Infant Formula
Regulatory Orientation Map

EU · UK · US · China · India · GCC

ORIENTATION GUIDE ONLY — NOT REGULATORY ADVICE

This document is intended only to help readers identify which authorities and primary regulations apply in each jurisdiction. It is not regulatory advice, is not a current statement of the law, and is not a substitute for qualified regulatory counsel. All facts must be verified against current primary sources before any commercial decision or regulatory action. See full notice on page 2.

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Important Notice — Please Read Before Using This Document

> **THIS DOCUMENT IS A HIGH-LEVEL ORIENTATION GUIDE.** It is intended only to help readers identify the principal regulatory authorities and primary regulations that apply to infant formula in selected jurisdictions, so the reader can consult those primary sources directly.
>
> **IT IS NOT REGULATORY ADVICE.** It is not a substitute for qualified regulatory counsel in the relevant jurisdiction.

Why this matters

Infant formula is consumed by some of the most vulnerable people in the world. Errors in formulation, manufacturing, labelling or registration can result in product detention, recall, regulatory enforcement, financial loss and — most importantly — serious harm to infants.

Regulations change frequently

The information was compiled to the best of our understanding as of June 2026. **Any specific fact in this document may already be outdated by the time you read it.**

Required verification

Always verify any specific compositional limit, registration requirement, labelling rule, or other compliance fact against the current primary source published by the relevant authority before any commercial decision.

Engage qualified regulatory counsel

Watson Dairy Consulting strongly recommends that any commercial infant formula project engage qualified regulatory counsel in each jurisdiction where the product will be manufactured, marketed or sold.

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Contents

1. Why infant formula regulations are uniquely strict

Before navigating the regulatory framework set out in the rest of this guide, it is worth understanding **why infant formula attracts more rigorous regulatory oversight than almost any other food category in the world.** This context is essential for anyone using the guide commercially — the regulatory burden is not arbitrary, and treating it lightly carries consequences that go well beyond financial penalty.

Complete nutritional reliance

For infants who are not breastfed, infant formula is — by definition — the **sole source of nutrition** during the most rapid period of human growth and development. Unlike older infants and young children who eat a varied diet of solid foods, an exclusively formula-fed infant has no nutritional alternative. If the formula is compositionally inadequate, the infant is inadequate. If it is contaminated, the infant has no buffer. If a critical micronutrient is missing, the infant becomes deficient in that micronutrient.

This is the foundational reason infant formula regulations specify minimum *and* maximum levels for every regulated nutrient, prescribe mandatory microbiological testing per batch, set strict heavy-metal contamination limits, require pre-market notification or registration, and govern manufacturing in considerably greater detail than any other commercial food.

The critical developmental window

During the first 12 months of life, an infant typically triples its birth weight, the brain develops to a substantial fraction of its adult size, the immune system is establishing itself, the gut microbiome is being seeded, and metabolic patterns are being laid down that influence lifelong health. Nutritional inadequacy or excess during this window can produce consequences that are difficult or impossible to reverse later in life — including neurodevelopmental impacts, skeletal development problems, and lasting metabolic dysfunction.

Older infants who are introduced to complementary feeding have some dietary diversity to compensate for an imperfect formula. Newborn and young infants do not. **This is why the under-six-months period attracts the strictest controls across every jurisdiction** — and why most regulatory frameworks distinguish between ‘infant formula’ (suitable from birth) and ‘follow-on formula’ (only after six months, when complementary feeding has begun).

Why “breast milk is best” is mandated language

The WHO International Code of Marketing of Breast-milk Substitutes (1981) and subsequent World Health Assembly resolutions establish that breast milk is the gold standard for infant nutrition and that formula exists for situations where breastfeeding is not possible. EU Regulation 2016/127, the US Infant Formula Act, China’s GB 10765-2021, India’s IMS Act, and the GCC standards all reflect this hierarchy in their labelling, marketing, and information requirements. The required ‘breast milk is best’ (or equivalent) statement on infant formula packaging is not a marketing nicety — it is a deliberate regulatory mechanism to ensure consumers understand the order of preference.

Historical lessons shaping current regulation

Modern infant formula regulation is shaped by a series of historical failures that the framework is designed to prevent recurring. The regulatory architecture today reflects lessons learned from major incidents including **melamine adulteration** (notably the 2008 incident in China that affected an estimated 300,000 infants), **Cronobacter sakazakii contamination** events leading to facility shutdowns and large-scale product recalls, **micronutrient deficiency cases** in incorrectly fortified products, and **aggressive marketing practices** in developing markets that undermined breastfeeding. Each of these has driven the

addition of specific control measures into current regulations.

What this means for project planning

The combination of:

- Total reliance of newborn and young infants on formula for all nutrition
- Critical and largely irreversible developmental consequences of error
- A documented historical pattern of high-impact failures
- High public, political and media sensitivity around the category

...is precisely why infant formula carries the regulatory burden it does. **Treat that burden seriously.** Engage qualified regulatory counsel early. Verify every fact against current primary sources. Build comprehensive due diligence around the assumption that any compliance gap will eventually be found by someone — and that the consequences, both human and commercial, will be material.

> This guide deliberately does not include specific compositional figures, registration cost estimates, or precise timelines. Those numbers change, the consequences of relying on outdated numbers are too serious, and the right place to obtain them is from current primary regulatory sources and qualified regulatory counsel.

2. How to use this guide

Each jurisdiction section lists the principal regulatory authority, the primary regulation(s) by reference number, and headline requirements.

- **Identify** jurisdictions where your product will be sold
- **Locate** the primary regulations cited
- **Verify** against the authority's current published version
- **Engage** qualified regulatory counsel
- **Document** compliance against current verified regulations

3. Codex Alimentarius — the international baseline

The Codex Alimentarius Commission (FAO/WHO) sets the international reference standard.

- **CODEX STAN 72-1981** — Standard for Infant Formula. Revised 2007, amended through 2024.
- **CODEX STAN 156-1987** — Standard for Follow-Up Formula (revised 2017).

Source: www.fao.org/fao-who-codexalimentarius

> Verify against current published version on FAO Codex portal.

4. European Union

Authority: European Commission — DG Sante. Enforcement at Member State level. Scientific advice from EFSA.

- **Regulation (EU) No 609/2013** — Framework regulation on food for infants and young children.
- **Commission Delegated Regulation (EU) 2016/127** — Detailed compositional and information requirements.
- **Regulation (EC) No 2073/2005** — Microbiological criteria.

Sources: eur-lex.europa.eu, food.ec.europa.eu, www.efsa.europa.eu

5. United Kingdom

Authority: DHSC for policy. Enforcement by Local Authorities under FSA framework.

> **The Food for Specific Groups Regulations (England) 2020** — adopting EU Delegated Regulation 2016/127 as retained EU law.

Sources: www.legislation.gov.uk, www.gov.uk/dhsc, www.food.gov.uk

Northern Ireland operates under the Windsor Framework with EU rules applying directly.

6. United States — FDA framework

Authority: US Food and Drug Administration (FDA), CFSAN.

- **Federal Food, Drug, and Cosmetic Act, Section 412** — The Infant Formula Act.
- **21 CFR Part 106 & 107** — Infant formula CGMP, quality factors, labelling, recalls.

Sources: www.ecfr.gov, www.fda.gov/food/infant-formula-guidance-documents-regulatory-information

Mandatory FDA pre-market notification (90+ days); clinical growth study; per-batch microbiological testing for *Salmonella* and *Cronobacter*; FDA inspection and CGMP audit.

7. China

Authority: SAMR for product registration. NHC and SAMR jointly issue GB standards.

GB 10765-2021, GB 10766-2021, GB 10767-2021 — National Food Safety Standards for Stages 1, 2 and 3.

Sources: www.samr.gov.cn, www.nhc.gov.cn

Mandatory SAMR product registration; in-country clinical efficacy studies; SAMR on-site factory audits for overseas manufacturers.

> Do not attempt China registration without qualified in-country regulatory counsel.

8. India

Authority: FSSAI under Ministry of Health and Family Welfare. Marketing restrictions under IMS Act.

Food Safety and Standards (Foods for Infant Nutrition) Regulations, 2020

Infant Milk Substitutes Act, 1992 (the IMS Act)

Sources: www.fssai.gov.in, wcd.gov.in

Marketing compliance under the IMS Act requires specialist Indian legal counsel.

9. Gulf Cooperation Council

Authority: GSO regional; national authorities country-level (SFDA, MOHAP, etc.).

- **GSO 1366 / GSO 2333** — Gulf standards covering infant formula and follow-up formula.

Sources: www.gso.org.sa, www.sfda.gov.sa, www.mohap.gov.ae

10. Multi-jurisdiction formulation strategy

> **Strategic insight:** For many infant formula projects, the central commercial question is not *which* jurisdictions to enter — it is whether a **single formulation** can be sold across all target markets, or whether **market-specific formulations and SKUs** are required.

Why this question matters

The choice between a single global formulation and a portfolio of market-specific variants has cascading implications across every part of the project: ingredient supply, factory layout, batch size and scheduling, analytical specification, regulatory documentation, packaging, inventory, distribution, and pricing.

Case for a single formulation

- One production line, one batch process, one analytical specification
- Lower inventory, fewer SKUs, simpler supply chain
- Single source of regulatory and quality documentation
- Lower COGS through manufacturing scale
- Cleaner brand architecture and marketing positioning

Case for market-specific formulations

- Genuine regulatory divergence on specific nutrients
- Local population health needs reflected in national standards
- Distinct stage / age cut-offs in some jurisdictions
- Marketing or positioning benefits from local variants
- Clinical norms or local medical recommendations differ

The strategic question

> **The question to answer at project scoping is:**
>
> "Does the intersection of all target jurisdictions' min-max ranges leave a workable formulation window for every regulated nutrient?"
>
> • If **yes** — a single formulation may serve all target markets, at the cost of some optimisation compromise.
> • If **no** — separate formulations are required for at least some markets.

Where divergence is commonly found

- **Iron** — required ranges differ between regions, reflecting population deficiency rates.
- **Iodine** — populations with historically iodine-deficient diets may have higher requirements.
- **Vitamin D** — high-latitude markets may apply higher minimums.
- **DHA** — mandatory in EU/UK since February 2020; optional in some other major markets.
- **Protein composition** — Chinese Stage 1 standards have included specific whey-protein-to-casein ratios exceeding conventional formulations.
- **Permitted ingredients** — positive lists vary significantly between markets.

• **Prohibited ingredients** — for example sucrose was prohibited as a carbohydrate source in Chinese infant formula under GB 10765-2021 (with limited exceptions).

Stage cut-offs and product categories — all major markets have multi-stage commercial product structures, but the regulatory categories and their boundaries differ materially:

• **EU (Reg 2016/127)** defines two product categories: *infant formula* (suitable from birth, may be used through to 12 months) and *follow-on formula* (suitable only for infants over six months, per Article 6(3)(a)). Above 12 months sits outside this regulation.

• **US** treats the 0-12 month period as a single regulated category under the Infant Formula Act and 21 CFR 106/107. Toddler formulas (12+ months) are regulated as conventional foods.

• **China** explicitly defines three regulated stages under GB 10765-2021 (0-6m), GB 10766-2021 (6-12m), GB 10767-2021 (12-36m). All three sit within the SAMR registration regime.

Recommended analytical approach

1. **List every target market** the product is intended to enter.

2. **Source the current primary regulation** for each market.

3. **Build a comparative table** of every regulated nutrient and ingredient.

4. **For each nutrient, calculate the workable window:** highest minimum across all markets, lowest maximum across all markets. If highest min < lowest max, a single formulation window exists.

5. **Repeat for positive lists and negative lists.**

6. **Add stage / age boundaries** to the analysis.

7. **Consult qualified regulatory counsel** in each target market.

8. **Document the formulation decision** with rationale.

> Actual nutrient ranges, ingredient lists, and stage boundaries must be drawn from current primary regulations. The comparative table and resulting formulation decision must be reviewed and signed off by qualified regulatory counsel.

How Watson Dairy Consulting fits in

Watson Dairy Consulting operates as a technical and process partner — working **alongside your in-house team and your regulatory counsel**, not as a substitute for either.

Verifying findings and concerns alongside your team

Watson Dairy Consulting provides an **independent, experienced second opinion** — confirming where the team has it right, challenging where assumptions look fragile, and flagging issues internal teams under time pressure can miss. We have no vendor relationships, no equipment commissions, and no jurisdictional axe to grind.

Cross-checking regulatory counsel against operational reality

Regulatory counsel will give you the legally-correct answer on what each jurisdiction requires. The next question is whether that answer translates into an operationally-achievable formulation, process, and supply chain — and whether the implementation will hold up under regulator factory audit. We sit at that interface, bringing plant-floor and process engineering perspective to ensure the regulatory advice does not rest on assumptions about ingredients, equipment, analytical methods, or process windows that do not in fact hold in the real factory.

Supporting investor, board and lender due diligence

An independent expert review of the multi-jurisdiction formulation strategy and operational implementation plan **materially strengthens the due diligence pack** presented to the board, lenders, insurance underwriters and external investors.

Identifying risks the documentation may not surface

Independent expert review focuses on **what could go wrong in delivery** — ingredient supply risks, batch-to-batch variability, stability degradation paths, cross-contamination scenarios, and the practical robustness of the proposed control regime.

Translating the analysis into manufacturing reality

We help translate the regulatory analysis into the comparative analytical specification, production process design, ingredient supply implications, factory layout decisions, and operational plan that delivers compliance batch after batch.

Audit-readiness over the product lifecycle

Compliance is not a one-time event. We can be retained for ongoing review and to support the documentation trail that authorities will look at five years from now.

What we do not do

Watson Dairy Consulting does not provide the regulatory analysis itself, jurisdiction-specific legal advice, in-country agent appointments, or registration dossier preparation. We work with those specialists in support of them and your team — not in place of either.

11. Quick comparison — for orientation only

> High-level comparison for early-stage scoping only. Every entry subject to verification.

Aspect	EU/UK	US	China	India	GCC
Pre-market registration	Notification	Yes (90+ days)	Yes, comprehensive	Notification + licence	Yes (per state)
DHA in current standard	Mandatory	Optional	Per GB std	Per FSSAI std	Per Codex / GSO
Clinical efficacy study	No	Growth study	Yes, in-country	No	Subject to authority
On-site factory audit	By Member State	FDA	SAMR	FSSAI	Per national authority
Marketing restrictions	Strict	Moderate	Strict	Severe (IMS Act)	Moderate + halal
Typical time to market	Months	Many months	Year+	Months	Months

12. Common compliance failure modes — observed patterns

1. Designing only to Codex baseline

Codex provides international minimum standards. Major markets all add national overlays. Always design to the most stringent jurisdiction you intend to enter.

2. Skipping the multi-jurisdiction comparison at scoping

Discovering at registration that the planned formulation cannot meet a target market's ranges is one of the most expensive errors. The analysis described in Section 10 should be done before product development resource is committed.

3. Underestimating regulatory timelines

Pre-market registration — particularly China's SAMR — routinely takes longer than the regulation states.

4. Microbiological control insufficient for batch-testing regimes

EU 2073/2005 and US 21 CFR 106.55 both require negative testing of every batch for *Cronobacter sakazakii* and *Salmonella*.

5. Inadequate stability data for shelf-life claims

Stability data must demonstrate compositional compliance through the entire claimed shelf life.

6. Marketing material that breaches restrictions

EU Article 7 of 2016/127, India's IMS Act, and most jurisdictions impose strict restrictions on idealising imagery and breast-milk comparison.

7. Cross-contamination on shared production lines

Audit failures on this point are common and can result in plant shutdown.

13. About Watson Dairy Consulting

Watson Dairy Consulting is an independent dairy processing consultancy founded by John Watson, based in Aberdeen, Scotland, with project experience across the dairy industry including infant formula manufacturing, factory design, due diligence, and process optimisation.

We are not regulatory specialists. For project-specific regulatory work we strongly recommend engaging accredited regulatory consultancies and in-country counsel.

14. References and primary sources

- **Codex Alimentarius (FAO/WHO)**: www.fao.org/fao-who-codexalimentarius
- **EUR-Lex**: eur-lex.europa.eu
- **European Commission Food Safety**: food.ec.europa.eu
- **EFSA**: www.efsa.europa.eu
- **UK Legislation**: www.legislation.gov.uk
- **UK DHSC**: www.gov.uk/dhsc
- **UK FSA**: www.food.gov.uk
- **US eCFR**: www.ecfr.gov
- **US FDA Infant Formula**: www.fda.gov/food/infant-formula-guidance-documents-regulatory-information
- **China SAMR**: www.samr.gov.cn
- **China NHC**: www.nhc.gov.cn
- **FSSAI (India)**: www.fssai.gov.in
- **India MoWCD (IMS Act)**: wcd.gov.in
- **GSO**: www.gso.org.sa
- **Saudi SFDA**: www.sfda.gov.sa
- **UAE MOHAP**: www.mohap.gov.ae
- **WHO International Code of Marketing of Breast-milk Substitutes (1981)**: www.who.int/publications/i/item/9241541601

15. Final notice

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