

APPLICATION – CHECKLIST

DECEMBER 2015

TO:

FOOD STANDARDS AUSTRALIA NEW ZEALAND (FSANZ)

IN RELATION TO:

APPLICATION FOR APPROVAL OF ENDO β (1-4) XYLANASE
FROM A GENETICALLY MODIFIED STRAIN OF BACILLUS
SUBTILIS LMG S-24584 AS A PROCESSING AID

CHECKLIST

(As per section 3.1.11 of the Application Handbook 1 September 2013)

General requirements (3.1)		
Check	Page No.	Mandatory requirements
<input checked="" type="checkbox"/>	N/A	3.1.1 Form of application <input checked="" type="checkbox"/> <i>Application, abstracts and other key documents in English</i> <input checked="" type="checkbox"/> <i>Executive Summary (separated from main application electronically and in hard copy)</i> <input checked="" type="checkbox"/> <i>Relevant sections of Part 3 clearly identified</i> <input checked="" type="checkbox"/> <i>Pages sequentially numbered</i> <input checked="" type="checkbox"/> <i>Electronic copy (searchable)</i> <input checked="" type="checkbox"/> <i>1 hard copy</i> <input checked="" type="checkbox"/> <i>Electronic and hard copy identical</i> <input checked="" type="checkbox"/> <i>Hard copy capable of being laid flat</i> <input checked="" type="checkbox"/> <i>All references provided (in electronic and hard copy)</i>
<input checked="" type="checkbox"/>	8	3.1.2 Applicant details
<input checked="" type="checkbox"/>	9	3.1.3 Purpose of the application
<input checked="" type="checkbox"/>	10 14	3.1.4 Justification for the application <input checked="" type="checkbox"/> <i>Regulatory impact information</i> <input checked="" type="checkbox"/> <i>Impact on international trade</i>
<input checked="" type="checkbox"/>	15	3.1.5 Information to support the application <input checked="" type="checkbox"/> <i>Data requirements</i>
<input checked="" type="checkbox"/>	9	3.1.6 Assessment procedure <input checked="" type="checkbox"/> <i>General</i> <input type="checkbox"/> <i>Major</i> <input type="checkbox"/> <i>Minor</i> <input type="checkbox"/> <i>High level health claim variation</i>

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General requirements (3.1)		
Check	Page No.	Mandatory requirements
<input checked="" type="checkbox"/>	23, 28, 42	<p>3.1.7 Confidential commercial information</p> <p><input checked="" type="checkbox"/> <i>Confidential material separated in both electronic and hard copy</i></p> <p><input checked="" type="checkbox"/> <i>Formal request including reasons</i></p> <p><input checked="" type="checkbox"/> <i>Non-confidential summary provided</i></p> <p><i>Note – non CCI summary is provided within the main document in the relevant sections:</i></p> <p><i>7.1.3 p23</i></p> <p><i>7.1.4 p28</i></p> <p><i>7.4.1 p42</i></p>
<input checked="" type="checkbox"/>		<p>3.1.8 Exclusive Capturable Commercial Benefit</p> <p><input checked="" type="checkbox"/> <i>Justification provided</i></p> <p><i>Separate letter provided</i></p>
<input checked="" type="checkbox"/>	17	<p>3.1.9 International and other national standards</p> <p><input checked="" type="checkbox"/> <i>International standards</i></p> <p><input checked="" type="checkbox"/> <i>Other national standards</i></p>
<input checked="" type="checkbox"/>		3.1.10 Statutory Declaration
<input checked="" type="checkbox"/>		<p>3.1.11 Checklist/s provided with application</p> <p><input checked="" type="checkbox"/> <i>3.1 Checklist</i></p> <p><input checked="" type="checkbox"/> <i>All page number references from application included</i></p> <p><input checked="" type="checkbox"/> <i>Any other relevant checklists - Part 3.3.2</i></p>

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In relation to: Application for approval of ENDOβ(1-4) XYLANASE as a processing aid

Processing Aids (3.3.2)		
Check	Page No.	Mandatory requirements
<input checked="" type="checkbox"/>	21	A.1 Type of processing aid
<input checked="" type="checkbox"/>	22	A.2 Identification information
<input checked="" type="checkbox"/>	23	A.3 Chemical and physical properties
<input checked="" type="checkbox"/>	28	A.4 Manufacturing process
<input checked="" type="checkbox"/>	32	A.5 Specification information
<input checked="" type="checkbox"/>	32	A.6 Analytical method for detection
N/A		B.1 Industrial use information (chemical only)
N/A		B.2 Information on use in other countries (chemical only)
N/A		B.3 Toxicokinetics and metabolism information (chemical only)
N/A		B.4 Toxicity information (chemical only)
N/A		B.5 Safety assessments from international agencies (chemical only)
<input checked="" type="checkbox"/>	33	C.1 Information on enzyme use on other countries (enzyme only)
<input checked="" type="checkbox"/>	33	C.2 Toxicity information of enzyme (enzyme only)
<input checked="" type="checkbox"/>	38	C.3. Allergenicity information of enzyme (enzyme only)
<input checked="" type="checkbox"/>	39	C.4. Overseas safety Assessment Reports
<input checked="" type="checkbox"/>	40	D.1 Information on source organism (enzyme from microorganism only)
<input checked="" type="checkbox"/>	41	D.2 Pathogenicity and toxicity of source microorganism (enzyme from microorganism only)
<input checked="" type="checkbox"/>	41	D.3 Genetic stability of source organism (enzyme from microorganism only)
<input checked="" type="checkbox"/>	42	E.1 Nature of genetic modification of source organism (enzyme from GM source microorganism)
<input checked="" type="checkbox"/>	67	F.1 List of foods likely to contain the processing aid
<input checked="" type="checkbox"/>	67	F.2 Anticipated residue levels in foods
<input checked="" type="checkbox"/>	64	F.3 Information on likely level of consumption

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<input checked="" type="checkbox"/>	67	F.4 Percentage of food group to use processing aid
<input checked="" type="checkbox"/>	67	F.5 Information on residues in foods in other countries (if available)
<input checked="" type="checkbox"/>	67	F.6 Where consumption has changed, information on likely consumption

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