

1 **DRAFT GUIDANCE OF EFSA**

2 **Draft EFSA Guidance Document for predicting environmental**
3 **concentrations of active substances of plant protection products and**
4 **transformation products of these active substances in soil¹**

5 **European Food Safety Authority^{2,3}**

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7
8 **ABSTRACT**

9 This EFSA guidance document provides guidance for the exposure assessment of soil organisms to
10 plant protection products (PPPs) and their transformation products according to Regulation EC no
11 1107/2009 of the European Parliament and the Council. This guidance was produced by EFSA in
12 response to a question posed by the Commission. Guidance is provided for all types of concentrations
13 that are potentially needed for assessing ecotoxicological effects, i.e. the concentration in total soil and
14 the concentration in pore water, both averaged over various depths and time windows. The current
15 guidance is restricted to annual crops under conventional and reduced tillage. The recommended
16 exposure assessment procedure consists of five tiers; the first three tiers are explained in this guidance
17 document. To facilitate efficient use of the tiered approach in regulatory practice, user-friendly
18 software tools have been developed. In higher tiers of the exposure assessment, crop interception and
19 subsequent dissipation at the crop canopy may be included. To facilitate harmonisation of the
20 regulatory process, tables for the fraction of the dose reaching the soil have been developed, which
21 should be used at all tiers where crop interception is included. With respect to substance specific
22 model inputs, this guidance generally follows earlier documents; however, new guidance is included
23 for some parameters including the rapidly dissipating fraction at the soil surface.

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25 **KEY WORDS**

26 exposure assessment, soil organisms, exposure scenarios, tiered approaches; guidance; crop
27 interception; fraction reaching soil

28

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29 **SUMMARY**

30 This EFSA guidance document provides guidance for the exposure assessment of soil organisms to
31 plant protection products (PPPs) and their transformation products according to Regulation EC no
32 1107/2009 of the European Parliament and the Council. This guidance was produced by EFSA in
33 response to a question posed by the Commission. The recommended methodology is intended for the
34 assessment of active substances and metabolites in the context of approval at EU-level, and it is
35 expected to be useful for the assessment of products at zonal level as well. This guidance document
36 together with the EFSA Guidance Document on how to obtain *DegT50* values (EFSA, 2014a) and the
37 FOCUS Degradation kinetics report (FOCUS, 2006) is intended to replace the current SANCO
38 Guidance Document on persistence in soil (SANCO/9188VI/1997 of 12 July 2000).

39 This guidance document is based on the EFSA opinion on the science behind the guidance for scenario
40 selection and scenario parameterisation for predicting environmental concentrations of plant protection
41 products in soil (EFSA, 2012a). The goal is to assess the 90th-percentile concentration considering all
42 agricultural fields within a regulatory zone (North-Central-South) where a plant protection product
43 (PPP) is intended to be used. The guidance considers all types of concentrations that are potentially
44 needed for assessing the ecotoxicological effects, i.e. the concentration in total soil (mg kg^{-1}) and the
45 concentration in pore water (mg l^{-1}), both averaged over various depths and time windows. The
46 guidance also describes how to use older soil ecotoxicological studies in which exposure is expressed
47 in terms of the applied rate (in kg ha^{-1}). The current methodology is restricted to annual crops under
48 conventional and reduced tillage (excluding crops grown on ridges). Guidance for permanent crops,
49 no-tillage systems and crops grown on ridges will be made available at a later stage.

50 The recommended exposure assessment procedure consists of five tiers. The first three tiers are
51 explained in this guidance document. The guidance will not describe Tier 4 (spatially distributed
52 modelling with numerical models) and Tier 5 (post-registration monitoring). For guidance on these
53 tiers we refer to the relevant sections in EFSA (2012a).

54 To facilitate efficient use of the tiered approach in regulatory practice, user-friendly software tools
55 have been developed. This includes the new software tool PERSAM and new versions of the pesticide
56 fate models PEARL and PELMO. The software tools generate reports that can be submitted for
57 regulatory purposes. Users of this guidance are advised to use these software tools when performing
58 the exposure assessment. Other models than PEARL or PELMO may be used as well. The only
59 requirement is that the process descriptions in these models have a similar or higher level of detail
60 than those in PEARL and PELMO, that the scenarios used in the tiered approach are adequately
61 parameterised and that this parameterisation procedure is well documented.

62 This guidance has changed the tiered assessment scheme given in EFSA (2012a) with the goal to
63 simplify the exposure assessment for regulatory purposes. The exposure assessment starts with
64 simulations for one predefined scenario per regulatory zone North-Central-South. Simulations can be
65 done with the simple analytical model PERSAM at Tier 1 or with one of the numerical models
66 (PEARL or PELMO) at Tier 2A. At Tier 1, PERSAM has the advantage that the required number of
67 inputs is very limited and thus also the documentation will require little effort. Tier 2A requires
68 slightly more effort, however, this tier has the advantage that more realistic modelling approaches are
69 used and therefore this tier will deliver less conservative values.

70 Based on discussions with stakeholders, it was a boundary condition that the exposure assessment can
71 be applied by taking median or average substance properties from the dossiers. Such substance
72 properties are uncertain and inclusion of this uncertainty leads to probability density distributions that
73 are more spread. As a consequence, this boundary condition led to the need to base the exposure-
74 assessment procedure on the spatial 95th-percentile concentration instead of the spatial 90th-percentile
75 concentration.

76 The scenarios in Tier 1 and Tier 2A are based on the total area of annual crops in a regulatory zone.
77 However, the exposure assessment goal is based on the agricultural area where a PPP is intended to be
78 used. The applicant may therefore wish to perform an exposure assessment for a particular crop. For
79 this purpose, Tiers 2B and 2C are provided. At these tiers, a spatially distributed version of PERSAM
80 is used and the target percentile is directly calculated from the concentration distribution within the
81 area of a given crop. Should the assessment at Tier 2 still indicate an unacceptable risk to soil
82 organisms, the applicant has the option to move to Tier 3. Tier 3 is also based on the area of a given
83 crop, but uses numerical models (PEARL or PELMO). In Tier 3B crop-specific and substance-specific
84 scenarios have to be developed. Guidance is given on how to create these scenarios; however, because
85 this step is not (yet) automated, creating such scenarios is laborious for both applicants and regulators.
86 For this reason, this guidance document introduces a simple Tier 3A, which uses a refined scenario
87 adjustment factor based on results from Tier 2A and Tier 2B.

88 Tiers 1 and 2B are based on the assumption that crop interception of the substance does not occur. In
89 Tiers 2A, 2C, 3A and 3B this can be included. EFSA (2012a) proposed to base interception and
90 subsequent dissipation at the crop canopy on simulations with the numerical models. Since this could
91 lead to differences between models, tables for the fraction of the dose reaching the soil surface were
92 created based on simulations with PEARL and PELMO. These tables should be used in all tiers where
93 crop interception is included. The availability of these tables not only facilitates harmonisation of the
94 regulatory process but also simplifies the tiered approach since it is not necessary anymore to run Tier
95 2A before Tier 2C as suggested in EFSA (2012a).

96 The scenarios used at Tier 1 and 2A are based on the 95th spatial percentile considering the total area
97 of annual crops in each regulatory zone. However, the purpose of the exposure assessment is to
98 consider the total area of the crop where the PPP is intended to be applied. Since the 95th spatial
99 percentile of a given crop may be higher, scenario adjustment factors (named crop extrapolation
100 factors in EFSA, 2012a) have been included at Tier 1 and Tier 2A to ensure that these tiers are more
101 conservative than Tiers 2B, 2C, 3A and 3B.

102 The simple analytical model PERSAM is used in lower tiers. Since it cannot be *a priori* guaranteed
103 that the simple analytical model is more conservative than the more realistic numerical models used in
104 Tier 2A, 3A and 3B, model adjustment factors have been included in all tiers where the analytical
105 model is used. The model adjustment factors proposed in EFSA (2012a) have been reassessed for this
106 guidance document and the number of factors has been reduced to ease their use in the regulatory
107 process.

108 With respect to substance specific model inputs, this guidance document generally follows
109 recommendations given in the FOCUS Degradation kinetics report (FOCUS, 2006), the generic
110 guidance for Tier 1 FOCUS groundwater assessments (Anonymous, 2011) and the EFSA Guidance
111 Document on how to obtain *DegT50* values (EFSA, 2014a). New guidance is included for (i) the
112 calculation of the rapidly dissipating fraction at the soil surface, (ii) the sorption coefficient in air-dry
113 soil, and (iii) the *DegT50* or K_{om} of substances whose properties depend on soil properties such as pH
114 or clay content.

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DRAFT

190 **BACKGROUND AS PROVIDED BY EFSA**

191 During a general consultation of Member States on needs for updating existing Guidance Documents
192 and developing new ones, a number of EU Member States (MSs) requested a revision of the SANCO
193 Guidance Document on persistence in soil (SANCO/9188VI/1997 of 12 July 2000). The consultation
194 was conducted through the Standing Committee on the Food Chain and Animal Health.

195 Based on the Member State responses and the Opinion prepared by the PPR Panel (EFSA 2012a) the
196 Commission tasked EFSA to prepare a Guidance of EFSA for predicting environmental concentrations
197 of active substances of plant protection products and transformation products of these active
198 substances in soil in a letter of 31 July 2012. EFSA accepted this task in a letter to the Commission
199 dated 9 October 2012. The Commission requests this scientific and technical assistance from EFSA
200 according to Article 31 of Regulation (EC) no 178/2002 of the European Parliament and of the
201 Council.

202 Following public consultations on the Opinion (EFSA, 2012a), Member States and other stakeholders
203 requested “an *easy to use Guidance Document*” to facilitate the use of the proposed guidance and
204 methodology for the evaluation of PPPs according to Regulation (EC) No 1107/2009.

205 Once this Guidance Document is delivered, the Commission will initiate the process for the formal use
206 of the Guidance Documents within an appropriate time frame for applicants and evaluators.

207 **TERMS OF REFERENCE AS PROVIDED BY THE COMMISSION**

208 EFSA, and in particular the Pesticides Unit, is asked by the Commission (DG SANCO) to draft an
209 EFSA Guidance Documents entitled “EFSA Guidance Document for predicting environmental
210 concentrations of active substances of plant protection products and transformation products of these
211 active substances in soil”. The EFSA Guidance Documents should respect the science proposed and
212 methodology developed in the adopted PPR opinion mentioned in this document (EFSA 2012a).

213 EFSA was requested to organise public consultations on the draft Guidance Documents, to ensure the
214 full involvement of Member States and other stakeholders. To support the use of the new guidance,
215 EFSA is requested to organise training of Member State experts, applicants and other relevant
216 stakeholders.

217 **CONTEXT OF THE SCIENTIFIC OUTPUT**

218 The purpose is to address the Terms of References as provided by the Commission.

219

220

221 **ASSESSMENT**

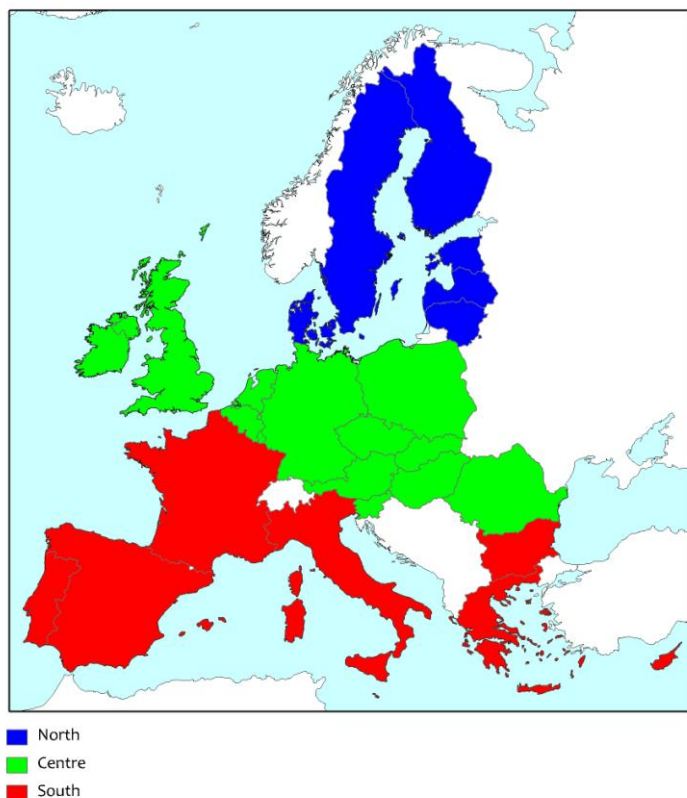
222 **1. INTRODUCTION**

223 **1.1. Aim of this guidance document**

224 This document provides guidance for the exposure assessment of soil organisms to plant protection
 225 products (PPPs) in the three regulatory zones according to Regulation EC no 1107/2009 of the
 226 European Parliament and the Council (Figure 1). The recommended methodology is intended for the
 227 assessment of active substances and metabolites in the context of approval at EU-level, and it is
 228 expected to be useful for the assessment of products at the zonal level as well.

229 This guidance document presents a brief overview of the recommended procedure and provides the
 230 guidance necessary to enable users to carry out the exposure assessment. A comprehensive description
 231 of the methodology and the science behind this methodology can be found in EFSA (2010; 2012a;
 232 2012b). Some further scientific developments have taken place after the publication of EFSA (2012a)
 233 with the goal to facilitate and further harmonise the exposure assessment. These scientific
 234 developments are described in appendices to this guidance document.

235 The recommended procedure consists of five tiers. The first three tiers are explained in this guidance
 236 document. This guidance document will not provide guidance on Tier 4 (spatially distributed
 237 modelling with numerical models) and Tier 5 (post-registration monitoring). For guidance on these
 238 tiers we refer to the relevant sections in EFSA (2012a). The scenarios in this guidance document were
 239 selected using a procedure that works well for parent substances and started with the compilation of a
 240 coherent database, which is available free at the European Soil Data Centre (Panagos et al. 2012)
 241 (<http://eussoils.jrc.ec.europa.eu/library/Data/EFSA/>). Additional analyses show that this methodology
 242 could with some restrictions also be used for soil metabolites. Therefore it is advised to use the
 243 exposure assessment scheme also for metabolites.



244

245 **Figure 1:** Map of the three regulatory zones according to Regulation EC no 1107/2009 of the
 246 European Parliament and the Council.

247 **1.2. The exposure assessment goal**

248 As described in EFSA (2012a), the methodology is based on the goal to assess the 90th-percentile
 249 concentration considering all agricultural fields within a regulatory zone (North, Centre, South) where
 250 the particular PPP is intended to be used. The agricultural area of use is represented by the crop in
 251 which the pesticide is intended to be used, e.g. for a pesticide that is to be applied in maize, the area is
 252 defined as all fields growing maize in a regulatory zone. Considerably fewer zones were distinguished
 253 here than in earlier guidance (e.g. in the leaching assessment to groundwater (FOCUS, 2000; 2009)
 254 nine climatic zones were distinguished). This was done to keep the regulatory process as simple as
 255 possible.

256 The exposure assessment is part of the terrestrial effect assessment. This guidance document therefore
 257 considers all types of concentrations that are potentially needed for assessing the ecotoxicological
 258 effects. EFSA (2009) indicated that the following types of concentrations are needed:

- 259 i. The concentration in total soil (mg kg⁻¹) averaged over the top 1, 2.5, 5 or 20 cm of soil for
 260 various time windows: peak and time-weighted averages (TWA) for 7-56 days;
- 261 ii. The concentration in pore water (mg l⁻¹) averaged over the top 1, 2.5, 5 or 20 cm of soil for the
 262 same time windows.

263 As indicated in EFSA (2012a), the peak concentration is approximated by the maximum concentration
 264 of time series of 20 years (application each year), 40 years (application every two years) or 60 years
 265 (application every three years). The TWA concentrations are calculated for periods over a maximum
 266 of 56 days following after the occurrence of the peak concentration.

267 Older soil ecotoxicological studies often expressed exposure only in terms of the applied rate (in
 268 kg ha⁻¹). This guidance document therefore also briefly describes how to obtain this exposure
 269 endpoint.

270 Presently, pore water concentrations are not used in standard risk assessments for soil organisms,
 271 however, the pore water concentrations were included in the methodology in case the standard
 272 approach would be revised in the future (as recommended by EFSA, 2009).

273 Based on discussions with stakeholders, it was a boundary condition that the exposure-assessment
 274 methodology can be applied by taking median or average substance properties from the dossiers. Such
 275 substance properties are uncertain and inclusion of this uncertainty leads to probability density
 276 functions that show more spread. As a consequence, this boundary condition led to the need to base
 277 the exposure-assessment procedure on the spatial 95th-percentile concentration instead of the 90th-
 278 percentile spatial concentration (see for details Section 4.2.5 of EFSA, 2012a). Together with the 100th
 279 percentile in time and the median or average substance properties, the overall goal (90th percentile
 280 concentration) is considered to be reached.

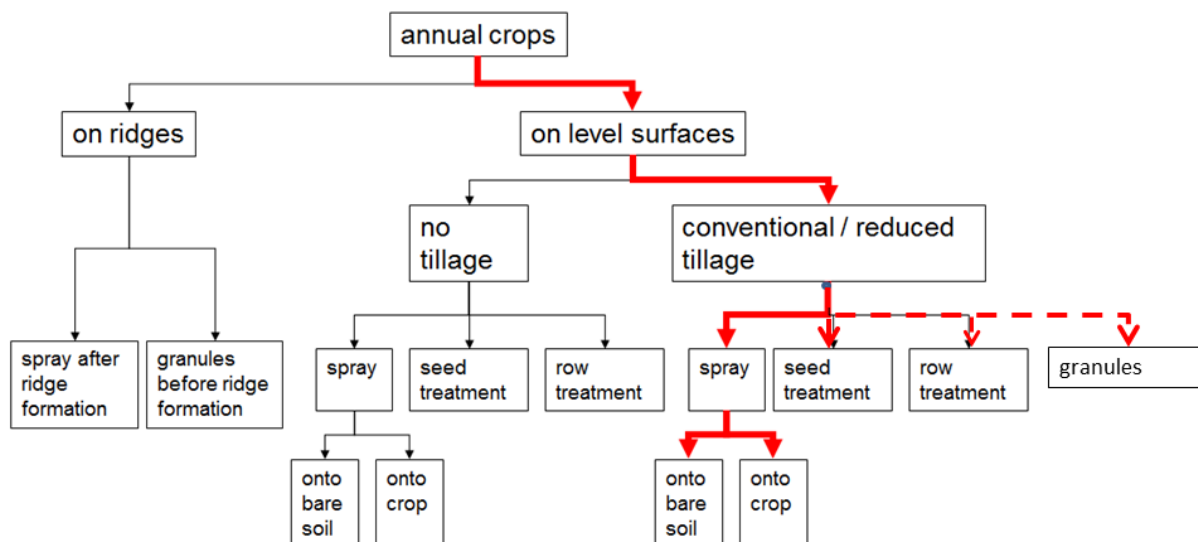
281 **1.3. Cropping and applications systems covered by this guidance**

282 The methodology has been developed for spray applications to annual crops under conventional and
 283 reduced tillage (excluding tillage systems with ridges and furrows, Figure 2). Hereby it is assumed that
 284 the soil is ploughed annually to a depth of 20 cm. It is assumed that for applications of granular
 285 products (to the soil surface or incorporated), this methodology can be used as well. With small
 286 modifications, the procedure covers reasonably well also row treatments.

287 The exposure assessment for annual crops differs from that for permanent crops (e.g. permanent crops
 288 often have a litter layer). The exposure assessment for no-tillage systems is also different because
 289 annual ploughing has a large diluting effect on the concentration in the top soil (which does of course
 290 not occur in no-tillage systems). The current guidance document is therefore not applicable to
 291 permanent crops and no-tillage systems (Figure 2). The exposure-assessment methodology for these

292 cropping systems is currently under development and guidance for these cropping systems will be
293 made available at a later stage.

294 Off-crop exposure (e.g. as a result of spray drift deposition or as a result of storage or disposal of
295 growing media used in horticultural production) is not covered by this guidance.



296
297 **Figure 2:** Cropping and application systems covered by this guidance are indicated by red lines. Solid
298 lines indicate that the guidance fully covers these cropping and application systems, dashed lines
299 indicate that guidance is provided but that the software tools for carrying out these assessments are not
300 fully operational.

301 1.4. Software tools

302 To facilitate efficient use of the tiered approach in regulatory practice, user-friendly software tools
303 have been developed. This includes the new software tool PERSAM (Decorte et al., 2014a based on
304 EFSA (2012a) and Tiktak et al. (2013) and new versions of the pesticide fate models PEARL (Tiktak
305 et al., 2000) and PELMO (Klein, 2011) that have been adapted so that they deliver the appropriate soil
306 exposure concentrations. Users of this guidance are advised to use these software tools when
307 performing the exposure assessment. For higher tier assessments other models than PEARL and
308 PELMO may be used as well. The only requirement is that the process descriptions in these numerical
309 models have a similar or higher level of detail than those in PEARL and PELMO, that the scenarios
310 used in the tiered approach are adequately parameterised, and that this parameterisation procedure is
311 well documented.

312 The software tools are operational for spray applications to annual crops under conventional and
313 reduced tillage (excluding tillage systems with ridges and furrows). These cropping systems are
314 indicated with solid red lines in Figure 2.

315 1.5. Structure of this guidance document

316 Chapter 2 gives an overview of the tiered approach and highlights some new developments that have
317 taken place since the publication of the scientific opinion (EFSA, 2012a) on which this guidance
318 document is based. Chapter 3 provides practical guidance on how to perform exposure assessments in
319 soil for annual crops for active substances of PPPs and for the metabolites of these active substances.
320 Chapter 3 is restricted to spray applications; the other application types (row treatments, seed
321 treatments and granules) are described in Chapter 4. Chapter 5 briefly describes documentation
322 requirements.

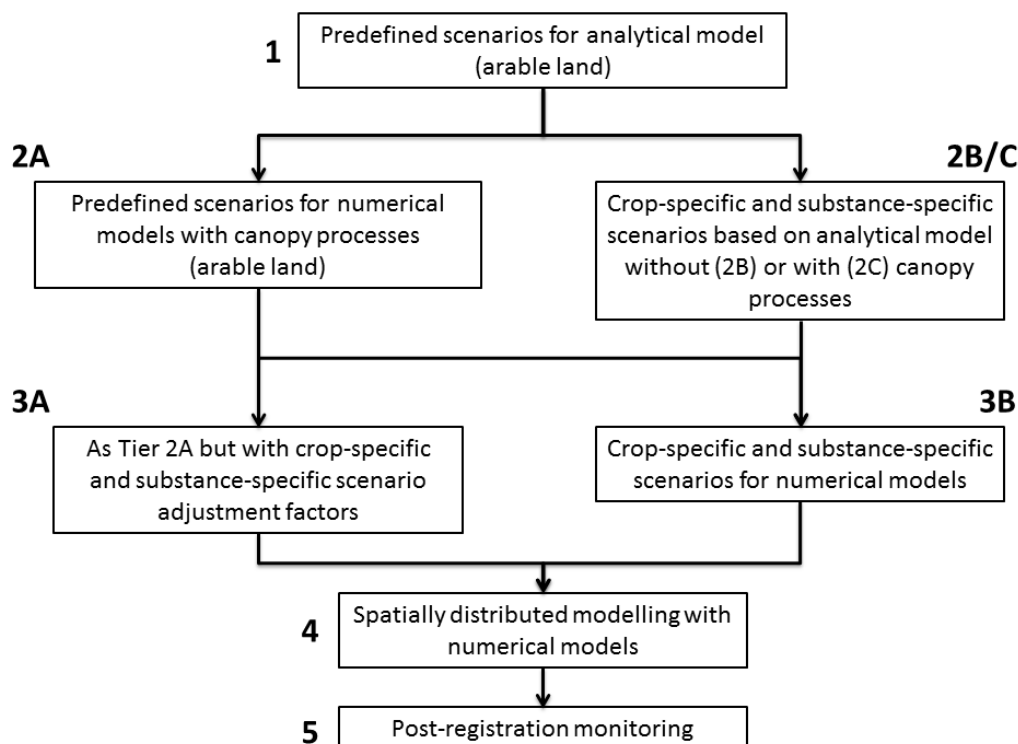
323 Scientific backgrounds to the new developments are given in the Appendices. Appendix A describes
 324 the applicability of the exposure assessment scheme for soil metabolites. Appendix B describes the
 325 scientific background to the table for the fraction of the dose reaching the soil as described in Section
 326 2.5; the full tables are provided in Appendix E. Appendix C describes the development of the scenario
 327 and model adjustment factors. Appendix D provides information on how the PERSAM crops were
 328 defined. Finally, Appendix E gives some practical examples.

329 2. OVERVIEW OF THE TIERED APPROACH AND NEW DEVELOPMENTS

330 This chapter provides a general overview of the tiered approach and highlights some new
 331 developments that have taken place since the publication of the scientific opinion on which this
 332 guidance document is based.

333 2.1. General overview

334 EFSA (2012a) proposed a tiered assessment scheme for the exposure assessment. This guidance has
 335 changed the tiered assessment scheme with the goal to simplify the exposure assessment for regulatory
 336 purposes. The revised scheme can be found in Figure 3. The lower tiers are more conservative and less
 337 sophisticated than the higher tiers but all tiers aims to address the same protection goal (i.e., the
 338 90th-percentile concentration within the area of intended use of a PPP). This principle allows moving
 339 directly to higher tiers without performing assessments for all lower tiers (an applicant may for
 340 example directly go to higher tiers without first performing a Tier 1 assessment). However, in the
 341 current tiered approach, some higher tiers (e.g. Tier 3A) depend on input from lower tiers. In those
 342 cases, the applicant should of course first carry out the lower tier assessments (see Section 3.6). For
 343 transparency and to allow comparison between substances, regulatory authorities may in such cases
 344 wish to request also the results derived from lower tiers.



345
 346 **Figure 3:** Tiered scheme for the exposure assessment of spray applications to annual crops under
 347 conventional or reduced tillage. The scheme applies both to the concentration in total soil and the
 348 concentration in pore water. Tiers 1, 2, and 3 are all based on one PEC for each of the regulatory zones
 349 North, Centre and South and allow for one or multiple applications every 1, 2 or 3 years. At Tiers 1,
 350 2A and 2B the analytical model in the software tool PERSAM is used. At Tiers 2A, 3A and 3B
 351 modelling is carried out with numerical models.

352 The exposure assessment starts with simulations for one predefined scenario per regulatory zone
 353 North-Centre-South. Simulations can be done with PERSAM at Tier 1 or with one of the numerical
 354 models at Tier 2A. At Tier 1, PERSAM has the advantage that the required number of inputs is very
 355 limited and thus also the documentation will require little effort. Tier 2A requires slightly more effort,
 356 however, this tier has the advantage that more realistic modelling approaches are used and therefore
 357 this tier will deliver less conservative values.

358 The scenarios in Tier 1 and Tier 2A are based on the total area of annual crops in a regulatory zone.
 359 However, the exposure assessment goal is based on the agricultural area where a substance is intended
 360 to be used. The applicant may therefore want to perform an exposure assessment for a particular crop.
 361 For this purpose, Tiers 2B and 2C are provided. At these tiers, a spatially distributed version of
 362 PERSAM is used and the target percentile is directly calculated from the concentration distribution
 363 within the area of a given crop. These tiers also offer the option to include relationships between
 364 substance properties ($DegT50$ and K_{om} or K_{oc}) and soil properties such as pH .

365 Should the assessment at Tier 2 still indicate an unacceptable risk to soil organisms, the applicant has
 366 the option to move to Tier 3. Tier 3 is based on the numerical models and on the area of a given crop.
 367 Tier 3 has two options:

- 368 i. Tier 3A, which uses a crop-specific and substance-specific scenario adjustment factor to refine
 369 the exposure assessment at Tier 2A. This refined scenario adjustment factor is based on the
 370 ratio between the PEC obtained at Tier 2B and Tier 1 and is therefore very simple to carry out.
 371 However, this procedure is only defensible for substances whose properties do not depend on
 372 soil properties.
- 373 ii. Tier 3B, which uses crop-specific and substance-specific scenarios. The scenario is first
 374 identified in the PERSAM software. The selected scenario should than be parameterised by
 375 the user. Guidance is given in Section 3.7 on how to perform this step; however, because this
 376 step is not (yet) automated, creating such scenarios is rather laborious for both applicants and
 377 regulators. It is therefore advised to only carry out Tier 3B for substances whose properties
 378 depend on soil properties.

379 The scheme also contains a Tier 4, which is a spatially distributed modelling approach based on
 380 calculations with the numerical models for many scenarios for each of the zones. Although amongst
 381 others Tiktak (2012) showed that the development of such a model is possible, this is not yet
 382 operational and is therefore not included in this guidance document. Tier 5 is a post-registration
 383 monitoring approach. For guidance on these tiers we refer to the relevant sections in EFSA (2012a).

384 2.2. Properties of the six soil exposure scenarios

385 As described in the previous section, Tiers 1, 2A and 3A are based on one predefined scenario per
 386 regulatory zone (North-Centre-South) for each of the two types of ERC (concentration in total soil and
 387 concentration in pore water). The properties of these six scenarios are summarised in Tables 1 and 2
 388 and their position is shown in Figure 4.

389 **Table 1:** Properties of the selected predefined scenarios used at Tier 1 and 2A for the concentration
 390 in total soil. T_{arit} is the arithmetic mean temperature, T_{Arr} is the Arrhenius-weighted mean temperature
 391 (explained in EFSA, 2012a), f_{om} (%) is the organic matter content and ρ (kg dm^{-3}) is the dry bulk
 392 density of the soil. Soil properties are those of the top 30 cm of the soil, for properties of the other soil
 393 layers refer to EFSA (2012b).

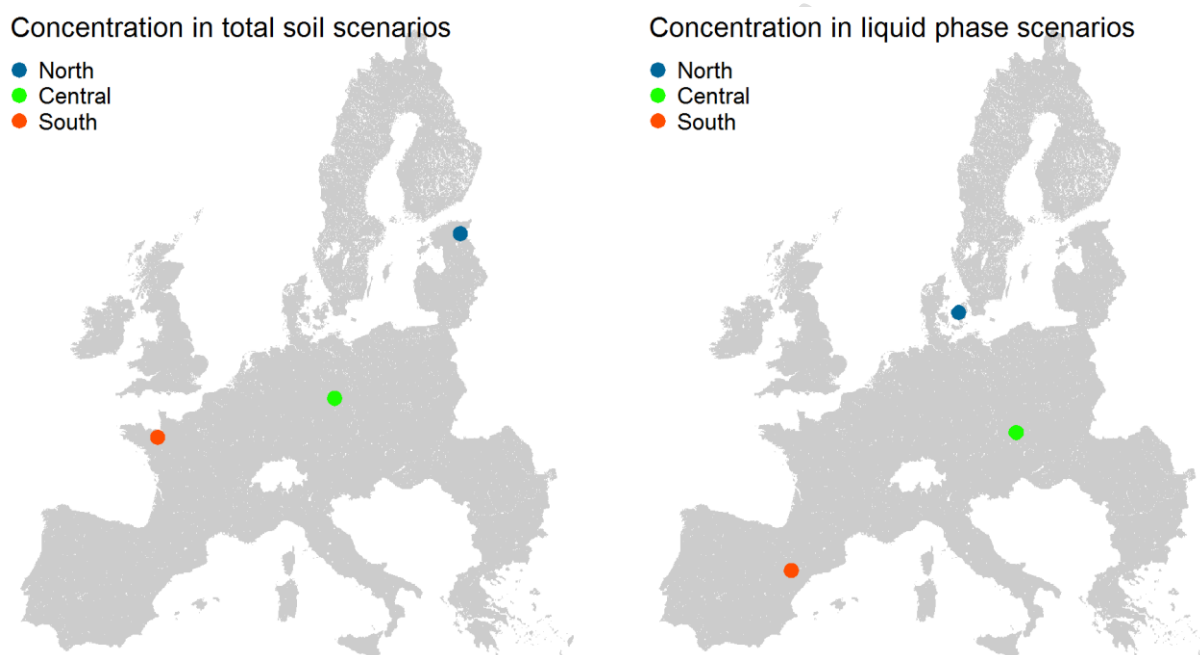
Zone	Code	Country	T_{arit} (°C)	T_{Arr} (°C)	Texture	f_{om} (%)	ρ (kg dm^{-3})
North	CTN	Estonia	4.7	7.0	Coarse	11.8	0.95
Centre	CTC	Germany	8.0	10.1	Coarse	8.6	1.05
South	CTS	France	11.0	12.3	Medium fine	4.8	1.22

394

395 **Table 2:** Properties of the selected predefined scenarios used at Tier 1 and 2A for the concentration
 396 in pore water. T_{arit} is the arithmetic soil temperature, T_{Arr} is the Arrhenius-weighted mean temperature
 397 (explained in EFSA, 2012a) and f_{om} (%) is the organic matter content and ρ (kg dm^{-3}) is the dry bulk
 398 density of the soil.. Soil properties are those of the top 30 cm of the soil, for properties of the other soil
 399 layers refer to EFSA (2012b).

Zone	Code	Country	T_{arit} (°C)	T_{Arr} (°C)	Texture	f_{om} (%)	ρ (kg dm^{-3})
North	CLN	Denmark	8.2	9.8	Medium	2.3	1.39
Centre	CLC	Czech republic	9.1	11.2	Medium	1.8	1.43
South	CLS	Spain	12.8	14.7	Medium	1.1	1.51

400



401

402 **Figure 4:** Position of the six predefined scenarios for carrying out Tier 1, 2A and 3A soil exposure
 403 assessments. Left-hand panel: scenarios for the concentration in total soil. Right-hand panel: scenarios
 404 for the concentration in pore water.

405 2.3. Crops and scenario adjustment factors

406 The scenarios in Tables 1 and 2 were based on the 95th spatial percentile considering the total area of
 407 annual crops in each regulatory zone. However, the purpose of the exposure assessment is to consider
 408 the total area of the crop where the PPP is intended to be applied. For any specific crop assessed, the
 409 spatial statistical distribution of the exposure concentrations would be different. Therefore in Tiers 1
 410 and 2A scenario adjustment factors (named crop extrapolation factors in EFSA, 2012a) are needed to
 411 ensure that these tiers are more conservative than Tiers 2B, 2C, 3A and 3B (Table 3).

412 This guidance has slightly modified the procedure for deriving these scenario adjustment factors and
 413 therefore the values of these factors have changed as well. Background is that the spatial dataset on
 414 which the exposure scenarios are based has been replaced by a new version (see Appendix C1 for
 415 background information).

416 **Table 3:** Overview of inclusion of canopy processes, scenario adjustment factors and model
 417 adjustment factors in the different tiers of Figure 3. '+' indicates that the process or factor is included,
 418 '-' indicates that it is not included and 'o' indicates that a non-default factor as indicated in the
 419 footnote is used.

Tier	Canopy processes	Scenario adjustment factors	Model adjustment factors
1	-	+	+
2A	+	+	-
2B	-	-	+
2C	+	-	+
3A	+	o ¹	-
3B	+	-	-
4	+	-	-

420 1) At Tier 3A, substance-specific and crop-specific scenario adjustment factors are used instead of the conservative default
 421 scenario adjustment factors given in Table 5.

422 Assessments are carried out for specific crops. EFSA (2012a) uses two lists of crops; i.e. one based on
 423 the so-called CAPRI crops or crop-groups (Leip et al., 2008) for which EU crop maps are available at
 424 a scale of 1x1 km², and a list of other crops or crop-groups for which these maps are not available. All
 425 annual CAPRI crops and crop groups have been included in the PERSAM software tool. However,
 426 some of the CAPRI crops or crop-groups included in PERSAM are not well enough defined to be used
 427 in the regulatory process (see Appendix D). For this reason, only the CAPRI crops given in Table 4
 428 should be used in the regulatory process. For crops that are included in Table 4, the scenario
 429 adjustment factors listed in Table 5 should be used.

430 **Table 4:** CAPRI crops or crop groups that may be used in the regulatory process. For the crops and
 431 crop groups in this table, the scenario adjustment factors listed in Table 5 should be used.

Crop	North	Centre	South
Barley	+	+	+
Common wheat	+	+	+
Durum wheat	-	+	+
Fallow	+	+	+
Floriculture and flower bulbs	+	+	+
Maize	+	+	+
Oats	+	+	+
Oilseed rapes	+	+	+
Other fresh vegetables ¹	+	+	+
Potatoes ²	+	+	+
Pulses	+	+	+
Rye	+	+	+
Soya beans	-	+	+
Sugar beets	+	+	+
Sunflowers	-	+	+
Texture crops	+	+	+
Tobacco	-	+	+

432 1) Tomatoes are also included in PERSAM; however, since this crop is not well defined in CAPRI, this crop should not be
 433 used. Instead, fresh vegetables should be taken as a surrogate.

434 2) Potatoes are included in PERSAM; however, this guidance document does not apply to crops grown on ridges.

435 For crops or crop groups that are not in Table 4, a surrogate crop or crop group should be selected to
 436 represent the area of intended use. The choice of this surrogate crop should be justified on a case-by-
 437 case basis. Please note that this procedure differs from the procedure as described in EFSA (2012a)
 438 where it was suggested to use higher (more conservative) scenario adjustment factors.

439 **Table 5:** Scenario adjustment factors (f_s) to be used when performing an assessment for one of the
 440 CAPRI crops included in Table 4 for both the three regulatory zones and for both the concentration in
 441 total soil and for the concentration in pore water. Refer to Appendix C for background information.

Zone	Scenario adjustment factors to be used for the	
	concentration in total soil	concentration in pore water
North	3.0	2.0
Centre	2.0	1.5
South	2.0	1.5

442 If a well-documented crop map is available, it is acceptable to use the Tier-2B procedure to calculate
 443 the 95th spatial percentile of the PEC for the crop considered. This 95th-percentile concentration can be
 444 used to derive a crop-specific and substance-specific scenario adjustment factor, which can be used to
 445 refine the assessment at Tier 2A (see Section 3.6 for details). Since the current version of the
 446 PERSAM tool does not provide the option to import other crop maps, the Tier 2B assessments should
 447 be done outside the software tool using e.g. the script in Appendix A6 of EFSA (2010a).

448 2.4. Model adjustment factors

449 The simple analytical model is generally used in lower tiers. Since it cannot be *a priori* guaranteed that
 450 the simple analytical model is conservative enough when compared with the more realistic numerical
 451 models used in Tier 2A, 3A and 3B, model adjustment factors are needed in all the tiers that use the
 452 analytical model (Table 3). The model adjustment factors proposed in EFSA (2012a) have been
 453 reassessed for this Guidance Document and the number of factors has been reduced to ease their use in
 454 the regulatory process (see Appendix C2 for details). The new factors are listed in Table 6. Note, as
 455 the model adjustment factors used in the tiered approach have been calculated using PEARL and
 456 PELMO, there is uncertainty if these factors are applicable for other models.

457 **Table 6:** Model adjustment factors (f_M) to be used when performing an assessment with the analytical
 458 model. Refer to Appendix C for background information.

Zone	Model adjustment factors to be used for the	
	concentration in total soil	concentration in pore water
North	2.0	4.0
Centre	2.0	4.0
South	2.0	4.0

459 2.5. Crop canopy processes

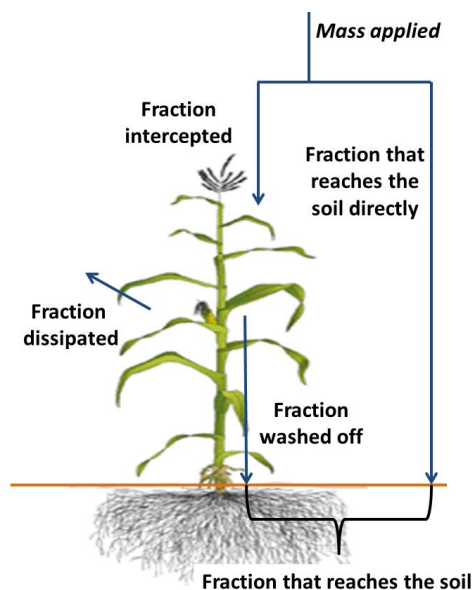
460 Tiers 1 and 2B are based on the assumption that crop interception of the substance does not occur. In
 461 Tiers 2A, 2C, 3A and 3B this can be included (Table 3).

462 EFSA (2012a) proposed to base interception and subsequent dissipation processes at the crop canopy
 463 on simulations with the numerical models. However, it is possible that this would lead to considerable
 464 differences between models because of differences in the descriptions of the processes on the plant
 465 surfaces between these models. So therefore tables for the fraction of the dose reaching the soil were
 466 created based on simulations with PEARL and PELMO. Herein, the fraction of the dose reaching the
 467 soil is defined as the sum of the fraction of the dose washed off and the fraction of the dose that
 468 directly reaches the soil (see also Figure 5):

$$469 \quad f_{soil} = (1 - f_i) + f_i f_w \quad (xx)$$

470 where f_{soil} is the fraction of the dose reaching the soil, f_i is the fraction of the dose intercepted and f_w is
 471 the fraction of the dose washed off from the canopy. The fraction of the dose intercepted was taken
 472 from EFSA (2014a). Further details on the development of the tables are given in Appendix B; the
 473 resulting calculations are summarised in Table 7. Note that in this guidance f_{soil} is used instead of
 474 $F_{soil,max}$ (which is used in EFSA 2012a and in current version of PERSAM). The background is that

475 this guidance document suggests using the average fraction washed-off instead of the maximum
 476 fraction washed off (Appendix B2).



477

478 **Figure 5:** Schematic overview of the processes occurring at the crop canopy. The fraction of the
 479 dose reaching the soil is the sum of wash-off from the canopy and the fraction of the dose that reaches
 480 the soil directly.

481 Note that the fraction of the dose reaching the soil in Table 3 should be used at all tiers where crop
 482 interception is included (i.e. Tier 2A, Tier 2C, Tier 3A and Tier 3B). Practical guidance on how to use
 483 these tables in the exposure assessment is given in Chapter 3.

484 The availability of these tables not only facilitates harmonisation of the regulatory process but also
 485 considerably simplifies the tiered assessment approach since it is not necessary anymore to run Tier
 486 2A before Tier 2C as suggested in EFSA (2012a).

487 For cultivations of protected crops it has been recommended to apply the same approaches as for open
 488 field crops (see further EFSA, 2014b). However, crops grown under cover are generally drip irrigated
 489 and protected from rainfall and therefore wash-off from the canopy is not relevant. Therefore, for
 490 annual crops grown under cover we recommend using the crop interception tables published in
 491 Appendix C to EFSA (2014a).

492 **Table 7:** Fraction of the dose reaching the soil (f_{soil}) considering crop interception and canopy
 493 dissipation processes as a function of crop development stage. Note that the figures are rounded to the
 494 nearest half.

Crop	BBCH code ^{1,2}				
	00-09	10-19	20-39	40-89	90-99
Beans (vegetable and field)	1.00	0.85	0.85	0.65	0.45
Cabbage	1.00	0.85	0.85	0.60-1.00 ³	1.00 ³
Carrots	1.00	0.85	0.70	0.45-1.00 ³	1.00 ³
Cotton	1.00	0.90	0.90	0.50	0.25
Maize	1.00	0.85	0.75	0.60	0.35
Onions	1.00	0.95	0.90	0.75-1.00 ³	1.00 ³
Peas	1.00	0.75	0.70	0.65	0.55
Oil seed rape (summer)	1.00	0.75	0.60	0.60	0.55
Oil seed rape (winter)	1.00	0.75	0.60	0.60	0.35
Sugar beets	1.00	0.90	0.75	0.50-1.00 ³	1.00 ³
Soybeans	1.00	0.85	0.80	0.70	0.55
Sunflowers	1.00	0.90	0.80	0.70	0.35
Tobacco	1.00	0.70	0.65	0.65	0.40
Tomatoes	1.00	0.75	0.75	0.65	0.65

Crop	BBCH code ⁴				
	00-19	20-29	30-39	40-69	70-99
Spring cereals	1.00	0.90	0.65	0.60	0.60
Winter cereals	1.00	0.90	0.60	0.55	0.55

- 495 1) The BBCH code is a decimal code ranging from 0 to 99 to characterise the crop development stage (Meier, 2001).
 496 2) BBCH 00-09: bare to emergence; BBCH 10-19: leaf development; BBCH 20-39: stem elongation; BBCH 40-89:
 497 flowering; BBCH 90-99 Senescence and ripening
 498 3) Since these crops are harvested at BBCH 50, the higher value of 1.00 should be used for BBCH code 50-99.
 499 4) BBCH 00-19: bare to leaf development; BBCH 20-29: tillering; BBCH 30-39: stem elongation; BBCH 40-69:
 500 flowering; BBCH 70-99 Senescence and ripening

501 2.6. Applicability of the tiered assessment scheme for soil metabolites

502 The scenarios in this guidance document were selected using a simple analytical model, which does
 503 not consider dissipation processes such as leaching and plant uptake. It was proven that this procedure
 504 works well for parent substances (EFSA, 2012a). Appendix A shows that in most cases the exposure
 505 assessment methodology also generates suitable estimates of the exposure concentrations of soil
 506 metabolites. This appendix also shows, however, that the scenario selection procedure that forms the
 507 basis of Tiers 2A, 3A and 3B is not completely appropriate for certain metabolites (i.e. metabolites
 508 that do leach significantly from the top 20 cm of soil and metabolites that do not accumulate over the
 509 years). So for these compounds, it cannot be guaranteed that the results generated at Tier 2A, 3A and
 510 3B are close to the 95th percentile of the spatial concentration distribution. Despite this, it is advised to
 511 use the exposure assessment scheme for all soil metabolites (including soil metabolites that show
 512 considerable leaching and for non-accumulating metabolites) until better alternatives become
 513 available.

514 2.7. Exposure assessment based on the total amount in soil

515 Older soil ecotoxicological studies often expressed exposure only in terms of the applied rate (in
 516 kg ha⁻¹). If such studies have to be used in the risk assessment, it is proposed to perform the exposure
 517 assessment on the basis of the concentration in the top 20 cm of soil (i.e., to re-calculate the PEC in
 518 total soil given in mg/kg into kg/ha exposure estimate to allow comparison with the ecotoxicological

519 endpoint). The value of 20 cm should be used because this is the largest value for the ecotoxicological
 520 averaging depth. This is a conservative approach for estimating the total amount in soil (EFSA, 2012a)
 521 since the total amount increases as the soil depth increases.

522 Only the scenarios for the concentration in total soil are relevant for such cases and the total amount in
 523 the top soil, Z (kg ha⁻¹) is calculated from the PEC in total soil (in mg kg⁻¹) for an ecotoxicological
 524 averaging depth (z_{eco}) of 20 cm and the dry bulk density ρ (in kg dm⁻³) with:

$$525 \quad Z = a\rho PEC \quad (1)$$

526 with $a = 2 \text{ kg dm}^3 \text{ ha}^{-1} \text{ mg}^{-1}$ (parameter a is needed to convert the concentration in the top 20 cm into
 527 the total amount in kg ha⁻¹). So if $\rho = 1.05 \text{ kg dm}^{-3}$ and the PEC is 1 mg kg^{-1} then $Z = 2 \times 1.05 \times 1 =$
 528 2.1 kg ha^{-1}). The value of ρ can be obtained from Table 1.

529 The procedure in Eqn. 1 may be used in combination with results from every tier of the exposure
 530 assessment scheme in this guidance.

531 **3. EXPOSURE ASSESSMENT IN SOIL OF SPRAY APPLICATIONS TO ANNUAL CROPS**

532 This chapter provides practical guidance on how to perform exposure assessments in soil for annual
 533 crops for active substances of PPPs and for the metabolites of these active substances. This chapter is
 534 restricted to spray applications; guidance on row treatments, seed treatments and granules is given in
 535 Chapter 4. This guidance is further restricted to Tier 1, 2 and 3 (see Section 2.1). This chapter starts
 536 with the tiers using the simple analytical model (Tier 1, 2B and 2C) and then describes the tiers based
 537 on the numerical models (Tier 2A, 3A and 3B).

538 **3.1. Required software tools**

539 To be able to perform the assessments in this chapter, the following versions of the software tools
 540 should be available:

- 541 i. The PERSAM software tool, which can be downloaded at
 542 <http://eusoils.jrc.ec.europa.eu/library/data/efsa/>
- 543 ii. An appropriate version of the numerical models PEARL or PELMO⁴. These models can be
 544 downloaded at the website of the respective models (i.e. www.pearl.pesticidemodels.eu and
 545 <http://server.ime.fraunhofer.de/download/permanent/mk/EFSA/PELMO/>). Other models than
 546 PEARL and PELMO may be used as well provided that they conform to the requirements
 547 given in Section 1.4.

548 Please refer to the manuals of the respective software tools for instructions on how to install the
 549 software.

550 **3.2. Tier 1 assessment using the PERSAM tool**

551 As described earlier, Tier 1 is based on a simple analytical model and on one scenario per regulatory
 552 zone North-Central-South for each of the two types of PECs (i.e. the concentration in total soil and the
 553 concentration in the liquid phase). The scenarios were selected using the total area of annual crops.
 554 Tier 1 is implemented in the PERSAM software tool. Practical guidance on how to input the substance
 555 properties and how to perform the calculations is given in Decorte et al. (2014b). The PERSAM
 556 software can generate an output report in pdf for use in regulatory submissions to competent
 557 authorities.

⁴ The provided model versions are not yet under (FOCUS) version control and are intended for testing during the public consultation only. They should not be used for regulatory submissions. To distinguish these model versions from official FOCUS versions, they are identified as SOIL_PEARL_Beta and SOIL_PELMO_Beta, respectively.

558 **3.2.1. Model input description**

559 At Tier 1, interception by the canopy is not considered and therefore the input to this analytical model
560 is restricted to:

- 561 i. the annual rate of application (kg ha^{-1}), i.e. the sum of the application rates within one growing
562 season in case of multiple applications;
- 563 ii. the application cycle (years);
- 564 iii. the organic-matter/water distribution coefficient (K_{om}) or the organic-carbon/water distribution
565 coefficient K_{oc} ($\text{dm}^3 \text{kg}^{-1}$),
- 566 iv. the half-life for degradation ($DegT50$) in top soil at 20°C and a moisture content
567 corresponding to field capacity (d),
- 568 v. the Arrhenius activation energy (kJ mol^{-1}),
- 569 vi. the molar mass of the molecule (g mol^{-1}),
- 570 vii. in the case of a transformation product: the molar fraction of formation (-) of the metabolite as
571 formed from its precursor.

572 EFSA (2014a) provides guidance for the calculation of the rapidly dissipating fraction at the soil
573 surface (F_{field}) from field dissipation studies. As described in Section 3.5, fast dissipation processes are
574 only relevant for the fraction of the dose that directly reaches the soil surface (see Figure 5). This
575 implies that this correction should not be applied at Tier 1, since at this Tier the full dose is input into
576 the model. We also do not recommend using this correction at Tier 2C, since the fraction of the dose
577 that directly reaches the soil is dependent on the crop stage, and the analytical model only allows input
578 of annual application rates.

579 In general, the selection of substance specific input values should follow recommendations given in
580 FOCUS (2006) and in the generic guidance for Tier 1 FOCUS ground water assessments
581 (Anonymous, 2011). EFSA (2007, 2012a, 2014a) give the following amendments to these two
582 documents:

- 583 i. Guidance on deriving the degradation half-life in top soil at reference conditions is given by
584 EFSA (2014a). This guidance document prescribes using the geometric mean from laboratory
585 and/or field experiments following normalisation to reference conditions (20°C , $\text{pH } 2$),
- 586 ii. The molar activation energy should be set to 65.4 kJ mol^{-1} (EFSA, 2007) and should only be
587 changed based on experimental evidence,
- 588 iii. The geomean K_{om} or K_{oc} of dossier values should be used since the geomean is the best
589 estimator of the median value of a population (EFSA, 2014a). This guidance holds for all
590 sample sizes, so also for sample sizes larger than nine for which currently the median value is
591 used,
- 592 iv. In the analytical model the formation fraction is based on molar fractions and is usually
593 derived from kinetic fitting procedures in line with FOCUS (2006). The arithmetic average
594 value is considered most appropriate. Formation fractions should be derived following the
595 stepped approach in Section 7.5 of EFSA (2012a).
- 596 v. When Tier 1 is used for substances whose K_{om} and/or $DegT50$ depend on soil properties such
597 as pH or clay content, the applicant should ensure that conservative values of K_{om} and $DegT50$
598 are used. EFSA (2012a) suggests taking a low value for K_{om} and a high value for $DegT50$,
599 since this leads to a conservative assessment at Tier 1. However, it is possible that this
600 combination of $DegT50$ and K_{om} is not conservative at Tier 2A (see second bullet in Section
601 3.5.3). It is therefore advised to always perform a conservatism analysis at Tier 2A and ignore
602 Tier 1 if results from Tier 2A are higher than those of Tier 1.

603 **3.2.2. Model results**

604 Please notice that the values given by the PERSAM software tool include the model adjustment factor
605 and the scenario adjustment factor (Table 3). The factors were added to ensure that Tier 1 delivers
606 more conservative values than higher tiers. The user might wish to calculate the “pure” PEC (i.e. the

607 result of the simple analytical model without these factors). This may be done using the following
 608 calculation:

$$609 \quad PEC = \frac{Result_{Tier1}}{f_M f_S} \quad (2)$$

610 where PEC is either concentration in total soil (mg/kg) or the concentration in pore water (mg/l),
 611 *Tier 1* is the result from the PERSAM tool, f_M (-) is the model adjustment factor for the respective type
 612 of concentration and f_S (-) is the scenario adjustment factor for the respective scenario and type of
 613 concentration. The values of the two adjustment factors (Tables 5 and 6) are given in the report
 614 generated by PERSAM.

615 3.3. Tier 2B assessment using the PERSAM tool

616 Tier 2B provides the option of an exposure assessment with the simple analytical model for a
 617 particular crop and a particular substance. Tier 2B is based on a spatially distributed version of the
 618 analytical model described in Tier 1. This implies that the exposure concentration is known for every
 619 pixel and therefore the 95th spatial percentile can be directly obtained from the spatial frequency
 620 distribution of the exposure concentration. At Tier 2B, no conservative scenario adjustment factors are
 621 applied (Table 3). For this reason, Tier 2B simulates less conservative values than Tier 1.

622 Tier 2B is implemented in the PERSAM software tool. Practical guidance on how to input the
 623 substance properties and how to perform the calculations is given in Decorte et al. (2014b). The
 624 PERSAM software can generate an output report in pdf for use in regulatory submissions to competent
 625 authorities.

626 3.3.1. Model input description

627 The user has to select a CAPRI crop for which the exposure assessment will be done. As described in
 628 Section 2.3, not all crops included in PERSAM are sufficiently well defined to be used in the
 629 regulatory process. A list of crops that can be used for regulatory purposes is provided in Table 4.

630 The other model inputs are exactly the same as those in Tier 1A with the exception of substance
 631 properties that depend on soil properties (item (v) in the second list). PERSAM basically provides two
 632 options, i.e.

- 633 i. The K_{om} or K_{oc} depends on the *pH* of the soil. In this case, the equation for sorption of weak
 634 acids as described by Van der Linden et al. (2009) may be applied. This equation requires the
 635 following additional parameters:
 - 636 a. The coefficient for sorption on organic matter under acidic conditions ($K_{om,acid}$);
 - 637 b. The coefficient for sorption on organic matter under basic conditions ($K_{om,anion}$);
 - 638 c. The negative logarithm of the acid dissociation constant (pK_a);
 - 639 d. A constant accounting for surface acidity (ΔpH).
- 640 ii. The K_{om} or $DegT50$ depend on soil properties according to other mathematical rules. When
 641 this option is used, the applicant should provide ample statistical evidence that such a
 642 relationship exists. Please note that this option has not yet been extensively tested (e.g.
 643 negative $DegT50$ or K_{om} values might occur). Therefore this option should be used with due
 644 care.

645 Section 3.6 in Boesten et al. (2012) provides comprehensive guidance on estimating sorption
 646 coefficients for weak acids with *pH*-dependent sorption. The most essential item in this guidance is
 647 that the sigmoidal function of Van der Linden et al. (2009) can be fitted to experimental sorption data
 648 using any software package capable of fitting non-linear functions to data. However, because of the
 649 existence of three different *pH*-measuring methods, the *pH*-values in the sorption experiments must

650 first be brought in line with the type of pH -data in the PERSAM dataset (i.e. pH_{H_2O}). This can be done
 651 using of the two equations below (Boesten et al., 2012):

$$652 \quad pH_{H_2O} = 0.982 pH_{CaCl_2} + 0.648 \quad (3a)$$

$$653 \quad pH_{H_2O} = 0.860 pH_{KCl} + 1.482 \quad (3b)$$

654 Where pH_{H_2O} refers to the measurement of pH in water, pH_{CaCl_2} is the pH measured in 0.01M $CaCl_2$
 655 and pH_{KCl} is the pH measured in 1M KCl . Using these corrected pH -values, the parameters of the
 656 sigmoidal function can be fitted. Because this function has four parameters, at least four pH - K_{om}
 657 values are required for an adequate fit. Furthermore, it should be checked that the surface acidity is in
 658 a plausible range (i.e. ΔpH should be between 0.5 and 2.5). For further details refer to Section 3.6 in
 659 Boesten et al. (2012).

660 3.3.2. Model results

661 Please notice that the values given by the PERSAM software tool include the model adjustment factor
 662 (Table 3). This factor was added to account for differences between PERSAM and the numerical
 663 models (EFSA, 2012a). The values given the PERSAM are to be used for the regulatory risk
 664 assessment. The user may wish to calculate the “pure” PEC (i.e. the result of the simple analytical
 665 model without these factors). This may be done using the following calculation:

$$666 \quad PEC = \frac{Result_{Tier2B}}{f_M} \quad (3)$$

667 where PEC is either concentration in total soil (mg/kg) or the concentration in pore water (mg/l),
 668 $Result_{Tier2B}$ is the result from the PERSAM tool and f_M is the model adjustment factor for the respective
 669 type of concentration. The value of the model adjustment factor is given in the report generated by
 670 PERSAM (see also Table 6).

671 The PERSAM tool offers the option to show maps of the concentration distribution. The user may
 672 wish to generate a more detailed map. Therefore the tool has the option to export an ASCIIGRID file.
 673 This file can be easily imported in most commonly used GIS programmes.

674 3.4. Tier 2C assessment using the PERSAM tool

675 Tier 2C offers the possibility of incorporating the effect of crop interception in the PEC calculation
 676 with the simple analytical model carried out for Tier 2B. EFSA (2012a) describes that this should be
 677 based on simulations with the numerical models for the Tier 2A scenarios. However, as described in
 678 Section 2.5, this would possibly undo harmonisation of the exposure assessments at EU level because
 679 of differences in the descriptions of the processes on the plant surfaces between these models. For this
 680 reason, the working group created a table for the fraction of the dose that reaches the soil. This table is
 681 presented in Table 7 and should be used as the basis for the exposure assessment at all tiers where crop
 682 interception is included (including Tier 2C).

683 3.4.1. Model input description

684 The inputs at Tier 2C are exactly the same as the inputs at Tier 2B. The only exception is the fraction
 685 of the dose that reaches the soil surface ($F_{soil,max}$, now called f_{soil}), which should be taken from Table 7.
 686 Using this value, the tool will simply perform the following calculation:

$$687 \quad Result_{Tier2C} = F_{soil,max} Result_{Tier2B} \quad (4)$$

688 **3.4.2. Calculating $F_{soil,max}$ in the case of multiple applications**

689 As described in Section 3.2.1, the applicant should input the annual rate of application (kg ha^{-1}), i.e.
 690 the sum of the application rates within one growing season in case of multiple applications. When crop
 691 interception is included, this annual rate should apply to the amount reaching the soil surface. This
 692 parameter can, however, not be directly input in PERSAM. Therefore the following equation should
 693 be applied to calculate $F_{soil,max}$ in the case of multiple applications

$$F_{soil,max} = \frac{\sum_{i=1}^n F_{soil,max,i} A_i}{\sum_{i=1}^n A_i} \quad (5)$$

695 where $F_{soil,max}$ (-) is the mean weighted fraction of the dose reaching the soil, $F_{soil,max,i}$ (-) is the fraction
 696 of the dose reaching the soil for application i and A_i is the rate of application for application i .

697 Consider the following example:

- 698 - Application 1 at a rate of 2 kg/ha and a fraction reaching the soil surface of 1.0;
- 699 - Application 2 at a rate of 3 kg/ha and a fraction reaching the soil surface of 0.5;
- 700 - Application 3 at a rate of 5 kg/ha and a fraction reaching the soil surface of 0.25.

701 For this example, the mean weighted fraction of the dose reaching the soil ($F_{soil,max}$) that is to be input
 702 in PERSAM should be calculated as: $F_{soil,max} = (1.0*2.0+0.5*3.0+0.25*5.0)/(2.0+3.0+5.0) =$
 703 $4.75/10 = 0.475$. Furthermore, a dose of $2+3+5 = 10$ kg/ha should be introduced.

704 **3.4.3. Model results**

705 As in Tier 2B, the values given by the PERSAM software tool include the model adjustment factor
 706 (Table 3). The user might wish to calculate the “pure” PEC (i.e. the result of the simple analytical
 707 model without these factors). This may be done using the following calculation:

$$PEC = \frac{Result_{Tier2C}}{f_M} \quad (6)$$

709 where PEC is either concentration in total soil (mg/kg) or the concentration in pore water (mg/l),
 710 $Result_{Tier2C}$ is the result from the PERSAM tool and f_M is the model adjustment factor for the respective
 711 type of concentration. The value of the model adjustment factor is given in the report generated by
 712 PERSAM (see also Table 6).

713 **3.5. Tier 2A assessment using the numerical models**

714 At Tier 2A, numerical models are applied to the same scenarios as those mentioned in Section 4.1. At
 715 Tier 2A no model adjustment factor is applied and therefore it is ensured that Tier 2A delivers less
 716 conservative concentrations than Tier 1. However, since the scenarios apply to the total area of annual
 717 crops, conservative scenario adjustment factors are still included since there is *a priori* no guarantee
 718 that the calculations are also conservative for a specific crop. The scenarios are described in EFSA
 719 (2012a) and are included in user-friendly software shells of the numerical models PEARL and
 720 PELMO. These model shells and documentation will be made available at the website of the
 721 respective models (see Section 3.1 for addresses).

722 To run the models, the following inputs are needed:

- 723 i. The crop for which the simulations are done,
- 724 ii. The application cycle (1 year, 2 years or 3 years),
- 725 iii. The application scheme of the PPP including the fraction of the dose that reaches the soil,
- 726 iv. Properties of the active substance and its transformation products (when applicable).

727 In addition to these model inputs, a scenario adjustment factor is needed as well. The model inputs and
728 the scenario adjustment factors are discussed hereafter.

729 **3.5.1. Selection of the crop for which the simulations are done**

730 As described in EFSA (2012a), Tier 2A scenarios have been developed for a range of annual crops.
731 Crop parameters were directly taken from FOCUS (2009). These FOCUS crops differ from the
732 CAPRI crops or crop groups that form the basis of the exposure assessment in Tier 2B/C. Therefore an
733 appropriate FOCUS crop must be selected for each CAPRI crop or CAPRI crop group. The most
734 appropriate links are given in Table 8. For certain scenario-CAPRI crop combinations, an appropriate
735 FOCUS crop is not available. In such cases, the applicant may choose another FOCUS crop. A
736 justification for this choice should be provided on a cases-by-case basis.

737 **Table 8:** FOCUS crop to be selected when performing an assessment for a specific CAPRI crop or
738 crop group in Tier 2A.

PERSAM crop	FOCUS crop
Barley	Spring cereals; winter cereals ¹
Common wheat	Spring cereals; winter cereals
Durum wheat	Spring cereals
Fallow	Fallow soil
Floriculture and flower bulbs	Onions ²
Maize	Maize
Oats	Spring cereals; winter cereals
Oilseed rapes	Peas (animal feed); vegetable beans ³
Other fresh vegetables	Tomatoes
Potatoes	Potatoes
Pulses	Spring oil seed rape; winter oil seed rape ⁴ ; linseed
Rye	Winter cereals
Soya beans	Soya beans
Sugar beets	Sugar beets
Sunflowers	Sunflowers
Texture crops	Cotton; spring oil seed rape; linseed
Tobacco	Tobacco

- 739 1) Since barley is not winter hardy, winter cereals should only be used where spring cereals are not available
740 (i.e. the CLS scenario)
- 741 2) Onions could be chosen as a surrogate for flower bulbs
- 742 3) Vegetable beans could be chosen as a surrogate for pulses in the CLS and CTS scenarios
- 743 4) Winter oil seed rapes are primarily used for soil coverage

744 **3.5.2. The application schedule including the fraction of the dose that reaches the soil**

745 In the numerical models, PPPs can be applied to the crop canopy, sprayed onto the soil surface or
746 incorporated into the soil. For each application, the applicant must introduce the application date and
747 the rate of application (kg ha⁻¹). So in contrast to the analytical model, it is not necessary to sum the
748 applications within a growing season.

749 When PPPs are applied to the crop canopy, the numerical models will simulate plant processes. As
750 mentioned in Section 2.5, this would possibly undo harmonisation efforts of the exposure assessments

751 at EU level because of differences in the descriptions of the processes on the plant surfaces between
 752 these models. For this reason, substances should be applied to the soil surface rather than to the crop
 753 canopy. The application rate should be calculated using the equation:

$$754 \quad A_{soil} = f_{soil} A \quad (7a)$$

755 where A_{soil} (kg ha^{-1}) is the rate of application to the soil surface, f_{soil} (-) is the fraction of the dose
 756 reaching the soil and A (kg ha^{-1}) is the rate of application. The fraction of the dose reaching the soil
 757 should be obtained from Table 7. Please note that the fraction of the dose reaching the soil is called
 758 $F_{soil,max}$ in PERSAM. The reason is that in the final guidance document the average fraction is used
 759 instead of the maximum fraction (see Appendix B2).

760 EFSA (2014a) provides guidance for the calculation of the rapidly dissipating fraction at the soil
 761 surface (F_{field}) from field dissipation studies. This correction should only apply to the fraction of the
 762 dose that directly reaches the soil surface (see Figure 5) since it is unlikely that fast dissipation
 763 processes play an important role for the fraction that is washed off from the canopy. The application
 764 rate to the soil surface can be calculated with the following equation:

$$765 \quad A_{soil} = (1 - f_i)(1 - F_{field})A + f_i f_w A \quad (7b)$$

766 where f_i is the fraction of the dose intercepted by the canopy, F_{field} (-) is the rapidly dissipating
 767 fraction, and f_w is the fraction washed off from the canopy. An Excel sheet enabling these calculations
 768 based on simulations by PEARL and PELMO will be made available at a later stage.

769 Notice that such a correction is only defensible when used in combination with an appropriately
 770 derived geometric mean $DegT50_{matrix}$ as described in EFSA (2014a). So the geomean $DegT50_{matrix}$ may
 771 be based on a mixture of $DegT50_{matrix}$ values obtained from laboratory studies, tailored $DegT50_{matrix}$
 772 field studies or legacy field studies. However, only experiments with surface application (legacy
 773 studies) can be used to derive the rapidly dissipating fraction provided that a clear biphasic decline is
 774 observed (see Equation 3 in EFSA (2014a)). If no such biphasic decline is observed, the F_{field} value for
 775 the respective field experiment should be set to zero. In line with EFSA (2010c), the worst case of at
 776 least four F_{field} values should be used for regulatory submissions. If more than four F_{field} values are
 777 available, the 12th-percentile F_{field} value may be used, because this is approximately the same as the
 778 worst case of four experiments (see EFSA, 2010c for details). When using a rapidly dissipating
 779 fraction to reduce the application rate, the user should ensure that processes such as volatilisation are
 780 not double counted.

781 As mentioned in EFSA (2012a), the exposure assessment scheme has been developed for spray
 782 applications to annual crops under conventional or reduced tillage. It is proposed to apply the current
 783 exposure assessment scheme also to incorporated granules and treatments of small seeds (Section 4.2)
 784 that are uniformly distributed over the surface area of the field. When this option is used, the applicant
 785 should use the option “incorporation in the soil” and provide the appropriate incorporation depth.

786 3.5.3. Substance specific input values

787 To guarantee consistency in the tiered approach, substance specific input values that were used in
 788 Tier 1 should also be used in Tier 2A (see Section 3.2.1). However, the numerical models require
 789 some more substance specific input values. The selection of these additional substance specific input
 790 values should follow recommendations given in FOCUS (2006) and in the generic guidance for Tier 1
 791 FOCUS ground water assessments (Anonymous, 2011). The following additional remarks apply:

- 792 i. As mentioned in EFSA (2012a), the all-time high concentration in pore water in the top
 793 centimetre may occur when this top centimetre is very dry. This is, however, not realistic since
 794 the sorption of pesticide may increase by several orders of magnitude if the soil becomes very

795 dry. A simple approach to describe this effect is to specify a maximum sorption coefficient for
 796 air-dry soil and to assume an exponential increase of the sorption coefficient when the soil is
 797 dryer than wilting point. This approach has been implemented in the PEARL model (see Van
 798 den Berg and Leistra (2004)). Petersen et al. (1995) and Hance (1977) found the sorption
 799 coefficient in air dry soil to be roughly 100 times higher than the sorption coefficient
 800 measured under reference conditions. We therefore recommend using a maximum sorption
 801 coefficient that is 100 times the sorption coefficient measured under reference conditions.

802 ii. For substances whose $DegT50$ or K_{om} depend on soil properties such as pH or clay content, it
 803 is *a priori* unknown which combination is conservative. The reason is that a low K_{om} may lead
 804 to more leaching, which may reduce the concentration in pore water. When Tier 2A is used for
 805 such substances, the applicant should therefore perform a conservatism analysis to
 806 demonstrate which combination is most conservative. Such a conservatism assessment has to
 807 be based on case-by-case analyses (e.g. calculations could be made with contrasting
 808 combinations of extreme values of input parameters).

809 3.5.4. Application of scenario adjustment factors

810 As described in Section 2.3, conservative scenario adjustment factors are needed for Tier 2A.
 811 However, the PECs generated by the numerical models do not include such a factor. For regulatory
 812 submissions, the applicant should therefore multiply the PEC of Tier 2A with the corresponding
 813 scenario adjustment factor listed in Table 5:

$$814 \text{Result}_{Tier2A} = f_S \text{PEC} \quad (8)$$

815 in which Result_{Tier2A} is the final result of the Tier 2A simulation, PEC is the concentration generated by
 816 the numerical models and f_S (-) is the scenario adjustment factor.

817 3.6. Tier 3A assessment using the numerical models

818 Results at Tier 2A refer to the area of annual crops and therefore conservative scenario adjustment
 819 factors as listed in Table 4 are applied. When an assessment is done for a specific CAPRI crop, the
 820 applicant may therefore want to develop crop- and substance dependent scenarios (Tier 3B). The
 821 derivation of such scenarios is, however, laborious and not yet standardised. For substances whose
 822 $DegT50$ and K_{om} do not depend on soil properties, a simple Tier 3A is therefore added to the tiered
 823 assessment scheme (Section 2.1). In this tier, Tier 2A results are simply corrected using crop-specific
 824 and substance-specific scenario adjustment factors. Tier 3A depends on results from Tier 1, Tier 2B
 825 and Tier 2A, so these tiers must be carried out first (Figure 6).

826 The procedure for deriving these adjustment factors is as follows:

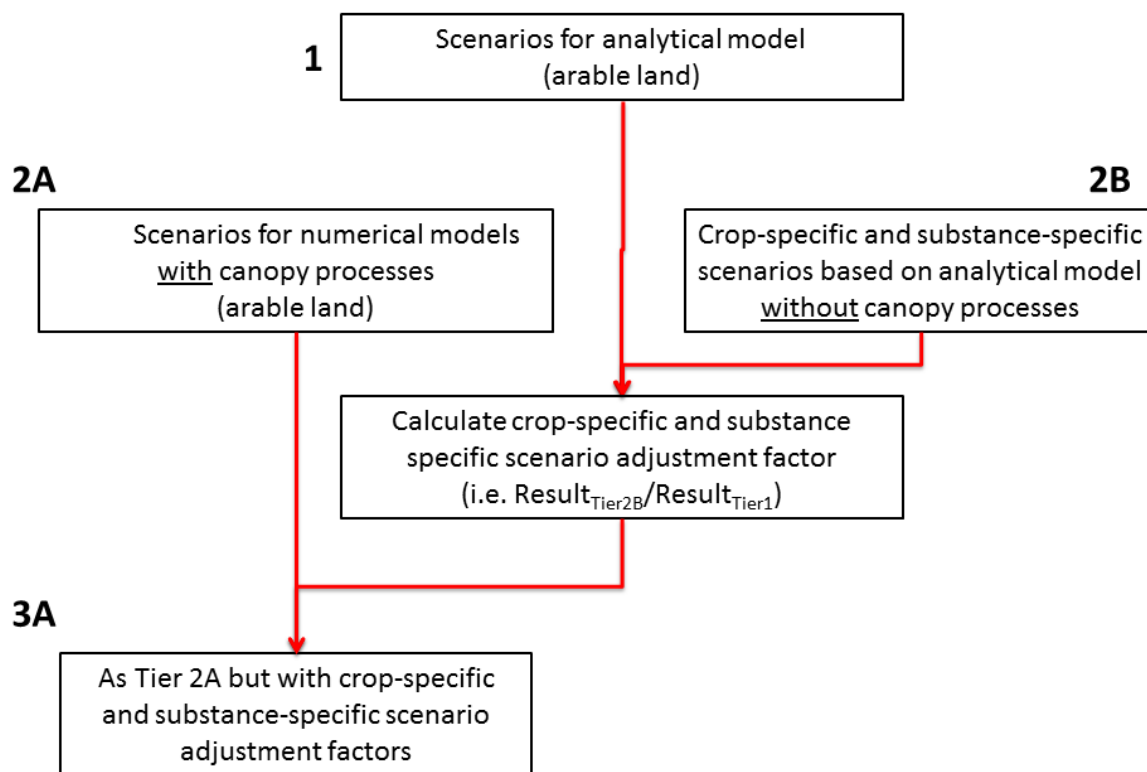
- 827 i. Calculate for the PPP under consideration the PEC of the Tier-1 scenario with the PERSAM
 828 tool and divide this result by the generic scenario adjustment factor as given in Table 5;
- 829 ii. Calculate also the Tier-2B PEC for this crop and this substance with PERSAM (this result
 830 should of course not be divided by the generic scenario adjustment factor);
- 831 iii. The ratio of these two values is the crop- and substance-specific scenario adjustment factor,
 832 which could be used to correct the Tier 2A results.

833 This entire approach can be summarised in the following equation:

$$834 \text{Result}_{Tier3A} = \frac{\text{Result}_{Tier1} / f_S}{\text{Result}_{Tier2B}} \text{Result}_{Tier2A} \quad (9)$$

835 where Result_{Tier1} is the result from the Tier 1 calculation, f_S is the generic scenario adjustment factor as
 836 taken from Table 5, Result_{Tier2B} is the result from Tier 2B, Result_{Tier2A} is the result from Tier 2A and

837 $Result_{Tier3A}$ is the result for the Tier 3A assessment. Results can be all types of concentrations,
838 evaluation depths and time weighted averages.



839
840 **Figure 6:** Procedure for carrying out a Tier 3A assessment. The ratio between the PECs obtained in
841 Tier 2B and Tier 1 are used to obtain a crop-specific and substance-specific scenario adjustment
842 factor. This factor is multiplied by the result from Tier 2A.

843 3.7. Tier 3B assessment using the numerical models

844 Tier 3 offers the possibility of simulating exposure concentrations with numerical models for crop-
845 specific and substance-specific scenarios focusing only on the type of concentration that is required.
846 As a consequence, neither a model adjustment factor nor a scenario adjustment factor is needed in Tier
847 3B.

848 Scenario development at Tier 3B consists of two steps, i.e. (i) selection of the pixel coordinates and
849 properties of the pixel that corresponds to the 95th percentile for the crop and substance under
850 consideration, and (ii) building the actual scenario. These two steps are explained in the following two
851 sections. It should be noted that the text in these two sections are preliminary since the model shells
852 will be changed in the near future to support also exposure assessments at Tier 3B.

853 It is advised to use Tier 3B only for substances whose properties depend on soil properties. For
854 ordinary substances (i.e. substances whose properties do not depend on soil properties), it is advised to
855 use the much simpler procedure at Tier 3A. Should the user decide to use Tier 3B, all steps must be
856 well described and submitted to regulatory authorities.

857 3.7.1. Selection of the Tier 3B scenario

858 The scenario can be selected by running Tier 3 in the PERSAM tool (notice that the current version of
859 PERSAM does not make a distinction between Tier 3A and Tier 3B). Since not all pixel properties are
860 available in the PERSAM tool, the user should only take the geographical coordinates (X and Y) from
861 the PERSAM tool. For building the scenario, the following parameters are needed:

- 862 i. The soil textural class;
 863 ii. The organic matter content (f_{om}) of the top soil (kg/kg);
 864 iii. The bulk density (ρ) of the top soil (kg dm⁻³);
 865 iv. The pH of the topsoil.
 866 v. The FOCUS climatic zone;
 867 vi. Mean monthly temperatures (°C).

868 An ASCII file has been created from which all relevant parameters can be obtained. This file is called
 869 “PERSAMDatav11.dat” and can be downloaded <http://eusoils.jrc.ec.europa.eu/library/data/efsa/>. The
 870 easiest procedure to finding the properties of the pixel is to concatenate the X-Y coordinates obtained
 871 by the PERSAM tool into one word. The resulting XY-coordinate should have exactly 14 digits (e.g.
 872 X=5679000 and Y=1452000 results in XY=56790001452000). Enter this number in the search box of
 873 an appropriate ASCII editor, and the corresponding pixel and its properties will be listed.

874 3.7.2. Building the Tier 3B scenario

875 The current model shells do not allow running a Tier-3B assessment, so the command line versions of
 876 PEARL and PELMO should be used for this purpose. Running Tier-3B assessments is therefore
 877 currently only possible for experienced users. However, since many building blocks of the input files
 878 are available in the current databases, the user doesn't need to start from scratch. The following
 879 procedure could be used to create an appropriate input file:

- 880 i. Use the model shell to create a template Tier-2A ASCII input file. This can best be done for
 881 the crop and scenario under consideration;
- 882 ii. The next step is to change the soil profile into one of the six soil profiles listed in Table 3 of
 883 EFSA (2010a). The soil profile is to be based on the soil textural class, which is obtained from
 884 the scenario selection procedure (Section 3.7.1). Changing the soil profile should be done in
 885 an ASCII editor (see the manual of the respective models for exact instructions);
- 886 iii. The user now has to change two soil parameters, i.e. the organic matter content and the pH.
 887 The other soil parameters should not be changed since these are already available in the
 888 selected soil profile (in the case of PEARL this includes bulk density, since this is simulated
 889 with the built-in PEARL pedotransfer function (Eqn. 2 in EFSA, 2010a):
- 890 a. The pH is obtained from the scenario selection procedure above. Since only pH of the
 891 topsoil is available, this pH value should be used for the other soil layers as well.
- 892 b. The soil profiles listed in EFSA (2010a) contain the relative organic matter content
 893 (i.e. $f_{z,om}$ in Table 3 of EFSA, 2010a). So the following step is to convert these relative
 894 organic matter contents into the organic matter content of the scenario pixel. This
 895 should be done by multiplying the relative organic matter content by the organic
 896 matter content of the topsoil as derived from the scenario selection procedure (see
 897 Eqn. 1 in EFSA, 2010a).
- 898 iv. The FOCUS zone of the Tier 2A scenario may differ from the FOCUS zone of the selected
 899 Tier 3B scenario. So the next step is to select the crop corresponding to the appropriate
 900 FOCUS zone (i.e. the FOCUS zone given by the scenario selection procedure). The easiest
 901 way to obtain the appropriate crop section is to run the latest FOCUS groundwater version of
 902 the model shell and paste this so-obtained crop section into the Tier-3B scenario. Since
 903 irrigation parameters are included in the crop section, selecting a different crop will also
 904 automatically select the appropriate irrigation option.
- 905 v. The final step is to create the weather files for the selected pixel. As described in EFSA
 906 (2012a), this should be done by scaling the daily values of the minimum and maximum air
 907 temperature of the corresponding FOCUS weather series to the arithmetic mean monthly
 908 temperature of the selected Tier 3B scenario:

$$909 T_{day,pixel} = T_{day,FOCUS} + T_{month,pixel} - T_{month,FOCUS} \quad (10)$$

910 where $T_{day,FOCUS}$ is the daily temperature in the FOCUS scenario, $T_{month,pixel}$ is the mean

911 monthly temperature obtained from the scenario selection procedure and $T_{month,FOCUS}$ is the
 912 mean monthly temperature of the FOCUS scenario as listed in Appendix IV of EFSA (2012a).
 913 Please note that precipitation should not be changed in this step.

914 **3.7.3. Model inputs and outputs**

915 To guarantee consistency in the tiered approach, substance specific input values that were used in
 916 Tier 2 should also be used in Tier 3B.

917 Since at Tier 3B neither a model adjustment factor nor a scenario adjustment factor is needed, the
 918 PECs generated by the numerical model do not need further processing.

919 **4. EXPOSURE ASSESSMENT IN SOIL FOR ROW TREATMENTS AND GRANULES**

920 As described in Section 1.3, it is assumed that for applications of granular products (to the soil surface
 921 or incorporated), the exposure assessment methodology can be used as well. With small modifications,
 922 the procedure should also cover reasonably well row treatments. This chapter provides calculation
 923 procedures for row treatments (Section 4.1) and granules (Section 4.2). It should be noted, however,
 924 that user-friendly software to perform the calculations in this chapter is not yet available.

925 **4.1. Calculation procedure for applications in rows**

926 For row treatments, the ecotoxicologically relevant type of concentration (ERC) has so far not been
 927 defined. There are at least three options: (i) the concentrations in the soil below the fraction of the soil
 928 surface that is treated (so below the rows), (ii) the concentrations in the soil averaged over the whole
 929 soil surface, (iii) both the concentrations in the soil below the rows and the concentrations in the soil
 930 below the untreated part of the soil surface. The exposure assessment in Chapter 3 will provide
 931 appropriate concentrations for option (ii) provided that the dosage used in the exposure assessment is
 932 defined as mass of active ingredient applied per surface area of the cropped field. The methodology is
 933 expected to reasonably well cover the background concentration for row treatments because this is
 934 calculated as a plateau after multi-year use assuming annual soil rotation and because the location of
 935 the rows is likely to change from year to year. However, the peak concentration will usually occur
 936 immediately or shortly after an application. So for options (i) and (iii) additional calculation
 937 procedures were developed that are explained in Section 4.1.2. As mentioned above, user-friendly
 938 software to perform these calculations is not yet available. For this reason, a simple conservative
 939 approach has been added (Section 4.1.1), which may be used until the user-friendly software has been
 940 updated to reflect the changes in Section 4.1.2.

941 ***Crop interception***

942 Crop interception should not be included in calculations for row treatments unless the spray is targeted
 943 just on the crop canopy. In just this situation the standard table values for the fraction of the dose
 944 reaching the soil (Table 7) may be used as a conservative estimate.

945 ***Scenario and model adjustment factors***

946 The PECs derived in this chapter should be multiplied with appropriate model adjustment factors (Tier
 947 1 and Tier 2B/C) and/or scenario adjustment factors (Tier 1). The values of these factors are listed in
 948 Tables 5 and 6.

949 **4.1.1. Simple conservative assessment**

950 As mentioned above, user friendly software to perform the calculations in this chapter is not yet
 951 available. The following calculation procedure can, however, easily be performed based on the results
 952 obtained in Chapter 3:

$$953 \quad PEC_{in_rows} = PEC / f_{rows} \quad (11)$$

954 where PEC is the concentration in soil averaged over the whole soil surface, PEC_{in_rows} is the
 955 concentration in soil below the fraction of the soil surface that is treated and f_{rows} is the fraction of the
 956 soil surface that is treated. The underlying assumption of this simple calculation procedure is that the
 957 position of the rows does not change with time, which is a conservative assumption for both the
 958 concentration in the rows and the concentration between the rows.

959 It is advised to base the exposure assessment for row treatments on Eqn. 11 until user friendly
 960 software is available; the calculation procedures described hereafter should only be performed when
 961 the margin of safety is small.

962 **4.1.2. More realistic exposure assessment**

963 *[GUIDANCE TO THE READER: section 4.1.2. will be moved to an appendix, since this is scientific*
 964 *background information on a new development and not yet operational guidance]*

965 **Concentration between the rows**

966 We describe here the procedure for calculations for spray applications in rows based on the simple
 967 analytical model. Let us assume that A is the annual application rate (kg ha^{-1}) defined as the mass of
 968 substance applied per surface area of the rows and that f_{row} is the surface area of rows divided by the
 969 surface area of the cropped field (so f_{row} is the fraction of the surface area of the field that is occupied
 970 by the rows). It is assumed that the rows are at different locations in the different application years and
 971 that this leads in the longer term to a plateau concentration that is constant across the surface area of
 972 the field.

973 The simple analytical model considers the situation of an application after a steady state plateau
 974 concentration has been reached. Based on the foregoing assumptions it seems justifiable to assume
 975 that in the area between the rows the maximum concentration is equal to this steady state plateau
 976 concentration. First the concentration in total soil is considered and thereafter the concentration in pore
 977 water. Based on EFSA (2012a) the plateau concentration in total soil ($C_{T,plateau}$ mg kg^{-1}), can for parent
 978 substances be calculated as:

$$979 \quad C_{T,between_rows} = \frac{f_{row} A}{\rho z_{til}} \frac{X}{1-X} \quad (12)$$

980 where ρ is the dry soil bulk density (kg L^{-1}), z_{til} (dm)⁵ is the plough depth (fixed at 2 dm) and X is
 981 defined as:

$$982 \quad X = e^{-t_{cycle} f_T k_{ref}} \quad (13)$$

983 where t_{cycle} is the time between applications (365, 730 or 1095 d), f_T is a factor describing the effect of
 984 soil temperature on the degradation rate coefficient, and k_{ref} (d^{-1}) is the first-order degradation rate
 985 coefficient at a reference temperature T_{ref} (i.e. 20 °C) and the soil moisture content at field capacity.
 986 The coefficient k_{ref} is calculated from the degradation half-life by:

$$987 \quad k_{ref} = \frac{\ln(2)}{DegT50} \quad (14)$$

988 where $DegT50$ (d) is the degradation half-life in soil at the reference temperature and at field capacity.
 989 The temperature factor f_T is calculated as:

⁵ The unit 'cm' is used usually for depths in this guidance because this is more common than 'dm'; here 'dm' is used as the unit for z_{til} and similarly for z_{eco} in Eqn 16 to ensure consistency of units within Eqn. 12 and 16 (1 dm = 10 cm).

990
$$f_T = \exp\left(\frac{-E}{R} \left[\frac{1}{(T_{Arr} + 273.15)} - \frac{1}{(T_{ref} + 273.15)} \right]\right)$$
 (15)

991 where E is the Arrhenius activation energy (65.4 kJ mol⁻¹), R is the gas constant (0.008314 kJ mol⁻¹
 992 K⁻¹), T_{Arr} is the so-called Arrhenius soil temperature (°C) of the scenario, and T_{ref} is the temperature at
 993 reference conditions (20 °C).

994 **Concentration in the rows**

995 The maximum concentration in the rows will be highest after the last application and is the sum of the
 996 plateau concentration and the concentration generated by this last application:

997
$$C_{T, in_rows} = \left(\frac{A}{\rho z_{eco}} + \frac{f_{row} A}{\rho z_{fil}} \frac{X}{1-X} \right)$$
 (16)

998 where z_{eco} (dm) is the ecotoxicological averaging depth (i.e. 1, 2.5, 5 or 20 cm as specified by EFSA,
 999 2012a).

1000 **Concentration in pore water**

1001 The maximum concentration in the pore water (liquid phase) is calculated from the maximum
 1002 concentrations in total soil (Eqn 12 or 16) assuming a linear sorption isotherm:

1003
$$C_L = \frac{C_T}{\theta / \rho + f_{om} K_{om}}$$
 (17)

1004 where C_L (mg L⁻¹) is the maximum concentration in the liquid phase, θ (m³ m⁻³) is the volume fraction
 1005 of liquid in soil at field capacity, f_{om} (kg kg⁻¹) is the mass fraction of organic matter, and K_{om} (L kg⁻¹) is
 1006 the coefficient for sorption on organic matter. The values for the scenario parameters ρ , θ , f_{om} and
 1007 T_{Arr} can be taken from Tables 1 and 2.

1008 **Time weighted averages**

1009 The model includes also calculation of TWA concentrations. A TWA concentration is defined as the
 1010 concentration that is averaged over a certain time period since the application time:

1011
$$C_{T, TWA} = \frac{C_T}{t_{avg} f_T k_{ref}} \left[1 - \exp(-f_T k_{ref} t_{avg}) \right]$$
 (18)

1012 The TWA concentration in the liquid phase, $C_{L, TWA}$, is calculated from an equation akin to Eqn 18 but
 1013 with C_L instead of C_T .

1014 **Soil metabolites**

1015 For soil metabolites, the calculation procedure is the same as described above with one exception: in
 1016 Eqn. 12 and 16 the annual application rate A is replaced by the equivalent annual application rate of
 1017 the metabolite (and of course using the $DegT50$ and K_{om} of the metabolite instead of the parent). For a
 1018 soil metabolite formed from the parent, this equivalent rate is given by:

1019
$$A_{met, t} = F_{f, t-p} \frac{M_{met, t}}{M_{parent}} A$$
 (19)

1020 where $F_{f,1-p}$ (-) is the formation fraction of this metabolite (i.e. the stoichiometric coefficient of the
 1021 formation of this metabolite from the parent substance), $M_{met,1}$ is the molar mass of this metabolite (g
 1022 mol⁻¹) and M_{parent} is the molar mass of the parent substance (g mol⁻¹).

1023 For a second soil metabolite formed from this first soil metabolite, the equivalent application rate is
 1024 given by:

$$1025 \quad A_{met,2} = F_{f,1-p} F_{f,2-1} \frac{M_{met,2}}{M_{parent}} A \quad (20)$$

1026 where $F_{f,2-1}$ is the formation fraction (-) of this second metabolite as formed from the first metabolite
 1027 and $M_{met,2}$ is the molar mass of this second metabolite (g mol⁻¹).

1028 4.2. Calculations for granules that are incorporated and seed treatments for small 1029 seeds

1030 The procedure for calculations with the analytical model for incorporated granules and treated small
 1031 seeds (< 0.5cm)⁶ applies only to situations when the material is distributed uniformly under the whole
 1032 surface area of the field, so not when there may be uneven crop row spacing and the active substance
 1033 will have higher concentrations within the crop row. The procedure also only applies to tillage systems
 1034 with a level soil surface (so not to systems with ridges and furrows).

1035 It is assumed that the incorporation depth of the granules or treated seeds is not deeper than 20 cm (i.e.
 1036 the depth of annual ploughing assumed in the calculations with the simple analytical model). The
 1037 definition of the ecotoxicologically relevant type of concentrations in this guidance is based on the
 1038 concept that concentrations are averaged over the ecotoxicological averaging depth, z_{eco} (ranging
 1039 between 1 and 20 cm). The consequence is that the procedure for first-tier calculations for
 1040 incorporated granules and treated small seeds is identical to that for spray applications unless the
 1041 incorporation depth is deeper than z_{eco} . So if the incorporation depth is greater than 20 cm (or less than
 1042 1 cm) the calculations are to be carried out manually according to the equations below. The increase of
 1043 the concentration resulting from the last application has to be based on averaging over the
 1044 incorporation depth instead of averaging over z_{eco} . This results in the following calculation procedure
 1045 for the concentration in total soil:

$$1046 \quad z_{eco} < z_{inc} \quad C_T = \left(\frac{A}{\rho z_{inc}} + \frac{A}{\rho z_{til}} \frac{X}{1-X} \right) \quad (21a)$$

$$1047 \quad z_{eco} > z_{inc} \quad C_T = \left(\frac{A}{\rho z_{eco}} + \frac{A}{\rho z_{til}} \frac{X}{1-X} \right) \quad (21b)$$

1048 where z_{inc} is the incorporation depth of the granules or small seed (dm) and A is the application rate of
 1049 the active substance in the granules or on the seed (kg/ha). The concentration in the pore water can be
 1050 calculated with Eqn 17 based on C_T from Eqn 21. The values for the scenario parameters ρ , θ , f_{om} and
 1051 T_{Arr} can be taken from Tables 1 and 2.

1052 5. DOCUMENTATION TO BE PROVIDED

1053 This section briefly summarises the documentation requirements. The assumption is that the notifier
 1054 uses one of the standardised tools as described in this guidance document (i.e. PERSAM for lower tier
 1055 assessments and PEARL or PELMO for higher tier assessments). If this is not the case, the notifier

⁶ Definition of small seeds is taken from draft SANCO guidance on seed treatments. For this EFSA guidance it is proposed to handle maize seeds and pelleted seeds as small seeds.

1056 should demonstrate that the scenarios used in the tiered approach are adequately parameterised and
1057 that the alternative models provide comparable results as the existing software tools (see also EFSA
1058 PPR Panel, 2014) for guidelines on model development and model documentation).

1059 The substance properties and the application regime (i.e. application rate, type of application,
1060 frequency of application and fraction of the dose reaching the soil) determine the outcome of a
1061 regulatory assessment to a large extent and should therefore be well documented. Whenever possible,
1062 harmonised approaches as described in this guidance should be used. Justifications should be provided
1063 for using other approaches, assumptions, or inputs than those recommended in this guidance.

1064 As described in Chapter 2, the selected crop has a large effect on the outcome of the regulatory
1065 assessment. A justification for the selected crop should therefore be provided with specific attention to
1066 how the crop links to the area of the intended use of the PPP. In case the crop relevant for risk
1067 assessment is not one of the CAPRI crops (in PERSAM), a surrogate crop needs to be selected. The
1068 selection of a crop should in such cases be supported by a justification. If the notifier imports his own
1069 crop map, its suitability and reliability should be demonstrated. This is also true for the FOCUS crop
1070 defined in the numerical models.

1071 As described in EFSA PPR Panel (2014), sufficient information should be provided so that the
1072 calculations can be reproduced. In practice this means that the following information must be provided
1073 to the regulator:

- 1074 i. The versions of the models that have been used in the regulatory assessment. If non-standard
1075 software tools have been used, a description of these models including a justification of their
1076 applicability should be provided (see first paragraph of this chapter);
- 1077 ii. All input files and reports generated by the PERSAM (Tier 1, 2B and 2C) or the numerical
1078 models (Tier 2A and 3B);
- 1079 iii. A document describing all manual calculations including (i) the fraction of the dose in the
1080 case of multiple applications at Tier 2C, (ii) the scenario adjustment factors at Tier 2A, and
1081 (iii) the substance-specific and scenario-specific scenario adjustment factors at Tier 3A.
- 1082 iv. When applicable – a comprehensive description of all steps of the development of Tier 3B
1083 scenarios. This includes both the scenario selection with PERSAM and the parameterisation of
1084 the numerical models.

1085 **6. EXPOSURE ASSESSMENT IN SOIL FOR PERMANENT CROPS**

1086 The exposure assessment in soil for permanent crops is currently under development.

1087 **7. EXPOSURE ASSESSMENT IN SOIL FOR CROPS GROWN ON RIDGES**

1088 Exposure assessment in soil for crops grown on ridges such as potatoes is currently under
1089 development.

1090

1091 **RECOMMENDATIONS**

- 1092 i. The current guidance document is restricted to annual crops under conventional and reduced
1093 tillage (excluding crops grown on ridges). Methodologies for performing exposure
1094 assessments for permanent crops, crops grown on ridges and for no-tillage systems are
1095 currently being developed. It is recommended to develop guidance for these cropping systems
1096 as soon as these methodologies have become available.
- 1097 ii. This guidance has changed the tiered assessment scheme given in EFSA (2012a) with the goal
1098 to simplify the exposure assessment for regulatory purposes. Many of these changes could not
1099 yet be included in the user-friendly software tool PERSAM. It is recommended to include
1100 these changes in an update of PERSAM as soon as possible. This includes:
- 1101 a. Exposure assessments for applications of granular products and row treatments;
 - 1102 b. Calculation of the fraction of the dose reaching the soil in the case of multiple
1103 applications;
 - 1104 c. Implementation of well-defined crop lists based on Appendix D of this guidance
1105 document;
 - 1106 d. Generation of an output file with the purpose to ease the automated generation of
1107 crop-specific and substance-specific scenarios at Tier 3B;
 - 1108 e. Possibility to import crop maps for higher tier assessment.
- 1109 iii. The procedure for generating the crop-specific and substance-specific scenarios can be
1110 automated based on the procedure described in this guidance document. It is therefore
1111 recommended to implement this procedure in the numerical models.
- 1112 iv. The calculation of the rapidly dissipating fraction requires some manual calculations,
1113 particularly when crop interception takes places. It is recommended to develop an Excel sheet
1114 with the purpose to ease its use for regulatory purposes.
- 1115 v. For regulatory purposes, it is needed that applicants use commonly agreed versions of the
1116 software tools. It is therefore recommended to develop a procedure for version control and
1117 updating the software tools, including PERSAM, PEARL and PELMO.

1118
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- 1203

1204 GLOSSARY AND ABBREVIATIONS

1205

BBCH code	Biologische Bundesanstalt, Bundesortenamt und Chemische Industrie code: decimal code ranging from 0 to 99 to characterise the crop development stage (Meier, 2001).
CAPRI	Common Agricultural Policy Regionalised Impact modelling system. An economic model developed to support EU-policy.
CLC	Scenario for the concentration in pore water for the central zone
CLN	Scenario for the concentration in pore water for the northern zone
CLS	Scenario for the concentration in pore water for the southern zone
CTC	Scenario for the total concentration in the central zone
CTN	Scenario for the total concentration in the northern zone
CTS	Scenario for the total concentration in the southern zone
DFOP	Double first-order in parallel.
EFSA	European Food Safety Authority
ERC	Ecological Relevant Concentration.
F_{field}	Rapidly dissipating fraction that is not related to degradation in the soil matrix (EFSA, 2010c).
FOCUS	Forum for co-ordination of pesticide fate models and their use
$F_{soil,max}$	Fraction of the dose that reaches the soil. The suffix <i>max</i> was added, because EFSA (2012a) suggested taking the maximum value from a time series of 20, 40 or 60 years. Based on additional calculations, the current guidance document suggests taking the average value and therefore in this guidance document $F_{soil,max}$ is replaced by f_{soil} .
f_{soil}	Fraction of the dose that reaches the soil.
GeoPEARL	General name for spatially distributed version of the PEARL model
HS	Hockey stick
Model adjustment factor (f_M)	A factor that accounts for differences between the simple analytical model used at lower tiers and the more realistic numerical models used at higher tiers. The model adjustment factor should ensure that lower tiers are more conservative than higher tiers.
PEARL	Pesticide Emission At Regional and Local Scales. A pesticide fate model intended for higher tier exposure and leaching assessments.

PEC	Predicted Environmental Concentration
PELMO	Pesticide Leaching Model. A pesticide fate model intended for higher tier exposure and leaching assessments.
PERSAM	Persistence in Soil Analytical Model. Software tool for performing lower tier soil exposure assessments.
PPR	Plant protection products and their residues
PPP	Plant Protection Product
Scenario adjustment factor (f_s)	A factor that accounts for the effect of using in lower tiers the total area of annual crops instead of the area of intended use. The scenario adjustment factor should ensure that lower tiers are more conservative than higher tiers.
TWA	Time Weighted Average

1206

1207

DRAFT

1208 **APPENDICES**

1209 **APPENDIX A APPLICABILITY OF THE EXPOSURE ASSESSMENT SCHEME FOR SOIL METABOLITES**

1210 **A1 Introduction**

1211 The guidance opinion (EFSA, 2012a, p. 64) indicated that the exposure assessment for soil metabolites
1212 was not based on the specified exposure-assessment goals because the scenario selection procedure
1213 (based on the simple analytical model) was developed only for parent substances. In this appendix it is
1214 explored under which circumstances parts of the proposed exposure assessment methodology can
1215 nevertheless be used to assess the exposure of soil metabolites.

1216 **A2 Applicability of the scenario-selection procedure for Tiers 1 and 2B/C**

1217 Let us first consider Tier 2B/C. In this tier the 95th spatial percentile of the exposure concentration of
1218 soil metabolites can be calculated with the simple analytical model based on the conservative
1219 assumption that each metabolite is applied at the application time of the parent at a dose that is
1220 corrected for the kinetic formation fraction and the molar mass of the metabolite (see EFSA, 2012a, p.
1221 24). A correct way of calculating this 95th spatial percentile would be to derive it from calculations for
1222 all pixels in the area of use with one of the numerical models, i.e. Tier 4 of the exposure assessment as
1223 proposed by EFSA (2012a). This is impossible because the required spatially distributed modelling
1224 tools are as yet not available; see EFSA, 2012a. However, let us assume that these calculations with
1225 such a tool would be available. Let us compare for a single pixel the metabolite concentration
1226 calculated with the numerical model and that calculated with Tier 2B/C. For each such a pixel the
1227 concentration calculated with Tier 2B/C is very likely to be lower than that calculated with the
1228 numerical model because (i) a model adjustment factor is used in Tier 2B/C to account for differences
1229 between the numerical and analytical models, (ii) the calculation for the metabolite in the simple
1230 model is based on the conservative assumption that its total amount formed is applied at the
1231 application time of the parent, (iii) metabolites may also leach from the top soil in the numerical model
1232 whereas this is impossible in the simple model. If for each pixel Tier 2B/C generates higher
1233 concentrations for metabolites than the numerical model, the 95th spatial percentile as derived from
1234 Tier 2B/C has to be higher than the 95th spatial percentile as calculated with the numerical model. So
1235 Tier 2B/C is likely to give conservative estimates for concentrations of soil metabolites.

1236 The tiered approach ensures that Tier 1 generates higher concentrations than Tier 2B/C, so if Tier
1237 2B/C is conservative for soil metabolites, this has also to be the case for Tier 1. So it is concluded that
1238 both Tiers 1 and 2B/C can be used to assess the exposure of soil metabolites with the simple model.

1239 **A3 Applicability of the scenario-selection procedure for Tiers 2A and 3**

1240
1241 **A3.1 Introduction**

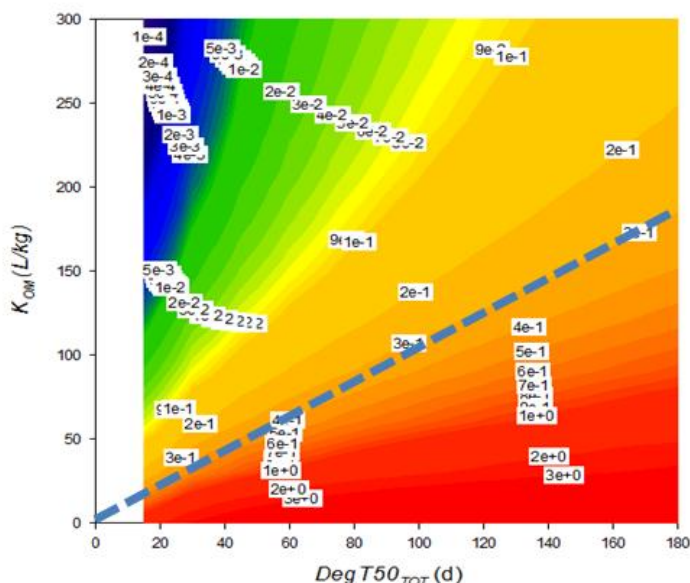
1242 The above considerations do not apply to Tiers 2A and 3 because these tiers require that the scenario
1243 selection procedure selects a pixel that corresponds to the 95th spatial percentile. There is no such
1244 guarantee that the ranking of concentrations based on the simple model is correct for metabolites
1245 because this ranking has not been tested for metabolites. Nevertheless there may be circumstances in
1246 which this ranking based on the simple models is correct also for metabolites. The simple model is
1247 based on two assumptions that may not be valid for metabolites: (i) there is no significant leaching
1248 from the top 20 cm, (ii) the temperature-dependence of the plateau concentration follows the
1249 Arrhenius equation. These aspects are discussed in more detail in the following sections.

1250 **A3.2 Restrictions resulting from the requirement of no significant leaching from the top 20 cm**

1251 The basis of the use of the simple analytical model for the scenario selection is that this model gives
1252 the same ranking of soil exposure concentrations for the 1×1 km² grid cells of the EU-wide databases
1253 as a more realistic numerical model (see EFSA, 2012a, p. 29 for further explanation). For parent
1254 substances this was checked by performing calculations for 1051 scenarios with both the simple

1255 analytical model and the PEARL model for three substances ($DegT50 = 15$ d and $K_{om} = 15$ L kg⁻¹,
 1256 $DegT50 = 50$ d and $K_{om} = 200$ L kg⁻¹, $DegT50 = 200$ d and $K_{om} = 1000$ L kg⁻¹). These calculations
 1257 showed good correspondence between the ranking by the two models both for the concentration in
 1258 total soil and the concentration in pore water for peak concentrations and TWA concentrations for
 1259 time windows up to 56 days (EFSA, 2012a, p. 31). This ranking can be expected to be good only for
 1260 substances that do not leach significantly from the top 20 cm because the simple analytical model
 1261 assumes no leaching from this layer. This restriction was considered not to be a problem for parent
 1262 substances because it is unlikely that these substances leach significantly below 20 cm in view of the
 1263 groundwater protection goal of the EU regulatory process. Therefore the ranking was tested also only
 1264 for substances with limited leaching from the top 20 cm. So use of the simple analytical model is *a*
 1265 *priori* unlikely to be acceptable for soil metabolites that show significant leaching below 20 cm depth
 1266 for a considerable fraction of these grid cells of the EU-wide databases; the same restriction applies of
 1267 course to any precursor of a metabolite. As described before it is unlikely that parent substances show
 1268 significant leaching below 20 cm depth but a soil metabolite may also be formed from another soil
 1269 metabolite.

1270 It would be useful to have a criterion for ‘no significant leaching’. This was assessed based on
 1271 calculations for the FOCUS groundwater scenario Okehampton (FOCUS, 2009). This is one of the EU
 1272 scenarios with the highest leaching concentrations so this should be suitable for assessment of a
 1273 criterion for the assessment of significant leaching. Calculations were made for winter cereals and
 1274 application of 1 kg/ha just before emergence (17 October at Okehampton). Calculations were made for
 1275 a range of K_{om} - $DegT50$ combinations using default values for all other parameters assuming annual
 1276 applications. This gives a 20-year evaluation period. Both total leaching from the top 20 cm (in kg/ha)
 1277 and the total transformation in this top 20 cm over these 20 years (in kg/ha) were calculated. The
 1278 contour diagram below shows the quotient of total leaching divided by total transformation.



1279
 1280 **Figure A1:** The quotient of total leaching (kg/ha) from the top 20 cm of soil divided by total
 1281 transformation (kg/ha) in the top 20 cm of soil over a 20-year simulation period as calculated for the
 1282 FOCUS groundwater scenario Okehampton for winter cereals and annual application of 1 kg/ha at 1
 1283 day before emergence. The dashed line is the 1:1 line, i.e. $K_{om} = DegT50$.

1284 A3.3 Temperature-dependence of peak concentrations of soil metabolites in soil

1285 1286 A3.3.1 Introduction

1287 Another complication of the use of the simple analytical model for soil metabolites is that this model
 1288 calculates a plateau concentration in soil for parent substances based on first-order degradation.
 1289 However, the plateau concentration of soil metabolites is the result of a combination of first-order

1290 formation and degradation. The simple analytical model is based on the Arrhenius equation for the
 1291 description of the temperature-dependency of the plateau concentration. This temperature-dependency
 1292 is an important element of the ranking of the scenarios. Therefore the simple analytical model may not
 1293 be suitable for the scenario selection of soil metabolites if the temperature-dependency of the peak
 1294 concentration of soil metabolites in the numerical models would differ significantly from the
 1295 temperature-dependency of peak concentrations of parent substances in these models.

1296 There are qualitatively two possible cases for soil metabolites: (i) their degradation is so slow that a
 1297 plateau develops (at a time scale of many years) as a result of repeated applications, and (ii) the
 1298 degradation is so fast that the concentration of the metabolite has decreased again considerably before
 1299 the first application in the next year (or in later years) takes place. Both cases are considered below.

1300 **A3.3.2 Assessment of temperature dependency of the plateau value of an accumulating soil** 1301 **metabolite**

1302 The simple analytical model is used as a starting point for the assessment of the temperature
 1303 dependency of the plateau value of an accumulating soil metabolite. The simple analytical model
 1304 calculates the plateau level of a parent substance based on the analytical solution of a single
 1305 application and by summing up the solution for all the applications via the sum of an infinite
 1306 geometric series (EFSA, 2010, p. 23). This summing up is impossible for a soil metabolite because the
 1307 analytical solution of a single application for a metabolite is too complex an equation. Therefore a
 1308 more simplified approach is used: it is assumed that there is a continuous application to the soil
 1309 surface which mimics the single application as good as possible. So let us assume that in reality there
 1310 is an application at a rate A (mg dm^{-2}) which takes place at an time interval t_{cycle} (d). Then the
 1311 corresponding continuous application rate equals A / t_{cycle} . Let us consider a soil layer of z_{til} in which
 1312 the substance is perfectly mixed. The rate of increase of the concentration in this layer, α ($\text{mg kg}^{-1} \text{d}^{-1}$),
 1313 is then defined as:

$$1314 \quad \alpha \equiv \frac{A}{\rho z_{\text{til}} t_{\text{cycle}}} \quad (\text{A1})$$

1315 So for such a continuous application rate the rate equation for the parent substance reads:

$$1316 \quad \frac{d C_{\text{parent}}}{dt} = \alpha - k_{\text{parent}} C_{\text{parent}} \quad (\text{A2})$$

1317 where C_{parent} (mg kg^{-1}) is the concentration of the parent in total soil, t is time (d), and k_{parent} is the
 1318 degradation rate coefficient of the parent in soil (d^{-1}). This gives the steady-state solution:

$$1319 \quad C_{\text{parent}} = \frac{\alpha}{k_{\text{parent}}} = \frac{A}{\rho z_{\text{til}} t_{\text{cycle}} k_{\text{parent}}} \quad (\text{A3})$$

1320 Please note that this equation is only valid for relatively small values of t_{cycle} because it is assumed that
 1321 the application rate is continuous.

1322 Eqn A3 can be compared with the steady state solution (so for the plateau concentration) of the simple
 1323 analytical model as described by EFSA (2012, p. 23) which can be rewritten as:

$$1324 \quad C_{\text{parent}} = \frac{A}{\rho z_{\text{til}}} \frac{\exp(-t_{\text{cycle}} k_{\text{parent}})}{1 - \exp(-t_{\text{cycle}} k_{\text{parent}})} \quad (\text{A4})$$

1325 It can be shown mathematically that Eqn A4 reduces to Eqn A3 if $t_{cycle} k_{parent}$ goes to zero (which
 1326 mimics a continuous application rate).

1327 The rate equation for the metabolite is:

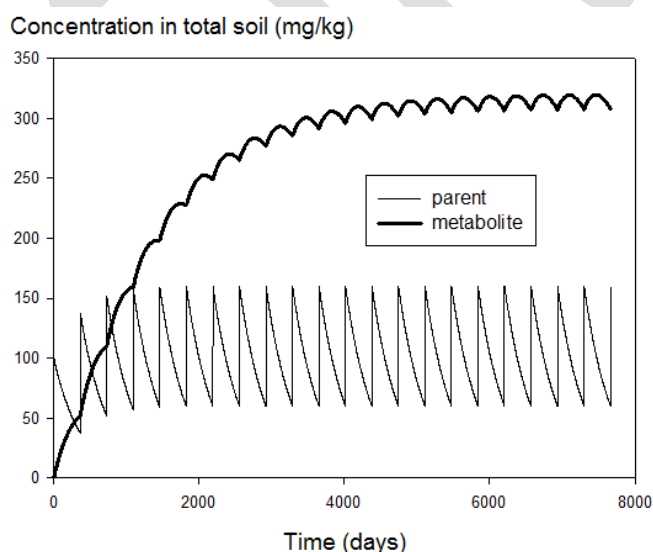
1328
$$\frac{d C_{metabolite}}{dt} = +F_f \frac{M_{metabolite}}{M_{parent}} k_{parent} C_{parent} - k_{metabolite} C_{metabolite}$$
 (A5)

1329 where $C_{metabolite}$ (mg kg⁻¹) is the concentration of the metabolite in total soil, F_f (-) is the formation
 1330 fraction of the metabolite (i.e. the stoichiometric coefficient of the formation of this metabolite from
 1331 the parent substance), $M_{metabolite}$ is the molar mass of the metabolite (g mol⁻¹), M_{parent} is the molar mass
 1332 of the parent substance, and $k_{metabolite}$ is the degradation rate coefficient of the metabolite. The steady-
 1333 state solution can be obtained by requiring that $d C_{metabolite} / d t$ is zero. Combination with Eqn A3 gives
 1334 then:

1335
$$C_{metabolite} = +F_f \frac{M_{metabolite}}{M_{parent}} \frac{\alpha}{k_{metabolite}}$$
 (A6)

1336 So k_{parent} has vanished from Eqn A6; the consequence is that the plateau value of the metabolite does
 1337 not depend on the rate of formation of the metabolite. Comparison of Eqns A3 and A6 shows that the
 1338 plateau concentrations of parent and metabolite are both inversely proportional to their degradation
 1339 rate coefficient, so not only qualitatively but also quantitatively the temperature dependence of their
 1340 plateau values is expected to be the same. So the conclusion is that for accumulating soil metabolites,
 1341 there are no reasons to assume that the temperature-dependency of the transformation rate in the
 1342 simple model will lead to inappropriate ranking of scenarios.

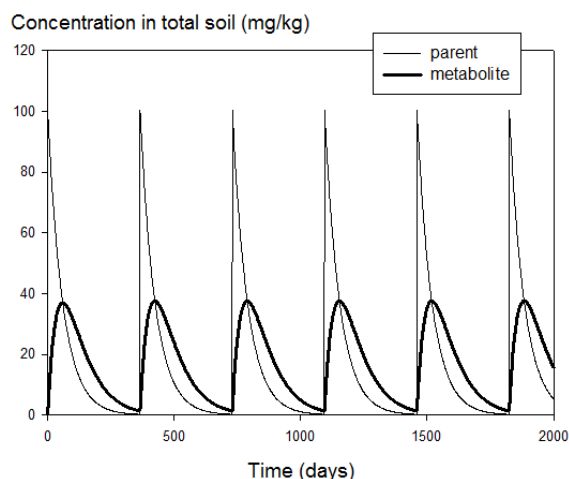
1343 The prediction based on Eqn A6 was compared to a numerical solution of the rate equations for parent
 1344 and metabolite assuming an annual application (so Eqn A2 but without α combined with Eqn A5). The
 1345 rate equations were integrated with Euler's rectangular method and the time step was 1 day. A
 1346 metabolite was considered with a half-life of 800 d leading to clear accumulation (see Figure A2). Eqn
 1347 A6 predicted in this case a plateau concentration for the metabolite of $(100/365) \times (800/\ln(2)) = 316$
 1348 mg/kg which is quite close to the numerical result.



1349
 1350 **Figure A2:** Numerical solution of the simple analytical model for a parent and a metabolite for an
 1351 annual dose corresponding to $A/(\rho z_{it})$ of 100 mg/kg, a half-life of the parent of 258 d, a half-life of the
 1352 metabolite of 800 d, a formation fraction of 100% and equal molar masses of parent and metabolite.

1353 **A3.3.3 Assessment of the temperature dependency of the peak concentration if the metabolite**
 1354 **does not accumulate**

1355 If the metabolite does not accumulate, the steady state solution based on a continuous application of
 1356 the substance as described in the previous section does not give a meaningful approximation of the
 1357 time course of the concentration of the metabolite. This is illustrated with Figure A3. Eqn A6 predicts
 1358 for this case a plateau of 16 mg/kg which is clearly not a meaningful result.



1359 **Figure A3:** Numerical solution of the simple analytical model for a parent and a metabolite for an
 1360 annual dose corresponding to $A/(\rho z_{ii})$ of 100 mg/kg, for half-lives of the parent and metabolite of 10 d
 1361 at 20°C, $Q_{10} = 2.58$, a temperature of 5°C (corresponding to a half-life of parent and metabolite of 41
 1362 d), a formation fraction of 100% and equal molar masses of parent and metabolite.
 1363

1364 Adriaanse and Beltman (2014) analysed the maximum in time for a parent-metabolite system with
 1365 first-order transformation and formation after a single application. The time course of the
 1366 concentration of the metabolite for such a system can be described with:

1367
$$C_{metabolite} = F_f C_{0,parent} \frac{M_{metabolite}}{M_{parent}} \frac{k_{parent}}{k_{metabolite} - k_{parent}} \left[\exp(-k_{parent} t) - \exp(-k_{metabolite} t) \right]$$
 (A7)

1368 where $C_{metabolite}$ (mg kg⁻¹) is the concentration of this metabolite in total soil, F_f (-) is the formation
 1369 fraction of this metabolite (i.e. the stoichiometric coefficient of the formation of this metabolite from
 1370 the parent substance), $M_{metabolite}$ is the molar mass of this metabolite (g mol⁻¹), M_{parent} is the molar mass
 1371 of the parent substance (g mol⁻¹), k_{parent} is the degradation rate coefficient of the parent (d⁻¹), $k_{metabolite}$ is
 1372 the degradation rate coefficient of this metabolite (d⁻¹) and $C_{0,parent}$ (mg kg⁻¹) is the concentration in
 1373 total soil of the parent at the application time and t is the time elapsed since application (d).

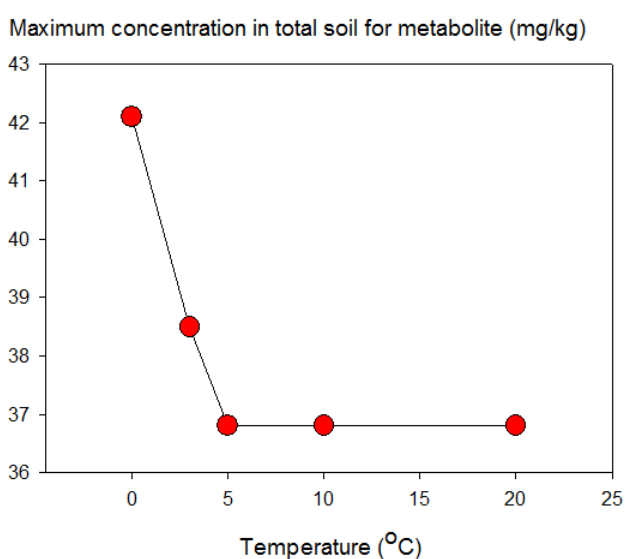
1374 Adriaanse and Beltman (2014) showed that the maximum of the concentration of the metabolite in
 1375 time is given by:

1376
$$C_{metabolite,max} = F_f C_{0,parent} \frac{M_{metabolite}}{M_{parent}} Y^{\frac{Y}{1-Y}}$$
 (A8)

1377 where $Y = k_{metabolite} / k_{parent}$. This ratio of these two rate coefficients does not depend on temperature if
 1378 their Arrhenius activation energy is the same. It is of course possible that activation energies for parent
 1379 and metabolites differ but the consequence of Eqn A8 is that a much lower temperature dependency is
 1380 expected for a maximum concentration of a metabolite that does not accumulate.

1381 This is illustrated by calculations with a numerical solution of the simple analytical model in which the
 1382 maximum concentration in time was calculated for annual applications as a function of temperature,
 1383 assuming equal Arrhenius activation energies for parent and metabolite. Figure A4 shows that for such
 1384 a case the maximum level of the metabolite does decrease between 0 and 5 °C but thereafter remains
 1385 constant with temperature. The background of the decrease between 0 and 5 °C is that at 0 °C there is
 1386 still overlap between the pulses of the different years (leading to an accumulation effect) but this
 1387 overlap does not occur anymore at 5 °C (this is the calculation shown in Figure A3). If there is no
 1388 overlap anymore, the maximum concentration does not depend on temperature as is predicted by Eqn
 1389 A8. In this case Eqn A8 predicts a maximum concentration of 36.8 mg/kg which corresponds well
 1390 with the result shown in Figure A4 (in this case Y happens to 1; therefore the calculation of Eqn A8 is
 1391 not straightforward but has to be based on the limit for Y going to 1; this can be calculated by e.g.
 1392 using $Y = 0.99999$).

1393 So the consequence is that the scenario selection procedure is expected not to work well for soil
 1394 metabolites that do not accumulate.



1395 **Figure A4:** Maximum concentration in total soil as a function of temperature calculated with a
 1396 numerical solution of the simple analytical model for a parent and a metabolite for an annual dose
 1397 corresponding to $A/(\rho z_{ii})$ of 100 mg/kg, for half-lives of the parent and metabolite of 10 d at 20°C,
 1398 $Q_{10} = 2.58$, a formation fraction of 100% and equal molar masses of parent and metabolite. Note that
 1399 the vertical axis does not start at 0.
 1400

1401 A3.4 Accumulation criterion for metabolites

1402 So the scenario selection procedure is likely to work only well for soil metabolites that accumulate
 1403 over the years (and do not leach significantly below 20 cm depth as described before). It is then useful
 1404 to have a criterion for the *DegT50* that checks whether a metabolite accumulates to such an extent that
 1405 concentration increases due to formation have only a limited effect on the peak concentration (such as
 1406 in the example in Figure A1).

1407 Let us consider the maximum increase in the metabolite concentration resulting from a single
 1408 application in an ecotoxicological averaging layer with depth z_{eco} . This equals $[A/(\rho z_{eco})] \times F_f$
 1409 $(M_{metabolite} / M_{parent})$. This is the concentration increase in case the degradation of the parent substance
 1410 would be extremely fast. This increase has to be small compared to the plateau level of the metabolite
 1411 (Eqn A6). Let us require that the plateau concentration level is at least equal to this maximum
 1412 increase. This leads to the requirement:

$$1413 \quad \frac{A}{\rho z_{til} t_{cycle} k_{metabolite}} \geq \frac{A}{\rho z_{eco}} \quad (A9)$$

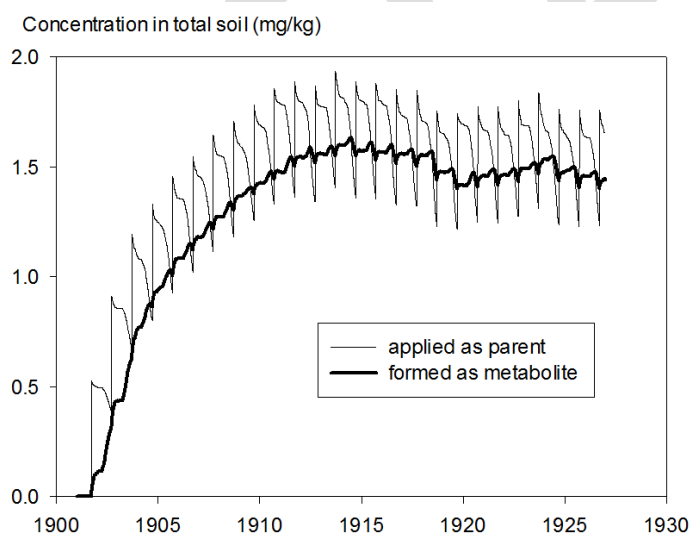
1414 This leads to the following requirement for the *DegT50* of the metabolite:

$$1415 \quad DegT50_{metabolite} \geq \frac{z_{til}}{z_{eco}} t_{cycle} \ln(2) \quad (A10)$$

1416 Note that Eqn A10 refers to the *DegT50* under field conditions, so not to the reference temperature of
 1417 20°C. Table 9 of EFSA (2010) shows that the *DegT50*s for the six scenarios are expected to be 1.7 to
 1418 3.4 times longer than the *DegT50* at 20°C based on the average temperature of the scenarios.

1419 Eqn A10 leads in general to long *DegT50* values for the metabolites. The value of t_{cycle} is at least 1
 1420 year and the ratio z_{til} / z_{eco} ranges from 1 to 20. So the minimum *DegT50* value is 0.7 years for
 1421 application every year and an ecotoxicological averaging depth of 20 cm but it may become as high as
 1422 42 years for application every three years and an ecotoxicological averaging depth of 1 cm. This poses
 1423 considerable restrictions to the use of the selected scenarios as appropriate 95th percentile scenarios for
 1424 soil metabolites.

1425 To illustrate the above analysis, calculations were made with the PEARL model. This was done for the
 1426 scenario for the concentration in total soil in the zone north for $z_{eco} = 20$ cm and an annual application
 1427 in winter wheat and for a soil metabolite with $DegT50 = 200$ d at 20°C and $K_{om} = 1000$ L/kg.
 1428 Calculations were made for the case where this soil metabolite was formed from a parent substance
 1429 (with a parent *DegT50* of 50 d at 20°C) and for a hypothetical case where the soil metabolite was
 1430 applied as the parent substance (assuming 100% formation and no difference in molar mass between
 1431 parent and metabolite to facilitate the comparison). The latter case would approximate the case of a
 1432 soil metabolite that is very rapidly formed from a parent substance (see Figure A5 for details).

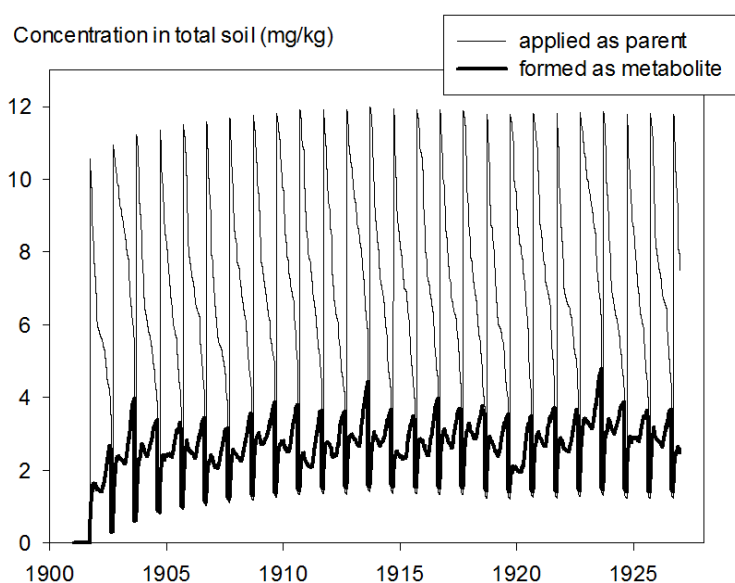


1433
 1434 **Figure A5:** Average concentration in total soil in the 20-cm top layer for a substance with $DegT50 =$
 1435 200 d at 20°C and $K_{om} = 1000$ L/kg (further called ‘substance A’) as calculated with PEARL for the
 1436 scenario ‘concentration in total soil’ in the zone north and winter wheat. Results are shown for
 1437 application of this substance A itself and for application of another substance (‘substance B’) that
 1438 degrades into substance A with a formation fraction of 100%. Substances A and B have equal molar
 1439 masses. Substance B has a $DegT50$ of 50 d at 20°C and a K_{om} of 1000 L/kg. Both substance A and B
 1440 were applied each year at a dose of 1 kg/ha one day before emergence.

1441 In this case Eqn A10 requires that the $DegT50 \geq 0.69$ years. This criterion is fulfilled because the
 1442 $DegT50$ of 200 d at 20°C corresponds to a $DegT50$ of 694 days, so 1.9 years under field conditions for
 1443 the scenario for the concentration in total soil in the zone north (see Table 9 of EFSA, 2010). The
 1444 result in Figure A5 shows that in this case accumulation dominates over the annual fluctuations so the
 1445 selected scenario is likely to be also a valid 95th percentile case for this metabolite.

1446 Figure A5 shows a plateau concentration of about 1.5 mg/kg. This result can be used to check the
 1447 applicability of Eqn A6 for this scenario. The dry bulk density of the top 20 cm for this scenario was
 1448 0.95 kg/L (EFSA, 2010, p. 37) and the effective $DegT50$ was 1.9 year as described above. This gives a
 1449 predicted plateau concentration of 1.44 mg/kg which corresponds well with the numerical result in
 1450 Figure A5.

1451 Figure A6 shows the results of the same calculations but now for an ecotoxicological mixing depth of
 1452 1 cm. For this case Eqn A10 requires that the $DegT50 \geq 14$ years whereas it is about 1.9 years. The
 1453 figure clearly shows that the effects of formation cannot be ignored when assessing the peak
 1454 concentrations. When applied as a parent (mimicking a very rapidly degrading metabolite) the peak
 1455 concentrations are about four times higher than when formed as a soil metabolite.



1456 **Figure A6:** Average concentration in total soil in the 1-cm top layer for a substance with $DegT50 =$
 1457 200 d at 20°C and $K_{om} = 1000$ L/kg (further called 'substance A') as calculated with PEARL for the
 1458 scenario 'concentration in total soil' in the zone north and winter wheat. Results are shown for
 1459 application of this substance A itself and for application of another substance ('substance B') that
 1460 degrades into substance A with a formation fraction of 100%. Substances A and B have equal molar
 1461 masses. Substance B has a $DegT50$ of 50 d at 20°C and a K_{om} of 1000 L/kg. Both substance A and B
 1462 were applied each year at a dose of 1 kg/ha one day before emergence.
 1463

1464 **A4 Conclusions**

1465 Tiers 1 and 2B/C are expected to generate exposure concentrations for soil metabolites that are
 1466 conservative enough given the exposure assessment goal.

1467 The scenario selection procedure that forms the basis of Tiers 2A and 3 is considered not appropriate
 1468 for soil metabolites that do leach significantly from the top 20 cm of soil or have precursors that do
 1469 leach significantly from this top 20 cm of soil. The requirement of no significant leaching of a
 1470 substance is considered to be met if the ratio $K_{om}/DegT50$ is above 1 L/(kg d). Furthermore this

1471 selection procedure is considered only appropriate for soil metabolites that show accumulation over
1472 the years (to be assessed with Eqn A10).

1473 So for metabolites that do not accumulate or that penetrate significantly below 20 cm depth (either by
1474 leaching of the metabolite itself or by leaching of one of its precursors), the methodology offers only
1475 conservative values based on Tiers 1 and 2B/C. However, it is questionable whether such higher-tier
1476 estimates will be needed often for such substances.

1477 So this analysis indicates that the exposure assessment methodology as proposed by EFSA (2012a)
1478 may with certain restrictions also generate suitable estimates of the exposure concentrations of soil
1479 metabolites.

1480

DRAFT

1481 **APPENDIX B PROCEDURE FOR ASSESSING THE FRACTION OF THE DOSE REACHING THE SOIL**
 1482 **SURFACE**

1483 **B1 Introduction**

1484 Since the introduction of the FOCUS groundwater scenarios in 2001, it has been common practice in
 1485 the leaching assessment at EU level to use the FOCUS interception tables to correct the dosage that
 1486 reaches the soil surface. So it was assumed that all intercepted substance will dissipate on the plant
 1487 surface and will thus never reach the soil. EFSA (2012a) considered this approach not defensible and
 1488 proposed to use as defaults in the exposure assessment a wash-off factor of 0.1 mm^{-1} and a half-life for
 1489 the decline of dislodgeable foliar residue on plants of 10 d. In principle, it would be possible to let the
 1490 simulation models calculate the wash-off using these default values. However, it is possible that this
 1491 would lead to considerable differences of the exposure assessments at EU level because of differences
 1492 in the descriptions of the processes on the plant surfaces between these models. So it is considered a
 1493 better option to change the FOCUS interception tables to include the effect of wash-off. This could be
 1494 done by calculating this effect for all relevant crop-location combinations with a few simulation
 1495 models with the intention to use the average result in the form of tables similar to the FOCUS
 1496 interception tables. Therefore calculations were set up for PEARL and PELMO in which the wash-off
 1497 was calculated for all crop-location combinations of the soil exposure scenarios.

1498 The calculation procedure was as follows:

- 1499 i. runs were made with one application per year, so simulation time was 26 years of which the
 1500 last 20 years were evaluated;
- 1501 ii. at the application time a dose of 1 kg ha^{-1} was applied to the plant surface;
- 1502 iii. for each year the annual wash-off (kg ha^{-1}) was calculated using a wash-off factor of 0.1 mm^{-1}
 1503 and a half-life for the decline of dislodgeable foliar residue on plants of 10 d and this annual
 1504 wash-off was transformed into an annual fraction washed off (division by 1 kg ha^{-1}).
 1505

1506 Calculations were made with PELMO and PEARL on a decade basis because a monthly basis was
 1507 considered not accurate enough in view of the sometimes considerable differences in crop
 1508 development within a month. The application times for the three decades of a month were set at the
 1509 5th, 15th and 25th of each month. Calculations were made only for periods when a crop was present.

1510 This results in wash-off tables based on absolute application dates. The FOCUS tables are based on
 1511 crop-development stages using so-called BBCH-codes (Meier, 2001). How these two tables are linked
 1512 is described in Section B4.

1513 **B2 How to deal with differences in wash-off between the 20 years?**

1514 So the runs mentioned above provided 20 fractions washed off for the 20 different years. It is a point
 1515 of debate whether the correction of the FOCUS interception tables should be based on the maximum
 1516 of these 20 fractions or on the average fraction. To explore the consequences of these two options,
 1517 scenario calculations were made with PEARL for the scenario CTN sugar beets, substance P3
 1518 ($DegT50 = 200 \text{ d}$, $K_{om} = 1000 \text{ L/kg}$), annual application of 1 kg/ha on 25 August (so simulation period
 1519 of 26 years), and ecotoxicological averaging depths of 1 and 20 cm. The interception (according to the
 1520 FOCUS interception table) was 90%. The PEARL wash-off calculations for this scenario as described
 1521 above showed that the average annual wash-off fraction was 0.639 and that the maximum annual wash
 1522 off was 0.974.

1523 Subsequently three types of PEARL calculations were made and results compared:

- 1524 i. annual application of 0.1 kg/ha to the soil, 0.9 kg/ha on the crop and simulation of wash-off by
 1525 PEARL using the wash-off factor of 0.1 mm^{-1} and a half-life for the decline on plants of 10 d;
 1526 this calculation is further called 'simulated wash-off';

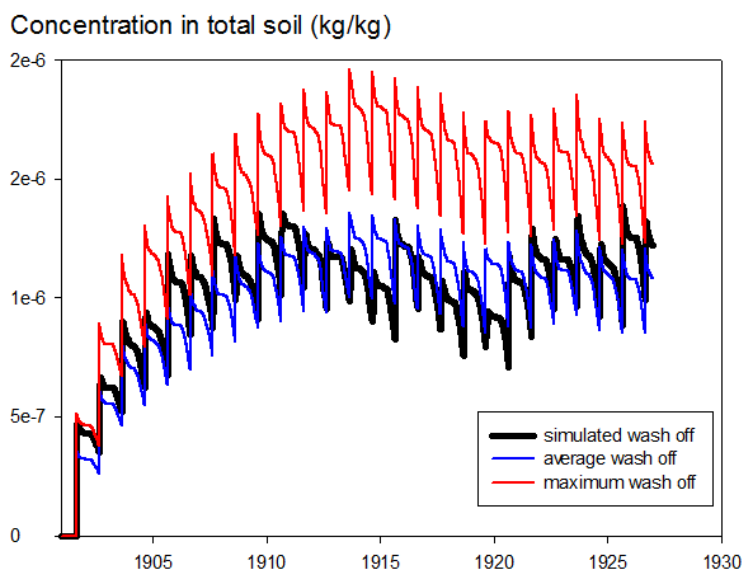
- 1527 ii. annual application of 0.675 kg/ha to the soil surface, corresponding with the annual average
- 1528 wash-off fraction; this calculation is called ‘average wash-off’;
- 1529 iii. annual application of 0.977 kg/ha to the soil surface, corresponding with the maximum annual
- 1530 wash-off fraction; this calculation is called ‘maximum wash-off’.

1531
1532 The calculation of these soil loads of 0.675 and 0.977 kg/ha was based on the equation:

$$1533 \quad A_{soil} = A \quad (1 - f_i) + f_i f_w \quad (B1)$$

1534 where A_{soil} is the soil load (kg ha⁻¹), A is the dosage (kg ha⁻¹), f_i is the fraction of the dose that is
1535 intercepted by the crop (-) and f_w is the fraction (-) washed off.

1536 The time course for the concentration in total soil averaged over the top 20 cm in Figure B1 shows that
1537 use of the average wash-off fraction leads to a time course that is close to the PEARL run in which the
1538 plant processes were simulated. Use of the maximum wash-off fraction resulted in a considerable
1539 overestimation of the plateau value which is the result of assuming that the maximum wash-off occurs
1540 every year.

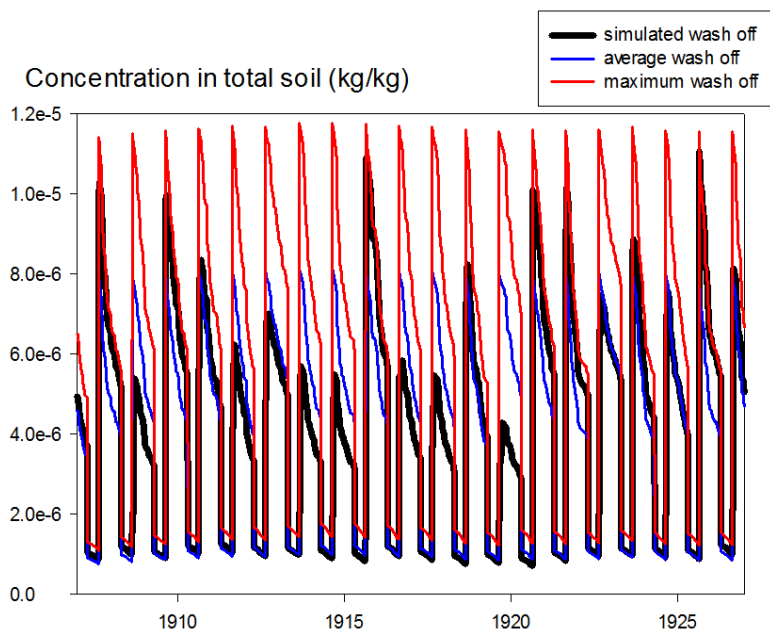


1541
1542 **Figure B1:** Concentration in total soil (average over top 20 cm) as a function of time as calculated
1543 with PEARL for the scenario CTN and sugar beets, substance P3 ($DegT50 = 200$ d, $K_{om} = 1000$ L/kg),
1544 annual application of 1 kg/ha on 25 August for the three types of PEARL calculations as indicated in
1545 the graph.

1546 The results for the concentration in total soil in the top 1 cm (Figure B2) are different from those of the
1547 top 20 cm. In this case the annual fluctuations dominate the time course of the concentration and the
1548 background plateau level does not play a role. Because the endpoint of the simulation is the maximum
1549 value over the whole simulation period, use of the maximum wash-off leads to a good correspondence
1550 with run with the simulated wash-off and use of the average wash-off leads to an underestimation. The
1551 pattern as shown in Figure B2 is probably representative for this scenario when deeper
1552 ecotoxicological averaging depths than 1 cm are considered for substances that do not accumulate.

1553 The results of the PEARL run with the simulated plant processes (Figure B2) show that the annual
1554 peak concentrations vary by almost a factor 3. Comparison of the different runs in *Figure B2* indicates
1555 that this variation is mainly caused by the differences in the wash-off from year to year. In the scenario
1556 selection procedure for the exposure assessment of soil organisms by EFSA (2012a) it was assumed
1557 appropriate to use a 100th percentile of the concentration in time based on the assumption that there

1558 would be only small differences between peak concentrations between different years (see p. 31 of
 1559 EFSA, 2012a). The line for the simulated wash-off in Figure B2 shows that this is not the case for this
 1560 scenario for the concentration in total soil in the zone North when combinations of substances and
 1561 ecotoxicological averaging depths are considered that do not lead to accumulation. So for uses that
 1562 lead to a high fraction intercepted by the crop, the exposure assessment goal of an overall 90th
 1563 percentile should in principle have led to a scenario selection procedure that included the wash-off
 1564 process. However, such a procedure is as yet impossible given the limited knowledge on the processes
 1565 that determine the wash-off (see EFSA, 2012a). Moreover it would also have made the exposure
 1566 assessment overly complicated because then different approaches would be needed for uses with low
 1567 and high crop interception.



1568
 1569 **Figure B2:** Concentration in total soil (average over top 1 cm) as a function of time as calculated with
 1570 PEARL for the scenario CTN and sugar beets, substance P3 ($DegT50 = 200$ d, $K_{om} = 1000$ L/kg),
 1571 annual application of 1 kg/ha on 25 August for the three types of PEARL calculations as indicated in
 1572 the graph.

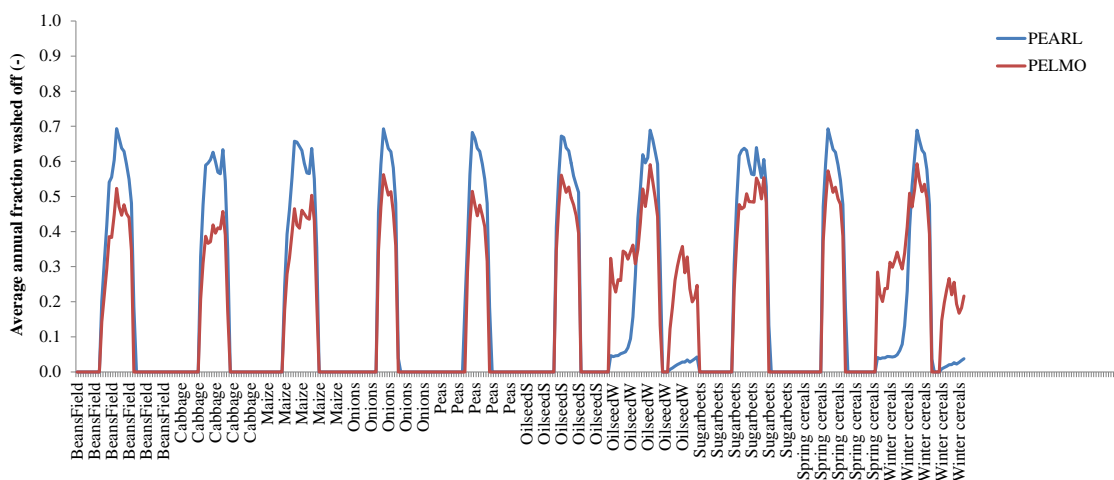
1573 In view of the foregoing and because the wash-off factor of 0.1 mm^{-1} is considered a conservative
 1574 default value (EFSA, 2012a) it is proposed to base the approach on the annual average wash-off
 1575 fraction; so the maximum annual wash off will not be considered.

1576 B3 Fraction of the dose reaching the soil calculated with PEARL and PELMO

1577 Figure B3 and B4 show the results of the calculations with PELMO and PEARL for the six scenarios
 1578 as a function of time. For the irrigated scenarios (CTC, CLC and CLS), wash-off is generally higher
 1579 than for the non-irrigated scenarios (CTN, CTS and CLN). Typically, in irrigated scenarios, the
 1580 fraction of the dose reaching the soil is between 0.7 and 0.9; for non-irrigated scenarios, these
 1581 fractions are between 0.4 and 0.6. The high wash-off in irrigated scenarios is caused by the relatively
 1582 short time-interval between the time of application and the next irrigation or rainfall event (and hence
 1583 less dissipation at the crop canopy).

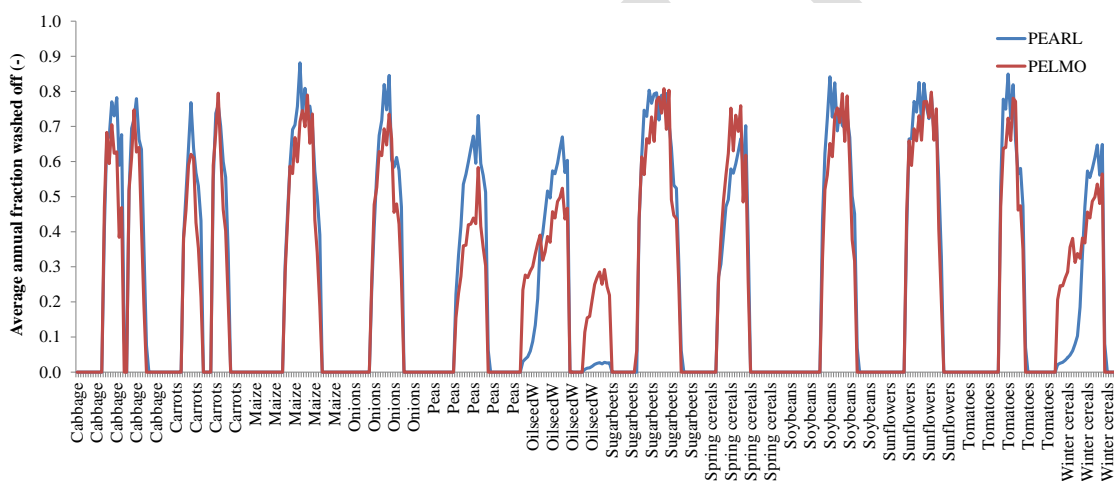
1584 For the irrigated scenarios, there is generally a good agreement between the PEARL and PELMO
 1585 simulations. For the non-irrigated scenarios, PEARL usually gives washed off fractions that are 0.05
 1586 to 0.2 higher than those of PELMO. Apparently, dissipation at the crop canopy is slower in PEARL.
 1587 The cause of these differences is not known.

1588



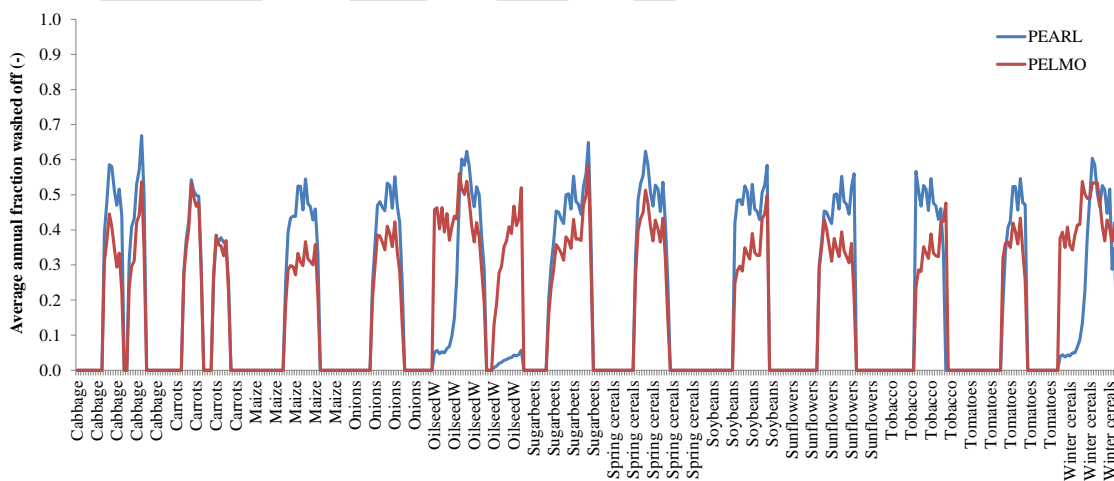
1589

1590 A total soil north



1591

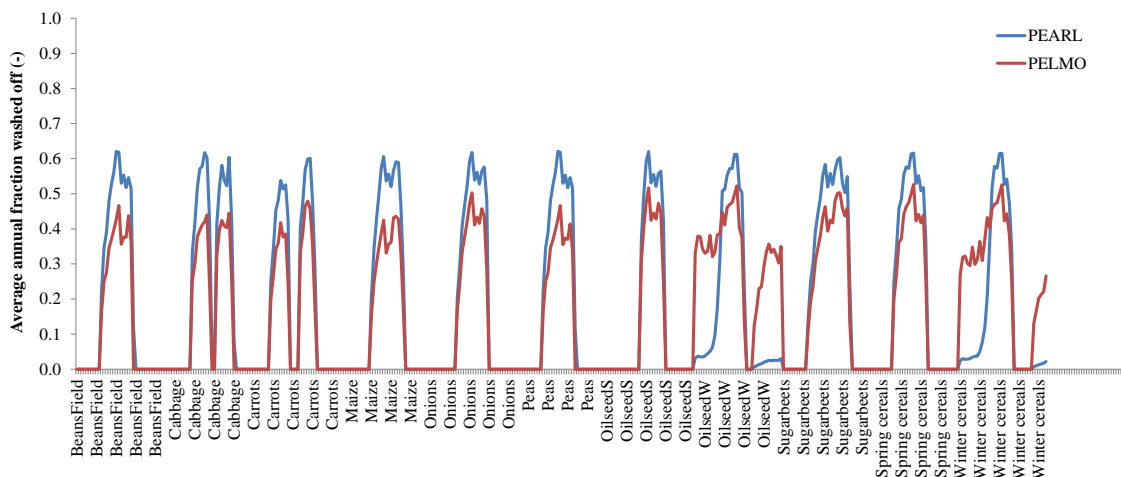
1592 B total soil centre



1593

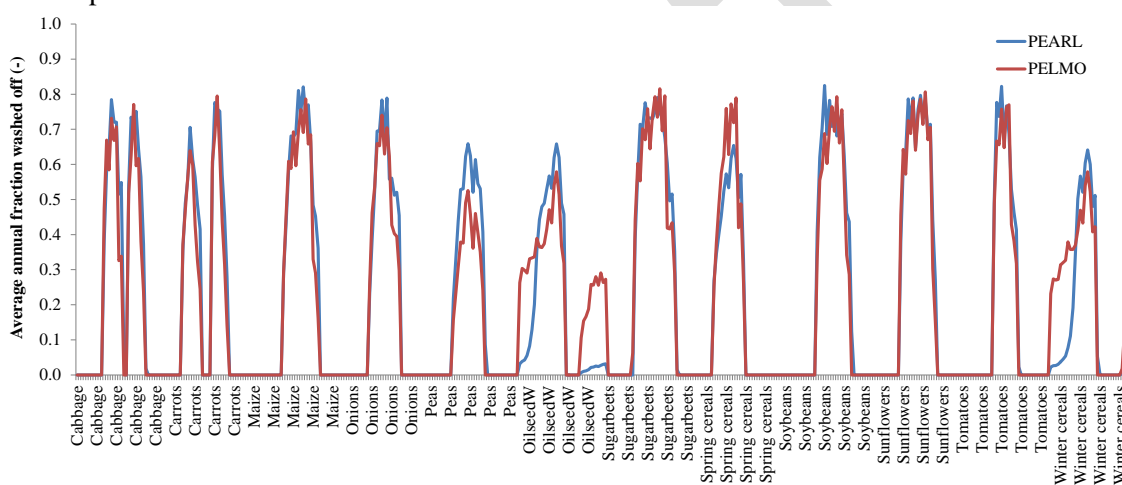
1594 C total soil south

1595 **Figure B3:** Time course of the average annual fraction washed off for the three scenarios for the
 1596 concentration in total soil as calculated with PELMO and PEARL. The distance between two ticks on
 1597 the horizontal axis is a decade.



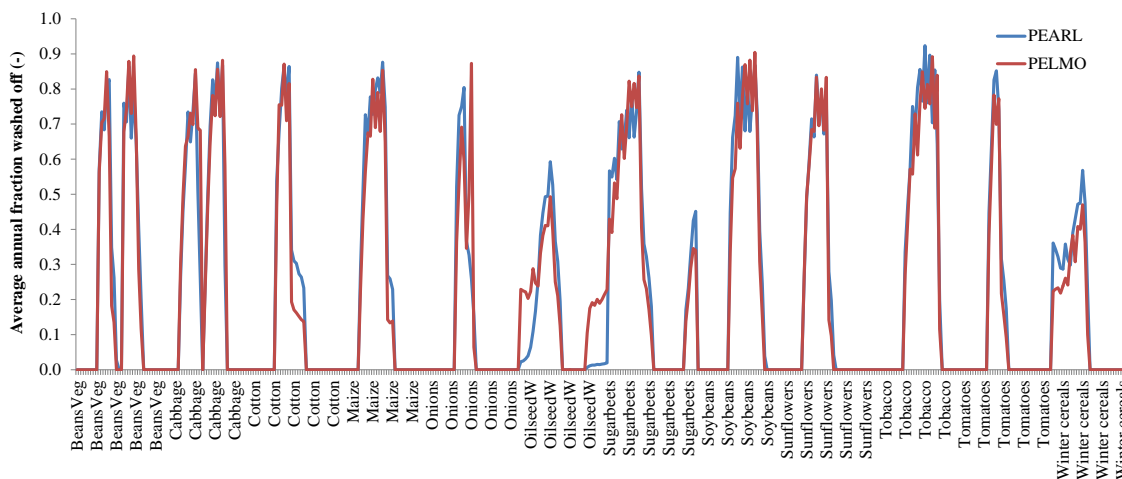
1598
1599
1600

A pore water north



1601
1602
1603
1604

B pore water centre



1605
1606

C pore water south

Figure B4: Time courses of the average annual fraction washed off for the three scenarios for the concentration in the liquid phase as calculated with PELMO and PEARL for the different crops. The distance between two ticks on the horizontal axis is a decade.

1610

1611 In all six scenarios, there are systematic differences between PEARL and PELMO for early
 1612 development stages in winter wheat and winter oil seed rapes (note that the sequence of the decades is
 1613 based on the calendar year so crops that grow from autumn to summer show a bimodal pattern in
 1614 Figure B3 and B4). This systematic difference is caused by the spring-point that is implemented in
 1615 PEARL but not in PELMO.

1616 In summary it can be concluded that the differences between PEARL and PELMO are generally small.
 1617 Furthermore, the temporal pattern is the same. We therefore judged it defensible to use average values
 1618 of PEARL and PELMO for building the tables.

1619 **B4 Development of tables for the fraction of the dose reaching the soil**

1620 The tables that are needed in the regulatory exposure assessment should consider the fraction of the
 1621 dose that reaches the soil (F_{soil}). This fraction considers crop interception at the time of application as
 1622 well as wash-off in the following days (where the latter is of course affected by dissipation processes
 1623 at the plant canopy). Crop interception is based on the tables provided in EFSA (2014a). Wash-off
 1624 fractions are calculated with PEARL and PELMO following the recommendations in EFSA 2012a
 1625 (i.e. using a default wash-off factor of 0.1 mm^{-1} and a half-life of 10 d for the decline of pesticide
 1626 residues on plants).

1627 The wash-off factors are based on calculations with PELMO and PEARL over 26 years of which the
 1628 last 20 years were used considering annual applications for every scenario-crop combination. For each
 1629 of these scenarios 36 simulations were performed with different application dates (always on the 5th,
 1630 15th or 25th of every month). In the simulations it was assumed that crop interception was 100%.
 1631 However, as PELMO and PEARL consider harvesting of crops and application of pesticide to crops
 1632 with different sequences, simulations were not done for those situations where application would be
 1633 on harvest date.

1634 The wash-off fraction was calculated based on the average wash-off in PELMO and PEARL for the
 1635 last 20 years of the simulations (see Section B2 for a justification for taking the average wash-off
 1636 fraction). Though the calculations were somewhat different in both computer models (e.g. a spring
 1637 point was used for winter crops by PEARL and but not by PELMO), their results were found to be
 1638 identical in most of the situations (Section B3). Therefore, the tables were based on the arithmetic
 1639 mean of the PELMO and PEARL results.

1640 In order to combine these wash-off fractions with reasonable crop interception values all application
 1641 dates had to be linked to BBCH crop stages (Meier, 2001). Gericke et al. (2014) found a linear
 1642 relationship between date and the BBCH code for annual crops. This implies that it is justifiable to use
 1643 linear interpolation starting at emergence date (BBCH 9) and ending at harvest date (i.e. BBCH 99 in
 1644 the case of annual crops or BBCH 50 in the case of biennial crops such as onions, sugar beet or
 1645 cabbage). However, to improve the link for winter crops with their dormancy shortly after emergence,
 1646 BBCH stage 9 was attached to the spring point rather than to the date of emergence.

1647 The actual wash-off fraction were calculated according to following equation:

$$1648 \quad W_{act} = \frac{W_{100} CI}{100} \quad (B2)$$

1649 where W_{act} (-) is the actual wash-off fraction (i.e. the wash-off fraction considering the appropriate
 1650 crop interception), W_{100} is the wash-off fraction considering 100% interception (i.e. the results of the
 1651 above simulations), and CI (%) is the actual crop interception according to the EFSA crop interception
 1652 tables. Finally, F_{soil} (i.e. the value that should be used in the exposure assessment) was calculated
 1653 according to following equation:
 1654

1655
$$F_{soil} = \frac{(100 - CI)}{100} + W_{act}$$
 (B3)

1656

where F_{soil} (-) is the fraction of the dose reaching the soil.

1657 As mentioned above, simulations were done for each crop-scenario combination. Since wash-off
 1658 depends on the weather conditions (and therefore on the scenario), also the fraction of the dose
 1659 reaching the soil is scenario dependent. However, the variability of these fractions between the
 1660 scenarios is generally less than 10% (only in some cases the coefficient of variation is higher; refer to
 1661 Table B1). We therefore judged it defensible to use one average fraction of the dose reaching the soil
 1662 for all six scenarios. Using such an average avoids too much complexity in the regulatory process.

1663 **Table B1:** Fraction of the dose reaching the soil ($F_{soil,max}$) considering crop interception and canopy
 1664 dissipation processes as a function of crop development stage. Figures are averages for the six
 1665 scenarios. Figures between brackets refer to the coefficient of variation (i.e. the standard deviation
 1666 divided by the mean).

Crop	BBCH code ^{1,2}				
	00-09	10-19	20-39	40-89	90-99
Beans (vegetable and field)	1.00 (0.00)	0.84 (0.06)	0.85 (0.08)	0.67 (0.04)	0.47 (0.24)
Cabbage ³	1.00 (0.00)	0.87 (0.03)	0.84 (0.06)	0.58 (0.13)	1.00 (0.00)
Carrots ³	1.00 (0.00)	0.86 (0.03)	0.71 (0.09)	0.44 (0.20)	1.00 (0.00)
Cotton	1.00 (0.00)	0.92 (0.00)	0.88 (0.00)	0.50 (0.00)	0.27 (0.00)
Maize	1.00 (0.00)	0.83 (0.01)	0.77 (0.09)	0.62 (0.20)	0.33 (0.09)
Onions ³	1.00 (0.00)	0.94 (0.01)	0.89 (0.02)	0.77 (0.03)	1.00 (0.00)
Peas	1.00 (0.00)	0.77 (0.02)	0.71 (0.03)	0.63 (0.06)	0.57 (0.08)
Oil seed rape (summer)	1.00 (0.00)	0.75 (0.00)	0.62 (0.03)	0.63 (0.02)	0.53 (0.17)
Oil seed rape (winter)	1.00 (0.00)	0.76 (0.06)	0.58 (0.09)	0.60 (0.07)	0.36 (0.23)
Sugar beets ³	1.00 (0.00)	0.90 (0.03)	0.73 (0.13)	0.51 (0.16)	1.00 (0.00)
Soybeans	1.00 (0.00)	0.83 (0.05)	0.80 (0.09)	0.71 (0.16)	0.54 (0.24)
Sunflowers	1.00 (0.00)	0.89 (0.02)	0.79 (0.09)	0.71 (0.18)	0.36 (0.31)
Tobacco	1.00 (0.00)	0.70 (0.01)	0.67 (0.17)	0.64 (0.37)	0.41 (0.33)
Tomatoes	1.00 (0.00)	0.73 (0.10)	0.75 (0.17)	0.64 (0.12)	0.66 (0.09)

Crop	BBCH code ⁴				
	00-19	20-29	30-39	40-69	70-99
Spring cereals	1.00 (0.00)	0.89 (0.01)	0.63 (0.04)	0.61 (0.12)	0.58 (0.08)
Winter cereals	1.00 (0.00)	0.90 (0.02)	0.59 (0.14)	0.56 (0.18)	0.56 (0.05)

- 1667 1) The BBCH code is a decimal code ranging from 0 to 99 to characterise the crop development stage (Meier, 2001).
 1668 2) BBCH 00-09: bare to emergence; BBCH 10-19: leaf development; BBCH 20-39: stem elongation; BBCH 40-89:
 1669 flowering; BBCH 90-99 Senescence and ripening
 1670 3) These crops are harvested at BBCH 50 and therefore the value of 1 should be used for crop stage 50-99.
 1671 4) BBCH 00-19: bare to leaf development; BBCH 20-29: tillering; BBCH 30-39: stem elongation; BBCH 40-69:
 1672 flowering; BBCH 70-99 Senescence and ripening

1673

1674

1675 **APPENDIX C PROCEDURE ON HOW THE SCENARIO AND MODEL ADJUSTMENT FACTORS HAVE**
 1676 **BEEN DERIVED**

1677 **C1 Derivation of scenario adjustment factors**

1678 The assessment of the Tier 1 scenarios (95th spatial percentile of the concentration in total soil and soil
 1679 pore water for the total area of annual crops in the EU) as well as the crop extrapolation factors were
 1680 based on the first release of a set of spatial data published in 2011, later referred to as the EFSA
 1681 Spatial Data Version 1.0 (Hiederer, 2012). In 2012 the new release of the EFSA Spatial Data
 1682 Version 1.1 was made available and published on the European Soil Portal of the European
 1683 Commission Joint Research Centre (<http://eusoiils.jrc.ec.europa.eu/library/data/efsa/>). Subsequently,
 1684 the updated version has also been implemented in PERSAM. The issues addressed in the updated
 1685 version of the EFSA Spatial Data are (Hiederer, 2012):

- 1686 - Enlargement of spatial frame to include all EU27 Member States and candidate countries;
- 1687 - Country boundaries adjusted to Eurostat GISCO Country 2010;
- 1688 - EU Regulatory Zones layer enlarged to EU27;
- 1689 - Land use based on CLC2000, V16. CLC map reprocessed;
- 1690 - General Land Use map reprocessed;
- 1691 - EFSA data mask reprocessed;
- 1692 - Mean monthly temperature data reprocessed;
- 1693 - Mean annual temperature recalculated;
- 1694 - Mean monthly precipitation data reprocessed;
- 1695 - Mean annual precipitation recalculated;
- 1696 - Arrhenius weighted mean annual temperature recalculated;
- 1697 - FOCUS zones recalculated;
- 1698 - All soil data reprocessed and extended to EU27;
- 1699 - Topsoil Water Content at Field Capacity reprocessed;
- 1700 - CAPRI2000 data reprocessed and adjusted to new EFSA spatial data Frame;
- 1701 - Units of CAPRI2000 data set to percent;
- 1702 - Background value set consistently for integer (0) and real (-9000.0) data.

1703 In principle, these changes in the EFSA Spatial Data introduced with version 1.1 would require a full
 1704 reassessment of the location and properties of the Tier 1 and Tier 2A scenarios as well as the crop
 1705 extrapolation factors. This can be seen in Table C1 which shows that the current exposure scenarios
 1706 partly represent a lower spatial percentile if they would have been based on the updated dataset. This
 1707 is in particular true for the concentration in the total soil. For that reason, the crop extrapolation factors
 1708 as given in EFSA (2012a) are not sufficiently conservative to cover the updated EFSA spatial data as
 1709 well. However, the working group decided not to change the Tier 1 scenarios but to reassess the crop
 1710 extrapolation factors only in order to keep the non-revised Tier 1 scenarios sufficiently conservative.

1711 **Table C1:** Ranges of spatial percentiles of the current Tier 1 scenarios in respect to the updated
 1712 dataset (based on the total annual crops). Example calculations were made for the standard substances
 1713 1, 9 and 19, for an ecological averaging depth z_{eco} of 1 and 20 cm considering the peak concentration
 1714 only. The area of total annual crops is considered equal to the sum of all CAPRI crops or crop groups.

	$C_{T,peak}$		$C_{L,peak}$	
	Minimum	Maximum	Minimum	Maximum
North	69	76	94	99
Centre	79	82	94	95
South	84	86	93	97

1715

1716

In EFSA (2012a) the 95th-percentile crop ratio is defined as follows:

$$\zeta = \frac{P_{95,x}}{P_{95,annual}} \quad (C1)$$

1718 where $P_{95,x}$ is the spatial 95th percentile of the concentration for the area of crop x and $P_{95,annual}$ is the
 1719 spatial 95th percentile of the concentration for the total area of annual crops, both values based on the
 1720 EFSA Spatial Data version 1.0. The magnitude of ζ was assessed in EFSA (2012a) based on
 1721 calculations with the simple analytical model for most of the CAPRI crops and crop groups and for the
 1722 substances P1, P2 and P3. Finally, the PPR Panel proposed to use the maxima of the crop
 1723 extrapolation factors to be used in Tiers 1 and 2A (Table C2).

1724 Following the update of the EFSA Spatial Data from version 1.0 to version 1.1 the Panel decided to
 1725 replace the crop extrapolation factors by so called scenario adjustment factors, which are based on a
 1726 revised 95th-percentile crop ratio as follows:

$$\xi = \frac{P_{95,x}}{C_{Tier-1}} \zeta = \frac{P_{95,x}}{P_{Tier1}} \quad (C2)$$

1728 where $P_{95,x}$ is the spatial 95th percentile of the concentration for the area of crop x based on the EFSA
 1729 Spatial Data Version 1.1 and P_{Tier1} is the PEC calculated at Tier1 (so calculated with the simple
 1730 analytical model without any adjustment factors) based on the EFSA Spatial Data Version 1.0. As
 1731 with the original factor, this ratio applies either to $C_{T,peak}$ or $C_{L,peak}$ and to a specific substance in a
 1732 certain regulatory zone.

1733 To assess the possible magnitude of the revised ξ , the working group made calculations with the
 1734 simple analytical model for all CAPRI crops or crop groups in PERSAM (see Table D1 in Appendix
 1735 D). This was done for the standard substances 1 to 19 (refer to EFSA, 2012a for substance properties)
 1736 for all regulatory zones and for an ecological averaging depth z_{eco} of 1 and 20 cm considering the peak
 1737 concentration only. In analogy with EFSA (2012a) the working group proposes to use the maxima of
 1738 these values of each regulatory zone (rounded up to the nearest half) to be used as scenario adjustment
 1739 factors in Tiers 1 and 2A (Table C2).

1740 **Table C2:** Ranges (and final values) of the new scenario adjustment factors in comparison to ranges
 1741 of the former crop extrapolation factors for the three regulatory zones and for both the concentration in
 1742 total soil ($C_{T,peak}$) and the concentration in the liquid phase ($C_{L,peak}$).

	Scenario adjustment factor ^a						Crop extrapolation factor ^b (EFSA, 2012a)			
	$C_{T,peak}$			$C_{L,peak}$			$C_{T,peak}$		$C_{L,peak}$	
	Min.	Max.	Final ^c	Min.	Max.	Final ^c	Min.	Max.	Min.	Max.
North	0.75	2.89	3.0	0.58	1.53	2.0	0.64	1.79	0.87	1.02
Centre	0.86	1.63	2.0	0.63	1.23	1.5	0.74	1.16	0.93	1.15
South	0.83	1.73	2.0	0.52	1.28	1.5	0.86	1.07	0.86	1.13

1743 ^a Based on the standard substances 1 to 19

1744 ^b Based on the substances P1, P2 and P3

1745 ^c Rounded up to the nearest half

1746

1747 C2 Derivation of model adjustment factors

1748 The model adjustment factors as derived in EFSA (2012a) were based on simulations with PEARL
 1749 and PELMO for 19 substances. In these simulations, only $DegT50$ and K_{om} were changed. However, at
 1750 Tier 2A, users can change other substance properties, such as the Freundlich adsorption coefficient

1751 ($1/n$), the molar activation energy (E_{Act}), the moisture dependence of degradation exponent (B), and the
 1752 transpiration concentration stream factor ($TCSF$). Changing these parameters may affect the model
 1753 adjustment factors; because it cannot *a priori* be guaranteed that the predicted concentrations are
 1754 lowered by changing these parameters.

1755 To investigate the effect of these four parameters on the model adjustment factors, a simple sensitivity
 1756 analysis was carried out. In this analysis, for each parameter, three runs were done, i.e. one with the
 1757 lower limit of plausible values, one with the normal value as reported in EFSA (2012a) and one with
 1758 the upper limit of plausible values. All parameters were varied one-by-one, and 19 substances
 1759 (reported in EFSA, 2012a) were simulated. The following range of parameters was considered:

- 1760 i. $1/n$ was varied between 0.7 and 1.0. This value is based on Boesten et al. (2012).
- 1761 ii. E_{Act} was varied between 35 and 115 kJ mol⁻¹. According to EFSA (2007), 95% of the reported
 1762 values are within this range.
- 1763 iii. B was varied between 0.1 and 1.5 (EFSA, 2010).
- 1764 iv. $TCSF$ was varied between 0 and 1, i.e. the full range of possible values in the numerical
 1765 models.

1766 C3.1 Results

1768 Results are summarised in Figures C1-C4. Each figure shows the ratio between the results obtained by
 1769 PEARL and the results obtained by PERSAM. The maximum of all these ratios is the required model
 1770 adjustment factor.

1771 C3.1.1 Effect of the Freundlich exponent

1772 Figure C1 shows that the effect of the Freundlich exponent on the concentration in total soil is
 1773 negligible (only some effect is visible, which is due to slightly different mobility and hence transport
 1774 of the pesticide from the top layer). The predicted ratio is always below the model adjustment factor
 1775 for the respective scenario as reported in EFSA (2012a), so adaptation of this factor is not necessary.

1776 For the concentration in pore water, a clear effect is visible. An exponent of 0.7 leads to a higher ratio
 1777 PEARL/PERSAM, an exponent of 1.0 leads to a lower ratio. This effect was unexpected as a lower
 1778 Freundlich coefficient leads to a higher leaching of substance at the 0.1 µg/L level. However, in the
 1779 top soil, the concentration is above the reference concentration for the Freundlich adsorption isotherm
 1780 of 1 mg/L and at this concentration level a higher concentration in the pore water is predicted. For the
 1781 CL and CS scenarios, the ratio is higher than the original model adjustment factor for the respective
 1782 scenario.

1783 C3.1.2 Effect of the molar activation energy

1784 In the simulations, the same value for the molar activation energy was used in PEARL and PERSAM.
 1785 Results are shown in Figure C2.

1786 A lower value of the molar activation energy leads to a higher ratio of the predicted concentration in
 1787 total soil, whereas a higher value leads to a lower ratio (Figure C2A and C2C). This effect is most
 1788 pronounced when using an evaluation layer of 20 cm. This is most probably caused by the difference
 1789 in the molar activation energy used in the model and the molar activation energy used in the
 1790 calculation of the Arrhenius weighted average temperature that has been used for the scenario
 1791 selection procedure (the scenarios were selected assuming E_{Act} of 65.4 kJ mol⁻¹). For the CTN scenario
 1792 and an evaluation depth of 20 cm, the original model adjustment factor is (slightly) exceeded.

1793 For the concentration in liquid phase, the effect is generally in the same direction. However, the
 1794 original model adjustment factors were not exceeded.

1795 C3.1.3 Effect of the moisture dependence of degradation

1796 A low value of the exponent in the moisture dependence of degradation leads to higher concentrations
 1797 in total soil and hence a higher ratio PEARL/PERSAM (Figure C3). For the lowest value ($B=0.1$), the
 1798 original model adjustment factor is exceeded in many cases.

1799 For the concentration in pore water, the effect is in the same direction but less pronounced. The
 1800 original model adjustment factor is slightly exceeded in one case (scenario CLS, TWA=56 days).

1801 **C3.1.4 Effect of the transpiration concentration stream factor**

1802 A lower transpiration concentration stream factor leads to higher concentrations in total soil and hence
 1803 a higher ratio PEARL/PERSAM (Figure C4). This effect is most pronounced for the 20 cm evaluation
 1804 layer. For this evaluation layer, the model adjustment is exceeded in five out of six cases.

1805 For the concentration in pore water, no effect is observable for the 1 cm evaluation layer. For the 20
 1806 cm layer, the effect is in the same direction as for the concentration in total soil but the model
 1807 adjustment factor is exceeded in only one case (scenario CLS).

1808 **C3.2 Conclusions**

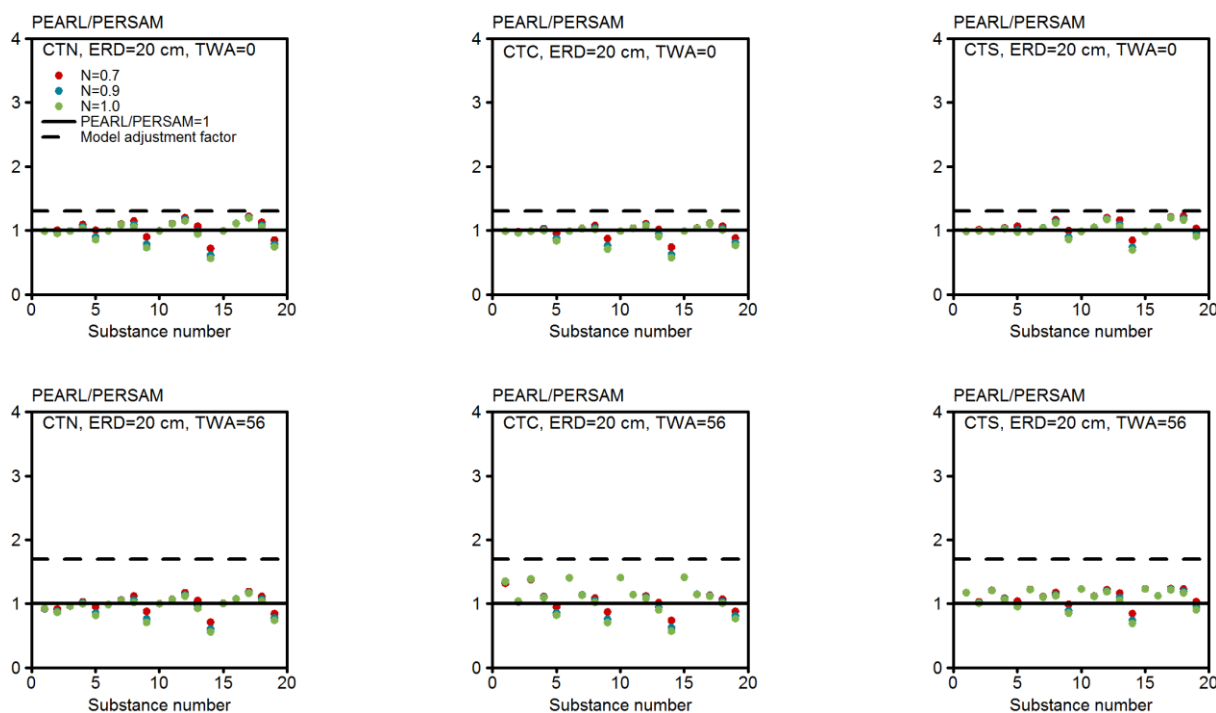
1809 Based on these findings, the model adjustment factors would have to be changed to the following
 1810 values (see EFSA 2012a, page 45 for the old values):

- 1811 i. $f_m = 1.2$ (was 1.1) for the peak concentration in total soil for $z_{eco} = 1$ cm
- 1812 ii. $f_m = 2.0$ (was 1.3) for the peak concentration in total soil for $z_{eco} = 20$ cm
- 1813 iii. $f_m = 2.0$ (was 1.7) for all TWA concentrations in total soil
- 1814 iv. $f_m = 2.5$ (was 2.0) for all pore water concentrations in zones North and Central
- 1815 v. $f_m = 4.0$ (was 3.0) for all pore water concentrations in zone South

1816 Note that these findings are based on only two evaluation depths, i.e. 1 cm and 20 cm. Furthermore,
 1817 worst case combinations of parameters (i.e. TCSF = 0 in combination with $1/n = 0.7$) have not been
 1818 studied. If such combinations would have been studied, higher model adjustment factors would have
 1819 been calculated. For the sake of simplicity and to ensure consistency within the tiered approach, it
 1820 therefore proposed to use model adjustment factors that are rounded up, i.e. $f_m = 2$ for all concentration
 1821 in total soil scenarios and $f_m = 4$ for all concentration in pore water scenarios. These model adjustment
 1822 factors should be used in all tiers where the analytical model is used.

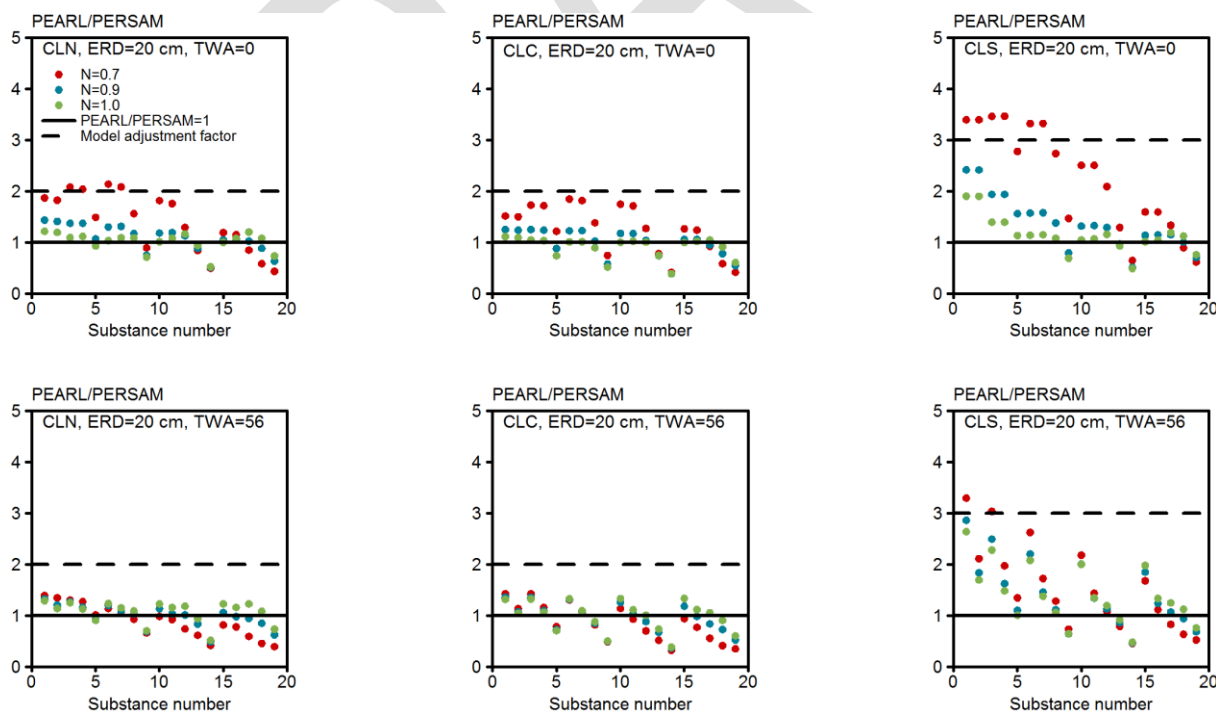
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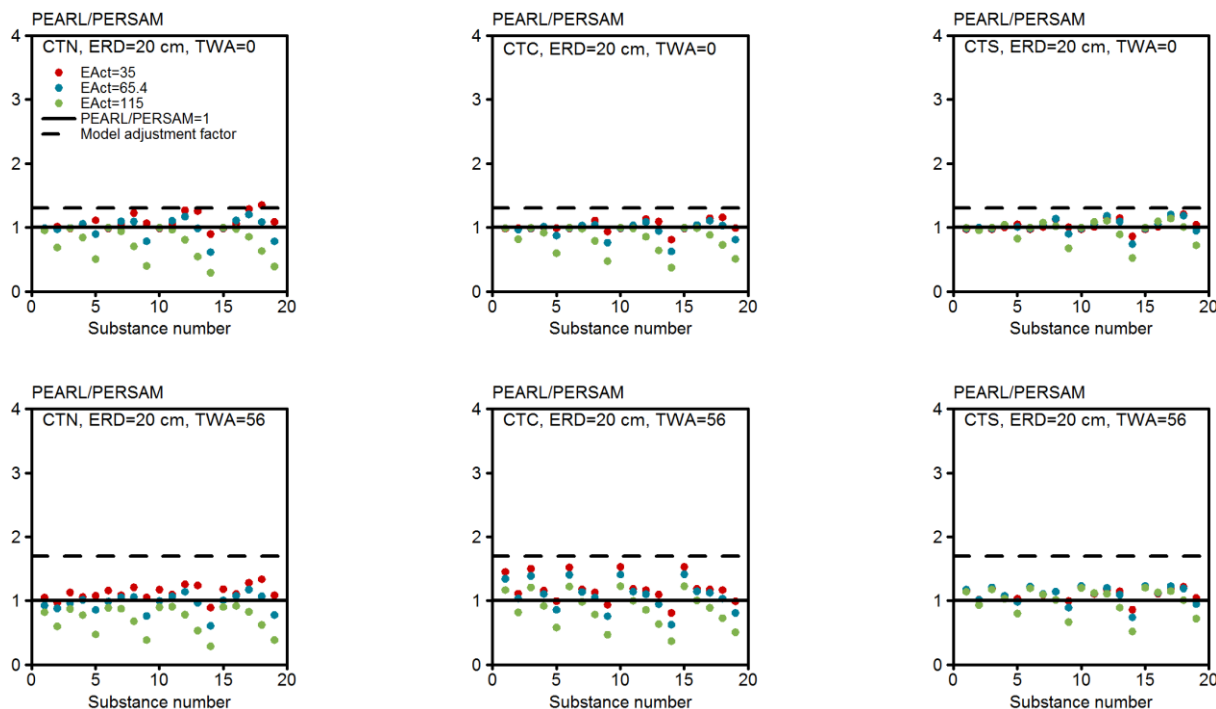
1826 **Figure C1a:** Effect of the Freundlich exponent on the ratio between the concentration in total soil
 1827 predicted by PEARL and the concentration predicted by PERSAM. The evaluation layer is 20 cm.
 1828 Upper panels: peak concentration. Lower panels: time weighted average concentration (56 days). The
 1829 dashed line is the model adjustment factor reported in EFSA (2012a).



1830

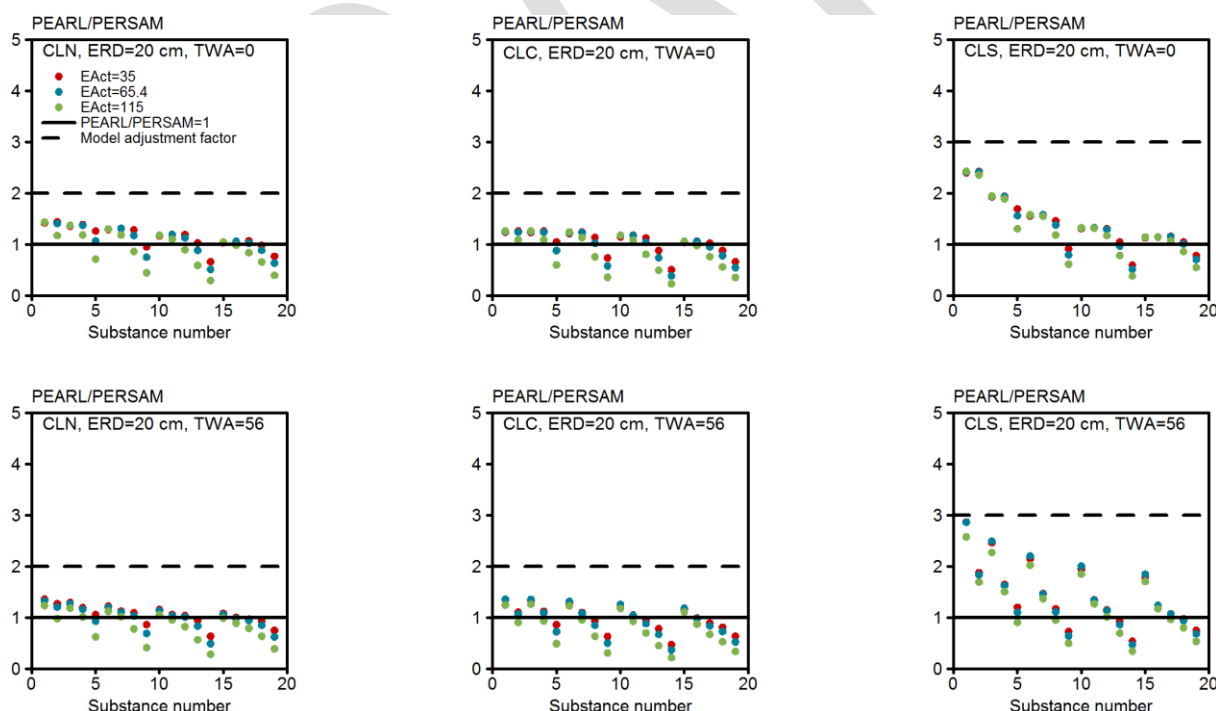
1831 **Figure C1b:** Effect of the Freundlich exponent on the ratio between the concentration in pore water
 1832 predicted by PEARL and the concentration predicted by PERSAM. The evaluation layer is 20 cm.
 1833 Upper panels: peak concentration. Lower panels: time weighted average concentration (56 days). The
 1834 dashed line is the model adjustment factor reported in EFSA (2012a).

1835



1836

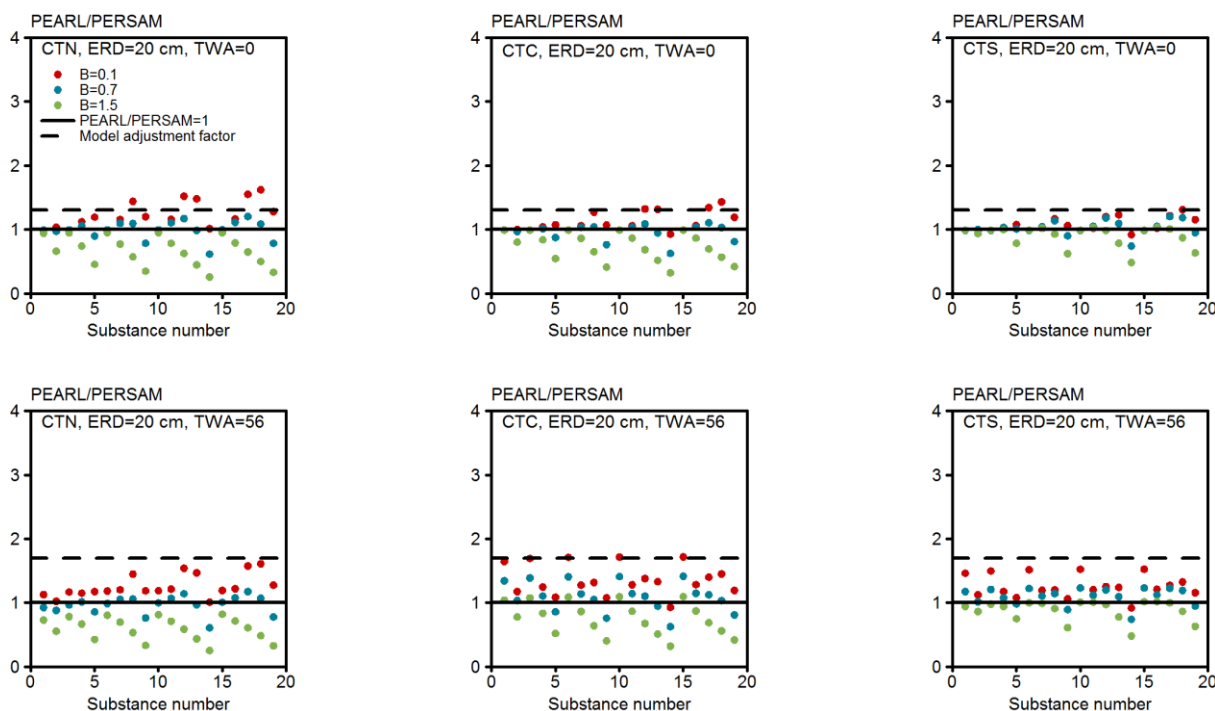
1837 **Figure C2a:** Effect of the molar activation energy on the ratio between the concentration in total
 1838 soil predicted by PEARL and the concentration predicted by PERSAM. The evaluation layer is 20 cm.
 1839 Upper panels: peak concentration. Lower panels: time weighted average concentration (56 days). The
 1840 dashed line is the model adjustment factor reported in EFSA (2012a).



1841

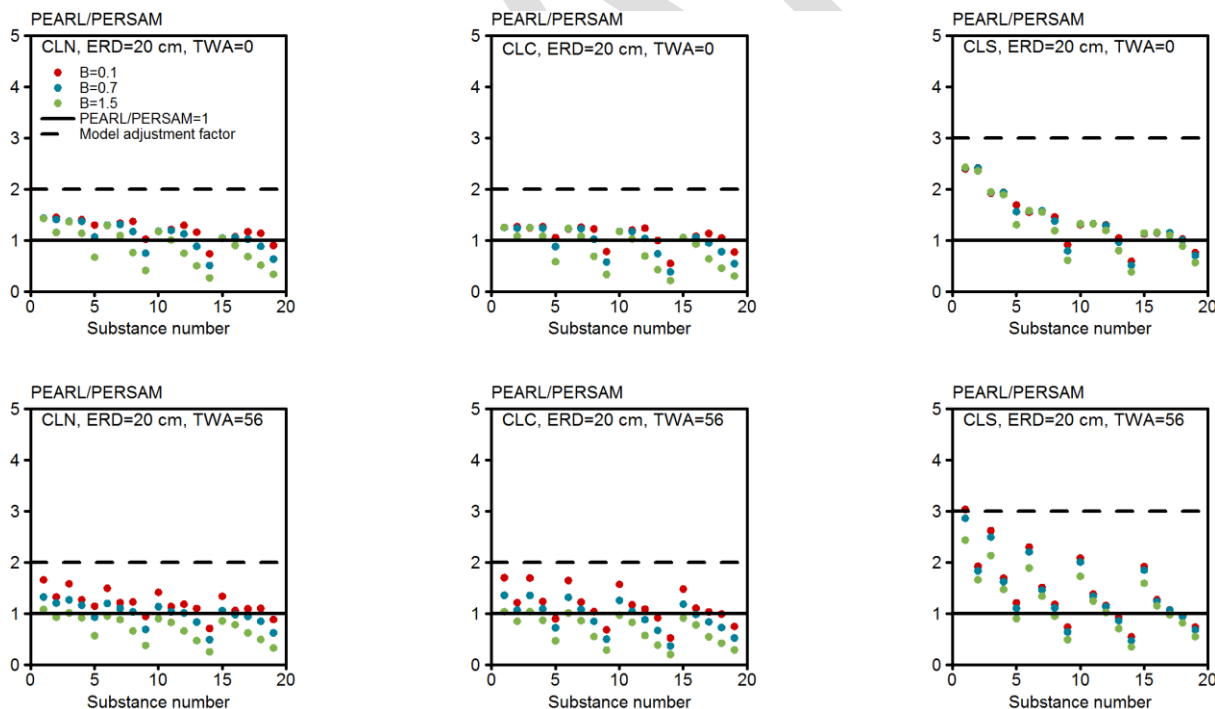
1842 **Figure C2b:** Effect of the molar activation energy on the ratio between the concentration in pore
 1843 water predicted by PEARL and the concentration predicted by PERSAM. The evaluation layer is 20
 1844 cm. Upper panels: peak concentration. Lower panels: time weighted average concentration (56 days).
 1845 The dashed line is the model adjustment factor reported in EFSA (2012a).

1846



1847

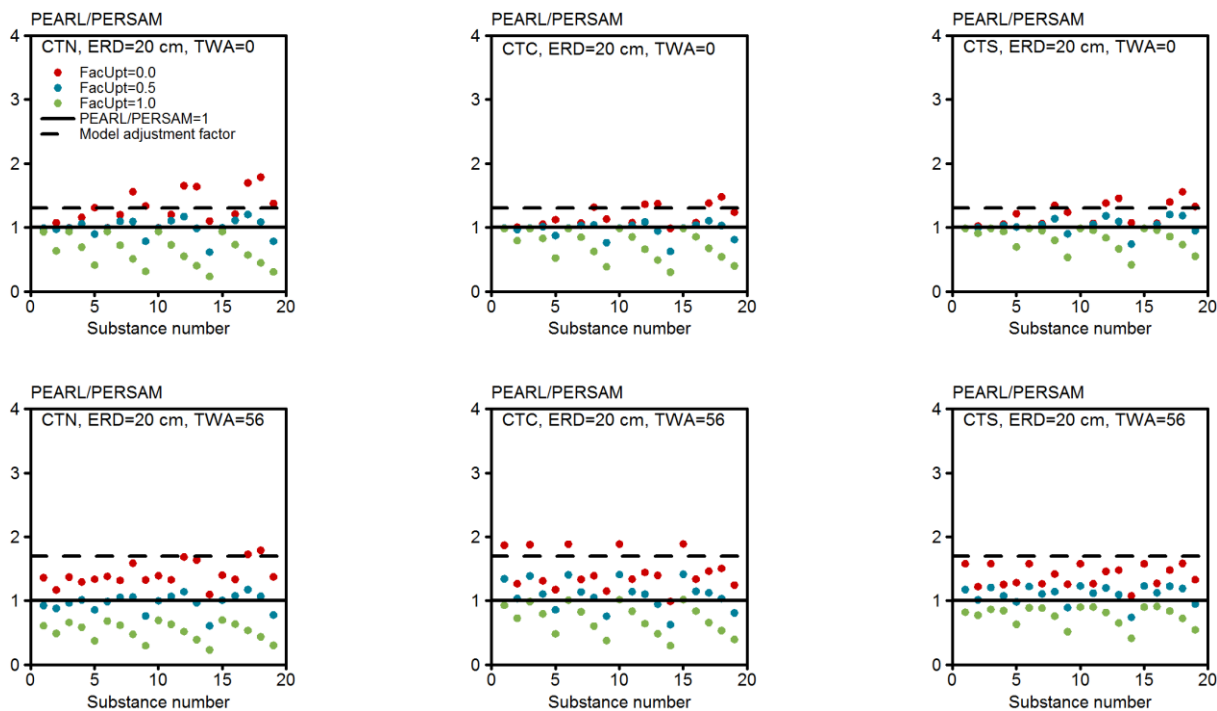
1848 **Figure C3a:** Effect of the exponent in the equation of soil moisture on the ratio between the
 1849 concentration in total soil predicted by PEARL and the concentration predicted by PERSAM. The
 1850 evaluation layer is 20 cm. Upper panels: peak concentration. Lower panels: time weighted average
 1851 concentration (56 days). The dashed line is the model adjustment factor reported in EFSA (2012a).



1852

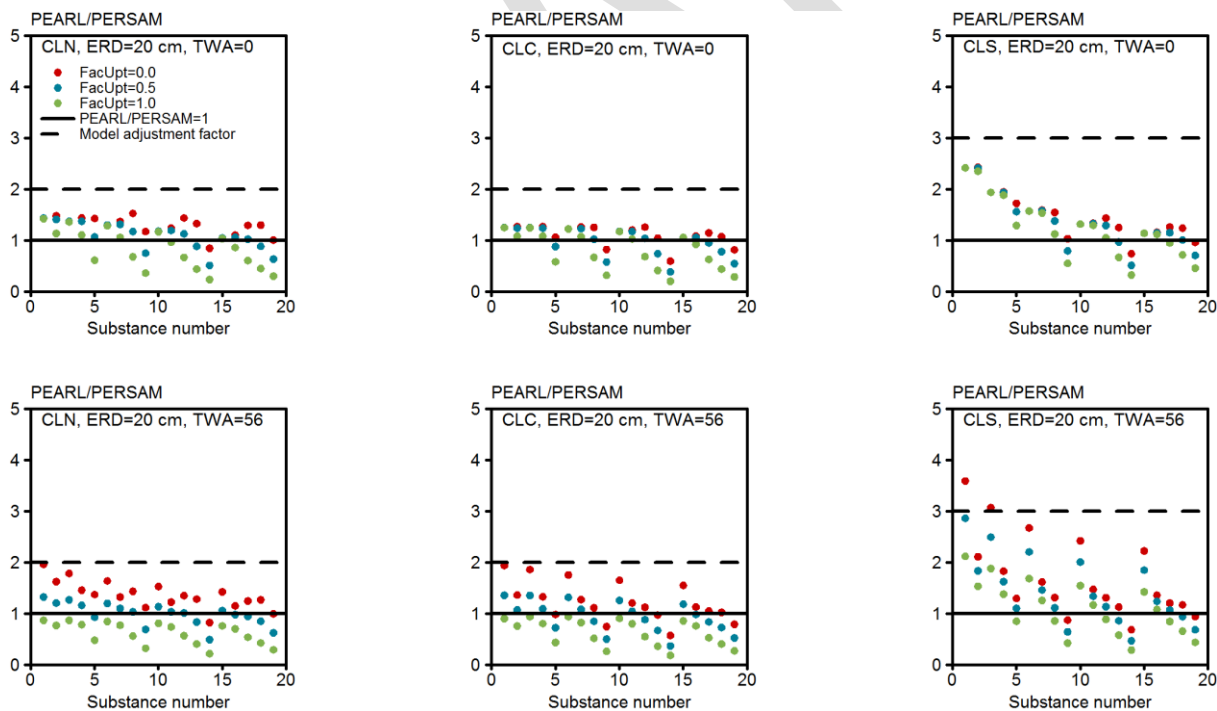
1853 **Figure C3b:** Effect of the exponent in the equation of soil moisture on the ratio between the
 1854 concentration in pore water predicted by PEARL and the concentration predicted by PERSAM. The
 1855 evaluation layer is 20 cm. Upper panels: peak concentration. Lower panels: time weighted average
 1856 concentration (56 days). The dashed line is the model adjustment factor reported in EFSA (2012a).

1857



1858

1859 **Figure C4a:** Effect of the transpiration concentration stream factor on the ratio between the
 1860 concentration in total soil predicted by PEARL and the concentration predicted by PERSAM. The
 1861 evaluation layer is 20 cm. Upper panels: peak concentration. Lower panels: time weighted average
 1862 concentration (56 days). The dashed line is the model adjustment factor reported in EFSA (2012a).



1863

1864 **Figure C4b:** Effect of the transpiration concentration stream factor on the ratio between the
 1865 concentration in pore water predicted by PEARL and the concentration predicted by PERSAM. The
 1866 evaluation layer is 20 cm. Upper panels: peak concentration. Lower panels: time weighted average
 1867 concentration (56 days). The dashed line is the model adjustment factor reported in EFSA (2012a).

1868

1869 **APPENDIX D DEFINITION OF PERSAM CROPS**

1870 Information on the regional distribution of annual crop or crop groups in the EU as implemented in
 1871 PERSAM is based on the so-called Common Agricultural Policy Regional Impact assessment
 1872 (CAPRI) database (Leip et al., 2008). This database contains official data obtained from the European
 1873 statistical offices (available at <http://epp.eurostat.ec.europa.eu>). In short, statistical information about
 1874 agricultural production including annual and permanent crops was obtained at the regional level of the
 1875 so-called Nomenclature of Territorial Units for Statistics (NUTS 2). Data on crop areas were
 1876 downscaled to the level of the so-called Homogeneous Spatial Mapping Units (HSMU) using a two-
 1877 step statistical approach combining prior estimates based on observed behaviour with a reconciliation
 1878 procedure achieving consistency between the scales (Kempen et al., 2007). The area under analysis
 1879 covered 25 Member States of the European Union; Malta and Cyprus were not included. Table D1
 1880 gives the nomenclature of the annual crops or crop groups as stated in PERSAM in relation to the
 1881 CAPRI database and the EFSA Spatial Data Version 1.1 (Hiederer, 2012).

1882 **Table D1:** Nomenclature of annual crops or crop groups as stated in PERSAM in relation to the
 1883 CAPRI database and the EFSA Spatial Data Version 1.1 (Hiederer, 2012).

PERSAM	CAPRI field name	Agricultural land use 2000 field name	EFSA File Name (EFSA Spatial Data Set1.1)
Barley	barl	Barley	*_BARLEY
Common wheat	swhe	Common wheat	*_COMMON_WHEAT
Durum wheat	dwhe	Durum Wheat	*_DURUM_WHEAT
Fallow	lfall	Fallow land	*_FALLOW
Floriculture and flower bulbs	flow	Floriculture	*_FLOWER
Maize	lmaiz	Maize	*_MAIZE
Oats	oats	Oats	*_OATS
Oilseed rapeseeds	lrape	Rape and turnip rape	*_RAPES
Other annual crops	ocro	Other crops	*_OTHER_CROPS
Other cereals	ocer	Other cereals	*_OTHER_CEREALS
Other fodder on arable land	ofar	Fodder other on arable land	*_OTHER_FODDER
Other fresh vegetables	oveg	Vegetables	*_OTHER_VEGETABLES
Other non-permanent industrial crops	oind	Other non-permanent industrial crops	*_OTHER_INDUSTRIAL
Other root crops	roof	Other root crops	*_OTHER_ROOTCROPS
Potatoes	pota	Potatoes	*_POTATOES
Pulses	puls	Dry pulses	*_PULSES
Rye	ryem	Rye	*_RYE
Soya beans	soya	Soya	*_SOYA
Sugar beets	sugb	Sugar beet	*_SUGARBEET
Sunflowers	sunf	Sunflower	*_SUNFLOWERS
Texture crops	ltext	Fibre and oleaginous crops	*_TEXTURE_CROPS
Tobacco	toba	Tobacco	*_TOBACCO
Tomatoes	toma	Tomatoes	*_TOMATOES

1884 * EFSA_CAPRI

1885

1886 The working group reassessed the definition of the crops or crop groups in the table above. It was
 1887 found that tomatoes and vegetables could not be distinguished because of inconsistencies in the
 1888 database. The working group therefore regrouped and redefined some of the CAPRI crops into new
 1889 categories that could be used in future version of the PERSAM tool. The proposed list of annual crops
 1890 is shown in Table D2.

1891 **Table D2:** Proposed list of well-defined annual crops or crop groups based on the CAPRI database.

Crop	CAPRI field name	Agricultural Land use 2000 Field Name
Barley	barl	Barley
Common wheat	swhe	Common wheat
Durum wheat	dwhe	Durum Wheat
Fallow	lfall	Fallow land
Floriculture and flower bulbs	flow	Floriculture
Maize	lmaiz	Maize
Oats	oats	Oats
Oilseed rapeseeds	lrape	Rape and turnip rape
Other annual crops including root vegetables	ocro + ocer + ofar + oind + roof	Other crops + other cereals + fodder other on arable land + other non-permanent industrial crops + other root crops
Vegetables including fruiting vegetables but excluding root vegetables ^a	oveg + toma	Vegetables + Tomatoes
Potatoes ^b	pota	Potatoes
Pulses	puls	Dry pulses
Rye	ryem	Rye
Soya beans	soya	Soya
Sugar beets	sugb	Sugar beet
Sunflowers	sunf	Sunflower
Texture crops ^b	ltext	Fibre and oleaginous crops
Tobacco	toba	Tobacco

1892 ^a Vegetables and tomatoes cannot be distinguished in CAPRI due to inconsistencies

1893 ^b Grown on ridges

1894 ^c Includes cotton, but > 90% is hemp and flax

1895

1896

- 1897 **APPENDIX E PRACTICAL EXAMPLES ON HOW THE EFSA GUIDANCE DOCUMENT CAN BE USED**
- 1898 Practical examples on how this EFSA Guidance Document can be used will be provided after the
- 1899 public consultation.
- 1900

DRAFT

1901

1902 **APPENDIX F EXCEL SHEET FOR THE FRACTION OF THE DOSE REACHING THE SOIL**

1903 The Excel sheet provides background information on how to use tables for the fraction of applied
1904 substance reaching the soil.

DRAFT