

Packaging Compliance Documentation

Gap Check — Sample Report

Sample reference: PKG-2026-003 | Date: 2026-09-29 | Prepared by: Lucas — Quality systems and supplier verification, Guangdong, China

Subject of this sample: food-contact packaging supplied from China to a buyer in the EU and in the United States.

This is an illustrative sample. It is not a client project, not a certificate, not a test report and not legal advice.

1. Scope — what this document is, and what it is not

You have a supplier, you have documents from that supplier, and you want to know whether those documents are the ones your market actually requires. This deliverable answers exactly that: it sets out what applies to your packaging in your target market, what your supplier holds, where the gap is, and what to ask for next.

It is a documentation gap check. It works on paper, against a stated regulatory baseline, and it produces a list of what is missing and who can close it. It does not test anything and it does not certify anything.

What this sample is not

- Not a client project. No company, supplier, product, price or project reference in this document is real. Everything is generic and illustrative; the numbers and wording exist only to show the shape of the output.
- Not legal advice. It is not a legal opinion and it does not determine your legal obligations.
- Not a certificate or a declaration of conformity. Those are issued by the manufacturer.
- Not a test report. Migration, PFAS, heavy-metal and other chemical results must come from an accredited third-party laboratory.
- Not a market-access guarantee. A complete document file reduces risk; it does not guarantee clearance at a border.

2. Method — how the check is carried out

1. Fix the product and use profile first.

Material and layers, coating weight, inks and adhesives, whether the packaging touches food directly, the food type, the maximum temperature, the contact time, and the markets you sell into. Without this, every answer downstream is guesswork.

2. Fix the regulatory baseline for that profile.

EU and US requirements that apply to that material and use, at the date of the check, with the article or section reference for each one.

3. Inventory the documents the supplier actually holds.

Not the documents the supplier says it can get. For each one: what it covers, who issued it, when, and whether it names this material and this use.

4. Compare line by line and grade the evidence.

Each requirement is marked present, partial, absent or not applicable. "Partial" is the normal result and is where most of the risk sits - an undated report, a report for a different grade, a certificate that is not the document the law asks for.

5. Attribute every gap to whoever can actually close it.

A supplier document, an accredited laboratory test, or an action for the buyer or the importer. This is what stops a gap list from turning into an unactionable wish list.

6. Rank by exposure.

What can stop a shipment or a listing first, then what creates cost or delay, then what is administrative and can wait.

The check is desk-based and document-based. I do not sample, I do not visit the plant, and I do not run tests. Anything that requires a physical measurement is identified as such and handed to an accredited laboratory.

3. Regulatory baseline at the date of this sample

Restated in full so that nothing has to be taken on trust. References are to the article or section, so each item can be checked at source. This is a working baseline for food-contact packaging, not an exhaustive statement of law, and it is deliberately conservative where a requirement is still being settled.

EU

- PPWR - Regulation (EU) 2025/40

Applies since 12 August 2026 (Art. 71) and replaces Directive 94/62/EC. OJ L, 22 January 2025. Design for recycling (Art. 6(2)), recycled content (Art. 7), void ratio (Art. 24), format bans (Annex V) and reuse targets (Art. 29) follow from 1 January 2030; labelling under Art. 12 awaits implementing acts.

- Substance limits - Art. 5

Heavy metals: lead + cadmium + mercury + hexavalent chromium not more than 100 mg/kg per item or component (Art. 5(4)). PFAS in food-contact packaging: 25 ppb per individual PFAS, 250 ppb total PFAS, 50 ppm including polymeric PFAS (Art. 5(5)); where total fluorine exceeds 50 mg/kg the evidence must be available on request (Art. 5(6)).

- PFAS testing approach

Commission communication C/2026/3084 (OJ, 10 June 2026): total fluorine screening, then identification of the fluorine source, then targeted PFAS and precursor analysis.

- Conformity assessment and DoC

Internal production control with technical documentation (Art. 38, Annex VII): description, drawings and materials, standards applied, the Arts. 6/10/11 design assessments, test reports. EU Declaration of Conformity from the manufacturer (Art. 39, Annex VIII). Keep 5 years single-use / 10 years reusable (Art. 15(3)).

- Marking - from 12 August 2026

Producer name or trade mark plus postal address, and a type, batch or serial number.

- Framework Reg. (EC) 1935/2004

Safety (Art. 3). Labelling (Art. 15): "for food contact" or the Annex II glass-and-fork symbol, the name and EU address of the responsible operator, and any restriction on use. Written declaration of compliance with documentation on demand (Art. 16). Traceability one step back and one step forward (Art. 17).

- Plastics - Reg. (EU) 10/2011

Annex I Union list; Annex II restrictions and specific migration limits including primary aromatic amines; overall migration limit 10 mg/dm²; Annex III and V test conditions; Annex IV declaration content. Amended by Reg. (EU) 2025/351 (21 February 2025).

- GMP and BPA

Reg. (EC) 2023/2006: a documented quality assurance and control system for food-contact materials. Reg. (EU) 2024/3190 restricts BPA in food-contact materials; the transition dates depend on the material and the application.

- Paper, board, inks, adhesives, coatings

No EU-wide specific measure. National rules and recognised standards apply - German BfR recommendations for paper and board (currently under revision), Council of Europe Resolution AP(2002)1, French DGCCRF guidance. Ask which standard the supplier actually works to.

United States

- Authorisation of each substance

Under section 409 of the FD&C Act a food-contact substance must be authorised by an effective Food Contact Notification (FCN), a listing in 21 CFR Parts 173-189, a Threshold of Regulation exemption (21 CFR 170.39), or be GRAS for the use. FDA publishes both inventories, so a citation can be checked.

- Food Contact Notifications

21 CFR 170.100 to 170.106. An FCN is effective only for the manufacturer or supplier named in it; another converter must file its own (21 CFR 170.100(a)), and the holder must keep a current address on file.

- General provisions

21 CFR 174.5: components of articles that contact food must be of a purity suitable for the intended use and must not be used in amounts greater than reasonably required.

- Listings that matter

21 CFR 175.300 coatings; 176.170 paper and paperboard for aqueous and fatty foods; 176.180 paper and paperboard for dry food; 177.1520 olefin polymers; 177.1210 closures with sealing gaskets.

- Facility registration

Registration under 21 CFR Part 1 Subpart H does not cover food contact substances - "food" for that subpart excludes them (21 CFR 1.227). "FDA registered" therefore does not demonstrate food-contact compliance.

- Marking and origin

Country-of-origin marking for imported articles is set by US Customs, 19 CFR Part 134.

- PFAS and state law

FDA has worked with manufacturers on phasing out certain PFAS used as grease-proofing agents in food packaging. Separately, several states now restrict intentionally added PFAS in food packaging, and California Proposition 65 can require a warning for listed substances.

Point in time: compiled from the public sources listed in section 8. Requirements and, in places, start dates are still moving - notably the PPWR labelling rules under Article 12 and the 2030 design deadlines that depend on implementing and delegated acts. Each item that matters to a live shipment is re-checked against the source before it is relied on.

4. Gap matrix

One line per requirement. "What the supplier typically holds" is what I see most often from Chinese packaging converters on a first request - a starting expectation, not a claim about your supplier. The last column matters most: it separates what the supplier can fix by writing a document, what needs an accredited laboratory, and what is your own action as buyer or importer.

Requirement	What the supplier typically holds	Typical gap	Risk level	Action needed	Who can close it
EU - Written Declaration of Conformity for this material and grade (Art. 16 Reg. (EC) 1935/2004; Art. 15(2)/39 Reg. (EU) 2025/40), with Annex IV content where plastics are involved	A generic "food grade" certificate, or an ISO 22000 / ISO 9001 certificate	No DoC naming the material, the intended use and the legal basis; use restrictions missing	HIGH	Request a signed, dated DoC per material and grade, in the Annex IV format for plastics	Supplier
EU - PPWR technical documentation (Annex VII): description, drawings and materials, standards list, design assessments, test reports	Scattered QC files and certificates	No structured file; no analysis of the risk of non-conformity	HIGH	Build the Annex VII file before the next shipment	Supplier
EU - PFAS in food-contact packaging: 25 ppb per individual PFAS, 250 ppb total PFAS, 50 ppm including polymeric PFAS (Art. 5(5) Reg. (EU) 2025/40)	A "PFAS-free" claim with no test data behind it	No total-fluorine screening result; no targeted PFAS analysis	HIGH	Total-fluorine screening first, then targeted PFAS analysis if above 50 mg/kg	Accredited lab
EU - Heavy metals: lead + cadmium + mercury + hexavalent chromium not more than 100 mg/kg per item or component (Art. 5(4) Reg. (EU) 2025/40)	Nothing, or a test report on the ink only	No test on the finished packaging or the component as placed on the market	HIGH	Test the finished packaging by product family	Accredited lab
EU - Migration testing: overall migration limit 10 mg/dm ² and applicable specific migration limits under the real use conditions (Annex III and V Reg. (EU) 10/2011)	An undated report issued for a different grade, gauge or food type	Scope mismatch: the report does not cover what you are buying	HIGH	Re-test the actual material under the actual use conditions	Accredited lab
EU - Good manufacturing practice for food-contact materials (Reg. (EC) No 2023/2006): QA/QC system and records	ISO 9001 certificate	ISO 9001 is not FCM GMP; no FCM-specific procedure or release record	MEDIUM	Add FCM GMP procedures and batch release records	Supplier
EU - Labelling and marking: "for food contact" or the Annex II symbol, name and EU address of the responsible operator, restrictions on use (Art. 15 Reg. (EC) 1935/2004); producer identification and a type, batch or serial number from 12 August 2026 (Reg. (EU) 2025/40)	Artwork carrying no food-contact statement and no batch code	Non-compliant label and no recall capability	MEDIUM	Correct the artwork; nominate the EU responsible operator; add the batch code	Buyer + supplier
EU - Traceability one step back and one step forward (Art. 17 Reg. (EC) 1935/2004)	Sales orders and shipping documents only	No link from the delivered lot back to the raw-material lot	MEDIUM	Introduce lot-level raw-material records	Supplier
EU - Bisphenol A restriction in food-contact materials (Reg. (EU) 2024/3190), including coatings and inks	No statement either way	No declaration on BPA content for coatings and can linings	MEDIUM	Written declaration; test only where coatings or linings are involved	Supplier / lab

Requirement	What the supplier typically holds	Typical gap	Risk level	Action needed	Who can close it
EU - Future-facing obligations: recyclability, minimisation and reusability design file (Arts. 6, 10, 11 Reg. (EU) 2025/40, main deadlines 2030) and your own EPR registration (Art. 44)	The word "recyclable" in marketing material; no registration on the buyer side	No design assessment or evidence; the buyer assumes the supplier has registered	LOW, RISING	Start the design file now; register in each member state where you place packaging	Supplier + buyer
US - Authorisation route for every food-contact component: a listing in 21 CFR 175.176/177, an effective Food Contact Notification, or a 21 CFR 170.39 exemption. An FCN covers only the company named in it (21 CFR 170.100(a))	An "FDA approved" statement, or an upstream resin supplier's FCN number	No citable 21 CFR section, and reliance on an FCN the converter is not named in	HIGH	Get the exact citation per component; verify it in the FDA inventories	Supplier + buyer
US - Chemistry and migration data supporting the authorised use (21 CFR 174.5 and the applicable listing)	A report for a different resin, coating weight or food type	Data not representative of the product you are buying	MED-HIGH	Test the actual construction and conditions of use	Accredited lab
US - Country-of-origin marking (19 CFR Part 134) and the state rules: note that food facility registration does not cover food-contact substances (21 CFR 1.227), and that several states restrict intentionally added PFAS in food packaging	A supplier claim of being "FDA registered"; no awareness of state rules	False comfort, plus packaging lawful in one state and not in another	MEDIUM	Mark origin correctly; map the states you sell into and request PFAS data for them	Buyer + supplier

Risk level: HIGH - the document does not exist, or the gap can stop a shipment, a listing or a market entry. MEDIUM - it will be raised by an importer, a customer audit or a surveillance check, and is fixable with paperwork. LOW - not blocking today, but a deadline is already visible.

5. Ranked priority list — what to close first

Tier 1 — before the next order is placed (EU)

The Declaration of Conformity for each material and grade, the PPWR Annex VII technical file, and the PFAS and heavy-metal evidence. Since 12 August 2026 these are conditions for placing food-contact packaging on the EU market, and they come first in any market surveillance request. None of them can be created by the buyer.

Tier 1 — before the next order is placed (US)

The authorisation route for every food-contact component, with a citation you can verify: a 21 CFR section, or an FCN number together with the company it is effective for. An FCN held by someone else does not cover your converter.

Tier 2 — before the goods are manufactured

Migration testing under the real conditions of use, and the labelling and batch-marking corrections. Testing is the expensive item, which is why the material and use profile is fixed before a laboratory is instructed: a report produced against the wrong simulant, temperature or contact time is money spent twice.

Tier 3 — in parallel, over one or two quarters

Food-contact GMP procedures and batch release records, lot-level traceability, and the BPA statement for coatings and inks. Inexpensive to fix, and the first thing a customer audit looks at.

Tier 4 — start now, deadline visible

The recyclability, minimisation and reusability design file (Arts. 6, 10, 11), and your own EPR registration in each member state where you place packaging (Art. 44). The 2030 deadlines look distant; the design file is built from data that has to be collected now.

6. Document request list — forward this to your supplier

Written so that it can be sent as it stands, in English, without further editing. It asks for answers rather than for documents in the abstract, and it tells the supplier that a refusal is an acceptable answer, which is what makes the replies worth reading.

Document request - food-contact packaging. Please answer every numbered line. If you cannot provide an item, say so in writing. Do not send a substitute document instead.

1. Company and factory: full legal name, registered address, and the address of the plant that will actually produce this order. Name the entity that will issue the invoice.
2. Product identification: material and grade of every layer, coating weight per square metre, and the printing inks and adhesives used by brand and type.
3. Declaration of Conformity, one per material and grade: signed, dated, on company letterhead, naming this material and the intended use. Give the regulation it is issued under.
4. For plastic layers, the Declaration of Conformity in the Annex IV format of Regulation (EU) No 10/2011, stating the food types, the maximum temperature, the maximum contact time and any restriction on use.
5. Migration test reports: overall migration and the specific migration limits that apply, with the accredited laboratory name and accreditation number, the report date, a photograph or description of the sample tested, and the test conditions (food simulant, temperature, time).
6. PFAS: total fluorine result, and targeted PFAS analysis if total fluorine exceeds 50 mg/kg. State which laboratory did the work.
7. Heavy metals: lead, cadmium, mercury and hexavalent chromium on the finished packaging or component, with the test method.
8. Good manufacturing practice for food-contact materials: your FCM procedure, your batch release record, and the certificate and scope of any quality system you hold. State clearly whether ISO 9001 is being offered in place of FCM GMP.
9. Traceability: how a delivered lot can be traced back to the raw-material lot, and what records you keep.
10. Bisphenol A: written statement on whether BPA or BPA-based substances are used in the material, coatings or inks.
11. Labelling: the artwork or a specimen label showing the food-contact statement and the name and address of the operator responsible in the destination market.
12. Batch marking: how the type, batch or serial number is applied.
13. United States only: for every food-contact component, the exact authorisation - the 21 CFR section number, or the FCN number together with the name of the company the FCN is effective for, or the 21 CFR 170.39 exemption. State whether you are named in that FCN.
14. United States only: chemistry or migration data supporting the authorised use for this specific construction and food type.
15. Any change control: tell us in advance about any change of resin supplier, ink, adhesive, coating weight or plant, and reissue the affected documents when a change is made.

Reading the replies

- A refusal is information. A supplier who says "we do not have that" is more useful to you than one who sends a document that does not cover your material.
- Check the scope of every document: the material, the grade, the plant, the food type and the test conditions. A correct-looking report for the wrong product is the most common failure I see.
- Check the dates and the issuer. An accredited laboratory report has an accreditation number and a sample description. A declaration of conformity has a date and a signature.
- Treat certificates as supporting evidence, not as the answer. ISO 9001 does not address food-contact compliance, and no certificate replaces the declaration or the test report that the market requires.

7. What I do not do

Scope and status

This is a sample of the deliverable. It describes the method and the shape of the output, not the result of a real assignment. No client, supplier, product or project is depicted, and no confidential information from any real engagement appears anywhere in it.

Not legal advice

This document does not provide legal advice, a legal opinion, or a statement of your obligations under any law. Regulatory interpretation is for your own counsel or regulatory consultant in the market concerned.

Not a certificate and not a test report

I do not issue certificates, conformity declarations, accreditation marks or test reports, and I do not sign them on anyone's behalf. A Declaration of Conformity is issued by the manufacturer; a test report is issued by an accredited laboratory.

Testing

Any chemical testing must be performed by an accredited third-party laboratory, on samples drawn from the production you are actually buying, under the conditions of use. I flag which tests are needed and review the report for scope and consistency - I do not produce the result.

Point in time

The regulatory summary is compiled from public sources on the date shown and is a working baseline. Requirements change, and some of the 2027-2030 deadlines depend on implementing acts that are not yet final. Verify before you rely on it for a shipment.

Documents only

This is a desk-based document check. It is not a factory audit, not a sampling visit, and not an inspection of production. Physical verification is a separate service.

8. Basis and sources

Compiled on 2026-09-29 from the public sources below. Where a requirement was not confirmed at source in the form stated, it is written more generally and marked as such in section 7.

- Regulation (EU) 2025/40 (PPWR), OJ L, 22 January 2025 - eur-lex.europa.eu/eli/reg/2025/40/oj
- PPWR application from 12 August 2026, Art. 5 limits, Annex VII content and 5/10-year retention - packaging-journal.de/en/ppwr/ and packaging-journal.de/en/ppwr/technical-documentation/
- PPWR Art. 5(4) heavy metals, PFAS thresholds and the 12 August 2026 marking obligations - noerr.com/en/insights/new-eu-packaging-regulation-what-companies-must-now-take-into-account
- PFAS thresholds and Commission communication C/2026/3084 (OJ, 10 June 2026) three-step testing approach - ine.fr/en/node/6039
- Regulation (EC) No 1935/2004 Arts. 15, 16 and 17 - legislation.gov.uk/eur/2004/1935 ; declaration of compliance content under Annex IV of Reg. (EU) No 10/2011 - packaginglaw.com
- Regulation (EU) No 10/2011: Annex I Union list, 10 mg/dm² overall migration limit, Annex IV declaration, and amendment (EU) 2025/351 - ruokavirasto.fi (Plastic regulation (EU) 10/2011)
- Regulation (EC) No 2023/2006 on good manufacturing practice for food-contact materials - eur-lex.europa.eu (consolidated text)
- Regulation (EU) 2024/3190 on bisphenol A in food-contact materials - eur-lex.europa.eu/eli/reg/2024/3190/oj
- FDA, Packaging & Food Contact Substances, and Understanding How the FDA Regulates Substances that Come into Contact with Food - fda.gov
- 21 CFR 170.100 and 170.39 (FCN scope; threshold of regulation), 21 CFR 1.227 (food excludes food contact substances), 21 CFR 174.5, 175.300, 176.170, 177.1520 - law.cornell.edu / ecfr.gov
- 19 CFR Part 134 (country-of-origin marking) - ecfr.gov
- State-level restrictions on intentionally added PFAS in food packaging (multi-state summaries) - BCLP and Shipman & Goodwin client publications

Scope note: this document is an illustrative sample of a documentation gap check. It is not a certificate, not a declaration of conformity, not a laboratory test report and not legal advice. No client, supplier or project is depicted. The regulatory summary is a point-in-time working baseline compiled on 2026-09-29 and must be re-verified before it is relied on for a shipment.