



Terms of use of the Feed additives Environmental Risk Assessment (FERA) calculator

Version 1.0 - 10 December 2019

Please read this End-User License Agreement ("Agreement") carefully before using the Feed additives Environmental Risk Assessment (FERA) calculation tool for the first time.

By using and/or downloading the FERA calculator, the user agrees to be bound by the terms and conditions of this Agreement.

1. General information

The purpose of the Feed additives Environmental Risk Assessment (FERA) calculation tool is to provide a standardised instrument to calculate Phase I and II exposure levels (predicted environmental concentration), and the predicted no effect concentration of sediment compartment based on the equilibrium partitioning method (PNEC_{sed,EqP}) for the environmental risk assessment (ERA) of feed additives.

2. The purpose of use of FERA calculator

The FERA calculator is intended to be used by applicants, risk assessors and risk managers to make predictions on the environmental exposure to a given feed additive and to simplify the potential risk assessment process. The information provided by the calculator is not intended to constitute advice from the European Food Safety Authority (EFSA) or any EU institution, body or other agency of any kind or the rendering of consulting, or other professional services of any kind. It does not represent scientific, legal or regulatory advice and it is without prejudice to the actual scientific evaluation to be provided by EFSA under the applicable legal framework.

3. Scope

These terms apply between the user and EFSA and they set out the conditions applicable to the use of the calculator.

The "user" means the natural or legal person (e.g. the individual, company, organisation) who makes use of this calculator and, by doing so, becomes subject to terms and conditions set out in this Agreement.

By the acceptance of these terms by the user, EFSA grants the user a revocable, nonexclusive, non-transferable and limited license to use the calculator solely for individual purposes strictly in accordance with the terms of this Agreement.

4. Intellectual Property Rights

EFSA owns the Calculator. Copyright (©) is asserted by EFSA for the Calculator, unless otherwise stated. By allowing the usage and/or downloading of the Calculator, EFSA does not waive ownership of the Calculator and reserves all rights to maintain it, update it, or improve it as it sees fit.

The EFSA logo is the exclusive property of EFSA - EFSA's name and its logo are registered under Article 6ter of the Paris Convention for the protection of industrial property. Their use is prohibited without the prior written permission of EFSA.

This Calculator does not disclose any commercially sensitive or otherwise confidential information.

EFSA is not the owner of the data generated by the Calculator. By gaining access to the Calculator, the user is not granted access to the underlying datasets used by the Calculator. Should the user



intend to gain access to the relevant datasets, or to re-use these for any purpose, the user is required to obtain the explicit consent from the owner(s) of these datasets.

5. Liability

EFSA produced this Calculator to support applicants in the preparation and presentation of dossiers for feed additives' authorisations. The FERA calculator is meant as a living tool, to be updated and maintained by EFSA to the best of its knowledge and available resources. If factual errors are brought to EFSA's attention, EFSA intends doing its utmost to correct them as soon as possible. The Calculator may also be updated to incorporate new information or data resulting from EFSA's scientific activities and data collections. Results obtained through the Calculator represent the data that were available in the Calculator at the moment it was used, and EFSA does not provide any reassurance on the accuracy or suitability of any information or data provided as a result of the use of the Calculator by the user which is without prejudice to the outcome of EFSA's evaluation processes.

The use and/or downloading of the Calculator do not establish any contractual relationship between the user and EFSA. Any user of the Calculator is advised to consult with an attorney, consultant or other professional to determine what may be best for their respective individual needs. By using and/or downloading the Calculator, the user also acknowledges that the data or information made available by EFSA may contain inaccuracies or errors. The content of the information provided as a result of the use of the Calculator is for information only.

EFSA accepts no responsibility or liability (including, but not limited to, any direct or consequential loss or damage that might be caused to the user and/or any other third party) arising out of, or in connection with, the information provided by this Calculator. EFSA cannot be held liable for errors, inaccuracies or inconsistencies with regard to data available on its Calculator being different from the scientific and administrative documents officially adopted, issued or endorsed by its responsible bodies.

It is EFSA's goal to minimise disruption caused by technical errors. However, some data or information on EFSA's website or Calculator may have been created or structured in files or formats that are not error-free and EFSA cannot guarantee that its service will not be interrupted or otherwise affected by problems. EFSA accepts no responsibility with regard to such problems which may be incurred as a result of the use of this Calculator, EFSA's website or any linked external sites.

6. Restrictions

The user agrees not to license, sell, rent, lease, assign, distribute, transmit, host, outsource, disclose or otherwise exploit the FERA calculator.

7. Modifications to FERA calculator

EFSA reserves itself the right to modify, suspend or discontinue, temporarily or permanently, the FERA calculator or any service to which it connects, with or without prior notice. All this shall not in any case hold EFSA liable towards the user.

8. Entry into force

The present Terms shall enter into force on the date of the first use of the Calculator by the user.

9. Termination/Suspension

This notice applies until terminated by the user or by EFSA.

EFSA may, in its sole discretion, at any time and for any or no reason, suspend or terminate the accessibility to the Calculator with or without prior notice. However, users shall be notified of the suspension/termination on the EFSA website and shall be provided with reasons therefor.

The user's rights on the Calculator will terminate immediately, without prior notice from EFSA, in the event of failure to comply with any provision of this notice.

10.Amendments to this notice

EFSA reserves itself the right, at its sole discretion, to modify or to replace this notice at any time. Users shall be notified thereof on the EFSA website and shall be provided with reasons therefor.

11.Personal Data protection and privacy statement

EFSA is committed to user privacy. It processes your personal data only for the purposes indicated below.

The policy on the processing of personal data by the Union institutions is based on Regulation (EU) No 2018/1725 of the European Parliament and of the Council of 23 October 2018.

At EFSA, the Data Protection Officer, <u>DataProtectionOfficer@efsa.europa.eu</u>, monitors compliance with the Regulation and advises controllers on fulfilling their obligations (see Article 45 of the Regulation); for all EU Institutions and Agencies, the European Data Protection Supervisor acts as an independent supervisory authority with regard to data protection (see Article 44 of the Regulation).

12. Arbitration clause

EFSA and the user intends making reasonable endeavours to try to amicably settle any dispute arising among them in relation to the use of FERA calculator and for such purpose, to bring the dispute at the appropriate executive body levels.

The General Court or, in the case of an appeal, the Court of Justice of the European Union, have sole jurisdiction to hear any dispute between EFSA and the user relating to the validity, application or interpretation of these terms and conditions.

13.Contact Information

In case of any questions about this Agreement or the use of the FERA calculator, please contact us by writing to: feedadditives@efsa.europa.eu.