

Comparison of Safety Assessment

Manufacturing step	Required document/information	Description	FDA (US) (based on dossiers of Upside & Good Meat)	USDA FSIS (US) (FSIS Directive 7800 and FSIS Notice 31-23)	SFA (Singapore)	FSA (UK) from (2022), (2023), and FSA/FSS request for information	EFSA (EU)	FSANZ (AUS/NZ) (Hazard & risk assessment of Vow's application and Application Handbook for novel foods)	MFDS (South Korea)	FAO/WHO	Vireo recommendations in the report
Cell sourcing	Cell origin	Description of cell origin (species, biopsy, slaughtered animal, cell line provider, etc.)	X		X	X	X	X	X		X
	Type of cell	Description of type of cell (GMO, immortalized, stem cell, tissue, etc.)	X		X	X	X	X	X		X
	GMO	If GMO, description of type of genetic modification process & safety evaluation of the GMO	X		X	X	X	X	X		X
	Biopsies/Cell sourcing	If applicable, information to demonstrate that biopsies/cell sourcing comply with animal health and food safety requirements. Health of the source animal (even if gathered from slaughtered animal)	X		X		X	X	X	X	X
	Analysis of inputs	Listing of substances used (antibiotics, substances for sterilization, etc.) and safety assessment of these	X		X	X	X	X	X	X	X
	Prions	Description of prevention/mitigation steps to avoid prion contamination	X			X	X	X		X	X
	Microbial toxin contamination	Safety assessment of the cells - testing for microbial toxins					X	X	X (?)	X	
	Residual hormones	Safety assessment of residual agricultural hormones from source animal	X (Good Meat only)								
	Food allergens (source animal)	Food allergens assessment (from source animals)				X				X	
	Microplastics	Safety assessment of microplastics (including nanoplastics) introduced from water, air, equipment, ingredients, etc.							X (?)	X	
Establishment of cell lines	Species verification	Verification of species identity	X		X			X	X (verification methods for established cell lines)	X	X
	Cells (visual inspection)	Visual inspection of cells, physicochemical inspection	X						X		X
	Cell growth characteristics	Documentation of cell viability, doubling time, cell stability, cell density & protein yield	X				X (they mention "stability of cells")		X		X
	Genetic modification	If genetic modification introduced here (e.g., for cell line enhancement or for nutritional enhancement), description of type of genetic modification process & safety evaluation	X		X	X	X	X	X		X
	Genetic stability	Assessment of genetic stability	X		X		X (they mention "stability of cells")	X	X	X	
	Tumorigenicity	Assessment of tumorigenicity	X						X		
	Analysis of inputs	Media components and other substances used & safety assessment of these; Hazardous chemical / food additive residues & safety assessment of these.	X		X	X	X	X	X	X	X

Comparison of Safety Assessment

Manufacturing step	Required document/information	Description	FDA (US) (based on dossiers of Upside & Good Meat)	USDA FSIS (US) (FSIS Directive 7800 and FSIS Notice 31-23)	SFA (Singapore)	FSA (UK) from (2022), (2023), and FSA/FSS request for information	EFSA (EU)	FSANZ (AUS/NZ) (Hazard & risk assessment of Vow's application and Application Handbook for novel foods)	MFDS (South Korea)	FAO/WHO	Vireo recommendations in the report
Cell harvest	Species verification	Verification of species and cell lineage identity							X		
	Residue analysis	Safety assessment of residues	X		X	X	X	X	X	X	X
	Washing efficiency	Assessment of the efficacy of the removal steps	X (Good Meat - albumin and pluronic F-68)		X (Information demonstrating the removal of culture media)			X	X		
	Microbiological contamination	Measurement of viruses, bacteria, yeast, mold	X	X	X	X	X	X	X	X	X
	Genetic stability	Production of unintended toxins or allergens	X		X	X	X	X	X		X
	Transference of GM DNA	Evaluation of the potential for DNA to be transferred to gut or environmental microbes									
	Toxicity testing (if needed)	Toxicity (acute, sub-chronic and chronic)			X	X	X	X	X		
	Toxicity testing (if needed)	Genotoxicity			X		X	X	X		
	Toxicity testing (if needed)	General systemic toxicity, chronic toxicity/ carcinogenicity/ mutagenicity (if critical findings were reported in the genotoxicity and sub-chronic/acute toxicity studies). Reproductive and developmental toxicity. Metabolism or toxicokinetic studies including (ADME)			X		X	X	X		
	Chemical contaminants (from environment)	Measurement of chemical contaminants from equipment, cleaning products, ingredients, etc.	X	X	X	X	X		X	X	X
	Chemical contaminants (from inputs)	Measurement of hazardous chemicals from inputs (e.g., antimicrobials, heavy metals, etc.)	X	X	X	X	X		X	X	X
	Physical contaminants	Foreign object contamination (e.g. plastic, metal, hair, jewelry, glass, etc.) & microplastics (including nanoplastics) introduced from water, air, equipment, ingredients, etc.				X	X		X	X	
	Composition	Analysis of nutritional composition	X		X	X	X	X	X	X	X
	Food allergen	Assessment for food allergens	X		X	X	X	X	X	X	X
Food processing Estimated dietary intake and Intended use	Other added ingredients during food processing	Safety assessment of added ingredients		X	X			X	X		X
	Use level	Proposed maximum use level/serving size portion	X		X		X	X	X		
	Food category	Food category			X			X	X		

Comparison of Safety Assessment

Manufacturing step	Required document/information	Description	FDA (US) (based on dossiers of Upside & Good Meat)	USDA FSIS (US) (FSIS Directive 7800 and FSIS Notice 31-23)	SFA (Singapore)	FSA (UK) from (2022), (2023), and FSA/FSS request for information	EFSA (EU)	FSANZ (AUS/NZ) (Hazard & risk assessment of Vow's application and Application Handbook for novel foods)	MFDS (South Korea)	FAO/WHO	Vireo recommendations in the report
History of safe use	History of safe use	Description of the history of use and safe consumption for food ingredient safety assessment	X		X	X	X	X	X	X	
Shelf life	Shelf life	Shelf life analysis	X		(may be requested after sale allowed)	X	X	X			
Packaging/shipping material	Packaging	Inspection of packaging/shipping materials of raw materials and the final product packaging to ensure they have not been damaged and no microbial contamination could have taken place.						X	X		
Quality control systems	Quality control measures	Description of food safety programs, including Hazard Analysis and Risk-Based Preventive Controls (HARPC), Quality control measures, HACCP, GMP, Good Cell Culture Practices (GCCP)	X	X	X	X	X	X	X		X
		Training plans and records of staff members in food safety/food handling/food hygiene courses, as well as in aseptic techniques or cleanroom training (where appropriate).			X	X					(As part of food safety program)
		Safety documentation for raw materials	X				X	X			(As part of food safety program)
		Production control and quality and safety assurance	X		X	X	X	X		X	(As part of food safety program)
		Supplier Approval Program	X					X			(As part of food safety program)
		Sanitation controls, and sanitary design of equipment and tools	X			X		X			(As part of food safety program)
		Equipment qualification/facility design						X			(As part of food safety program)
		Regulatory status of inputs	Analysis of the regulatory status of each input material i.e. , regulations and guidelines established by regulatory bodies to prioritize materials with approved regulatory status							X	
Information as of 24th May 2024											