Presentation of studies used as supporting information in the assessment report

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Background

TECHNICAL REPORT

efsa
European Food Safety Authority
Supporting Publications

APPROVED: 27 March 2019

doi: 10.2903/sp.efsa.2019.EN-1612

Administrative guidance on submission of dossiers and assessment reports for the peer-review of pesticide active substances

European Food Safety Authority (EFSA)

This guidance requests to provide full information on the peer-reviewed articles used for the dossier preparation

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Problem

- Especially for micro-organisms there is often a large number of published studies (sometimes up to 300)
- For some studies (biological properties) there is no added value to present a full summary according to Appendix E
- Section B2 becomes very extensive while only a small part is relevant for the actual risk assesment

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Former discussions

- Discussed previously in PSN in October 2023: proposal to only include abstract of paper in case of supporting information, instead of including all the information in point 2 of appendix E (full summary of the study)
- Response EFSA: If the information is not fully completed then an independent assessment is not possible at the course of the peer review.

- Also discussed during the meeting of the Working Group on Biopesticides of September 2024

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Proposal

- peer-reviewed articles used for fulfilling specific endpoints (e.g., toxicity of metabolites): follow the full provisions of the EFSA GD
- peer-reviewed articles used only as supporting/supplemental/background information: only the abstracts of these studies would be useful, and providing all the other info (e.g., material and methods) is just an unnecessary burden.

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Proposal

Appendix E- Template for presenting individual study summaries

1. Information on the study

Data point:	EU data requirement No.
Report author	Chuck Norris et al.
Report year	2002
Report title	The usefulness of art martial in environmental risk assessment
Report No	AMR 1631-90
Document No	M-301383-01-1
Guidelines followed in study	U.S. EPA 162-1 None
Deviations from current test guideline	If yes, deviations have to be presented based on expert judgement with an explanatory text.
Previous evaluation	Please choose in the following list the appropriate category: • Yes, evaluated and accepted + mention in which document e.g. *in the DAR (2005)/in the Addendum to the DAR (2006).* • Yes, evaluated and classified as supplemental + mention in which document e.g. *in the DAR (2005)/in the Addendum to the DAR (2006).* • Yes, evaluated and not accepted+ mention in which document e.g. *in the DAR (2005)/in the Addendum to the DAR (2006).* • No, submitted after the legal deadline and hence, not evaluated • No, not previously submitted
GLP/Officially recognised testing facilities[1,2]	• Yes, conducted under GLP/Officially recognised testing facilities • No, not conducted under GLP/Officially recognised testing facilities (give justification e.g., state that GLP was not compulsory at the time the study was performed)
Acceptability/Reliability:	Yes/Supportive only (in which case reason should be provided)

2. Full summary of the study according to OECD format

This should include study description and study results presented in tabular format if relevant (see details in respective section 'Assessment and presentations of studies' of the Administrative guidance).

The study summary should contain a description of the study design and the results as presented by the applicant in the respective Document M, but verified and where relevant corrected by the RMS in the assessment report. It should be limited to the facts and not contain any opinion, nor from the applicant, nor from the RMS.

Materials and methods

Study description - Text / Tables / Figures

Results

Study results - Text / Tables / Figures

Proposal BPWG + PSN 2023 -> use abstract for this point

3. Assessment and conclusion

Assessment and conclusion by applicant:

Assessment and conclusion by RMS:
Outcome and conclusion of the study: RMS should indicate if they agree to the results and conclusions of the APPL.

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Example

Supporting information in dossier:

MO (species-level) occurs naturally in food items

Research Note

Metabolic Characterization of *Bacillus subtilis* and *Bacillus amyloliquefaciens* Strains Isolated from Traditional Dry-Cured Sausages

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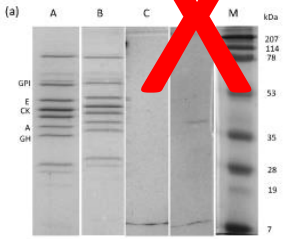
MS 14-145: Received 27 March 2014/Accepted 29 April 2014

ABSTRACT

The aim of this study was to investigate the effect of pH, temperature, and NaCl on growth, proteolytic and lipolytic activities, and the ability to produce biogenic amines of 19 strains of *Bacillus* isolated from Androlla and Botillo (two Spanish traditional sausages) to elucidate the role of these bacteria in sausage manufacture. All strains grew in the presence of 10% salt and at pH values of 5.0 and 5.5, whereas only 9 strains grew at 10°C. Proteolytic activity was assessed by the agar plate method, which revealed that 100 and 94.7% of the strains were able to hydrolyze sarcoplasmic and myofibrillar proteins, respectively. These results were confirmed by electrophoretic assays. The titration method revealed that only two strains hydrolyzed pork fat to any extent, and the profiles of the fatty acids freed were different. Most strains produced biogenic amines, but the quantities were generally low.

TABLE 3. *Free fatty acid profiles of low, interm*

Fatty acid(s)[a]	Low lipolytic activity (n = 14)[c] Mean	SEM	F	I
C10:0	13.25	3.20		
C12:0	24.52	1.95		
C14:0	22.92	0.59		
C15:0	9.29	1.07		
C16:0	69.85	6.42		
C16:1	22.94	1.75		
C17:0	9.47	0.43		
C17:1	11.63	0.30		
C18:0	44.01	3.70		
C18:1 n9	77.84	8.11		
C18:2 n6	38.17	4.17		
C18:3 n3	19.37	1.30		
C20:0	19.60	0.39		
C20:1 n9	12.09	0.37		
C20:2 n6	11.64	0.98		
C20:4 n6	11.78	0.26		
C22:0	5.17	2.28		
C22:2 n6				
C24:0				
SFA			27.54	736.63	836.50	***
UFA			20.65	498.58	547.59	***
MUFA			13.66	238.05	288.91	***
PUFA			61.07	1,868.33	2,212.82	***
Total						



MATERIALS AND METHODS

***Bacillus* strains and preparation of cell suspensions.** The *B. subtilis* and *B. amyloliquefaciens* strains used in this study (Table 1) were isolated on standard plate count agar (Oxoid, Basingstoke, UK) plus 7.5% NaCl *(16, 17)*. For the Androlla and Botillo sausages, 13 of the 200 isolates and 17 of the 150 isolates, respectively, found on standard plate count agar plus 7.5% NaCl were later determined to be *Bacillus* spp. Strains were identified by sequencing the 16S rRNA gene and comparing the obtained sequences with those available in the GenBank database (National Center for Biotechnology Information, Bethesda, MD). The genomic DNA extracted from the *Bacillus* isolates was then subjected to repetitive sequence–based PCR analysis using the single oligonucleotide primer $(GTG)_5$ as described by Fonseca et al. *(14)*. The 19 strains selected for this study had different $(GTG)_5$-PCR fingerprinting profiles, indicating differences among strains of the same species. Strains were stored at −80°C in brain heart infusion (BHI) broth (Oxoid) with 20% (vol/vol) glycerol as a cryoprotective agent.

To prepare the cell suspensions, a correlation between the log CFU per milliliter and the absorbance at 650 nm was established for each strain. Samples of BHI broth cultures were collected after 24 h of incubation, and the absorbance at 650 nm was measured. The cultures were then centrifuged at 12,000 × *g* for 10 min, and the [illegible] pellets were washed twice with 20 mM phosphate [illegible] pH 7.0 and then resuspended in the same buffer to obtain [illegible] approximately 10^9 CFU/ml.

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Thank you

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