BIOLOGICAL PRODUCTS
HALAL CERTIFICATION SHEET

1	**DOCUMENT BASED ON CERTIFICATION AND PRODUCT DEFINITION**			
	1.1	Document No and Name (Standard/Criteria etc.) that forms the basis for certification	π LAW OF REPUBLIC OF INDONESIANUMBER 33 YEAR 2014 π REDULA¢IONS OF ¢ I E I ALAL PRODUC¢ ASSURANCEORDANI½IND ADENCY óBP‖P I ú NUMBER 3 OF 2023 ON DUIDELINES FOR ACCREDI¢A¢ION ANDĸOR ASSESSMEN¢ OF CONFORMI¢Y OF FOREIDN I ALAL CER¢IFICA¢ION BODY π ¢ I E DECREE OF ¢ I E MINIS¢ER OF RELIDIOUS AFFAIRS OF ¢ I E REPUBLIC OF INDONESIA NUMBER τ4y YEAR 2021 - SNI 99002:201c, SNI 99003:2018	
	1.2	Product name/Class/Type/ Species	***K-PRODUCTION OF (BIO)CHEMICALS - FOOD ADDITIVES (HALAL)*** ***Product Group:****Biological Products*	
			- Monoclonal antibody - Hormone - Stem cell product - Gene therapy product - Vaccines - Immunocerra - Therapeutic protein - Amino acid - Peptide - DNA Recombinant and other biological products	- Nucleotide - Nucleic acid - Microbial culture - Dry yeast etc. products - Dry bread yeast - Semi-dry baker's yeast - Cream yeast - Compressed yeast - Koji or ''tauco'' yeast or soy sauce yeast
			Other (Other products to be added to the scope are named as specified in the legislation. Example: Raising Agents, Gelling Agents etc.) *Note 1: When determining the scope, the origin of the product may be stated explicitly where necessary.* Note 2: In case of application for products specified in the legislation other than those mentioned above, the method of evaluation and application is determined by GIMDES.	
	1.3	Legal Terms(if any)	-Law No. 5996 on Veterinary Services, Plant Health, Food and Feed -Biosafety Law -Turkish Food Codex Regulation -Turkish Food Codex Regulation on Food Contact Materials and Articles -Turkish Food Codex Regulation on Maximum Residue Limits of Pesticides -Turkish Food Codex Contaminants Regulation -Turkish Food Codex Food Additives Regulation -Turkish Food Codex Regulation on Specifications of Food Additives *-Turkish Food Codex. Food Labelling and Consumer Information Regulation* *-TS OIC/SMIIC 24* Note: In audits carried out abroad, the legal conditions of the relevant country are taken as basis.	

2	PRODUCTION FACILITY AND PROCESS REQUIREMENTS		
	2.1	Conditions for the Production Facility	The floor of the production facility must be waterproof, non-slippery, washable, made of material that does not allow pests and microorganisms to settle, must not have cracks, and must be easy to clean and disinfect. (Non-compliance Category: Minor) There should be odor trap channels with sufficient slope to prevent the accumulation of washing water on the production floor. (Non-compliance Category: Minor) The walls in the production area should be made of waterproof, washable, smooth and light-colored material that does not allow pests and microorganisms to settle, should not have cracks, should be easy to clean and disinfect, and the areas where the wall and the floor meet should be rounded and made in a way that does not trap dirt. (Non-compliance Category: Minor) Windows and frames, including ventilation fans, must be made of durable stainless material, and the opening wings must have window screens to prevent flies, insects and rodents from entering. (Non-compliance Category: Minor) Inputs, semi-finished products and finished products that are not suitable for halal production must be clearly identified and separated to prevent their accidental use. (Non-compliance Category: Critical/Important) Doors at the production site must be wide enough for internal transport vehicles to pass through, have smooth and waterproof surfaces, be made of stainless material, and be self-closing. (Non-compliance Category: Minor) The production area must be illuminated in a way that is equivalent to daylight, the lighting must be done in a way that does not change the natural colors of the meat, and the lighting devices must be protected. (Non-compliance Category: Minor) In all work areas and cleaning areas, there should be continuous, potable, hot and cold water with sufficient pressure and a sufficient number of taps, preferably not operated by hand or arm. The sinks in these areas should be equipped with liquid cleaning materials suitable for halal food production. Sinks should be equipped with liquid cleaning materials, paper towels and a trash can that can be opened with a foot. Toilets should not open directly into production areas. (Non-compliance Category: Critical/Important) In the toilets, liquid soap for personnel cleaning, disinfectant water suitable for halal food production and paper towels should be available. In addition, materials such as bonnets, shoe covers, etc. should be placed at the entrances to the production areas to ensure their effective use. (Non-compliance Category: Minor) *All areas of the factory, including the production area, cafeteria, storage areas, toilets, changing rooms, etc., must comply with cleaning and hygiene rules. (Non-compliance Category: Critical/Important)* Storage areas should be arranged in such a way that raw materials and finished products used in halal food production are stored separately from other non-halal inputs and finished products. Inputs, semi-finished products and finished products that are not suitable for halal food production should be clearly identified and separated to prevent their accidental use. (Non-compliance Category: Critical/Important) The chemicals used in the hygiene and sanitation of production equipment must be suitable for halal food production, stored in a separate place and used in accordance with the instructions for use. (Non-compliance Category: Critical/Important) If necessary, there must be a sufficient size and number of cold storage facilities according to the capacity of the production facility, and the cold storage facilities must have appropriate cooling equipment. (Non-compliance Category: Minor) Necessary protective measures must be taken to prevent cross-contamination. (Non-Compliance Category: Minor) If water is supplied from a source other than the city network, the water source must be protected against all kinds of contamination and water disinfection must be carried out within a plan and records must be kept. (Non-compliance Category: Minor)

			The analyses of water used in production must be carried out in accordance with the provisions of the Regulation on Water Intended for Human Consumption published by the Ministry of Health of the Republic of Turkey. (Non-compliance Category: Minor) After transportation, vehicles must be washed with hot water and Halal food-compatible chemicals as specified in the hygiene instructions and recorded. (Non-compliance Category: Minor) The packaging materials used must not be made of non-halal materials, must not be produced with machines that have come into contact with non-halal materials, must be physically separated from other non-halal materials during storage, and must not contain hazardous components that affect human health. (Non-compliance Category: Critical/Important) Disinfectant mats and hand sanitizers suitable for halal food production should be placed at the entrances and toilet exits of production areas. (Non-compliance Category: Minor) Detailed hygiene control programs should be prepared at the production site, these programs should be hung in the workplace, and the cleaning and disinfection processes should be marked and recorded. (Non-compliance Category: Minor) There should be dressing and rest rooms for the personnel working in the production area. (Non-compliance Category: Minor) The organization must appoint a person and/or work with expert organizations within the framework of the relevant legislation for pest control activities. Precautions must be taken against pests and pests. (Non-compliance Category: Minor) The resulting waste and residues must be disposed of and evacuated in accordance with hygienic conditions without harming the environment and public health. (Non-compliance Category: Minor) There must be instructions regarding occupational safety in the business and measures must be taken in accordance with these instructions. (Non-compliance Category: Minor) Inputs, semi-finished products and finished products that are not suitable for halal production must be clearly identified and separated to prevent their accidental use. (Non-compliance Category: Critical/Important)
	2.2	**Requirements Regarding Manufacturing Process/Equipment**	The parts that come into contact with the product, such as the system, unit, machine etc. used in production, must be made of stainless steel. (Non-Compliance Category: Minor) The facility must have temperature meters and weighing devices. (Non-compliance Category: Minor) There must be instructions for use, maintenance and repair of the machines and devices used in production. (Non-conformance Category: Minor) There must be a generator of sufficient power at the workplace. (Non-compliance Category: Minor) Oils used in production equipment must be food-grade and must not contain any non-halal ingredients. (Non-compliance Category: Critical/Important) After transportation, vehicles must be washed with hot water and halal chemicals as specified in the hygiene instructions. (Non-compliance Category: Minor)

3	DOCUMENTATION REQUIREMENTS		
	3.1	Minimum documentation to be implemented by the organization Terms of	1- Control of Documents and Records (Non-Conformance Category: Minor) 2- Responsibility and Authority Definitions (Non-Compliance Category: Minor) 3- Prerequisite Programs (Non-Compliance Category: Critical/Important) 4- Hazard Analysis (Operational Prerequisite Programs / HACCP Plans) (Non-Conformance Category: Critical/Important) 6- Control of Measuring and Monitoring Devices (Non-Conformance Category: Critical/Important) 7- Correction and Corrective Activities (Non-Conformance Category: Minor) 8- Production Flow Charts (Indicating Halal Control Points) (Non-Conformance Category: Minor)
	3.2	Additional Terms(if any)	In the conformity assessment activities of the halal certification program, compliance with legal conditions (defining the product in terms of physical, chemical, microbiological parameters) will be sought first. If there is no legal condition regarding the product to be examined, the conditions specified in the certification sheet prepared in accordance with the relevant Turkish Standard/Certification criteria will be sought.

4	QUALITY CONTROL REQUIREMENTS		
	4.1	Personnel Conditions and Qualifications	At least 1 technical staff (Food Eng., Agricultural Eng., Chemical Eng., Chemist, Biologist, Biochemist) must be employed within the company as the manager responsible for production and quality control. (Non-Compliance Category: Critical/Important) There must be a sufficient number of personnel according to the service capacity, they must wear clothes according to the work they do, their daily personal hygiene must be checked and these checks must be recorded. (Non-compliance Category: Minor) *Trainings should be planned and halal training records should be kept according to the training plan. (Non-compliance Category: Minor)* Before the personnel are hired, they must be examined by an official health institution; they must have a report stating that they do not carry a contagious disease, those who are sick or carriers must not be employed and these documents must be kept in their personal files. Health checks of all personnel related to production must be carried out in the periods specified in the relevant legislation and their records must be kept. Regarding personnel health checks, the conditions of the "Hygiene Education Regulation" prepared by the Ministry of Health, the Ministry of Internal Affairs and the Ministry of Agriculture and Forestry and published in the Official Gazette dated July 5, 2013 and numbered 28698 and entered into force must be sought. (Non-compliance Category: Critical/Important)
	4.2	Inspections and Tests that must be performed on each product (100%) at the Production Site	-

	4.3	Inspections and Tests to be done with sampling (Mandatory at the Production Site)	*The organization must perform the final product inspection and tests specified in the standard/criteria within the framework of a quality control plan. This quality control plan may include all or some of the tests requested by the standard.*
		Inspections and Tests that must be done with sampling (those that can be used in external laboratories)	*The organization must have inspections and tests that are within the scope of the standard/criteria and cannot be performed at the production site performed in external laboratories that can be monitored within the framework of a quality control plan.*
	4.4	Type Tests and Validity Periods (if any)	It is not applied in the Halal certification program.
	4.5	Additional Terms(if any)	1. For inspections and tests that the organization cannot perform in its own quality control laboratory but are included in other legal regulations of the Country; a. Test reports conducted in traceable laboratories should be requested from suppliers for input and auxiliary materials, including packaging material. b. Tests regarding the conformity of the final products must be carried out in a Public Institution/University Laboratory for inspections/tests that do not have an Accredited/Testing Service Laboratory Approval Certificate.**(Non-Compliance Category: Critical/Important)** *2. A declaration must be obtained from the company stating that the product does not contain or produce non-halal components.*

5	SAMPLE PROCEDURES		
	5.1	Test Laboratories to Which the Sample Will Be Sent	It is stated in the Table in ANNEX 1. Note: When receiving services from testing laboratories not specified in this certification sheet, the procedure is carried out in accordance with the PR-08 Laboratory Selection and Approval Procedure.
	5.2	Sample Determination (Selection) Method (According to Scope)	It is stated in the Table in ANNEX 1.
	5.3	Sampling Method and Sample Amount	It is stated in the Table in ANNEX 1. In cases where the sample cannot be taken with its original packaging, this situation should be stated in the FR-16 Sampling Report and the product should be described in a descriptive manner and supported visually if necessary.
	5.4	Conditions for Transporting the Sample to the Laboratory (if necessary)	Samples must be packaged in a way that will prevent them from being affected by external impacts, will not be exposed to direct sunlight, and will provide controlled temperature conditions, and must be delivered to the laboratory specified in Annex 2. Taking into account the place where the sample was taken and the service address of the inspection and testing laboratory; service can be received from inspection and testing laboratories not specified in the leaflet, provided that these laboratories are accredited in the relevant inspection and testing.

	5.5	Critical Inspections/Tests That Directly Affect Product Safety/Performance	It is stated in the Table in ANNEX 1.
	5.6	Special Circumstances(if any)	1) In the sampling process from the production site, a reference sample in the same amount as the test sample must be taken and delivered to the authorized person of the organization (if the customer requests). 2) If it is not possible to take samples in their original packaging, the compliance of the product with the relevant standard or legislation regarding the placing on the market must be assessed by the inspection team.

6	RESEARCH PROGRAM			
	Type of Audit	Duration (Month or Year)	Production Site Inspection (MEMBER)	From Production Site Sampling (SAMPLING)
	Documentation	-	X	X
	1. Surveillance	1 year	X	X
	2. Surveillance	1 year	X	X
	Document Renewal	1 year	X	X
	Unannounced	1 year (3 times)	X	X
	Special Condition(if any):			
	Note 1: If the organization has more than one brand certificate within the same product group, an examination can be carried out by taking a sample from one brand. In this case, the examination and test results of the brand from which the sample was taken are considered valid for the other brands of the organization. **Note 2:**Note 1: When determining the sample, samples can be taken from different products of different brands. **Note 3:**Note 1 conditions do not apply to products for which samples cannot be taken due to not being in production or stock at the time of inspection. **Note 4:**If the organization is a contract manufacturer of product/products within the same product group and is certified; the inspection and test results of the brand from which the sample was taken may be accepted as valid for the product/products of the contract manufacturer organization. **Note 5:**In sampling operations, planning is made in such a way that samples are taken from all products within the scope of the document within the 3-year validity period of the document. A single sampling operation is applied for products with the same production processes.			

7	EXPERIMENT PLAN	
	Type of Audit	Inspections and Tests to be Performed
	Documentation	All inspections and tests specified in the Annex-1 table
	1.Supervision	Moisture, Colorant, Protein Amount specified in the ANNEX-1 table;*Foreign Matter for All Grain Products*
	2.Supervision	Aflatoxin, Ochratoxin, Cadmium, Lead specified in the ANNEX-1 table,*Deoxynivalenol, Zearolenone*, Pesticides Residues; GMO
	Document Renewal	All inspections and tests in the Annex-1 table

	Special Condition (if any):

8	SCOPE OF CERTIFICATION
	Example: *Production of (Bio)Chemicals - Food Additives (Halal)* *In the Biological Products Product Group*

ANNEX 1 Table:

Samples must be taken in accordance with the rules specified in the Sampling and Analysis Methods section of the Turkish Food Codex Regulation.

The following steps should be followed during the implementation of the sampling plan:
a) Packaging size is determined as net quantity.
b) Under normal conditions, samples are taken according to ANNEX-37, and in suspicious and controversial cases, samples are taken according to ANNEX-38.
c) The lot size is determined.
d) The required number of sample units are separated from the batch according to the random selection rules, by giving appropriate codes or identification marks for the separation of samples.
e) The product is inspected in accordance with this Regulation and non-conforming sample units are separated.
f) Sampling plans from production sites are determined according to ANNEX-37 or ANNEX-38.
g) The number of defectives is determined. If this value is equal to or less than the acceptability number in the selected sampling plan, the batch is accepted as suitable.

In cases where the determination of samples to be taken according to the batch size requires a long time (Batch>1000 units), instead of the individual numbering method mentioned above, the total time from the beginning to the end of the batch production is divided by the number of samples specified in the table and the resulting time interval is taken into account.

TABLE: INSPECTIONS AND TESTS TO BE PERFORMED

Product Name	Relevant Legislation / Standard / Criteria	Experiment Name	Sample Determination Method	Sample Quantity	Experimental Laboratory	Product Safety/ Critical inspections/tests that directly affect performance
- Monoclonal antibody - Hormone - Stem cell product - Gene therapy product - Vaccines - Immunocerra - Therapeutic protein	TGK Contaminants Regulation TGK Microbiological Criteria Regulation Turkish Food Codex Regulation on	-Aflatoxin -Ochratoxin - Mold -Microbiological analyses -Purity criteria	Turkish Food Codex Contaminants Regulation TGK Microbiological Criteria Regulation Turkish Food Codex Regulation on Specifications of Food Additives Turkish Food Codex Regulation on Flavorings and Food Components with Flavoring Properties	5 units in original packaging representing the same batch (At least 1000g in total)	MIKROKIM, INTERTEK, SGS	✓✓

- Amino acid - Peptide - Nucleotide - Nucleic acid - Microbial culture - Dry yeast etc. products - Dry bread yeast - Semi-dry baker's yeast - Cream yeast - Compressed yeast - Koji or ''tauco'' yeast or soy sauce yeast	Specifications of Food Additives Turkish Food Codex Regulation on Flavorings and Food Components with Flavoring Properties	- E.coli, Salmonella, coliform bacteria - Frock sport				
	Turkish Food Codex Food Additives Regulation	Additive Colorant	Turkish Food Codex Food Additives Regulation	In original packaging representing the same party Original samples of at least 200 g of each product	MIKROKIM, INTERTEK, SGS	✓✓
	Regulation on Genetically Modified Organisms and Their Products	GMO	Regulation on Genetically Modified Organisms and Their Products	In original packaging representing the same party Original samples of at least 500 g of each product	MIKROKIM, INTERTEK, SGS	✓✓
In Food Additives of Animal Origin	TS OIC/SMIIC 1	Meat Type Determination	PR-09 Sampling Inspection and Testing Procedure	At least 1000g in total	MIKROKIM, INTERTEK, SGS	

Explanation:✓Minor non-conformity that does not affect halal production conditions (Minor)
✓✓Critical/important non-conformity affecting halal production conditions (Critical/Important)
bIf this product is introduced to the market with a sauce package, the content of the sauce package must also meet the requirements of the TS OIC/SMIIC 1 standard and the relevant certification sheet in terms of Halal Certification.

Notes:

1. Packaging and Marking control must be carried out in accordance with the relevant legislation and Article 12.1 of the TS OIC/SMIIC 1: 2019 standard. Findings are recorded in the LS-15 Halal Food Stage 2 Question List.
2. In assessing the conformity of packaging materials used in production to the TS OIC/SMIIC 1 standard, the inspections and tests specified in the HBF-036 Food Contact Materials and Articles Certification Sheet are taken as basis.
3. The additives used in the products must comply with the provisions in the Turkish Food Codex Food Additives Regulation.
4. Flavourings and food ingredients with flavouring properties used in products must comply with the provisions of the Turkish Food Codex Regulation on Flavourings and Food Ingredients with Flavouring Properties.
5. Colorants and additives used in productsThe maximum permitted amounts of food additives other than sweeteners in foods must comply with the Communiqué on Food Additives Other than Colorants and Sweeteners.
6. In order to detect non-halal content in the product, the Inspection Board may conduct analyses for the detection of genetically modified organisms (GMOs) in the product or input, in accordance with the provisions of the Regulation on Genetically Modified Organisms and Products, depending on the product characteristics and the raw materials used, Pesticide Analysis in accordance with the provisions of the Turkish Food Codex Regulation on Maximum Residue Limits of Pesticides, and DNA analysis in products with animal-derived inputs.