

EUROFINS CERTIFICATION FAQ

YOUR PATH TO EUROFINS PROTOCOL 102 COMPLIANCE

Why are we certifying against EU regulations versus US?

The certification program incorporates EU and EFSA-derived reference values within its defined certification scheme to address chemical contaminants for which infant formula regulations have not yet been established in other regions. EFSA benchmarks are applied because they are grounded in robust toxicological evaluations and, where available, dietary exposure assessments that account for sensitive populations such as infants. This results in risk-based reference values that support consistent, objective conformity assessment

By using these well-defined benchmarks, the program ensures transparency, scientific credibility, and avoids the acceptance gaps that can arise in jurisdictions lacking established regulatory limits. This approach is applied consistently to all applicants and is formally documented within the certification scheme.

What is the cost to certify my product?

Certification costs vary based on the number of products submitted and the number of manufacturing facilities included in the application. To receive an accurate quote, please contact EarlyNutrition@us4.eurofins-info.com.



How long does the certification process take?

Timelines depend on documentation readiness, audit availability, and sample logistics. After receiving a completed application, we review the materials, request any necessary clarifications, and evaluate audit availability typically within an 8–12-week scheduling window. Once availability is determined, initial audit dates are typically identified within 1–2 weeks.

Testing submissions supporting certification applications each take approximately 2 to 3 weeks.

What is the difference between Eurofins P102 certification and other contaminants programs?

Eurofins Protocol 102 certification evaluates conformity to defined, risk-based requirements grounded in regulatory standards and scientific best practices for infant formula. The program focuses on documented manufacturing controls, contaminant testing, and third-party verification. For a full list of these regulatory references, please contact EarlyNutrition@us4.eurofins-info.com

What information will I need to get started?

To begin, you'll need to provide:

- Complete formulation information, including:
 - the full composition of the product, expressed either as percentages or parts by weight for each ingredient, including nutrients, technological additives, etc.;
 - the component ID number (if applicable) for each ingredient, and chemical or material name;
 - a full list of packaging part numbers used to contain the finished product;
- A label for each representative product to be certified, including each product format and/or unique serving size;
- An accredited third-party certification to a GFSI benchmarked program with certification scope appropriate for infant formula manufacturing. These include, but are not limited to:
 - SQF Food Safety Code – Food Manufacturing (with infant formula applicability)
 - FSSC 22000 (food manufacturing)
 - BRCGS Food Safety (product category: dairy, scope infant formula manufacturing and/or packing)
- Any other documentation as determined necessary by Eurofins to evaluate product or good manufacturing practices (GMP) compliance as outlined in Eurofins Protocol 102 and Eurofins Assurance Product Certification Policies and Procedures. If preferred an NDA can be put into place prior to information being shared.

What happens after I sign the quote?

After signing, we'll schedule an engagement call to review key contacts, confirm the information provided and outline next steps in the certification process.

What if I use a contract manufacturer?

That's perfectly acceptable. Just ensure your manufacturer agrees to collaborate with us. We'll work directly with them to obtain the required information and conduct necessary audits or testing.

What if my product fails certification?

In the case of a noncompliant result, Eurofins Assurance will notify the Client and provide general options for resolution based upon the nature of the failure. The Client is responsible for investigating the cause of the failure and providing a written response with the root cause, corrective and preventive actions (a CAPA) within thirty (30) calendar days. Eurofins Assurance will review all documentation and determine if the nonconformance is resolved and if additional testing is required to validate that the correction fully resolves the issue.

What if I change my product's formulation, manufacturer, or label after certification?

Any changes made to a Eurofins-certified product—including ingredients, manufacturing site, or label claims—must be reported to Eurofins Assurance before the change is made. We'll assess whether documentation updates or retesting are needed to maintain certification. This will ensure your product's continued compliance with the Eurofins P102 standards.

How long does the certification last?

Certification remains valid unless withdrawn by you or Eurofins Assurance due to non-compliance or voluntary exit. Certification is maintained through annual audits of each manufacturing facility and product testing. If certification is in place, Eurofins will perform these audits and testing according to program policies and procedures. To remain compliant, certified products must undergo:

- Annual verification of formulation
- Facility audits to ensure continued adherence to manufacturing standards
- Notification and review of any changes to ingredients, suppliers, or manufacturing sites

How are annual verifications different from initial certification?

The initial certification is done by testing 3 lots of the product required to be certified. The annual re-certification will involve testing 3 lots/batches of the same product purchased independently by Eurofins from retail. The annual facility audit requirement does not change.

Ready to begin your certification journey?

Visit [Eurofins Product Certification](#) to complete the onboarding form and take the first step toward earning your Eurofins mark of quality and trust.

Need assistance or have questions?

Our team is here to help—reach out anytime at EarlyNutrition@us4.eurofins-info.com

