



Smart Regulatory Solutions

Where can I go and how do I get there?

Exporting Using Regulatory Intelligence

Key Trends



**REGULATORY
CONSIDERATIONS**



MARKET COMPLEXITY



RECOMMENDATIONS



REGULATORY CONSIDERATIONS

Regulatory Considerations



Regulatory Classification

Food

- Consumed as part of normal diet
- Beneficial effect on normal function
- *Contributes to normal function of the immune system*

Supplement

- Supplement normal diet typically with controlled dosage
- Support normal function or low level modifications to health
- *Sleep support, eye health, liver support*

Medicine

- Treatment or prevention of disease
- Therapeutic actions and claims
- *Lower blood pressure, cholesterol, anti-inflammatory*

Regulatory environment can be a subset of food or medicine regulation depending on the market

Product Considerations

- Does the product format influence classification?
- Are the ingredients are permitted?
 - Authorised ingredients
 - Innovative ingredients
- What claims can be made?
- How difficult is it to register a product?



Evidence Considerations

- What is enough?
 - Research papers
 - Systematic review
 - Ingredient or product specific clinical trials
- Study design, end points, and participants
 - Is it a health benefit or a therapeutic action?
 - How can published trials support claims?



Food or Pharmaceutical

- Pharmaceuticals aim to treat disease
 - A very clear process for different phases of clinical trials
- Foods aim to promote better health in healthy volunteers
 - A much less defined standard process for trial design
- Where do supplements fit in?





MARKET COMPLEXITY

Market Complexity Scale



LOW

Limited ingredient restrictions
Open access to claims
Minimal pre-market registration

HIGH

Approved ingredients only
Authorised claims
Significant pre-market registration

USA

	Food	Dietary Supplement	Drug
Ingredients	GRAS for all ingredients	Excipients must be GRAS	Approved inactive and active ingredients only
Claims	Recognised nutrients only	Support normal health and function	Authorised claims only
Registration	No registration. Notification prior to import	No registration. Notification prior to import	FDA approval required

Canada

	Food	Natural Health Product	Drug
Ingredients	Authorised additives only. History of consumption as a food for other ingredients	Approved ingredients only	Approved inactive and active ingredients only
Claims	Authorised claims for recognised nutrients	Normal health and low level therapeutic claims	Authorised claims only
Registration	No registration. Notification prior to import	Health Canada approval required	Health Canada approval required

Japan

	Food	Foods with Nutrient Function Claims (FNFC)	Foods with Function Claims (FFC)	Foods for Specified Health Uses (FOSHU)
Ingredients	Authorised additives only. History of consumption as a food for other ingredients	Authorised additives only. History of consumption as a food for other ingredients	Authorised additives only. History of consumption as a food for other ingredients	Authorised additives only. History of consumption as a food for other ingredients
Claims	No health benefit claims	Authorised claims for 17 vitamins and minerals	Support normal health and function. Supported by clinical trials and/or systematic review.	Authorised claims including disease risk reduction supported by clinical trials
Registration	No registration	No registration	CAA approval required	MHLW approval required

South Korea

	Food	Health Functional Food	Drug
Ingredients	Authorised additives only. History of consumption as a food for other ingredients	Approved ingredients only	Approved inactive and active ingredients only
Claims	No health benefit claims	Normal health and function claims supported by clinical trials	Authorised claims only
Registration	No registration. Notification prior to import.	MFDS approval required	MFDS approval required

China

	Food	Health Food	Drug
Ingredients	Authorised additives only. History of consumption as a food for other ingredients	Approved inactive and active ingredients only	Approved inactive and active ingredients only
Claims	Authorised claims for recognised nutrients only	Authorised claims for recognised nutrients only	Authorised claims only
Registration	Registration required prior to import	Blue or orange hat approval required	NMPA approval required

Singapore

	Food	Health Supplement	Drug
Ingredients	Authorised additives only. History of consumption as a food for other ingredients	Prohibited/restricted ingredients lists	Approved inactive and active ingredients only
Claims	Authorised claims for recognised nutrients only	Support normal health and function	Authorised claims only
Registration	No registration. Notification prior to import	No registration	HSA approval required

Malaysia

	Food	Health Supplement	Drug
Ingredients	Authorised additives only. History of consumption as a food for other ingredients	Combination of negative and prohibited substances lists	Approved inactive and active ingredients only
Claims	Authorised claims for recognised nutrients only	Normal health and low level therapeutic claims supported by recognised evidence sources	Authorised claims only
Registration	FSQD approval required	NPCB approval required	NPRA approval required

UK/EU

	Food	Food Supplement	Traditional Herbal Medicine	Medicine
Ingredients	Authorised additives only. History of consumption as a food for other ingredients	Authorised additives only. History of consumption as a food for other ingredients	Approved inactive and active ingredients only	Approved inactive and active ingredients only
Claims	Authorised claims for recognised nutrients	Authorised claims for recognised nutrients	Normal health and low level therapeutic claims	Authorised claims only
Registration	No registration	No registration	Traditional herbal medicine licence required	Medicine licence required



RECOMMENDATIONS

Recommendations

- Understand the landscape early
- Play to your strengths
- Research distribution partners
- Halo effect for claims
- IP protection



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