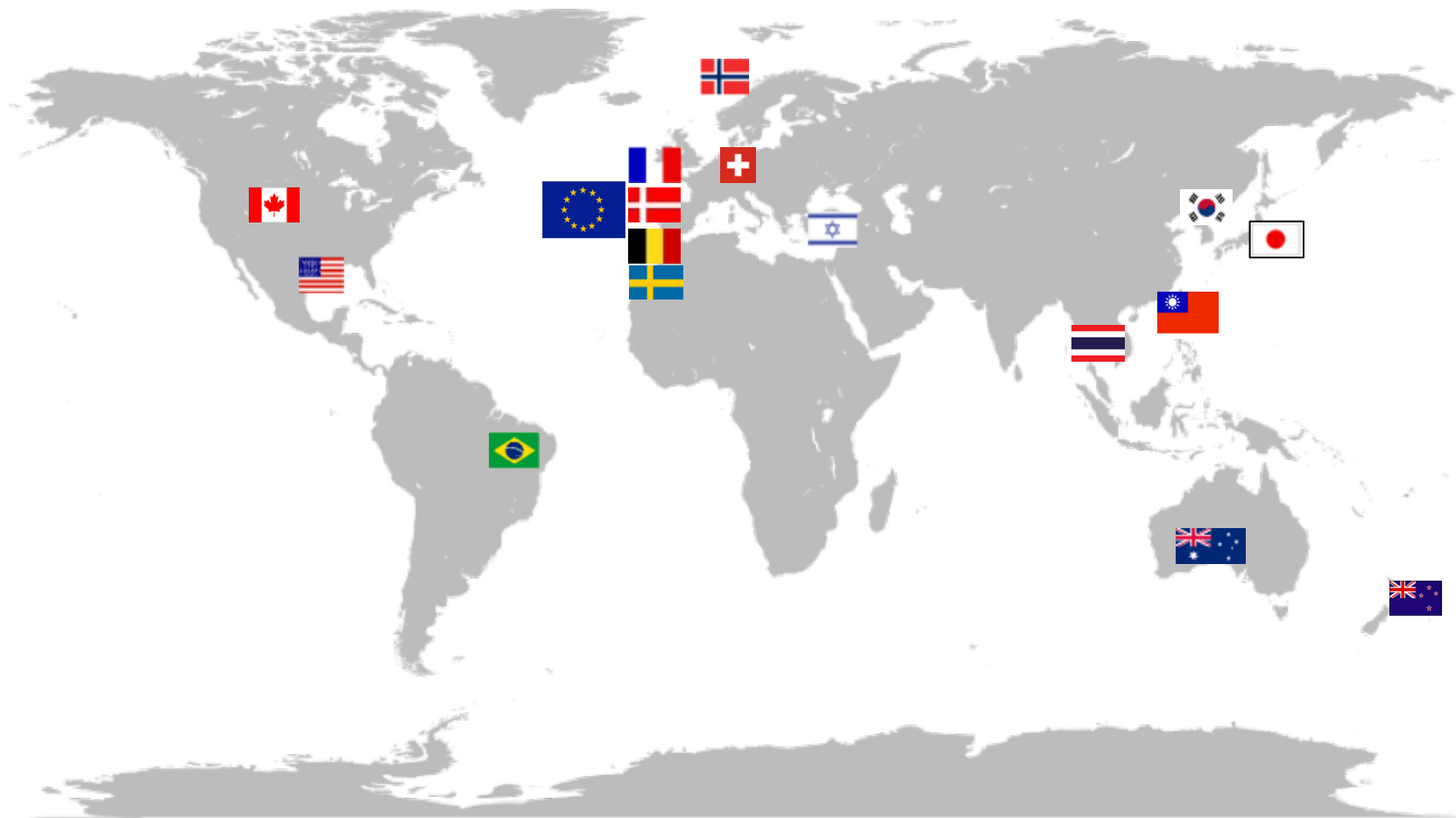
Global regulatory progression

Long-term alignment and collaboration with Europe

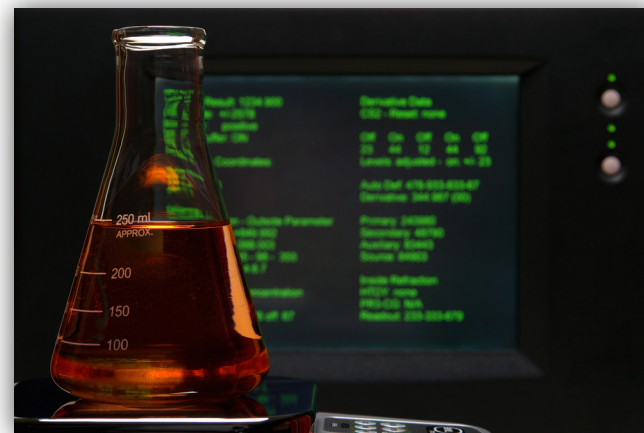


Brussels, 10 April 2018

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- **An EU influence?**
- **An update on regulatory actions in:**
 - The USA
 - Canada
 - Australia
 - South Korea
 - Switzerland
 - UK?
- **An influence from EU Member States?**
 - A new nanomaterial register in Sweden



- Health Canada and Environment and Climate Change Canada
- CEPA 1999 Paragraph 71(1)(b)
- 2015 Domestic Substance List mandatory survey on 206 substances in the nanoscale
- **53 substances** identified as being manufactured and/or imported at the nanoscale in Canada
- Prioritisation results for further regulatory action awaited **in Spring 2018**
- Expert consultations on the framework planned in 2018



Canada
Gazette

- Regulatory Reform of the Australian National Industrial Chemicals Notification and Assessment Scheme (NICNAS)
- Open consultations on
 - General Rules: Information requirements for the **‘Introduction of certain industrial chemicals at the nanoscale’**
 - Industrial Chemicals Categorization Guidelines (Categorization Guidelines)
 - Industrial Chemicals (Consequential Amendments and Transitional Provisions) Rules 2018

Consultation is now open until 31 May 2018

- Entered into force January 2015
- Many similarities with parent EU REACH...
- ...but quite a few differences too
- In September 2017, the Ministry of Environment announced at OECD having added nanomaterials to the '**list for hazard evaluation**':
 - Risk assessment decisions, including the type of: (a) nanomaterials assessed; (b) testing recommended; and (c) outcomes of the assessment;
 - Development related to exposure measurement and exposure mitigation;
 - Risk management approaches;
 - Any updates, including proposals or modifications to previous regulatory decisions; and/or
 - New regulatory challenge(s) with respect to any action for nanomaterials.



- Article 48: manufacturers are required to register, up to three months after the product has been placed on the market, any **nanomaterial intentionally containing fibres or biopersistent tubes of a length superior to 5µm**
- With information on:
 - composition of the nanomaterial (shape of particles, average size, when such information is available: granulometric distribution, volume specific surface, crystalline structure, aggregation state, surface coating and functionalisation)
 - quantities foreseen to be placed on the market
- Also for preparations containing such substances
- In force since 1 March 2018



- France's register is in its fifth year
 - Stable situation
 - Court actions over nano labelling
- Danish Nanoprodukt Register
- Belgium includes Mixtures
 - January 2018 Royal Decree
 - New exemption for Cosmetic Products
 - Mixtures now reportable (originally set for January 2017)
 - No public report available yet



- Implemented **1 January 2018**
- Ex –post annual registration for production and importations of nanomaterials in Sweden
- First registration with KEMI **by 28 February 2019**
- Exemptions for:
 - Turnover under SEK 5 million (EUR 486k)
 - Medicinal products
 - Food
 - Feed and animal by-products
 - Tattoo inks
 - Cosmetic products
 - Chemical and biological organisms that are waste
 - R&D under 1000 kilograms
- Swedish National Platform on Nanomaterial Safety – swenanosafe.se



Do not hesitate to contact anyone of us!

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