|  |  |
| --- | --- |
| Date of inspection: |  |
| People present: |  |
| Supervisory authority: |  |

|  |  |  |  |
| --- | --- | --- | --- |
| **A. COMPANY INFORMATION** | | | |
| Company name | | | Business ID |
|  | | |  |
| Visiting address/Postal address | | | |
|  | | | |
| Postal code | Town | | |
|  |
| Operator name/contact person | | | |
|  | | | |
| Telephone | | Email | |
|  | |  | |

|  |  |  |
| --- | --- | --- |
| **B. OPERATIONS** | | |
| **Type of operation: Import** | Import from a third country    Import from the internal (EU) market | From which countries? |
| **Distribution/marketing channels** | Own distribution/marketing  Internet marketing, www. address  Contract customers  e-commerce, www. address  Other distance selling, please specify  Only distance selling  Other distributing way, please specify | |
| **Target groups for food contact materials** | The products are intended to be sold directly to the consumers  The products are intended to be sold to food industry operators  The products are sold both directly to consumers and to food industry operators  The products are intended for sale to the food contact materials industry for further processing. | |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Details of operations** | | 1. Active and intelligent materials and supplies  2. Adhesives  3. Ceramics  4. Cork  5. Rubber  6. Glass  7. Ion exchange resins  8. Metals and alloys  9. Paper and paperboard | 10. Plastics  11. Printing inks  12. Regenerated cellulose (= cellophane)  13. Silicones  14. Textiles  15. Varnishes and coatings  16. Waxes  17. Wood  18. Other | |
| If other, please specify | | | | |
| **Purpose of contact materials**  Food packaging materials  Production equipment and devices for the food processing industry  Utensils intended for food storage  Kitchen equipment, tableware, utensils, etc.  Intermediate materials and articles for converting of final food contact materials  Other, please specify | | | | |
| **Other refinements**  Contact materials intended for toddlers (0–3 years old), please specify  Export, please specify destination  Recycled materials, please specify  Surface biocides, please specify | | | | |
| **Scope of operations** | Production volume  < 100 pcs/year or < 10,000 kg/year  100–1,000 pcs/year or 10,000-1 million kg/year  > 1,000 pcs/year or > 1 milj. kg/year  Turnover  < 2 M€/year  2–10 M€/year  > 10 M€/year | | | Floor area of the production and storage facilities  < 100 m2  100–500 m2  > 500 m2  No storage  Number of employees  < 15  15–100  > 100 |
| Miscellaneous (The inspector can enter here further details about the items above, such as matters brought up during discussions or the inspector’s own assessment of the items above) | | | | |
|  | | | | |

|  |
| --- |
| **C. ASSESSMENT OF THE QUALITY MANAGEMENT SYSTEM AND ITS IMPLEMENTATION** |

|  |
| --- |
| Assessment scale for the system and its implementation:  **A** = good, **B** = minor deficiencies, **C** = moderate deficiencies, corrective actions required, **D** = poor or missing entirely, corrective actions required |

|  |  |  |  |
| --- | --- | --- | --- |
| **1. Information of the quality management system** | | **Assesment** | |
|  | | **A**  **B**  **C**  **D** | |
| Own-check | GMP-quality management system | | |
| Complians to which standard? | | regularly certified and audited  When was the last audit performed (year)? | |
|  | |
| Is the responsibility for the compliance of the contact materials determined? | | yes, person (s) in charge?  no | |
| Are the employees competent enough to ensure compliance (are legislative changes followed, are the employees sufficiently trained and is further training available for them, is ensuring compliance considered in training?) | | yes  no | |
| Is the own-check or quality management system updated regularly? | | yes, when was it last updated and which parts were updated?    no | |
| Does the system take into account the management of exceptions and disruptions (product withdrawal plan) | | yes  no |  |
| **Observations** (The inspector can enter here further details about the items above, such as matters brought up during discussions or the inspector’s own assessment of the items above) | | | |
|  | | | |

|  |
| --- |
| Assessment scale for the system and its implementation:  **A** = good, **B** = minor deficiencies, **C** = moderate deficiencies, corrective actions required, **D** = poor or missing entirely, corrective actions required |

|  |  |  |
| --- | --- | --- |
| **2. Management of the composition of imported products** | **Assesment**  **A**  **B**  **C**  **D** | |
|  |
| Does the operator determine the composition and suitability of the materials and supplies selected for import/distribution for the use to which products will be marketed? | yes, always  for some products  no | |
| Does the operator require declarations of compliance for the materials and supplies selected for import/distribution? | yes  no | |
| Has the operator defined in advance what information is required in the declaration of compliance for each material/type of supplies (definition of minimum data)? | yes  no | |
| Does the operator require that the supplier provide research results concerning the contact materials in order to verify the information in the declaration of compliance and in the packaging labels. | yes  no | |
| Suppliers of goods have been selected on the basis of whether they can supply compliant materials and services. | yes  no |  |
| Observations (The inspector can enter here further details about the items above, such as matters brought up during discussions or the inspector’s own assessment of the items above) | | |
|  | | |

|  |  |  |
| --- | --- | --- |
| **3. Testing** | **Assesment**  **A**  **B**  **C**  **D** | |
|  |
| Does the importer carry out tests on imported contact materials on a sample basis or when there are doubts about the conformity of the products? | yes  no |  |
| What investigations have been performed? | | |
|  | | |
| Storage of investigation results | | |
|  | | |
| **Observations** (The inspector can enter here further details about the items above, such as matters brought up during discussions or the inspector’s own assessment of the items above) | | |
|  | | |

|  |
| --- |
| Assessment scale for the system and its implementation:  **A** = good, **B** = minor deficiencies, **C** = moderate deficiencies, corrective actions required, **D** = poor or missing entirely, corrective actions required |

|  |  |
| --- | --- |
| **4. Declarations of compliance supplied to customers** | **Assesment**  **A**  **B**  **C**  **D** |
|  |
| **Are declarations of compliance drawn up for the contact materials?** | yes, to all  yes, to some of them  no |
| **How does the operator draw up its own declaration of compliance?**  Personal name is added to the manufacturer’s declaration of compliance or a cover letter is annexed to it stating the importer’s contact information and role  The operator draws up an entirely new certificate in their own name  Other method, please specify | |
| Language of the declaration of compliance:  Finnish  Swedish  English  Other, please spesify | |
| **Do the declarations contain sufficient information on the contact material?** | yes  partly  no |
| Name and contact details of the issuer of the declaration |  |
| Date of the certificate |  |
| The trade name, name, or other identifying piece of information of the contact material |  |
| Information on the composition and/or structure of the contact material |  |
| Information on the raw materials permitted with certain limitations |  |
| Information on dual-use additives |  |
| **Observations** (The inspector can enter here further details about the items above, such as matters brought up during discussions or the inspector’s own assessment of the items above) | |
| **Does the declaration contain sufficient justification for compliance?** | yes  partly  no |
| References to legislation (EU and/or national legislation |  |
| * *Declarations of compliance to the requirements of the EU regulation 1935/2004 and that the product is manufactured under a quality management system compliant with the EU regulation 2023/2006.* | yes  no |
| * *The declaration of compliance of the plastic materials and supplies complies with the regulation 10/2011* | yes  no |
| * References to other safety references if no EU regulations apply   ***For example***   * *Paper and board – BfR recommendation XXXVI, EDQM technical instruction Paper and board used in food contact materials and articles* * *Metals – Nordic metal guidance Tema Nord 2015:522, stainless steel or aluminium standards, EDQM resolution on metals and alloys* * *Printing inks - EuPiAn printing ink guidelines, Swiss ordinance on printing inks 817.023.21 or Nordic printing ink guideline Thema Nord 2012:521.*   *Adhesives – FDA regulations* | yes  no |

|  |  |  |
| --- | --- | --- |
| Information on the results of studies (e.g. for plastic, overall migration + specific migrations of substances permitted in the regulations)) | | yes  no |
| Other security justification, please specify |  | |
| **Does the declaration contain sufficient information on the intended purpose and restrictions of use?** | | yes  partly  no |
| Types of foodstuffs for which the material is suitable | | |
| Restrictions on operating temperature | | |
| Restrictions on contact time | | |
| **Does the declaration also contain the following information?** | | |
| Information on the active or intelligent properties of the material, effect, and user instructions | | |
| Information on the use of surface biocides | | |
| Information on whether recycled materials were used in the manufacture of the material | | |
| **What other documents of compliance (e.g. risk assessment data, information on the chemical composition of the material, research results) does the operator have in addition to the actual declaration of compliance?** | | |
| **What are the practices for supplying and updating the declarations of compliance?** | | |
| Supplied automatically for all customers in each lot  Supplied only upon request  A new copy of the declaration of compliance is delivered regularly to regular customers, please state the frequency  A new declaration of compliance is delivered if changes have taken place in the composition of the products and/or legislation | | |
| **Observations** (The inspector can enter here further details about the items above, such as matters brought up during discussions or the inspector’s own assessment of the items above) | | |
|  | | |

|  |
| --- |
| Assessment scale for the system and its implementation:  **A** = good, **B** = minor deficiencies, **C** = moderate deficiencies, corrective actions required, **D** = poor or missing entirely, corrective actions required |

|  |  |
| --- | --- |
| **5. Labelling (especially products for consumers)** | **Assesment**  **A**  **B**  **C**  **D** |
|  |
| Before marketing/distributing the products, does the operator ensure, that the markings required by EU Regulation 1935/2004 have been applied (on the product itself, on the packaging or label) or that they are included in the documentation accompanying the consignment from business to business? | |
| yes  no | |
| Manufacturer’s name and contact details | |
| the words ‘for food contact’ or an equivalent label or a symbol indicating suitability for food contact | |
| Operating instructions/restrictions on use if applicable (to be checked from the declaration of compliance and its background documentation) | |
| Labelling is in Finnish and in Swedish | |
| **Observations** (The inspector can enter here further details about the items above, such as matters brought up during discussions or the inspector’s own assessment of the items above) | |
|  | |

|  |  |  |  |
| --- | --- | --- | --- |
| **6. Traceability** | **Assesment**  **A**  **B**  **C**  **D** | | |
|  |
| Is the contact material traceable one step back (where did it come from?) and one step forward (where was it delivered)? | yes  no | | |
| By which labels is the traceability ensured? |  |  |  |
| Can the supplier’s declarations of compliance, inspection results and other supporting documents and the manufacturer’s declaration of compliance be connected to each other and to product itself? | yes  no | | |
| **Observations** (The inspector can enter here further details about the items above, such as matters brought up during discussions or the inspector’s own assessment of the items above) | | | |
|  | | | |

|  |
| --- |
| Assessment scale for the system and its implementation:  **A** = good, **B** = minor deficiencies, **C** = moderate deficiencies, corrective actions required, **D** = poor or missing entirely, corrective actions required |

|  |  |  |
| --- | --- | --- |
| **7. Processing methods/processes** | **Assesment**  **A**  **B**  **C**  **D** | |
|  |
| **Vaara-analyysi ja riskinarviointi** | | |
| * - Description of the import process (description of import, possible storage, and delivery). | yes  no |  |
| * Hazard identification and assessment (whether any risks have been identified in relation to the import, e.g., material, country, or activity specific problems) | yes, please spesify?  no | |
| * Have critical control points or other control points been set and how are they monitored? | yes, please spesify?  no | |
| * Does the operator regularly verify compliance with the instructions and the reliability of the process documentation? | yes, how and how often?  no | |
| **Observations** (The inspector can enter here further details about the items above, such as matters brought up during discussions or the inspector’s own assessment of the items above) | | |
|  | | |
| **Management of cross contamination and/or secondary contamination** | | |
| Has the importer ensured that the products are adequately protected against contamination   * When a delivery is received, the goods are checked to verify that no contamination has occurred during transport * The goods are kept separate from sources of contamination, such as chemicals or waste, sufficiently protected, not in contact with the floor * Contamination during transport is prevented during transport to the customer | yes  no | |
| Have third parties been instructed on how to move in the production or storage area? | yes  no | |
| **Observations** (The inspector can enter here further details about the items above, such as matters brought up during discussions or the inspector’s own assessment of the items above) | | |
|  | | |

|  |
| --- |
| Assessment scale for the system and its implementation:  **A** = good, **B** = minor deficiencies, **C** = moderate deficiencies, corrective actions required, **D** = poor or missing entirely, corrective actions required |

|  |
| --- |
| **D. MEASURES TO BE TAKEN** |
| Guidance and counselling  Request  Start preparing coercive measures |
| Inspector’s statement |
|  |
| Deadline: |
|  |
| Hearing of the operator (if the coercive measures are going to start) |
|  |