



Wuhu Pacific Plastic Co., Ltd

Product Compliance & Certification Management System (Official English Version)

Company: Wuhu Pacific Plastic Co., Ltd

Applicable Product: Reusable Plastic Tableware

Covered Compliance Standards: ISO 9001 Quality Management, US FDA Food Contact Regulation, EU Food Contact Regulation, EU REACH Regulation

Document Purpose: This system standardizes the company's full-process product compliance control, certification maintenance, regulatory verification and market access management. It ensures all reusable plastic tableware fully meets global mainstream quality and food-contact safety requirements for domestic and overseas sales, including the United States and European markets, achieving standardized, traceable and fully compliant product delivery.

Effective Date: Immediately Valid

1. General Provisions

1.1 Management Objectives

To establish a full-life-cycle product compliance management mechanism, strictly implement ISO 9001 quality standard, US FDA food contact requirements, EU food contact regulations and REACH chemical compliance rules. Eliminate non-compliant materials and processes, ensure all products meet international market access standards, maintain valid certification status, and support long-term stable export business and customer audit requirements.

1.2 Scope of Application

This system applies to raw material selection, incoming inspection, production process control, finished product testing, certification maintenance, document

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management, market access and customer compliance declaration of all reusable plastic tableware produced by Wuhu Pacific Plastic Co., Ltd.

1.3 Core Compliance Principles

1. Standard alignment: All production and testing strictly match ISO, FDA, EU and REACH regulatory requirements;
2. Source control: Only compliant raw materials and additives are allowed for food-contact production;
3. Full traceability: Compliance batches, test reports and supplier data are fully archived;
4. Dynamic update: Timely follow up international regulation updates and adjust internal control standards;
5. Zero compromise: Prohibit non-compliant materials and non-certified products from mass production and shipment.

2. Compliance Management Organization & Responsibilities

The company establishes a dedicated compliance management group to ensure professional, unified and effective international standard compliance management.

2.1 Senior Management

1. Approve the company's global product compliance policy and standard implementation specifications;
2. Guarantee funds and resources for product testing, certification renewal and compliance training;
3. Review major compliance risk assessment results and approve rectification plans;
4. Ensure the long-term validity of ISO9001, FDA, EU and REACH compliance qualifications.

2.2 Quality & Production Department



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1. Implement production process control in accordance with international compliance standards;
2. Verify raw material compliance certificates and batch test reports;
3. Conduct internal compliance inspection and control non-compliant processes in real time;
4. Cooperate with third-party certification audits and product testing.

2.3 Purchasing & Supplier Management

1. Strictly screen suppliers with FDA, EU and REACH compliant material qualifications;
2. Collect and archive full valid compliance documents of raw materials and additives;
3. Conduct annual supplier compliance evaluation and eliminate unstable suppliers;
4. Ensure all incoming materials match food-contact grade requirements.

2.4 Sales & Document Management

1. Sort out and manage certification documents, test reports and compliance declarations;
2. Provide standardized compliance documents for customer audits and customs clearance;
3. Collect overseas market regulation updates and feed back to internal departments;
4. Complete product compliance declaration and market access support.

3. ISO 9001 Quality System Compliance Management

The company fully implements ISO 9001 international quality management standards to standardize full-process quality stability and system consistency.

3.1 System Implementation Requirements

Establish standardized quality management procedures covering document control, record management, supplier evaluation, incoming inspection, process control, finished product inspection, non-conforming product handling, internal audit and

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continuous improvement. All production and quality activities are carried out under ISO 9001 standardized management to ensure stable and consistent product quality.

3.2 Certification Maintenance

Maintain the validity of ISO 9001 certification, complete annual surveillance audit and regular recertification on time. Continuously optimize process management according to system audit requirements to ensure the quality management system operates effectively and meets international manufacturing quality standards.

4. US FDA Food Contact Compliance Management

All reusable plastic tableware comply with U.S. FDA 21 CFR Part 177 food contact material regulations, applicable for U.S. market access and export sales.

4.1 Core Compliance Standards

All plastic resins and finished products comply with FDA 21 CFR §177.1520 and relevant food contact provisions. Strictly control monomer residue, additive dosage, heavy metal limit and chemical migration to ensure no harmful substances migrate into food during repeated use.

4.2 Key Control Requirements

1. All raw materials are FDA food-contact grade approved resins without unapproved additives;
2. Strictly control carcinogenic, toxic and harmful substance residues to meet FDA trace limit requirements;
3. Finished products pass FDA standard migration testing under simulated food contact conditions;
4. No BPA, phthalates and other prohibited ingredients are added in the whole production process.

4.3 Document & Test Management

Archive supplier FDA compliance declarations, raw material test reports and finished

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product third-party FDA test reports. Ensure complete traceability documents to support U.S. customs clearance and customer compliance audit.

5. EU Food Contact Compliance Management

Products fully comply with EU food contact plastic regulations, adapting to all EU member states market sales and inspection requirements.

5.1 Core Regulatory Basis

Comply with EU Regulation (EU) No 10/2011 on plastic materials and articles intended for food contact, including overall migration limit, specific substance migration limit and material safety evaluation standards.

5.2 Key Compliance Indicators

1. Overall migration limit ≤ 10 mg/dm² under standard test conditions;
2. Strict compliance with EU restricted substance list for food contact plastics;
3. No abnormal precipitation, odor, color migration and contamination risks;
4. Meet repeated-use food contact safety evaluation requirements.

5.3 Implementation Control

Implement strict batch testing and verification for products exported to EU markets. All production formulas and auxiliary materials are registered and reviewed to ensure full compliance with the latest EU food contact regulatory updates.

6. EU REACH Compliance Management

The company strictly implements EU REACH Regulation (EC) No 1907/2006 to control hazardous substances and SVHC high-concern substances, ensuring environmental and chemical safety compliance for export products.

6.1 Core Control Scope

Fully control SVHC (Substances of Very High Concern), restricted heavy metals,



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persistent toxic substances and prohibited chemical ingredients in raw materials, color masterbatch and finished products.

6.2 Key Compliance Requirements

1. SVHC substance content meets EU REACH limit standards, no excessive high-risk chemicals;
2. Strictly restrict lead, cadmium, mercury, chromium and other heavy metal residues;
3. Prohibit the use of banned phthalate plasticizers and toxic additives;
4. Regularly update the latest REACH restricted substance list and synchronize internal control standards.

6.3 REACH Document Management

Maintain valid REACH test reports and compliance declarations for finished products and raw materials. Complete annual substance screening and testing to ensure continuous compliance with EU environmental chemical regulations.

7. Full Process Compliance Control Mechanism

7.1 Raw Material Access Compliance

All incoming materials must provide matching ISO9001 quality certification, FDA food grade declaration, EU food contact compliance report and REACH chemical safety report. Any material with incomplete documents or unqualified indicators is strictly rejected to ensure zero risk at the source.

7.2 Production Process Compliance

Unified compliant formulas and production processes are adopted. No unauthorized addition of additives, replacement of raw materials or process modification is allowed. The whole production process is isolated from non-food-grade materials to prevent cross-contamination and ensure consistent product compliance.

7.3 Finished Product Compliance Verification



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Finished products are sampled and tested regularly by third-party authoritative institutions to verify FDA, EU food contact and REACH compliance indicators. Only products with qualified test results are allowed to be released and exported.

7.4 Batch Traceability Management

Establish one-to-one batch traceability records of raw material batches, production batches and compliance test reports. Realize full-chain traceability of quality, food safety and chemical compliance to support global customer audits and market supervision.

8. Certification Maintenance & Dynamic Update

The company sets up a special compliance tracking mechanism to monitor the update of ISO, FDA, EU food contact and REACH regulations in real time. Timely adjust internal control standards, production processes and testing items to ensure that products always meet the latest international market access requirements. All certificates and test reports are updated regularly to maintain long-term validity.

9. Compliance Training & Risk Prevention

Carry out regular international compliance training for production, quality and purchasing teams, covering ISO9001 quality specifications, FDA food safety rules, EU food contact standards and REACH hazardous substance control requirements. Improve staff compliance awareness, standardize operational behaviors, and eliminate compliance risks caused by non-standard operation.

10. Continuous Improvement

Combined with third-party testing results, customer compliance feedback, regulatory updates and internal audit findings, the company continuously optimizes product formulas, raw material selection and process control standards. Consistently improve the level of product international compliance management, ensure long-term stability of product quality and safety, and support global market sustainable development.

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