Bringing biostimulants to the market with new regulation

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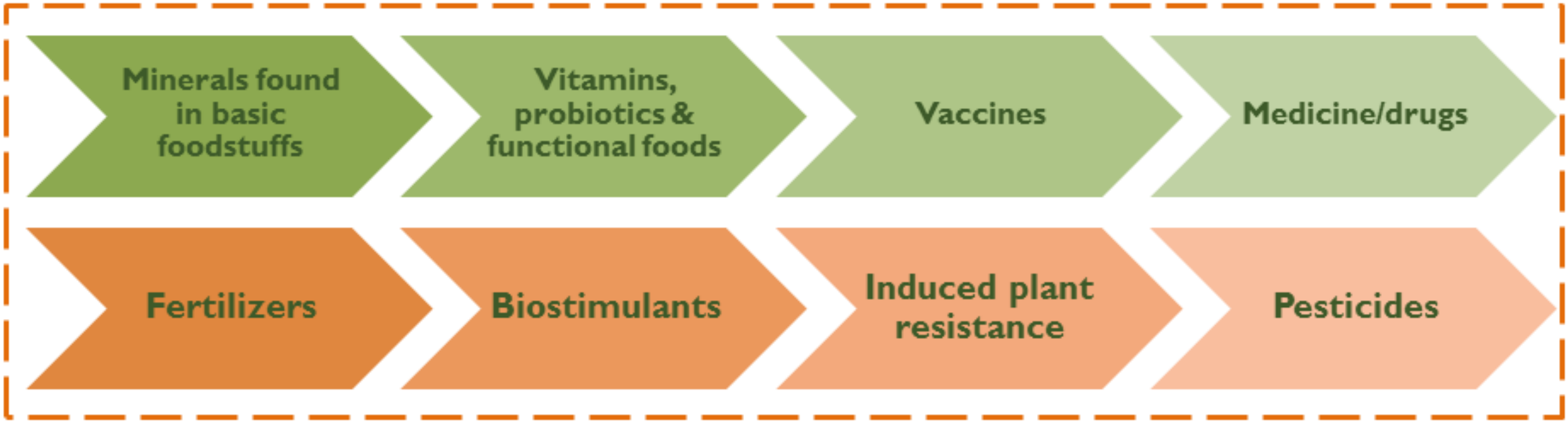
Rethinking the relationship between plant health & nutrition



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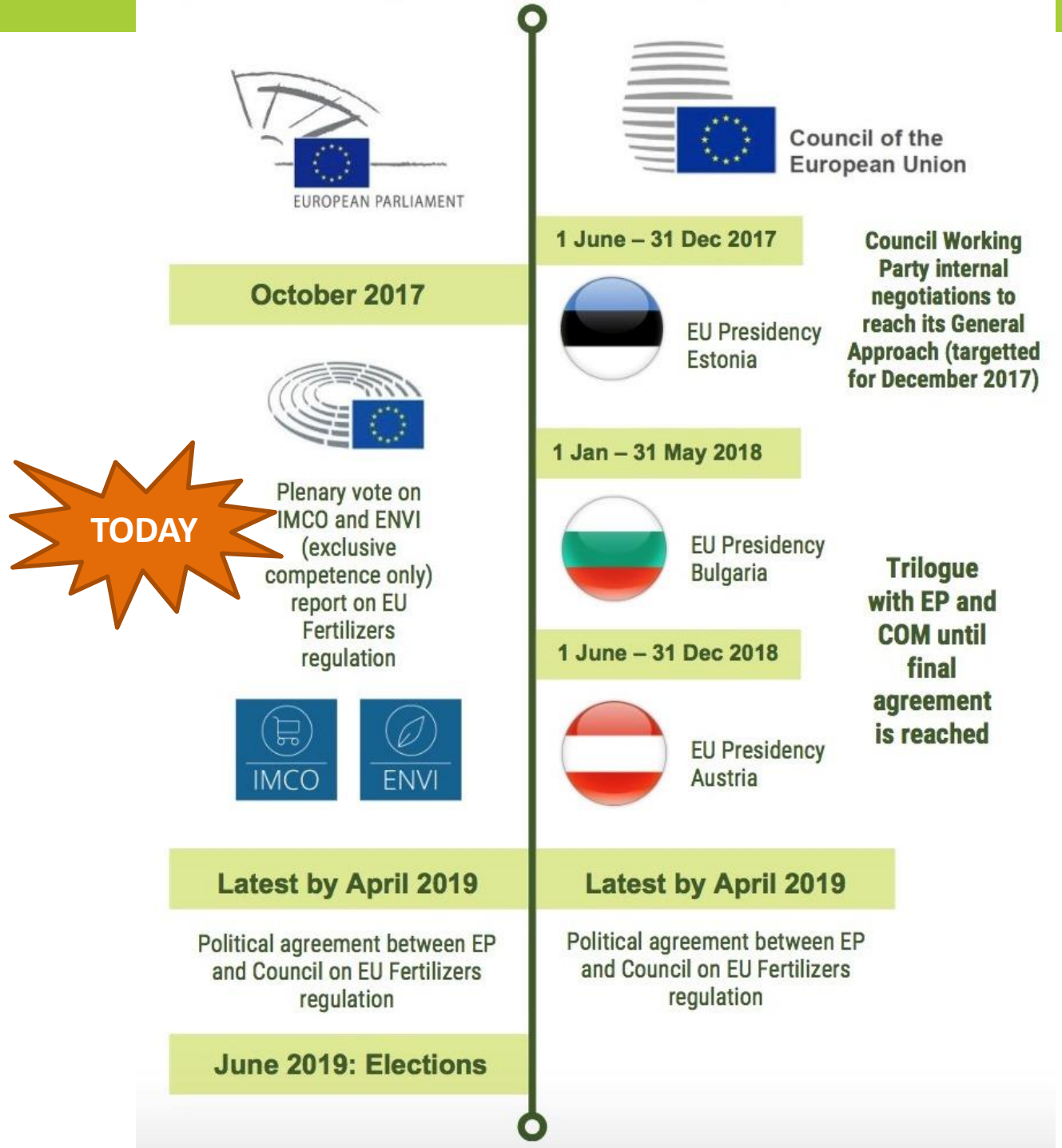
Timeline for developing a European regulation recognizing biostimulants



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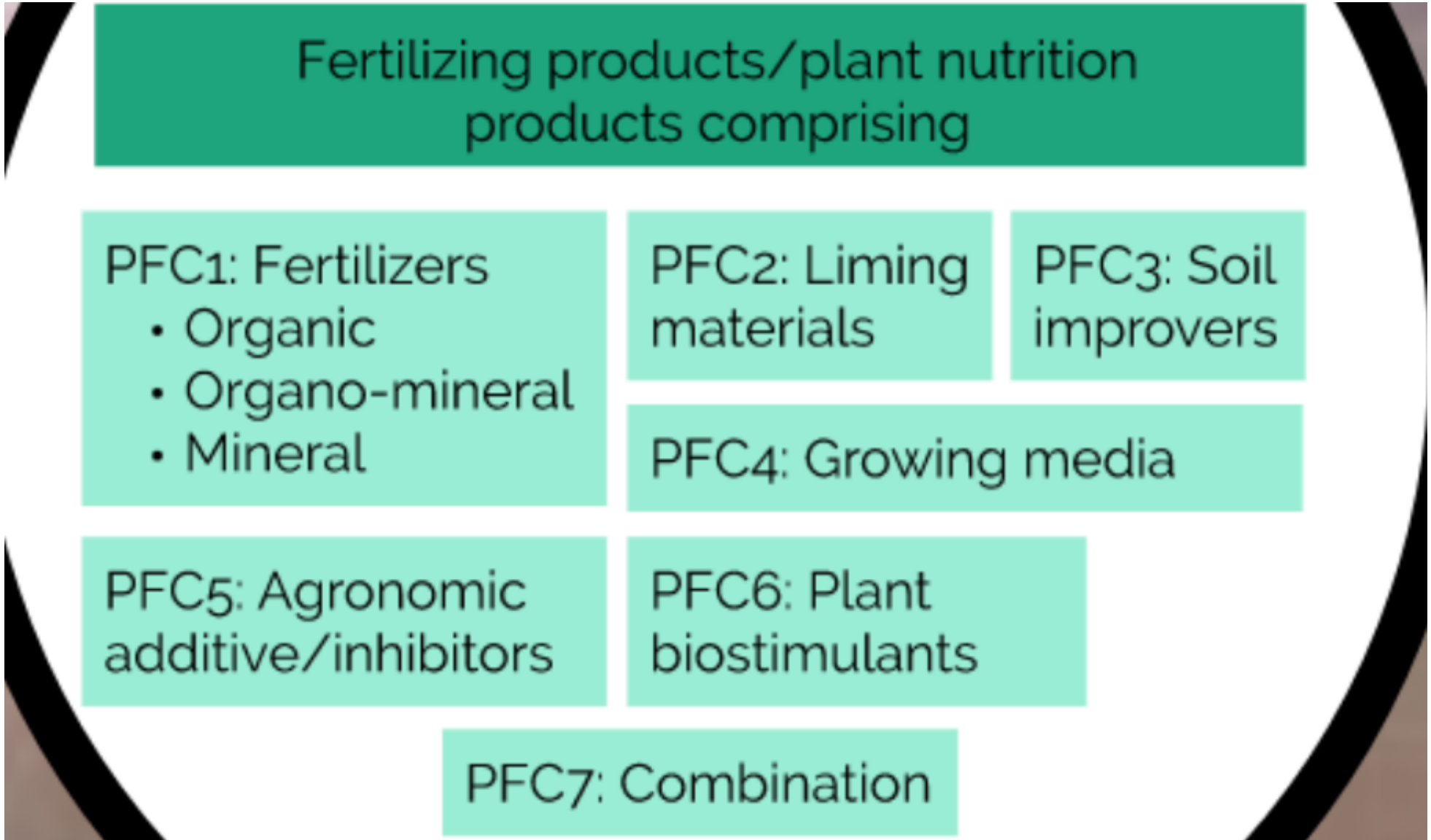
A 2-level definition in the future “fertilising products” regulation



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Definition of “fertilising products/plant nutrition products” in the E. Parliament position

‘plant nutrition product’ means a substance, mixture, micro-organism or any other material, applied or intended to be applied, either on its own or mixed with another material, on fungi or their mycosphere or on plants at any growth stage, including seeds, and/or rhizosphere, for the **purpose of providing plants or fungi with nutrients or of improving their physical or biological growth conditions or their general vigour, yields and quality,** including by increasing the ability of the plant to take up nutrients from the phyllosphere (**with the exception of plant protection products covered by Regulation (EC) No 1107/2009**).

Definition of plant biostimulants in the E. Parliament position

‘plant biostimulant’ means a product containing any substance or micro-organism stimulating plant nutrition processes independently of its nutrient content, or any combination of such substances and/or micro-organisms, with the sole aim of improving one or more of the following characteristics of the plant or the plant rhizosphere:

- **nutrient use efficiency**
- **degradation of organic compounds in the soil**
- **tolerance to abiotic stress**
- **crop quality traits**
- **availability of confined nutrients in soil, rhizosphere or phyllosphere**
  humification

Securing proportionate regulation

1 Upstream legislation

Components will only be eligible if they have met prerequisities like conformity to REACH or animal by-products legislation

2 Component material categories (CMCs)

Each CMC is subject to specific safety requirements (depending on the nature of the component)

3 Product function categories (PFCs)

Additional safety requirements are applied at the PFC level (again, depending on the nature of the product)

4 Ensuring product quality

The focus of the legislation is safety, but some quality parameters are included. Biostimulant producers will need to demonstrate that claims are justified.

5 CE-marking

Some CMCs and PFCs can "self-certify" (subject to verification). Biostimulants will have to seek "type" certification from a Notified Body.

6 Market surveillance

Member State surveillance officers can conduct controls and request full data from producers.

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The component material categories (CMCs)

(as listed in the March 2016 COM proposal)

1. Virgin substances and materials
2. Plant materials and extracts (including seaweeds)
3. Composts
4. Energy crop digestate
5. Other digestate
6. Food industry by-products
7. Microorganisms
8. Agronomic additives
9. Nutrient polymers
10. Other polymers
11. Materials derived from animal by-products

= most relevant CMCs for biostimulants

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Additional CMCs expected

- Other industrial by-products
- Struvite
- Biochar
- Ashes

Examples of relevant upstream legislation

- **REACH chemical legislation –** All components falling in **CMC 1 (Virgin substances and materials)** must be REACH registered with the fertilizer scenario, possibly with stricter requirements than foreseen just according to tonnage bands
- **Animal by-products legislation –** All components falling in **CMC 11 (Materials derived from animal by-products)** must have reach a defined “endpoint” relative to obligations under the animal by-product regulation. The endpoints are currently being defined and will inserted through a delegated act between the entry into force and the application of the regulation.

CMC-specific requirements

- **CMC 2 (plant materials and extracts) –** Positive list of defined treatment and extraction processes. **We would like to see the list broadened to any process that does not trigger REACH registration.**
- **CMC 6 (Food-industry by-products) –** Positive list. Again, progress has been made in Council negotiations, but **original list is too limited.**
- **CMC 7 (Microorganisms) –** Positive list to be populated by delegated act following evaluation by an Expert Group. **EBIC is concerned that positive list cannot cope with innovation, large number of microorganisms and strain-level particularities. We advocate the development of a criteria-based evaluation supported by harmonized standards.**

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Requirements for PFC 6 (Plant biostimulants)

- **Limits on heavy metal contaminants –** Cadmium, lead, hexavalent chromium, mercury, nickel, arsenic **(We advocate for this to be changed to inorganic arsenic.)**
- **Limits on pathogens –** List is modelled on OECD limits for microbial biocontrol agents and pathogens specified in the animal by-products regulation
- **Demonstrated effect –** The product shall have the effects claimed (and these must be within the effects specified in the definition).

The Conformity Assessment process for plant biostimulants to obtain the CE-mark

Dossier preparation

- Company compiles documentation demonstrating compliance with essential requirements

Review of "type" by Notified Body

- Notified Body checks that all analytical results are within limits, that relevant components / processes are in positive lists, that trial results support claimed effect, etc.
- Issues certificate of conformity

Self-certification of production

- Manufacturer places CE-Mark on products to reflect their conformity with regulatory requirements
- No changes can be made to the production process or product that would undermine conformity as checked by the NB

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The role of standards in implementation of the future regulation

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What is a standard?

‘Standard’ means a **technical specification, adopted by a recognized standardization body**, for repeated or continuous application, **with which compliance is not compulsory**, and which is one of the following:

- ‘International standard’ (ISO)
- **‘European standard’ means a standard adopted by a European standardization organization**:
CEN, CENELEC & ETSI
- **‘Harmonised standard’** means a European standard adopted on the basis of a **request made by the Commission** for the application of Union harmonisation legislation;
- ‘National standard’ (e.g. issued by ANSI)

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Objective of standardization

To agree on:

- **common specifications and/or procedures**
- in relation to **products, systems, processes or services,**
- that **respond to the needs of business** and **meet consumer expectations**

Specifications may concern:

- **Definitions:** “a toy for children under 3”
- **Requirements:** “no swallowable parts”
- **Test methods:** procedures, analytical methods, etc.
- **Processes:** environmental management systems

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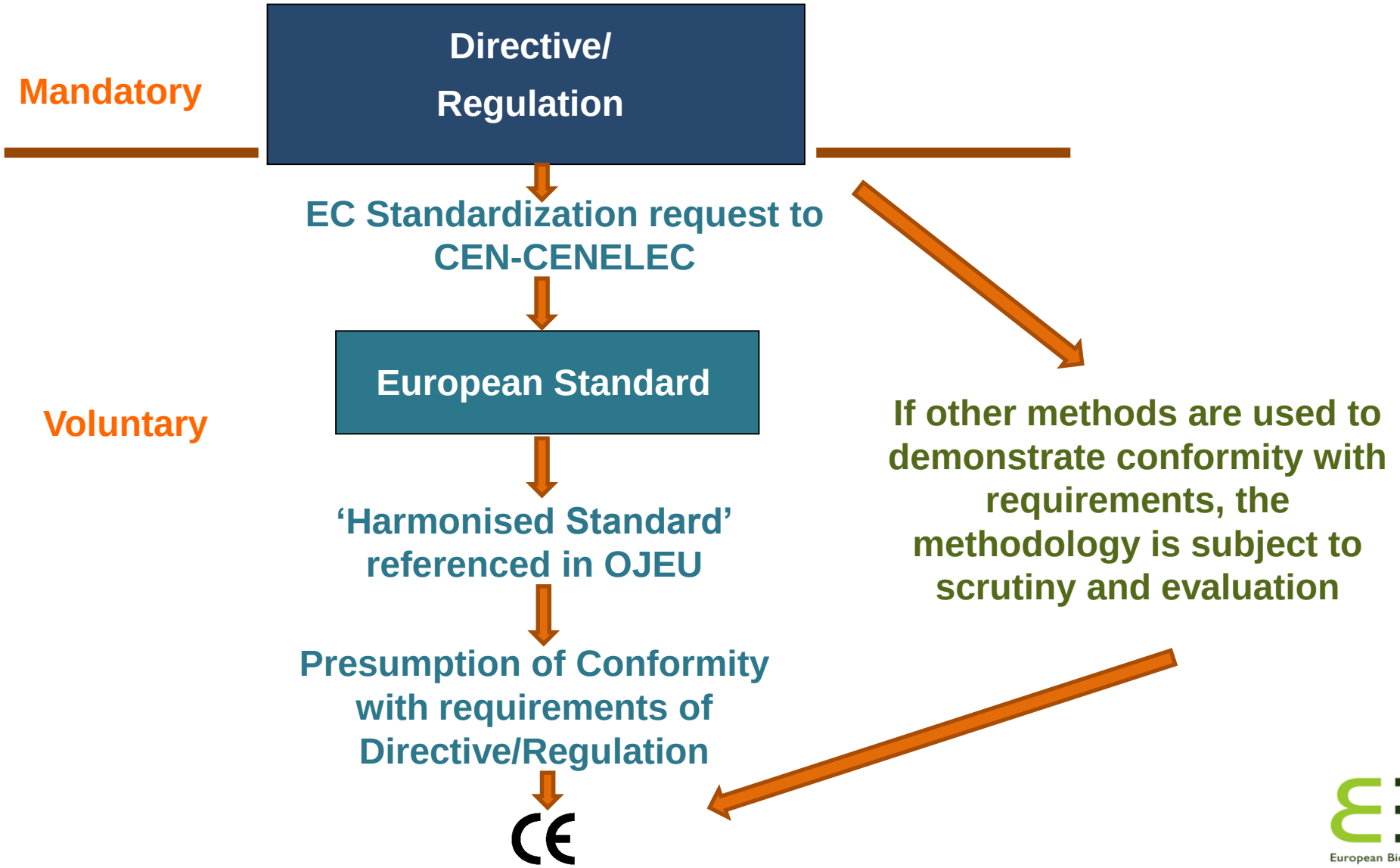
Some particularities of European standardization

- An EN is the result of a transparent, open and consensual development process (National authorities, industry, NGOs and academics/researchers can all participate.)

- Implies a strong national commitment:
  - It shall be implemented at national level in all member countries by being given the status of national standards, and
  - any conflicting national standard shall be withdrawn

Relationship between EU legislation & EN standards



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Main actors in European standardization: the example of CEN/TC 455 (Plant biostimulants)

Technical Committee – CEN/TC 455 on Plant biostimulants

- Chairman – Benoît Planques (Italpollina) & chairman of EBIC's internal Standardization Task Force
- Secretary (NSB/NC) – Afnor (French national standardization body)
- 5 Working Groups: Sampling (Spain), Claims (France), Pathogenic and beneficial microorganisms (Netherlands), Other safety parameters (Czech Republic), Labelling and denominations (UK)
- Liaison requested with CEN/TC 223 (soil improvers and growing media) and CEN/TC 260 (fertilizers and liming materials) to ensure coherence

National delegations – Each of the 34 CEN members

- National position – EBIC has encouraged members to become designated as national experts in as many countries as possible
- Voting Right

European Partners (CEN CENELEC Guide 25)

- Observers – EBIC has just obtained liaison status
- No voting right

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Upstream work currently underway

Identification of existing standards that can be adaptd or extended

- Already identified standards from organic fertilizers, soil improvers and growing media that could be adapted or extended
- In process of listing standards covering microbial pathogens & 4 MOs on the initial Qualified Presumption of Safety list

Consensus documents that can be used as the basis for CEN standards

- EBIC guidelines on making and justifying claims
- EBIC methodology to develop a criteria-based approach to evaluating safety

25 standards have been identified for the first phase of work

Priority 1 – 4 related to Sampling & claims

- General guidelines for field trials, nutrient use efficiency, tolerance to abiotic stress, quality traits

Priority 2 – 4 for the initial MOs on the Qualified Presumption of Safety list

- 1 standard for quantification/identification of each MO

Priority 3 – 15 on safety parameters (including microbial pathogens & heavy metals)

- Microbial pathogens
- Heavy metals
- Other contaminants

Priority 4 – 2 on labelling and instructions for use

- General labelling requirements
- Verification of terms like “sustainable”, “environmentally friendly”, etc.

For more information

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