



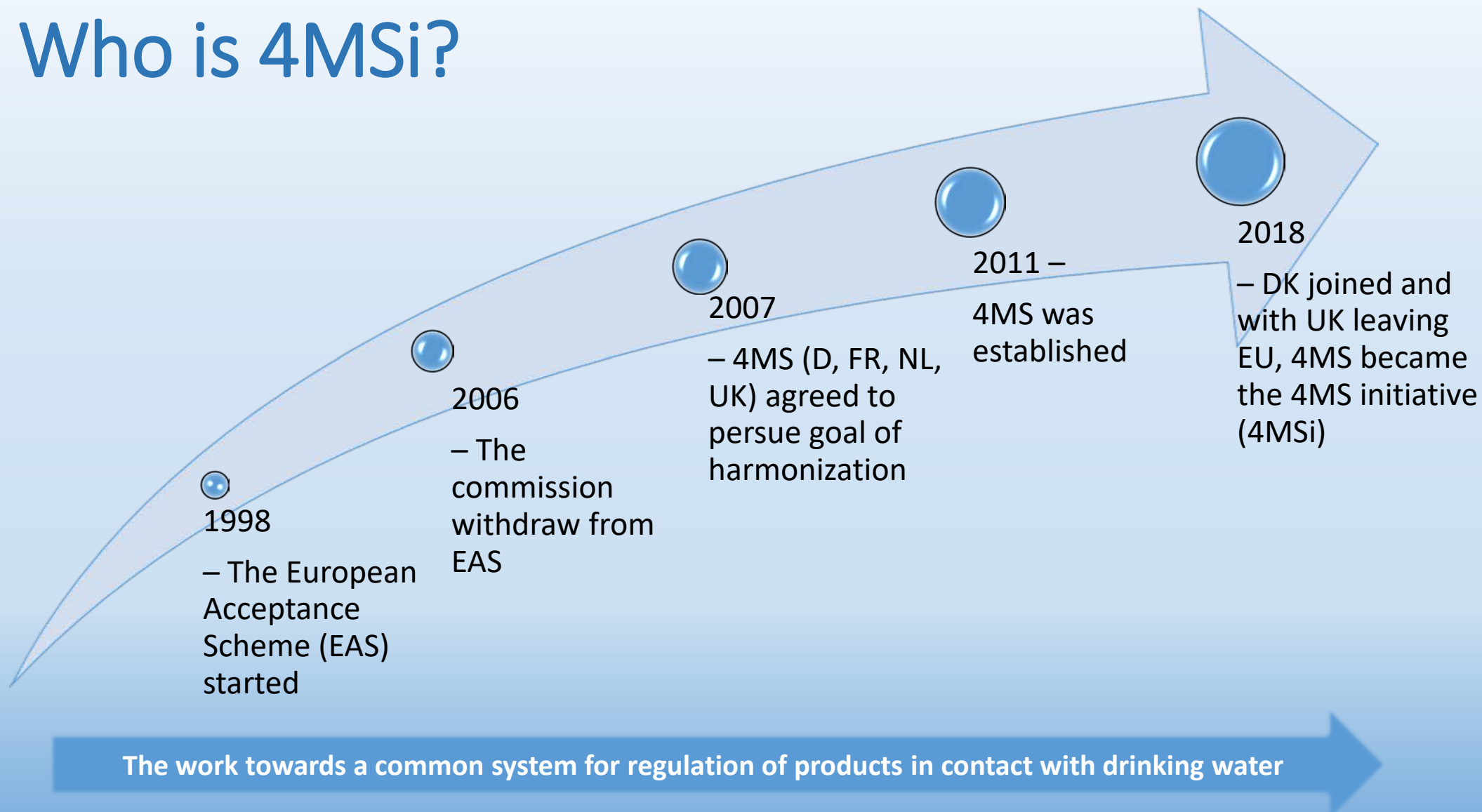
Introduction to the work of 4MSi

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Who is 4MSi?



Article 11 in the new Drinking water directive

- 4MSi have succeeded getting harmonization
- 4MSi will contribute with information about the common approaches
- Forming the new EU system
 - EU Positive lists and methodologies for testing and accepting - IA
 - Procedure for acceptance and removal of item from the PL - DA
 - Standard for testing and assessing final product – DA
 - Establish marking for products - DA

Article 11 in the new Drinking water directive

- Estimated entry into force – January 2021
- Through implementing act member states will establish:
 - *“by [2024], methodologies for testing and accepting starting substances, compositions and constituents to be included in European positive lists of starting substances, compositions or constituents, including specific migration limits and scientific pre-conditions related to substances or materials;” (Art. 11.2.a)*
CA part A
 - *“by [2025], on the basis of lists including expiry dates compiled by ECHA, European positive lists of starting substances, compositions or constituents for each group of materials, namely organic, cementitious, metallic, enamels and ceramic or other inorganic materials, which are authorised for use in the manufacture of materials or products in contact with water intended for human consumption, including, where appropriate, conditions for their use and migration limits, which are to be determined on the basis of the methodologies adopted pursuant to point (a) of this subparagraph, and taking into account paragraphs 3 and 4;” (Art. 11.2.b)*
CA part B
 - *“by [2024], procedures and methods for testing and accepting final materials as used in a product made from materials or combinations of starting substances, compositions or constituents on the European positive lists, including:*
 - (i) the identification of relevant substances and other parameters, such as turbidity, flavour, odour, colour, total organic carbon, the release of unexpected substances and enhancement of microbial growth, to be tested in migration water;*
 - (ii) methods for testing the effects on water quality, having regard to any relevant European standards;*
 - (iii) (iii) pass/fail criteria for the test results which take into account, inter alia, conversion factors for substance migration into estimated levels at the tap, and conditions of application or use, where appropriate.” (Art. 11.2.c)*
CA part C

*MTC= Maximum Tolerable Concentration

The 4MSi common approach (CA)



CA part A

*Acceptance on the list
according to toxicological
assessments*

4MSi CA for metallic materials,
and organic substances

CA part B

Positive lists

Starting substance	MTC*
a	X µg/l
b	Y µg/l
c	Z µg/l

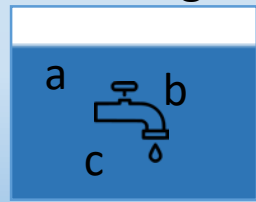
4MSi positive lists on metallic materials, organic materials
and cementitious products

CA on certification and approval

The product is safe to use, if the migration of the substances a, b and c are below the MTC-value* using suitable testing in controlled facilities.

Draft CA for Certification and Approval

Testing



Using the conversion factors (CF)

$$CF \left(\frac{\text{day}}{\text{dm}} \right) = F_g (\text{dm}^{-1}) \cdot F_o (\text{days})$$

F_g = Surface to Volume ratio
 F_o = dimension

CA part C

- Formulation
- Organoleptic
- TOC
- EMG
- unsuspected substances

Draft CA for organic materials

Thank you for listening
I hope today's presentations will be informative
for you!