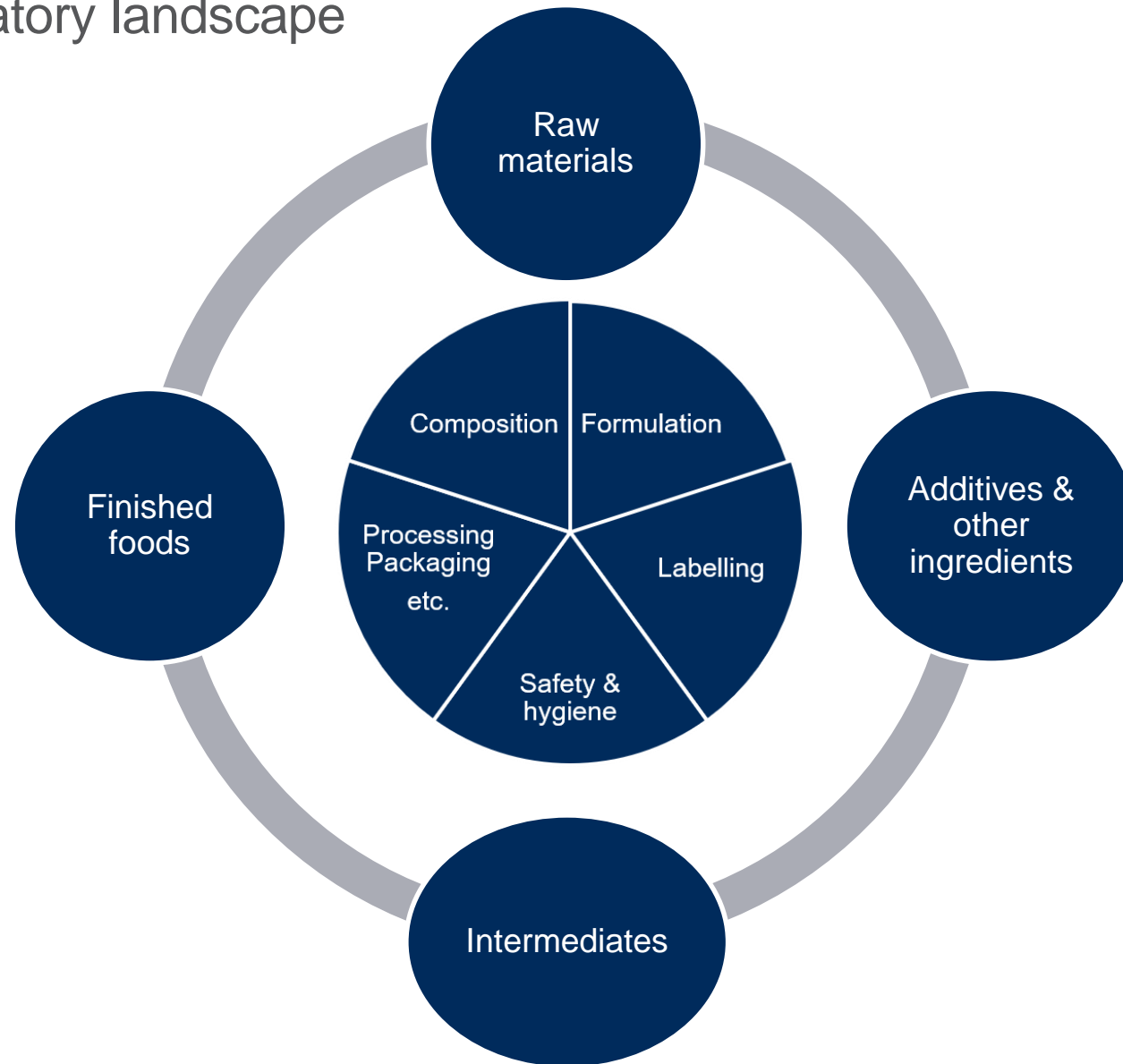




Efficiencies in multi-market launches – a focus on APAC, EU and the USA

Navigate complex regulatory landscape



Agenda

- 1 Food compositional standards
- 2 Ingredient permissibility
- 3 Food fortification
- 4 Labelling

A close-up photograph of a hand pushing a metal shopping cart. The hand is wearing a grey sleeve and is gripping a green handle with a red trigger. The cart is filled with various items, including green leafy vegetables and red plastic containers. The background is a blurred supermarket aisle with shelves of products.

Food compositional standards

Volume of compositional standards



Define product name and identity

CHINA

Fruit juice drinks – min.
10% juice content

Chocolate – max. 5%
veg fats other than
cocoa butter

If juice content < 10%,
but $\geq 5\%$, 'Fruit Drink'

If vegetable fats other
than cocoa butter > 5%,
'Chocolate Substitute'

Or adjust composition

Regulate composition and quality factors

	<i>Butter:</i>	<i>Fruit juices:</i>	<i>Milk chocolate:</i>		
	Min. milkfat content	Min. Brix level	Max. vegetable fats other than cocoa butter	Min. cocoa solids	Min. milk solids
China	80.0%	Established (reconstituted)	5%	25 g/100g	12 g/100g
Indonesia	80%	Established (reconstituted)	5%	25%	12%
Australia	80.0%	Not established	50 g/kg	Not established	Not established
EU	80% & < 90%	Established (reconstituted)	5%	25%	14%
USA	80%	Established (reconstituted)	Not permitted (Different std)	Established as chocolate liquor	12%
Codex	80%	Established (reconstituted)	5%	25%	A specified value btw 12% ~ 14%

May also regulate additive use



Positive lists of additives under Chapter 3*:

- 16 categories in the Food Category System
- List of generally permitted additives

INDIA

Compositional standards under Chapter 2*: e.g.

‘It may contain permitted specific additive categories’

‘Specific additives’ and ‘maximum limits’

* India Food Products Standards and Food Additives Regulation, 2011

Summary – Composition

1. There are some alignments in compositional requirements between certain APAC markets, particularly those influenced by Codex commodity standards
2. Generally, the parameters in APAC markets are not restrictive and rigorous; significant regulatory barriers caused by composition are rare; but need more attention when navigate the Indian legislation
3. Be mindful of primary commodities - the use of bulk ingredients can be standardised and more rules on physical and chemical properties
4. In the case of compositional standards with reserved descriptions, be flexible in naming the products when localising product labels

A high-angle photograph of two bakery staff members, a woman and a man, both wearing dark aprons over white shirts. They are standing behind a wooden bakery counter. The woman is holding a tablet and looking at it, while the man is also looking at the tablet. The counter is filled with various baked goods: long loaves of bread on shelves in the background, croissants in a glass display case, and several trays of pastries and sandwiches in the foreground. The scene is brightly lit, suggesting a clean and professional environment.

Ingredient permissibility

Regulatory landscape for ingredient permissibility

Are positive lists established?

	Additives	Flavourings	Processing aids	Fortificants	Enzymes
China	√	√	√	√	√
Japan	√	√	√	√	√
South Korea	√	√	√	√	√
India	√	X	√	√	√
Australia	√	X	√	√	√
USA	√	√	√	√	√
EU harmonised	√	√	X	√ (V&M only)	X

Food flavourings

In the absence of national provisions on the use of flavourings in food (e.g. positive lists), some APAC countries refer to JECFA and/or FEMA, amongst other countries flavouring legislation and/or international organisations, such as IOFI, US and EU



A few highlights on additive controls

Codex GSFA is highly influential in APAC

Involve composition standards in some countries

Additive functions are often not restrictive

Japan has a unique positive listing structure

S. Korea and Japan have generous additive provisions

US has a different approach

Summary - Ingredient permissibility

1. Codex GSFA is highly influential in APAC
2. Additive use is mainly regulated by the horizontal additive legislation in APAC; however, compositional standards need to be checked in conjunction with the additive legislation in a few markets
3. Additive functions are generally not restricted by the legislation in most markets
4. Artificial flavourings may need more attention where detailed positive lists are established
5. US is unlike other countries as it permits substances that would be considered food additives to be used without specific regulatory approval if they are GRAS

A close-up photograph of a white bowl filled with golden-brown, ring-shaped cereal. A single, vibrant red strawberry with green leaves is placed on top of the cereal on the right side of the frame. A semi-transparent white rectangular box is overlaid on the left side of the image, containing the text 'Food fortification' in a dark, sans-serif font.

Food fortification

Regulatory landscape in East Asia

Japan, China, South Korea, Taiwan

Voluntary fortification

Fortification is voluntary for general foodstuffs

Horizontal additive legislation

Fortificants are considered as additives. When fortified voluntarily, the use of fortificants must follow the additive legislation, i.e. permitted food applications, sources and levels

May also involve compositional standards

For certain commodities, particularly foods for special dietary uses, e.g. foods for infants and young children, the compositional requirements are also relevant

USA

- Fortification generally voluntary, but policy must be met (justification)
- Liberal compared to mandatory and positive listing requirements of other countries
- Where Standards for fortified products exist, accompanied by non-fortified Standards (e.g. flour)

EU

- List of permitted vitamins/minerals and sources
- Principles for the addition of certain other substances in food, but no EU positive lists
- Additionally, check Member States for national provisions

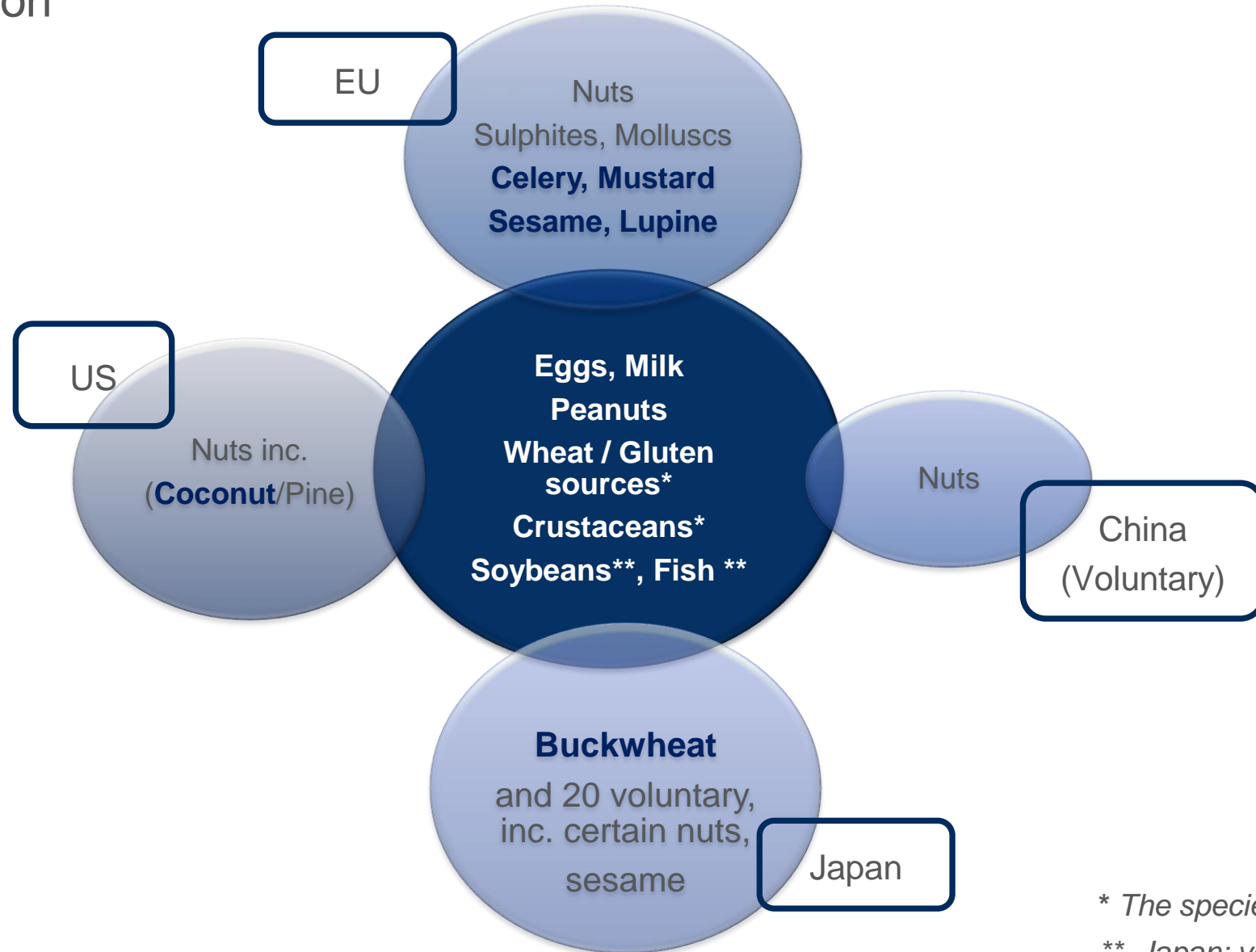
Summary - Food fortification

1. Mandatory fortification requirements exist in a few countries, but mostly voluntary in APAC, EU and US
2. Although voluntary, still often subject to horizontal and/or vertical legislation in certain APAC markets where fortification is heavily regulated (in which commodities, at what levels and permitted sources); watch out for inconsistent provisions
3. The lack of detailed rules on fortification in some APAC markets however can cause uncertainty; an insight into the local enforcement can be advantageous

Labelling



Allergen comparison



* The species included can vary

** Japan: voluntary; certain fish

Diversity in nutrition labelling

Japan

栄養成分表示 (Nutrition Labelling)	
(1食 (125g当たり) (1 serving (per 125 g))	
熱量 (Energy)	kcal
たんぱく質 (Protein)	g
脂質 (Fat)	g
－飽和脂肪酸(Saturated fat)	g
－n-3系脂肪酸 (n-3 fatty acids)	g
－n-6系脂肪酸 (n-6 fatty acids)	g
コレステロール(Cholesterol)	mg
炭水化物(Carbohydrates)	g
－糖質 (Sugar)	g
－糖類 (Sugars)	g
－食物繊維 (Dietary fibre)	g
食塩相当量(Edible salt equivalent)	g
Other nutrients	

South Korea

Nutrition facts 영양정보	
The total amount 00g 000kcal	
Total content (per one package) 총 내용량당	Percentage value based on daily nutritional value
Sodium 나트륨 00mg	00%
Carbohydrates 탄수화물 00g	00%
Sugar 당류 00g	00%
Fats 지방 00g	00%
Trans fat 트랜스지방 00g	
Saturated fat 포화지방 00g	00%
Cholesterol 콜레스테롤 00mg	00%
Protein 단백질 00g	00%
* Percentage value based on daily nutritional value	
* 1일 영양성분 기준치에 대한 비율(%)은 2,000kcal 기준이므로 개인의 필요 열량에 따라 다를 수 있습니다.	

Diversity in nutrition labelling

USA

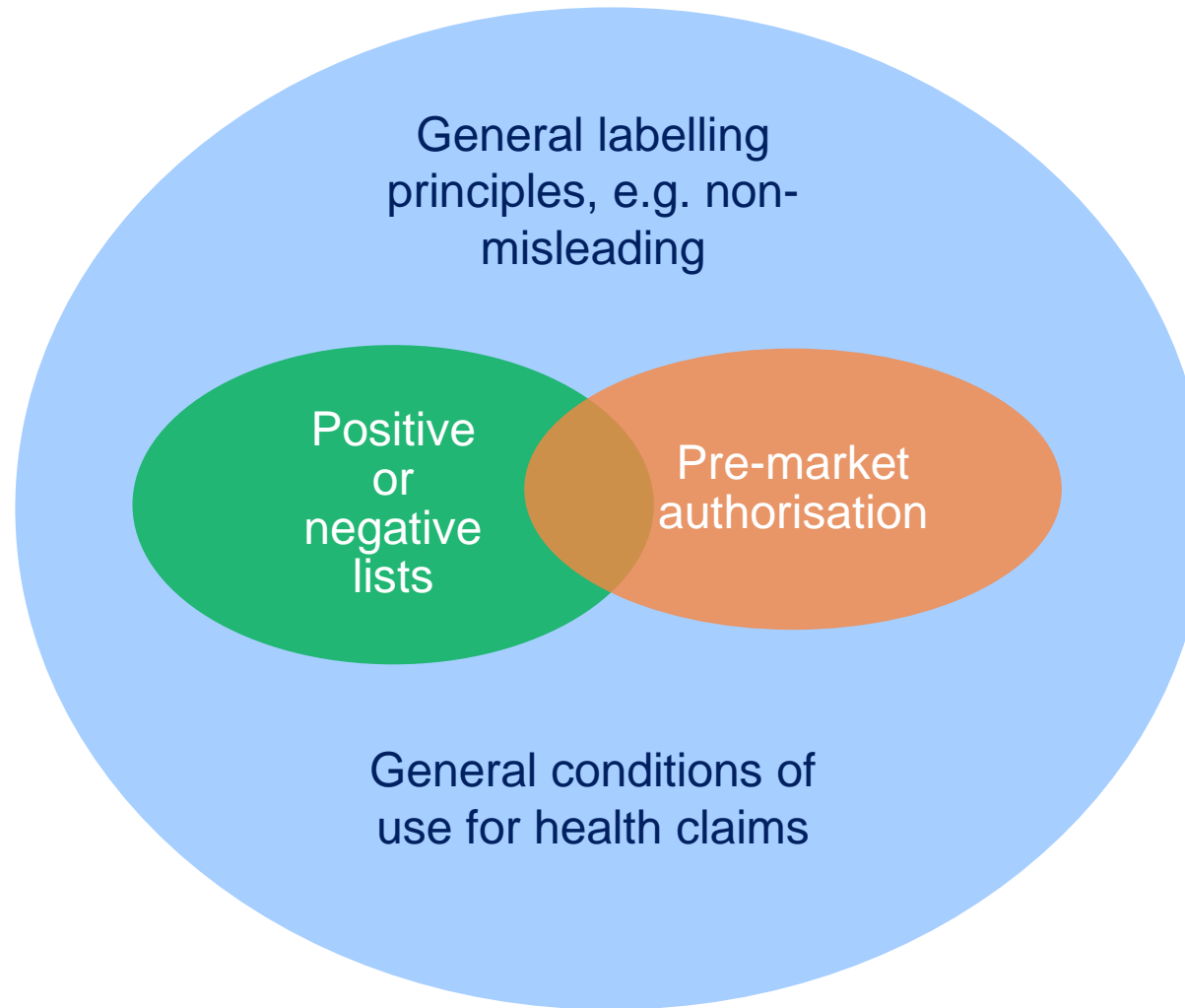
Nutrition Facts	
8 servings per container	
Serving size 2/3 cup (55g)	
Amount per serving	
Calories	230
% Daily Value*	
Total Fat 8g	10%
Saturated Fat 1g	5%
Trans Fat 0g	
Cholesterol 0mg	0%
Sodium 160mg	7%
Total Carbohydrate 37g	13%
Dietary Fiber 4g	14%
Total Sugars 12g	
Includes 10g Added Sugars	20%
Protein 3g	
Vitamin D 2mcg	10%
Calcium 260mg	20%
Iron 8mg	45%
Potassium 240mg	6%
* The % Daily Value (DV) tells you how much a nutrient in a serving of food contributes to a daily diet. 2,000 calories a day is used for general nutrition advice.	

China

营养成分表 Nutrition Information

项目/Items	每100g/ml或每份 Per 100 g/ml or per serving	营养素参考 值% / NRV%
能量 /Energy	kJ	%
蛋白质/Protein	g	%
脂肪/Fats	g	%
碳水化合物 /Carbohydrates	g	%
糖/Sugar	g	
膳食纤维/dietary fibre	g	%
钠/Sodium	mg	%
Vitamins and minerals	Specified unit	%

How health claims are regulated



Markets have different mechanisms regulating health claims

Singapore, Malaysia Indonesia, Australia

- General conditions of use
- Positive lists for Singapore, Malaysia and Indonesia, for which no pre-market authorisation is required

USA

- Several different types of health claims with different mechanisms
- Structure function claims separately regulated without pre-market approval but substantiation must be held

India

- General principles of use and a list with few approved health claims; certain types require pre-market approval

China, Japan, South Korea and Taiwan

- Strictly regulated through special functional food categories, mostly subject to pre-market approval, despite some positive lists established

Labelling considerations for internationalization

When expanding into new markets:

- Usually need to localise labelling information; using original labels or minimum adaption is very rare
- Language adaptation is the main consideration; watch out for translation errors and legally defined terms
- Multilingual product labelling can be effective, but difficult to execute
- Using over-stickers is a solution; be aware of grey area – cause uncertainty
- More challenging labelling aspects for localisation: nutrition labelling, allergen declarations, ingredient listing, and date mark
- May also involve composition standards, e.g. reserved descriptions - influence product naming, specific labelling requirements

Overall

- Codex Alimentarius has considerable influence in APAC; great benchmark, but treat with caution - watch out for regulatory gap and variations

The regulatory aspect of those discussed with the least amount of alignment tends to be labelling; label localisation requires more effort

The degree of alignment varies with composition and formulation

- Additionally, extensive botanical lists exist in East Asia, rules for religious reasons in Southeast and South Asia, as well as geopolitical and social factors
- Compliance hurdles have evolved over time; food businesses are facing more and more fresh challenges

Thanks for listening!

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Questions