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SCIENTIFIC OPINION

Safety of an extension of use of *Yarrowia lipolytica* yeast biomass as a novel food pursuant to Regulation (EU) 2015/2283

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Abstract

Following a request from the European Commission, the EFSA Panel on Nutrition, Novel Foods and Food Allergens (NDA) was asked to deliver an opinion on the safety of an extension of use of *Yarrowia* (*Y.*) *lipolytica* yeast biomass as a novel food (NF) pursuant to Regulation (EU) 2015/2283. The extension of use pertains to the use of the NF as a food ingredient in a number of food categories, in foods for special medical purposes and in foods for total diet replacement for weight control. In 2018, *Y. lipolytica* was attributed the qualified presumption of safety (QPS) status for production purposes, including food and feed products based on biomass. The Panel considers that the data provided sufficient information with respect to the stability of the NF, also when used as a food ingredient. The concentrations of the analysed processing contaminants do not raise safety concerns. The Panel also considers that consumption of the NF is not nutritionally disadvantageous under the proposed conditions of use. The Panel concludes that the NF, *Y. lipolytica* yeast biomass, is safe under the proposed conditions of use.

KEYWORDS

extension of use, novel foods, safety, *Yarrowia lipolytica*, yeast

CONTENTS

1 | INTRODUCTION

1.1 | Background and Terms of Reference as provided by the requestor

On 5 July 2020, the company Skotan S.A. submitted a request to the European Commission in accordance with Article 10 of Regulation (EU) 2015/2283 to authorise an extension of use of *Y. lipolytica* yeast biomass as a novel food.

The application requests to extend the use of the novel food *Y. lipolytica* yeast biomass in a number of foods.

In accordance with Article 10(3) of Regulation (EU) 2015/2283, the European Commission asks the European Food Safety Authority to provide a scientific opinion on the extension of use of *Y. lipolytica* yeast biomass as a novel food.

1.2 | Additional information

In 2018, *Y. lipolytica* was attributed the status of qualified presumption of safety (QPS) for production purposes, including food and feed products based on biomass (EFSA BIOHAZ Panel, 2018).

In 2019, the EFSA NDA Panel adopted a Scientific Opinion on the safety of *Y. lipolytica* yeast biomass as a novel food pursuant to Regulation (EU) 2015/2283 (EFSA NDA Panel, 2019).

In 2022, the EFSA NDA Panel adopted a Scientific Opinion on the safety of an extension of use of *Y. lipolytica* yeast biomass pursuant to Regulation (EU) 2015/2283 (EFSA NDA Panel, 2022).

2 | DATA AND METHODOLOGIES

2.1 | Data

The safety assessment of this NF is based on data supplied in the application and information provided by the applicant following a number of EFSA requests for additional information.

Administrative and scientific requirements for NF applications referred to in Article 10 of Regulation (EU) 2015/2283 are listed in Commission Implementing Regulation (EU) 2017/2469.[1]

A common and structured format on the presentation of NF applications is described in the EFSA Guidance on the preparation and presentation of a NF application (EFSA NDA Panel, 2016). As indicated in this guidance, it is the duty of the applicant to provide all the available (proprietary, confidential and published) scientific data (including both data in favour and not in favour) that are pertinent to the safety of the NF.

This NF application does not include a request for the protection of proprietary data.

2.2 | Methodologies

The assessment follows the methodology set out in the EFSA guidance on NF applications (EFSA NDA Panel, 2016) and the principles described in the relevant existing guidance documents from the EFSA Scientific Committee. The legal provisions for the assessment are laid down in Article 11 of Regulation (EU) 2015/2283 and in Article 7 of Commission Implementing Regulation (EU) 2017/2469.

This assessment concerns only the risks that might be associated with consumption of the NF under the proposed conditions of use and is not an assessment of the efficacy of the NF with regard to any (claimed) benefit.

3 | ASSESSMENT

3.1 | Introduction

The NF, which is the subject of the request for an extension of use, is the dried and heat-killed biomass of the yeast *Y. lipolytica*.

In 2018, *Y. lipolytica* was attributed the QPS status for production purposes, including food and feed products based on biomass (EFSA BIOHAZ Panel, 2018).

In 2019, the EFSA NDA Panel assessed the safety of *Y. lipolytica* yeast biomass as a NF (EFSA NDA Panel, 2019). The Panel concluded that the NF was safe under the proposed conditions of use, i.e. in food supplements at amounts of up to 3 g/day

[1]Commission Implementing Regulation (EU) 2017/2469 of 20 December 2017 laying down administrative and scientific requirements for applications referred to in Article 10 of Regulation (EU) 2015/2283 of the European Parliament and of the Council on novel foods. OJ L 351, 30.12.2017, pp. 64–71.

for children from 3 years to less than 10 years of age and up to 6 g/day thereafter. Following that assessment, *Y. lipolytica* yeast biomass was authorised by Commission Implementing Regulation (EU) 2019/760[2] for the above uses.

In 2022, the EFSA NDA Panel assessed the safety of an extension of use of *Y. lipolytica* yeast biomass in meal replacement products for weight reduction for adults up to 6 g per day (EFSA NDA Panel, 2022), which was considered safe by the Panel, and which was subsequently authorised by Commission Implementing Regulation (EU) 2023/938.[3]

This opinion addresses the applicant's request to extend the use of the NF as a food ingredient in a number of additional food categories.

3.2 | Identity of the NF

The NF is the dried and heat-killed biomass of the yeast *Y. lipolytica*.

3.3 | Compositional data

According to the specifications (as authorised by Commission Implementing Regulation (EU) 2019/760[2]; see Table 1 below), the NF consists primarily of proteins (45–55 g/100 g) and dietary fibre (24–30 g/100 g). The fat content in the NF is set at 7–10 g/100 g.

3.3.1 | Stability

In 2019, the Panel assessed the stability of the NF on the basis of results of stability testing for five independently produced batches of the NF. The Panel considered that the data provided sufficient information with respect to the stability of the NF (EFSA NDA Panel, 2019).

In order to investigate the stability when the NF is used as a food ingredient, the applicant performed stability tests in the following eight food categories: dairy products (yoghurt), powdered (dehydrated) milk, peanut butter, wholegrain flour (oat), heat-treated meat (pork ham), spice mix (for curing meat), ground coffee, ready to eat snacks (corn crisps). The NF was added to the various foods at 20 g/100 g. After mixing the dairy and the meat products with the NF, the food was heat treated (pasteurised).

Accelerated storage conditions, i.e. 44°C, were used for the powdered milk, peanut butter, wholegrain flour, spice mix, ground coffee and snacks, and testing was performed at baseline and after 4 and 8 weeks. The dairy and the meat products were stored at 7°C for 2 weeks. The foods were tested (in triplicate) for yeasts/moulds, *Salmonella*, Coliform bacteria and total aerobic microbial count. No yeasts/moulds, *Salmonella* or Coliform bacteria were detected in any sample at any time point. Total plate counts were slightly increased in some foods after storage at 44°C for 8 weeks, which was to be expected and which is not considered to be a consequence of the addition of the NF.

The Panel considers that the data provided sufficient information with respect to the stability of the NF when used as a food ingredient.

3.3.2 | Effect of processing

Given the chemical composition of the NF (45%–55% of protein; Table 1), the proposed uses (e.g. bread and rolls, snacks, fine bakery wares; Table 2) and use levels (up to 30% in snacks), as well as the corresponding processing conditions (i.e. baking at high temperature and low water activity in the resulting food commodities), the applicant was requested to investigate the potential formation of processing contaminants. In reply, the applicant submitted analytical data on the formation of acrylamide, furan, 3-methylfuran and 2-methylfuran during the manufacturing process of wheat bread and corn chips. Four batches of the NF were tested in these two food categories, plus controls (i.e. without addition of the NF).

The tested wheat bread contained 0.6 g NF per 100 g (as per the proposed conditions of use for 'Bread and Rolls' [#07.1]) and baking was performed at 190–200°C for 18–20 minutes. The addition of the NF did not result in an increased formation of process contaminants as compared to control (Appendix A, Table A1).

The corn chips contained 30 g NF per 100 g (as per the proposed conditions of use for 'Potato-, cereal-, flour- or starch-based snacks' [#15.1]). Baking was performed at 130–140°C (high pressure extrusion followed by long-term drying). The addition of the NF did not result in an increased formation of process contaminants as compared to control (Appendix A, Table A2).

[2]Commission Implementing Regulation (EU) 2019/760 of 13 May 2019 authorising the placing on the market of Yarrowia lipolytica yeast biomass as a novel food under Regulation (EU) 2015/2283 of the European Parliament and of the Council and amending Commission Implementing Regulation (EU) 2017/2470. *OJ L 125, 14.5.2019, p. 13–15*.

[3]Commission Implementing Regulation (EU) 2023/938 of 10 May 2023 amending Implementing Regulation (EU) 2017/2470 as regards the conditions of use of the novel food Yarrowia lipolytica yeast biomass. OJ L 125, 11.5.2023, p. 16–18.

The Panel considers that the concentrations of the analysed processing contaminants do not raise safety concerns.

3.4 | Specifications

The specifications of the NF, as authorised in Commission Implementing Regulation (EU) 2019/760,[4] are indicated in Table 1.

TABLE 1 Specifications of the NF.

Description/definition: The novel food is the dried and heat-killed biomass of the yeast *Y. lipolytica*.	
Characteristics/composition	
Protein	45–55 g/100 g
Dietary fibre	24–30 g/100 g
Sugars	< 1.0 g/100 g
Fat	7–10 g/100 g
Total ash	≤ 12%
Water content	≤ 5%
Dry matter content	≥ 95%
Microbiological criteria	
TAMC	$\leq 5 \times 10^3$ CFU/g
TYMC	$\leq 10^2$ CFU/g
Viable *Y. lipolytica* cells[a]	< 10 CFU/g (i.e. limit of detection)
Coliforms	≤ 10 CFU/g
Salmonella spp.	Not detected in 25 g

Abbreviations: CFU, colony forming units; TAMC, total aerobic microbial count; TYMC, total yeast and mould count.

[a]To be tested immediately after the heat-treatment step. Measures have to be in place to prevent cross-contamination with viable *Y. lipolytica* cells during packaging and/or storage of the NF.

Given the newly proposed uses of the NF as a food ingredient, the Panel considers that limits in accordance with compositional data should be added to the specifications for lead (≤ 0.1 mg/kg), mercury (≤ 0.1 mg/kg), cadmium (≤ 0.1 mg/kg) and arsenic (≤ 0.15 mg/kg).

3.5 | Proposed uses and use levels and anticipated intake

3.5.1 | Target population

The target population as proposed by the applicant is the general population.

3.5.2 | Proposed uses and use levels

The applicant proposed to extend the use of the NF as an ingredient in a number of food categories, as defined per Regulation (EC) No 1333/2008 on food additives.[5] These food categories and the maximum use levels are reported in Table 2.

TABLE 2 Food categories (according to Regulation (EC) No 1333/2008) and maximum use levels as proposed by the applicant.

Food category (#)	Food category (description)	Max use level (g NF/kg)
01.2	Unflavoured milk products, including natural unflavoured buttermilk (excluding sterilised buttermilk) non heat treated after fermentation	5

(Continues)

[4]Commission Implementing Regulation (EU) 2019/760 of 13 May 2019 authorising the placing on the market of *Yarrowia lipolytica* yeast biomass as a novel food under Regulation (EU) 2015/2283 of the European Parliament and of the Council and amending Commission Implementing Regulation (EU) 2017/2470. *OJ L 125, 14.5.2019, p. 13–15*.

[5]Regulation (EC) No 1333/2008 of the European Parliament and of the Council of 16 December 2008 on food additives. OJ L 354, 31.12.2008, p. 16–33.

TABLE 2 (Continued)

Food category (#)	Food category (description)	Max use level (g NF/kg)
01.4	Flavoured fermented milk products including heat-treated products	10
01.7	Cheese and cheese products	10
01.7.2	Ripened cheese	10
01.7.5	Processed cheese	10
01.7.6	Cheese products (excluding products falling in category 16)	10
04.2.5.4	Nut butters and nut spreads	30
04.2.6	Processed potato products	10
05.1	Cocoa and Chocolate products as covered by Directive 2000/36/EC	10
06.1	Whole, broken or flaked grain	20
06.3	Breakfast cereals	20
06.4	Pasta	10
06.4.2	Dry pasta	10
06.5	Noodles	10
06.7	Pre-cooked or processed cereals	10
07.1	Bread and Rolls	6
07.2	Fine bakery wares	15
08.3.2	Heat-treated meat products	15
12.1.1	Salt	30
12.2.1	Herbs and spices	50
12.2.2	Seasonings and condiments	50
12.5	Soups and broths	5
12.6	Sauces	10
12.7	Salads and savoury based sandwich spreads	30
12.8	Yeast and yeast products	30
12.9	Protein products, excluding products covered in category 1.8	30
14.1.4	Flavoured drinks	10
14.1.4.2	Flavoured drinks with sweetener	10
14.1.5.1	Coffee, coffee extracts	20
14.1.5.2	Other	10
15.1	Potato-, cereal-, flour- or starch-based snacks	300
15.2	Processed nuts	20

In addition to the above listed food categories, the applicant proposed the use of the NF in foods for special medical purposes (FSMPs) according to Regulation (EU) No 609/2013, at a maximum amount of 6 g NF/day.

The applicant also proposed the use of the NF in foods for total diet replacement for weight control, according to Regulation (EU) No 609/2013, at a maximum amount of 6 g NF/day.

The applicant proposed that food supplements and meal replacement products with *Y. lipolytica* biomass (as already authorised) should not be consumed on the same day as the newly proposed food categories containing the NF.

3.5.3 | Anticipated intake of the NF

The applicant and EFSA performed intake assessments of the anticipated daily intake of the NF based on the proposed uses and maximum proposed use levels (Table 2), using the EFSA Food Additives Intake Model (FAIM) tool,[6] which is based on data from the EFSA Comprehensive European Food Consumption Database (EFSA, 2011). The lowest and highest mean and 95th percentile anticipated daily intakes of the NF among the EU dietary surveys are presented in Table 3. The highest intake per kg bw (at the 95th percentile) was estimated for young children (age 1 to < 3 years) at 1117 mg/kg bw per day.

[6] https://www.efsa.europa.eu/it/applications/food-improvement-agents/tools

TABLE 3 Intake estimates resulting from the use of the NF as an ingredient in the intended food categories at the maximum proposed use levels.

Population group	Age (years)	Mean intake (mg/kg bw per day)		P95 intake (mg/kg bw per day)		P95 intake (mg/day)	
		Lowest[a]	Highest[a]	Lowest[b]	Highest[b]	Lowest[c]	Highest[c]
Infants	< 1	33	301	88	971	440	4855
Young children[d]	1 to < 3	141	430	313	1117	3756	13,404
Other children	3 to < 10	167	456	331	1054	7646	24,347
Adolescents	10 to < 18	80	269	204	682	12,505	41,807
Adults[e]	≥ 18	55	274	117	523	8190	36,610

Abbreviations: bw, body weight; FAIM, Food Additives Intake Model; NF, novel food; P95, 95th percentile.

[a]FAIM tool exposure estimate was generated on 26/05/2023. The lowest and the highest averages observed among all EU surveys are reported in these columns.

[b]FAIM tool exposure estimate was generated on 26/05/2023. The lowest and the highest P95th observed among all EU surveys are reported in these columns (P95th based on less than 60 individuals are not considered).

[c]Based on FAIM calculations and considering default body weights as set by the EFSA Scientific Committee (2012).

[d]Referred to as 'toddlers' in the EFSA food consumption comprehensive database (EFSA, 2011).

[e]Includes elderly, very elderly, pregnant and lactating women.

3.6 | Nutritional information

In 2019 and in 2022, the Panel considered that, taking into account the composition of the NF and the proposed conditions of use, consumption of the NF is not nutritionally disadvantageous. The amounts assessed were up to 6 g NF per day in food supplements (up to 3 g/day for children from 3 years to less than 10 years of age and up to 6 g/day thereafter; EFSA NDA Panel, 2019) and up to 6 g NF per day in meal replacement products (for adults only; EFSA NDA Panel, 2022).

Considering the newly proposed uses and use levels, which would lead to considerably higher intakes of the NF than those previously assessed, the applicant was requested to provide an updated nutritional analysis of the NF. In reply, the applicant provided newly generated analytical data for a number of vitamins and minerals for five independent batches of the NF (Table 4).

TABLE 4 Nutritional analysis of the NF.

Parameter (unit)	Batch nr. 01–22	02–22	03–22	04–22	05–22	Method
Vitamin B1 (Thiamin) (mg/100 g)	0.47	0.41	0.46	0.40	0.41	LC–MS
Vitamin B2 (Riboflavin) (mg/100 g)	6.32	6.93	6.26	6.33	6.66	LC–MS
Vitamin B7 (Biotin) (µg/100 g)	148	175	146	162	163	Nephelometry
Vitamin B9 (Folate) (µg/100 g)	1110	1090	1150	1020	969	Nephelometry
Vitamin B5 (Pantothenic acid) (mg/100 g)	5.91	6.28	6.21	6.25	6.41	LC–MS
Calcium (Ca) (mg/100 g)	27.0	32.8	30.9	32.6	47.8	ICP-OES
Phosphorus (P) (mg/100 g)	917	1014	996	943	1407	ICP-OES
Potassium (K) (mg/100 g)	2105	2205	2198	2158	2387	F-AAS
Iron (Fe) (mg/100 g)	1.52	2.04	2.00	2.08	2.97	ICP-OES
Copper (Cu) (mg/100 g)	0.77	0.89	0.91	0.97	2.8	LC–MS
Magnesium (Mg) (mg/100 g)	67.4	74.5	74.0	75.6	108.0	ICP-OES
Manganese (Mn) (mg/100 g)	0.32	0.48	0.43	0.48	0.77	ICP-OES
Sodium (Na) (mg/100 g)	336	372	415	380	357	Flame photometry method
Zinc (Zn) (mg/100 g)	6.62	7.12	7.81	7.94	23.6	ICP-OES

Abbreviations: F-AAS, flame atomic absorption spectroscopy; ICP-OES, inductively coupled plasma-optical emission spectroscopy; LC–MS, liquid chromatography–mass spectrometry.

In addition, the applicant submitted a nutritional assessment, based on average concentrations of vitamins, minerals, protein, fat and carbohydrates in the NF, considering high intakes of the NF (i.e. at the 95th percentile), and taking into account respective tolerable upper intake levels (ULs) or other reference values (e.g. adequate intakes [AI], average requirements [AR], population reference intakes [PRIs]), as available. The Panel notes that ULs were not exceeded in any population group for any of the analysed vitamins or minerals.

Based on the high (95th percentile) intake levels of the NF (Table 3) and considering a maximum possible content of protein of 55% in the NF as per the specifications (Table 1), the corresponding protein intake per kg bw per day from the NF would amount to 0.53 g for infants, 0.61 g for young children, 0.58 g for other children, 0.38 g for adolescents and 0.29 g

for adults. Such intakes would correspond to about half of the PRIs for protein for the respective age groups (EFSA NDA Panel, 2012).

Information on the protein composition of *Y. lipolytica* biomass is available in the literature (Jach & Malm, 2022; Michalik et al., 2014). Based on the amino acid profile published by Michalik et al. (2014), the amino acid score of the protein in *Y. lipolytica* biomass is about 75, with sulfur amino acids as the limiting ones. The true digestibility of the protein was reported as 43.41 and the biological value as determined in rats is 56.81.

Provided that the NF would not be the sole source of dietary protein, that it is integrated into a varied and mixed diet, and considering that the average protein intake in the EU population is high and frequently above the dietary reference values (DRVs) (EFSA NDA Panel, 2012), the consumption of the NF is not expected to negatively impact protein nutrition.

The Panel considers that taking into account the composition of the NF and the proposed conditions of use, consumption of the NF is not nutritionally disadvantageous.

4 | DISCUSSION

The NF, which is the subject of the request for the extension of use, is the dried and heat-killed biomass of the yeast *Y. lipolytica*.

In 2018, *Y. lipolytica* was attributed the QPS status for production purposes, including food and feed products based on biomass.

The NF is already authorised for the placing on the market in the European Union in food supplements for children from 3 years onwards, adolescents and adults and in meal replacement products for weight reduction for adults.

In this most recent request for an extension of use, the applicant proposes to add the NF as a food ingredient to a number of food categories, in FSMPs and in foods for total diet replacement for weight control. The target population is the general population.

The Panel considers that the newly submitted data accompanying the application provided sufficient information with respect to the stability of the NF when used as a food ingredient and that the concentrations of the analysed processing contaminants do not raise safety concerns.

Under the proposed conditions of use, the highest intake estimates of the NF (at the 95th percentile) range from 523 mg/kg bw per day for adults to 1117 mg/kg bw per day for young children (aged 1 to < 3 years). Considering a maximum protein content of 55% in the NF (as per the specifications), such intakes would provide about half of the PRIs for protein (EFSA NDA Panel, 2012) for the respective age groups.

The Panel considers that the consumption of the NF is not nutritionally disadvantageous under the proposed conditions of use.

5 | CONCLUSIONS

The Panel concludes that the NF, *Y. lipolytica* yeast biomass, is safe under the proposed conditions of use.

6 | STEPS TAKEN BY EFSA

1. On 09/11/2020 EFSA received a letter from the European Commission with the request for a scientific opinion on the safety of an extension of use of *Y. lipolytica* yeast biomass as a NF. Ref. Ares(2020)6506179.
2. On 09/11/2020, a valid application on an extension of use of *Y. lipolytica* yeast biomass as a NF, which was submitted by the company Skotan S.A., was made available to EFSA by the European Commission through the Commission e-submission portal (NF 2020/1908) and the scientific evaluation procedure was initiated.
3. On 16/03/2021 and 21/09/2021, EFSA requested the applicant to provide additional information to accompany the application and the scientific evaluation was suspended.
4. On 16/07/2021 and 24/09/2023, additional information was provided by the applicant through the Commission e-submission portal and the scientific evaluation was restarted.
5. During its meeting on 26/10/2023, the NDA Panel, having evaluated the data, adopted a scientific opinion on the safety of an extension of use of *Y. lipolytica* yeast biomass as a NF pursuant to Regulation (EU) 2015/2283.

ABBREVIATIONS

AI	adequate intake
AR	average requirement
BIOHAZ	EFSA Panel on Biohazards
bw	body weight
CFU	colony forming unit
DRV	dietary reference value
F-AAS	flame atomic absorption spectroscopy

FAIM	Food Additive Intake Model
FSMP	food for special medical purposes
GC–MS	gas chromatography–mass spectrometry
ICP-OES	inductively coupled plasma-optical emission spectroscopy
LC–MS	liquid chromatography–mass spectrometry
LC–MS/MS	liquid chromatography coupled with tandem mass spectrometry
NDA	EFSA Panel on Nutrition, Novel Foods and Food Allergens
NF	novel food
P95	95th percentile
PRI	population Reference Intake
QPS	qualified presumption of safety
TAMC	total aerobic microbial count
TYMC	total yeast and mould count
UL	tolerable upper intake level

CONFLICT OF INTEREST

If you wish to access the declaration of interests of any expert contributing to an EFSA scientific assessment, please contact interestmanagement@efsa.europa.eu.

REQUESTOR

European Commission

QUESTION NUMBER

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REFERENCES

EFSA (European Food Safety Authority). (2011). Use of the EFSA comprehensive european food consumption database in exposure assessment. *EFSA Journal*, *9*(3), 2097. https://doi.org/10.2903/j.efsa.2011.2097

EFSA BIOHAZ Panel (EFSA Panel on Biological Hazards), Ricci, A., Allende, A., Bolton, D., Chemaly, M., Davies, R., Fernández Escámez, P. S., Girones, R., Koutsoumanis, K., Lindqvist, R., Nørrung, B., Robertson, L., Ru, G., Sanaa, M., Simmons, M., Skandamis, P., Snary, E., Speybroeck, N., Ter Kuile, B., … Herman, L. (2018). Statement on the update of the list of QPS-recommended biological agents intentionally added to food or feed as notified to EFSA 8: Suitability of taxonomic units notified to EFSA until March 2018. *EFSA Journal*, *16*(7), 5315. https://doi.org/10.2903/j.efsa.2018.5315

EFSA NDA Panel (EFSA Panel on Nutrition, Novel Foods and Food Allergens). (2012). Scientific opinion on dietary reference values for protein. *EFSA Journal*, *10*(2), 2557. https://doi.org/10.2903/j.efsa.2012.2557

EFSA NDA Panel (EFSA Panel on Nutrition, Novel Foods and Food Allergens). (2016). Guidance on the preparation and presentation of an application for authorisation of a novel food in the context of Regulation (EU) 2015/2283. *EFSA Journal*, *14*(11), 4594. https://doi.org/10.2903/j.efsa.2016.4594

EFSA NDA Panel (EFSA Panel on Nutrition, Novel Foods and Food Allergens). (2019). Scientific opinion on the safety of *Yarrowia lipolytica* yeast biomass as a novel food pursuant to Regulation (EU) 2015/2283. *EFSA Journal*, *17*(2), 5594. https://doi.org/10.2903/j.efsa.2019.5594

EFSA NDA Panel (EFSA Panel on Nutrition, Novel Foods and Food Allergens). (2022). Safety of an extension of use of *Yarrowia lipolytica* yeast biomass as a novel food pursuant to Regulation (EU) 2015/2283. *EFSA Journal*, *20*(7), 7450. https://doi.org/10.2903/j.efsa.2022.7450

EFSA Scientific Committee. (2012). Guidance on selected default values to be used by the EFSA scientific committee, scientific panels and units in the absence of actual measured data. *EFSA Journal*, *10*(3), 2579. https://doi.org/10.2903/j.efsa.2012.2579

Jach, M. E., & Malm, A. (2022). *Yarrowia lipolytica* as an alternative and valuable source of nutritional and bioactive compounds for humans. *Molecules*, *27*, 2300.

Michalik, B., Biel, W., Lubowicki, R., & Jacyno, E. (2014). Chemical composition and biological value of proteins of the yeast *Yarrowia lipolytica* growing on industrial glycerol. *Canadian Journal of Animal Science*, *94*, 99–104.

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APPENDIX A

Processing contaminants

TABLE A1 Processing contaminants in wheat bread.

Parameter	Unit	Results	NF batch #
Acrylamide[a]	µg/kg	< 20	Control
		< 20	02–22
		< 20	03–22
		< 20	04–22
		< 20	05–22
Furan[b]	µg/kg	12 (± 5)	Control
		8 (± 3)	02–22
		15 (± 6)	03–22
		14 (± 5)	04–22
		10 (± 4)	05–22
3-Methylfuran[b]	µg/kg	< 5.0	Control
		< 5.0	02–22
		< 5.0	03–22
		< 5.0	04–22
		< 5.0	05–22
2-Methylfuran[b]	µg/kg	< 5.0	Control
		< 5.0	02–22
		< 5.0	03–22
		< 5.0	04–22
		< 5.0	05–22

[a]By LC–MS/MS (liquid chromatography coupled with tandem mass spectrometry).
[b]By GC–MS (gas chromatography–mass spectrometry).

TABLE A2 Processing contaminants in corn chips.

Parameter	Unit	Results	NF batch #
Acrylamide[a]	µg/kg	57 (± 23)	Control
		52 (± 21)	02–22
		50 (± 20)	03–22
		50 (± 20)	04–22
		55 (± 22)	05–22
Furan[b]	µg/kg	80 (± 32)	Control
		51 (± 20)	02–22
		49 (± 19)	03–22
		52 (± 21)	04–22
		44 (± 18)	05–22
3-Methylfuran[b]	µg/kg	59 (± 24)	Control
		52 (± 21)	02–22
		50 (± 20)	03–22
		52 (± 21)	04–22
		45 (± 18)	05–22
2-Methylfuran[b]	µg/kg	39 (± 16)	Control
		20 (± 8)	02–22
		19 (± 7)	03–22
		20 (± 8)	04–22
		17 (± 7)	05–22

[a]By LC–MS/MS (liquid chromatography coupled with tandem mass spectrometry).
[b]By GC–MS (gas chromatography–mass spectrometry).