

7-8 June 2023

08:45-18:30 / 09:00-17:30

MINUTES (Agreed on 23<sup>rd</sup> June 2023)

**Location:** EFSA, Parma (Italy)

**Attendees:**

○ CEP Panel Members:

José Manuel Barat Baviera, Claudia Bolognesi, Andrew Chesson, Pier Sandro Cocconcelli, David Gott, Konrad Grob, Claude Lambré (Chair), Evgenia Lampi, Marcel Mengelers, Alicja Mortensen, Gilles Rivière, Inger-Lise Steffensen, Henk Van Loveren, Laurence Vernis and Holger Zorn

○ European Commission:

C. Evrevin, B. Schupp, J. Briggs

○ EFSA:

Food Ingredients and Packaging (FIP) Unit: Jaime Aguilera, Zainab Al Harraq, Kyriaki Apergi, Magdalena Andryszkiewicz, Eric Barthélémy, Daniele Cavanna, Daniele Comandella, Ana Criado, Cristina Croera, Valeriu-Georghe Curtui, Ana Gomes, Natalia Kovalkovicova, Alexandros Lioupis, Yi Liu, Marta Lopez, Simone Lunardi, Remigio Marano, Eleonora Marini, Silvia Peluso, Francesco Pesce, Sandra Rainieri, Laura Sanmartin, Elisa Savini, Vasiliki Sfika, Emmanouil Tsochatzis, Katharina Volk

Legal service (LA) unit: Simone Gabbi for agenda item 9.

○ Hearing Expert: Laurence Castle for agenda item 6.4.

○ Observers: Attending via web-streaming:

Eva Reingruber (TRISKELION), Ángela García Domingo (LEVPROT Bioscience, S.L.U.), Thalia De Castelbajac (ANSES), Dachuan Zhang (ETH Zurich), Anni Honkanummi (AB Enzymes), Yrjo Roos (University College Cork), Giuseppe Sammarco (University of Parma), Laetitia Doly (TAKABIO), Ana Merino (ATOVA Regulatory Consulting), Yulia Efimova (DSM Food Specialties), Renata Cerqueira (CARGILL), Els Van Hoeck (SCIENSANO), Céline Benini (AMFEP), Sofia Almeida Costa (Instituto de Saúde Pública da Universidade do Porto), Bas Verhagen (AB Enzymes), Stefanie Geiser (EAS Strategies), Mariella Kuilman (DSM-firmenich), Paula Pescador (c-LEcta GmbH).

## **1. Welcome and apologies for absence**

The Chair welcomed the participants.

Apologies were received from Christina Tlustos - whole meeting, Marcel Mengelers - 7<sup>th</sup> June am.

## **2. Adoption of agenda**

The agenda was adopted without changes.

## **3. Declarations of Interest of Panel members**

In accordance with EFSA's Policy on Independence<sup>1</sup> and the Decision of the Executive Director on Competing Interest Management<sup>2</sup>, EFSA screened the Annual Declarations of Interest filled out by the Panel members invited to the present meeting. The expert Holger Zorn declared an interest

<sup>1</sup> [http://www.efsa.europa.eu/sites/default/files/corporate\\_publications/files/policy\\_independence.pdf](http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/policy_independence.pdf)

<sup>2</sup> [http://www.efsa.europa.eu/sites/default/files/corporate\\_publications/files/competing\\_interest\\_management\\_17.pdf](http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management_17.pdf)



related to agenda item 6.9 with the patent "Zorn H, Scheibner M, Hülzdau B, Berger RG, de Boer L, Meima RB (2006) Novel enzymes for use in enzymatic bleaching of food products. Eur Pat Appl EP 64132 20060712." A conflict of interest was identified. Therefore, the expert did not participate in the discussion of this agenda item.

#### **4. Agreement of the minutes of the 35<sup>th</sup> CEP Panel meeting held on 7-9 March 2023, in Parma or via web-conference**

The minutes of the [35<sup>th</sup> CEP Panel meeting](#) were agreed by written procedure on 24 March 2023.

#### **5. Report on written procedures since 35<sup>th</sup> Plenary meeting**

Following the endorsement by the CEP Panel on 06.12.2022 during the 33rd CEP Plenary meeting<sup>3</sup>, the technical dossier was subject to a public consultation (PC-0389<sup>4</sup>) and no comments were received until 23.03.2023. Subsequently, the scientific opinion on the safety evaluation of the endo-1,4- $\beta$ -xylanase from the genetically modified *Bacillus subtilis* strain XAN ([EFSA-Q-2022-00189](#)) was adopted by the CEP Panel on 05.04.2023 via a written procedure.

#### **6. Scientific outputs submitted for discussion and possible adoption**

##### **OPEN SESSION FOR OBSERVERS**

##### **6.4. Safety assessment of natural compounds/mixtures from renewable biological resources ([EFSA-Q-2023-00256](#))**

The updated proposal on the principles to be used for the safety assessment of natural compounds used to manufacture FCMs was presented to the Panel. The further comments and input received during the meeting will be taken into consideration for the further development of the principles.

##### **6.5. Food manufacturing processes and technical data used in the exposure assessment of food enzymes ([EFSA-Q-2023-00039](#))**

The draft guidance was revised by the working group on enzymes on the basis of comments collected from the public consultation<sup>5</sup> and the information session hold during the public consultation period<sup>6</sup>. The CEP Panel discussed all parts of the revised main document and its annexes. The guidance was unanimously adopted, subject to the incorporation of changes as suggested during the meeting and editorial changes.

##### **Questions from observers and Answers from EFSA (in application of the guidelines for Observers)**

<sup>3</sup> <https://www.efsa.europa.eu/sites/default/files/2022-12/061222-m.pdf>

<sup>4</sup> <https://connect.efsa.europa.eu/RM/s/publicconsultation2/a0109000006qhfA/pc0389>

<sup>5</sup> <https://connect.efsa.europa.eu/RM/s/publicconsultation2/a0109000006qpdK/pc0399>

<sup>6</sup> <https://www.efsa.europa.eu/en/events/info-session-input-data-development-food-enzyme-intake-model-feim>



The following questions were collected from the online registration form and answered by EFSA during the plenary meeting.

*Q1 - Could you share an update/estimation on the timelines for the pending food enzyme evaluations required prior publishing the Union List of authorised food enzymes?*

Reply: EFSA currently is evaluating both enzyme applications submitted before March 2015 and those submitted afterwards at the same time. Up to now, EFSA has received more than 400 dossiers for safety assessment, of which 60% have been finalised. Efficiency is managed by grouping similar applications in the evaluation process. Last year more than 60 opinions were adopted. With the milestone reached by the adoption of the exposure guidance in this plenary meeting, EFSA expects to maintain the same productivity also in the next 12 months. The CEP panel will be renewed in July 2024, making the predication of timeline difficult. However, EFSA's commitment to deliver enzyme scientific opinions remains unchanged.

*Q2 - What do we have to know about the hygiene circuit? What are the main topics/rules?*

Reply: Food hygiene is governed by regulations in the European Union, please consult the Commission website ([https://food.ec.europa.eu/safety/biological-safety/food-hygiene\\_en](https://food.ec.europa.eu/safety/biological-safety/food-hygiene_en)).

The following questions were received from observers in the plenary meeting, and answered by EFSA in the meeting.

*Q3 - In the regulations sought to know that m.o are accepted to produce chymosin are the following: Kluyveromices lactis, E coli K-12 and Aspergillus niger var awarmoni, in the following order we can see that the strains are not specified. Where can I see which strains are allowed to produce chymosin in Europe?*

Reply: The name/code of each microbial production strain is identified in the EFSA scientific opinion.

*Q4 - Orden de 14 de enero de 1988 por la que se aprueba la norma general de identidad y pureza para el cuajo y otras enzimas coagulantes de leche destinados al mercado interior. (Translation: The order of January 14, 1988 approved the general standard of identity and purity for rennet and other milk coagulating enzymes for the internal market.)*

Reply: This is a comment, not a question.

*Q5 - To change polygalacturonase into pectolytic enzymes, AMFEP proposed to replace peptidase by the broader category of proteases. Could you provide your view on this?*

Reply: EFSA enzyme opinions evaluate the activities claimed in the technical dossier by the applicant. In the exposure guidance, the term "pectinolytic enzymes" encompasses several cell-wall degrading enzymes, which include polygalacturonase. Peptidase is a broader term than protease.

*Q6 - The sentence on the analytical data should only apply when on a certain process EFSA has not received generic data for the process. In the case of the plant and algae oil, only for non-refined oil?*

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Reply: When the food enzyme-TOS is expected during certain food manufacturing processes, the exposure guidance made clear two situations. For certain food manufacturing processes, there is no longer the need for individual applicants to provide technical information and analytical data, since they have been provided by food manufacturer associations. However, for processes those information and data are not available, the burden of proof still lies within the enzyme applicants.

*Q7 - The AMFEP proposed to broaden the production of protein hydrolysate to modified protein. Could you please comment on this?*

Reply: In the exposure guidance, it has been made clear that the collection of food manufacturing processes reflects only uses claimed in the enzyme applications received so far. EFSA cannot anticipate future development made by food industry. As of today, EFSA has received only hydrolytic enzymes for uses in the production of protein hydrolysates. However, the modification of proteins cannot be excluded. Should those new uses be claimed in future applications, EFSA is open to consider a modification.

## **7. Feedback from the Scientific Committee/Panel(s), EFSA, European Commission**

### **7.1. Scientific Committee/Panel(s) including their Working Groups**

The Chair reported the main points discussed during the 113<sup>th</sup> Scientific Committee Plenary, held on 18-20<sup>th</sup> April 2023.

### **7.2. CEP Panel Working Groups /Task Forces**

#### **7.2.1. CEP WG on Food Contact Materials**

An update on the risk assessment of Styrene was presented to the Panel. No additional issues were brought to the attention of the CEP Panel further to what is already recorded in the [minutes of the WG](#).

#### **7.2.2. CEP WG on Recycling Plastic**

An update on the development of a Guidance on post-consumer mechanical PET recycling processes was presented to the CEP Panel. No additional issues were brought to the attention of the CEP Panel further to what is already recorded in the [minutes of the WG](#).

#### **7.2.3. CEP WG on Enzymes**

The WG chair gave an overview on the progress made in the evaluation of enzyme applications in recent years. No additional issues were brought to the attention of the CEP Panel further to what is already recorded in the [minutes of the WG](#).

### **7.3. EFSA**

None

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## 7.4. European Commission

None

## 8. New mandates

### 8.1. New questions received since the 35<sup>th</sup> CEP Plenary

The following new mandates have been received since the 35<sup>th</sup> CEP Plenary meeting.

Food Sector	EFSA-Q-Number	Subject	Reception date
ENZ	EFSA-Q-2023-00194	Scientific risk assessment on the food enzyme: cellulase, glucanase and xylanase produced with <i>Trichoderma reesei</i> AR-999 strain - data package AB ENZYMES	10/03/2023
ENZ	EFSA-Q-2023-00199	Scientific risk assessment on the food enzyme: Glucanase from <i>R.emersonii</i> _DP-Rzm102 - data package Genencor International B.V.	14/03/2023
ENZ	EFSA-Q-2023-00208	Scientific risk assessment on the food enzyme: Cellulase and Hemicellulase covering Xylanase from <i>Aspergillus luchuensis</i> AE-C - data package Amano Enzyme Inc.	20/03/2023
ENZ	EFSA-Q-2023-00215	Scientific risk assessment on the food enzyme: Subtilisin from <i>Bacillus sonorensis</i> AE-AP - data package Amano Enzyme Inc.	27/03/2023
ENZ	EFSA-Q-2023-00219	Scientific risk assessment on the food enzyme: Glucoamylase from <i>Aspergillus niger</i> AGME 1415 KY - data package ENMEX	29/03/2023
ENZ	EFSA-Q-2023-00220	Scientific risk assessment on the food enzyme: Leucyl aminopeptidase, Oryzin, and Aspergillopepsin I from <i>Aspergillus oryzae</i> AE-PR - data package Amano Enzyme Inc.	30/03/2023
ENZ	EFSA-Q-2023-00221	Scientific risk assessment on the food enzyme: Xylanase produced with the <i>Aspergillus Luchuensis</i> (formerly <i>A. Niger</i> ) strain AR-682 - data package AB enzymes	31/03/2023
ENZ	EFSA-Q-2023-00222	Scientific risk assessment on the food enzyme: Pectin esterase produced by a non-genetically strain of <i>Aspergillus luchuensis</i> - data package Soufflet Biotechnologies	31/03/2023
ENZ	EFSA-Q-2023-00223	Scientific risk assessment on the food enzyme: Glucan 1,4- $\alpha$ -glucosidase from <i>Aspergillus niger</i>	31/03/2023



		AE-GN - data package Amano Enzyme Inc.	
ENZ	EFSA-Q-2023-00225	Scientific risk assessment on the food enzyme: Endo-1,4-beta-xylanase, IUBMB 3.2.1.8 from <i>Aspergillus luchuensis</i> DP-Azd103 - data package Genencor International B.V.	02/04/2023
ENZ	EFSA-Q-2023-00226	Scientific risk assessment on the food enzyme: Papain from <i>Carica papaya</i> - data package Nagase (Europe) GmbH	02/04/2023
ENZ	EFSA-Q-2023-00227	Scientific risk assessment on the food enzyme: Pectinase produced by <i>Aspergillus niger</i> CCTCC 2023236 - data package Suntaq International Limited	02/04/2023
ENZ	EFSA-Q-2023-00228	Scientific risk assessment on the food enzyme: Glucoamylase produced by <i>Aspergillus niger</i> CCTCC M 2023310 - data package Suntaq International Limited	02/04/2023
ENZ	EFSA-Q-2023-00229	Scientific risk assessment on the food enzyme: Cellulase and Endo-1,3(4)-beta-glucanase from <i>Trichoderma reesei</i> DP-Nzc104 - data package Genencor International, B.V.	02/04/2023
ENZ	EFSA-Q-2023-00230	Scientific risk assessment on the food enzyme: Xylanase (IUBMB 3.2.1.8) produced by non-genetically modified strain of <i>Aspergillus tubingensis</i> - data package Soufflet Biotechnologies	02/04/2023
ENZ	EFSA-Q-2023-00233	Scientific risk assessment on the food enzyme: Cellulase produced by <i>Trichoderma reesei</i> CCTCC M 2023312 - data package Suntaq International Limited	03/04/2023
ENZ	EFSA-Q-2023-00234	Scientific risk assessment on the food enzyme: Xylanase produced by <i>Aspergillus niger</i> CCTCC M 2023311 - data package Suntaq International Limited	03/04/2023
ENZ	EFSA-Q-2023-00235	Scientific risk assessment on the food enzyme: $\beta$ -glucanase (IUBMB 3.2.1.6) produced by non-genetically modified strain of <i>Aspergillus tubingensis</i> - data package Soufflet Biotechnologies	03/04/2023
ENZ	EFSA-Q-2023-00236	Scientific risk assessment on the food enzyme: Subtilisin from <i>Bacillus paralicheniformis</i> (DP-Dzx96) - data package Genencor International B.V.	03/04/2023
ENZ	EFSA-Q-2023-00238	Scientific risk assessment on the food enzyme: Glucose oxidase from	05/04/2023



		Aspergillus tubingensis strain - data package DSM	
ENZ	EFSA-Q-2023-00239	Scientific risk assessment on the food enzyme: Glucoamylase from Aspergillus niger strain - data package DSM	05/04/2023
ENZ	EFSA-Q-2023-00240	Scientific risk assessment on the food enzyme: Cellulase from Aspergillus Niger strain AC 4-984 - data package Shin Nihon Chemical Co., Ltd.	07/04/2023
ENZ	EFSA-Q-2023-00241	Scientific risk assessment on the food enzyme: Arabanase produced by non-genetically modified strain of Aspergillus aculeatinus - data package Soufflet Biotechnologies	07/04/2023
ENZ	EFSA-Q-2023-00242	Scientific risk assessment on the food enzyme: Cellulase from Aspergillus Niger strain ACH 12-525 - data package Shin Nihon Chemical Co., Ltd.	07/04/2023
ENZ	EFSA-Q-2023-00243	Scientific risk assessment on the food enzyme: Pectinase from Aspergillus Tubingensis strain GPA41 - data package Shin Nihon Chemical Co., Ltd.	07/04/2023
ENZ	EFSA-Q-2023-00244	Scientific risk assessment on the food enzyme: Pectinase from Aspergillus Luchuensis strain AP2 903-6 - data package Shin Nihon Chemical Co., Ltd.	07/04/2023
ENZ	EFSA-Q-2023-00245	Scientific risk assessment on the food enzyme: Pectinase from Aspergillus Tubingensis strain ARS R7-60 - data package Shin Nihon Chemical Co., Ltd.	07/04/2023
ENZ	EFSA-Q-2023-00246	Scientific risk assessment on the food enzyme: Protease from Aspergillus Sojae strain ACP 112-311 - data package Shin Nihon Chemical Co., Ltd.	08/04/2023
ENZ	EFSA-Q-2023-00247	Scientific risk assessment on the food enzyme: Peptidase From Aspergillus sojae Strain DAP 19-109 - data package Shin Nihon Chemical Co., Ltd.	08/04/2023
ENZ	EFSA-Q-2023-00248	Scientific risk assessment on the food enzyme: Protease From Aspergillus sojae Strain FL 72-230 - data package Shin Nihon Chemical Co., Ltd.	08/04/2023
ENZ	EFSA-Q-2023-00263	Scientific risk assessment on the food enzyme: Cellulase and endo-1,3(4)-beta-glucanase from Trichoderma reesei 480KY - data package Kerry Ingredients & Flavours Ltd.	14/04/2023



ENZ	EFSA-Q-2023-00264	Scientific risk assessment on the food enzyme: Protease from <i>Aspergillus sojae</i> Strain FP 12-385 - data package Shin Nihon Chemical Co., Ltd.	14/04/2023
ENZ	EFSA-Q-2023-00265	Scientific risk assessment on the food enzyme: Pectinase from <i>Aspergillus luchuensis</i> Strain GSP 4-404 - data package Shin Nihon Chemical Co., Ltd.	14/04/2023
ENZ	EFSA-Q-2023-00266	Scientific risk assessment on the food enzyme: Pectinase From <i>Aspergillus luchuensis</i> Strain LC-07 - data package Shin Nihon Chemical Co., Ltd.	14/04/2023
ENZ	EFSA-Q-2023-00267	Scientific risk assessment on the food enzyme: Protease from <i>Aspergillus oryzae</i> Strain LP 4-1281 - data package Shin Nihon Chemical Co., Ltd.	14/04/2023
ENZ	EFSA-Q-2023-00268	Scientific risk assessment on the food enzyme: Protease from <i>Aspergillus oryzae</i> Strain LPL 3U-3-10 - data package Shin Nihon Chemical Co., Ltd.	14/04/2023
ENZ	EFSA-Q-2023-00269	Scientific risk assessment on the food enzyme: Pectin Methylesterase from <i>Aspergillus luchuensis</i> Strain AP2 903-6 - data package Shin Nihon Chemical Co., Ltd.	14/04/2023
ENZ	EFSA-Q-2023-00270	Scientific risk assessment on the food enzyme: Pectinase from <i>Aspergillus tubingensis</i> Strain PX 22-272 - data package Shin Nihon Chemical Co., Ltd.	14/04/2023
ENZ	EFSA-Q-2023-00271	Scientific risk assessment on the food enzyme: Pectinase from <i>Aspergillus tubingensis</i> Strain SPG 10-1199 - data package Shin Nihon Chemical Co., Ltd.	14/04/2023
ENZ	EFSA-Q-2023-00272	Scientific risk assessment on the food enzyme: Pectinase From <i>Aspergillus niger</i> Strain CICC2214 - data package Erbslöh Geisenheim GmbH	15/04/2023
ENZ	EFSA-Q-2023-00275	Scientific risk assessment on the food enzyme: Papain enzymatic complex from <i>Carica papaya</i> - data package Enzybel International SA	17/04/2023
ENZ	EFSA-Q-2023-00277	Scientific risk assessment on the food enzyme: Tannase from <i>Aspergillus oryzae</i> NBRC 110971 - data package Mitsubishi Chemical Corporation	18/04/2023
ENZ	EFSA-Q-2023-00294	Scientific risk assessment on the food enzyme: Cellulase From <i>Trichoderma citrinoviride</i> Strain C1-	26/04/2023





		5-2 - data package Shin Nihon Chemical Co., Ltd	
ENZ	EFSA-Q-2023-00295	Scientific risk assessment on the food enzyme: $\beta$ -Glucanase from <i>Trichoderma reesei</i> Strain TG-M5-337 - data package Shin Nihon Chemical Co., Ltd	26/04/2023
ENZ	EFSA-Q-2023-00297	Scientific risk assessment on the food enzyme: Cellulase from <i>Trichoderma citrinoviride</i> Strain X31 - data package Shin Nihon Chemical Co., Ltd	26/04/2023
ENZ	EFSA-Q-2023-00300	Scientific risk assessment on the food enzyme: Tannase preparation from <i>Aspergillus oryzae</i> No. 11-5 - data package Kikkoman Biochemifa Company	27/04/2023
ENZ	EFSA-Q-2023-00303	Protease (Aqualysin) from a genetically modified strain of <i>Bacillus subtilis</i> (LMG S-25520)	28/04/2023
ENZ	EFSA-Q-2023-00305	Alpha-amylase from <i>Bacillus licheniformis</i> (strain AE-TA)	28/04/2023
ENZ	EFSA-Q-2023-00306	Alpha-amylase from <i>Bacillus amyloliquefaciens</i> (strain AE-BAA)	28/04/2023
ENZ	EFSA-Q-2023-00307	Application for an endo-1,4-beta-xylanase from <i>Bacillus subtilis</i> AR-153	28/04/2023
ENZ	EFSA-Q-2023-00308	Beta-amylase from <i>Bacillus flexus</i> (strain AE-BAF)	28/04/2023
ENZ	EFSA-Q-2023-00309	Alpha-glucosidase from <i>Aspergillus niger</i> (strain AE-TGU)	28/04/2023
ENZ	EFSA-Q-2023-00356	Glutaminase from <i>Bacillus amyloliquefaciens</i> (strain AE-GT)	12/05/2023
ENZ	EFSA-Q-2023-00357	4-alpha-glucanotransferase from <i>Geobacillus pallidus</i> (strain AE-SAS)	15/05/2023
ENZ	EFSA-Q-2023-00358	Pullulanase from <i>Pullulanibacillus naganensis</i> (strain AE-PL)	15/05/2023
ENZ	EFSA-Q-2023-00359	Alpha-L-rhamnosidase from <i>Penicillium decumbens</i> (strain AE-HP)	15/05/2023
ENZ	EFSA-Q-2023-00360	alpha-amylase from <i>Aspergillus oryzae</i> strain FUA	15/05/2023
ENZ	EFSA-Q-2023-00361	Triacylglycerol lipase from <i>Burkholderia ubonensis</i> (strain AE-LRE)	15/05/2023
ENZ	EFSA-Q-2023-00366	Authorisation of an invertase from a genetically modified <i>Trichoderma reesei</i> strain AR-996	17/05/2023
ENZ	EFSA-Q-2023-00367	Authorisation of a serine endopeptidase from a genetically modified <i>Trichoderma reesei</i> strain AR-201	17/05/2023
ENZ	EFSA-Q-2023-00370	Triacylglycerol lipase from <i>Rhizopus oryzae</i> (strain AE-TL)	25/05/2023
ENZ	EFSA-Q-2023-00371	Triacylglycerol lipase from <i>Mucor javanicus</i> (strain AE-LM)	25/05/2023



ENZ	EFSA-Q-2023-00372	Authorisation of a polygalacturonase from a genetically modified <i>Trichoderma reesei</i> strain AR-414	25/05/2023
ENZ	EFSA-Q-2023-00373	Triacylglycerol lipase from <i>Candida cylindracea</i> (strain AE-LAYH)	30/05/2023
ENZ	EFSA-Q-2023-00381	Glucoamylase from <i>Rhizopus oryzae</i> (strain AE-G)	01/06/2023
ENZ	EFSA-Q-2023-00382	Beta-glucosidase from <i>Penicillium multicolor</i> (strain AE-GLY)	01/06/2023
ENZ	EFSA-Q-2023-00383	Laccase from <i>Trametes hirsuta</i> (strain AE-OR)	02/06/2023
ENZ	EFSA-Q-2023-00384	Triacylglycerol lipase from <i>Penicillium roqueforti</i> (strain AE-LRF)	02/06/2023
ENZ	EFSA-Q-2023-00385	Application for extension of use of Peroxidase from <i>Aspergillus niger</i> (MOX)	02/06/2023
ENZ	EFSA-Q-2023-00386	MODIFICATION OF AN ALREADY AUTHORISED ENZYME PRODUCED WITH T. REESEI STRAIN AR-256	02/06/2023
FCM	EFSA-Q-2023-00216	Paraffin waxes and hydrocarbon waxes C13 – C93, oxidised	27/03/2023
FCM	EFSA-Q-2023-00256	Proposal for the safety assessment of the use of substances from renewable biological origin to manufacture food contact materials	12/04/2023
FCM	EFSA-Q-2023-00278	Lietpak_ EREMA MPR®	18/04/2023
FCM	EFSA-Q-2023-00351	Development of a scientific guidance on the criteria for the evaluation and on the preparation of applications of post-consumer mechanical PET recycling processes intended to be used for manufacture of materials and articles in contact with food	11/05/2023
FCM	EFSA-Q-2023-00365	Re-assessment of the risks to public health related to the presence of Styrene in plastic materials and articles intended to come into contact with food	17/05/2023

## 8.2. Valid questions since the 35<sup>th</sup> CEP Plenary:

The following mandates have been validated since the 35<sup>th</sup> CEP Plenary meeting.

Food Sector	EFSA-Q-Number	Subject	Validity date
ENZ	EFSA-Q-2022-00842	Authorisation of a glucose oxidase from a modified strain of <i>S. cerevisiae</i> (LALL-GO)	20/04/2023



ENZ	EFSA-Q-2023-00194	Scientific risk assessment on the food enzyme: cellulase, glucanase and xylanase produced with <i>Trichoderma reesei</i> AR-999 strain - data package AB ENZYMES	10/03/2023
ENZ	EFSA-Q-2023-00199	Scientific risk assessment on the food enzyme: Glucanase from <i>R. emersonii</i> _DP-Rzm102 - data package Genencor International B.V.	14/03/2023
ENZ	EFSA-Q-2023-00208	Scientific risk assessment on the food enzyme: Cellulase and Hemicellulase covering Xylanase from <i>Aspergillus luchuensis</i> AE-C - data package Amano Enzyme Inc.	20/03/2023
ENZ	EFSA-Q-2023-00215	Scientific risk assessment on the food enzyme: Subtilisin from <i>Bacillus sonorensis</i> AE-AP - data package Amano Enzyme Inc.	27/03/2023
ENZ	EFSA-Q-2023-00219	Scientific risk assessment on the food enzyme: Glucoamylase from <i>Aspergillus niger</i> AGME 1415 KY - data package ENMEX	29/03/2023
ENZ	EFSA-Q-2023-00220	Scientific risk assessment on the food enzyme: Leucyl aminopeptidase, Oryzin, and Aspergillopepsin I from <i>Aspergillus oryzae</i> AE-PR - data package Amano Enzyme Inc.	30/03/2023
ENZ	EFSA-Q-2023-00221	Scientific risk assessment on the food enzyme: Xylanase produced with the <i>Aspergillus Luchuensis</i> (formerly <i>A. Niger</i> ) strain AR-682 - data package AB enzymes	31/03/2023
ENZ	EFSA-Q-2023-00222	Scientific risk assessment on the food enzyme: Pectin esterase produced by a non-genetically strain of <i>Aspergillus luchuensis</i> - data package Soufflet Biotechnologies	31/03/2023
ENZ	EFSA-Q-2023-00223	Scientific risk assessment on the food enzyme: Glucan 1,4- $\alpha$ -glucosidase from <i>Aspergillus niger</i> AE-GN - data package Amano Enzyme Inc.	31/03/2023
ENZ	EFSA-Q-2023-00225	Scientific risk assessment on the food enzyme: Endo-1,4-beta-xylanase, IUBMB 3.2.1.8 from <i>Aspergillus luchuensis</i> DP-Azd103 - data package Genencor International B.V.	02/04/2023
ENZ	EFSA-Q-2023-00226	Scientific risk assessment on the food enzyme: Papain from <i>Carica papaya</i> - data package Nagase (Europe) GmbH	02/04/2023



ENZ	EFSA-Q-2023-00227	Scientific risk assessment on the food enzyme: Pectinase produced by <i>Aspergillus niger</i> CCTCC 2023236 - data package Suntaq International Limited	02/04/2023
ENZ	EFSA-Q-2023-00228	Scientific risk assessment on the food enzyme: Glucoamylase produced by <i>Aspergillus niger</i> CCTCC M 2023310 - data package Suntaq International Limited	02/04/2023
ENZ	EFSA-Q-2023-00229	Scientific risk assessment on the food enzyme: Cellulase and Endo-1,3(4)-beta-glucanase from <i>Trichoderma reesei</i> DP-Nzc104 - data package Genencor International, B.V.	02/04/2023
ENZ	EFSA-Q-2023-00230	Scientific risk assessment on the food enzyme: Xylanase (IUBMB 3.2.1.8) produced by non-genetically modified strain of <i>Aspergillus tubingensis</i> - data package Soufflet Biotechnologies	02/04/2023
ENZ	EFSA-Q-2023-00233	Scientific risk assessment on the food enzyme: Cellulase produced by <i>Trichoderma reesei</i> CCTCC M 2023312 - data package Suntaq International Limited	03/04/2023
ENZ	EFSA-Q-2023-00234	Scientific risk assessment on the food enzyme: Xylanase produced by <i>Aspergillus niger</i> CCTCC M 2023311 - data package Suntaq International Limited	03/04/2023
ENZ	EFSA-Q-2023-00235	Scientific risk assessment on the food enzyme: $\beta$ -glucanase (IUBMB 3.2.1.6) produced by non-genetically modified strain of <i>Aspergillus tubingensis</i> - data package Soufflet Biotechnologies	03/04/2023
ENZ	EFSA-Q-2023-00236	Scientific risk assessment on the food enzyme: Subtilisin from <i>Bacillus paralicheniformis</i> (DP-Dzx96) - data package Genencor International B.V.	03/04/2023
ENZ	EFSA-Q-2023-00238	Scientific risk assessment on the food enzyme: Glucose oxidase from <i>Aspergillus tubingensis</i> strain - data package DSM	05/04/2023
ENZ	EFSA-Q-2023-00239	Scientific risk assessment on the food enzyme: Glucoamylase from <i>Aspergillus niger</i> strain - data package DSM	05/04/2023
ENZ	EFSA-Q-2023-00240	Scientific risk assessment on the food enzyme: Cellulase from <i>Aspergillus Niger</i> strain AC 4-984 - data package Shin Nihon Chemical Co., Ltd.	07/04/2023



ENZ	EFSA-Q-2023-00241	Scientific risk assessment on the food enzyme: Arabinase produced by non-genetically modified strain of <i>Aspergillus aculeatus</i> - data package Soufflet Biotechnologies	07/04/2023
ENZ	EFSA-Q-2023-00242	Scientific risk assessment on the food enzyme: Cellulase from <i>Aspergillus Niger</i> strain ACH 12-525 - data package Shin Nihon Chemical Co., Ltd.	07/04/2023
ENZ	EFSA-Q-2023-00243	Scientific risk assessment on the food enzyme: Pectinase from <i>Aspergillus Tubingensis</i> strain GPA41 - data package Shin Nihon Chemical Co., Ltd.	07/04/2023
ENZ	EFSA-Q-2023-00244	Scientific risk assessment on the food enzyme: Pectinase from <i>Aspergillus Luchuensis</i> strain AP2 903-6 - data package Shin Nihon Chemical Co., Ltd.	07/04/2023
ENZ	EFSA-Q-2023-00245	Scientific risk assessment on the food enzyme: Pectinase from <i>Aspergillus Tubingensis</i> strain ARS R7-60 - data package Shin Nihon Chemical Co., Ltd.	07/04/2023
ENZ	EFSA-Q-2023-00246	Scientific risk assessment on the food enzyme: Protease from <i>Aspergillus Sojae</i> strain ACP 112-311 - data package Shin Nihon Chemical Co., Ltd.	08/04/2023
ENZ	EFSA-Q-2023-00247	Scientific risk assessment on the food enzyme: Peptidase From <i>Aspergillus sojae</i> Strain DAP 19-109 - data package Shin Nihon Chemical Co., Ltd.	08/04/2023
ENZ	EFSA-Q-2023-00248	Scientific risk assessment on the food enzyme: Protease From <i>Aspergillus sojae</i> Strain FL 72-230 - data package Shin Nihon Chemical Co., Ltd.	08/04/2023
ENZ	EFSA-Q-2023-00263	Scientific risk assessment on the food enzyme: Cellulase and endo-1,3(4)-beta-glucanase from <i>Trichoderma reesei</i> 480KY - data package Kerry Ingredients & Flavours Ltd.	14/04/2023
ENZ	EFSA-Q-2023-00264	Scientific risk assessment on the food enzyme: Protease from <i>Aspergillus sojae</i> Strain FP 12-385 - data package Shin Nihon Chemical Co., Ltd.	14/04/2023
ENZ	EFSA-Q-2023-00265	Scientific risk assessment on the food enzyme: Pectinase from <i>Aspergillus luchuensis</i> Strain GSP 4-404 - data package Shin Nihon Chemical Co., Ltd.	14/04/2023



ENZ	EFSA-Q-2023-00266	Scientific risk assessment on the food enzyme: Pectinase From <i>Aspergillus luchuensis</i> Strain LC-07 - data package Shin Nihon Chemical Co., Ltd.	14/04/2023
ENZ	EFSA-Q-2023-00267	Scientific risk assessment on the food enzyme: Protease from <i>Aspergillus oryzae</i> Strain LP 4-1281 - data package Shin Nihon Chemical Co., Ltd.	14/04/2023
ENZ	EFSA-Q-2023-00268	Scientific risk assessment on the food enzyme: Protease from <i>Aspergillus oryzae</i> Strain LPL 3U-3-10 - data package Shin Nihon Chemical Co., Ltd.	14/04/2023
ENZ	EFSA-Q-2023-00269	Scientific risk assessment on the food enzyme: Pectin Methylesterase from <i>Aspergillus luchuensis</i> Strain AP2 903-6 - data package Shin Nihon Chemical Co., Ltd.	14/04/2023
ENZ	EFSA-Q-2023-00270	Scientific risk assessment on the food enzyme: Pectinase from <i>Aspergillus tubingensis</i> Strain PX 22-272 - data package Shin Nihon Chemical Co., Ltd.	14/04/2023
ENZ	EFSA-Q-2023-00271	Scientific risk assessment on the food enzyme: Pectinase from <i>Aspergillus tubingensis</i> Strain SPG 10-1199 - data package Shin Nihon Chemical Co., Ltd.	14/04/2023
ENZ	EFSA-Q-2023-00272	Scientific risk assessment on the food enzyme: Pectinase From <i>Aspergillus niger</i> Strain CICC2214 - data package Erbslöh Geisenheim GmbH	15/04/2023
ENZ	EFSA-Q-2023-00275	Scientific risk assessment on the food enzyme: Papain enzymatic complex from <i>Carica papaya</i> - data package Enzybel International SA	17/04/2023
ENZ	EFSA-Q-2023-00277	Scientific risk assessment on the food enzyme: Tannase from <i>Aspergillus oryzae</i> NBRC 110971 - data package Mitsubishi Chemical Corporation	18/04/2023
ENZ	EFSA-Q-2023-00294	Scientific risk assessment on the food enzyme: Cellulase From <i>Trichoderma citrinoviride</i> Strain C1-5-2 - data package Shin Nihon Chemical Co., Ltd	26/04/2023
ENZ	EFSA-Q-2023-00295	Scientific risk assessment on the food enzyme: $\beta$ -Glucanase from <i>Trichoderma reesei</i> Strain TG-M5-337 - data package Shin Nihon Chemical Co., Ltd	26/04/2023



ENZ	EFSA-Q-2023-00297	Scientific risk assessment on the food enzyme: Cellulase from <i>Trichoderma citrinoviride</i> Strain X31 - data package Shin Nihon Chemical Co., Ltd	26/04/2023
ENZ	EFSA-Q-2023-00300	Scientific risk assessment on the food enzyme: Tannase preparation from <i>Aspergillus oryzae</i> No. 11-5 - data package Kikkoman Biochemifa Company	28/04/2023
FCM	EFSA-Q-2022-00523	CeltiPak_KREYENBORG IR Clean+	14/04/2023
FCM	EFSA-Q-2022-00526	Calcium <i>tert</i> -butylphosphonate	19/04/2023
FCM	EFSA-Q-2022-00548	Rekis d.o.o._VACUNITE®(EREMA Vacurema® Basic + Polymetrix SSP V-LeaN)	21/03/2023
FCM	EFSA-Q-2022-00613	Triphenyl phosphite, polymer with CHDM and polypropylene glycol, C10-16 alkyl esters	08/03/2023
FCM	EFSA-Q-2022-00744	Enplater_KREYENBORG IR Clean+	14/04/2023
FCM	EFSA-Q-2022-00751	GTX Hanex_KREYENBORG IR Clean+	14/04/2023
FCM	EFSA-Q-2022-00796	Lerg-PET_Starlinger iV+	16/03/2023
FCM	EFSA-Q-2023-00021	Mixture of CHDM, Ether-Dimer and Ester-Dimer	11/05/2023
FCM	EFSA-Q-2023-00022	Amendment to the SML(T) applicable to Crotonic Acid as a NIAS related to FCM 1059 (PHBH)	11/05/2023

### 8.3. Withdrawn questions since the 35<sup>th</sup> CEP Plenary:

None

## 9. Other scientific topics for information and/or discussion

The CEP Panel discussed the comments submitted by the applicant, following the pre-notification of the adopted opinion ,for application EFSA-Q-2022-00366 (adoption date 7 March 2023). The Panel confirmed the adoption of this scientific opinion without changing its conclusion.

## 10. Any other business

None

### Questions from and answers to Observers (in application of the guidelines for Observers)

The Panel coordinators reported the question(s) received from Observers in advance to the plenary as follows:

*Q8 - EFSA expressed in recent Scientific Opinions (for instance, Safety assessment of the process Starlinger recoSTAR HDPE, FC 1 – PET2PET used to recycle post-consumer HDPE closures into food contact closures) that there is not sufficient data to define reference contamination levels for (for*



instance) HDPE. Are there currently initiatives running to gather the corresponding data, eventually coordinated by EFSA? Triskelion/Triskelion's client would be happy to contribute.

How many participants from which locations would need to submit contamination data, so that a reference contamination level can be defined?

Reply: According to the new EU Regulation 2022/1616 on recycled FCM there are suitable technologies, listed in Annex I, which are capable of recycling waste into recycled plastic materials and articles that comply with Article 3 of Regulation (EC) No 1935/2004 and are microbiologically safe. These are (a) closed loop recycling and (b) mechanical recycling of PET under specific conditions of input and use.

All the other technologies, including mechanical recycling of polyolefins (including PE) are considered as "novel technologies" and for them, the articles 10-16 of the Regulation apply. Therefore, for these technologies, the developer shall submit to the EC extensive reasoning, and scientific evidence and studies, demonstrating that the novel technology can manufacture complying recycled plastic FCM, with microbiological safety, including a characterisation of contaminant levels in the plastic input and in the recycled plastic, a determination of the decontamination efficiency (at pilot or industrial level), migration tests and reasoning for meeting those requirements.

Each developer can designate a number of recyclers who will monitor the process including contamination of the input material (identification and quantification of contaminants). A monitoring report shall be published by the developer every 6 months. After at least four consecutive reports (2 years) the developer could apply to the EC for assessment. The submitted data will be evaluated by the EC and, in case they will be found sufficient, EFSA will be requested to assess the technology. In this case EFSA will elaborate and publish a specific guidance with the relevant requirements.

Therefore, there is no initiative by EFSA. The requirements of the new EU regulation should be followed.

## **CLOSED SESSION FOR OBSERVERS**

### **6.1. Animal rennet from the abomasum of calves and cows (*Bos taurus*) (EFSA-Q-2022-00482)**

The CEP Panel discussed all parts of the draft opinion. The opinion was unanimously adopted, subject to the incorporation of changes as suggested during the meeting and editorial changes.

### **6.2. Endo-1,4- $\beta$ -xylanase from *Aspergillus tubingensis* strain LYX (EFSA-Q-2022-00776)**

The CEP Panel discussed all parts of the draft opinion. The opinion was unanimously adopted, subject to the incorporation of changes as suggested during the meeting and editorial changes.

### **6.3. Triacylglycerol lipase produced by a non-genetically modified strain of *Saccharomyces cerevisiae* (LALL-LI) (EFSA-Q-2022-00529)**

Following the endorsement by the CEP Panel on 08.03.2023 during the 35th CEP Plenary meeting<sup>7</sup>, the technical dossier was subject to a public consultation (PC-0437<sup>8</sup>) and no comments were received until 05.05.2023. The opinion was unanimously adopted in this plenary meeting.

<sup>7</sup> <https://www.efsa.europa.eu/sites/default/files/2023-03/070323-m.pdf>

<sup>8</sup> <https://connect.efsa.europa.eu/RM/s/publicconsultation2/a0109000004LZ5X/pc0437>





**6.6. Recycling process Cirrec Netherlands B.V. (EREMA Basic technology) ([EFSA-Q-2021-00575](#))**

The CEP Panel discussed all parts of the draft opinion. The opinion was unanimously adopted, subject to the incorporation of changes as suggested during the meeting and editorial changes.

**6.7. Recycling process CCH CIRCULARPET (NGR technology) ([EFSA-Q-2021-00567](#))**

The CEP Panel discussed all parts of the draft opinion. The opinion was unanimously adopted, subject to the incorporation of changes as suggested during the meeting and editorial changes.

**6.8. Recycling process Coca-Cola HBC Romania (NGR technology) ([EFSA-Q-2022-00029](#))**

The CEP Panel discussed all parts of the draft opinion. The opinion was unanimously adopted, subject to the incorporation of changes as suggested during the meeting and editorial changes.

**6.9. Peroxidase from the genetically modified *Aspergillus niger* strain MOX ([EFSA-Q-2015-00274](#))**

The CEP Panel discussed all parts of the draft opinion. The opinion was unanimously adopted, subject to the incorporation of changes as suggested during the meeting and editorial changes.

**6.10. Polygalacturonase from a genetically modified strain of *Trichoderma reesei* (RF6197) ([EFSA-Q-2014-00798](#))**

The CEP Panel discussed all parts of the draft opinion. The opinion was unanimously adopted, subject to the incorporation of changes as suggested during the meeting and editorial changes.

**6.11. Pectin esterase from a genetically modified strain of *Trichoderma reesei* (RF6201) ([EFSA-Q-2014-00799](#))**

The CEP Panel discussed all parts of the draft opinion. The opinion was unanimously adopted, subject to the incorporation of changes as suggested during the meeting and editorial changes.

**6.12. Triacylglycerol lipase from *Rhizopus oryzae* (strain AE-TL) ([EFSA-Q-2014-00112](#))**

The CEP Panel discussed all parts of the draft opinion. The opinion was unanimously adopted, subject to the incorporation of changes as suggested during the meeting and editorial changes.

**6.13. Alpha-amylase from *Microbacterium imperiale* (strain AE-AMT), extension of use ([EFSA-Q-2022-00532](#))**

The CEP Panel discussed all parts of the draft opinion. The opinion was unanimously adopted, subject to the incorporation of changes as suggested during the meeting and editorial changes.

**6.14. Cellulase produced by *Aspergillus niger* 294 ([EFSA-Q-2021-00693](#))**

The CEP Panel discussed all parts of the draft opinion. The opinion was unanimously adopted, subject to the incorporation of changes as suggested during the meeting and editorial changes.

**6.15. Glucan-1,4- $\alpha$ -maltohydrolase from the genetically modified *Bacillus subtilis* strain AR-453 ([EFSA-Q-2021-00299](#))**

The CEP Panel discussed all parts of the draft opinion. The opinion was unanimously adopted, subject to the incorporation of changes as suggested during the meeting and editorial changes.

**6.16. OLA 8 – Oligomeric lactic acid ([EFSA-Q-2021-00179](#))**

The CEP Panel discussed all parts of the draft opinion. The opinion was unanimously adopted, subject to the incorporation of changes as suggested during the meeting and editorial changes.

**6.17. Alpha-amylase from *Aspergillus niger* strain AS 29-286 ([EFSA-Q-2016-00576](#))**

The CEP Panel discussed all parts of the draft opinion. The opinion was unanimously adopted, subject to the incorporation of changes as suggested during the meeting and editorial changes.

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