



# **Draft Assessment Report**

## **Evaluation of Active Substances**

Plant Protection Products

Prepared according to **Regulation (EC) 1107/2009**  
as it applies in Great Britain

### **Elemental iron**

#### **Volume 3 – B.8 (PPP) – Final Bite**

Great Britain

February 2022

---

## Version History

When	What
November 2021	Initial DAR
February 2022	Updated post Expert Committee on Pesticides (ECP) Independent Scientific Advice (ISA) (November 2021 meeting)

## Table of contents

<b>B.8. ENVIRONMENTAL FATE AND BEHAVIOUR .....</b>	<b>4</b>
<b>B.8.1. FATE AND BEHAVIOUR IN SOIL.....</b>	<b>5</b>
B.8.1.1. Route and rate of degradation in soil.....	5
B.8.1.2. Mobility in soil.....	5
<b>B.8.2. PREDICTED ENVIRONMENTAL CONCENTRATIONS IN SOIL (PEC<sub>s</sub>).....</b>	<b>5</b>
<b>B.8.3. PREDICTED ENVIRONMENTAL CONCENTRATIONS IN GROUND WATER (PEC<sub>GW</sub>).....</b>	<b>13</b>
<b>B.8.4. FATE AND BEHAVIOUR IN WATER AND SEDIMENT .....</b>	<b>19</b>
B.8.4.1. Aerobic mineralisation in surface water .....	19
B.8.4.2. Water/sediment study .....	19
B.8.4.3. Irradiated water/sediment study.....	19
<b>B.8.5. PREDICTED ENVIRONMENTAL CONCENTRATIONS IN SURFACE WATER AND SEDIMENT (PEC<sub>sw</sub>, PEC<sub>sd</sub>) .....</b>	<b>19</b>
<b>B.8.6. FATE AND BEHAVIOUR IN AIR .....</b>	<b>28</b>
B.8.6.1. Route and rate of degradation in air and transport via air.....	28
B.8.6.2. Predicted environmental concentrations from airborne transport.....	28
<b>B.8.7. PREDICTED ENVIRONMENTAL CONCENTRATIONS FROM OTHER ROUTES OF EXPOSURE .....</b>	<b>28</b>
<b>B.8.8. REFERENCES RELIED ON .....</b>	<b>28</b>

## B.8. ENVIRONMENTAL FATE AND BEHAVIOUR

The formulated product containing elemental iron is a ready-to-use granular bait called ‘Final Bite ®’. The molluscicide formulated as pellets is intended for use on all edible and non-edible crops in outdoor or protected situations. The intended UK GAP is presented below.

Table 3CP B.8-1 Critical UK GAP for Elemental Iron 10 RB ‘Final Bite ®’

Crop	Situation	Application timing	Application number	Application rate (g a.s./ha)	Application interval (days)
All edible crops	Outdoor	When infestation appears (peak mainly in spring & autumn)	1-6	80	5
	Protected				
All non-edible crops	Outdoor				
	Protected				

A complexing agent (a chelate) is present in the formulation of ‘Final Bite ®’ granules. The HSE Chemistry evaluator requested further information on the role of the complexing agent on behalf of all specialist areas. Their question and the response from the applicant are presented below:

*HSE: Please provide further clarification regarding the role of [the complexing agent] in the formulation. It appears that [the complexing agent] is present to form a complex with elemental iron when formulated in the representative product. The description as a ‘precursor’ may suggest that the active substance elemental iron requires this chelating agent [the complexing agent] to be present to perform as an active substance (as the species  $Fe^{2+}$ ). This description may also suggest that the chelating agent is required to deliver the active substance to the site of action where it breaks down forming the original elemental iron ( $Fe^0$ ) active substance. Please provide additional information, which may include reaction schemes, to clarify the role of [the complexing agent] in the formulation and its relationship with elemental iron. Please also consider the impact of this on other areas of the risk assessment.*

*Applicant: The co-formulant [the complexing agent] in the product is a chelating agent. Chelating agents are viewed as adjuvants that enhance the uptake of the active substance, as concluded for other iron containing molluscicides on the market. This is also analogous e.g. to surfactants in insecticides which also enhance the penetration of plant protection products. Please also refer to the Renewal Assessment Report for Ferric Phosphate RAR 05 Volume 3 B3. The chelating agent and the active substance are separately present in the product. Once the granules are eaten by the target pests, the low pH of the gastric fluid in the mollusc’s alimentary canal promotes the oxidation of the elemental iron ( $Fe(0)$ ) to ferric iron ( $Fe^{3+}$ ):  $Fe(0) \rightarrow Fe(III)$ .*

After considering the applicant’s response and the information provided in the RAR Volume 3CA Section B3 of the previously authorised Ferric Phosphate, the HSE is satisfied that the complexing agent is not part of the active substance and is a co-formulant. The complexing agent can be viewed as an adjuvant, enhancing the uptake of the active substance. As the complexing agent is not bound to iron within the formulation, it is not necessary to consider this substance within the environmental fate risk assessment.

### Outcome of the consultation with the Expert Committee on Pesticides (ECP):

The ECP acknowledged that the HSE assessment represents a weight of evidence approach making the most of standard tools in a qualitative fashion. However, a quantitative assessment requires the application of more appropriate models or tools. Overall, the ECP advised that there are unlikely to be significant levels of exposure in soil, groundwater or surface waters from use of the product compared to natural background levels of iron in the environment. If the active substance is approved, the subsequent UK product assessments should not repeat the same modelling using standard tools. Ideally alternative models should be used. But if this is not possible, then a weight of evidence approach comparing application rates with natural background levels could be employed. HSE should consider placing guidance on the acceptability of the use of the weight of evidence approach on their website.

### B.8.1. FATE AND BEHAVIOUR IN SOIL

Iron is a naturally occurring metal, ubiquitously found in the environment. The total iron content in soils typically ranges from 0.2 % to 5 % (Scheffer & Schachtschabel, 1992 and the ferric phosphate DAR). The environmental behaviour of naturally occurring iron in soil is described in section 3CA B.8.1.1. A case was made to waive data requirements, which was accepted by the HSE, and so standard environmental fate laboratory and field soil studies have not been performed. It is considered that iron applied as the active substance in granular form will not behave differently to that which is already present in the environment. Therefore, the applicant has compared the predicted environmental concentrations in soil ( $PEC_{SOIL}$ ) arising from application of the product to background levels of iron reported in the literature.

#### B.8.1.1. Route and rate of degradation in soil

Iron is a metal element and cannot be degraded as such. Therefore, standard route and rate soil studies have not been performed to derive endpoints. It is considered that iron applied as the active substance in granular form will not behave differently to that which is already present in the soil environment.

#### B.8.1.2. Mobility in soil

The environmental behaviour of iron is described in section 3CA B.8.1.1. In typical aerobic soils (pH 5- 9), iron will be present in insoluble  $Fe^{3+}$  complexes such as oxides and hydroxides, and relatively immobile. Applications of elemental iron granules will not undergo any processes in the environment that are not already occurring.

### B.8.2. PREDICTED ENVIRONMENTAL CONCENTRATIONS IN SOIL ( $PEC_s$ )

The formulated product is a ready to use granular bait that will be applied via a mechanical spreader or scattered by hand, with no incorporation. In order to account for the wide range of crops and growth stages, a 0 % crop interception was used by the applicant. The HSE agrees with this and notes that granular pellets are normally directed to bare soil rather than foliage to increase efficacy. Furthermore, the label advises that for certain crops such as cereals and oilseed rape, slug activity is present before crop emergence and so pre-emergent applications are recommended.

The HSE agrees with the applicant that it is appropriate to model the maximum total application rate as a single dose (i.e. 480 g a.s./ha) as elemental iron will not degrade between applications. In the absence of calculated soil  $DT_{50}$  values, the applicant has used the FOCUS default value of 1000 days. This value is appropriate for a slowly degrading persistent organic compound, however it is not suitable for a metal element. The FOCUS default value considers some degradation occurs, albeit slowly. The HSE considers that elemental iron will not degrade in the soil and so to ensure the  $PEC_{SOIL}$  accumulation value does not consider any degradation, has calculated this by multiplying the  $PEC_{SOIL}$  initial value by 20. This ensures the  $PEC_{SOIL}$  accumulation value is based on a tillage depth of 5 cm, which is appropriate to reflect the wide range of proposed uses as some may not experience any cultivation techniques.

Table 3CP B.8.2-1 Proposed UK GAP

Crop and situation	Application rate (g a.s./ha)	Crop interception (%)	Number of applications	Application interval (days)	Total maximum application rate (g a.s./ha)
All edible and non-edible crops (outdoor & protected)	80	0	1-6	5	480

Table 3CP B.8.2-2 Input parameters used in the PEC<sub>SOIL</sub> calculations for elemental iron

Input parameters	Applicant's value	HSE's value
Soil DT <sub>50</sub> (days)	1000	N/A*
Application rate (g a.s./ha)	480	480
Crop interception (%)	0	0
Soil depth (cm) for PEC <sub>SOIL</sub> initial	5	5
Soil depth (cm) for PEC <sub>SOIL</sub> accumulation	20	5*
Soil density (g/cm <sup>3</sup> )	Unknown	1.5

\*The HSE calculated the PEC<sub>SOIL</sub> accumulation value by multiplying the PEC<sub>SOIL</sub> initial value by 20. This ensured no degradation between applications or years. As the PEC<sub>SOIL</sub> initial value was calculated over a soil depth of 5 cm, this applies to the PEC<sub>SOIL</sub> accumulation value.

It is considered that the PEC<sub>SOIL</sub> values represent all iron compounds and speciation, including Fe<sup>3+</sup> ions, Fe<sup>2+</sup> ions, iron oxides, iron hydroxides and elemental iron itself. The exact ratio of mobile Fe<sup>2+</sup> ions to insoluble Fe<sup>3+</sup> ions and oxyhydroxide complexes cannot be determined as this will vary depending on the specific redox conditions of the receiving soil. However, this is not expected to be significantly different from the existing iron present in the soil environment. The HSE agrees with the applicant's initial PEC<sub>SOIL</sub> value of 0.640 mg/kg. However, the HSE calculated a much higher PEC<sub>SOIL</sub> accumulation value of 12.8 mg/kg based on repeated applications after 20 years, compared to the applicant's value of 1.196 mg/kg.

Table 3CP B.8.2-3 HSE's PEC<sub>SOIL</sub> values for elemental iron following applications of 1x 480 g a.s./ha of 'Final Bite ®' (0 % interception)

PEC <sub>SOIL</sub> iron	Single application (1x 80 g a.s./ha)		Maximum total dose (1x 480 g a.s./ha)	
Day	PEC <sub>SOIL</sub> initial (mg/kg)		PEC <sub>SOIL</sub> initial (mg/kg)	
	Actual	TWA	Actual	TWA
0	0.107	0.107	0.640	0.640
1	0.107	0.107	0.640	0.640
2	0.107	0.107	0.640	0.640
4	0.107	0.107	0.640	0.640
7	0.107	0.107	0.640	0.640
14	0.107	0.107	0.640	0.640
21	0.107	0.107	0.640	0.640
28	0.107	0.107	0.640	0.640
48	0.107	0.107	0.640	0.640
100	0.107	0.107	0.640	0.640
PEC <sub>SOIL</sub> accumulation (mg/kg) after 20 years (based on 5 cm, no tillage)	2.140	-	12.800	-
PEC <sub>SOIL</sub> accumulation (mg/kg) after 20 years (based on 20 cm tillage)	0.620	-	3.680	-
PEC <sub>SOIL</sub> accumulation (mg/kg) after 50 years (based on 5 cm, no tillage)	5.350	-	32.000	-

The HSE performed additional calculations to consider applications to crops that will undergo tillage or other cultivation practices that involve soil disturbance. The PEC<sub>SOIL</sub> accumulation value of 12.8 mg/kg represents a worst case scenario of no-tillage over 20 years. The HSE calculated a PEC<sub>SOIL</sub> accumulation value of 3.68 mg/kg based on 20 cm tillage over 20 years. This is the PEC<sub>SOIL</sub> initial value of 0.64 mg/kg (total dose 480 g a.s./ha) for the first year of applications added to the PEC<sub>SOIL</sub> initial value for a depth of 20 cm, 0.16 mg/kg

multiplied by 19 years. The HSE notes that this is conservative and assumes no dissipation of the active substance over time or plant uptake.

Comparison of calculated  $PEC_{SOIL}$  values with measured concentrations of iron in soil reported in the literature

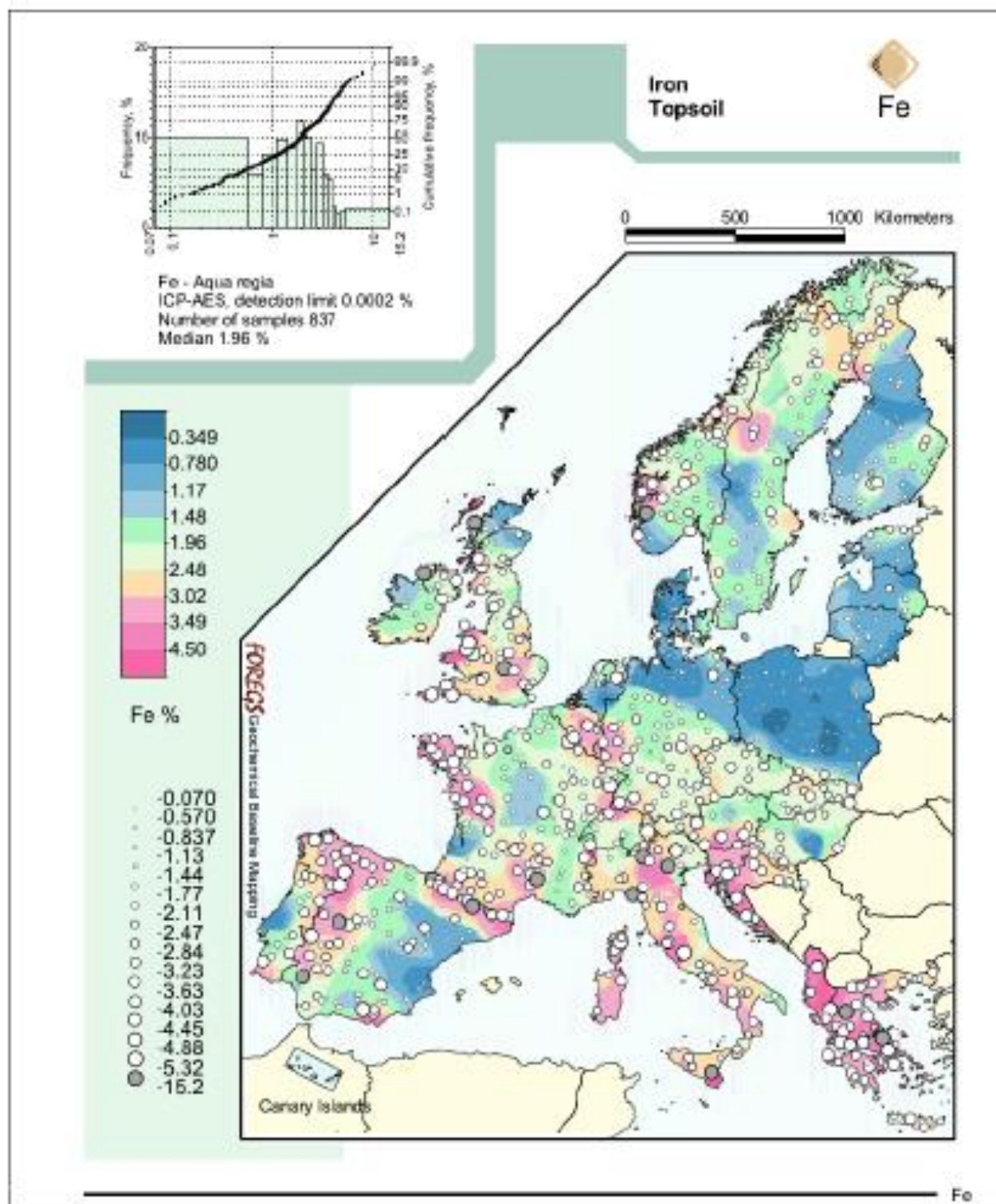
The  $PEC_{SOIL}$  accumulation value of 12.8 mg/kg represents a worst-case scenario, assuming no degradation or dissipation of the active substance over 20 years, following year on year applications of the maximum dose i.e. 6 applications of 80 g a.s./ha. Furthermore, it does not consider any mixing of the iron granules to a depth greater than 5 cm through cultivation. However, the  $PEC_{SOIL}$  accumulation from multiple applications of 'Final Bite ®' is still less than the naturally occurring background levels present in the soil environment. The table below shows the concentrations of iron in subsoil and topsoil across Europe provided by the applicant (FOREGS database, 2005). The HSE considers that the values expressed in percentage of soil, should be multiplied by 10,000 to convert to mg/kg (this is based on a conversion of 1 kg= 1,000,000 mg). Figures 3CP B.8.2-1 and -2 show the distribution of total iron and iron oxide ( $Fe_2O_3$ ) respectively, expressed as percentage in topsoil and subsoil across Europe, as reported in the FOREGS database.

Table 3CP B.8.2-4 Median concentrations of iron in European subsoil and topsoil by weight (information provided by the applicant from the FOREGS database, 2005)

Soil depth	Extraction method	Number of samples	Median (%)	Mean (%)	Range (%)	
					Min	Max
Subsoil	Total (XRF)	788	3.75	4.05	0.11	15.6
	Aqua regia (ICP-AES)	784	2.11	2.32	0.07	9.42
Topsoil	Total (XRF)	845	3.51 (3510 mg/kg <sup>+</sup> )	3.80	0.16	22.3
	Aqua regia (ICP-AES)	837	1.96 (1960 mg/kg <sup>+</sup> )	2.17	0.07	15.2

\*applicant conversion of median % values to mg/kg via multiplication by 1000. The HSE considers that the values should be multiplied by 10,000 to convert to mg/kg.

Figure 3CP B.8.2-1 Iron distribution in European topsoil (top) and subsoil (bottom) by aqua regia digestion and ICP-AES analysis (FOREGS, 2005)





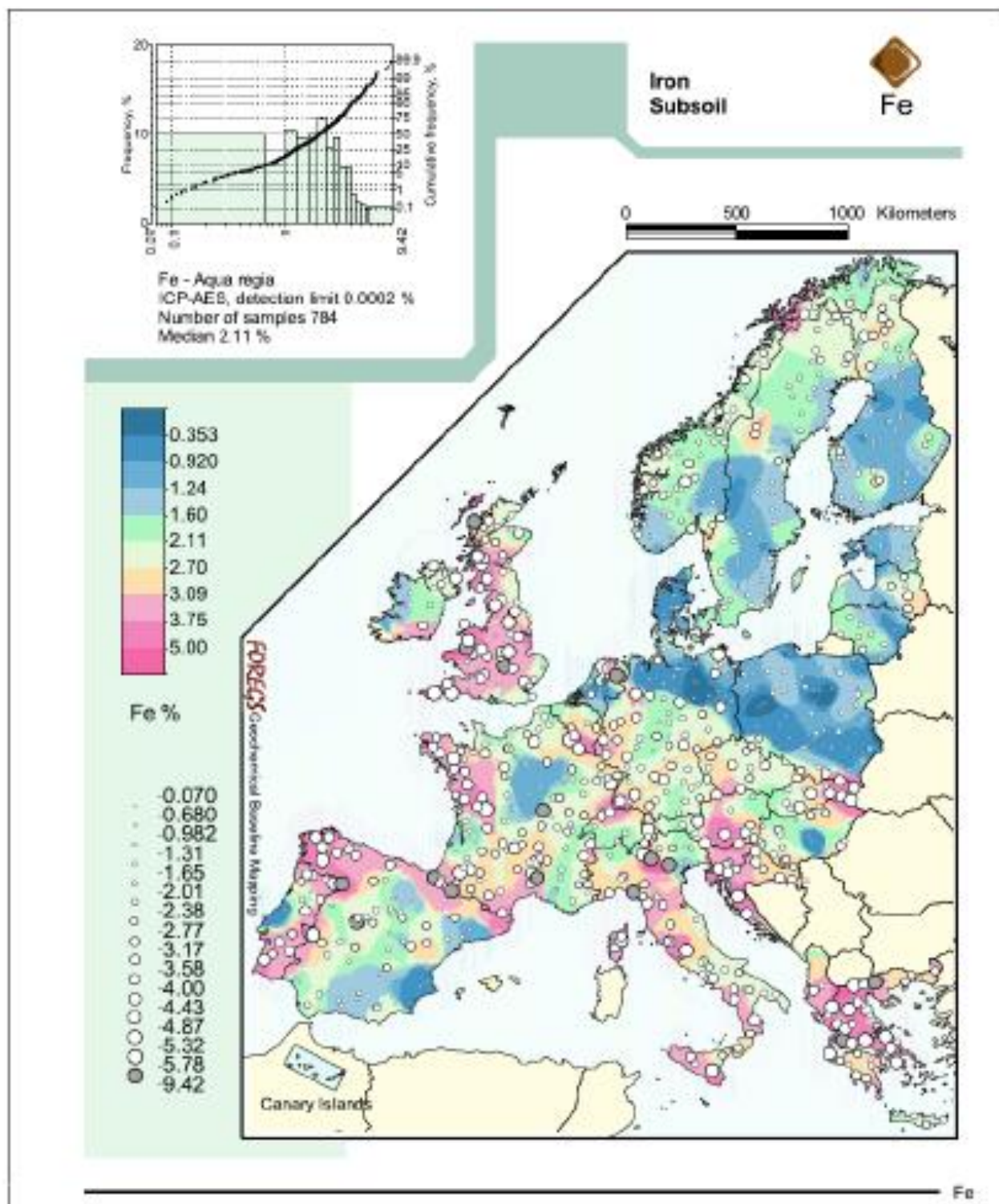
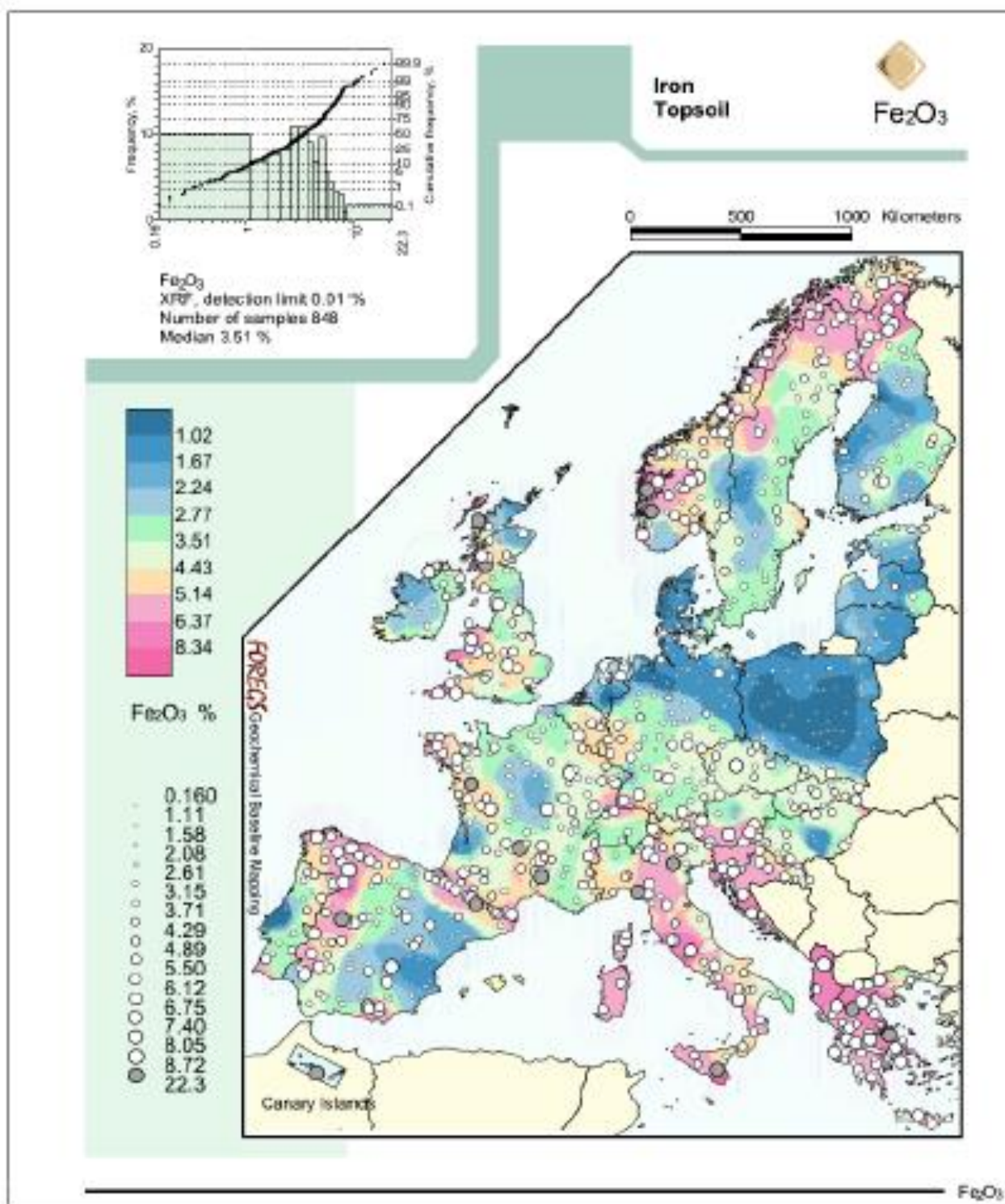
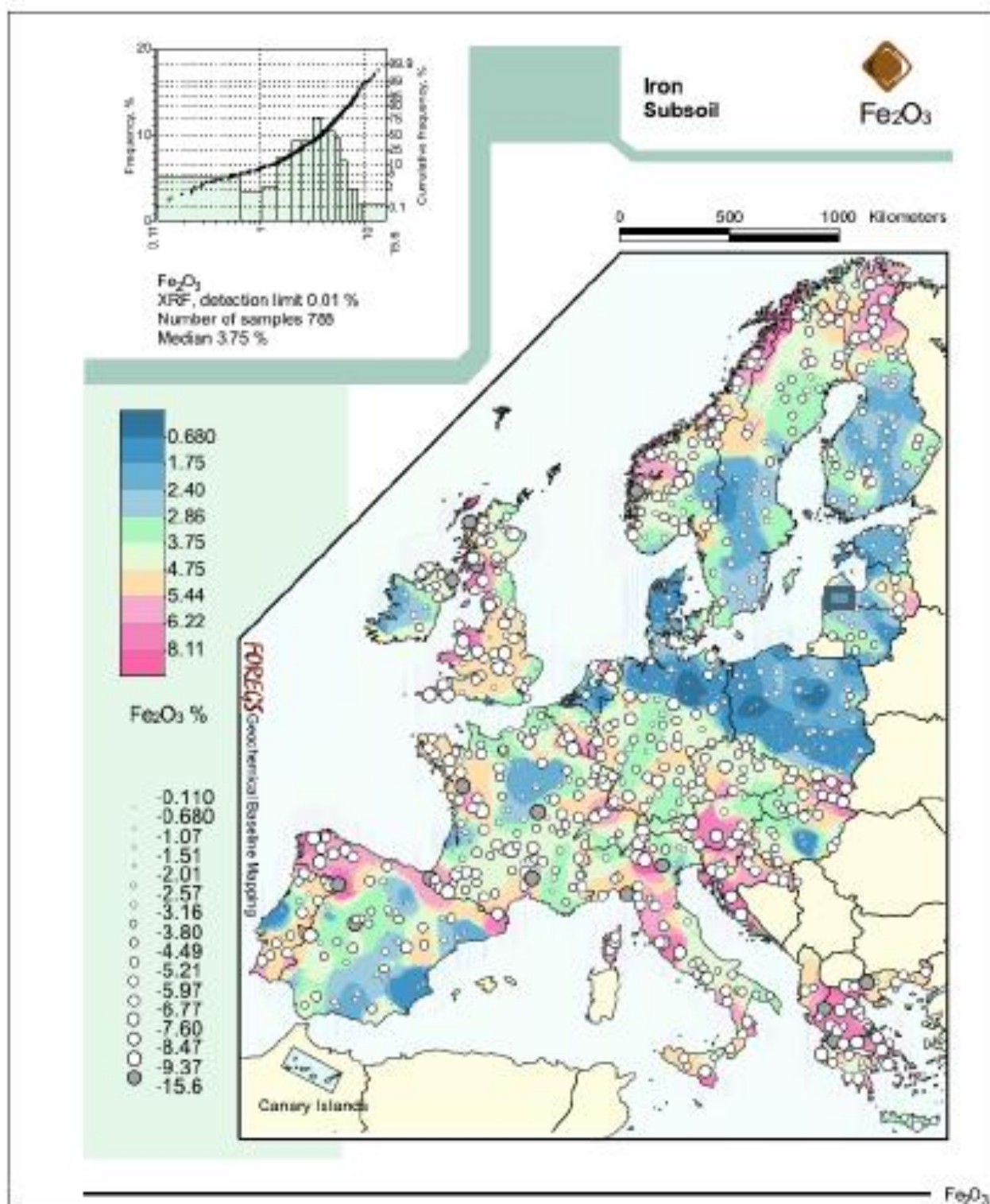


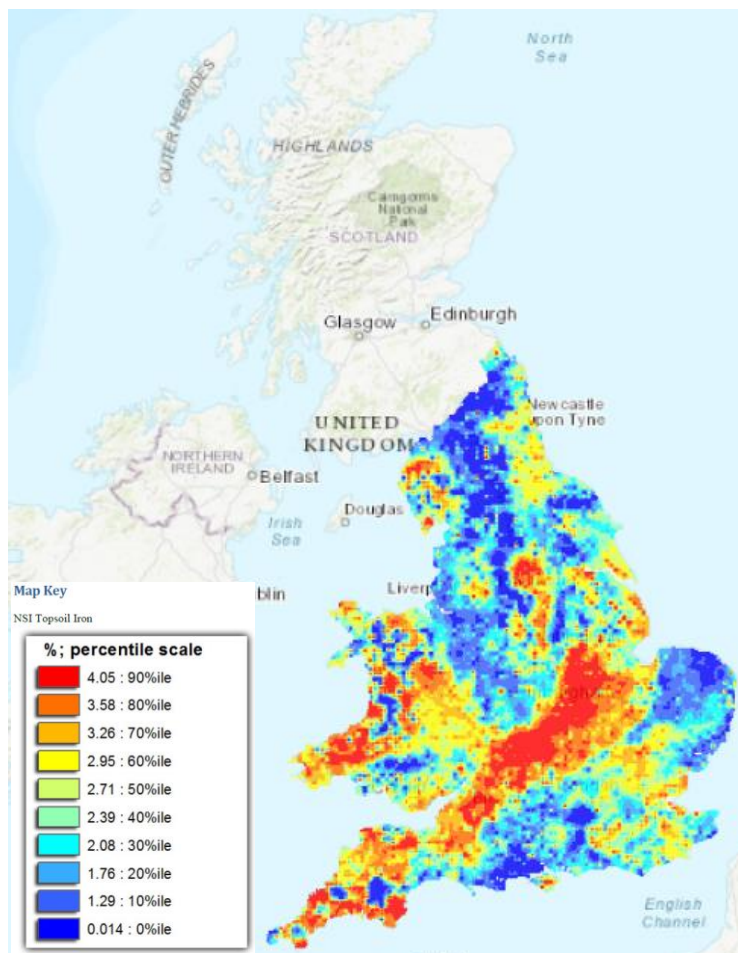
Figure 3CP B.8.2-2 Total iron as Fe<sub>2</sub>O<sub>3</sub> distribution in European topsoil (top) and subsoil (bottom) by X-ray fluorescence spectrometry (XRF) (FOREGS, 2005)







Natural background levels of iron in soils vary between 2000 and 50,000 mg/kg (i.e. 0.2-5 %) (Scheffer & Schachtschabel, 1992, and reported in the ferric phosphate and iron sulphate DARs). Data from the UK soil observatory (Figure 3CP B.8.2-3 below) indicates that the percentage of iron in UK soils varies between 0.014 % and >4.05 %.

Figure 3CP B.8.2-3 Topsoil iron concentrations in England and Wales (UK Soil Observatory, no date.)

The process for data collection and analysis of soil samples collected for the National Soil Inventory database is described in appendix 3CA B.8.7.

Table 3CP B.8.2-5 compares the  $PEC_{SOIL}$  initial and accumulation values with the minimum observed background levels reported in the literature. The HSE has compared the information provided by the applicant, derived from the FOREGS database, with concentrations reported in the literature and the UK soil observatory database. The minimum observed background concentration was divided by the  $PEC_{SOIL}$  value to calculate ratios.

The natural content of iron in soil is hundreds of times greater than the  $PEC_{SOIL}$  value after one year of applications of iron granules, even when considering soils with a relatively low iron content. The worst-case  $PEC_{SOIL}$  accumulation value of 12.8 mg/kg considering 20 years of applications is over ten-fold lower than the minimum observed amount in UK soils (140 mg/kg). This represents the lowest 10<sup>th</sup> %ile of UK soils and so most soils will contain significantly more iron than this. Overall, by comparing the  $PEC_{SOIL}$  values for granular applications of 'Final Bite ®' to the observed background concentrations of iron in soil, it is demonstrated that the natural content of iron in soil is far greater, even after repeated applications over many years. The HSE considers that the additions of iron to the soil from use of 'Final Bite ®' will be negligible compared to the existing background levels in the soil environment.

The HSE evaluator originally calculated  $PEC_{SOIL}$  values considering 20 years of consecutive applications in order to be consistent with the groundwater modelling approach which considers a 20-year time frame. Following consultation with the ECP, it was advised that as the active substance cannot degrade, a much longer timeframe than the standard 20 years should be considered in the evaluation of  $PEC_{SOIL}$ . The HSE calculated a  $PEC_{SOIL}$  accumulation value of 32 mg/kg for 50 consecutive years of applications without tillage. This value is still significantly less than natural background levels of iron and its compounds in soil. The ECP were of the opinion that the application of the product is unlikely to disrupt the biogeochemical cycling of iron in soils or

significantly alter the concentration of iron in soils.

Table 3CP B.8.2-5 Ratios of natural background concentrations of iron in soil with the PEC<sub>SOIL</sub> initial and accumulation values for 'Final Bite ®'

Database/ reference	Range min-max (%)	Minimum observed natural background concentration in soil (mg/kg)	Ratio minimum background level/ PEC <sub>SOIL</sub> initial (0.640 mg/kg) <sup>d</sup>	Ratio minimum background level/ PEC <sub>SOIL</sub> accumulation (12.8 mg/kg) <sup>d</sup>
FOREGS subsoil (Total XRF extraction method <sup>a</sup> )	0.11- 15.6	1100	1718.75	85.938
FOREGS subsoil ( <i>Aqua regia</i> ICP- AES extraction method <sup>b</sup> )	0.07- 9.42	700	1093.75	54.688
FOREGS topsoil (Total XRF extraction method <sup>a</sup> )	0.16- 22.3	1600	2500.00	125.00
FOREGS topsoil ( <i>Aqua regia</i> ICP- AES extraction method <sup>b</sup> )	0.07- 15.2	700	1093.75	54.688
Scheffer & Schachtschabel (1992)	0.2- 5	2000	3125.00	156.250
UK soil observatory (wavelength dispersive XRF <sup>c</sup> )	0.014- 4.05	140	218.75	10.938

a Total X-ray fluorescence.

b Digestion by *aqua regia* then analysis by inductively coupled plasma atomic emission spectrometry.

c Wavelength dispersive X-ray fluorescence spectrometry

d Ratios calculated by dividing the minimum observed background concentration value by the calculated initial or accumulation PEC<sub>SOIL</sub> value. Reported to 3 d.p.

The ecotoxicology assessment is driven by the toxicity of the product formulation. Therefore, the HSE has calculated a PEC<sub>SOIL</sub> formulation based on the product application rate 48 kg product/ha. The PEC<sub>SOIL</sub> of 'Final Bite ®' is 64 mg/kg.

### B.8.3. PREDICTED ENVIRONMENTAL CONCENTRATIONS IN GROUND WATER (PEC<sub>GW</sub>)

The applicant did not provide a groundwater exposure assessment, considering the active substance as "practically insoluble". The HSE considers that iron will undergo various reactions in the environment, changing oxidation states and forming complexes and ions which vary in their physicochemical properties, including solubility. Redox reactions have a significant impact on the presence of Fe ions in groundwater. One of the dominant redox reactions in groundwater is the reduction of largely insoluble Fe<sup>3+</sup> ions to soluble, aqueous Fe<sup>2+</sup> ions under anoxic and acidic conditions (Shand *et al.*, 2007). Uncomplexed Fe<sup>2+</sup> ions are normally soluble under moderately reducing conditions and mobile below pH ~7-8.

Because of the relative solubility and mobility of the Fe<sup>2+</sup> ion compared to the Fe<sup>3+</sup> ion, the HSE has considered both forms in the groundwater exposure assessment. As elemental iron and its ions are metalloid, inorganic compounds, standard environmental fate endpoints such as soil DT<sub>50</sub> values, are not applicable. Furthermore, the HSE appreciates that environmental exposure models were not designed for use with inorganic metal compounds. Therefore, the HSE has selected worst-case parameters to account for the potential uncertainty associated with using the models to calculate the potential exposure of groundwater following use of iron. A DT<sub>50</sub> value of 100,000 days was selected which equates to >273 years. This represents a conservative value, several times greater than the model running time of 20 years and accounts for virtually no degradation. To represent high solubility and low sorption for Fe<sup>2+</sup> ions, the HSE selected an aqueous solubility of 10,000 mg/L

and the FOCUS default  $K_{OC}$  of 10 mL/g for poorly adsorbing compounds. This represents a worst-case scenario of all the applied iron forming  $Fe^{2+}$  ions under anaerobic conditions, with no uptake by biota or complexation with other compounds in the soil, followed by leaching to groundwater. For the relatively immobile and insoluble  $Fe^{3+}$  ions, an aqueous solubility value of  $1 \times 10^{-9}$  mg/L was used with the FOCUS default  $K_{OC}$  value of 10,000 mL/g for strongly adsorbing compounds. A plant uptake factor value of zero was selected for both ions, although this represents a worst-case scenario as iron is actively uptaken by plants due to it being an essential nutrient.

Table 3CP B.8.3-1 Physicochemical parameters of  $Fe^{2+}$  and  $Fe^{3+}$  ions used in the groundwater exposure assessment of 'Final Bite ®'

Parameters	$Fe^{2+}$	$Fe^{3+}$	Remarks
<i>Physico-chemical parameters</i>			
Molecular weight (g/mol)	55.9	55.9	-
Aqueous solubility (mg/L)	10,000	$1 \times 10^{-9}$ (PEARL, PELMO) (0.001 MACRO)	Worst case assumption for soluble and insoluble compounds.
Molar enthalpy of dissolution (kJ mol <sup>-1</sup> )	27	27	Default
Kind of application (-)	Soil application	Soil application	-
Henry's law constant (Pa m <sup>3</sup> mol <sup>-1</sup> )	0	0	Iron is non-volatile under ambient environmental conditions.
Vapour pressure (Pa)	0	0	
Molar enthalpy of vaporisation (kJ mol <sup>-1</sup> )	95	95	Default
Diffusion coefficient air (cm <sup>2</sup> /s)	0	0	Default
<i>Degradation parameters</i>			
DT <sub>50</sub> (days)	100,000	100,000	Conservative value
Reference temperature (°C)	20	20	Default
Exponent for the effect of liquid (-)	0.7	0.7	Default
Molar activation energy (kJ mol <sup>-1</sup> )	65.4	65.4	Default
Q10-factor (-)	2.58	2.58	Default
Wash-off factor (m <sup>-1</sup> )	0.0001	0.0001	Default
Half-life at crop surface (days)	1000000	1000000	Default
Crop uptake factor (-)	0	0	Conservative default
<i>Sorption parameters</i>			
$K_{OC}$ value (mL/g)	10	10,000	FOCUS default values for weakly and strongly adsorbing compounds. <sup>+</sup>
$K_{OM}$ (mL/g) calculated from $K_{OC}/1.724$	5.80	5800.46	
Exponent of the Freundlich isotherm (-)	1	1	Conservative default

\*Maximum DT<sub>50</sub> possible in PEARL

+ Default  $K_{OC}$  values agreed by Member States in 2002 for surface water calculations (EFSA Journal 2013;11(7):3290 Guidance on tiered risk assessment for PPPs for aquatic organisms in edge-of-field surface waters). The HSE considers these default values are acceptable to use in the groundwater exposure assessment.

The critical UK GAP is shown below, however the HSE modelled the total dose 480 g a.s./ha in a single application to assume no degradation between applications. To model possible all-year round applications, the HSE selected a date within each season, however the product is more likely to be used during the peak slug infestations in spring and autumn, and so those simulations are most relevant. Winter cereals was used as a surrogate crop with 0% interception. Groundwater exposure modelling was performed in FOCUS PELMO v5.5.3, FOCUS PEARL v4.4.4 and MACRO v5.5.4. Only the UK relevant scenarios were investigated: Châteaudun, Hamburg, Okehampton and Kremsmünster.

Table 3CP B.8.3-2 Proposed UK GAP

Crop and situation	Application rate (g a.s./ha)	Number of applications	Application interval (days)	Total maximum application rate (g a.s./ha)
All edible and non-edible crops (outdoor & protected)	80	1-6	5	480

Table 3CP B.8.3-3 Application input parameters used in the groundwater exposure assessment of ‘Final Bite ®’

Parameter	Value
Surrogate FOCUS crop	Winter cereals
Application rate (g a.s./ha)	480
Application interval (days)	N/A
Application dates:	
Spring application scenario	15 <sup>th</sup> March (074)
Summer application scenario	15 <sup>th</sup> June (166)
Autumn application scenario	15 <sup>th</sup> October (288)
Winter application scenario	15 <sup>th</sup> January (015)
Incorporation depth (cm)	0
Interception by crops (%)	0

Julian days in parenthesis for MACRO groundwater modelling

Table 3CP B.8.3-4 80<sup>th</sup> percentile PEC<sub>GW</sub> values (µg/L) of iron Fe<sup>2+</sup> ions following application of ‘Final Bite ®’ at 1x 480 g a.s./ha to winter cereals (0% interception) using PELMO v5.5.3

FOCUS scenario	Spring	Summer	Autumn	Winter
Châteaudun	520.326	508.366	512.635	536.115
Hamburg	245.317	239.114	231.502	237.861
Kremsmünster	204.759	195.661	195.199	203.839
Okehampton	148.328	132.794	138.887	143.030

PEC<sub>GW</sub> values should not be relied upon in the risk assessment and are for reference only.

Table 3CP B.8.3-5 80<sup>th</sup> percentile PEC<sub>GW</sub> values (µg/L) of iron Fe<sup>3+</sup> ions following application of ‘Final Bite ®’ at 1x 480 g a.s./ha to winter cereals (0% interception) using PELMO v5.5.3

FOCUS scenario	Spring	Summer	Autumn	Winter
Châteaudun	<0.001	<0.001	<0.001	<0.001
Hamburg	<0.001	<0.001	<0.001	<0.001
Kremsmünster	<0.001	<0.001	<0.001	<0.001
Okehampton	<0.001	<0.001	<0.001	<0.001

PEC<sub>GW</sub> values should not be relied upon in the risk assessment and are for reference only.

Table 3CP B.8.3-6 80<sup>th</sup> percentile PEC<sub>GW</sub> values (µg/L) of iron Fe<sup>2+</sup> ions following application of ‘Final Bite ®’ at 1x 480 g a.s./ha to winter cereals (0% interception) using PEARL v4.4.4

FOCUS scenario	Spring	Summer	Autumn	Winter
Châteaudun	497.831	504.756	475.996	496.735
Hamburg	283.139	283.906	276.153	266.004
Kremsmünster	162.317	155.820	165.222	165.577
Okehampton	148.235	136.011	133.512	141.808

PEC<sub>GW</sub> values should not be relied upon in the risk assessment and are for reference only.



Table 3CP B.8.3-7 80<sup>th</sup> percentile PEC<sub>GW</sub> values (µg/L) of iron Fe<sup>3+</sup> ions following application of 'Final Bite ®' at 1x 480 g a.s./ha to winter cereals (0% interception) using PEARL v4.4.4

FOCUS scenario	Spring	Summer	Autumn	Winter
Châteaudun	<0.001	<0.001	<0.001	<0.001
Hamburg	<0.001	<0.001	<0.001	<0.001
Kremsmünster	<0.001	<0.001	<0.001	<0.001
Okehampton	<0.001	<0.001	<0.001	<0.001

PEC<sub>GW</sub> values should not be relied upon in the risk assessment and are for reference only.

Table 3CP B.8.3-8 80<sup>th</sup> percentile PEC<sub>GW</sub> values (µg/L) of iron Fe<sup>2+</sup> and Fe<sup>3+</sup> ions following application of 'Final Bite ®' at 1x 480 g a.s./ha to winter cereals (0% interception) for the Châteaudun scenario using MACRO v5.5.3

Application season	Fe <sup>2+</sup>	Fe <sup>3+</sup>
Spring	567.000	<0.001
Summer	536.000	<0.001
Autumn	541.000	<0.001
Winter	557.000	<0.001

PEC<sub>GW</sub> values should not be relied upon in the risk assessment and are for reference only.

The maximum 80<sup>th</sup> percentile PEC<sub>GW</sub> value for Fe<sup>2+</sup> ions was 567 µg/L for the Châteaudun scenario, winter applications calculated using MACRO. All PEC<sub>GW</sub> values for Fe<sup>2+</sup> ions were significantly greater than 100 µg/L for all scenarios and seasons. The HSE notes that the PEC<sub>GW</sub> values for Fe<sup>2+</sup> ions calculated for the Châteaudun scenario are significantly higher (ranging 476 to 567 µg/L) than those calculated for the other locations, the highest of which is 284 µg/L for the Hamburg scenario (summer timing, PEARL). The 80<sup>th</sup> percentile PEC<sub>GW</sub> values for the Fe<sup>3+</sup> ions were <0.001 µg/L for all scenarios and application timings.

The HSE notes that the FOCUS groundwater models are not suitable to accurately describe the environmental behaviour of metal compounds or ions. Therefore, the calculated PEC<sub>GW</sub> values cannot be assumed as accurate predictions of real world concentrations following application of the formulated product. The PEC<sub>GW</sub> values, assuming all iron is either in the ferric form (Fe<sup>3+</sup>) or in the ferrous form (Fe<sup>2+</sup>) provide a worst case risk envelope. Actual environmental exposure would be much lower than the PEC<sub>GW</sub> values generated using the ferrous iron assumption but may be higher than those generated using the ferric iron assumption. **Therefore the PEC<sub>GW</sub> values presented here should not be relied upon in the risk assessment and are for reference only.**

#### Comparison of modelled PEC<sub>GW</sub> values with measured iron concentrations in groundwater reported in the literature

In groundwater systems studied in England and Wales, iron concentrations varied by three to four order of magnitude, with higher amounts of iron found in the reducing anaerobic groundwaters (Shand et al., 2007). The cumulative frequency plots below show groundwaters based on chalk geology had similar amounts of iron, with median concentrations often <10 µg/L. Other geological regions show a greater variety in iron concentrations (up to four orders of magnitude) and have median concentrations around 100 µg/L (Shand et al., 2007). Overall, there are a large number of sampling sites where iron in groundwater exceeds 1000 µg/L. Figure 3CP B.8.3-2 shows measured concentrations of iron in groundwater for Scotland (>200 samples), demonstrating that a significant number of sites have concentrations of iron between 100 and 500 µg/L, with some exceeding 1500 µg/L. In comparison, the PEC<sub>GW</sub> values for the Fe<sup>2+</sup> ions are high, but not greater than levels found naturally at some sites in the UK.

The highest calculated PEC<sub>GW</sub> 567 µg/L for the Châteaudun scenario corresponds to ca 60<sup>th</sup> percentile on most of the plots below, corresponding to ca 80-90<sup>th</sup> percentile for some lines. PEC<sub>GW</sub> values for the Hamburg, Okehampton and Kremsmünster scenarios, between 133 and 284 µg/L, tend towards the 50<sup>th</sup> percentile or lower. The HSE has not further considered the cumulative effect of applications of 'Final Bite ®' on background levels of iron in groundwater. Some groundwater environments are more vulnerable to elevated iron levels due to the overlying geology, redox conditions of the aquifer or proximity to activities such as mining. The HSE considers that it is unlikely that applications of iron-containing granules will significantly impact on already vulnerable groundwater environments. The iron within the slug pellets once released into the soil environment, will not



behave differently to the iron naturally present in the soil environment. Furthermore, it is highly unlikely that the granules will be applied at the maximum rate in a manner that covers the entire aquifer.

Figure 3CP B.8.3-1 Cumulative frequency plots for Fe in groundwaters in England and Wales (Shand *et al.*, 2007)

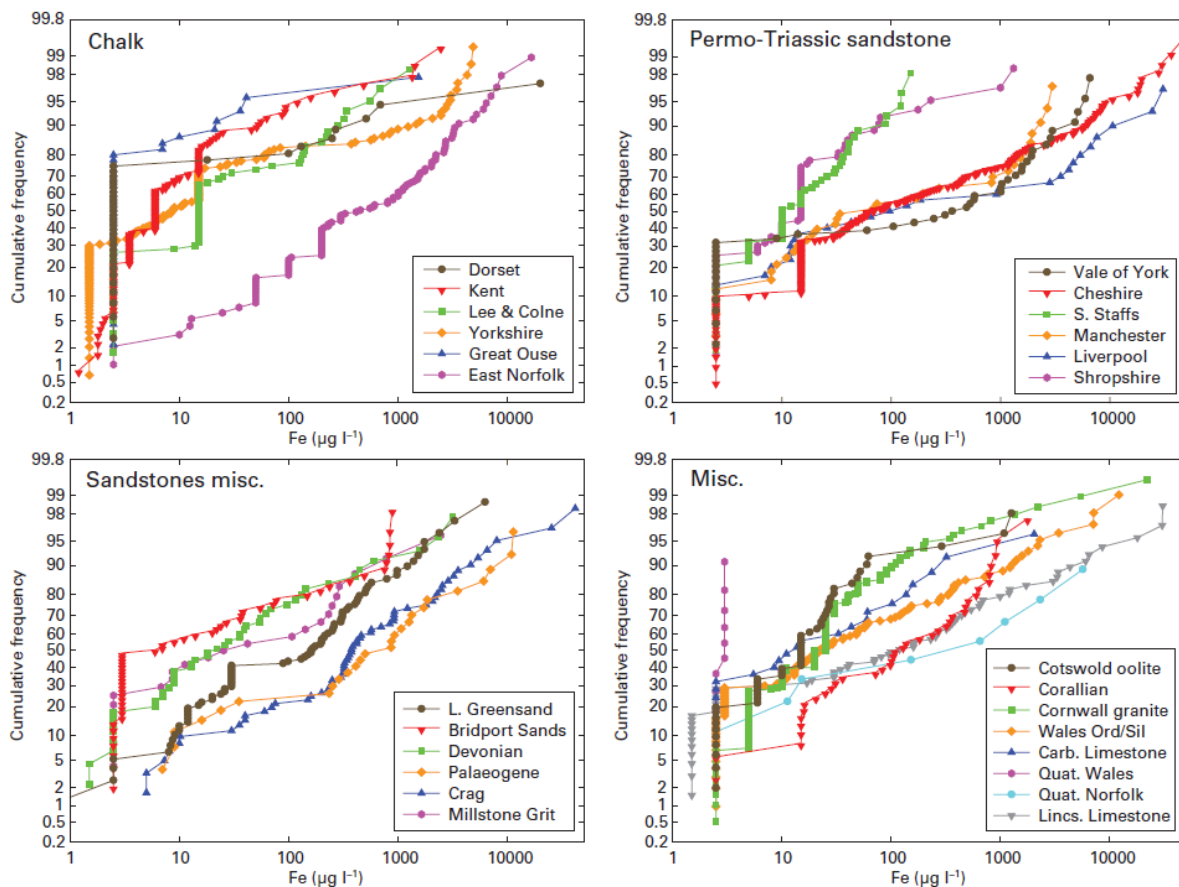
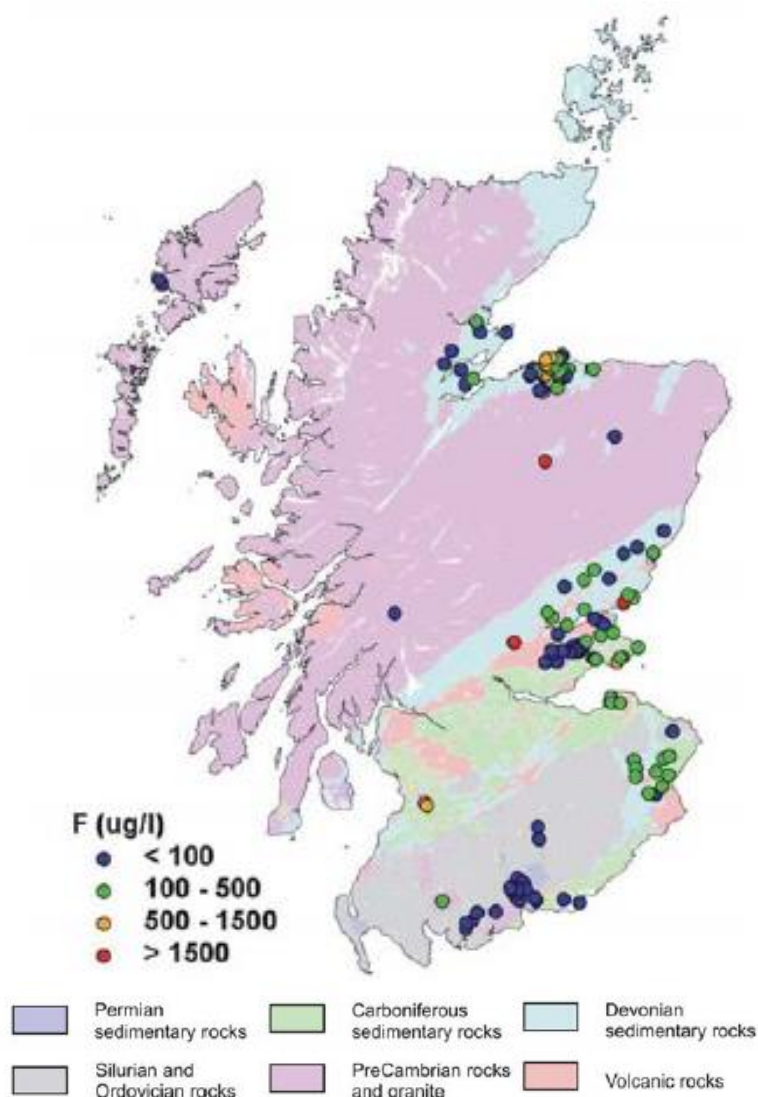


Figure 3CP B.8.3-2 Concentrations of Fe in groundwater in Scotland (MacDonald &amp; Dochartaigh, 2005)



The drinking water standard for iron in the UK is 200 µg Fe/L at the point of consumers' taps (Drinking water inspectorate, 2017). Section 3CA B.8.2.3.1 describes the processes used by water treatment plants for iron removal from abstracted water. Aeration of  $\text{Fe}^{2+}$  ions to  $\text{Fe}^{3+}$  ions is particularly important for abstracted groundwater as these insoluble ions can then be removed by filtration.

The  $\text{PEC}_{\text{GW}}$  values for  $\text{Fe}^{2+}$  ions calculated for applications of 'Final Bite ®' granules represent an unrealistic worst-case scenario. For all the applied iron to reduce to  $\text{Fe}^{2+}$  ions, the granules would need to be applied to anaerobic soils, likely under prolonged waterlogged conditions. It would be highly unlikely for the majority of these ions to then leach to groundwater without any uptake from plants or other organisms, or bonding to soil cation exchange sites or forming compounds with other elements. Furthermore, it would only be under anoxic and low pH conditions in groundwater that all iron present would exist as the soluble  $\text{Fe}^{2+}$  form. Under such conditions, it is likely that elevated levels of  $\text{Fe}^{2+}$  ions would naturally exist. Under normal environmental conditions, the iron powder in the granules will react with oxygen and water, oxidising over time to initially form insoluble  $\text{Fe}^{3+}$  ions and eventually iron oxides and hydroxides. The soil exposure assessment under 3CP B.8.2 demonstrates that the  $\text{PEC}_{\text{SOIL}}$  arising from applications of 'Final Bite ®' is negligible compared to natural background levels in soil. The  $\text{PEC}_{\text{SOIL}}$  accumulation based on 20 consecutive years without tillage is 12.8 mg/kg which is considerably less than the range naturally observed in UK and European soils (140- 22,300 mg/kg). Therefore, the HSE does not consider the risk to groundwater will be any greater than natural leaching of iron from soils to aquifers. Although the  $\text{PEC}_{\text{GW}}$  values for  $\text{Fe}^{2+}$  ions greatly exceed the drinking water parametric value of 0.1 µg/L for pesticides and in many cases exceed the drinking water standard for iron of 200 µg/L (Drinking Water Inspectorate, 2017), they are not outside of the normal range of iron concentrations

observed in UK groundwater. The HSE considers that existing water treatment processes will adequately remove iron from groundwater and will not be unnecessarily burdened by applications of 'Final Bite ®'.

During consultation with the ECP, it was concluded that the environmental fate models typically used for modelling leaching to groundwater (i.e. FOCUS PEARL, PELMO and MACRO) do not accurately describe the behaviour of metals in the environment. These models require parameters that cannot be derived for metals. The HSE acknowledges that the FOCUS groundwater models are limited in their ability to describe the behaviour of metal compounds and that more suitable environmental fate models should be sought for future risk assessments.

The ECP recognised that HSE's PEC<sub>gw</sub> values, assuming all iron was either in the ferric form (Fe<sup>3+</sup>) or in the ferrous form (Fe<sup>2+</sup>) provide a worst case risk envelope. Actual environmental exposure would be much lower than the PEC<sub>gw</sub> values generated using the ferrous iron assumption but may be higher than those generated using the ferric iron assumption. The HSE has made it clear in the footnotes of the tables above that **the calculated PEC<sub>gw</sub> values should not be relied upon in the risk assessment and are for reference only.**

#### **B.8.4. FATE AND BEHAVIOUR IN WATER AND SEDIMENT**

Iron is a naturally occurring metal, ubiquitously found in the environment. An overview of the environmental behaviour of naturally occurring iron in the aquatic environment is described in DAR section 3CA B.8.2. A case was made and accepted by the HSE to waive data requirements and so standard environmental fate water studies have not been performed. It is considered that iron applied as the active substance in granular form will not behave differently to that which is already present in the environment. Most iron in the aquatic environment is present in the sediment compartment. The solubility, mobility and form of the iron compounds will be governed by redox reactions and the presence of other organic and inorganic compounds.

##### **B.8.4.1. Aerobic mineralisation in surface water**

Iron is a metal element and cannot undergo aerobic mineralisation. Therefore, standard studies have not been performed to derive endpoints. It is considered that iron applied as the active substance in granular form will not behave differently to that which is already present in the aquatic environment.

##### **B.8.4.2. Water/sediment study**

Iron is a metal element and as such cannot undergo degradation via biological processes. Therefore, standard water/sediment studies have not been performed to derive endpoints. It is considered that iron applied as the active substance in granular form will not behave differently to that which is already present in the aquatic environment. The behaviour of naturally occurring iron in water and sediment is described in DAR section 3CA B.8.2. Iron tends to associate with the sediment compartment rather than the water layer, where it is subject to various redox reactions and will form ions and compounds of varying bioavailability and mobility. Typically, the ratio of Fe<sup>2+</sup> ions to Fe<sup>3+</sup> ions in sediment increases with depth as anoxic conditions prevail.

##### **B.8.4.3. Irradiated water/sediment study**

The HSE considers it acceptable that irradiated water/sediment studies have not been performed for elemental iron.

#### **B.8.5. PREDICTED ENVIRONMENTAL CONCENTRATIONS IN SURFACE WATER AND SEDIMENT (PEC<sub>sw</sub>, PEC<sub>sd</sub>)**

The applicant provided an exposure assessment of iron in the sediment compartment using the FOCUS STEP 1-2 v3.2 model. The HSE considers that both PEC<sub>sw</sub> and PEC<sub>sed</sub> values should be calculated to reflect the different physicochemical properties of the Fe<sup>2+</sup> and Fe<sup>3+</sup> ions. Furthermore, as this assessment is for a UK-only active substance the exposure assessment has been conducted in accordance with the UK approach rather than using FOCUS surface water models, which are not accepted in support of UK exposure assessments. The HSE considers that a spray drift assessment is not necessary due to the intended application method and the nature of the formulated product; 'Final Bite ®' is a ready-to-use granular bait that will be scattered by mechanical applicator or by hand to the soil surface. The UK 'PEC sw-sed (drainage)' EXCEL spreadsheet was used to assess exposure to the aquatic environment via the drainflow route.

The active substance is unlikely to remain as pure  $\text{Fe}^0$  in the environment as it will react with oxygen and water in soils over time. The HSE has considered both oxidation states of iron in the drainflow assessment to reflect the different physicochemical properties and environmental behaviours of the different ions. It is noted that under normal, aerobic soil conditions the vast majority of iron exists as the insoluble, immobile  $\text{Fe}^{3+}$  form and so consideration of  $\text{Fe}^{2+}$  represents a worst-case assumption. To represent the high mobility of  $\text{Fe}^{2+}$  ions, the HSE selected the FOCUS default  $K_{OC}$  of 10 mL/g for poorly adsorbing compounds. This represents a worst-case scenario of all the applied iron forming  $\text{Fe}^{2+}$  ions under anaerobic conditions, with no uptake by biota or complexation with other compounds in the soil, followed by transport via drains to surface water. For the relatively immobile and insoluble  $\text{Fe}^{3+}$  ions, the FOCUS default  $K_{OC}$  value of 10,000 mL/g for strongly adsorbing compounds was used.

A value of 1 was used for the fraction in sediment to represent 100% dissipation of the active substance to the sediment compartment. This is appropriate as iron particles are unlikely to remain suspended in the water column and will precipitate to the sediment phase where they may accumulate. In line with the other exposure assessments, the six applications were modelled as a single, maximum total dose to ensure that no degradation was accounted for. The granular applications are intended to be directed onto bare soil as foliar interception would decrease efficacy; therefore, the crop interception was set to zero.

Table 3CP B.8.5-1 Input parameters for the UK drainflow assessment of elemental iron

Parameter	$\text{Fe}^{2+}$	$\text{Fe}^{3+}$	Remarks
$K_{OC}$ (mL/g)	10	10,000	FOCUS default values for weakly and strongly adsorbing compounds.*
Fraction in sediment	1	1	Conservative assumption for 100% dissipation to the sediment compartment
Application rate (g a.s./ha)	480	480	Maximum total dose to account for no degradation between applications.
Crop interception (%)	0	0	Granular applications will be directed to bare soil rather than intercepted by foliage.

\* Default  $K_{OC}$  values agreed by Member States in 2002 for surface water calculations (EFSA Journal 2013;11(7):3290 Guidance on tiered risk assessment for PPPs for aquatic organisms in edge-of-field surface waters).

The indicative  $\text{PEC}_{\text{SW}}$  drainflow value for the more mobile  $\text{Fe}^{2+}$  ions is much greater at 70.154  $\mu\text{g/L}$  than the  $\text{PEC}_{\text{SW}}$   $\text{Fe}^{3+}$  ions at 0.295  $\mu\text{g/L}$ . This is due to the contrasting  $K_{OC}$  values used for poorly and strongly sorbing compounds; the  $\text{Fe}^{2+}$   $\text{PEC}_{\text{SW}}$  represent a conservative assessment whereby very little active substance is retained on soil particles so more is available in water for transport via subterranean drains. The  $\text{PEC}_{\text{SED}}$  value for  $\text{Fe}^{2+}$  ions 323.787  $\mu\text{g/kg}$  is also much greater due to the higher amount entering the water body which then precipitates to the sediment layer. The HSE selected the default  $K_{OC}$  values to represent the relative mobility of the  $\text{Fe}^{2+}$  ions compared to the relative immobility of the  $\text{Fe}^{3+}$  ions. However, it should be noted that such adsorption parameters are intended to describe the environmental behaviour of organic compounds rather than elemental metals. The iron ions will interact and bond with soil surfaces, however  $K_{OC}$  values cannot adequately describe these processes.

Table 3CP B.8.5-2  $\text{PEC}_{\text{SW}}$  and  $\text{PEC}_{\text{SED}}$  via drainflow of the iron  $\text{Fe}^{2+}$  and  $\text{Fe}^{3+}$  ions following applications of 'Final Bite ®' at 1x 480 g a.s./ha (0% interception) using the first tier EXCEL 'PEC sw-sed (drainflow)' spreadsheet

Compartment	$\text{Fe}^{2+}$	$\text{Fe}^{3+}$
$\text{PEC}_{\text{SW}}$ ( $\mu\text{g/L}$ )	70.154	0.295
$\text{PEC}_{\text{SED}}$ ( $\mu\text{g/kg}$ )	323.787	1.363

$\text{PEC}_{\text{SW}}$  and  $\text{PEC}_{\text{SED}}$  values should not be relied upon in the risk assessment and are for reference only.

The surface water exposure assessment for  $\text{Fe}^{2+}$  represents an extreme worst-case scenario of applications of 'Final Bite ®' to anaerobic soils and 100% conversion of  $\text{Fe}^0$  to  $\text{Fe}^{2+}$  ions, followed by transport via drainflow to the surface water body. Under normal environmental conditions, in aerobic soils over a pH range 4-9, most iron will be in the oxidised form  $\text{Fe}^{3+}$ . Furthermore, any  $\text{Fe}^{2+}$  is likely to oxidise and hydrolyse to  $\text{Fe}^{3+}$  ions and insoluble compounds upon entering the surface water compartment which would then precipitate to the sediment compartment. Under circumneutral, oxic surface waters  $\text{Fe}^{2+}$  is expected to oxidise to  $\text{Fe}^{3+}$  ions within minutes to hours (WFD, 2012). The HSE considers that granular applications of elemental iron will be applied to the soil surface under aerobic conditions, as agricultural crops are not grown under prolonged anaerobic conditions.

Most of the iron in the bait which is not consumed will come into contact with oxygen and water and essentially rust, converting to  $\text{Fe}^{3+}$  ions.

Comparison of calculated  $\text{PEC}_{\text{SW}}$  and  $\text{PEC}_{\text{SED}}$  values with measured values in surface water and sediment reported in the literature

Background concentrations of iron in surface waters vary greatly worldwide, with levels ranging from 100  $\mu\text{g/L}$  to 194,700  $\mu\text{g/L}$  total iron (Vuori, 1995) and the median concentration reported by the WHO (2003) as 700  $\mu\text{g/L}$ . The highest concentrations are often a result of pollution from acid mine drainage, farming or industrial activities. However, similarly with the soil environment, iron is naturally abundant in the aquatic environment, and is often found in quantities far higher than other metal compounds. European data provided by the applicant (taken from the FOREGS database, 2005) indicates median and mean concentrations of iron in stream water as 67  $\mu\text{g/L}$  and 268  $\mu\text{g/L}$  respectively. Sampling in the UK undertaken for the Water Framework Directive found concentrations ranging from 17  $\mu\text{g/L}$  to 11,700  $\mu\text{g/L}$  total iron based on 3397 samples taken from 1617 sites (WFD, 2012). In concurrence with effects data, the report recommended an environmental quality standard (EQS) for iron of 730  $\mu\text{g/L}$  in order to protect sensitive taxa. The table below compares the  $\text{PEC}_{\text{SW}}$  for  $\text{Fe}^{2+}$  ions and  $\text{Fe}^{3+}$  ions with the median measured background concentration (67  $\mu\text{g/L}$ ) and the EQS value (730  $\mu\text{g/L}$ ). The HSE chose to compare to these values rather than the minimum measured background levels because the reported ranges are so large, and to take into consideration the worst-case nature of the calculated values. The  $\text{PEC}_{\text{SW}}$  value for  $\text{Fe}^{2+}$  ions 70.154  $\mu\text{g/L}$  is slightly higher than the median measured concentration of total iron in European stream water, however the  $\text{PEC}_{\text{SW}}$  value for the  $\text{Fe}^{3+}$  ions (0.295  $\mu\text{g/L}$ ) is much lower. It is noted that figure 3CP B.8.5-1 shows the measured concentrations of iron in stream water are higher in most parts of the UK compared to Europe. Furthermore, the  $\text{PEC}_{\text{SW}}$  values for both oxidation states of iron are considerably less than the EQS value of 730  $\mu\text{g/L}$  set by the WFD.

Table 3CP B.8.5-3 Ratios of natural background concentrations of iron in surface water and sediment with PEC<sub>SW</sub> and PEC<sub>SED</sub> values for 'Final Bite ®'

Database/ reference	Range min-max (%)	Median observed natural background concentration (µg/L or µg/kg)	Ratio average background level/ PEC <sub>SW</sub> (µg/L) <sup>e</sup>	Ratio average background level/ PEC <sub>SED</sub> (µg/kg) <sup>e</sup>
<b>Surface water</b>				
FOREGS (2005) European stream water (dissolved ICP-MS extraction method <sup>b</sup> ) 807 samples	<0.1- 4820 µg/L	67	0.995 (Fe <sup>2+</sup> ) 227.119 (Fe <sup>3+</sup> )	-
WFD (2012) UK 3397 samples	17- 11700 µg/L	730 <sup>a</sup>	10.406 (Fe <sup>2+</sup> ) 2474.58 (Fe <sup>3+</sup> )	-
<b>Sediment</b>				
FOREGS (2005) European stream sediment (total XRF method <sup>c</sup> ) 852 samples	0.11- 20.9	35700	-	110.258 (Fe <sup>2+</sup> ) 26192.223 (Fe <sup>3+</sup> )
FOREGS (2005) European stream sediment ( <i>Aqua regia</i> ICP-AES method <sup>d</sup> ) 845 samples	0.06- 20.0	19700	-	60.842 (Fe <sup>2+</sup> ) 14453.412 (Fe <sup>3+</sup> )
FOREGS (2005) European floodplain sediment (total XRF method <sup>c</sup> ) 747 samples	0.25- 35.8	33300	-	102.845 (Fe <sup>2+</sup> ) 24431.401 (Fe <sup>3+</sup> )
FOREGS (2005) European floodplain sediment ( <i>Aqua regia</i> ICP-AES method <sup>d</sup> ) 747 samples	0.16- 19.5	19500	-	60.225 (Fe <sup>2+</sup> ) 14306.676 (Fe <sup>3+</sup> )

a Average value not reported. The ecological quality standard for UK freshwaters was set to 730 µg/L as recommended by the WFD.

b Dissolved inductively coupled plasma mass spectrometer.

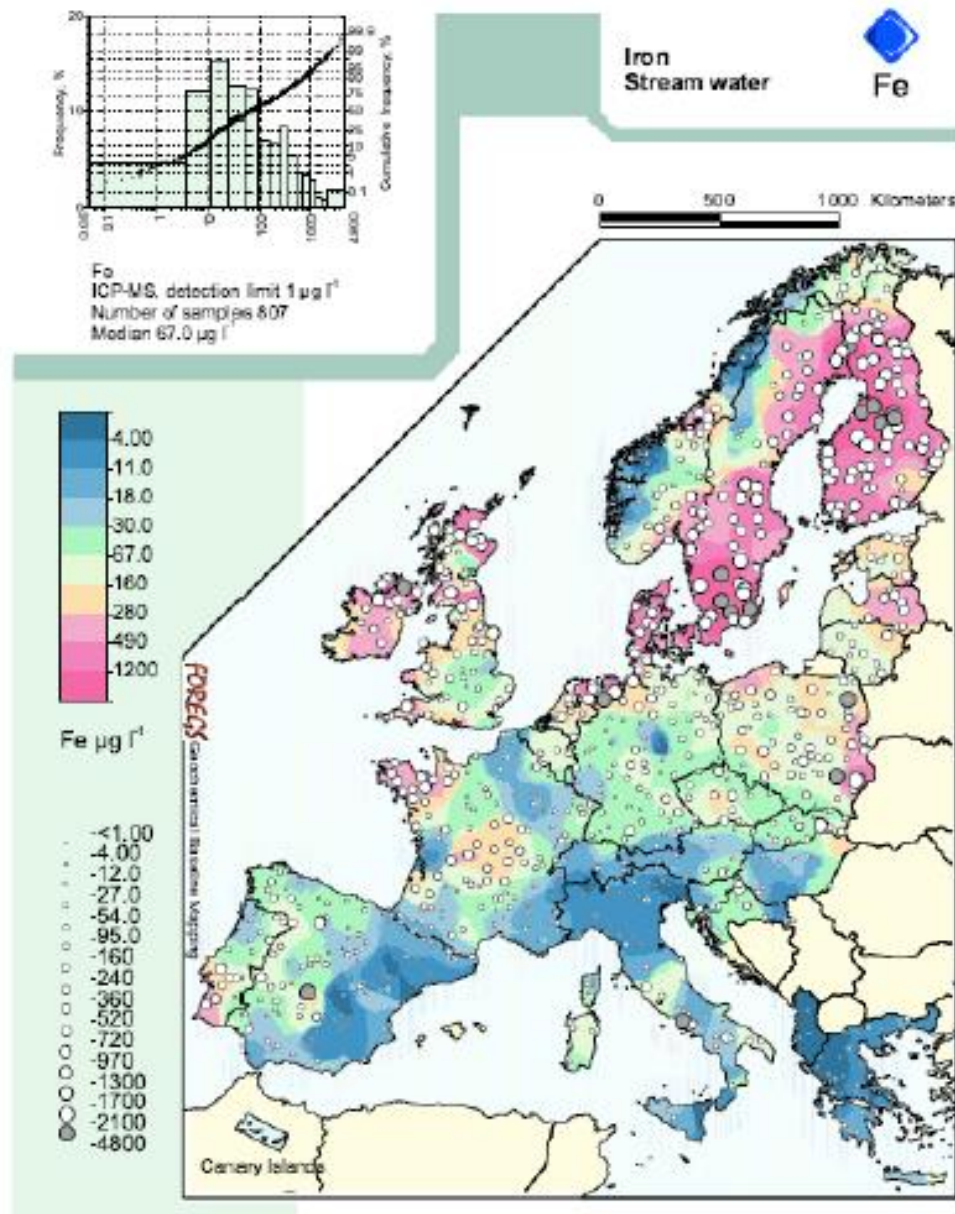
c Total X-ray fluorescence.

d Digestion by *aqua regia* then analysis by inductively coupled plasma atomic emission spectrometry

e Ratios calculated by dividing the median observed value by the calculated PEC<sub>SW</sub> or PEC<sub>SED</sub> value for either Fe<sup>2+</sup> or Fe<sup>3+</sup>.

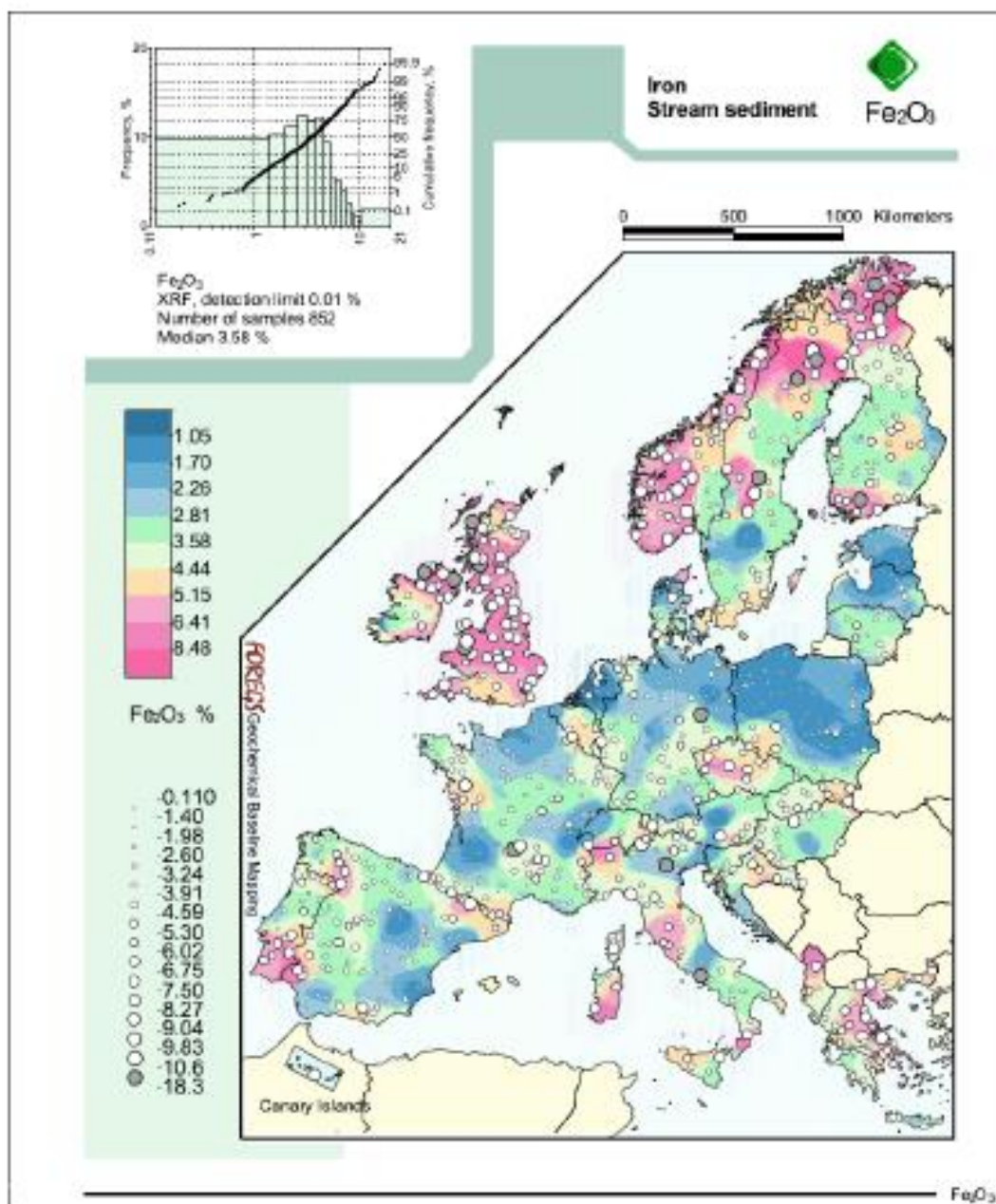


Figure 3CP B.8.5-1 Dissolved iron distribution in European stream water by ICP-MS analysis (FOREGS, 2005)



Iron naturally precipitates from the water column to accumulate in sediments. Within the sediment layer, iron will be present as a mixture of  $\text{Fe}^{2+}$  ions,  $\text{Fe}^{3+}$  ions, iron compounds and minerals of varying solubility and bioavailability. Generally, the ratio of  $\text{Fe}^{2+}$  to  $\text{Fe}^{3+}$  ions increases with depth as oxygen decreases (3CA B.8.2). Therefore, the  $\text{PEC}_{\text{SED}}$  values for  $\text{Fe}^{2+}$  and  $\text{Fe}^{3+}$  ions represent a more realistic scenario than those calculated for the water column. Table 3CP B.8.5-3 shows that both  $\text{PEC}_{\text{SED}}$  values calculated for the UK drainflow assessment ( $313.787 \mu\text{g/kg}$  for  $\text{Fe}^{2+}$  and  $1.363 \mu\text{g/kg}$  for  $\text{Fe}^{3+}$ ) are much lower than the background levels of iron in European sediment reported in the FOREGS database (2005), which range from 600-358,000  $\mu\text{g/kg}$ . Figures 3CP B.8.5-2 and -3 indicate that the iron concentrations in UK sediments are typically higher than average compared with Europe.

Figure 3CP B.8.5-2 Total iron as  $\text{Fe}_2\text{O}_3$  distribution in European stream sediment (top) and floodplain sediment (bottom) by XRF (FOREGS database, 2005)





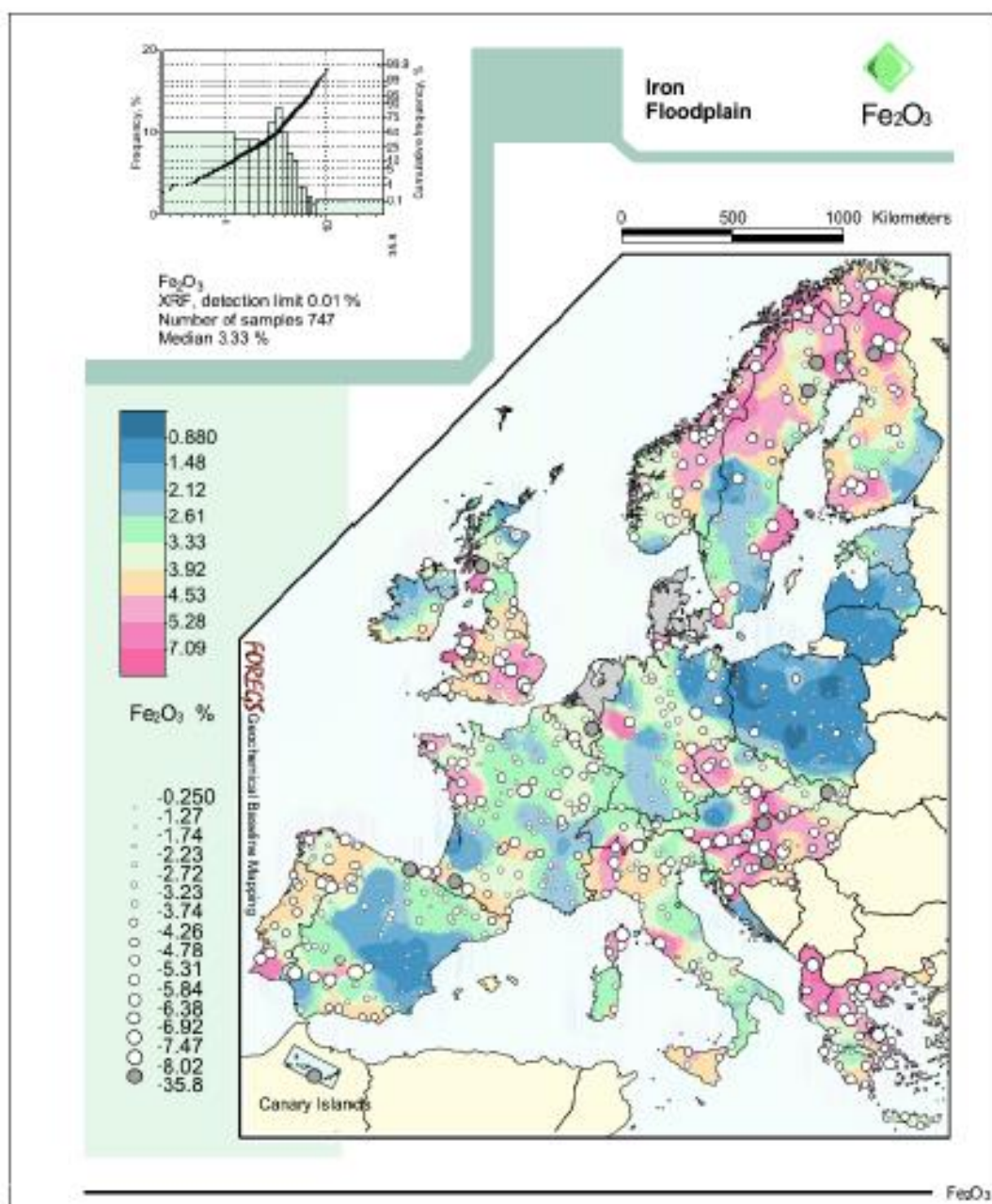
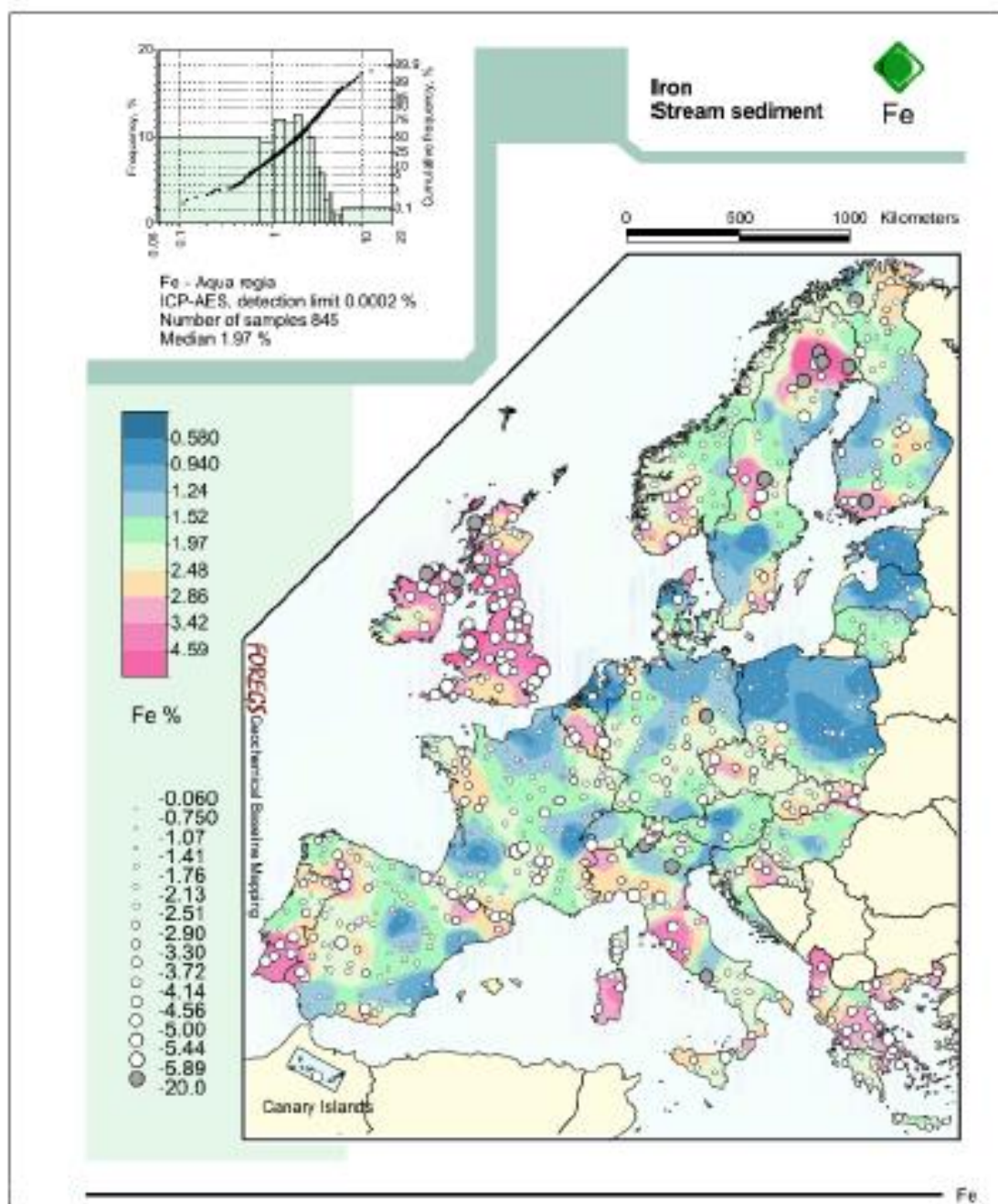
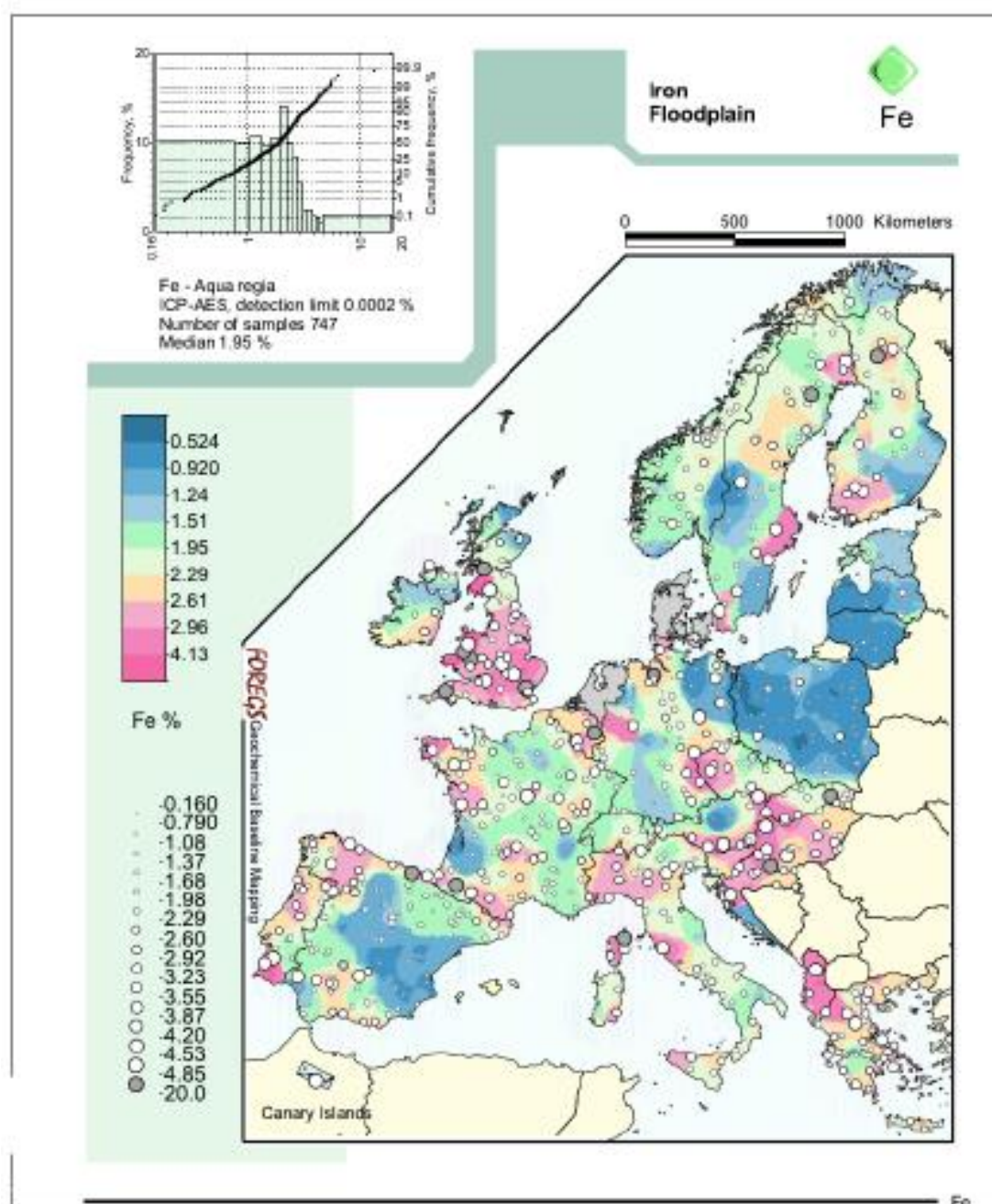


Figure 3CP B.8.5-3 Iron distribution in European stream sediment (top) and floodplain sediment (bottom) by aqua-regia digestion and ICP-AES analysis (FOREGS database, 2005)





The ECP acknowledged that standard environmental fate models are also not designed to adequately describe the behaviour of metals in surface water or sediment. As such, the  $PEC_{SW}$  and  $PEC_{SED}$  values represent risk envelopes. The actual exposure to the aquatic environment from use of the product is likely to be between the PEC values generated using the two assumptions (all iron in ferric or ferrous form) and would be much lower than the worst-case predictions generated assuming all iron is in the ferrous form ( $Fe^{2+}$ ). The Committee noted that the applicant did not describe any attempts within their assessment summary to find alternative models that may have been more suitable. The ECP recognised that an assessment with alternative models would be difficult unless the model that HSE accepts was specified and guidance on use of the model were provided. Nonetheless, the applicant could consider providing fate modelling for both drainflow and groundwater using models which are more suitable for metal substances, if this were required to resolve uncertainties in the assessment.

The soil exposure assessment under section 3CP B.8.2 demonstrated that the initial  $PEC_{SOIL}$  arising from applications of 'Final Bite ®' is negligible compared to natural background levels in soil. The  $PEC_{SOIL}$  accumulation based on 20 consecutive years without tillage is 12.8 mg/kg which is considerably less than the range naturally observed in UK and European soils (140- 22,300 mg/kg). The HSE considers that in situations



where large amounts of iron naturally transport via drainflow or runoff from soils into adjacent water bodies, the use of ‘Final Bite ®’ will not impact significantly on this. The surface water exposure assessment represents a worst-case scenario for the mobile  $\text{Fe}^{2+}$  ions, which are more prevalent under anaerobic conditions. The HSE considers that it is highly unlikely ‘Final Bite ®’ granules will be applied during flooding events in which anaerobic conditions may prevail. Furthermore, in situations where the soil is under prolonged anaerobic conditions, most of the mobile  $\text{Fe}^{2+}$  ions would be naturally occurring. The HSE does not consider the addition of iron from ‘Final Bite ®’ would impact on the natural existing environmental processes.

In order to limit the addition of iron from the ‘Final Bite ®’ granules to the aquatic environment, a voluntary ‘no spread zone restriction’ should be included on the label. Wording could be as follows:

- Pellets should not fall within 6 m of a watercourse or ditch. To achieve this, users should determine the spread width of the applicator with the product to be applied prior to any application (to the rear as well as the side of the applicator).
- Calibrate the applicator before use.

### B.8.6. FATE AND BEHAVIOUR IN AIR

Elemental iron is non-volatile under ambient environmental conditions. Furthermore, iron ions and compounds are not expected to undergo significant volatilisation. The HSE considers it acceptable that  $\text{PEC}_{\text{AIR}}$  values have not been calculated for elemental iron.

#### B.8.6.1. Route and rate of degradation in air and transport via air

See section 3CP B.8.6; the HSE considers it acceptable that the route and rate of degradation of elemental iron in air or transport via air have not been considered.

#### B.8.6.2. Predicted environmental concentrations from airborne transport

See section 3CP B.8.6; the HSE considers it acceptable that the airborne transport of elemental iron has not been considered.

### B.8.7. PREDICTED ENVIRONMENTAL CONCENTRATIONS FROM OTHER ROUTES OF EXPOSURE

The HSE does not consider it necessary to investigate other routes of exposure for elemental iron. The iron applied via ‘Final Bite ®’ granules will not behave in the environment differently to iron that exists naturally in the environment.

### B.8.8. REFERENCES RELIED ON

Data Point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner	Previous evaluation
3CP B.8.2	FOREGS	2005	Geochemical Atlas of Europe [online]. Available at: <a href="http://weppi.gtk.fi/publ/foregs">http://weppi.gtk.fi/publ/foregs</a>	N	N	N/A	-	N/A

Data Point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner	Previous evaluation
			<a href="#">atlas/</a> Non- GLP Published					
3CP B.8.2	Scheffer & Schachtschab el	1992	<i>Lehrbuch der Bodenkunde</i> (textbook of soil science). Springer: Berlin. Non- GLP Published	N	N	N/A	-	N/A
3CP B.8.2	UK soil observatory	n.d	UKSO maps [online] Available at: <a href="http://mapapps2.bgs.ac.uk/ukso/home.html">http://mapapps2.bgs.ac.uk/ukso/home.html</a>	N	N	N/A	-	N/A
3CP B.8.3	Drinking Water Inspectorate	2017	<i>What are the drinking water standards?</i> [pdf]. Available at: <a href="http://dwi.defra.gov.uk/consumers/advice-leaflets/standards.pdf">http://dwi.defra.gov.uk/consumers/advice-leaflets/standards.pdf</a> Non- GLP Published	N	N	N/A	-	N/A
3CP B.8.3	MacDonald, A.M., & Dochartaigh, B.É.Ó	2005	<i>Baseline Scotland: an overview of available groundwater chemistry data for Scotland.</i> [online] Available at <a href="http://nora.nerc.ac.uk/id/eprint/11335/1/CR05239N.pdf">http://nora.nerc.ac.uk/id/eprint/11335/1/CR05239N.pdf</a> Non- GLP Published	N	N	N/A	-	N/A
3CP B.8.3	Shand, P., Edmunds, W.M., Lawrence, A.R.,	2007	<i>The natural (baseline) quality of groundwater in England and</i>	N	N	N/A	-	N/A

Data Point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner	Previous evaluation
	Smedley, P.L. & Burke, S.		<i>Wales.[online]</i> Available at: <a href="https://core.ac.uk/download/pdf/62722.pdf">https://core.ac.uk/download/pdf/62722.pdf</a> Non- GLP Published					
3CP B.8.5	FOREGS	2005	Geochemical Atlas of Europe [online]. Available at: <a href="http://weppi.gtk.fi/publ/foregs_atlas/">http://weppi.gtk.fi/publ/foregs_atlas/</a> Non- GLP Published	N	N	N/A	-	N/A
3CP B.8.5	Vuori, K-M.	1995	Direct and Indirect effects of iron on river ecosystems. [online] In <i>Annales Zoologici Fennici</i> 32(3) pp.317-329. Available at: <a href="https://www.researchgate.net/publication/241686376_Direct_and_Indirect_effects_of_iron_on_river_ecosystems">https://www.researchgate.net/publication/241686376_Direct_and_Indirect_effects_of_iron_on_river_ecosystems</a> Non- GLP Published	N	N	N/A	-	N/A
3CP B.8.5	Water Framework Directive	2012	Proposed Quality Standards for Iron in Freshwaters Based on Field Evidence ( <i>For consultation</i> ). [pdf] Available at: <a href="https://www.wfd.org/sites/d">https://www.wfd.org/sites/d</a>	N	N	N/A	-	N/A

Data Point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner	Previous evaluation
			<a href="#">efault/files/Media/Iron%20-%20UKTAG.pdf</a> Non- GLP Published					
3CP B.8.5	World Health Organisation	2003	<i>Iron in drinking water: Background document for development of WHO Guidelines for Drinking-water Quality.</i> [online] Available at: <a href="https://www.who.int/water_sanitation_health/dwq/chemicals/iron.pdf">https://www.who.int/water_sanitation_health/dwq/chemicals/iron.pdf</a> Non- GLP Published	N	N	N/A	-	N/A