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

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

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| **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. |

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

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| 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 |

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| **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 auditedWhen 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) |
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| 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 |

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| **2. Management of the composition of imported products** | **Assesment**[ ]  **A** [ ]  **B** [ ]  **C** [ ]  **D** |
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| 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) |
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| **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) |
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| 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 |

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| **4. Declarations of compliance supplied to customers** | **Assesment**[ ]  **A** [ ]  **B** [ ]  **C** [ ]  **D** |
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| **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 nameOther 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      |

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| 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) |
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| **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) |
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| **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) |
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| 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 |

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| **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) |
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| 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 |

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| **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)  |
|  |