

## Specific Business Requirements

### For ESAN Portfolio

#### Technical & Regulatory Requirements for ESAN

##### **Terms and Conditions of Trading:**

With reference to the Terms and Conditions of Trading the following will apply:

- a) All products must comply with all relevant European Union and national legislation, regulations, directives, or practices and any other requirements, which may from time to time be in force, relating to the supply, offer for sale, sale, and safety of the products, for all countries in which they are offered for sale.
- b) The Supplier to provide all documentation required by ESAN procurement or any European Union or national or local governmental authority or agency necessary to prove and demonstrate compliance with the requirements of paragraph (a) above and any required marks such as CE mark. The Supplier shall supply only products so certified.
- c) The Supplier to ensure that all tests necessary to obtain certification under (a) or (b) above have been carried out in accordance with any and all applicable legislation, requirements, rules or regulations, and that any and all such tests are conducted by a test house approved by the European Union, as may from time to time appear in the Official Journal of the European Union.
- d) Supplier warrants that product claims shall at all times be true and accurate. The Supplier shall, upon the request of ESAN Procurement, and as may otherwise be required by any national or local governmental authority or agency immediately provide any and all documentation necessary to prove or otherwise substantiate any and all product claims.
- e) In accordance with REACH Regulation (EC) No 1907/2006, Article 33(1), the Supplier must notify ESAN Procurement if any article supplied contains a Substance of Very High Concern (SVHC) in a concentration above 0.1% w/w. Where applicable, the Supplier is responsible for submitting a SCIP notification to the European Chemicals Agency (ECHA) prior to placing the article on the EU market and must provide ESAN with the SCIP number or dossier reference upon request. The list of SVHCs is updated periodically; therefore, the Supplier must maintain ongoing surveillance and ensure compliance with the latest Candidate List published by ECHA.

##### **Product Specifications**

Following written notification from ESAN procurement that you have been provisionally selected, you will be issued product specification referred to in the Terms and Conditions of Trading. These will be drafted by the Research and Development (R&D) department and submitted to the supplier. The product specifications are part of the Trading Terms and Conditions between both parties.

The Product Specifications used are product specific. The product specification drafts are submitted to the supplier by the R&D department or ESAN PROCUREMENT for the document to be completed, signed and returned. The product specification is a working document updated when required with information incited by R&D or ESAN PROCUREMENT and signed off by the supplier to implement the agreed updates.

Each product requires 'Certificate of Analysis' 'Certificate of Quality' 'Certificate of Free Sale' and 'Certificate of Compliance', templates of these forms upon request can be sent to the supplier by ESAN PROCUREMENT or R&D.








**Please refer to the Product Specification for specific product requirements or contact the Research & Development (R&D) department if you have any concerns.**

**Please see the following information for examples of some of the current legislation that are product specific, this information is subject to change.**

##### **Mobius Symbols:**

Packaging component materials must be labeled with the triangular international symbol (mobius logo). This mobius symbols must be visible on the outside of the packaging with the number and letter designation for the type of material used.

Mobius symbols for packaging Plastics Coding System consists of a number from 1 to 7 inside a chasing arrows triangle, please see following:

	Polyethylene terephthalate (PET)		Polypropylene (PP)
	High density polyethylene (HDPE)		Polystyrene (PS) or Expandable polystyrene (EPS)
	Unplasticised polyvinyl chloride (UPVC) or Plasticised polyvinyl chloride (PPVC)		Other or O (acrylic, nylon, polycarbonate, PLA and multilayer combination of different plastics)
	Low density polyethylene LDPE		

Materials other than plastics use the same chasing arrows triangle mobius symbol with the letter and number codes as follows:

Material	Code	EU Identification number
Corrugated Fibreboard	PAP	20
Solid Fibreboard	PAP	21
Paper	PAP	22
Wood	FOR	50
Cork	FOR	51

Please ensure that mobius symbols are shown for all packaging components. By accessing the internet, you will be able to obtain any additional mobius symbols that have not been provided above.

Please note that it is the vendor's/factories responsibility to ensure that the correct mobius symbols have been used and are amended if the packaging components should change.

ANZ: [Guideline for recycle symbol:](#)

### REACH Regulation:

Manufacturers will need to ensure that all chemical ingredients used in the products comply with the REACH regulation (2024/2462/EU). All chemical ingredients used in products must be pre-registered and at a later date registered by either the manufacturer, the relevant raw material manufacturer, or the importer into the EU. Access Business Group will require the manufacturer to confirm compliance.

Ukraine: Manufacturers must ensure all chemical substances used in products comply with Ukraine's chemical safety law (Law No. 2804-IX) and Technical Regulation (CMU Resolution No. 946). All substances produced, imported, or placed on the market over 1 tonne/year require prior state registration with the Ministry of Environmental Protection. Importers must confirm compliance.

Food products are exempt.

### Cosmetic Products:

Cosmetic products must comply with Regulation (EC) No 1223/2009, including all relevant annexes such as Annex II (prohibited substances) and other applicable annexes for restricted or allowed substances.

As proof of compliance, Access Business Group (ABG) requires the supplier to provide a complete Product Information File (PIF) in accordance with Article 11 of Regulation 1223/2009. The PIF must include a full Cosmetic Product Safety Report (CPSR), which must be prepared and signed by a qualified safety assessor as defined in Article 10.

The safety assessment must evaluate:

- Human exposure to the finished product,
- The chemical structure of ingredients,
- The toxicological profiles of all ingredients based on available data, and
- The analytical profile of the final formulation.

Access Business Group (ABG), as the Responsible Person (RP) based in the European Union, will ensure that all obligations under Article 4 of the Regulation are fulfilled, including compliance oversight, safety documentation, and product labelling requirements.

All cosmetic product labels must comply with Article 19 of Regulation (EC) No 1223/2009. This includes, but is not limited to:

The name and address of the Responsible Person established in the EU,

- Nominal content at the time of packaging (by weight or volume),
- Date of minimum durability or Period After Opening (PAO),
- Precautions for use, if applicable,
- Batch or lot number,
- Product function, unless it is clear from presentation,
- Full ingredient list using INCI nomenclature.
- Storage and usage conditions,

This information must be indelible, easily legible, and visible on the product packaging and/or container.

All product claims made in relation to cosmetic products must comply with Regulation (EU) No 655/2013, which lays down common criteria for the justification of such claims, including legal compliance, truthfulness, evidential support, honesty, fairness, and enabling informed decision-making by consumers. The Supplier must ensure that all claims are substantiated and, upon request by ESAN Procurement or relevant authorities, must promptly provide the necessary documentation to support them.

Cosmetic products placed on the Ukrainian market must comply with the Technical Regulation on Cosmetic Products (CMU Resolution No. 635/2021), which aligns with the EU Regulation (EC) No 1223/2009 and its relevant annexes.

Manufacturers or importers are responsible for ensuring product labeling meets Ukrainian requirements.

#### ANZ Cosmetic Regulation:

Australia: Follow [AICIS](#) for ingredients, formula, label claims etc. and [Poison standard](#) for labelling DG.

Primary sunscreen and Secondary Sunscreen with SPF >15 classify as a Therapeutic goods. Follow [TGA Sunscreen Guideline](#)

New Zealand: [Cosmetic Group Standard](#)

For further information on Technical and Regulatory requirements please refer to the Technical Specification

#### **Home care Detergent Products:**

Detergents Directives 648/2004/EU and its amendment 907/2006/EC

CLP Regulation: Regulation (EC) No 1272/2008 of the European Parliament and of the council of 16 December 2008 on classification, labelling and packaging of substances and mixture.

For further information on Technical and Regulatory requirements please refer to the Technical Specification.

#### Ukraine:

Manufacturers and importers of detergent products in Ukraine must comply with the Technical Regulation on Detergent Products (CMU Resolution No. 717/2008), which regulates composition, safety, labeling, and environmental impact of detergents.

#### ANZ:

Australia: Follow [AICIS](#) for ingredients and formula, and label claims etc. and [Poison standard](#) for labelling DG.

New Zealand: [Cleaning Product Group Standard](#)

For further information on Technical and Regulatory requirements please refer to the Technical Specification.

#### **Electrical and Battery Operated Products:**

RoHS Directive 2011/65/EU; Hazardous Substances in Electrical and Electronic Equipment:

The RoHS Directive will ban placement into the EU market of new electrical and electronic equipment containing more than designated maximum allowable levels of lead, cadmium, mercury, hexavalent chromium, polybrominated biphenyl (PBB) and polybrominated biphenyl ether (PBDE) flame retardants, effective July 1, 2006. Manufacturers will need to ensure that their products, parts and components comply with RoHS in order to be distributed and sold in the EU.

Manufacturers and importers of electrical and battery-operated products in Ukraine must comply with the Law of Ukraine No. 1875-IX «On Restriction of the Use of Hazardous Substances in Electrical and Electronic Equipment», which is the national equivalent of the EU RoHS Directive 2011/65/EU.

WEEE Directive 2012/19/EU (Waste Electrical and Electronic Equipment)

All battery and mains operated products must comply with the WEEE Directive. Products are required to be manufactured so it is easier to dismantle for recycling and crossed out dustbin logo printed on product or packaging and explanation instructions on consumer recycling.

Low Voltage Directive 2014/35/EU CB Test Report is also required Electromagnetic Compatibility Directive 2014/30/EU

REACH Regulation No 1907/2006 Article 33(1) Obligation

Energy Efficiency Directive 2010/30/EU required for certain domestic electrical products

For further information please refer the website <http://eur-lex.europa.eu>

Ukraine: Waste management for electrical and electronic equipment is governed by the Law of Ukraine No. 1874-IX «On Waste». Manufacturers and importers should ensure product conformity through appropriate testing, certification, and documentation as required by Ukrainian authorities.

ANZ: [Electrical safety standard](#); and [Australian Communication Media Authority](#)

For safety of the product please follow [Product safety standard for coin battery](#).

For further information on Technical and Regulatory requirements please refer to the Technical Specification.

## Food Products & Food Supplements

EU Regulations which need to be followed for all kind of products are EU General Food Law (Reg (EC) 178/2002), Food Additives (Reg (EC) 1333/2008) and (Reg (EU) 231/2012), Labelling (Reg (EU) 1169/2011), Health Claims (Reg (EC) 1924/2006 and Reg (EU) 432/2012), Flavourings (Reg (EC) 1334/2008), Hygiene (Reg (EC) 852/2004, Reg (EC) 853/2004 and Reg (EC) 854/2004) and all connected regulations, Contaminants (Reg (EU) 915/2023), Microbiology (Reg (EC) 2073/2005), Novel Food (Reg (EU) 2283/2015 and Reg (EU) 2470/2017), Extraction Solvents (Dir 2009/32/EC), Food Enzymes (Reg (EC) 1332/2008), Pesticides (Reg (EC) 396/2005), etc. (listing may be incomplete due to constant regulatory updates). There are special regulations for special food products, here are listed only a few examples: Meal Replacements (Reg (EU) 609/2013), Fortified Food (Reg (EC) 1925/2006), Food Supplements (Directive 2002/46/EC). Furthermore, there are several non-harmonized national requirements to be taken into account, for instance upper levels on vitamins & minerals and the acceptability of botanicals and herbals. All products must not be subject to GMO labelling and must be compliant with Reg (EC) 1829/2003 and Reg (EC) 1830/2003 and must not be irradiated or treated with Ethylene Oxide.

Non-EU countries like Switzerland, Norway, UK, Turkey, South Africa, Australia & New Zealand may have more or less differing Regulations. It is highly recommended to come to an understanding with R&D before starting a project with at least one of these countries involved.

Ukraine: Law of Ukraine No. 771/97 is equivalent to EU General Food Law (Reg (EC) 178/2002, Hygiene (Reg (EC) 852/2004)

Order № 45 "On Approval of Requirements for Food Flavourings, Food Additives, and Food Enzymes" is equivalent to Food Additives (Reg (EC) 1333/2008), Flavourings (Reg (EC) 1334/2008, Enzymes (Reg (EC) 1332/2008)

Law No. 2639-VIII is equivalent to Labelling (Reg (EU) 1169/2011

Order № 1145 is equivalent to Health Claims (Reg (EC) 1924/2006 and Reg (EU) 432/2012)

Order № 813 is equivalent to Reg (EC) 853/2004

Order № 368 is equivalent to Contaminants (Reg (EU) 915/2023

Order № 548 is equivalent to Microbiology (Reg (EC) 2073/2005

Order № 625 is equivalent to Pesticides (Reg (EC) 396/2005

Order № 1114 is equivalent to Food Supplements (Directive 2002/46/EC)

Others (i.e. Extraction Solvents Dir 2009/32/EC etc)

ANZ: Food regulation: [Food Standard Australia and New Zealand](#)

Food Supplement/Dietary Supplements: Need a listing with [Therapeutic Goods Administration](#) as a listed medicine.

For import of animal or dairy ingredients into Australia, need [BICON permit](#).

## Food Contact Products:

Food contact products require certification, confirming compliance with European Framework Regulation (EU) 1935/2004 on Materials & Articles intended to come in contact with food, Reg. (EU) 10/2011 on plastic materials and articles intended to come into contact with food, Reg. (EU) 2025/40 on packaging and packaging waste, and any additional relevant regulation related to the specific material.

Health Certificates are required if the product is being supplied into Türkiye.

Ukraine: Food contact products in Ukraine require Declaration confirming compliance with the **Law of Ukraine № 2718-IX "On Materials and Articles Intended to Come into Contact with Food Products"** and a set of implementing regulations. These regulations define both general safety and hygiene requirements and specific rules for certain material types. Notably, written **declarations of conformity** are required for materials and articles covered by **special requirements**, and the structure and content of such declarations are strictly regulated by **Order № 2343 "Requirements for the Written Declaration of Conformity for Food Contact Materials and Articles and the List of Supporting Documents"** (provides the mandatory content and format of the declaration)

The relevant implementing acts include:

- **Order № 2343**— *Special Requirements for Plastic Materials and Articles Intended for Food Contact*;
- **Order № 2199** — *Requirements for Materials and Articles Containing Vinyl Chloride Intended for Food Contact*;
- **Order № 2373** — *Requirements for Ceramic Articles Intended for Food Contact*;
- **Order № 2374** — *Requirements for Materials and Articles Made from Regenerated Cellulose Film Intended for Food Contact*;
- **Order № 460** — *Special Requirements and Detailed Rules for the Circulation of Plastic Tableware Made of Polyamide and Melamine*.

ANZ: [Food Standard Australia and New Zealand code provide food contact packaging](#)

### EU Toy Safety Directive 2009/48/EU

For further information on Technical and Regulatory requirements please refer to the Technical Specification.

ANZ: [Australian Competition and Consumer Commission safety standards.](#)

### Costume Jewellery Regulations

REACH ANNEX XVII Nickel release for metal parts that come into prolonged contact with the skin EN 1810 Body piercing post assemblies

EN 1811:2011+A1:2015 Nickel release for metal parts that come into prolonged contact with the skin

EN 12472 Method of simulation of wear and corrosion for the detection of nickel release from coated items

EU 836/2012 Total lead content in metal EU494/2011 Total cadmium content in metal

EN1122 for Total cadmium content in plastics and paints and coatings

ANZ: [Australian Competition and Consumer Commission safety standards.](#)

### Textile Products

REACH ANNEX XVII Nickel release for metal parts that come into prolonged contact with the skin REACH Directive 1907/2006 Restriction of Chemicals Annex XVII

EN ISO 6330 Dimensional stability( +/-5%)

EN ISO 3071 for Textiles,

EN ISO 4045 for leather

REACH Directive 1907/2006/ Free Formaldehyde EN ISO 14184-1

EC & amend.552/2009/EC, azocolourants EN14362 Textile Pentachlorophenol (PCP), ortho Phenylphenol (OPP), Dimethyl Fumarate (DMF)

EN 1811:2011 + A1:2015 Nickel release for metal parts in contact with the skin Colour fastness to water EN ISO 105 E01

Colour fastness to rubbing EN ISO 105 X12 PH 4.0-8.5 Test

Fibre composition verification

EN ISO 6330:2001 Appearance after wash as care label

ANZ: [Australian Competition and Consumer Commission safety standards.](#)

### Leather and PU Bag Regulations

REACH ANNEX XVII Nickel release for metal parts that come into prolonged contact with the skin REACH Directive 1907/2006/EC & amend.552/2009/EC, azocolourants

REACH Directive 1907/2006 Restriction of Chemicals Annex XVII

ANZ: [Australian Competition and Consumer Commission safety standards.](#)

Leather may need [BICON permit](#).

### Sunglasses Regulations

Personal Protective Equipment Directive 2016/425 EEC

REACH ANNEX XVII Nickel release for metal parts that come into prolonged contact with the skin

Ukraine: National standards (DSTU EN/ISO) are used as recognized testing methods for verifying compliance.

Australia: [Product safety guideline for sunglasses.](#)

### Packaging Requirements:

All packaging must comply with the EU Packaging and Packaging Waste Regulation (PPWR), this regulation introduces legally binding targets for recyclability, reuse, and recycled content, as well as standardised labelling requirements for all packaging components.

The Supplier is responsible for ensuring all packaging used complies with these obligations, including:

- Packaging design for full recyclability,
- Reduction of empty space and excessive packaging,
- Compliance with digital labelling and traceability systems,
- Phased adoption of recycled content targets in plastic packaging.

ESAN Procurement will provide further implementation guidance as new rules come into force.

EU Packaging and Packaging Waste Regulation (PPWR), expected to apply progressively from 2025 onward.

Until the above EU PPWR regulations are in force all packaging must comply with the European Directive 94/62/EC. It is specified in the requirements of the directive, that the maximum permitted limit for total lead, hexavalent chromium, cadmium and mercury in packaging is 100ppm. CEN Report CR 13695-1:2000 contains suggested test methods to use for packaging materials.



If a polyethylene bag is part of the packaging and has an opening diameter of 190mm or more and is less than 40 micrometers thick it must carry a suffocation warning in all required languages.

Translation of the required suffocation warning is available from European Strategic Procurement in all required languages. It is acceptable to have polyethylene bags (PE) with a thickness over 40 micrometers with no suffocation warnings or polypropylene (PP) with no suffocation warnings.

**Plastic in Products**

All individual plastic components of all products and packaging must comply with REACH Directive no 1907/2006 Annex XVII. Please use the total cadmium test method EN1122. All plastic components are required to have less than 100ppm total cadmium content in all production batches of plastic raw materials.

**Eliminating Mould in Product Shipments:**

It is important to control the moisture in our products and to prevent mould growth in any shipments sent to ABG. Please use plastic tape adhesive on boxes instead of paper tape.

Ensure any wet process the product has been subjected to during production is full dry before packing.

The products should be protected from moisture and kept in a controlled humidity area during production and storage after packing.

The fungicide DMF dimethyl fumarate used to control mould growth has been banned in Europe. Please use an alternative where required, that complies with the European regulations to prevent mould growth.

Silica gel sachets absorb moisture but do not inhibit the growth of mould. Here is suggested alternative anti-mould patches that can be used, which are produced by a company called Micro-Pak Ltd ([website www.micropakltd.com](http://www.micropakltd.com)).

For the regulation on wood packaging please refer to 'Shipping – Pallets' section on Portal.

**Implication of Non Conformity:**

In the event that the Supplier supplies products which do not conform with the provisions as detailed above, these products may be returned to the Supplier or the country of origin (if different) at the Supplier's expense. The price of such non-conforming products may, with the Supplier's agreement, be deducted from sums otherwise payable to the Supplier in relation to other products or batches of products, save that if the price payable has already been paid, Access Business Group Companies may require immediate reimbursement of same, such reimbursement in no circumstances to take place later than 10 days following such a request.