|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| 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 m2  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) | | |
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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** |

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| --- | --- | --- | --- | --- | --- |
| **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) | | | | | |
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| **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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| **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** | |
|  | |