|  |  |
| --- | --- |
| 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 (from a third country or the internal market)    Distribution/marketing | From which countries? | | |
| **Distribution/marketing channels** | | Own distribution/marketing  Distribution/marketing via wholesalers of central trading arms  Internet marketing  Contract customers  Other distribution/marketing channel, please specify | | | |
| **Target groups for food contact materials** | | The products are solely intended to be sold directly to the consumers  The products are solely intended to be sold to food industry operators  The products are sold both directly to consumers and to food industry operators | | | |
| **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.  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) | | | | | |
|  | | | | | |

|  |
| --- |
| 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 |

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

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **1. General information on the quality management system** | | **Assessment of the system** | **Assessment of implementation** | |
|  | | **A**  **B**  **C**  **D** | **A**  **B**  **C**  **D** | |
| Own-check plan | GMP quality system | | | |
| Compliant 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 taken into account in training?) | | yes  no | | |
| Is the 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) | | | | |
|  | | | | |

|  |  |  |  |
| --- | --- | --- | --- |
| **2. Management of the composition of imported products** | **Assessment of the system** | **Assessment of implementation** | |
|  | **A**  **B**  **C**  **D** | **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. Investigations of contact materials to be imported** | **Assessment of the system** | **Assessment of implementation** | |
|  | **A**  **B**  **C**  **D** | **A**  **B**  **C**  **D** | |
| Does the importer investigate the contact materials either by random sampling or when non-compliance of the product is suspected? | 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** | | **Assessment of the system** | **Assessment of implementation** | | |
|  | | **A**  **B**  **C**  **D** | **A**  **B**  **C**  **D** | | |
| **Are declarations of compliance drawn up for the contact materials?** | | Yes, to all materials  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 specify | | | | | |
| **Do the declarations contain sufficient information on the contact material?** | | yes  partly  no | 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 | 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 | | yes  no | | | | |
| ***For example***   * *Paper and paperboard - BfR recommendations, paper resolution ResAP (2002) 1* * *Metals – Nordic metal guidance Tema Nord 2015:522, stainless steel or aluminium standards, EU resolution on metals and alloys 2013* * *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* | | | | |
| 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 smart properties of the material, efficiency 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 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 to be attached to the contact materials (consumer products)** | **Assessment of the system** | **Assessment of implementation** |
|  | **A**  **B**  **C**  **D** | **A**  **B**  **C**  **D** |
| Before marketing/distributing the products, does the operator ensure that the labelling required by EU regulation 1935/2004 is present (on the product itself, on the packaging or on the label) | | |
| 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** | **Assessment of the system** | **Assessment of implementation** | |
|  | **A**  **B**  **C**  **D** | **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 conformity, inspection results and other such background documents and the manufacturer’s declaration of compliance be connected to each other? | 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** | **Assessment of the system** | **Assessment of implementation** |
|  | **A**  **B**  **C**  **D** | **A**  **B**  **C**  **D** |
| **Hazard analysis and risk assessment** | | |
| * Description of the import process (description of import and delivery) | yes  no |  |
| * Hazard identification and assessment (have any risks been perceived in the import process, such as problems related to the material, country or operations) | yes, please specify  no | |
| * Have critical control points or other control points been set and how are they monitored? | yes, please specify  no | |
| * Does the operator regularly verify compliance with the instructions and the reliability of the process documentation? | Yes, please specify 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 AS A RESULT OF THE INSPECTION ACCORDING TO VATI 2 (KUTI 2)** |
| Guidance and counselling  Request  Start preparing coercive measures |
| Inspector’s statement |
|  |
| Deadline: |
|  |
| Hearing of the operator |
|  |