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

Version 1.1

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; and the third one for aquaculture ERA.

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
Koc (L/kg)	1.0
DT$_{50}$ (days)	1

- MW: Molecular weight
- VP: Vapour pressure
- SOL: Solubility
- K_{oc}: Organic carbon-water partitioning coefficient
- DT_{50}: 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	Fixed input parameters
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	
Fwater susp	0.9	
L/m^3	1000	
Fsolid susp	0.1	
Foc susp	0.1	

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 (Kp$_{soil}$, K$_{soil-water}$, K$_{air-water}$) or page 23 (Kp$_{susp}$ and K$_{susp-water}$). These set of values are automatically re-calculated by the tool depending on the substance properties.

Kp_{soil} dm^3/kg	0.02	
$K_{soil-water}$ m^3/m^3	0.23008441	Dependent distribution coefficients
$K_{air-water}$ m^3/m^3	0.00042203	
Kpsusp 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). These values are automatically adjusted when the fraction excreted (Fa) is modified in cell H2
- PEC$_{soil}$ (p. 12)
- Fraction of additive (parent compound) degraded in 1 year (Fd; p. 21)
- PEC$_{soil\ dw\ plateu}$ (p. 21)
- PEC$_{soil\ ww}$ (Concentration of additive in soil; wet weight; p. 13/14)
- PEC$_{soil\ ww\ plateu}$ (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 (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 $PEC_{surface\ waterr}$ (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.
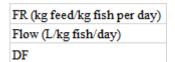
CF (kg feed to kg tot C in faeces)
k_{dep} kg C/($m^2 \times day$)
$T_{production}$ (day)
RHO_{solid} kg/m^3
$DEPTH_{sed}$ (m)
F_{solid} (m^3/m^3)
PC_{faeces} mg/kg C

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.

Document history

Document reference	Version 1.1
Prepared by	FEED Unit
Reviewed by	APDESK Unit
Last date modified	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