CONCLUSION ON PESTICIDES PEER REVIEW

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Peer review of the pesticide risk assessment of the active substance ABE-IT 56 (components of lysate of *Saccharomyces cerevisiae* strain DDSF623)

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Abstract

The conclusions of EFSA following the peer review of the initial risk assessments carried out by the competent authority of the rapporteur Member State, France, for the pesticide active substance ABE-IT 56 (components of lysate of *Saccharomyces cerevisiae* strain DDSF623) are reported. The context of the peer review was that required by Regulation (EC) No 1107/2009 of the European Parliament and of the Council. The conclusions were reached on the basis of the evaluation of the representative use of ABE-IT 56 as a fungicide on grapes. The reliable endpoints, appropriate for use in regulatory risk assessment, are presented. Missing information identified as being required by the regulatory framework is listed.

Keywords: ABE-IT 56, *Saccharomyces cerevisiae* strain DDSF623, peer review, risk assessment, pesticide, fungicide

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Summary

ABE-IT 56 (components of lysate of *Saccharomyces cerevisiae* strain DDSF623) is a new active substance for which, in accordance with Article 7 of Regulation (EC) No 1107/2009 of the European Parliament and of the Council (hereinafter referred to as 'the Regulation'), the rapporteur Member State (RMS), France, received an application from the Task Force ABE IT 56 (Jouffray Drillaud and Danstar Ferment AG) on 1 April 2016 for approval. Complying with Article 9 of the Regulation, the completeness of the dossier was checked by the RMS and the date of admissibility of the application was recognised as being 25 May 2016.

The RMS provided its initial evaluation of the dossier on ABE-IT 56 in the draft assessment report (DAR), which was received by the European Food Safety Authority (EFSA) on 20 June 2017. The peer review was initiated on 30 August 2017 by dispatching the DAR for consultation to the Member States and the applicants of the Task Force ABE IT 56 (Jouffray Drillaud and Danstar Ferment AG).

Following consideration of the comments received on the DAR, it was concluded that additional information should be requested from the applicants, and that there was no need to conduct an expert consultation.

In accordance with Article 12 of the Regulation, EFSA should adopt a conclusion on whether ABE-IT 56 can be expected to meet the approval criteria provided for in Article 4 of the Regulation taking into consideration recital (10) of the Regulation. Furthermore, this conclusion also addresses the assessment required from EFSA under Article 12 of Regulation (EC) No 396/2005, provided the active substance will be approved under Regulation (EC) No 1107/2009 without restrictions affecting the residue assessment.

The conclusions laid down in this report were reached on the basis of the evaluation of the representative use of ABE-IT 56 as a fungicide on grapes as proposed by the applicants. Full details of the representative uses can be found in Appendix A of this report.

The use of ABE-IT 56 according to a higher application rate than the representative use proposed results in a sufficient efficacy on grapevine as an elicitor of natural defences of the plant to delay the occurrence of downy mildew.

A data gap was identified for a literature search to recover peer reviewed scientific articles that might inform on data requirements that followed the EFSA guidance (2011). The available literature search had used inappropriate relevance criteria that did not concur with the approach defined in this EFSA guidance.

In the section identity, physical–chemical and technical properties and analytical methods, there were not data gaps identified.

Human exposure to ABE IT 56 (components of lysate of *S. cerevisiae* strain DDSF623) can widely occur from exposure to *S. cerevisiae*, and although a sensitisation potential by inhalation cannot be excluded, human safety concerns are not expected from the use of this substance as a plant protection product. Data gaps are identified for skin sensitisation and eye irritation studies.

Due to the nature and properties of ABE IT 56, the investigation of residues in plant and animal commodities, consumer exposure assessment and maximum residue level (MRL) setting are not relevant. It is proposed to include ABE IT 56 in Annex IV of Regulation (EC) No 396/2005.

The information provided regarding environmental fate and behaviour was considered sufficient to complete the necessary environmental exposure assessments for the representative uses assessed.

Areas of concern or data gaps were not identified for ecotoxicology.

Table of contents

Background

Regulation (EC) No 1107/2009 of the European Parliament and of the Council[1] (hereinafter referred to as 'the Regulation') lays down, inter alia, the detailed rules as regards the procedure and conditions for approval of active substances. This regulates for the European Food Safety Authority (EFSA) the procedure for organising the consultation of Member States and the applicants for comments on the initial evaluation in the draft assessment report (DAR), provided by the rapporteur Member State (RMS), and the organisation of an expert consultation, where appropriate.

In accordance with Article 12 of the Regulation, EFSA is required to adopt a conclusion on whether an active substance can be expected to meet the approval criteria provided for in Article 4 of the Regulation (also taking into consideration recital (10) of the Regulation) within 120 days from the end of the period provided for the submission of written comments, subject to an extension of 30 days where an expert consultation is necessary, and a further extension of up to 150 days where additional information is required to be submitted by the applicants in accordance with Article 12(3).

ABE-IT 56 (components of lysate of *Saccharomyces cerevisiae* strain DDSF623) is a new active substance for which, in accordance with Article 7 of the Regulation, the RMS, France (hereinafter referred to as the 'RMS'), received an application from the Task Force ABE IT 56 (Jouffray Drillaud and Danstar Ferment AG) on 1 April 2016 for approval. Complying with Article 9 of the Regulation, the completeness of the dossier was checked by the RMS and the date of admissibility of the application was recognised as being 25 May 2016.

The RMS provided its initial evaluation of the dossier on ABE-IT 56 in the DAR, which was received by EFSA on 20 June 2017 (France, 2017). The peer review was initiated on 30 August 2017 by dispatching the DAR for consultation of the Member States and the applicants of the Task Force ABE IT 56 (Jouffray Drillaud and Danstar Ferment AG), for consultation and comments. EFSA also provided comments. In addition, EFSA conducted a public consultation on the DAR. The comments received were collated by EFSA and forwarded to the RMS for compilation and evaluation in the format of a reporting table. The applicants were invited to respond to the comments in column 3 of the reporting table. The comments and the applicant response were evaluated by the RMS in column 3.

The need for expert consultation and the necessity for additional information to be submitted by the applicants in accordance with Article 12(3) of the Regulation were considered in a telephone conference between EFSA and the RMS on 14 December 2017. On the basis of the comments received, the applicants' response to the comments and the RMS's evaluation thereof, it was concluded that additional information should be requested from the applicants, and that there was no need to conduct an expert consultation.

The outcome of the telephone conference, together with EFSA's further consideration of the comments is reflected in the conclusions set out in column 4 of the reporting table. All points that were identified as unresolved at the end of the comment evaluation phase and which required further consideration, were compiled by EFSA in the format of an evaluation table.

The conclusions arising from the consideration by EFSA, and as appropriate by the RMS, of the points identified in the evaluation table, were reported in the final column of the evaluation table.

In accordance with Article 12 of the Regulation, EFSA should adopt a conclusion on whether ABE-IT 56 can be expected to meet the approval criteria provided for in Article 4 of the Regulation, taking into consideration recital (10) of the Regulation. A final consultation on the conclusions arising from the peer review of the risk assessment took place with Member States via a written procedure in July 2018.

This conclusion report summarises the outcome of the peer review of the risk assessment on the active substance and the representative formulation evaluated on the basis of the representative use of ABE-IT 56 as a fungicide on grapes as proposed by the applicants. Furthermore, this conclusion also addresses the assessment required from EFSA under Article 12 of Regulation (EC) No 396/2005[2], provided the active substance will be approved under Regulation (EC) No 1107/2009 without restrictions affecting the residue assessment. In the event of a non-approval of the active substance or an approval with restrictions that have an impact on the residue assessment, the Annex IV proposal

[1] Regulation (EC) No 1107/2009 of 21 October 2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC. OJ L 309, 24.11.2009, p. 1–50.

[2] Regulation (EC) No 396/2005 of the European Parliament and of the Council of 23 February 2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin and amending Council Directive 91/414/EEC. OJ L 70, 16.3.2005, p. 1–16.

from this conclusion might no longer be relevant and a new assessment under Article 12 of Regulation (EC) No 396/2005 will be required. A list of the relevant end points for the active substance and the formulation is provided in Appendix A.

In addition, a key supporting document to this conclusion is the peer review report (EFSA, 2018), which is a compilation of the documentation developed to evaluate and address all issues raised in the peer review, from the initial commenting phase to the conclusion. The peer review report comprises the following documents, in which all views expressed during the course of the peer review, including minority views where applicable, can be found:

- the comments received on the DAR;
- the reporting table (14 December 2017);
- the evaluation table (5 July 2018);
- the comments received on the assessment of the additional information (where relevant);
- the comments received on the draft EFSA conclusion.

Given the importance of the DAR including its revisions (France, 2018) and the peer review report, both documents are considered as background documents to this conclusion.

It is recommended that this conclusion report and its background documents would not be accepted to support any registration outside the European Union (EU) for which the applicant has not demonstrated that it has regulatory access to the information on which this conclusion report is based.

The active substance and the formulated product

The active substance ABE IT 56 is a fractionation product of the lysate of *S. cerevisiae* strain DDSF623 originating from Lallemand Yeast Culture Collection, Canada.

The representative formulated product for the evaluation was 'JDE 01', a suspension concentrate (SC) containing 296 g/kg (326 g/L) of components of lysate of *S. cerevisiae* strain DDSF623. A FAO specification does not exist for this product.

The representative uses evaluated as elicitor of the plant natural defence to control pathogen diseases comprise applications by spraying against downy mildew in grapes, in the EU. Full details of the Good Agricultural Practice (GAP) can be found in the list of end points in Appendix A.

Data were submitted to conclude that the uses of ABE IT 56 according to a higher application rate than the representative uses proposed at EU level resulted in a sufficient efficacy as an elicitor of natural defences of the plant to delay the occurrence of downy mildew, following the guidance document SANCO/10054/2013-rev. 3 (European Commission, 2013).

A data gap has been identified for a literature search for all sections to recover peer reviewed scientific articles that might inform on data requirements that followed the EFSA guidance (2011). In particular, the relevance criteria reported in the available search are not compatible with the EFSA guidance.

Conclusions of the evaluation

1. Identity, physical/chemical/technical properties and methods of analysis

The following guidance documents were followed in the production of this conclusion: SANCO/3029/99-rev. 4 (European Commission, 2000a), SANCO/12116/2012–rev. 0 (European Commission, 2012) and Guidance on the assessment of bacterial susceptibility to antimicrobials of human and veterinary importance (EFSA FEEDAP Panel, 2012).

The active substance is composed by a non-modified fractionation product of *S. cerevisiae* strain DDSF623. Three different markers of quantification: total proteins, free amino acids and total reducing sugars were proposed, because they reflect the yeast origin of ABE IT 56. The specifications for the chemical markers for ABE IT 56 are based on batch data on these three markers. The specification ranges for the markers are: total proteins: 58.88–62.12%, total reducing sugars: 1.39–3.43%, free amino acids: 29.05–31.75%. It should be noted, however, that the composition markers proposed are not adequate to identify the product as an extract of *S. cerevisiae* strain DDSF623 as other yeasts would provide comparable quantities.

Real-time quantitative polymerase chain reaction (PCR) analysis can be used for the identification of the yeast strain DDSF623.

The technical active substance does not contain any relevant microbial contaminants in accordance with the guidance SANCO/12116/2012_rev.0 (European Commission, 2012).

There is no evidence of direct relationship of *S. cerevisiae* strain DDSF623 to known plant, animal or human pathogens.

The assessment of the data package revealed no issues that need to be included as critical areas of concern with respect to the identity, physical and technical properties of the representative formulation. The nominal content of the active substance markers in the final product JDE 01 are: Total proteins: 196.9 g/L (17.9%), total reducing sugars: 7.7 g/L (0.7%) and free amino acids: 99 g/L (9%). The preparation must be stored at a temperature below 30°C.

Acceptable methods are available for the determination of the marker compounds in the technical material and the representative formulation and for the determination of the content of contaminating microorganisms.

Since residue definitions were not defined in any compartments, methods for post-authorisation control and monitoring purposes are not required.

2. Mammalian toxicity

The active substance ABE IT 56 is composed by the components of lysate of *S. cerevisiae* strain DDSF623. *S. cerevisiae* is the most widely used yeast in industrial/commercial food and beverage production and it is consumed as a nutritional supplement. EFSA considered *S. cerevisiae* safe for consumers having a presumption of safety status (EFSA BIOHAZ Panel, 2018).

The applicant submitted only acute oral, dermal and inhalation Good Laboratory Practice (GLP)-compliant studies with the product. These studies demonstrated that the product was of low acute toxicity to rats. A skin sensitisation and eye irritation studies are ongoing (data gaps).

Based on previous discussions during the peer review of cerevisane (EFSA, 2014), a closely-related substance to ABE IT 56, EFSA considered appropriate not to exclude the sensitisation hazard by inhalation of ABE IT 56. The risk phrases R42 'May cause sensitisation by inhalation' and H334 'May cause allergy or asthma symptoms or breathing difficulties if inhaled' are proposed for ABE IT 56.[3]

Despite the limited number of toxicity studies, EFSA concludes that human exposure to the substance can widely occur from exposure to *S. cerevisiae,* and although a sensitisation potential by inhalation cannot be excluded (which is however not expected to exceed the level arising from exposure to ubiquitous inhalation allergens), human safety concerns including endocrine disruption are not expected from the use of this substance as a plant protection product. Based on the toxicological profile, health based reference values are not needed to be set and a quantitative non-dietary exposure assessment is not needed.

3. Residues

As human safety concerns are not expected from the use of ABE IT 56 as a plant protection product, which is are components derived from the lysate of the most widely used yeast in industrial/ commercial food and beverage production, the investigation of residues in plant and animal commodities and the assessment of consumer and livestock exposure is not considered relevant for ABE IT 56.

It is therefore proposed to include ABE IT 56 in Annex IV of Regulation (EC) No 396/2005 as a substance for which maximum residue levels (MRLs) are not required.

4. Environmental fate and behaviour

ABE IT 56 (components of lysate of *S. cerevisiae* strain DDSF623) was readily biodegradable in an OECD 301F ready biodegradability study (that utilised a sewage sludge inoculum). Following ECHA (2016) REACH R16 guidance, this evidence is sufficient to indicate that the formation of transformation products that would reach levels that would need further assessment is unlikely and that soil, water and sediment single first-order (SFO) DT_{50} at 20°C can be estimated as 14.1, 7.1 and 141 days[4] (when respective values of 30, 15 and 300 days at 12°C from the REACH guidance are considered). This indicates that the active components are expected to exhibit moderate persistence in soil, low persistence in water and high persistence in sediment. The dossier also includes peer reviewed

[3] Refer to evaluation table section 2, EFSA response to data requirement 2.3 (EFSA, 2018).
[4] Using the agreed Q10 of 2.58 (following EFSA, 2008).

scientific literature indicating that *S. cerevisiae* is ubiquitously present in soil, water and sediment in all temperate and tropical regions. The RMS also correctly indicated that the components of lysate of *S. cerevisiae* will also originate from the cells of other organisms. Regarding the potential for the exposure of groundwater by components of lysate of *S. cerevisiae* strain DDSF623, this was considered unlikely based on the estimated soil DT_{50}. If any component were to reach a groundwater aquifer it would be indistinguishable from components that may be present there that originated from cells of other micro- and macroorganisms.

The predicted environmental concentration (PEC) in soil and surface water covering the representative uses assessed can be found in Appendix A of this conclusion. Note these PEC correspond to a GAP that has higher application rate than that requested by the applicant in their original dossier.

5. Ecotoxicology

Toxicity studies on non-target organisms performed with ABE IT 56 (components of lysate of *S. cerevisiae* strain DDSF623) or the representative formulation 'JDE01' were not available for most non-target organisms. Only acute toxicity studies on mammals, aquatic organisms and bees were available. According to the available literature review, *S. cerevisiae* is ubiquitous in environment; therefore non-target organisms are expected to be naturally exposed to it. It is also noted that the *Saccharomyces cerevisiae* present in the product 'JDE01' are inert; biological activity is, therefore, not expected.

Considering the above, harmful effects are not expected to occur for non-target organisms due to the identity and the nature of ABE IT 56. Therefore, the risk to non-target organisms can be concluded as low.

Data were not available for addressing the potential endocrine disrupting properties of ABE IT 56 in non-target organisms; however, considering the toxicological profile of this active substance, the provision of further data was considered unnecessary.

6. Overview of the risk assessment of compounds listed in residue definitions triggering assessment of effects data for the environmental compartments (Tables 1–4)

Table 1: Soil

Compound (name and/or code)	Persistence	Ecotoxicology
Components of lysate of *Saccharomyces cerevisiae* strain DDSF623	Moderate persistence Single first-order DT_{50} 14.1 days (20°C)	Low risk

DT_{50}: period required for 50% dissipation.

Table 2: Groundwater

Compound (name and/or code)	Mobility in soil	> 0.1 µg/L at 1 m depth for the representative uses[a]	Pesticidal activity	Toxicological relevance
Components of lysate of *Saccharomyces cerevisiae* strain DDSF623	No data	Considered unlikely based on evidence of ready biodegradability. If any component were to reach a groundwater aquifer, it would be indistinguishable from components that may be present there having originated from cells of other micro- and macroorganisms	Yes	No

(a): At least one FOCUS scenario or a relevant lysimeter.

Table 3: Surface water and sediment

Compound (name and/or code)	Ecotoxicology
Components of lysate of *Saccharomyces cerevisiae* strain DDSF623	Low risk

Table 4: Air

Compound (name and/or code)	Toxicology
Components of lysate of *Saccharomyces cerevisiae* strain DDSF623	Low acute toxicity by inhalation to rats (> 3.8 mg/L air per 4 h (maximum attainable concentration) based on results obtained with the representative product JDE01 containing 325.6 g/L of ABE IT 56)

7. Data gaps

This is a list of data gaps identified during the peer review process, including those areas in which a study may have been made available during the peer review process but not considered for procedural reasons (without prejudice to the provisions of Article 56 of the Regulation concerning information on potentially harmful effects).

7.1. Data gaps identified for the representative uses evaluated

- Skin sensitisation study on ABE IT 56 (relevant for the representative uses evaluated; submission date proposed by the applicant: ongoing; see Section 2).
- Eye irritation study on ABE IT 56 (relevant for the representative uses evaluated; submission date proposed by the applicant: ongoing; see Section 2).
- A literature search to recover peer reviewed scientific articles for all sections that might inform on data requirements that followed the EFSA guidance (2011) was not available. In particular, the relevance criteria reported in the available search are not compatible with the EFSA guidance for fate and behaviour. For toxicology, a relevant paper was not submitted for reliability assessment (relevant for the representative uses evaluated; submission date proposed by the applicant unknown; applicable for Sections 2, 3, 4 and 5; see open points 2.8 and 3.1, data requirement points 4.5 and 5.3 in EFSA, 2018).
- An aerobic mineralisation in surface water study or information to demonstrate that contamination of open water (freshwater, estuarine and marine) will not occur was not available (though a data requirement, not needed for any of the representative uses evaluated when following noted EU environmental exposure assessment guidance, submission date proposed by the applicant: unknown; see Section 4 of the evaluation table contained in the peer review report (EFSA, 2018)).

8. Particular conditions proposed to be taken into account to manage the risk identified

No particular conditions are proposed for the representative uses evaluated.

9. Concerns

9.1. Issues that could not be finalised

An issue is listed as 'could not be finalised' if there is not enough information available to perform an assessment, even at the lowest tier level, for the representative uses in line with the uniform principles in accordance with Article 29(6) of the Regulation and as set out in Commission Regulation (EU) No 546/2011[5] and if the issue is of such importance that it could, when finalised, become a concern (which would also be listed as a critical area of concern if it is of relevance to all representative uses).

An issue is also listed as 'could not be finalised' if the available information is considered insufficient to conclude on whether the active substance can be expected to meet the approval criteria provided for in Article 4 of the Regulation.

None identified.

9.2. Critical areas of concern

An issue is listed as a critical area of concern if there is enough information available to perform an assessment for the representative uses in line with the uniform principles in accordance with Article 29 (6) of the Regulation and as set out in Commission Regulation (EU) No 546/2011, and if this assessment does not permit the conclusion that, for at least one of the representative uses, it may be expected that a plant protection product containing the active substance will not have any harmful effect on human or animal health or on groundwater or any unacceptable influence on the environment.

[5] Commission Regulation (EU) No 546/2011 of 10 June 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards uniform principles for evaluation and authorisation of plant protection products. OJ L 155, 11.6.2011, p. 127–175.

An issue is also listed as a critical area of concern if the assessment at a higher tier level could not be finalised due to lack of information, and if the assessment performed at the lower tier level does not permit the conclusion that, for at least one of the representative uses, it may be expected that a plant protection product containing the active substance will not have any harmful effect on human or animal health or on groundwater or any unacceptable influence on the environment.

An issue is also listed as a critical area of concern if, in the light of current scientific and technical knowledge using guidance documents available at the time of application, the active substance is not expected to meet the approval criteria provided for in Article 4 of the Regulation.

No critical areas of concern have been identified.

9.3. Overview of the concerns identified for each representative use considered

(If a particular condition proposed to be taken into account to manage an identified risk, as listed in Section 8, has been evaluated as being effective, then 'risk identified' is not indicated in Table 5.)

Table 5: Overview of concerns

Representative use		Grape vines
Operator risk	Risk identified	
	Assessment not finalised	
Worker risk	Risk identified	
	Assessment not finalised	
Resident/bystander risk	Risk identified	
	Assessment not finalised	
Consumer risk	Risk identified	
	Assessment not finalised	
Risk to wild non-target terrestrial vertebrates	Risk identified	
	Assessment not finalised	
Risk to wild non-target terrestrial organisms other than vertebrates	Risk identified	
	Assessment not finalised	
Risk to aquatic organisms	Risk identified	
	Assessment not finalised	
Groundwater exposure to active substance	Legal parametric value breached	
	Assessment not finalised	
Groundwater exposure to metabolites	Legal parametric value breached	
	Parametric value of 10 μg/L[(a)] breached	
	Assessment not finalised	

The superscript numbers relate to the numbered points indicated in Sections 9.1 and 9.2 in this case no superscript number occurs, see Sections 2–6 for further information.

(a): Value for non-relevant metabolites prescribed in SANCO/221/2000-rev. 10 final, European Commission, 2003.

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Abbreviations

DAR	draft assessment report
DT_{50}	period required for 50% dissipation (define method of estimation)
ECHA	European Chemicals Agency
EEC	European Economic Community
FAO	Food and Agriculture Organization of the United Nations
FOCUS	Forum for the Co-ordination of Pesticide Fate Models and their Use
GAP	Good Agricultural Practice
GLP	Good Laboratory Practice
ISO	International Organization for Standardization
MRL	maximum residue level
PCR	polymerase chain reaction
PD	proportion of different food types
PEC	predicted environmental concentration
PEC_{soil}	predicted environmental concentration in soil
PEC_{sw}	predicted environmental concentration in surface water
REACH	Registration, Evaluation, Authorisation of Chemicals Regulation
RMS	rapporteur Member State
SC	suspension concentrate
SFO	single first-order
SMILES	simplified molecular-input line-entry system

Appendix A – List of end points for the active substance and the representative formulation

Appendix A can be found in the online version of this output ('Supporting information' section): https://doi.org/10.2903/j.efsa.2018.5400

Appendix B – Used compound codes

Code/trivial name[a]	IUPAC name/SMILES notation/InChiKey[b]	Structural formula[c]
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IUPAC: International Union of Pure and Applied Chemistry; SMILES: simplified molecular-input line-entry system; InChiKey: International Chemical identifier Key.
(a): The metabolite name in bold is the name used in the conclusion.
(b): ACD/Name 2015 ACD/Labs 2015 Release (File version N20E41, Build 75170, 19 December 2014).
(c): ACD/ChemSketch 2015 ACD/Labs 2015 Release (File version C10H41, Build 75059, 17 December 2014).