



Formulation and composition – one product, many markets

Mapping the global regulatory landscape to identify product opportunities

Agenda

1 What internationalization means to you?

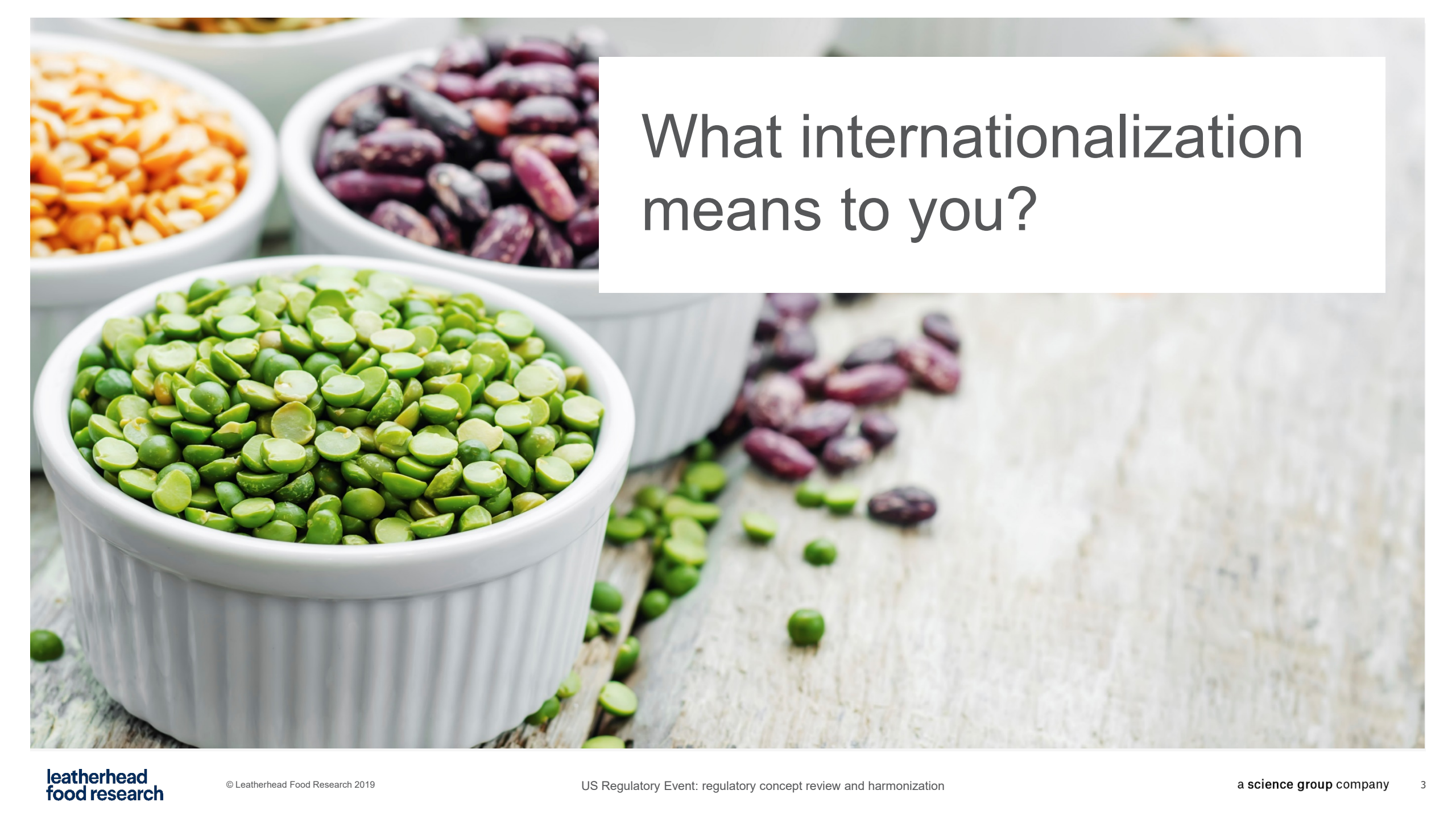
2 Key principles and approach:

The importance of Codex: additives, flavourings and commodity standards

Other international harmonizing bodies: MERCOSUR, GCC and EAEU

3 Our learnings

4 In summary

The background of the slide features three white ceramic bowls filled with different types of beans. The bowl in the foreground is filled with bright green, sliced beans. Behind it, to the left, is a bowl of orange beans, and to the right is a bowl of purple beans. Some beans are scattered on a light-colored wooden surface in the foreground.

What internationalization means to you?

What internationalization means to you?

- Efficiency and margin improvement initiative have become increasingly important to multi-national food businesses as challenger brands stifle growth in core markets and commodity prices increase
- It is therefore strategically important to develop a product formulation that can be sold across as many markets as possible to support lean operating practice
- The global regulatory landscape is highly fragmented, even where sentiment or intent maybe shared
- We will share the key principles that we consider for market expansion/entry strategies



Key principles and approach - Codex



A good place
to start?

Codex Alimentarius

A joint FAO/WHO
international food
standards programme
initiated in 1962

Simply stated, the Codex Alimentarius is a collection of standards, codes of practice, guidelines and other recommendations.

Some of these texts are very general, and some are very specific. Some deal with detailed requirements related to a food or group of foods; others deal with the operation and management of production processes or the operation of government regulatory systems for food safety and consumer protection.

Codex standards and related texts are **voluntary** in nature. They need to be translated into national legislation or regulations in order to be enforceable.

‘Codex standards and related texts **are not a substitute for, or alternative to**, national legislation.’ – Procedural Manual 25th Edition

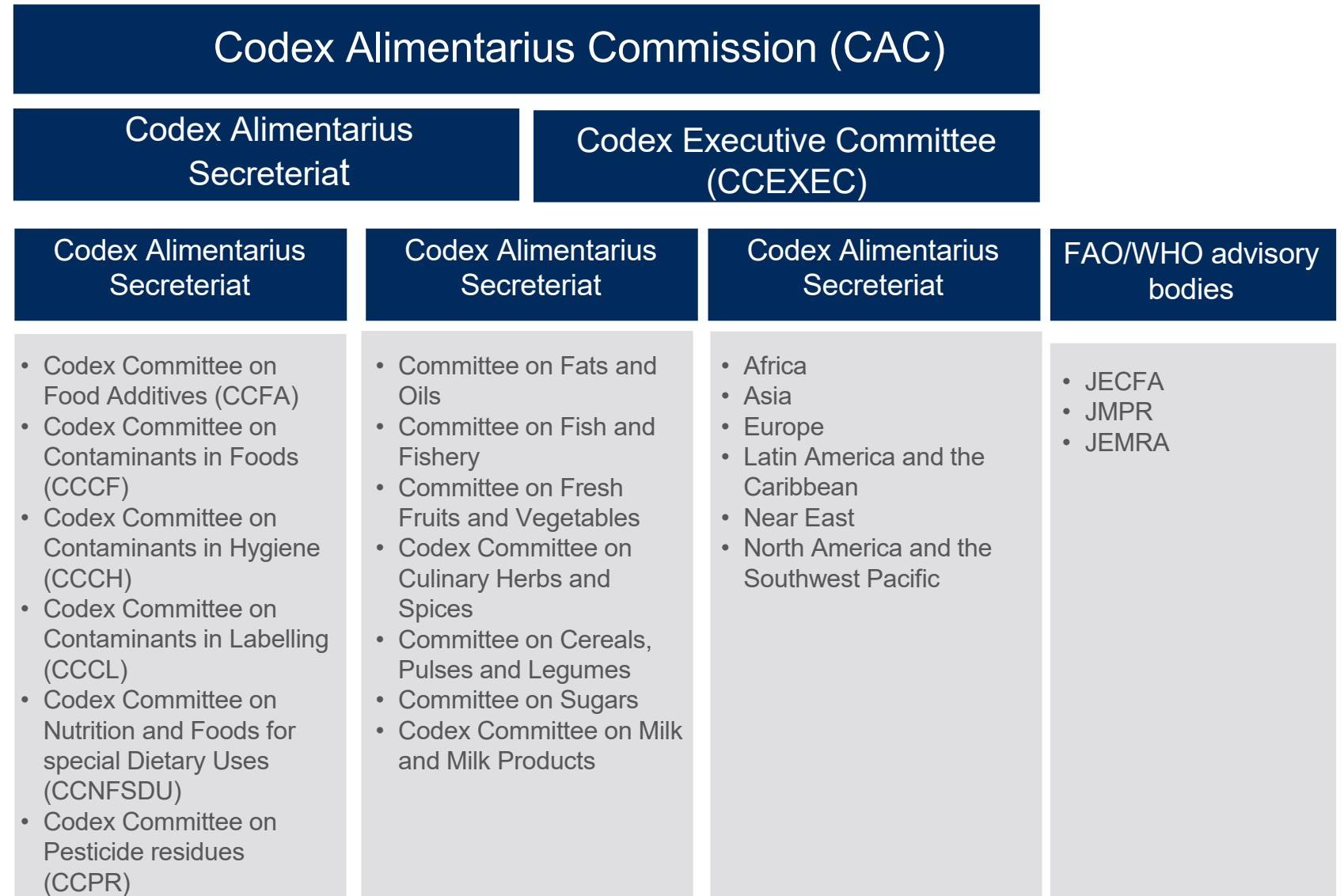
Source: Codex Alimentarius

Codex participation

Currently the Codex Alimentarius Commission has:



The Codex system




Codex texts

As of September 2018:

- 221 commodity standards
- 78 guidelines
- 53 codes of practice
- 106 maximum levels for contaminants (18) in food
- Over 4130 maximum levels covering food additives or groups of food additives (224)
- 5231 maximum residue limits for pesticides (303)
- 623 maximum residue limits for veterinary drugs (63) in food and risk management recommendations (12)

Source: Understanding Codex – 5th edition



Key principles and approach - Codex General Standard for Food Additives

Food additives - GSFA

Codex General Standard for
Food Additives

([GSFA, Codex STAN 192-1995](#),
as revised)

- Definitions
- General principles for the use of food additives (safety, justification, GMP)
- Carry-over of food additives into foods
- Food category system
- Conditions of use for additives
- Table 3 generally permitted additives



Food additives

Food category system in GSFA

- A tool for assigning food additive uses
- Hierarchical structure
- Food category descriptors and product examples
(The descriptors are not to be legal product designations nor are they intended for labelling purposes)



Food additives

Generally permitted additives in [Table 3 of GSFA](#)

Table 3 lists additives with Not Specified or Not Limited JECFA ADIs that are acceptable for use in foods in general when used at quantum satis levels and in accordance with the principles of GMP.

However, the Annex to Table 3 lists food categories and individual food items excluded from the general conditions of Table 3.

Additives Permitted for Use in Food in General, Unless Otherwise Specified, in Accordance with GMP

INS No	Additive	Functional Class	Year Adopted	Acceptable, including foods conforming to the following commodity standards
260	Acetic acid, glacial	Acidity regulator, Preservative	1999	CS 117-1981, CS 309R-2011, CS 70-1981, CS 94-1981, CS 119-1981, CS 291-2010, CS 302-2011, CS 319-2015
472a	Acetic and fatty acid esters of glycerol	Emulsifier, Sequestrant, Stabilizer	1999	CS 117-1981, CS 309R-2011
1422	Acetylated distarch adipate	Emulsifier, Stabilizer, Thickener	1999	CS 117-1981, CS 309R-2011, CS 70-1981, CS 94-1981, CS 119-1981
1414	Acetylated distarch phosphate	Emulsifier, Stabilizer, Thickener	1999	CS 117-1981, CS 309R-2011, CS 70-1981, CS 94-1981, CS 119-1981
1451	Acetylated oxidized starch	Emulsifier, Stabilizer, Thickener	2005	CS 117-1981, CS 309R-2011
1401	Acid-treated starch	Emulsifier, Stabilizer, Thickener	1999	CS 117-1981, CS 105-1981, CS 309R-2011, CS 70-1981, CS 94-1981, CS 119-1981
406	Agar	Bulking agent, Carrier, Emulsifier, Gelling agent, Glazing agent, Humectant, Stabilizer, Thickener	1999	CS 96-1981, CS 97-1981, CS 117-1981, CS 309R-2011, CS 70-1981 (for use in packing media only), CS 94-1981 (for use in packing media only), CS 119-1981 (for use in packing media only)

Food additives

GSFA is highly influential – food additive regulations in some markets are very similar to or follow GSFA, for example:

Gulf
Cooperation
Council

Jordan

India

Egypt

Thailand

Pakistan
(Punjab
province)

Peru

Vietnam

Indonesia


Panama

Malaysia

Ecuador

Dominican
Republic

Zambia



Key principles
and approach
- JECFA
specifications
for flavourings

Food flavourings

- No positive list of flavourings as such
- Codex Guidelines for the Use of Flavourings (CAC/GL 66-2008)
- Principles for the safe use of flavourings components evaluated by JECFA (safety concerns or assigned ADIs...)
- [Specifications for flavourings evaluated by JECFA](#)



Food flavourings

In the absence of national provisions on the use of flavourings in food (e.g. positive lists), many countries refer and draw reference to JECFA and/or FEMA (amongst other countries flavouring legislation and/or international organizations*), for example:

Canada, Australia, Argentina, Brazil, South Africa, Hong Kong, Singapore, the Philippines, Malaysia, Thailand

* such as IOFI, US and EU



A man and a woman are smiling and looking at each other while preparing food in a kitchen. The man is wearing a blue sweater and is cutting vegetables on a wooden cutting board. The woman is wearing a light blue shirt and is smiling. There are several white bowls and a bunch of green herbs on the counter in front of them.

Key principles and approach - Codex commodity standards

Codex commodity standards

- Usually consist of definitions or descriptions, classifications or categories, **composition and quality factors**, additional additive use, safety factors (such as: hygiene, contaminants, pesticides), specific labelling, packaging, methods of analysis and sampling, and sometimes weights and measures
- Broad categories with most Codex commodity standards established: dairy products (particularly cheese), fruits and vegetables, fish and fish products, cereal and cereal products, oils and fats
- Products with most composition and quality factors set in the commodity standards: vegetable oils and fats, chocolate and chocolate products

Codex commodity standards

Food compositional standards in some countries are based on or similar to Codex commodity standards, such as:

Uganda

Central America

Ghana

Venezuela

Nigeria

Jordan

Gulf Cooperation Council

Bolivia

Ecuador

Cambodia

Peru

Lebanon

Egypt

Dominican Republic

Botswana

Some countries refer to Codex commodity standards in the absence of national provisions, such as South Africa and Kenya

What are the limitations of Codex Alimentarius?

Provide international benchmark to facilitate free trade and consumer protection, however...

- It only offers recommendations and **member countries are free to implement the framework in their own way**. This can lead to discrepancies in how guidelines are interpreted, legislated and enforced.
- Understanding where differences lie and how to navigate them without compromising product quality or consumer enjoyment is crucial for efficient development of global products
- There are still a number of matters Codex has not addressed or are in a process of standards or related texts being formulated and this can take long time
- Details in Codex standards and guidelines can be generic



Other international harmonizing bodies

MERCOSUR

- Members states: Argentina, Brazil, Uruguay, Paraguay and Venezuela
- MERCOSUR Resolutions need to be implemented into the Member States' Law within a specific period of time
- However, take much longer to implement in certain MS; can have additional national provisions for harmonized regulations; many non-harmonized topics, e.g. sweeteners in general and additive use in certain food commodities.



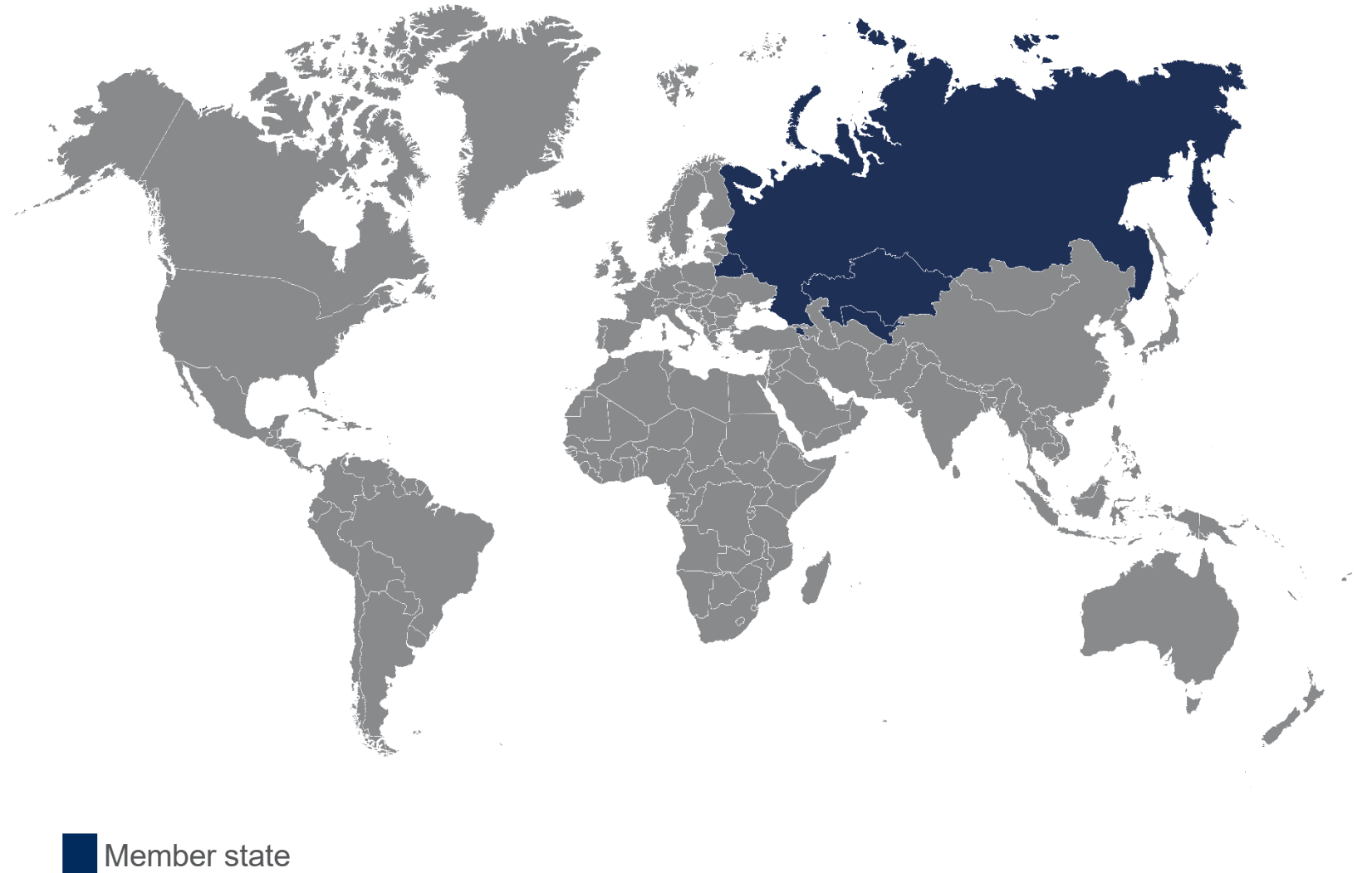
GCC

- Member states: Saudi Arabia, United Arab Emirates, Qatar, Oman, Bahrain, Kuwait and Yemen
- MS is expected to adopt GSO standards into national standards
- However, different timeframes for implementation and variations in national implementing standards, e.g. additive standards UAE.S CAC 192/2016, SFDA.FD 2500/2019 (KSA), GSO 2500/2015 (other MS).



Customs Union / Eurasian Economic Union (EAEU)

- Members states: Russia, Belarus, Kazakhstan, Armenia and Kyrgyzstan
- Technical Regulations of Customs Union directly applicable to MS
- Be mindful of Russian national provisions/standards and import ban



Leatherhead's learnings on internationalization



Things to consider - compositional requirements

Primary food commodities

For primary food commodities, such as vegetable oils and fats, certain dairy, cereal or meat products, be mindful of the key physical and chemical properties, e.g.

- Acid value and peroxide value for vegetable oils and fats
- Milk fat content for butter
- Brix level for fruit juices

Highly processed foods

For highly processed composite products, certain key parameters, e.g.

- Fruit juice content for juice drinks
- Cocoa butter/solids content for chocolate

Barriers are more often caused by the use of additives, rather than composition

Don't forget labelling implications, e.g. product names

Things to consider when using bulk ingredients

Primary or simple compound food vs complex composite products

Botanical ingredients, potential novel status, ingredients with special function or properties

Ingredient specifications

GM and other new technology

Alcohol and ingredients from animal origin

Thing to consider when using additives and fortificants

- More often regulated by horizontal legislation on additives. However, in conjunction with compositional standards in certain countries (particularly Latin America)
- Sweeteners, preservatives, antioxidants and colours are the categories often **more strictly regulated**, and hence more inconsistencies across different markets
- If fortification is involved, can be **more challenging due to strict and detailed rules**, e.g. mandatory requirements (hence inconsistency) or the lack of specific or sufficient regulatory controls (hence uncertainty).
- Regulatory controls for processing aids and enzymes vary
- Don't forget purity criteria

Summary

- 1 Codex and other trade/harmonizing bodies are good starting points but must be treated with caution
- 2 Therefore when expanding into new markets you must consider the intricate web of regulatory requirements within your target markets
- 3 Achieving single formulation is rare, but it is possible to rationalise formulations whilst addressing the regulatory and consumer needs of market clusters
- 4 It is very complicated and it is hard to define step by step guidance as there are so many factors and variables depending on e.g. the market and product category combinations
- 5 It is a capability founded (mainly) on expert market and category knowledge rather than a fixed process

Thanks for listening!

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Questions

leatherhead food research

innovate | access new markets | realise global opportunities