

Smarter Futures



Food Fortification – Legislation and Standards

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Figure 3: TBT or SPS?

Which agreement does a measure come under?

Is the measure applied to protect:

- human or animal life from risks arising from additives, contaminants, toxins or disease-causing organisms in their food, beverages, feedstuffs?
- human life from plant- or animal-carried diseases (zoonoses)?
- animal or plant life from pests, diseases, or disease-causing organisms?
- a country from damage caused by the entry, establishment or spread of pests?

YES

SPS

NO

Is the measure...

...a document that lays down product characteristics or their related processes and production methods, including the applicable administrative provisions, with which compliance is mandatory?

YES

TBT (Technical regulation)

...a document approved by a recognized body, that provides, for common and repeated use, rules, guidelines or characteristics for products or related processes and production methods, with which compliance is not mandatory?

YES

TBT (Standard)

...any procedure used, directly or indirectly, to determine that relevant requirements in technical regulations or standards are fulfilled?

YES

TBT (Conformity assessment procedures)

NO

OTHER

Box 1: TBT measures

Technical regulations	Standards	Conformity assessment procedures
<p>Technical regulations lay down product characteristics or their related processes and production methods. Compliance is <i>mandatory</i>. They may also deal with terminology, symbols, packaging, marking and labelling requirements.</p>	<p>Standards are approved by a recognized body which is responsible for establishing rules, guidelines or characteristics for products or related processes and production methods. Compliance is <i>not mandatory</i>. They may also deal with terminology, symbols, packaging, marking and labelling requirements.</p>	<p>Conformity assessment procedures are used to determine that relevant requirements in technical regulations or standards are fulfilled.</p> <p>They include procedures for sampling, testing and inspection; evaluation, verification and assurance of conformity; and registration, accreditation and approval.</p>



DEFINITIONS

From WTO TBT Annex 1

https://www.wto.org/english/res_e/publications_e/tbttotrade_e.pdf

https://www.wto.org/english/docs_e/legal_e/17-tbt.pdf

- *A "Standard" is a document approved by a recognized body that provides, for common and repeated use, rules, guidelines or characteristics for products or related processes and production methods, with which compliance is not mandatory. It may also include or deal exclusively with terminology, symbols, packaging, marking or labelling requirements as they apply to a product, process or production method.*


- *A “Technical regulation” is a document which lays down product characteristics or their related processes and production methods, including the applicable administrative provisions, with which compliance is mandatory. It may also include or deal exclusively with terminology, symbols, packaging, marking or labelling requirements as they apply to a product, process or production method.*

Explanatory note


- The terms as defined in ISO/IEC Guide 2 cover products, processes and services. This Agreement deals only with technical regulations, standards and **conformity assessment procedures** related to products or processes and production methods.
- Standards as defined by ISO/IEC Guide 2 may be mandatory or voluntary. For the purpose of this Agreement standards are defined as voluntary and technical regulations as mandatory documents. Standards prepared by the international standardization community are based on consensus. This Agreement covers also documents that are not based on consensus.

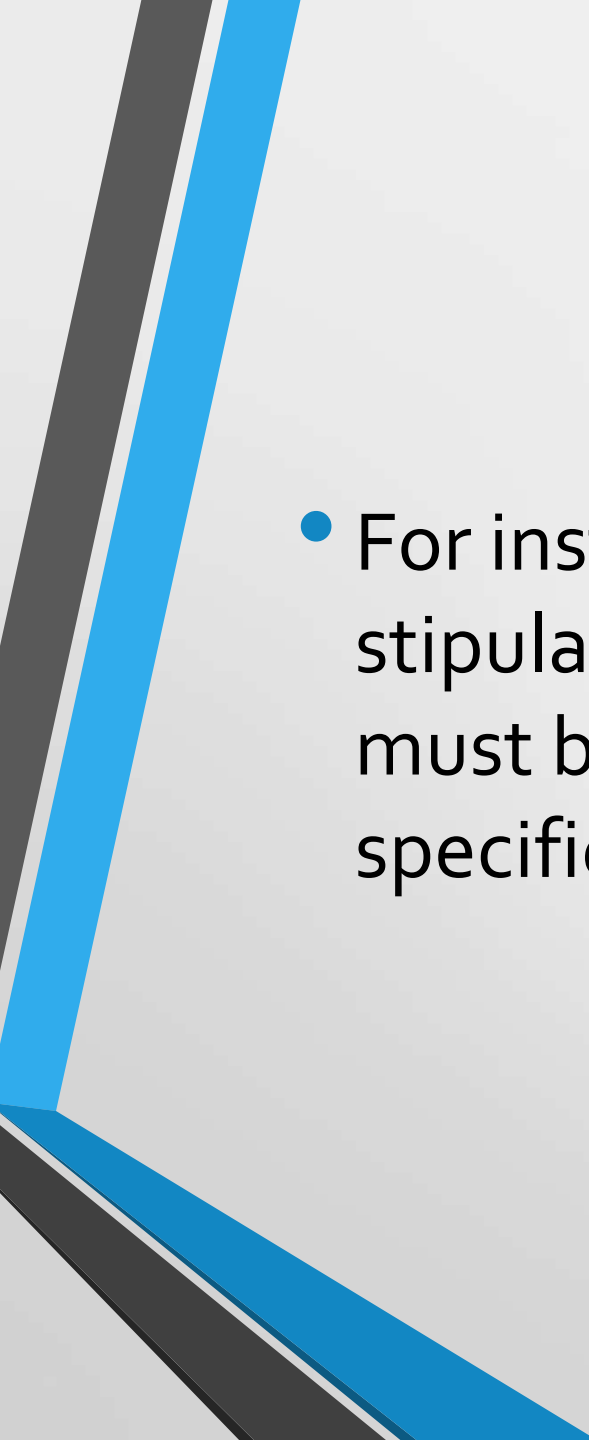
Conformity assessment procedures

- Any procedure used, directly or indirectly, to determine that relevant requirements in technical regulations or standards are fulfilled.
- *Explanatory note*
 - Conformity assessment procedures include, *inter alia*, **procedures for sampling, testing and inspection; evaluation, verification and assurance of conformity; registration, accreditation and approval as well as their combinations.**

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- For the purpose of this Agreement standards are defined as voluntary and technical regulations as mandatory documents. Standards prepared by the international standardisation community are based on consensus.
 - This Agreement covers also documents that are not based on consensus.

- While both technical regulations and standards are technical product requirements, the main difference between the two is that compliance with **technical regulations is mandatory**, whereas compliance with **standards is voluntary**.
- A law that stipulated that a nominated food must contain a minimum amount of a micronutrient (as is the case with mandatory fortification) is an example of a technical regulation

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- The TBT Agreement encourages WTO Members to develop technical regulations and standards that are based on product performance requirements, rather than on design requirements.
 - The former creates fewer obstacles to trade, providing exporters greater leeway in terms of fulfilling the objectives of the technical requirements

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- For instance, it would be preferable for a country to stipulate the minimum amount of a micronutrient that must be present in a specific type of food rather than a specific process for the addition of that micronutrient.

When the absence of legal certainty is a new NTB - Tralac Newsletter 11th March 2015

- The relevant legal instruments are treaties which apply between and not in the participating States. **Ultimately most of the NTBs involve a decision or act by a specific government official, exercising a discretion under enabling legislation.** If the applicable international agreement has not been domesticated or the relevant principles are not part of the domestic legislative framework, the responsible officials will not take them into account when making their decisions. **It is the responsibility of the member governments to rectify this state of affairs.** They should make such obligations part of the law of the land – in order to give effect to the duties which they have accepted when they ratified the Protocols in question. And they should do so in unambiguous terms.

Draft East African Standards – Maize and Wheat

- ECSCA-HC has 10 active member states namely Kenya, Uganda, Tanzania, Malawi, Zambia, Zimbabwe, Lesotho, Swaziland, Mauritius and Seychelles
- EAC Partner States have enacted an East African Standardization, Quality Assurance, Metrology and Testing Act, 2006 (EAC SQMT Act, 2006) to make provisions for ensuring standardization, quality assurance, metrology and testing of products produced or originating in a third country and traded in the Community in order to facilitate industrial development and trade as well as helping to protect the health and safety of society and the environment in the Community.

- Article 15(1) of the EAC SQMT Act, 2006 which provides that —Within six months of the declaration of an East African Standard, the Partner States shall adopt, **without deviation from the approved text of the standard**, the East African Standard as a national standard and withdraw any existing national standard with similar scope and purpose

http://www.eac.int/legal/index.php?option=com_docman&task=doc_details&gid=158&Itemid=227

DEAS 767 and 768 of 2011

- ISO 16050, Foodstuffs — Determination of aflatoxin B₁, and the total content of aflatoxins B₁, B₂, G₁ and G₂ in cereals, nuts and derived products — High-performance liquid chromatographic method
 - *"..... products shall conform to those maximum mycotoxin limits established by the Codex Alimentarius Commission for this commodity. The milled maize products shall not exceed total aflatoxin of 10 µg/kg and 5 µg/kg for aflatoxin B₁ when tested in accordance with ISO 16050."*
 - **ISO 16050:2003** notes. The **limit of quantification** for aflatoxin B₁, and for the sum of aflatoxins B₁, B₂, G₁ and G₂, is 8 micrograms per kilogram
- Wheat zinc levels 88 ± 28 mg/Kg
- Maize zinc levels 49 ± 16 mg/Kg

- Wheat paragraph 5.3 Pre-Mix Note states *"For the addition of iron, premix producers may either use NaFeEDTA at the levels provided, which should be tried first to test for compatibility with the flour and if low levels are needed, producer may switch to ferrous fumarate."*

- Both Standards in paragraph 5.4 state *“The Vitamin fortificants and premixes shall have storage stability such that no more than 20 % of its original activity will be lost when stored for 21 days at 45 °C in a **well closed container** at a level **2.5 g per kg** in wheat flour (milled maize product) having moisture content in the range of 13.5 % to 14.5 %.*
- *Maximum moisture wheat (dosage 500 or 600 g/MT) and maize 13% (dosage 500 g/MT)*



Development Process

STEP 1

- Get industry fortifying and being confident in their skills. Industry and Standards Institutes testing at Mill level and **MUTUALLY** establishing what is acceptable variation in terms of addition and in terms of plant variability and in analytical capability.
- Share the results (sanitised)

STEP 2

- Test fortified wheat flour in the marketplace taking into account the various methods by which the flour is sold i.e. Open market, small retailer, large retailer, “walkmans” etc.
- Share the results (sanitised)

STEP 2 cont

- If the results indicate significant losses at this stage in the distribution chain then:
- Determine if this loss can be mitigated through better handling, changing source of pre-mix, education etc – IF NOT increase the level of addition at the Mill, wait a month or so and repeat step 2 until the level in the marketplace is acceptable (on or above the desired level)

STEP 3

- Repeat survey but at Household level and determine if household level is at desired level. For consumers purchasing daily assume level of addition is same as at marketplace.

STEP 3 (cont)

- If levels are low at household level investigate why - thoroughly - before considering increasing levels at the Mill; but if necessary increase as required.
- Share the results (sanitised)



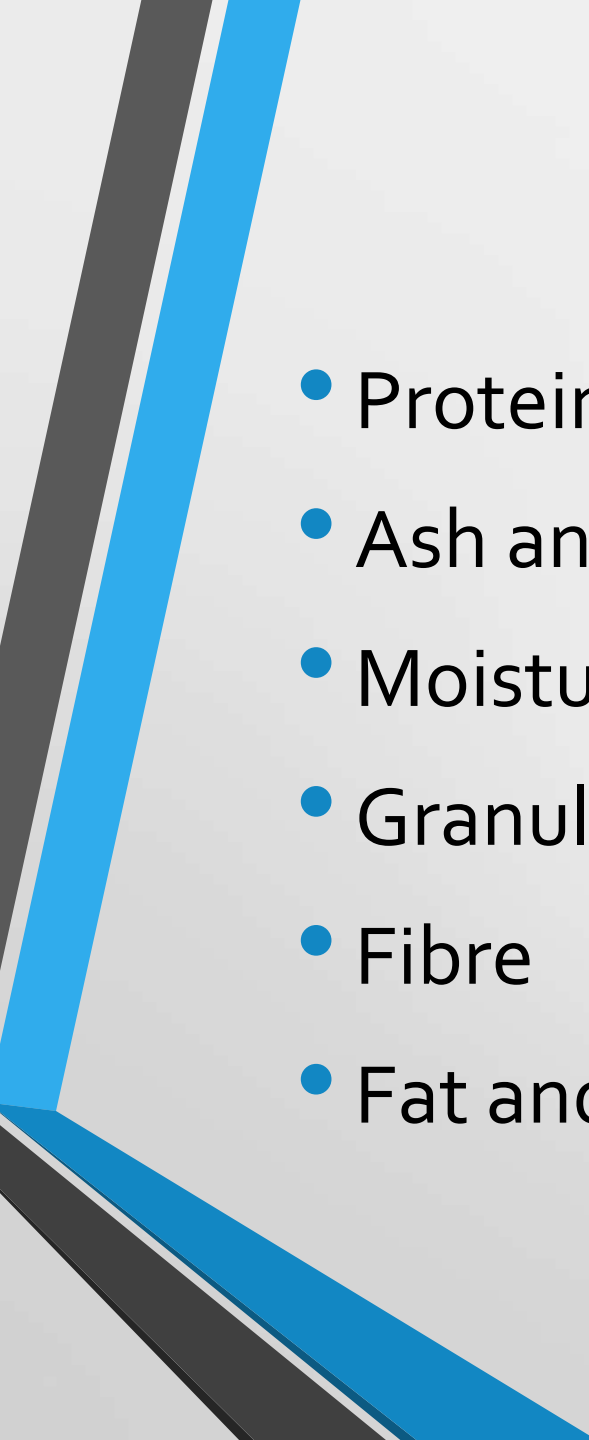
**NOW you can think about
developing a Fortification
Technical Regulation**

**Industry must be part of the process of both the
Technical Regulation and the National Standard**

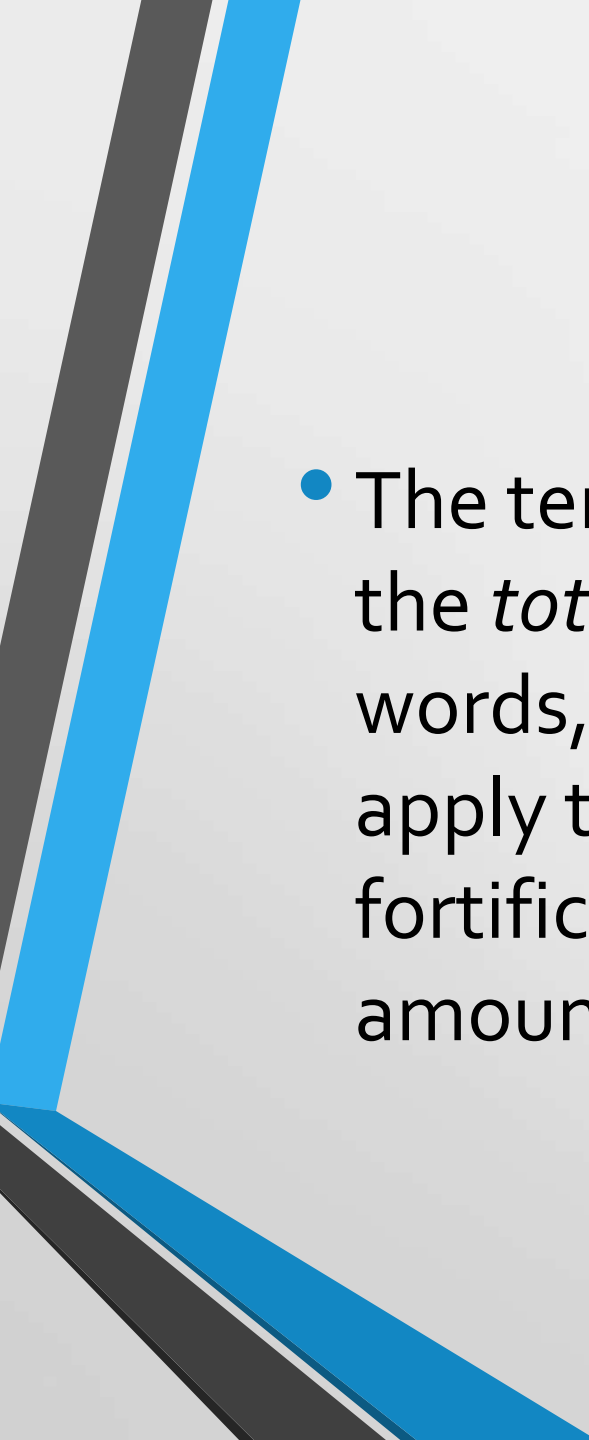


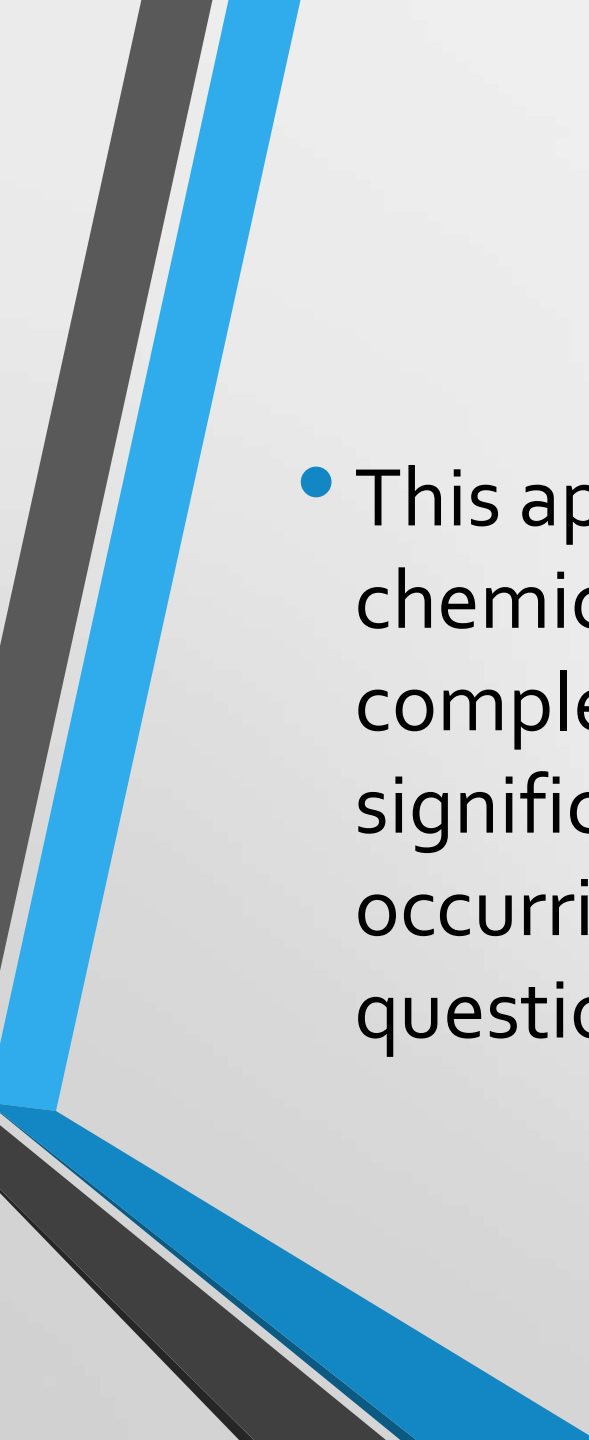
What parameters **MUST** be included?

CODEX STAN 152 (Rev 1995)

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- Protein
 - Ash and acid insoluble ash
 - Moisture
 - Granularity – sieve size
 - Fibre
 - Fat and fat acidity

- Microorganisms specified
- Coliform is not a taxonomic classification but rather a working definition used to describe a group of Gram-negative, facultative anaerobic rod-shaped bacteria that ferments lactose to produce acid and gas within 48 h at 35°C.
- Heavy metals specified

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- The term “contain”, or some such similar term, refers to the *total amount of* micronutrient in the food. In other words, the legal minimum (and maximum levels if stated) apply to the amount of both naturally-occurring and fortificant micronutrient present in a food, not just to the amount of fortificant that is added

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- This approach suits those micronutrients whose different chemical forms have similar bio availabilities; more complex regulation is needed in cases where there are significant differences in bioavailability between naturally-occurring and fortificant forms of the micronutrient in question.

Discussion

- What is the intrinsic content of each of the micronutrients being added?
- What is our level of analytical precision and accuracy for each micronutrient?
- MAXIMUM level – WHAT value and WHY?