

Date of inspection:	20.9.2022																			
People present:	Ksenia Shigaeva (Clayful) ja Vilja Iivonen (Environment Centre)																			
Supervisory authority:	Hanna Sippola (Environment Centre)																			
<b>A. COMPANY INFORMATION</b>																				
Company name Clayful	Business ID 3213872-5																			
Visiting address/postal address Jänismäentie 3 A	Postal code and town 01260 Vantaa																			
Name and e-mail address of the contact person Ksenia Shigaeva, e-mail: ksenia(at)shigaeva.net	Telephone number 044 245 2149																			
<b>B. OPERATIONS</b>																				
Type of operation	<input checked="" type="checkbox"/> Manufacture/further processing <input type="checkbox"/> Import (from a third country or the internal market) <input type="checkbox"/> Distribution/marketing																			
Distribution/marketing channels	<input type="checkbox"/> Own distribution/marketing <input checked="" type="checkbox"/> Distribution/marketing via wholesalers of central trading arms <input checked="" type="checkbox"/> Internet marketing <input type="checkbox"/> Contract customers <input checked="" type="checkbox"/> Other distribution/marketing channel, please specify																			
Target groups for food contact materials	<input type="checkbox"/> The products are solely intended to be sold directly to the consumers <input type="checkbox"/> The products are solely intended to be sold to food industry operators <input checked="" type="checkbox"/> The products are sold both directly to consumers and to food industry operators																			
Details of operations	<table border="0"> <tr> <td><input type="checkbox"/> 1. Active and intelligent materials and supplies</td> <td><input type="checkbox"/> 10. Plastics</td> </tr> <tr> <td><input type="checkbox"/> 2. Adhesives</td> <td><input type="checkbox"/> 11. Printing inks</td> </tr> <tr> <td><input checked="" type="checkbox"/> 3. Ceramics</td> <td><input type="checkbox"/> 12. Regenerated cellulose (= cellophane)</td> </tr> <tr> <td><input type="checkbox"/> 4. Cork</td> <td><input type="checkbox"/> 13. Silicones</td> </tr> <tr> <td><input type="checkbox"/> 5. Rubber</td> <td><input type="checkbox"/> 14. Textiles</td> </tr> <tr> <td><input type="checkbox"/> 6. Glass</td> <td><input type="checkbox"/> 15. Varnishes and coatings</td> </tr> <tr> <td><input type="checkbox"/> 7. Ion exchange resins</td> <td><input type="checkbox"/> 16. Waxes</td> </tr> <tr> <td><input type="checkbox"/> 8. Metals and alloys</td> <td><input type="checkbox"/> 17. Wood</td> </tr> <tr> <td><input type="checkbox"/> 9. Paper and paperboard</td> <td><input type="checkbox"/> 18. Other</td> </tr> </table>		<input type="checkbox"/> 1. Active and intelligent materials and supplies	<input type="checkbox"/> 10. Plastics	<input type="checkbox"/> 2. Adhesives	<input type="checkbox"/> 11. Printing inks	<input checked="" type="checkbox"/> 3. Ceramics	<input type="checkbox"/> 12. Regenerated cellulose (= cellophane)	<input type="checkbox"/> 4. Cork	<input type="checkbox"/> 13. Silicones	<input type="checkbox"/> 5. Rubber	<input type="checkbox"/> 14. Textiles	<input type="checkbox"/> 6. Glass	<input type="checkbox"/> 15. Varnishes and coatings	<input type="checkbox"/> 7. Ion exchange resins	<input type="checkbox"/> 16. Waxes	<input type="checkbox"/> 8. Metals and alloys	<input type="checkbox"/> 17. Wood	<input type="checkbox"/> 9. Paper and paperboard	<input type="checkbox"/> 18. Other
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If other, please specify																				
Purpose of contact materials <input type="checkbox"/> Food packaging materials <input type="checkbox"/> Production equipment and devices for the food processing industry <input type="checkbox"/> Utensils intended for food storage																				

<input checked="" type="checkbox"/> Kitchen equipment, tableware, utensils, etc. <input type="checkbox"/> Other, please specify		
Other refinements <input type="checkbox"/> Contact materials intended for toddlers (0–3 years old), please specify  <input checked="" type="checkbox"/> Export, please specify destination worldwide  <input type="checkbox"/> Recycled materials, please specify  <input type="checkbox"/> Surface biocides, please specify		
Scope of operations	Production volume <input checked="" type="checkbox"/> < 100 pcs/year or < 10,000 kg/year <input type="checkbox"/> 100–1,000 pcs/year or 10,000-1 million kg/year <input type="checkbox"/> > 1,000 pcs/year or 1 million kg/year  Turnover <input checked="" type="checkbox"/> < 2 MEUR/year <input type="checkbox"/> 2–10 MEUR/year <input type="checkbox"/> > 10 MEUR/year	Floor area of the production and storage facilities <input checked="" type="checkbox"/> < 100 m <sup>2</sup> <input type="checkbox"/> 100–500 m <sup>2</sup> <input type="checkbox"/> > 500 m <sup>2</sup>  Number of employees <input checked="" type="checkbox"/> < 15 <input type="checkbox"/> 15–100 <input type="checkbox"/> > 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

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

1. Information on the quality management system	Assessment <input checked="" type="checkbox"/> A <input type="checkbox"/> B <input type="checkbox"/> C <input type="checkbox"/> D
<input checked="" type="checkbox"/> Own-check plan	<input type="checkbox"/> GMP quality system
Compliant to which standard?	<input type="checkbox"/> certified <span style="float: right;">When (year)?</span>
Responsibility for the compliance of the contact materials is specified	<input checked="" type="checkbox"/> yes <input type="checkbox"/> no
The employees have sufficient resources and know-how to ensure compliance with the requirements	<input checked="" type="checkbox"/> yes <input type="checkbox"/> no
The quality management system is updated regularly	<input checked="" type="checkbox"/> yes <input type="checkbox"/> no
The system takes into account the management of exceptions and disruptions (product withdrawal plan)	<input checked="" type="checkbox"/> yes <input type="checkbox"/> 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) It is important to write down the batch numbers of raw materials.	
2. Management of the composition of the products	Assessment <input checked="" type="checkbox"/> A <input type="checkbox"/> B <input type="checkbox"/> C <input type="checkbox"/> D
The suppliers of goods have been selected on the basis of whether they can supply compliant materials and services	<input checked="" type="checkbox"/> yes <input type="checkbox"/> no
When an order for packages is received, the customers are contacted to determine the future operating conditions and the appropriate material quality.	<input checked="" type="checkbox"/> yes <input type="checkbox"/> no
Written recipes or descriptions of structure exist for the products	<input checked="" type="checkbox"/> yes <input type="checkbox"/> 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	<input checked="" type="checkbox"/> yes <input type="checkbox"/> no
- Information on the basic raw materials and/or raw materials whose use is subject to restrictions	<input checked="" type="checkbox"/> yes <input type="checkbox"/> no
- Information on components/intermediate products (such as adhesives, varnishes, colouring agents, waxes)	<input type="checkbox"/> yes <input checked="" type="checkbox"/> 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)	<input type="checkbox"/> yes <input checked="" type="checkbox"/> no

- Information on dual-use additives and their concentrations	<input type="checkbox"/> yes <input checked="" type="checkbox"/> no
- Information on the use of surface biocides and their concentrations	<input type="checkbox"/> yes <input checked="" type="checkbox"/> no
- Model calculations for the migration from plastics	<input type="checkbox"/> yes <input checked="" type="checkbox"/> 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)	
<b>3. Investigations performed on manufactured products</b>	<b>Assessment</b> <input type="checkbox"/> A <input checked="" type="checkbox"/> B <input type="checkbox"/> C <input type="checkbox"/> D
Investigations	<input checked="" type="checkbox"/> yes <input type="checkbox"/> partly <input type="checkbox"/> no
Water absorbent test, lemon juice test and temperature shock test	
Model calculations (see the monitoring instructions)	<input type="checkbox"/> yes <input type="checkbox"/> partly <input checked="" type="checkbox"/> no
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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) The manufacturer must show by tests that the limit values for lead and cadmium are not exceeded.	
<b>4. Declarations of compliance for manufactured products</b>	<b>Assessment</b> <input checked="" type="checkbox"/> A <input type="checkbox"/> B <input type="checkbox"/> C <input type="checkbox"/> D
Declarations of compliance exist for the contact material	<input checked="" type="checkbox"/> yes <input type="checkbox"/> partly <input type="checkbox"/> 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	<input checked="" type="checkbox"/> yes <input type="checkbox"/> partly <input type="checkbox"/> no
- Name and contact details of the issuer of the declaration	<input checked="" type="checkbox"/> yes <input type="checkbox"/> no
- Date of the certificate	<input checked="" type="checkbox"/> yes <input type="checkbox"/> no
- The trade name, name or identifying piece of information of the contact material	<input checked="" type="checkbox"/> yes <input type="checkbox"/> no
- Information on the composition and/or structure of the contact material	<input checked="" type="checkbox"/> yes <input type="checkbox"/> no
- Information on the raw materials permitted with certain limitations (specific migration)	<input type="checkbox"/> yes <input checked="" type="checkbox"/> no
- Information on dual-use additives	<input type="checkbox"/> yes <input checked="" type="checkbox"/> no
The declaration contains sufficient justification for compliance	<input type="checkbox"/> yes <input type="checkbox"/> partly <input type="checkbox"/> no
- References to legislation (EU and/or national legislation)	<input checked="" type="checkbox"/> yes <input type="checkbox"/> no
- References to BfR or FDA regulations (unless EU regulations)	<input checked="" type="checkbox"/> yes <input type="checkbox"/> no
- Information on investigations conducted	<input type="checkbox"/> yes <input checked="" type="checkbox"/> no
- Other justification, please specify	
The declaration contains sufficient information on the intended purpose and restrictions of use	<input type="checkbox"/> yes <input type="checkbox"/> partly <input type="checkbox"/> no

- Types of foodstuffs for which the material is suitable	<input type="checkbox"/> yes	<input checked="" type="checkbox"/> no
- Restrictions on operating temperature	<input type="checkbox"/> yes	<input checked="" type="checkbox"/> no
- Restrictions on contact time	<input type="checkbox"/> yes	<input type="checkbox"/> no
The following information is also present:		
- Information on the active or smart properties of the material, efficiency and user instructions	<input type="checkbox"/> yes	<input checked="" type="checkbox"/> no
- Information on the use of surface biocides	<input type="checkbox"/> yes	<input checked="" type="checkbox"/> no
Certificate Update Policies: It is recommended that certificates are at most three years old.		
Additional information on the use of recycled material:		
Language of the declarations: english		
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) Declarations of compliance of ceramics are compliant.		
5. Labelling to be attached to the contact materials (especially consumer products)	Assessment <input checked="" type="checkbox"/> A <input type="checkbox"/> B <input type="checkbox"/> C <input type="checkbox"/> D	
Labelling made (on the packaging or on the label)		
- Manufacturer's name and contact details	<input checked="" type="checkbox"/> yes	<input type="checkbox"/> no
- the words 'for food contact' or a symbol indicating suitability for food contact	<input type="checkbox"/> yes	<input checked="" type="checkbox"/> no
- Instructions for use if necessary	<input checked="" type="checkbox"/> yes	<input type="checkbox"/> 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)		
6. Traceability	Assessment <input checked="" type="checkbox"/> A <input type="checkbox"/> B <input type="checkbox"/> C <input type="checkbox"/> D	
- Traceability one step back	<input checked="" type="checkbox"/> yes	<input type="checkbox"/> no
- Traceability one step forward	<input checked="" type="checkbox"/> yes	<input type="checkbox"/> no
Ensuring traceability		
- Own records	<input checked="" type="checkbox"/> yes	<input type="checkbox"/> no
- Documents	<input checked="" type="checkbox"/> yes	<input type="checkbox"/> 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			
	<input checked="" type="checkbox"/> A	<input type="checkbox"/> B	<input type="checkbox"/> C	<input type="checkbox"/> D
<b>Hazard analysis and risk assessment</b>				
- Description of process	<input checked="" type="checkbox"/> yes			<input type="checkbox"/> no
- Identification and assessment of hazards	<input checked="" type="checkbox"/> yes			<input type="checkbox"/> no
- Critical control points and their monitoring	<input checked="" type="checkbox"/> yes			<input type="checkbox"/> no
- Measures taken to prevent the migration of printing ink	<input type="checkbox"/> yes			<input checked="" type="checkbox"/> no
- Corrective actions	<input checked="" type="checkbox"/> yes			<input type="checkbox"/> no
- Verification	<input checked="" type="checkbox"/> yes			<input type="checkbox"/> no
- Records of control point monitoring	<input checked="" type="checkbox"/> yes			<input type="checkbox"/> 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)				
<b>D. MEASURES TO BE TAKEN AS A RESULT OF THE INSPECTION ACCORDING TO VATI (KUTI 2)</b>				
<input checked="" type="checkbox"/> Guidance and counselling <input type="checkbox"/> Request <input type="checkbox"/> Start preparing coercive measures				
<b>Inspector's statement</b> The own-check plan, management of the composition of the products, declaration of compliance for manufactured products, labelling things, traceability and processing methods are compliant.  The manufacturer must show by laboratory tests that the limit values for lead and cadmium are not exceeded. There is no relief in The Ceramics regulation for replacing the lead and cadmium test results by raw material specifications.				
Deadline:				

Hearing of the operator