



Instructions to the feed additives environment risk assessment (FERA) calculation tool

Version 1.5

The EFSA Guidance on the assessment of the safety of feed additives for the environment (doi: 10.2903/j.efsa.2019.5648) provides clear definitions for phase I and phase II calculations of exposure and effect. The calculation tool, developed in Microsoft Excel, implements these definitions in order to provide a standardised tool to calculate phase I and II exposure levels and $PNEC_{sed, EqP}$ for environmental risk assessment (ERA) of feed additives. Symbols and definitions in this excel tool are consistent with the guidance. Three sheets are available in the tool. The first one provides calculations for the terrestrial animals ERA Phase I; the second for the terrestrial animals ERA Phase II; the third one for aquaculture ERA; and the fourth one for parameters related to the assessment of secondary poisoning.

ERA of additives for terrestrial animals phase I (1st spreadsheet)

Input values

In the top left, there is an area where basic input data about the feed additive has to be filled in to obtain phase I PEC values.

Additive input data	
MW	1.00
VP (Pa)	1.000E+00
SOL (mg/L)	1.000
K _{oc} (L/kg)	1.0
DT ₅₀ (days)	1

- MW: Molecular weight
- VP: Vapour pressure
- SOL: Solubility
- K_{oc}: Organic carbon-water partitioning coefficient
- DT₅₀: Disappearance time in soil

Row 12 is another set of input fields: it is the concentration of the feed additive in the feed. Values are to be reported in mg/kg and can be differentiated for the different applications/target species. Rows 13 and 14 contain the specific values of feed intake and N excretion taken from the ERA guidance (Table 1).

Cells C9 and C10 contain the constant depths used to calculate PEC_{soil} (defined in section 2.6.1/page 12 of the abovementioned guidance document: 0.05 m) and $PEC_{porewater/groundwater}$ (defined in section 2.6.2/page 13: 0.2 m). These values are default ones and should not be changed.

Parameter used in equations		
Q kg N/ha/y		170
$RHO_{dry\ soil}$ kg/m ³		1500
$CONV_{area\ field}$ m ² /ha		10000
$RHO_{fresh\ soil}$ kg m ⁻³		1700
R Pa m ³ mol ⁻¹ K ⁻¹		8.314
Temp K		285
$F_{solid\ soil}$ m ³ /m ³		0.6
$F_{water\ soil}$		0.2
$F_{air\ soil}$		0.2
Foc_{soil} kg/kg		0.02
RHO_{solid} kg/m ³		2500
RHO_{susp} kg/m ³		1150
$F_{water\ susp}$		0.9
L/m ³		1000
$F_{solid\ susp}$		0.1
Foc_{susp}		0.1

Fixed input parameters

A box on the right hand side of the sheet, in columns V and W, contain all the constants which are set throughout the guidance (rows 12-27), such as the annual nitrogen emission standard, soil bulk densities, and fractions of air, water and solids in soil. These values do not depend on other inputs and are default values.

In addition, rows 28-32 in column W contain the implementation of the calculation of distribution coefficients, as defined on page 13 ($K_{p\ soil}$, $K_{soil-water}$, $K_{air-water}$) or page 23 ($K_{p\ susp}$ and $K_{susp-water}$). These set of values are automatically re-calculated by the tool depending on the substance properties.

$K_{p\ soil}$ dm ³ /kg	0.02	Dependent distribution coefficients
$K_{soil-water}$ m ³ /m ³	0.23008441	
$K_{air-water}$ m ³ /m ³	0.00042203	
$K_{p\ susp}$ dm ³ /kg	0.1	
$K_{susp-water}$ m ³ /m ³	0.925	

Output values

PEC manure mg/kgdw N
PEC soil dw (µg/kg) - Phase I
PEC soil dw 1year (mg/kg)
Fd (% of FA degraded within 1 year)
PEC Soil dw plateau (µg/kg)
PEC soil ww (µg/kg)
PEC soil ww plateau (µg/kg)
PEC porewater (µg/L) - Phase I

In rows 15 – 22, a series of phase I values is calculated and provided, including:

- PEC_{manure} (definition on p. 12 of the abovementioned guidance document).
- PEC_{soil} (p. 12)
- Fraction of additive (parent compound) degraded in 1 year (Fd; p. 21)
- $PEC_{soil\ dw\ plateau}$ (p. 21)
- $PEC_{soil\ ww}$ (Concentration of additive in soil; wet weight; p. 13/14)
- $PEC_{soil\ ww\ plateau}$ (p. 22)
- $PEC_{porewater}$ (p. 13/14)

$PEC_{soil\ dw}$ and $PEC_{porewater}$ are here phase I endpoints which have to be compared to the trigger values of 10 µg/kg (soil) or 0.1 µg/L (porewater). Cells C16 – S16 and C22–S22 use conditional formatting, in case the trigger values are exceeded they turn red, otherwise green.

ERA of additives for terrestrial animals phase II (2nd spreadsheet)

Input values

In the top left, there is an area where basic input data about the feed additive has to be filled in (copied from 1st spread- sheet) to obtain phase II PEC values. It has the same structure as in phase I. In the top middle, another input field allows to input values for PEC refinement, derived from the metabolism in the animal or manure storage (cells H2-H6).

Data for PEC refinement	
Fa (% excreted, [0 - 1])	
N _{spreading}	
T _{interval spreading} (days)	
DT _{50 in manure} (days)	
T _{st} (days)	

- Fa: Fraction of the dose considered to be active
- N_{spreading}: Number of spreading events
- T_{interval_spreading} : Time between spreading events
- DT_{50 in manure} : Disappearance time in manure
- T_{st}: Length of time manure is stored

Cells C9 – C10, rows 12 – 14 and the box 'Parameters used in the equations' in columns V and have also the same structure as in phase I spread sheet.

Output values

Phase II PEC values are provided in rows 15-35, including recalculation of PECs based on metabolism (described in page 20 of EFSA FEEDAP Panel guidance on environmental risk assessment of feed additives [2019]), based on degradation in soil (described in p. 21) and based on multiple application (described in p. 21). From those refinements the following are calculated: PEC_{surface water} (described in p. 23); PEC_{plateau porewater} and PEC_{surface water} (described in p. 22/23); PEC_{sediment} and PEC_{sediment plateau} (described in p.23).

Row 29 contains calculated application rates (kg/ha), which can be used for PEC_{groundwater} refinement with FOCUS PEARL in case a phase IIB refinement is needed (section 3.4.2.1 and appendix B, p.59/60).

All calculations are available for the use of the additive in feed for all target species, from column C (piglets) up to column S (horse for fattening).

Refinement for the calculation of PEC_{soil}, based on degradation in soil under multiple applications is reported in line 30.

From line 32 to line 35, Phase II B refinement, based on degradation in manure, is calculated.

ERA of additives for aquaculture (3rd spreadsheet)

Two different calculations are available in this sheet: PEC_{sed} for sea cages and PEC_{swaq} for surface water aquaculture.

Sediment aquaculture sea cages

In cell C5 the concentration of the feed additive in the fish feed has to be reported in mg/kg.

CF (kg feed to kg tot C in faeces)
k_{dep} kg C/(m ² × day)
$T_{production}$ (day)
RHO_{solid} kg/m ³
$DEPTH_{sed}$ (m)
F_{solid} (m ³ /m ³)
PC_{faeces} mg/kg C

Cells C6 to C12 contain the default parameters, described in the guidance in section 2.7.1 (p. 15), which are used for calculations.

Cell C13 provides PEC_{sed} values for sediment under sea cages and use conditional formatting: in case the trigger value (10 µg/kg) is exceeded it turns red, otherwise green.

Surface water aquaculture raceway/pond/tanks

In row 6 concentrations of the FA in fish feed has to be reported in units of mg/kg for the different types of target fish species in columns G - J.

FR (kg feed/kg fish per day)
Flow (L/kg fish/day)
DF

Rows 7 to 9 in columns G-J contain the default parameters for the target fish species, described in the guidance in section 2.7.2, table 2, page 15, used for calculations of the surface water concentrations.

Row 10 provides PEC_{swaq} for surface water aquaculture raceway/pond/tanks for the different types of target species and use conditional formatting: in case the trigger value (0.1 µg/L) is exceeded it turns red, otherwise it becomes green.

In the top left, there is an area where basic input data about the feed additive has to be filled in ($PEC_{surface\ water}$, $PEC_{porewater}$ and PEC_{soil} are from 1st and 2nd spreadsheet) to obtain phase II PNEC and PEC values for the assessment of secondary poisoning via the aquatic and terrestrial food chain.

ERA of additives for secondary poisoning (4th spreadsheet)

In the top left, there is an area where basic input data about the feed additive has to be filled in ($PEC_{\text{surface water}}$, $PEC_{\text{porewater}}$ and PEC_{soil} are from 1st and 2st spreadsheet) to obtain phase II PNEC and PEC values for the assessment of secondary poisoning via the aquatic and terrestrial food chain.

In cells D4 and D5, the species and the length of the toxicity test for determination of NOAEL value have to be selected. After that, the conversion factor (CV) and the assessment factor (AF) are presented in cells C4 and C5. Values for CV and AF are also presented in rows H-K of the spreadsheet.

Additive input data		Select
LogKow	4,48	
NOAEL (mg/kg bw day-1)	11	
CV - Conversion factor (kg bw day/kg feed)	33,3	Oryctolagus cuniculus
AF - Assessment factor	90	NOECmammal, food,chr - 90 days
PEC surface water ($\mu\text{g/L}$)	0,0024	
PEC porewater ($\mu\text{g/L}$)	0,1	
PEC soil ($\mu\text{g/kg}$)	732	

- LogK_{ow}: Partitioning coefficient octanol-water
- NOAEL: No observed adverse effect level
- CV: Conversion factor from NOAEL to NOEC
- AF: Assessment factor applied in extrapolation of NOEC to $PNEC_{\text{oral}}$

Three different calculations are available in this sheet: $PNEC_{\text{oral}}$ for birds and mammals; PEC_{fish} for the assessment of secondary poisoning via the aquatic food chain; and $PEC_{\text{earthworm}}$ for the assessment of secondary poisoning via the terrestrial food chain.

PNEC_{oral}

In cell C10, NOEC is calculated considering the appropriate conversion factor. In cell D13, also Log K_{ow} value has to be selected in order to determine an appropriate biomagnification factor (BMF) value, presented in C13. Values for BMF are also presented in rows H-K of the spreadsheet. In cell C11, the calculated $PNEC_{\text{oral}}$ that is used for the assessment of secondary poisoning via the aquatic and terrestrial food chain is presented.

Secondary poisoning via the aquatic food chain

In cells C15 and C16, the calculated BCF_{fish} and PEC_{fish} are presented, respectively. In cell C17 calculated quotient $PEC_{\text{fish}}/PNEC_{\text{oral}}$ is presented and with this calculation, risk for secondary poisoning via the aquatic food chain is evaluated.

Nota bene: If the logK_{ow} is >6, the applicant is invited to calculate the BCF_{fish} according to what is established in the Guideline on environmental impact assessment for veterinary medicinal products in support of the VICH guidelines GL6 and GL38, Rev 1 (EMA, 2016)

Secondary poisoning via the terrestrial food chain

In cells C18-C23, default values for this calculation are presented. In cells C24 and C25, the calculated $BCF_{\text{earthworm}}$ and $PEC_{\text{earthworm}}$ are presented, respectively. In cell C26, the calculated quotient $PEC_{\text{earthworm}}/PNEC_{\text{oral}}$ is presented and with this calculation, risk for secondary poisoning via the terrestrial food chain is evaluated.

Document history

Document history	
Document reference	Version 1.4
Prepared by	FEED Unit
Reviewed by	APDESK Unit
27 April 2020	In April 2020, this FERA calculation tool has been modified due to an issue related to the calculation of the refined PEC soil when the effect of metabolism was considered. In the previous version of the FERA calculation tool, the outcome was compared with the threshold value of Phase I (10 µg/kg soil) and output cells were coloured according to the results. It is noted that the outcome of this refinement of Phase II cannot be compared with the threshold of Phase I, which aims at a worst-case approach. The outcome of any refinement of Phase I must be compared with predicted non effect concentrations. In this new version, specific spreadsheets are available for ERA for terrestrial Phase I, for ERA for terrestrial Phase II, and for the ERA for application in aquaculture.
19 February 2021	The FERA calculation tool was modified to correct a mistake in the second spreadsheet (ERA terrestrial – Phase II) in the formulas of row 32 (PEC soil manure): Although the units of PEC soil manure indicated µg/kg, the formula was giving results in mg/kg. It has not been corrected
3 September 2021	In September 2020, the Instructions to FERA calculation tool have been modified to remove the last explanatory sentence of the first bullet point on PECmanure at the end of page 2: 'These values are automatically adjusted when the fraction excreted (Fa) is modified in cell H2.' This was done because this refinement step belongs to Phase II instead of Phase I
February 2022	The instructions and the calculation tool for the formulas and default values for calculation of parameters related to secondary poisoning are included in the FERA tool as an additional spreadsheet. The related instructions to guide the user are also included
16 March 2022	The excel file has been updated by unblocking the input cells of the spreadsheet on assessment of secondary poisoning and improving the formula of cell C24. In addition, instructions on how to calculate BCF _{fish} when log K _{oc} is >6 have been added.