|  |  |
| --- | --- |
| Date of inspection: |  |
| **People present:** |  |
| **Supervisory authority**: |       |
| **A. COMPANY INFORMATION** |
| Company name | Business ID |
|  |  |
| Visiting address/postal address  | Postal code and town |
|       |       |
| Name and e-mail address of the contact person | Telephone number  |
|  |  |
| **B. OPERATIONS** |
| **Type of operation**  | [ ]  Manufacture/further processing[ ]  Import (from a third country or the internal market) [ ]  Distribution/marketing |
| **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       |

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| **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 million kg/year Turnover[ ]  < 2 MEUR/year [ ]  2–10 MEUR/year[ ]  > 10 MEUR/year | Floor area of the production and storage facilities [ ]  < 100 m2[ ]  100–500 m2[ ]  > 500 m2Number 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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| Assessment scale:**A** = compliant, **B** = good, minor deficiencies might exist, **C** = deficiencies that jeopardise food safety, corrective actions must be taken, **D** = = deficiencies that jeopardise food safety, immediate corrective actions required |

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

|  |  |
| --- | --- |
| **1. Information on the quality management system** | **Assessment****[ ]  A** **[ ]  B** **[ ]  C** **[ ]  D** |
|  |  |
| [ ]  Own-check plan | [ ]  GMP quality system |
| Compliant to which standard? |  | When (year)? |
|       | [ ]  certified |  |
| Responsibility for the compliance of the contact materials is specified | [ ]  yes [ ]  no |
| The employees have sufficient resources and know-how to ensure compliance with the requirements | [ ]  yes [ ]  no |
| The quality management system is updated regularly | [ ]  yes [ ]  no |
| The system takes 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 the products** | **Assessment** [ ]  **A** [ ]  **B** [ ]  **C** [ ]  **D** |
| The suppliers of goods have been selected on the basis of whether they can supply compliant materials and services | [ ]  yes [ ]  no |
| When an order for packages is received, the customers are contacted to determine the future operating conditions and the appropriate material quality. | [ ]  yes [ ]  no |
| Written recipes or descriptions of structure exist for the products | [ ]  yes [ ]  no |
| **The following information is available for the raw materials** |  |
| - The raw materials’ chemical names and CAS numbers or generic names or declarations of compliance | [ ]  yes [ ]  no |
| - Information on the basic raw materials and/or raw materials whose use is subject to restrictions | [ ]  yes [ ]  no |
| - Information on components/intermediate products (such as adhesives, varnishes, colouring agents, waxes) | [ ]  yes [ ]  no |
| - The raw materials are in the positive lists of EU legislation(plastics) or have undergone a national safety assessment (for example BfR or FDA) | [ ]  yes [ ]  no |
| - Information on dual-use additives and their concentrations | [ ]  yes [ ]  no |
| - Information on the use of surface biocides and their concentrations | [ ]  yes [ ]  no |
| - Model calculations for the migration from plastics | [ ]  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 performed on manufactured products** | **Assessment** |
|  | [ ]  **A** [ ]  **B** [ ]  **C** [ ]  **D** |
| **Investigations** | [ ]  yes [ ]  partly [ ]  no |
|       |
| **Model calculations** (see the monitoring instructions) | [ ]  yes [ ]  partly [ ]  no |
|       |
| **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) |
|       |
| **4. Declarations of compliance for manufactured products** | **Assessment** |
|  | [ ]  **A** [ ]  **B** [ ]  **C** [ ]  **D** |
| **Declarations of compliance exist for the contact material** | [ ]  yes [ ]  partly [ ]  no |
| **What other compliance documents does the operator have in addition to the actual declaration of compliance?** |
| **The declarations contain sufficient information on the contact material** | [ ]  yes [ ]  partly [ ]  no |
| - Name and contact details of the issuer of the declaration | [ ]  yes |  [ ]  no |
| - Date of the certificate | [ ]  yes |  [ ]  no |
| - The trade name, name or identifying piece of information of the contact material | [ ]  yes |  [ ]  no |
| - Information on the composition and/or structure of the contact material | [ ]  yes |  [ ]  no |
| - Information on the raw materials permitted with certain limitations (specific migration) | [ ]  yes |  [ ]  no |
| - Information on dual-use additives | [ ]  yes |  [ ]  no |
| **The declaration contains sufficient justification for compliance** | [ ]  yes [ ]  partly [ ]  no |
| - References to legislation (EU and/or national legislation) | [ ]  yes [ ]  no |
| - References to BfR or FDA regulations (unless EU regulations) | [ ]  yes [ ]  no |
| - Information on investigations conducted | [ ]  yes [ ]  no |
| - Other justification, please specify  |
| **The declaration contains sufficient information on the intended purpose and restrictions of use** | [ ]  yes [ ]  partly **[ ]**  no |
| - Types of foodstuffs for which the material is suitable | [ ]  yes |  [ ]  no |
| - Restrictions on operating temperature | [ ]  yes [ ]  no |
| - Restrictions on contact time | [ ]  yes [ ]  no |
| **The following information is also present:** |
| - Information on the active or smart properties of the material, efficiency and user instructions | [ ]  yes |  [ ]  no |
| - Information on the use of surface biocides | [ ]  yes |  [ ]  no |
| **Certificate Update Policies:** |       |
| **Additional information on the use of recycled material:** |       |
| **Language of the declarations:** |       |
| **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 to be attached to the contact materials (especially consumer products)** | **Assessment** [ ]  **A** [ ]  **B** [ ]  **C** [ ]  **D** |
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| **Labelling made (on the packaging or on the label)** |
|       |
| - Manufacturer’s name and contact details | [ ]  yes [ ]  no |
| - the words ‘for food contact’ or a symbol indicating suitability for food contact | [ ]  yes [ ]  no |
| - Instructions for use if necessary | [ ]  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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| **6. Traceability** | **Assessment**[ ]  **A** [ ]  **B** [ ]  **C** [ ]  **D** |
|  |
| - Traceability one step back | [ ]  yes [ ]  no |
| - Traceability one step forward | [ ]  yes [ ]  no |
| **Ensuring traceability** |
| - Own records | [ ]  yes [ ]  no |
| - Documents | [ ]  yes [ ]  no |
| **Based on which information?** |
|   |
| **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:**A** = compliant, **B** = good, minor deficiencies might exist, **C** = deficiencies that jeopardise food safety, corrective actions must be taken, **D** = = deficiencies that jeopardise food safety, immediate corrective actions required |

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| **7. Processing methods/processes** | **Assessment**[ ]  **A** [ ]  **B** [ ]  **C** [ ]  **D** |
|  |
| **Hazard analysis and risk assessment** |
| - Description of process | [ ]  yes [ ]  no |
| - Identification and assessment of hazards | [ ]  yes [ ]  no |
| - Critical control points and their monitoring | [ ]  yes [ ]  no |
| - Measures taken to prevent the migration of printing ink | [ ]  yes [ ]  no |
| - Corrective actions | [ ]  yes [ ]  no |
| - Verification | [ ]  yes [ ]  no |
| - Records of control point monitoring | [ ]  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) |
|  |
| **D. MEASURES TO BE TAKEN AS A RESULT OF THE INSPECTION ACCORDING TO VATI (KUTI 2)** |
| [ ]  Guidance and counselling [ ]  Request [ ]  Start preparing coercive measures |
| **Inspector’s statement** |
|       |
| **Deadline**: |
|  |
| **Hearing of the operator** |
|       |