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No. 82

GUIDANCE DOCUMENT FOR CONDUCTING PESTICIDE TERRESTRIAL FIELD DISSIPATION STUDIES

IOMC

INTER-ORGANIZATION PROGRAMME FOR THE SOUND MANAGEMENT OF CHEMICALS

A cooperative agreement among FAO, ILO, UNDP, UNEP, UNIDO, UNITAR, WHO, World Bank and OECD

Environment Directorate
ORGANISATION FOR ECONOMIC CO-OPERATION AND DEVELOPMENT
Paris 2016

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FOREWORD

This Guidance Document for conducting pesticides terrestrial field dissipation (TFD) studies has been developed by an *ad hoc* Expert Group of the OECD Working Group on Pesticides (WGP).

Developing guidance for conducting terrestrial field dissipation studies is part of a global project that includes constructing an ecoregion crosswalk between North America and European ecoregions. The ecoregion crosswalk objectives are to: (i) identify similar eco-regions between North America and Europe; (ii) provide a GIS (geographic information systems)-based decision support to assist in the selection of regions for TFD studies; and (iii) provide background information on pesticide use areas (crop-based), soils and climate.

The outcome of the project is the present international guidance document for conducting pesticide field dissipation studies and identifying similar ecoregions. A harmonised methodology, based on a conceptual model and modular approach, is provided to conduct the study. This will allow for pesticide field dissipation/ accumulation studies conducted at foreign sites to be evaluated and considered by other countries and regulatory agencies.

In parallel to this guidance document, an ENASGIPS model – Europe-North America Soil Geographic Information for Pesticide Studies – has been developed and is available publicly (www.enasgips3.org). It is a GIS-based model for identifying similar ecoregions between Europe and North America and a tool for field site selection based on concerns identified in the conceptual model.

After two rounds of comments in 2014-2015 among the WGP and the Working Group of National Co-ordinators of the Test Guidelines Programme (WNT), the TFD Guidance Document was approved by the WGP and WNT in October 2015, and declassified in February 2015.

This document is being published under the responsibility of the Joint Meeting of the Chemicals Committee and the Working Party on Chemicals, Pesticides and Biotechnology.

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LIST OF ABBREVIATIONS

CV	Coefficient of Variation
DQO	Data Quality Objectives
DT_{50}	Refer **Appendix 2**
EEC	Estimated Exposure Concentration
EPA	United States Environmental Protection Agency
EXAMS	Exposure Analysis Modeling System
FAO	Food and Agriculture Organization of the United Nations
GIS	Geographical Information System
NAFTA	North American Free Trade Agreement
NRCS	Natural Resources Conservation Service, USDA
PMRA	Pest Management Regulatory Agency
PRZM	Pesticide Root Zone Model
RRA	Refined Risk Assessment
$t_{1/2}$	Refer **Appendix 2**
TDR	Time Domain Reflectometry
TFD	Terrestrial Field Dissipation
USDA	United States Department of Agriculture

I. INTRODUCTION

1. This OECD guidance for conducting terrestrial field dissipation studies (TFD) was prepared following the recommendations made by the *OECD Workshop on the Development of Harmonized International Guidance for Pesticide Terrestrial Field Dissipation Studies and Crosswalk of North American and European Eco-regions*, held in Ottawa, Canada, in March 2011. The workshop report published in the series on Pesticides, No. 68 is available on the Internet http://www.oecd.org/env/ehs/pesticides-biocides/seriesonpesticides.htm . The main purpose of this workshop was to elicit OECD country experts' input on issues related to harmonizing guidance for pesticide terrestrial field dissipation (TFD) studies. By sharing their views and expertise, the participants contributed to further progress towards harmonization among OECD countries in this scientific and regulatory area.

2. This document provides guidance on how to conduct terrestrial field dissipation (TFD) studies to demonstrate the transformation, transport and fate of pesticides under representative actual use conditions when a pesticide product is used according to the label. These field studies can help to substantiate the physicochemical, mobility and transformation data from laboratory studies, and indeed, may be a standard regulatory requirement in some jurisdictions. Environmental fate studies have shown that pesticide dissipation may proceed at different rates under actual field conditions and may result in degradates forming at levels different from those observed in laboratory studies.

3. The objective of this guidance document is to ensure that TFD studies are conducted in a manner that will provide risk assessors with more confidence in the data generated and with a better understanding of the assumptions and limitations of the data and estimated dissipation half-lives of the chemical. In addition, the TFD studies will provide the risk assessors with the end-points needed to carry out exposure and risk assessments according to supra national and national requirements in the EU countries. Properly designed field dissipation studies will also provide a feedback mechanism for testing the hypothesis generated during the problem formulation phase of the risk assessment. Often, the interpretation of the field results relative to the hypothesis of expected behaviour requires an understanding of the specific site conditions under which the study was conducted. **Appendices 1-11** provide examples of the data elements deemed critical for evaluating the hypothesis.

4. One method, which can be used to help in the design of a TFD study, is the 'conceptual model' approach. In this approach, a conceptual model is developed and environmental concerns are identified for an individual pesticide using assumptions derived from laboratory data in combination with the formulation type and field conditions under which the study will be conducted. In addition to the mandatory basic study, a TFD study includes only those fate processes that are significant to the pesticide in question. The conceptual model is based on the chemical's physicochemical properties, laboratory environmental fate studies, formulation type and intended use pattern. The conceptual model is therefore a prediction of the relative importance of each of the transformation and transport processes that may be involved in the dissipation of a pesticide under field conditions and represents the sum total of all potential dissipation processes. As such, it can be used as a working hypothesis for which aspects of dissipation the TFD studies should address. Although the responsibility for determining which processes are significant rests with the study sponsor, the regulatory authorities in EU, NAFTA and OECD countries may be consulted after the development of the pesticide-specific conceptual model if there is a question about whether a particular dissipation process (i.e., represented by individual study modules)

should be included in the study protocol. Through the use of the conceptual model approach, study sponsors should be able to provide data that are useful in the assessment and characterization of exposure and risk, fully support claims of dissipation in the final analysis, and reduce the number of rejected studies.

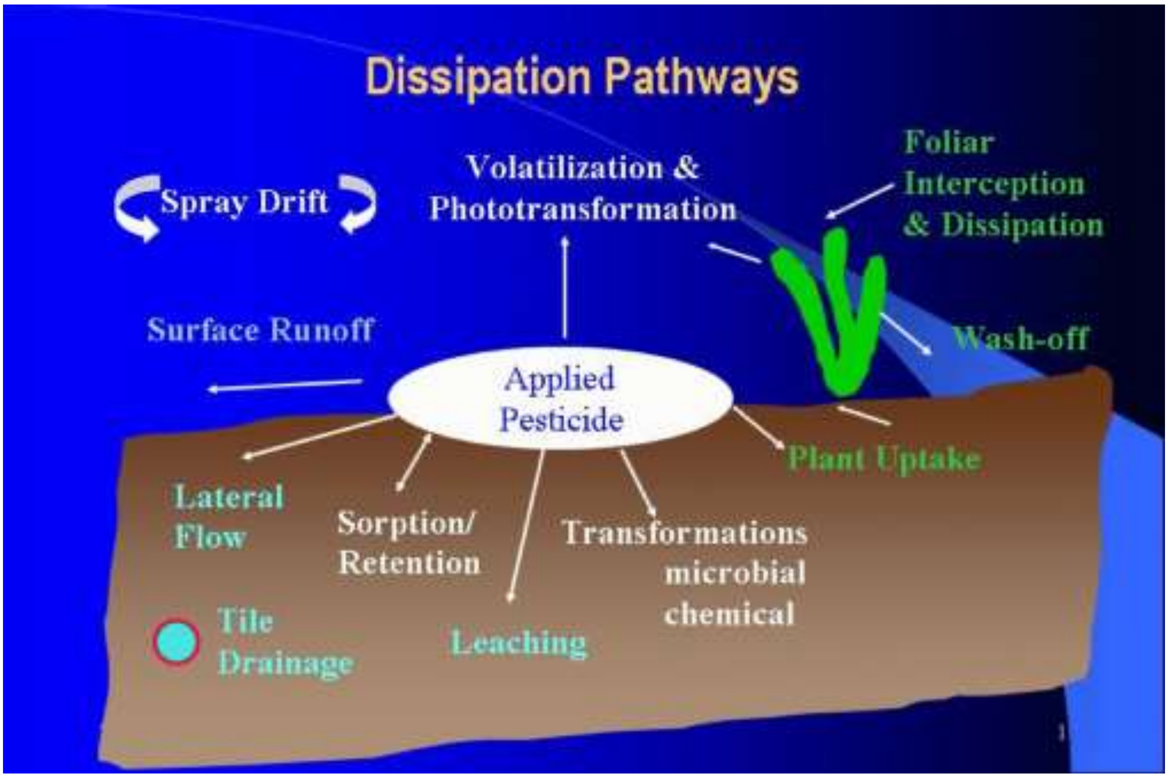
5. As the ecological risk assessment evolves, so does the need for more complete characterization of the data supporting the risk assessment. Critical in this characterization is an understanding of the assumptions and limitations inherent in the data. The TFD study is a keystone study that provides the primary means for testing the hypothesis of pesticide behaviour under actual use conditions. Although laboratory data is the foundation for the hypothesis and the basis for the conceptual model approach, the TFD study can provide a mechanism for testing and refining the hypothesis for the environmental fate and transport of a pesticide under actual use conditions.

I-A. Conceptual Model/Modular Approach

6. Well-designed Terrestrial Field Dissipation (TFD) studies answer the risk assessor's basic questions: Where did the pesticide go when applied in the field in accordance with label directions? How does the pesticide behave under field conditions? Different regulatory regimes have different end uses for the TFD; however, by using a conceptual model in the study design phase, the study sponsor can address this question by determining the overall rate of dissipation. In addition, the study sponsor can investigate, as appropriate, which routes of dissipation need to be evaluated in order to adequately characterize the behaviour of a pesticide in the field under actual use conditions. Where required by the appropriate regulatory regime, the study sponsor should consider a study design suited to answer the following questions: Is the chemical persistent and is there a potential for residue carry over? Does the chemical have potential for leaching and groundwater contamination? Does the chemical have potential for volatilization and long range transport? Does it form major transformation products or other transformation products of toxicological significance? Does the chemical have potential for surface runoff to non-target areas? In addition, the use pattern may need to be considered and steps taken to ensure that the overall study design accounts for potential formulation effects. Different designs may be necessary to investigate the effect of multiple formulation types, for example, granules and emulsifiable concentrates. The relative requirements of different regulatory regimes for TFD studies may be found by consulting their respective data requirements.

7. Before conducting a study, the study sponsor needs to carefully consider all potential processes and routes of dissipation as well as determine which of these are critical to answering the risk assessor's basic question (**Figure 1**)

Figure 1: Conceptual Model of the Factors Affecting the Field Dissipation of a Chemical



(Note: Not all pathways shown in this figure, such as spray drift, are tracked in the TFD study)

8. One way to approach the study design is to consider each route of dissipation or regulatory requirement for the TFD study as a potential study module. Using the conceptual model, the study sponsor can determine which modules are needed to adequately characterize the overall dissipation and active routes of dissipation in the chosen field. An advantage of this approach is that it offers flexibility in addressing data needs by including modules either concurrent with or separate from the basic field study. With this approach, not all modules need to be included in the same study. For example, runoff experiments may be conducted in separate plots, and volatility experiments may be conducted as separate experiments. Ultimately, the decision regarding when to include a module rests with the study sponsor.

9. Before initiating a TFD study, the study sponsor should develop a working hypothesis of the pesticide-specific conceptual model. This working hypothesis can form the foundation for optional consultations with the regulatory agencies and can be included as a section in the final report. The working hypothesis is the foundation for the pesticide-specific conceptual model and forms the basis for determining how well the study design captures the fate of the pesticide in the field under actual use conditions.

10. The working hypothesis should include estimates for each module's contribution to the dissipation process (quantitative and/or qualitative) based on laboratory physicochemical and fate properties. The study should include the basic modules and may include some of the additional modules, noting that:

(1) The basic modules for North American registration include:
   - Soil abiotic/biotic transformation

- o movement (leaching) down the soil column via soil concentration measurement

(2) The additional modules are:

- o Runoff
- o Volatilization
- o Leaching to depth
- o Plant uptake
- o Others

11. For the “basic Study” module (see section II), both North American and EU registration requirements have been met. The Basic Study is likely to address EU requirements for a TFD study in the circumstances that TFD studies have been triggered by the criteria in the EU regulations. Under certain circumstances, additional modules may be required for North American registration for certain pesticide products and their uses. For EU registration, an additional module (the Deg T_{50} module) may also be conducted as a higher tier option even when TFD studies have not been triggered as a regulatory requirement.

12. Mainly with respect to North American registration needs, the conceptual model described above should take in consideration anticipated conditions at the individual TFD study sites. These conditions include field soil properties compared to soils used in laboratory studies, weather data, water balance, formulation type, mode of delivery, crop influence (if any), agronomic practices and other factors. Additionally, laboratory estimated contribution to dissipation for each module (both quantitative and/or qualitative) should be described for both the basic study modules and any additional modules that are necessary based upon a review of laboratory data.

13. The study sponsor should consider the following when determining if an additional module, other than the basic study modules, should be included or excluded:

(1) Only those routes of dissipation that are included in the field can be claimed to significantly affect the fate of a pesticide and/or its degradates in the field. However laboratory studies may be more reliable to quantify certain dissipation processes, such as plant uptake.

(2) Additional modules should not be excluded from the study when data indicate that associated processes may contribute to significant pesticide dissipation or result in any pesticide dissipation of toxicological concern. Refer to **Section B**, below, for a discussion of indicators that are used to determine inclusion of additional modules).

(3) Ideally, when all modules are chosen, total dissipation attributed to excluded modules should not exceed 20%.

(4) Because drift modules are not included in the study, best application management practices should be used to minimize any loss due to spray drift.

14. Ultimately, it is the responsibility of the study sponsor to establish a hypothesis of the routes of dissipation (i.e., the conceptual model) that will affect the outcome of the TFD study. The TFD study should test the established hypothesis, and the final report should include the hypothesis and the results analysed in order to confirm or modify the hypothesis.

I-B. Additional Study Modules

15. Laboratory studies on adsorption/desorption, column leaching, solubility and persistence can predict the possibility of leaching beneath the root zone. The basic TFD study has traditionally incorporated a leaching component and requires analyses of soil cores extending below the surface (generally considered as 6 in. or 15 cm increments) to a given depth (Agriculture Canada, 1987; Fletcher et al., 1989; Cheng, 1990). If neither the parent nor degradates of concern are detected in all cores below a given depth, analysis of deeper cores is usually not necessary unless deep leaching is expected to occur. A conservative tracer, such as bromide ion, must be applied to the test plot to verify the depth of water leaching over the course of the study, when a leaching-to-depth module is included.

16. The basic TFD study focuses on pesticide dissipation (degradation and transport) from the soil surface layer in a bare ground study; it can be used to estimate field degradation only when other major routes of dissipation (e.g., leaching, volatilization, runoff and plant uptake) are quantified and shown to be negligible. In addition to the guidance described in this document, the regulatory authorities may require other dissipation studies to answer specific risk assessment questions. In deciding if an additional study module is necessary in a field study, the study sponsor should ask the following questions:

(1) Is the $DegT_{50}$ module required?

(2) What is the potential for dissipation of the parent compound and its major transformation products by a given route other than leaching (e.g., volatilization, photolysis, runoff, plant uptake, etc.)?

(3) Is the potential route of dissipation great enough to warrant measurement under field conditions representative of actual use?

17. In summary, the process of selecting modules to include TFD studies depends on the pesticide-specific conceptual model and the identified concerns, including data required for water modeling as defined in the conceptual model. The study design should anticipate the needs of the risk assessor who will rely on a clear explanation of the assumptions used in the development of the study design. Although not required, the study sponsor may consult with the risk assessor and the risk manager on the design of the pesticide-specific conceptual model early in the process. Early consultation will give the study sponsor time to assess the needs of the risk assessor and avoid unnecessary expenditure of time and resources. A well-developed pesticide specific conceptual model should be prepared and used as the basis for such consultation.

18. As noted above, the TFD study is a keystone study in that it provides the primary means for testing the hypothesis of environmental dissipation (transformation/degradation, transport) developed during the problem formulation phase of a risk assessment. The current guidance has been developed to provide the risk assessor with a better understanding of the assumptions and limitations inherent in the data, an improved perspective on the estimate of error in the study results and ultimately better confidence in the data generated. The guidance has been written to provide maximum flexibility for the study design while increasing confidence in the data. Therefore, the study designer should look to the overall hypothesis of pesticide fate based on a combination of data, including laboratory studies and physicochemical properties as well as climate, soil, agronomic and site characteristics. Once a hypothesis is developed, the study design may include additional modules as needed. The modules may be run concurrently with the basic field soil or may be plugged in using other data, as long as the data are scientifically valid and

appropriate. One of the most important points to remember when designing this study is that the results of the study describe the pesticide's major routes of dissipation in the environment.

19. In most cases, using the suggested criteria found in **Appendix 1** or a lines-of-evidence approach based on physicochemical properties and laboratory fate data is the best way to answer these questions and to determine if an additional module(s) should be included in the TFD study. Using this approach, the following modules should be considered in all phases of the study design:

20. **DegT$_{50}$ module:** This module is optional. The objective for including this module is to facilitate a higher tier option for generating a robust estimation of kinetic parameters that are used for estimating the DegT$_{50}$. In this case, the DegT$_{50}$ is the half-life due to degradation within the bulk soil matrix of the field.

21. First, the study sponsor should determine if inclusion of the DegT$_{50}$ module is necessary. The decision on whether or not to include this module could be based on the results of the first tier EU groundwater modeling (FOCUS modeling) or proposed terrestrial risk assessment using laboratory derived kinetic endpoints.

Second, the experimental design of module is left to the study sponsor; however, the following should be considered:

1. Apply only a single application to bare ground.
2. Minimize possible surface losses such as photolysis and volatilization by incorporating or watering in the pesticide by irrigation, or by covering the plot surface with a layer of sand (photolysis only) soon after application.
3. Use relatively small plots compared to the size of the plots used in a typical DT$_{50}$ module.

22. **Runoff module:** Runoff is possible for both weakly adsorbed, highly soluble chemicals and strongly adsorbed, slightly soluble chemicals. The former may runoff in the dissolved phase, and the latter may adsorb on the particulate phase. However, the potential for runoff often depends more on the type of formulation, cover crop, mode of application (e.g., surface application versus soil incorporation) and site factors (e.g., slope, type of soil, infiltration capacity and rainfall intensity) than on the chemical properties of the active ingredient(s) and transformation product(s). Depending on the conditions of the particular field dissipation study site, loss due to runoff may be a significant or insignificant component of pesticide dissipation from the surface. A simple runoff collector at the down slope edge of the field may be adequate to monitor for the amount of pesticide loss due to runoff from an unanticipated event (i.e., storm).

23. **Volatilization Module:** refer to **Section V**, below.

24. **Leaching to depth module:** This module should be considered when a chemical is identified as having a leaching potential in the conceptual model. It should also be considered when lower tier simulation modelling indicates a leaching potential for the test substance or its transformation products and when the results from deep leaching investigations might inform higher tier approaches for groundwater exposure assessment. It might also be selected if preferential flow or karst topography would be issues at an experimental location.

25. **Plant Uptake module:** For systemic pesticides and transformation products whose mode of action involves uptake through plant tissues (roots, leaves, etc.), this pathway may be a significant route of dissipation. (For example, plant uptake may be an important route of exposure for non-target

organisms, such as honeybees). The study sponsor can characterize this route by conducting a cropped-plot study in the field or by greenhouse studies on the same crop.

II. BASIC STUDY

26. The design of a field study depends on the predicted behaviour, concerns and major routes of dissipation identified in the conceptual model. A basic study in a bare soil plot should include determination of the concentrations of parent compound and major (or toxicologically important) transformation products over time and by soil depth in a representative use area using a typical formulation product. Additional modules include volatilization, runoff, leaching to depth/ groundwater, plant uptake and a design for estimating kinetics of transformation within bulk soil that aims to minimise dissipation processes, particularly those that occur at the soil surface ($DegT_{50/90}$).

II-A. Information on the Test Substance

27. The test substance should be applied in a suitable formulation; it may be possible to provide justification that a test formulation rather than a final formulated product is acceptable if the tested formulation would be unlikely to affect fate and behaviour of the substance under field conditions. Substances that are intended to be marketed in formulations that influence their rate of release into the environment should include testing with the end-use product(s). Such formulations cannot be substituted by other formulations if the environmental effects are assumed to not occur. (Appendix 2 contains a list of definitions and units discussed throughout this guidance document).

28. The TFD study should address the effect of pesticide formulation on dissipation where applicable. Different formulations may influence the fate or transport properties of the pesticide. For example, granular or microencapsulated formulations may release the active ingredient more slowly than emulsifiable concentrate formulations. For this reason, separate studies may be needed on representative formulations from the applicable formulation groups listed below if it is anticipated that these may influence dissipation behaviour. Applicants are strongly encouraged to consult with regulatory authorities with respect to which formulation types to test if it is anticipated that the final end-use formulation(s) may influence dissipation. If the various commercial formulations of a given pesticide are not expected to change the fate of the active ingredient, the applicant should provide the necessary justification in support of this assumption within the body of the study report. In general, it may be possible to compare a field study conducted using water soluble liquids/water soluble powders/emulsifiable concentrates with water dispersible liquids/wettable powders/water dispersible granules. However, separate field studies will be needed for microencapsulated and granular formulations unless convincing evidence indicates that these studies will not influence the dissipation behaviour. The recommended groupings of pesticide formulations are as follows:

1) Water soluble liquids, water soluble powders and emulsifiable concentrates:

The release of an active ingredient into the environment is controlled by the formulation type and the site-specific environmental conditions. Water soluble liquids and powders form true solutions when mixed with water, and emulsifiable concentrates consist of oil soluble pesticides and emulsifiers. These formulations are expected to have little effect on the transport of the pesticide in soil (Flury, 1996).

2) Water dispersible liquids, wettable powders and water dispersible granules:

Water dispersible liquids, wettable powders, and dispersible granules consist of finely ground solids of various dimensions. Various studies indicate that these formulations may affect the transport of pesticides in soil (Ghodrati and Jury' 1992; Hurto and Prinster, 1993 and Wauchope, 1987). For example, Ghodrati and Jury (1992) showed wettable powder formulations may be more resistant to preferential flow than emulsifiable concentrates and technical grade material dissolved in water.

3) Granules:

After precipitation or irrigation, granular formulations release the active ingredient gradually as a function of diffusion or leaching (Furmidge, 1984). Therefore, this formulation may have a significant effect on transport of the active ingredient if a rain event or irrigation occurs after application.

Granular formulations are of particular concern with respect to runoff if the granules are applied and not watered into the soil. To rely on rainfall to move the active ingredient into the soil always carries the risk of off-site movement via runoff.

4) Microencapsulated pesticides:

Microencapsulated/controlled-release formulations can reduce the potential of leaching through the soil (Flury, 1996), but may result in higher surface losses of a chemical when compared to other formulations (Kenimer et al. 1997). Available literature studies on the effects of microencapsulated and controlled-release formulations are inconsistent, and testing of this formulation type needs to be evaluated on a case-by-case basis.

5) Volatile and semi-volatile chemicals:

Highly volatile and semi-volatile chemicals (i.e., fumigants) are different from many conventional pesticides. Although fumigants can be applied as a solid, liquid, or liquified gas, soil fumigants rapidly volatilize and become a gas. In gaseous form, the fumigant can disperse and result in multiple dissipation pathways such as volatilization, runoff, and leaching from soil. Based on formulation type and laboratory studies, the study sponsor should identify the active ingredient(s) and the transformation products that must be tracked in the field. If the formulation product contains more than one active ingredient, the properties and data from laboratory studies for all the active ingredients must be provided.

6) Non-radiolabelled or radiolabelled substances can be used for the test although non-radiolabelled substances are preferred. The application of radiolabelled substances to field environments is subject to pertinent national and local regulations.

29. The following information on the test substance (and transformation products if available) should be included in the study report:

Description of the formulation product and active ingredient(s)

- Solubility in water (Cheng, 1990; Agriculture Canada, 1987; OECD, 1993; and US EPA, 1988)
- Vapour pressure (Cheng, 1990; Agriculture Canada, 1987 OECD, 1993; and US EPA, 1988)
- Henry's law constant

- *n*-octanol-water partition coefficient (Cheng, 1990; Agriculture Canada, 1987; OECD, 1993; and US EPA, 1988)
- Dissociation constant in water, reported as pK_a or pK_b (Cheng, 1990; OECD, 1993; and US EPA, 1988)
- Hydrolysis as a function of pH (Cheng, 1990; Agriculture Canada, 1987; OECD, 1993; US EPA, 1982; and Creeger, 1985)
- Photolysis on soil (Cheng, 1990; Agriculture Canada, 1987; US EPA, 1982; SETAC-Europe, 1995; and Whetzel and Creeger, 1985)
- Soil aerobic biotransformation (Cheng, 1990; Agriculture Canada, 1987; US EPA, 1982; SETAC-Europe, 1995; and Fletcher and Creeger, 1985)
- Soil anaerobic biotransformation (Cheng, 1990; Agriculture Canada, 1987; US EPA, 1982; and SETAC-Europe, 1995)
- Adsorption/desorption coefficients (Cheng, 1990; Agriculture Canada, 1987; US EPA, 1982; and SETAC-Europe, 1995).

30. These data are important in developing the conceptual model, identifying the potential routes of dissipation (modules) to be studied and aiding in the experimental design with respect to the sampling strategies, site locations, sample size and quantity, frequency of sampling, analytes to include in the analytical method, etc. The data are also necessary to interpret the results of the study. (Refer to **Appendix 3** for a data sheet that can be used in providing this information).

31. An appropriate analytical method of known accuracy, precision and sensitivity for the quantification of the active ingredient and major transformation products should also be included in the study. In most cases, cold (i.e., non-radiolabelled) analytical methods that are sufficiently sensitive to detect and monitor pesticide residues in the field are used. In order to be useful for terrestrial exposure assessments, the limit of quantitation (LOQ) of the chosen procedure should be less than 5% of initial concentration (molar mass) and should ideally be less than the important endpoints for non-target organisms. The analytical methods are subject to independent laboratory validation (Marlow *et al*., 1995; SANCO 3029/99 rev.4 of 11/07/00; OCSPP 850.6100), unless the analytical method was developed as part of the TFD study and is only used in the context of the TFD study. **Appendix 4** contains a description of environmental chemistry information that is needed for validating analytical methods used in conducting field dissipation studies.

II-B. Field Plot Systems

32. Plot size should be adequate to demonstrate the transformation, mobility and fate of the test material in soil under field conditions representative of actual use. The decision concerning the plot size in field studies should be based on factors such as application methods, crop and management factors, site characteristics and anticipated total number of samples. For pesticides typically applied to cropped or conservation tillage plots (e.g., with at least 30% crop residues on the surface), bare ground pesticide-treated plots are necessary to help distinguish dissipation pathways.

33. Large-scale studies (Birk and Roadhouse, 1964; Hunter and Stobbe, 1972; and Khan *et al*., 1976) are conducted using normal agricultural practices (e.g., cultivation prior to planting, etc.) and equipment. These studies may be used in combination with other field studies, such as crop residue studies, provided the TFD studies are not disturbed. Small plots (Chapman and Harris, 1982; Harris *et al*., 1971; Harvey, 1983; Hill, 1981; and Walker and Brown, 1985) are treated using research-plot application techniques (e.g., hand-held or backpack sprayers) that, in some cases, may reduce the variability seen in large-scale studies. These small-plot techniques can also limit

the ability to interpret results and obtain satisfactory pesticide dissipation curves. Large-scale and small-plot studies have the following characteristics:

1. Large-scale studies: Large-scale studies typically cover a treated area of 8 cropped rows by 25 m, but may range up to an entire field of several hectares, depending on the design of the experiment and the use for which the product is intended. Typical plot sizes range from 4 × 10 m to 10 × 40 m.

2. Small-plot studies: Small plots (e.g., up to 2 x 2-6 m or 4-12 m^2 in area) are preferable when pesticide dispersion is uneven and dissipation curves are difficult to generate or interpret.

34. It is important to select appropriate plot sizes depending on the chemical, number of core samplings required and management practices.

II-C. Site Selection

35. Field study sites should be representative of the soil, climatic and management factors under which the pesticide will be used. Selected sites should be typical of the proposed use areas or based on concerns (worst case scenario) identified in the conceptual model. For example, if the pesticide properties and laboratory studies indicate a potential for leaching and groundwater contamination, the selected site should provide ideal conditions for leaching, e.g., coarse textured soil, high rainfall, shallow groundwater table, low organic matter content, low adsorption (K_d and K_{oc}), etc. The following factors should be considered in selecting field study sites:

- Number of uses/crops
- Geographic extent and acreage of the crops/use patterns
- Soil characteristics
- Topography
- Climate (including temperature, amount and distribution of precipitation, solar exposure and intensity)
- Use and management practices
- Crop impacts on pesticide dissipation
- Pesticide formulation
- Timing, frequency and method of pesticide application
- Label restrictions regarding usage, sites or conditions

36. If selected field sites are not representative of the major use patterns, or use areas of the pesticide or not based on concerns, the applicability of the study results may be limited. Tools, such as geographic information system (GIS)-based decision support models or other GIS-based vulnerability assessment tools that account for the critical factors affecting pesticide dissipation, can be used to determine the most appropriate field sites (Kroetsch *et al*., 1998; Gangaraju *et al*., 2013; and Ruhman *et al*., 2013). It is strongly recommended to use ENAS_GIPS (Europe-North America Soil Geographic Information for Pesticide Studies) in selecting sites for field dissipation studies and in accepting studies conducted at foreign sites. The studies conducted at foreign sites in similar ecoregions are considered by other countries. This model uses ecoregion concept and is based on geospatial soil and agricultural crops databases, climatic information, and pesticide properties, including laboratory fate data. This model also helps to identify sites based on concerns (worst case scenarios) identified by the conceptual model and has the advantage that another field study may not be required if there is a use expansion to new areas or new crops. Comparable field

study area selection is based on environmental conditions and the conceptual pesticide dissipation model developed from laboratory fate studies.

37. The TFD study should include multiple field sites, generally four to six study sites. The actual number of sites needed depends on factors such as the types of formulations, the geographical extent of the use pattern, the number of uses and management practices as well as the range in soil and climatic conditions within the geographic extent of the uses. If pesticide use is limited geographically and/or to minor crops, a reduced number of field studies may be appropriate.

II-D. Field Plot Design

38. An assessment of the fate of the pesticide in the terrestrial environment should include all processes that can affect the fate of the chemical, including transformation, leaching, volatilization, runoff, and sorption to soil and plant uptake (Cheng, 1990). Terrestrial field studies should be designed, conducted and evaluated to assess the most probable routes and rates of pesticide dissipation under conditions representative of actual use. The physicochemical properties of the pesticide, laboratory environmental fate data, and application techniques/use pattern and site characteristics should be considered in designing the study.

39. The basic field study design evaluates field dissipation in soil at a bare ground site. If the pesticide-specific conceptual model suggests that volatilization, leaching, runoff or plant uptake are potentially important dissipation routes, then a modular approach is recommended whereby dissipation pathways that can be studied concurrently at one site are included, while those pathways that are incompatible are evaluated in separate studies.

40. The study design should encompass the range of practices and conditions that reflect the actual usage of the test substance. For all field dissipation studies, non-cropped (bare ground) plots must be included. If the sponsor considers that plant uptake of residues from the soil may be an important dissipation pathway, then the trial should be conducted with a cropped soil in addition to the non-cropped (bare ground) plots. Data generated from laboratory or greenhouse studies may be used to supplement the field data. However, the use of laboratory or greenhouse data will require an explanation of the conditions under which the data were collected and how any differences between conditions in the laboratory/greenhouse, the field study results, and the laboratory hypothesis may influence the evaluation of the field results. The studies should also include an untreated control plot.

41. Because of field-scale variability, the experimental units in each TFD study should be replicated. Replication serves the following functions (Steel and Torrie, 1980):

- Provides an estimate of experimental error.
- Improves precision by reducing standard deviation of a mean.
- Increases the scope of inference of the experiment by selection and appropriate use of variable experimental units.
- Effects control of the error variance.

II-E. Procedure

1. Site Characterization

42. Assessing pesticide dissipation requires detailed description of the site characteristics as well as characterization of representative soils at each test site. Ideally, the site selected for the TFD study should be represented by a single soil type in order to reduce variability in the field. Site characterization information is critical to assess *in situ* chemical and physical properties of the test soil.

a. Site Description

43. The study site should be described according to geographic coordinates (e.g., latitude, longitude), location on a map (e.g., topographic map, aerial photograph or soil survey map), landforms, landscape position, land surface configuration (e.g., slope length and gradient, aspect and direction, micro-relief, roughness, shape, elevation) and depth to groundwater. A suggested site description sheet can be found in **Appendix 5**.

b. Soil Characterization

44. At each site, a representative soil pedon should be identified, and a minimum of one soil profile should be described by soil horizons (preferably 1.5 m in depth) using standard soil morphological properties (depth to and thickness of horizons or layers, Munsell color, texture, structure, macro porosity, depth to a root restricting layer, etc.). Soil profiles will be described and classified at the family or series level (taxonomic description and classes) according to an internationally recognized system representative of the areas where the study is conducted. Taxonomic description should be compatible with the databases in the ecoregion crosswalk project extension, including those of the EU. The only three internationally recognized systems are the World Reference Base (WRB) of the Food and Agriculture Organization of the United Nations (FAO), the Harmonized World Soil Database and the US Soil Taxonomy of the United States Department of Agriculture (USDA), Natural Resources Conservation Service (NRCS). In addition to the description of soil morphology, information on the soil parent material, vegetation, erosion class, natural drainage class, surface runoff, infiltration and saturated hydraulic conductivity should be reported. It is also preferable to include the relevant soil moisture characteristics in SI units (kPa as well as bars). A suggested soil profile description can be found in **Appendix 6**.

45. Soil samples from each horizon should be collected and characterized by determining the physicochemical properties in the laboratory. The physical properties should include particle size distribution (i.e., % sand, % silt and % clay, with size fractions specified), textural class (according to ISO standard methods), undisturbed bulk density, and soil moisture characteristic curve (0-15 bar) to help determine the soil water balance throughout the study. The soil chemical properties should include pH, percentage of organic carbon and cation exchange capacity. Internationally recognized standardized methods (e.g., ISO, OECD, U.S. standard methods, etc.) should be used and referenced for the determination of these properties. Depending on the chemical properties or use site, additional analyses of the surface soil layer or epipedon and the subjacent horizon (layer) may be helpful for determining sorption potential at the field site. Additional analyses include clay mineralogy, specific surface area and anion exchange capacity, especially in soils dominated by low activity clays or derived from volcanic materials. A suggested format for reporting the soil properties is given in **Appendix 7**.

c. Environmental Conditions

46. Historical climatological data should be obtained to help evaluate site data with respect to long-term regional variation, and the source and location of the historical data should be specified. Historical climatic information should include monthly average rainfall, average monthly minimum and maximum temperatures, and the dates and the number of days in the average annual frost-free period. A suggested format for reporting the historical meteorological conditions is given in **Appendix 8**.

d. Management History

47. Information on the use of the study site, for example, crops grown, pesticides and fertilizers used, should be provided for the previous three years. The site selected should not have a history of the use of the study pesticide or other pesticides of similar nature (chemical class, common non-volatile transformation products, etc.) for at least three years prior to the study. This requirement is necessary to reduce analytical interferences and potential microbial adaptations for the test. Management factors, such as tillage and cultivation methods, irrigation practices, etc., should be described in detail. A suggested format for reporting the land use and management history can be found in **Appendix 9**.

2. Application of the Test Substance

48. In the TFD study, the pesticide product should be applied at the maximum proposed use rate utilizing the same application method(s) as stated on the label. In limited instances (e.g., for ultra-low application rates), it may be necessary to apply the pesticide at a rate greater than the maximum proposed use rate due to analytical detection limits.

49. Recommended equipment for pesticide delivery in the TFD study should be of high precision, suited for the particular pesticide formulation (some pesticides may need to be homogenized by a continuous mixing device in the tank) and outfitted with a device to keep drift loss to a minimum.

50. The pesticide application, including timing and the number of applications, should be consistent with labelling. However, to be appropriate for robust calculation of dissipation of active substance (and where appropriate, metabolites), the maximum total annual or seasonal dose should be applied in a single application. Where the maximum total annual or seasonal dose is to be applied, care should be taken that the dose does not influence soil microbial functions. The pesticide application should:

- occur at the typical time(s) of the year and stage(s) in crop development when it is normally used;
- be performed according to label instructions for the specific formulation;
- be incorporated if the pesticide is typically incorporated; and
- be measured by spray cards or similar verification techniques and related to the target application rate and measured concentration in the spray tank.

3. Study Duration

51. The duration of the TFD study, which has historically taken up to two years to complete, should be sufficient to determine the DT_{90} of the parent compound as well as the pattern of formation and decline of major transformation products in the soil. Whilst in an ideal situation the basic study should be conducted until 90% dissipation has been achieved, there are potential circumstances in which there may be limited practical advantage to continuation of the study where the aim of the study is limited to estimation of the persistence of the applied substance and its metabolites/breakdown products. Therefore it may be possible to provide a justification to terminate the basic study before 90% dissipation of the applied substance has been reached, provided that the reasoning is robust and supported by the collected data. However, it is extremely important that the specific use of the TFD basic study within the regulatory framework where the submission is being made and the reasons for early termination are considered extremely carefully. In situations where 90% dissipation of the applied substance has not been reached, there is no absolute maximum or minimum duration of the study, but the study must have experienced multiple yearly cycles of weather conditions. Slow decline due solely to cold soil temperature or low soil moisture must also be eliminated as reasons for any slowing of observed declines. Study directors must consider the possibility for biphasic behaviour or plateauing of decline to manifest itself after the early termination point as this could impact estimates of predicted soil concentrations where such persistent substances are likely to be used either in successive years or in rotational situations. A way of reliably estimating potential for accumulating concentrations that includes slow phases where biphasic kinetics can occur is also important for informing appropriate rotational crop metabolism and residues trials that support the consumer risk assessment and MRL setting. In addition, where metabolites/degradation products have been identified in laboratory studies which need to be investigated under field conditions, the potential for compromising the elucidation of the behaviour of those metabolites/breakdown products must be taken into consideration. This is not an exhaustive list and illustrates that the decision to terminate the study before 90% dissipation is achieved is potentially complex.

52. In determining the decline of the major transformation products, the study duration should be sufficient to determine the time required for major transformation products to dissipate to 10% of their maximum detected values in the soil. A major transformation product is one accounting for ≥10% of the applied amount at any time during the laboratory studies, or one that has been identified as being of potential toxicological or ecological concern. In the EU, though, this >10% criteria is applied when: (a) transformation products are formed at > 5% of the applied at any time during the laboratory incubations for more than two consecutive sampling times and (b) when, at the termination of laboratory incubations, concentrations have reached 5% but are still increasing. Therefore it is recommended that these additional EU criteria be applied for defining the transformation products when the EU lab incubation DT criteria (Lab $DT_{50}/_{90}$ >60/200 days at 20°C and pF 2 soil moisture) for triggering field investigations are reached.

4. Management

53. The management (e.g., fertilization, seed bed preparation, weed control, sowing and tillage) of the field dissipation study site should be carried out in accordance with good agronomic practices. Tillage practices prior to application (conventional tillage, conservation tillage or no-till) should be typical of those used for the particular crop and label recommendations, or after application where they encourage shallow incorporation of the test substance. Deeper tillage operations that might be associated with specific crops are not recommended if these were to occur after application of the pesticide.

5. Irrigation

54. It is important that the study design include sufficient water to meet the crop need in quantity and timing. Any irrigation applied should be based on normal agronomic practices for the region in which the site is situated. If the use pattern includes irrigation to supplement the water requirements of the plants, then the study should be conducted under irrigated conditions. In this case, the study design should ensure appropriate timing and sufficient water to meet a minimum of 110% of the crop need. In the case of bare plots, the site should receive sufficient excess water at the appropriate time to provide an additional minimum 10% of the target crop water demand so that the amount of excess water applied to the bare plot is equivalent to the amount of excess water that would have been applied if the crop had been present. Alternatively, if the use pattern does not involve irrigation, then the field studies do not necessarily have to be conducted with supplemental irrigation. However, it may be necessary to prepare the site for irrigation in case of drier than normal conditions. For non-irrigated sites, the study design should ensure that a minimum of 110% of normal monthly rainfall is delivered to the site.

6. Environmental Conditions and Monitoring

55. Measurement of meteorological variables is necessary to understand pesticide dissipation in the field. Daily records of maximum, minimum and mean temperature (air and soil), total precipitation, mean wind speed and potential evapotranspiration are recommended from five days prior to the first application of the pesticide through to the conclusion of the study. Modelling approaches for soil temperatures and moisture from air temperatures and precipitation may be acceptable. When irrigation is used to supplement rainfall, timing and amounts of irrigation water should also be reported**.**

56. The following environmental conditions should be recorded daily at the study site:

- Precipitation and irrigation
- Mean air temperature
- Potential evapotranspiration or pan evaporation (can be determined from a nearby site, or evapotranspiration may be calculated from other environmental data)
- Hours of sunshine and intensity of solar radiation
- Mean soil temperature
- Soil moisture content

57. It is recommended to take soil moisture samples for measurements in 0 to 5 cm and 5 to 10 cm depth for the purposes of generating a $DegT_{50}$.

a. Soil Water Balance

58. Soil water content can affect the mode of degradation, degree of microbial activity, potential for volatilization, plant growth and potential for movement (i.e., up or down in the soil profile). To interpret routes and patterns of dissipation of the test substance, the soil water content needs to be measured on a regular basis to adequately determine the flux of soil water. Continuous or daily measurements are preferred, but at a minimum, readings should be collected at each sampling time. Various methods of measuring soil water include tensiometers, time domain reflectometry

(TDR), neutron probes, gypsum blocks and direct measurement of the moisture content of the soil samples (Klute, 1986).

b. Using Tracers to Track the Potential Depth of Leaching

59. A conservative tracer can be applied along with the test chemical to help determine the direction, depth and rate of soil water movement through the vadose zone. Tracer selection should consider the chemistry of the tracer, including potential sources of interference, background/baseline levels, analytical detection limits and potential losses such as plant uptake. If a tracer is used, background concentrations need to be analysed prior to the study.

c. Soil Temperature

60. The soil temperature can also affect the rate of degradation, degree of microbial activity, potential for volatilization, plant growth, and potential for and direction of water movement (i.e., up or down in the soil profile). Soil temperature should be measured at depths and at time intervals relevant to the expected primary distribution of pesticide residues. Alternatively, modelling approaches may be used to derive soil temperature profiles.

7. Soil Sampling

61. Soil samples for residue analysis should be representative of each replicate plot at each sampling time. Replicate plots can be defined as repetitive, homogeneous sections of a field treated with the test pesticide in a similar manner to allow comparison between treatments. Sampling procedures can have a major effect on variability of pesticide concentrations in soil; accurate and consistent sampling is vital for meaningful results. Variables such as plot size, soil variability, crop management practices, pesticide application method and existing knowledge of the behaviour of the pesticide in the environment should be considered in designing an appropriate soil-sampling protocol.

a. Sampling Patterns

62. Soil core holes should be marked after sampling. Filling holes with soil from untreated areas of the site or replacing the removed core with a blank coring tube to the same depth of sampling will prevent the cross-contamination at greater depths and subsequent anomalous results. Cores should be marked so that another sample will not be taken from the same/nearby sampled core.

63. A random or systematic soil sampling pattern (Roadhouse and Birk, 1961) may be followed, depending on the type of pesticide application and other variables listed above. For example, the soil may be sampled in-row only (e.g., seed furrow or band treatment) or by a random pattern that covers the entire treatment area (i.e., broadcast application). Because it may be difficult to obtain interpretable results using an in-row sampling pattern, extreme care should be taken in the application and sampling procedures.

64. In order to avoid variability resulting from possible under-coverage, drift or edge effects, outside rows of treated areas should be excluded from sampling.

65. In small plots, systematic sampling is preferred to ensure that all treated sectors of the plot are represented and to make it easier to avoid sampling from a previous core hole or in zones where spray patterns in successive passes of the application equipment may have overlapped or failed to cover the surface adequately.

66. Larger diameter cores are expected to reduce variability in the field. Typically, a core of 2.5 cm to 5 cm (1 to 2 inches) in diameter has been used in TFD studies, but use of larger diameter cores should be considered in the field design.

b. Depth of Soil Sampling

67. In order to fully demonstrate the fate and transport of the pesticide under study, soil should be collected from a depth sufficient to encompass the vertical distribution of the pesticide and its major transformation products at each sampling time. Data from laboratory studies (physicochemical properties, mobility and transformation) can be used in conjunction with water recharge estimates (e.g., average rainfall data and expected irrigation coupled with evapotranspiration estimates) and soil permeability properties to establish appropriate core depths. Soil sampling should typically proceed to at least a depth of one meter, particularly for pesticides with laboratory fate characteristics that indicate leaching is an important route of dissipation.

68. The major transformation processes usually occur within the biologically active zone of the soil. For sampling purposes, this zone can be defined as the maximum depth of tillage, rooting depth of agronomic plants or the depth of an impermeable soil layer, whichever is deepest. If the laboratory studies indicate a low potential of a pesticide to leach, the emphasis of soil sampling designs should be placed on this zone of soil rather than sub-soils. The biologically active soil zone concept will allow flexibility in experimental design because of different agronomic practices, types of soil and site characteristics.

69. For most studies, soil cores should be collected to 1 m in depth and divided into six or more depth increments for analysis (e.g., 15 cm, 15 cm, 15 cm, 15 cm, 20 cm and 20 cm). For low application rate pesticides or where the results of the laboratory studies indicate very low mobility of the parent chemical and its major transformation products in soil, core depths could be sectioned into shorter increments to circumvent dilution of the chemical residues with excess soil. In all cases, analysis of the sectioned cores should clearly define the extent of leaching of the parent chemical and its major transformation products in the soil profile.

70. Soils should be sampled to a sufficient depth such that the lowest section of the sampled cores does not contain detectable amounts of the active ingredient or major transformation products. In the absence of rainfall or irrigation, the initial or zero time samples can be taken to at least one sample increment below the depth of incorporation. For example, a pesticide incorporated to 3 inches below the surface should be sampled from 0 to 6 inches (15 cm) and from 6 to 12 inches (15 to 30 cm), assuming a 6-inch (15 cm) interval.

c. Times of Soil Sampling

71. Soil sampling should be carried out prior to treatment, immediately after treatment (zero time) and at increasing intervals (daily, weekly, monthly) between sampling times. If more than one application is made, then soil sampling should be done just before and immediately after each application and then at increasing intervals after the last application. Time intervals should be based on the results of laboratory studies and other field studies, if available. Sampling frequency should consider laboratory half-life estimates with increased frequency of sampling for shorter half-life compounds. Other factors that may affect sampling frequency include compound mobility and site-specific environmental conditions (e.g., rainfall and micro-climate). The frequency of sampling should be concentrated after each application time to characterize the dissipation of the test substance. However, the number and distribution of sample times should also be sufficient to

adequately characterize the formation and decline of the transformation products. The dissipation of a product used in multiple applications over a season should be studied through a full cycle of applications (Hill, 1981).

72. Residue data should be obtained until at least 90% of the pesticide and/or its major transformation products have dissipated from the soil profile or the pattern of dissipation has been clearly delineated (US EPA, 1975a and Smith, 1971). The study sponsor should determine the DT_{50} and DT_{90} from the initial concentration because the dissipation rate constant often decreases with time (i.e., the half-life is not constant as in first-order kinetics). If 90% dissipation is not reached by the time of freezing temperature in the fall (autumn), the study should be continued in the following year(s).

73. The plot should be sampled at the end of the growing season to determine residue carryover to the next season; sampling in subsequent years may be necessary. Long-term studies may be recommended if dissipation is slow to occur. This is particularly important for persistent, low mobility pesticides or for those chemicals that show pesticidal activities at low concentrations.

74. Soil sampling of the control plot need only be conducted during the early stages of the study with a sufficient number of samples to demonstrate absence of the pesticide prior to application and to provide control soil for use in the analytical phase fortification and recovery experiments

d. Time Zero Sampling

75. The time zero concentration lays the foundation for all subsequent sampling and is used to build confidence that the pesticide was applied uniformly and accurately. The following points should be considered in developing a time zero sampling protocol for a single application on bare ground:

- Availability of an appropriate analytical method with limits of quantitation low enough to detect the parent and key degradates at relevant concentrations
- Handling of all fortification samples in the same manner as soil samples
- Testing of verification devices before use to provide confidence in compatibility with the test substance
- Verification of the actual rate applied
- Calculation of an expected concentration in the field
- Comparison of time zero concentrations with the expected concentration

76. For multiple applications, each application should be treated as time zero, and concentrations prior to and immediately after application should be determined.

77. For cropped plots, the time zero sampling strategy should be modified to measure the portion of pesticide reaching foliage as well as the portion reaching the ground surface.

78. The initial concentration in the soil immediately after treatment ("time zero") is a crucial benchmark value. Time zero sampling is recommended to verify residue concentrations reaching the target and to confirm uniformity of its distribution. The pesticide residues in all subsequent soil samples are evaluated in relation to this benchmark value. It cannot be emphasized enough how critical accounting of a pesticide at time zero is ~~are~~ for the evaluation of the study results. Ideally, a

study should utilize techniques that maximize the delivery of the pesticide to the field at the target rate and keep the differences between measured and target rates to a minimum.

79. Determination of time zero concentration involves soil sampling immediately after application. Preferably, actual time zero sampling is conducted in duplicate, and the two sets of soil samples are processed separately to provide two estimates of the mean time zero concentration. Time zero sampling data should be used to confirm that the pesticide was applied uniformly to each plot. Techniques used and any deficiencies associated with the delivery of the pesticide to the field should be described and accounted for when analysing the study results.

80. Although not routinely required, there may be instances where a cropped plot should be sampled concurrently with a bare soil plot. In this case, the following factors should be considered in the sampling strategy of a well-designed protocol:

- Time zero samples
- Types of samples (i.e., soil versus plant) and sampling frequency
- Sample locations (e.g., between rows, under rows)
- Accounting for plant uptake versus foliar dissipation
- Residues in roots
- Chemical factors such as formulation and application method
- Crop characteristics

e. Number and Pooling of Samples

81. The purpose of soil sampling in the TFD study is to measure the mean concentration of the pesticide and its degradates or transformation products so that dissipation may be followed quantitatively over time. In order to generate a reliable estimate of the mean concentration that represents the entire treated plot, a sufficient number of core samples should be taken to achieve acceptable variability in the concentration across the plot. The number of cores needed to estimate the mean concentration (statistically, the sample size) will then depend on the desired precision (i.e., standard deviation around the mean) and the variability of the pesticide concentration in the field (the field or population variability).

82. The statistics of this estimation were developed several years ago (Gilbert, 1987) and have been made into a calculator (DQO-PRO) by EPAs Superfund program to support the development of Data Quality Objectives (DQOs). The DQO process is an experimental design exercise intended to quantitatively define the sampling effort, given the data precision needed to support decision-making.

83. In the case of the TFD study, the major DQO is measurement of the mean concentration at each sampling time with a small enough error (standard deviation) that the means at different sampling times over the course of the study can be used to calculate a statistically significant rate of dissipation from the soil. Data presented by Jones *et al.* (2004) at the 227th American Chemical Society National Meeting suggest that the standard deviation among 16 samples individually analysed from a variety of TFD studies is about 110%. (This analysis provides an estimate of field or population variability). Further analysis by industry (Van Wessenbeck, 2004) suggests that the variability in calculated half-lives is less than the variability of the mean concentrations from which they are calculated (assuming constant variability of the soil means over the course of the

study), and that standard deviations of up to 100% in the mean concentration result in tolerable error for half-lives up to one year in length.

84. The following table, based on calculations with DQO-PRO, provides the number of individually analysed cores needed to estimate, at a 95% confidence level, the mean concentration at any time, within a known error (standard deviation), given various assumptions about the population variability. Using the assumption of 110% for a population, a sample size of 15 or 16 cores is expected to estimate the mean concentration to within 60% standard deviation. (The actual number of cores calculated by DQO-PRO was 16, but 15 facilitates the use of 3 replicate subplots.)

85. The TFD study sponsor may use 15 cores per sampling episode as a minimum, although this minimum number implies that the mean concentration calculated from the 15 cores is no more precise than the 60% coefficient of variation (CV). If the cores are composited before analysis, the standard deviation of the results should be corrected for compositing. (Note: If the standard deviation calculated from the core analysis is greater than the expected 60%, the assumption of 110% CV in the field population may not be valid, and a larger number of cores should be collected.)

86. If greater precision is desired to support more quantitative uses of TFD study results, or if greater than 110% variability in the field is expected, then the study sponsor should use **Table 1**, below, or the DQO-PRO calculator to find the number of cores necessary to achieve the desired level of precision (Keith *et al*, 2001. http://www.instantref.com/dqopro1.htm).

87. In **Table 1**, the shaded area indicates the tolerable error that can be achieved in estimating the mean concentration (top row) when 30 to 45 cores are taken from fields having variable concentrations indicated by the CV figures in the left-most column (population). These calculations assume that samples are analysed individually or that a correction for compositing is made. For example, if a 200% population (field) CV is assumed, 34 cores will estimate the mean concentration to within 70% error, and 46 cores will estimate it to within 60% error, after correction for compositing. If a 100% population (field) CV is assumed, then 46 cores will estimate the mean concentration to within 30% error, after correction for compositing.

Table 1. Tolerable Error in Estimation of Mean Concentration

Population (field) % CV	**Tolerable Error in Estimation of Mean Concentration (%) Number of Non-composited Cores Needed to Estimate Mean to within Tolerable Error at 95% Confidence**									
	100 %	**90%**	**80%**	**70%**	**60%**	**50%**	**40%**	**30%**	**20%**	**10%**
200	18	22	27	34	46	64	99	174	387	1540
190	17	20	25	31	41	58	90	157	350	1390
180	15	18	22	28	38	53	81	141	314	1248
170	14	17	20	26	34	47	72	126	280	1113
160	13	15	18	23	30	42	64	112	249	986
150	12	14	16	21	27	38	57	99	219	867

Population (field) % CV	Tolerable Error in Estimation of Mean Concentration (%) Number of Non-composited Cores Needed to Estimate Mean to within Tolerable Error at 95% Confidence									
	100 %	90%	80%	70%	60%	50%	40%	30%	20%	10%
140	11	13	15	18	24	33	50	87	191	756
130	10	11	13	16	21	29	44	75	165	652
120	9	10	12	14	18	25	38	64	141	556
110	8	9	11	12	16	22	32	55	119	468
100	8	9	9	11	14	18	27	46	99	387
90	-	8	9	10	12	15	22	38	81	314
80	-	-	8	8	10	13	18	30	64	249
70	-	-	-	8	9	11	15	24	50	191
60	-	-	-	-	8	9	12	18	38	141
50	-	-	-	-	-	8	9	14	27	99
40	-	-	-	-	-	-	8	10	18	64
30	-	-	-	-	-	-	-	8	12	38
20	-	-	-	-	-	-	-	-	8	18

88. Finally, certain principles apply to the study design, regardless of the intended use of the study results. The number and diameter (typically 3 to 12 cm) of soil cores should be based on the size of the plot, the type of soil and the amount of soil necessary for analysis. Corresponding depths of soil cores from a single replicate plot can be pooled and mixed thoroughly to produce one representative composite sample that can be analysed. An adequate number of cores per plot should be collected at each sampling time to ensure the sample is representative of the plot. For example, a composite sample from a 2×1 m small plot may consist of 15 soil cores (3-cm diameter) per sampling time over a period of one year (Chapman and Harris, 1982; Harris *et al*., 1971; Chapman and Harris. 1980a; and Chapman and Harris, 1980b). In large plots, cores of greater diameter are usual (Birk and Roadhouse, 1964 and Roadhouse and Birk, 1961). The variability within a large plot is typically greater than in a small plot because of less uniform pesticide application and soil spatial variability. For field studies of longer duration with small plots, the plot area should be increased to accommodate collection of a greater number of cores, resulting from an increased number of sampling times. If a large-scale plot contains areas of different types of soil, soil organic matter content, etc., or knolls/depressions, then representative cores from areas of different soil types should be pooled and analysed separately from other samples.

f.Handling of Samples

89. Soil samples should be handled in the following manner.

- Soil samples should be deep frozen as soon as possible (at least within 24 h) if they cannot be extracted immediately.
- Air-drying of soil samples before extraction is not recommended because of possible loss of chemical residues from the samples via volatilization.

90. Sample transport, processing and storage procedures should be demonstrated to have no significant effect on the residues present in the analytical sample. This can be achieved by storage stability data and by comparison to field spiked samples transported/processed/stored similar to the core samples. Where there is evidence that comminution (cutting and homogenisation) at ambient temperature has a significant influence on the degradation of certain pesticide residues, it is recommended that samples be homogenised at low temperature (e.g., frozen and/or in the presence of "dry ice").

8. Sampling of Other Media

91. Measuring pesticide residues in soil over time provides direct information on a limited number of dissipation routes, e.g., transformation, sorption and leaching. Other dissipation routes that often play major roles in the environmental fate of a compound include accumulation and metabolism in plants; volatilization from soil, water and/or plant surfaces; soil binding; runoff; and spray drift. To meet the objectives of the TFD study and to determine where the pesticide goes in the environment, the study sponsor may need to design the sampling scheme to account for routes of dissipation that cannot be accounted for through soil core sampling alone.

a. Sampling Plants and Foliage

92. Refer to plant uptake module for details (**Section VII**).

b. Air Sampling

93. Refer to volatilization module for details (**Section V**).

c. Sampling for Pesticide Residues in Runoff

94. Refer to runoff module for more details (**Section IV**).

9. Sampling Strategies to Increase Sensitivity

95. Strategies that could be used to increase the detection sensitivity of pesticides in TFD study samples include the following:

- Decreasing the thickness of sample soil depth (thinner increments)
- Increasing the area of soil or foliage samples
- Increasing the volume of runoff water or air samples
- Increasing the application rates, if appropriate
- Increasing the number of replications, if appropriate

- Refining/improving analytical methods for parent and major transformation products
- Improving recovery efficiencies

II-F. Data Analysis, Interpretation and Reporting

1. Statistical Analysis

96. Data gathered from the study should be analysed by statistical methods that describe the pesticide's rate of dissipation. Methods should be specified and consistent with the study design; goodness of fit of the data to the statistical analysis should be provided. Analysis should emphasize the dissipation of the pesticide from the upper soil layer to which the pesticide is applied, as well as comparisons of within-site and among-site variability.

2. Data Interpretation and Quantitative Assessment

97. An evaluation of the data collected in the field dissipation study and interpretation of the results should include the following considerations:

- Half-life and times for 50% and 90% dissipation of the parent chemical (DT_{50} and DT_{90} respectively) under field conditions, determined from the residue data;
- Dissipation parameters of the major transformation products (e.g., quantities and rates of formation and decline, including kinetic formation fraction from a precursor, DT_{50} and DT_{90}); vertical movement of detectable residues of the parent compound and the major transformation products under field conditions;
- A comparison of the dissipation and mobility parameters from the field studies with corresponding results from laboratory studies and predictions based on the pesticide physical/chemical properties (e.g., solubility in water, vapour pressure, Henry's law constant, dissociation constant and *n*-octanol-water partition coefficient);
- If relevant, plant uptake of pesticide residues in the field compared with that under laboratory or greenhouse conditions, within the context of the experimental parameters at the field site, e.g., application, climatic (precipitation and temperature), edaphic (soil properties and moisture conditions) and cropping parameters; and
- Identification and discussion of discrepancies between the results of field studies and predictions based on conceptual model.

3. Mass Accounting Considerations

98. The residue data for the parent chemical, each of the major transformation products and the total major chemical residues should be expressed in terms of equivalent amounts of parent chemical on a dry-weight basis, and then as percentages of the 0-day concentration. These percentages can then be summed for the sampled environmental compartments (e.g., soil depths, air, water, and plants) and plotted *versus* time to estimate an overall mass accounting. If the overall mass accounting is unexpectedly low, major route(s) of dissipation are possibly not adequately addressed in the field study design. In that case mass balance laboratory studies with radiolabelled compounds can be used to infer the magnitude of these pathways.

4. Reporting

99. The study report should be clear and succinct with definitive conclusions regarding the environmental fate and transport of the pesticide after field application. Soil samples results should always be reported on a dry-weight basis along with percent moisture. The study conclusion should be discussed both in terms of the data developed in the field study and in terms of the expected route(s) of dissipation suggested by the laboratory studies. Discussion of how the study compares with other field studies of this active ingredient should be included. The report should clearly identify those aspects of the study having a direct bearing on the author's conclusions and the validity of the study results.

100. In addition to a full description of the analytical methods used, the following data should be reported:

- Information on the test substance and relevant transformation products:
    - Formulation of the test substance
    - Limits of analytical detection/quantification
    - Physicochemical and environmental fate properties
    - Specific activity and labelling positions (if appropriate)
- Information on the field study site:
    - Location
    - Climatic conditions and history
    - Soil taxonomic classification and properties with depth
    - Hydrologic setting
    - Size and configuration of the treatment and control plots
    - Crop, management and pesticide-use history
    - Depth to the water table
- Application of the test substance:
    - Time(s) of application
    - Rate(s) of application
    - Method of application
    - Confirmation of application rate
    - Field condition at the time of application
    - Meteorological conditions at the time of application
- Tracer(s) used, if any:
    - Type of tracer(s)
    - Rate and method of application
- Maintenance activities:
    - Type of vegetation
    - Agricultural practices (date of seeding, time of harvest, yields, etc.)
    - Weed control
- Conditions during test:
    - Daily air temperature (minimum, maximum)
    - Daily precipitation and irrigation (reporting of single rainfall events), intensity and duration
    - Irrigation technique
    - Weekly and monthly sums of precipitation and irrigation

  - Weekly mean soil temperature
  - Soil water content
  - Daily evapotranspiration or pan evaporation
  - Movement of tracers (if used)

- Residues in soil (as mg/kg dry weight and % of applied amount) at each sample interval:
  - Concentration of test substance in each soil depth
  - Concentration of transformation products in each soil depth
  - Concentration of extractable radioactivity in each soil depth, if applicable
  - Concentration of non-extractable radioactivity in each soil depth, if applicable
  - Total amounts of test substance, transformation products, other unidentified extractable residues and non-extractable radioactivity, if appropriate

- Residues on and in plants (in mg/kg fresh weight and % of applied amount) at each sample interval, if appropriate. In addition, plant residues should be reported based on how much of the pesticide was removed from a unit area of the field in order to be useful in mass accounting.

- Residues detected via other avenues of dissipation (e.g., volatility, runoff, leaching), if appropriate

- Mass accounting (recovered percentage of applied test substance) at each sample interval

- Appropriate statistical analyses of the collected data

- Protocol deviations and amendments

101. Data should be presented in both tabular and graphical forms.

III DEGT$_{50}$ MODULE

102. This guidance for DegT$_{50}$ is specifically provided to meet field data requirements for European regulatory agencies.

103. The objective of the DegT$_{50}$ module is to provide guidance for field studies which estimate the degradation half-life (DegT$_{50}$) in top soil at 20^{o}C and at a moisture content corresponding to field capacity, following inverse modelling procedures (time step normalization) proposed by EFSA (2014). These DegT$_{50}$ values are used in combination with DegT$_{50}$ values from laboratory aerobic soil incubation studies to assess the geomean DegT$_{50}$ in top soil at 20^{o}C and at a moisture content corresponding to field capacity for the area of use of the substance. This geomean is used as an input parameter in simulation models that estimate environmental exposure to pesticides (leaching to groundwater, exposure of aquatic and soil organisms) within the EU. Environmental exposure assessments are usually based on the median DegT$_{5}$0 in the area where the substance is used, and the geomean is considered the best estimator of the median (EFSA, 2012).

104. In the context of the DegT$_{50}$ module, FOCUS (2006) treats soil bound residues as degradation products with regards to the definition of degradation. Definitions of bound residues, in this context, are also defined in FOCUS (2006).

105. For exposure assessments, it is essential that the DegT$_{50}$ reflects the degradation rate within the soil matrix (DegT$_{50matrix}$) and excludes other loss processes such as photodegradation or volatilization. This result can be achieved either by designing the experiment in such a way that the measured decline reflects almost exclusively the degradation in the soil matrix (e.g., by incorporating the

dose immediately after application) or by spraying the substance onto the soil surface combined with an analysis of the data that ensures that loss processes other than degradation do not influence the $DegT_{50}$ value. (See EFSA, 2014 for details of this analysis).

106. The inverse modelling procedure for estimating a $DegT_{50}$ is commonly based on the decline of the total mass per surface area that is present in the soil profile. The purpose of the DegT50 module is to provide guidance for assessing this decline.

107. The following text in this module indicates where a difference in approach is needed to that outlined in the basic study method description (i.e., **Section II**). Note that the section letter/numbering used below is the same as that of the basic study method. Unless indicated to the contrary below, guidance contained in the basic study method description (i.e., **Section II** and its appendices) is considered appropriate. Thus, when a different recommendation is given in this module, it should be adhered to as it replaces the guidance set out in the basic study method.

III-A Information on the Test Substance

108. The test substance can be the active substance to be marketed or a transformation product of the test substance for which a field $DegT50_{matrix}$ value is desired.

109. Usually, if transformation products are used as a test substance, they will have reached levels that trigger assessment in appropriate laboratory (lab) soil aerobic, anaerobic or photolysis experiments. These levels and where applicable lab $DegT_{50}$ triggers for field studies can be found in the relevant regulatory requirements of official regulatory authorities, or in the case of European Union countries, the legal data requirements of the European Union Regulation (EC) No 1107/2009. If reliable transformation $DegT_{50\ matrix}$ values can be derived from experiments where precursors in a transformation pathway have been dosed, then the applicants have discretion over whether they will carry out field experiments and which transformation products they will analyse, where a transformation product is applied as the test substance.

110. The test substance should be prepared/formulated so that it can be evenly applied to a test plot, and variation in the mass of test substance applied per unit area should be minimized. Preparation as a formulation may not be necessary when the test substance is soluble in or miscible with the diluents being employed in the experiment. The formulation does not need to be a typical end use product. End use products that have been used to treat seeds or are ready to use granules should be avoided, as the use of these will increase variation in the mass of test substance applied per unit area at the spatial scale of soil core sampling.

111. Note in the European context, the only time a $DegT_{50}$ study with an end use product would be essential (according to legal product data requirements of Regulation (EC) No 1107/2009) is when the test substance is the commercialized formulated active substance and the commercialized formulation technology affects the rate of release of the active substance from the formulation. In other words, this study is essential when the study sponsor cannot justifiably extrapolate the $DegT_{50}$ value estimated for the test substance and the kinetic formation fractions involving any transformation product from investigations carried out with any other preparation or formulation of the active substance.

III-B Field Plot System

112. Test plots should never be cropped at the time of application as this will increase variation in the mass of test substance applied per unit area at the spatial scale of soil core sampling. When plant uptake cannot be excluded as a significant route of dissipation for any of the compounds of interest, the experimental design has to maintain bare plots throughout the experiment, Where robust data are available in the dossier to confirm that crop uptake is not a significant route of dissipation from soil for any of the compounds of interest (e.g., evidence from OECD Test Guideline 502 studies on metabolism in rotational crops), both plots, maintained bare and plots where grass will germinate, can be prepared, resulting in parallel experiments for both plot types at each study site. When this option is followed, grassed plots can be seeded after the test substance has been mechanically incorporated. (Refer to **Section III-E-2**). Alternatively grassed plots can be pre-seeded so that the grass crop will emerge after application when test substance incorporation is to be achieved via irrigation (Refer to **Section III-E-2**). When results from parallel maintained bare and grass-emerged plots are available, soil root zone models should be parameterised for the conditions of the experimental sites[1] to provide an interpretation of any difference in DT_{50} values between bare and grassed plots[2]. $DegT_{50\ matrix}$ should only be derived from the grass emerged plots when the results of a soil root zone modelling exercise have confirmed that plant uptake has not contributed significantly to lower substance mass in the root zone and was not a reason for shorter DT_{50} values estimated from grass-emerged plots.

III-C Site Selection

113. As the purpose of these experiments is to obtain a median $DegT_{50\ matrix}$ for the population of agricultural/horticultural fields in the area of use of the substance, sites can be randomly selected from this population. Note it is considered indefensible to mix $DegT_{50}$ populations derived from experiments carried out on temperate mineral soils with those carried out on tropical soils. A check should be made that the soil pH, organic matter and clay contents are within the range of values to be expected for top soils in the area of use of the substance. Use of sites with a soil mineral content derived from volcanic activity where there has been limited pedology is considered inappropriate for extrapolating to regions where there has not been recent volcanic activity. In this case, the chemical and physical properties of these soils differ substantially from those of other mineral soils. For other aspects of site selection the basic study method description (i.e., **Section II**) can be considered. Note that study sponsors should avoid estimating $DegT_{50\ matrix}$ values in sites where soil characteristics indicate possible significant movement of substances of interest out of the microbially active topsoil layers. For example, sites where soils have coarse textures combined with low organic carbon, such as the 'Borstel' soils typically used in European lysimeter experiments should be avoided as far as possible.

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1 When using the soil root zone models recommended by the European guidance of FOCUS, in the first instance, the transpiration stream concentration factor(s) (TSCF) needed for each compound can be calculated from measured log P_{ow} values, in line with the FOCUS recommendations and EFSA (2013) or from appropriate TSCF measurement in grass.

2 This interpretation is to inform what contribution plant uptake may have made to any difference in DT values compared to the contribution the presence of plant roots may have to enhancing microbial degradation.

III-D Field Plot Design

114. When designing an experiment to estimate $DegT_{50\ matrix}$ in topsoil, all processes that can affect the fate of the chemical, except the formation of transformation products or extracted residues, (e.g., leaching, volatilization, soil surface photolysis, runoff and plant uptake) should be minimized as far as possible. Therefore, test plots should be level without any slope. (Refer to **Section III-E-2** for more information on the approaches to minimize surface processes impacting the $DegT_{50\ matrix}$ estimates).

115. The basic $DegT_{50\ matrix}$ field study design, which evaluates field degradation in topsoil in bare ground plots or which may additionally include plots where grass emerges after application (refer to **Section III-B**, above), should exclude the influence of surface processes as far as is practical.

116. The study design should encompass the range of environmental conditions that reflect the actual usage of the test substance, although surface processes should be excluded, even if these might occur as a result of the actual usage. The studies should also include an untreated control plot. The purpose of the control plot is to ensure that the pesticide is not present prior to application and to provide a sufficient quantity of soil for carrying out the necessary analytical method fortification and recovery experiments that must be carried out throughout the experiment. The plot preparation/cultivation depth and mixing of samples from the control plot should mirror that of the treated plots to minimize different matrix effects in recovery experiments. Measures to prevent contamination of the control plot from treated plots, in particular through spray drift at the time of application, should be made.

117. Because of field-scale variability, the experimental units in each study should be replicated. The considerations of the basic study method description (i.e., **Section II**) regarding replication in **Section II-D**, field plot design, are considered appropriate. At least three subplots should be used as the basis for the replicated sampling strategy.

III-E Procedure

1. Site Characterization

118. Consideration of the basic study method description (i.e., **Section II**) is appropriate. Note that the use of the word dissipation in **Section II** does not apply in **Section III**, where the focus is degradation/transformation. See Appendix 2 for a definition of the term dissipation.

2. Application of the Test Substance

119. The test substance should be applied to the surface of test plots as evenly as possible and formulated as necessary, as already discussed in **Section III-A**, above. For active substances, at least the maximum proposed/intended annual total dose use rate, as stated on the label, should be used. When necessary, the active substance should be applied at a rate greater than the maximum proposed use rate to ensure that analytical quantification/detection limits for the compounds of interest enable determination of ≤10% / ≤5% of the initial measured soil residues for the active substance. Where the test substance is a transformation product, the application rate should cover at least the maximum formation level expected, considering the results of the relevant laboratory experiments. As for the active substance, when necessary an application rate greater than this value should be used when it is necessary to ensure that analytical quantification/detection limits for the compounds of interest enable ≤ 10% / ≤ 5% of initial measured soil residues to be determined respectively.

120. Recommended equipment for pesticide delivery to experimental plots should be of high precision, suited for the particular pesticide formulation and fitted with a device to keep drift loss to a minimum. Some pesticides may need to be homogenized by a continuous mixing device in the tank.

121. Only a single application should be made to each test plot. The applied mass per surface area should be measured in parallel in two ways. The first is based on measurements of (i) the speed of the spray boom or other application method, (ii) the flow rate of the liquid from the nozzles or other flow rate and (iii) the concentration of the pesticide in the diluent. The second is based on measurements of deposition of pesticide on the soil surface (e.g., spray cards). The results of these two estimates of the applied mass per surface area should be compared with the mass per surface area recovered from the soil sampled at the day of application.

122. Following application of the substance, one of the following procedures should be employed to minimize the impact of surface processes (e.g., photolysis, volatilization) on the $DegT_{50\ matrix}$ value that can be estimated for each test plot:

- Incorporation of the substance in the soil immediately after spraying to the soil surface; mixing should be over a target depth of 7 cm. A plot power harrow can be used for this type of application for most soil textures. Following harrowing, the plots should be rolled.
- Injection of the substance within the top layer (0-30 cm) of the soil, followed by mixing through the soil over a minimum target depth of 7 cm. Again, a plot power harrow can be used to achieve this result. Following harrowing, the plots should be rolled.
- Irrigation immediately after application of the substance to the soil surface; the irrigation volume should be sufficient for the substance to reach an average penetration depth of 10 mm (to be calculated with models such as PELMO and PEARL).
- Even application of a layer of commercial fine sand to the soil surface, achieving a depth of at least 3 mm. Note that this approach should not be used if any of the substances of interest has a vapour pressure $> 1\times10^{-4}$ Pa[3]. unless other experimental evidence is available, indicating that volatilization losses from soil are not a route of dissipation. Observations should be made and recorded to confirm that the sand layer remained in place until at least 10 mm of rainfall/irrigation has occurred.

124. In all cases, the first soil sampling should take place after the incorporation, irrigation or covering has taken place.

3. *Study Duration*

125. It is expected that the study will be continued until the concentration of test substance has reached ≤ 10% of initial measured test substance in the target top 10 cm soil layer or the transformation products of interest formed from the test substance have peaked and subsequently declined such that they no longer account for more than 10 % of the molar mass of the initial mass of the test substance. Movement out of the top 10 cm soil layer does not invalidate the study for the purpose

3 The function of such a vapour pressure limit for this study design, is to exclude that the process of volatilization is a significant factor in the DT value that can be estimated, particularly in relation to earlier sampling times

of calculating $DegT_{50\ matrix}$ and $DegT_{90\ matrix}$ values. However if measurement of residues of interest in the top 10 cm indicates that the decline is plateauing when > 10% remains, the study can be terminated, provided the study has included a winter and spring period This study duration ensures that an observed plateau is not based on colder winter temperatures.

4. Management

126. Consideration of the basic study method description (i.e., **Section II**) is appropriate, except: (a) tillage operations before application should ensure that soil mixing is as even as possible over the top 15 cm of soil, (b) an even fine seed bed type tilth is achieved over the top 7 cm of soil and (c) that any cultivation incorporating the substance results in even incorporation over at least the top 7 cm soil layer.

5. Irrigation

127. Treated plots that are maintained bare may not require irrigation except in the following situations:

- Irrigation is used to move the test substance into the soil immediately after application. (Refer to **Section III-E-2**for further details).
- Some soil textures (e.g. high clay content) may benefit from irrigation during prolonged dry periods to facilitate the sampling of intact soil cores.
- Study durations can also be prolonged if there are extended dry periods reducing microbial activity, in which case irrigation can be used as a tool to optimize (shorten) study durations.

Irrigation for these purposes is appropriate. The irrigation amounts applied should aim to keep soil moisture contents in the top 30 cm below field capacity, thus substances of interest remain within the microbially active topsoil. When plots have grass cover, irrigation to sustain the grass is appropriate. Again the irrigation amounts applied should aim to keep soil moisture contents in the top 30 cm below field capacity.

6. Environmental Conditions and Monitoring

128. Consideration of the basic study method description (i.e., **Section II**) is appropriate. Use of tracers to track the potential depth of leaching, however, is not pertinent as the study design should minimize the potential for substances to leach from the upper soil layers. In this case, the best practice is to measure the daily average soil temperatures at a depth of 10 cm.

7. Soil Sampling

129. Consideration of the basic study method description (i.e. **Section II**) is appropriate, soil sampling should usually proceed to a depth of 1 metre, except at sites where the soil is so shallow that this is not physically possible. For samples taken immediately after application, a depth of 30 cm can be accepted, except when injection to this depth or deeper was used as the method of application. Depth segments should continue to be analysed until the depth is reached, where a segment no longer contains the compounds of interest at levels above the limit of detection for the analytical method. The time intervals chosen for sampling should be based on the results of laboratory studies and other field studies, if available. Sampling frequency should take into account lab $DegT_{50}$ estimates with increased frequency of sampling for compounds with lower $DegT_{50}$ values. The number and distribution of sampling times should also be sufficient to adequately characterise the formation and decline of the transformation products of interest. A minimum of eight time intervals should be sampled. Significantly more sampling times than this may be required when a

number of transformation products are of interest and kinetic fitting of both formation and decline of these needs to be determined.

130. It is recommended dividing the experimental plots into at least three subplots and to randomly take at least 10 samples from each subplot. The diameter of the sampling core should be at least 5 cm in the top 30 cm. It is important that the basic study method description (i.e., **Section II-E-7-F**) on the handling of samples is followed. All samples from one subplot and the same depth segment may be mixed before analysis.

131. It is unacceptable to mix all samples from the plot for each depth segment into one sample because it is essential that the $DegT50_{matrix}$ time-step normalization procedure include information on the uncertainty of the measured residue at each sampling time. This information will allow the study sponsor to allocate a lower weight to measured time points with a large uncertainty in the inverse modelling procedure than measured time points with a small uncertainty (e.g., often the scatter immediately after application is larger than at later sampling times).

132. The total mass of moist soil from each mixed sample should be recorded because it is the intention to assess the mass per surface area present in each depth segment (soil layer). If this mass of moist soil is not measured and recorded, the mass per surface area can be calculated only after the bulk density of the soil has been estimated. This estimation may be inaccurate. This inaccuracy can be avoided simply by measuring and recording the total mass of moist soil of each mixed sample. For each mixed sample, the mass of substance per sampled surface area should be calculated from the content of substance in the soil, the total mass of soil in the sample and the sampled surface area. Results from all depth segments containing detectable residues for the compound(s) of interest should be used when estimating $DegT_{50\ matrix}$ values. Therefore, a final manipulation of the results must be completed. The masses per surface area of the different depth segments from the same subplot should be summed to give the total mass per surface area for each subplot. These total masses per surface area form the basic data for the further $DegT_{50\ matrix}$ estimation.

8. Sampling Strategies of Other Media to Increase Sensitivity

133. Consideration of the basic study method description (i.e., **Section II**) is appropriate, although plant material sampling, air sampling and sampling of runoff are not relevant for $DegT_{50\ matrix}$ experiments.

III-F. Handling and Analysis of Samples

134. It is appropriate that the basic study method description (i.e., **Section II-E-7-F** and **Appendix 4**) is considered although the following additional recommendations should be followed:

135. Because the efficiency of the sample extraction procedure influences the $DegT_{50\ matrix}$ that is calculated from the experiment (more efficient extraction procedures, will usually result in longer $DegT50_{matrix}$ being estimated), adequate and consistent extraction procedures should be followed for all samples taken at a trial site. It is desirable that the same extraction procedure(s) be used in all field and laboratory $DegT_{50}$ experiments in a dossier. While this situation may not be usual, particularly for substances for which regulatory data bases have been developed over many years, it is preferable that extraction procedure(s) used in new field $DegT_{50}$ experiments be similar to those that have been used in the laboratory soil incubations and already available soil field experiments.

IV. RUNOFF MODULE

IV-A. Introduction

136. Runoff studies may be conducted on a single field, a watershed, or a river basin. The experimental layout proposed here is for the small-scale field level as a component of terrestrial field dissipation study or a stand-alone runoff field study. The objective is to measure runoff losses at the edge of agricultural fields. Runoff is often an important route of dissipation of pesticide residues under field conditions, and in some landscapes, it is the major process by which pesticides are transported from the land into water bodies. The information presented in this guidance is designed to provide the user with a framework for developing and designing components of a pesticide runoff study.

137. Evaluation of pesticide risk to the environment by agricultural runoff requires an understanding of pesticide properties and agronomic practices, soil properties and field scale hydrologic processes. Pesticide loss in runoff is the sum of the loss in the dissolved phase (in water) and in the adsorbed phase (on suspended soil or sediment particles).

138. Factors that are important in describing the processes of runoff and sediment transport are climate, topography, soil properties, and management practices. The chief climatic factor is the intensity of rainfall. Intensities must be great enough to exceed soil infiltration rates or to cause surface saturation by rapidly rising water tables to produce runoff. Once runoff occurs, topographic features, such as long, steep slopes, will tend to produce higher runoff velocities, increasing the capability of flow to detach and transport pesticides sorbed to soil particles/sediment.

IV-B. Field Site Selection and Description

139. Site selection is a critical component of a runoff study, as it defines the climatic regime and soil/field/cropping characteristics. These factors affect virtually all aspects of pesticide transport.

1. *Site: Location, Climate, Topography, Soils, Geology and History*

140. The site selected should be representative of the area where a pesticide is going to be used. Factors to be considered include:

Climate: rainfall duration and intensity, and evapotranspiration
Topography: slope length and steepness
Type of soil: erodibility, infiltration characteristics and organic matter
Management practices: tillage, crop rotation, cover crop use, and irrigation

141. Climatically total rainfall, duration and intensity affect total runoff and peak runoff rates, both of which affect sediment transport. Crop evapotranspiration as well as use of supplemental irrigation affects the antecedent soil water condition prior to runoff events. Two topographical factors, slope length and steepness, will affect runoff velocities and, hence, the capability of flow to detach and transport sediment. The type of soil is also a primary factor. Erodibility determines the sediment yield per unit shear stress on the soil; the organic matter content affects erodibility and the degree of pesticide adsorption and desorption. Infiltration characteristics affect the timing and quantity of runoff water.

2. *Soil Characteristics*

142. The characterization of soil properties is an essential part of a field runoff study because these properties affect sampling design and runoff and erosion losses. It is preferred that soil core samples be taken from the field site for analysis and characterization. In addition to soil characteristics as described elsewhere in this document (e.g., **Section II-E),** additional soil properties that affect runoff, such as infiltration rate, permeability and erodibility, etc, should be provided.

143. Specific soil characterization data that are essential include soil taxonomy, hydrologic soil group, soil texture, organic carbon content, bulk density, soil water content, soil pH, the soil water characteristic curve, and saturated hydraulic conductivity. These data are needed to a depth of 30 cm.

144. For information on soil groups based on infiltration rates, refer to USDA (1973).

145. Infiltration capacity of the soil should be given major consideration, as it will strongly impact the quantity of runoff produced from the area. The moisture content of field soils has a direct influence on the dissolved-phase concentrations of a pesticide and also has a substantial impact on the attenuation and transport processes. Soil moisture measurements are needed as a function of time and depth. Some runoff models require the soil moisture release characteristic curve (metric potential versus water content). These data range from saturated hydraulic conductivity (0 bar) to field capacity (-0.33 bar; EU -0.1 bar) and permanent wilting point (15 bar).

IV-C. Runoff Plot Design

146. Delineation of runoff test area: The runoff test area should be defined and hydrologically isolated from neighbouring fields or the TFD study area by creating an earthen dike or other physical barrier around the test area. A collection ditch should be created along the lower field edge immediately inside the earthen dike. With this drainage system, runoff water will be free to drain off the field and then along the collection ditch to the sampling area. Ditches may not be needed if berms are constructed and fields have uniform grade.

147. First, in the process of selecting a suitable site to study runoff of pesticides, one must conduct site visits and determine whether runoff does occur. Secondly, it must be determined that the field has a drainage pattern that converges to a central draw or drainage channel and that outside boundaries are well established. To ensure that runoff water from other areas does not enter the site, a soil berm (embankment) or dike can be established on the outside boundary of the field. In predominantly level geographic areas where well defined drainage channels are not apparent, it may be necessary to construct a system of barriers to direct runoff to a central collection point. Depending on the specific field situation, these might be metal or concrete barriers or simple soil terraces. Pesticide application can be made either before or preferably after constructing the dike.

IV-D. Pesticide Application

148. Refer to **Section II-A and II-E-2**.

149. Following pesticide application, soil samples must be collected and analysed to determine the 0-day residue concentration. Subsequent runoff losses are estimated as a percentage of this initial amount. Soil samples should also be analysed at the end of the runoff events/study period. Also, soil samples are collected by either grid or random sampling. (For details of soil sampling, refer to Section II-E-7).

IV-E. Collection of Runoff Samples (Measurement of Runoff)

150. Surface runoff occurs when the rainfall intensity and duration exceeds the infiltration rate. The amount of runoff produced, however, is a function of site size, antecedent soil moisture content, soil permeability, vegetation, evaporation rate, slope and surface roughness (Wauchope *et al.*, 1977 and 1985). The pesticide concentration in runoff is affected by these properties, as well as the pesticide properties that include water solubility, degradation rate in soil, sorption to soil and sediment, and method of application (plant foliage, soil surface or soil incorporated) and formulation (Wauchope *et al.*, 1977 and 1985). The flow from a field site is intermittent and can vary from low to high with varying time intervals (few minutes to several hours), depending on the rainfall intensity and duration, and site characteristics.

151. The design of the sampling network must specify the measurement of certain variables or parameters at defined points in space and time. The frequency of sampling will depend on the dynamics of the process being sampled. The length of the sampling period will, in general, depend upon the persistence of the chemical, although some time series measurements may be required year round if a multiple year study is being conducted.

152. Composite runoff samples are collected for each event after application until the analytes of interest decrease in concentration below the level of detection. Depending on the site and its topography, small plots can be instrumented to allow automated collection of runoff water from the entire field by installing collection devices at the down-slope edge. Larger plots require installation of collection devices at several predetermined locations.

IV-F. Equipment for Runoff Flow Measurements

153. Once the sampling network has been designed procedures for taking samples should be specified. These procedures will require the availability of certain equipment to collect, store, and transport samples.

154. Devices for monitoring flow commonly consist of various types of flumes and weirs. For field-scale runoff studies involving intermittent storms, H-type measuring flumes (H and HL type) are appropriate. Weirs, on the other hand, are inappropriate for monitoring intermittent flows (i.e., ponding conditions are created, as well as sediment deposition). H-type flumes have the capability of measuring a wide range of flow rates with a high degree of accuracy. They are more accurate at lower flows, as compared to other types (i.e., Parshall). An H-flume is commonly used as the primary device for measuring open channel flow, and is engineered in such a way that flow can be related to the measured depth of water passing through the flume by a defined, non-linear equation.

155. To monitor the rate of flow and runoff volume, a continuous water stage record for depth of flow (stage or head) with time during the event is required. This record can be obtained by using pressure transducers in conjunction with a stilling well attached to the flume and electronic data loggers. Multiple units can be installed to ensure that stage height data are not lost due to recorder failure. The stage record from the water level recorders (derived from breakpoint values or at even time intervals) are converted into rates of flow, i.e., discharge in cm^3 (or ft^3)/sec, by using the rating table for the flume type being used.

IV-G. Selection of Automatic Sampler

156. The field under study must be instrumented to allow automated collection of runoff water samples.

157. To determine the amount of pesticide residue transported in runoff, samples must be taken in proportion to flow volume or elapsed time during the event (flow weighted composites). Pesticide concentration measurements and stage height measurements must be "paired" in time sequence to allow calculation of pesticide runoff quantities due to the dynamic nature of the runoff hydrograph. The sampler must be set to ensure an adequate number of samples are collected at low flows (small runoff events) and a practical number of samples are obtained during high flow storm events. Dynamic sampling techniques are particularly important because of the non-linear relationship between flow rate and sediment/pesticide transport.

158. Although several different runoff samplers are available for field runoff studies, automatic samplers (e.g., ISCO) are widely used. These samplers are flexible in that sample times can be pre-set for timed sampling during the event or proportional to flow by using an attached flow meter. The number of samples collected should be sufficient to represent the runoff event. The limitation on the number of samples is determined by the volume of sample required for analysis; sample volumes of 1000 mL or greater are often used. To obtain samples of such volumes with an automatic sampler that has lower capacities requires programming the sampler to allow a sample to be collected in several bottles. Glass containers (10 L) are recommended to collect one flow-weighted composite sample per event.

IV-H. Metrological Record

159. Monitoring weather or meteorological parameters at the field site is an essential data requirement because these parameters influence runoff volume and pesticide concentrations. Data may be required hourly, daily, monthly, etc., for the various meteorological parameters. The required data include precipitation (rain and snow), pan evaporation, solar radiation, air temperature, relative humidity and wind. A record of irrigation use is also essential.

IV-I. Handling and Analyses of Samples

160. It is important that runoff samples are removed from the field soon after runoff events so that sampling equipment is ready for new events. Samples also should be analyzed for pesticide residues as soon as possible to minimize errors due to potential degradation losses. Runoff samples can be transported to the laboratory in ice coolers and stored as frozen samples in a refrigerator at 4°C until processed. If both chemical (pesticide residue) and physical (particle size distribution) analyses are desired, runoff samples should be subdivided. Separate pesticide analysis should be performed in the sediment and water phases and sediment weights should be determined. The relative effort exerted in analyzing either the sediment or solution phases should reflect the main transport mode of the pesticide.

IV-J. Results

161. Pesticide residue concentrations in sediment and water should be determined separately. Sediment should also be analysed for particle size distribution, organic carbon, and CEC. Information on particle size distribution in runoff is important because fine particles (silt, clay) normally have enriched pesticide contents. This enrichment effect results from the increased surface areas, cation exchange capacities, and organic carbon contents of the fine fractions. Organic carbon content of runoff sediments is important because of the influence it has in determining overall pesticide sorption (Karickhoff, 1983). CEC influences sediment sorption capacity particularly for ionizable compounds.

162. For details of data analysis, including statistical analysis, interpretation and reporting, refer to **Section II-F**.

163. The results expected from this runoff specific module study are as follows:

- Initial 0-day residue concentration in soils after pesticide application
- Amount of rainfall received at each event and in total
- Quantity of runoff that occurred after each rainfall event
- Time series residue concentration in runoff water
- Total quantity of runoff that occurred during study period
- Total quantity of pesticide residues lost due to runoff water

164. Residues transported in runoff water should include parent, major transformation products, and residues adsorbed to sediments that are extractable. Residues analysed and quantified in the study report should be based on those identified under laboratory studies.

165. **Appendix 10** contains suggested tables for data required for this runoff module.

V. VOLATILIZATION MODULE

V-A. Introduction

166. Post application volatilization of applied pesticides from soil and plant surfaces is an important route of dissipation for selected pesticides. Volatilization processes not only may result in reduced efficacy in controlling pests, but also have the potential to adversely impact terrestrial and aquatic natural systems far from the intended target (Peck and Hornbuckle, 2005). Many air monitoring studies available in the scientific literature corroborate field volatilization of conventional pesticides from application sites (Glotfelty *et al.*, 1990; Majewski and Capel, 1995; LeNoir *et al.*, 1999; Majewski and Baston, 2002; Zamora *et al.*, 2003; and USEPA, 2008a). Pesticide volatilization from application sites involves the interaction of a number of complex variables. Physical and chemical properties, such as vapor pressure and solubility of active ingredients (AIs) and the environmental and meteorological conditions, as well as nature of the soil or the crop, are key parameters influencing volatilization, along with management practices. In addition, solvents, and other additives used in formulations and in tank mixtures, may also influence the volatility of pesticide from application sites. Since volatilization can be an important route of field dissipation for some pesticides, it needs to be considered under regulatory frameworks to address risk from volatile and semi-volatile chemicals. In such cases, a field volatilization module can be prescribed as an additional module of field dissipation study and should only be considered for the compounds shown to have inherent physicochemical characteristics for volatilization and/or detected as trapped volatile organics in standard laboratory studies as well as detected in the atmospheric samples.

V-B. Criteria for Volatility Module Selection

167. Important physicochemical properties of chemical compounds that influence volatilization are vapor pressure and solubility in water. The partitioning of a chemical between air and water is described by the Henry's Law Constant, which can be used to determine the potential for volatilization of applied chemicals from water. Adsorption to soil is also an important process that reduces volatilization and needs to be considered during the selection of a volatility module for the field dissipation study. When needed, volatilization from soil and water may be specifically

studied under laboratory conditions to gain additional knowledge. Quantification of trapped volatile organics in standard laboratory studies of biotransformation/metabolism in soil and aquatic systems also addresses volatilization of the parent compounds and their transformation products.

168. Other factors that may be considered include method of application (*e.g.*, foliar versus soil surface versus soil incorporated, injected and watered-in), temperature, soil moisture content, soil organic carbon content, soil texture, soil porosity, residue persistence and leaching. However, a weight-of-evidence approach based on the physical and chemical properties of the test substance and laboratory studies is the best way to prescribe the inclusion of a volatility module as a part of the field dissipation study. The following criteria have been used in initiating a field volatility module as part of the field dissipation study described in the guideline for terrestrial field dissipation study (US EPA, 2008b).

1. *Vapor Pressure*

169. The measured vapor pressure of a chemical compound is a guide to its volatility and to the probability of its movement into the atmosphere. Woodrow *et al*., (1997) and Smit *et al*., (1997 and 1998) have demonstrated that the vapor pressure of an active ingredient could be a reliable predictor of volatilization from soil and plant surfaces. The rate of volatilization from plants seems to be higher than that from soil, but limited data are available (Bedos et al., 2002). A volatility classification based solely on vapor pressure is best suited to dry, non-adsorbing surfaces. In general, pesticides with vapor pressures $\leq 1 \times 10^{-6}$ mm Hg (1.33×10^{-4}Pa = 1.33×10^{-1} mPa) are considered relatively non-volatile under field conditions, whereas pesticides with vapor pressures ≥ 3.9×10^{-5} mm Hg (5.20×10^{-3}Pa = 5.2 mPa) are considered to be of intermediate to high volatility under field conditions (Kennedy and Talbert, 1977; and Guth et al., 2004) suggested that pesticide volatilization is not expected from compounds with a vapor pressure less than 10^{-4} Pa for crops and 10^{-3} Pa for soil. Thus, a vapor pressure of $\geq 3.9 \times 10^{-5}$mm Hg or 5.2 mPa at 25°C raises concern regarding potential volatilization and vapor drift of the active ingredient, and a field volatility study may be warranted as an additional module for the terrestrial field dissipation study.

2. *Henry's Law Constant*

170. Henry's Law Constant (HLC) addresses the partitioning of a compound between water and air, a process that can increase or decrease the overall volatilization of the compound from a water or moist surface. The OCSPP 835.6100 Guideline (USEPA, 2008b) has a volatility classification to characterize potential volatilization from water and moist surfaces using the unitless water/air distribution ratio (C_{water}/C_{air}) or air-water distribution coefficient ($K_{AW,}$ dimensionless HLC) as shown in Table 1. Either of these coefficients can be used as a criterion to consider a field volatility module for the terrestrial field dissipation study. The unitless water/air distribution ratio can be estimated when a measured value is not available, using Equation 1 or the reciprocal of K_{AW}.

$C_{water} / C_{air} = (S \times T \times R \times 760) / (P \times GMW \times 10^6)$ ***Equation 1***

Where:
C_{water} is the concentration of the compound in water in µg/mL,
C_{air} is the concentration of the compound in air in µg/mL,
S is the solubility of the compound in water in µg/mL,
T is absolute temperature in K [K = °C + 273.15],
R is the ideal gas constant of 82.08 mL-atm/K-mole,
760 is a conversion factor to convert mmHg or torr to atm [760 mmHg = 1 atm],

P is vapor pressure in torr or mmHg, and
GMW = gram molecular weight in g/mole
10^6 is a conversion factor to convert from g to µg.

Table 1. Volatility Classification from a Water or Moist Surface		
C_{water}/C_{air*}	K_{AW}	Volatility Class Water
$< 10^2$	$> 10^{-2}$	Rapidly lost from a water surface
$10^2 - 10^3$	$10^{-2} - 10^{-3}$	Volatile from a water surface
$10^3 - 10^5$	$10^{-3} - 10^{-5}$	Slightly volatile from a water surface
$> 10^5$	$< 10^{-5}$	Non-volatile**
* The original document (USEPA, 2008b) reported the classification as C_{water}/C_{air}. This value is the inverse of the commonly reported air-water distribution coefficient (K_{AW}). **Note that all chemicals may volatilize to some extent; this classification simply indicates that the volatility potential is very low.		

3. *Soil Adsorption Effects*

171. Adsorption of a pesticide to soil can significantly reduce volatilization. A volatility classification from moist soil is provided in Table 2, according to the OCSPP 835.6100 Guideline (USEPA, 2008b). This classification accounts for sorption of the compound to soil that could reduce subsequent volatilization and is based on a distribution ratio between wet soil and air as shown in Equation 2 below, according to USEPA (2008b). The classifications in Table 2 assume that the soil contains 2% organic carbon, that the soil/water weight ratio (r) is 6, and that the soil water/soil air volume ratio is 1.

$C_{water + soil} / C_{air} = (C_{water} / C_{air}) ((1/r) + K_d)$ ***Equation 2***

Where
$C_{water+soil}$ is the concentration of the compound in wet soil (w/w on a dry weight basis),
C_{water} is the concentration of the compound in water (w/v),
C_{air} is the concentration of the compound in air (w/v),
r is the ratio of weight of soil/weight of water, and
K_d is the soil-water distribution coefficient.

Table 2. Volatility Classification from Moist Soil Based on $C_{water+soil}/C_{air}$	
$C_{water+soil} / C_{air}$	**Volatility Class from Moist Soil***
$< 1 \times 10^3$	Rapidly lost from moist soil
$1 \times 10^3 - 1.5 \times 10^4$	Volatile from moist soil
$1.5 \times 10^4 – 1 \times 10^5$	Intermediately volatile from moist soil
$1 \times 10^5 - 2 \times 10^6$	Slightly volatile to non-volatile from moist soil
$> 2 \times 10^6$	Non-volatile from moist soil**
*Assuming 2% organic carbon, soil to soil water (w/w) =6, and soil water to soil air (v/v) = 1. ** Note that all chemicals may volatilize to some extent; this classification simply indicates that the volatility potential is very low.	

172. Based on this classification system, volatilization of chemicals from soil under laboratory or field conditions is important for chemicals with a $C_{soil+water}/C_{air}$ value $\leq 10^5$ (USEPA, 2008b). Many chemicals that are predicted to be non-volatile (*e.g.*, to have a very low potential for volatilization) based on the vapor pressure alone are shown to be volatile or semi-volatile in the field or to

undergo long range transport. If a $C_{soil+water}/C_{air}$ value $\leq 10^6$ and if open literature data indicate that volatilization or long range transport is commonly observed, a field volatility module may be warranted as an additional module for the terrestrial field dissipation study.

173. In addition to physico-chemical and environmental fate properties as screening criteria described above, the following screening tools are also available to determine potential volatilization of applied pesticide from application sites. These screening tools can be used in determining whether volatilization is a major route of dissipation of applied pesticide.

- Exposure Via Air (EVA 2.1) was developed by the Federal Biological Research Center for Agriculture and Forestry, Germany to assess volatilization of applied pesticide and potential deposition http://www.bvl.bund.de/SharedDocs/Downloads/04_Pflanzenschutzmittel/zul_umwelt_eva_prog-EN.xlsx;jsessionid=31F818833DD1CC709D6F0CBCFE12D0BD.1_cid340?__blob=publicationFile&v=3

- The Screening Tool for Inhalation Risk (STIR) of U.S. EPA estimates inhalation-type exposure based on pesticide-specific information. Physical properties of each chemical, such as molecular weight and vapor pressure, are used to estimate vapor phase exposure. http://www.epa.gov/oppefed1/models/terrestrial/index.htm#stir

- "An Improved Screening Tool for Predicting Volatilization of Pesticides Applied to Soils" developed by Davie-Martin et al. (2013). Pesticides and the conditions under which the greatest volatilization losses exist can be easily identified using this visual screening technique. The multiphase partitioning approach based on soil–air (C_{soil}-C_{air}) and water-air (C_{water}-C_{air}) partition coefficients was found to most accurately model pesticide volatilization losses from soils.

V-C. Study Design and Field Site Selection

174. The field volatility module is generally performed in a bare-ground soil surface layer to address pesticide off-gassing and subsequent loss from the application site to the atmosphere. However, for systemic pesticides and transformation products with a similar mode of action, uptake through plant tissues (*i.e.*, roots, leaves, etc.) may be a significant route of dissipation. The study design needs to also include this route of dissipation by conducting a cropped-plot study in the field. Field volatility investigations may occur coupled with the field module of a terrestrial field dissipation study, or it may be a stand-alone field volatility study. Field study sites should be representative of the soil, major crop, climate and management factors under which the pesticide will be used. In addition, the selected site, including the field volatility study module, should provide ideal conditions for volatilization, *e.g.*, light textured soils (*i.e.*, sandy textured soils), low organic matter content, low soil adsorption coefficient (K_d or K_{oc}), low rainfall, warm temperature, as well as soil and atmospheric moisture conditions and how they would be expected to impact volatilization.

V-D. Test Substance

175. The test substance should be similar to the basic requirement for a terrestrial field dissipation study. However, volatilization potential of an active ingredient may depend on pesticide formulation. Therefore, appropriate formulation of test material needs to be considered for the volatilization module. For example, if a chemical is in the form of emulsifiable concentrate or a

granule, the emulsifiable concentrate formulation would be the appropriate formulation for field volatility module.

V-E. Air Sampling

176. For a volatility module, robust air monitoring of applied pesticide and its degradates, if volatile, is critical to quantify emissions as flux, or the mass of pesticide emitted per unit time through a specific surface area (*i.e.*, typically presented in units of mass/area-time). Flux represents how quickly a mass of pesticide moves or volatilizes into the surrounding atmosphere. Sampling intervals of at least hour increments for the day of application should be followed by 12 – 24-hour increments in subsequent sampling periods following application. Sampling should be continued until all air monitors indicate that air concentrations have clearly approached the level of detection.

V-F. Environmental Conditions and Meteorological Record

177. Volatilization of an applied chemical is a function of partitioning of the chemical from solid and liquid to gaseous phases in the environment as well as meteorological conditions such as air temperature, relative humidity, wind velocity and direction, net radiation (or solar radiation and cloud cover), and barometric pressure. These meteorological parameters need to be monitored throughout the entire volatility module. In general, a one-minute sampling interval is adequate for meteorological variables for a field volatility study.

V-G. Development of the Field Volatility Protocol

178. A well designed field volatility study protocol needs to be developed to address field volatilization from the application sites. This protocol is critical in designing a field volatility study and should be available for review by the pesticide regulatory authorities before conducting the field volatility study. Several peer reviewed articles that provide the procedure for performing effective field volatility studies are cited below. Cliath *et al.* (1980) and Soderquist *et al.* (1975) described well executed field studies of volatilization with simultaneous study of other modes of dissipation of test substances. Methods for the trapping, extraction, cleanup and quantitation of pesticides are described in Lewis (1976) and Harper *et al*. (1976). Harper *et al*. (1976) also provided an example of using ethylene glycol vapor traps and non-specific GLC quantitation used in field volatility studies. Parmele et al. (1972) used hexylene glycol vapor traps and sampling periods adjusted to compensate for the decrease in pesticide vapor concentration during the study. Majewski (1999) and Parmele et al. (1972) provided pesticide vapor flux calculations from soil in relation to micrometeorological measurements. OCSPP835-8100 guideline (USEPA, 2007) also provides useful information for conducting field volatility study.

V-H. Reporting and Evaluation of Data

179. ***Calculation and tabular, graphic information:*** The principal mathematical equations in generating and analyzing data, as well as representative calculations using equations should be captured in the study protocol. The formation and decline of parent compounds should be expressed as amounts, concentrations, and corresponding percentages. Rate constants, when appropriate, should be reported in conjunction with rate data. Tabular formatted raw data (*e.g.,* detections of trapped vapors in air cartridges, sampling flow rates, and sampling durations), meteorological data, as well as plots showing the temporal trend in volatilization flux should be submitted by the registrant. Examples of critical data summary tables related to field volatility studies are presented in **Appendix 11**.

180. ***Empirical Flux Determination Method Description and Applicability:*** Descriptions of the empirical approaches used in determining the volatilization flux rates, as well as their appropriateness to the study design, are essential. The most commonly used methods to estimate volatilization flux are the indirect method (Johnson *et al.*, 1999), aerodynamic method (Majewski *et al*., 1990) and Integrated Horizontal Flux Method (Majewski *et al*., 1990). Majewski (1999) also provided a wide variety of micrometeorological measurement methods and the advantage/disadvantages of these methods to estimate the post-application volatilization of pesticides from treated fields. He also emphasized that the accuracy of these volatilization flux determinations will only be resolved by conducting careful mass balance experiments. The flux profile is essential for each sampling period to determine the concentrations of the chemical in the atmosphere after application. An example of the reporting table for volatilization flux rate is provided in **Appendix 11**.

V-I. Utility of Experimental Results in Assessment

181. As with all field studies, the results will be directly relevant to the climatic and agronomic (crop, timing, application rate, etc.) conditions as well as spatial scale pertinent to the studies conducted. However, a modelling exercise using the results of estimated flux rate from these experiments can be extrapolated on spatial and temporal scales, often using air dispersion models to evaluate potential exposure in the atmosphere beyond the experimental sites.

VI. Leaching to Depth Module

VI-A. Introduction

182. In field dissipation studies, the detection and consideration of residues present in soil samples in the soil profile, below the cultivation depth and or root zone, is one way of determining that leaching is a contributor to dissipation from the topsoil layers. It is also an indicator that leaching to groundwater may be a concern. However, non-detection of residues in soil samples in a field dissipation study, from below the depth where cultivation would mix topsoil, is not satisfactory evidence to conclude that undesirable levels of contamination of groundwater resources will not occur. In this case, the limits of analytical detection and quantification that can be achieved routinely in bulk soil samples are usually much higher than is possible in samples of soil water or groundwater. This situation is particularly true in relation to the legal parametric concentration limits that have to be considered in the regulatory framework of the EU and other regulatory frameworks where risk characterization following exposure to contaminated groundwater resources may need to be considered. Consequently, modelling approaches to characterize solute concentrations in soil water moving vertically below the root zone, which have the potential to

recharge groundwater resources, have been developed. To supplement these modelling approaches, applicants may choose or regulators may request that field investigations measure substance concentrations in soil water samples taken from the unsaturated zone and/or in shallow groundwater samples. Such field investigations have been termed ‘field leaching studies’ (EU regulatory framework terminology) and ‘prospective groundwater monitoring studies’ (North American regulatory framework terminology).

VI-B. Study Design

183. The experimental layout that may be followed for such field investigations is either at the small-scale field level as a component of a terrestrial field dissipation study or it may be a stand-alone field leaching study. The objective is to characterize recharge concentrations that may leach below the root zone and or the measurement of groundwater concentrations in shallow, vulnerable aquifers that result from the known applications made at an experimental site. Water is drawn out of the soil profile and or taken directly from ground water at different depths (for which a range of techniques are available) and analysed for the presence of the compounds of interest. For a detailed framework and detailed guidance in designing such experiments, including recommended sampling techniques, practitioners should consult US EPA Guidance for Prospective Ground-water Monitoring Studies (US EPA, 2008c). Some further considerations of methodological issues regarding soil water sampling approaches are also contained in Carter and Fogg (1995); Weihermüller *et al*. (2005 and 2006); and Ferrari *et al*. (2007) (‘suction cup samplers’) and in Byre *et al*. (1999); Kosugi and Katsuyama (2004) and Mertens *et al*. (2005) (‘equilibrium tension plate lysimeters'). Such further considerations of methodological issues regarding sampling from the saturated zone (shallow groundwater) can also be found in Ferrari *et al*. (2007).

184. Several factors influence the magnitude and duration of potential contamination of groundwater such as pesticide properties (water solubility, sorption, persistence and volatility), soil and site conditions (soil chemical, physical and hydrological properties, topography, depth of water table, groundwater hydrology and climatic conditions) and agronomic practices. Although most of this information is available in the basic TFD study report, additional information such as depth to/ movement within the saturated zone/groundwater table over the duration of the study and hydraulic conductivity of the unsaturated and saturated zones are required. These and other ancillary data are required to enable the results to be interpreted. Sites selected for the study should be highly vulnerable for leaching, and as an example might have coarse textured soils, high rainfall, low evapotranspiration potential (at least in some seasons), a shallow groundwater table, etc. For full details, consult US EPA Guidance for Prospective Ground-water Monitoring Studies (US EPA, 2008c). A well planned study should track the movement of the active substance and transformation product residues in soil core samples, soil water and/or the saturated zone. If piezometers or sampling wells are installed into the saturated zone, results should enable a time-series of concentrations in the saturated zone/groundwater to be produced for each sampling location installation.

185. It is also important to note that US EPA (2008c) states that ‘All pesticides and major pesticide degradates in the study and the conservative tracer compound to be used on the site are considered compounds of interest. A major degradate is one accounting for >10% of the applied at any time during the laboratory studies, or one that has been identified as of potential toxicological, environmental or ecological concern. While these criteria are also applied in the EU, there are additional EU criteria that require assessment of groundwater transformation products formed at > 5% of the applied at any time during the laboratory studies for more than 2 consecutive sampling times or when, at the termination of laboratory incubations, concentrations have reached 5% but are still increasing (Commission regulation (EU) No 283/2013, European Commission, 2013). Therefore, it is recommended that these additional EU criteria be applied when defining the major degradates that are investigated in these studies if they will be used to support an authorisation in the EU.

186. For studies not located in the U.S. that will not be submitted to U.S. competent authorities, (where US EPA (2008c) states that 'reports must be submitted to EPA' or 'Design Reports must be submitted to and approved by EPA' etc., applicants should consult the competent authorities in the territory where the regulatory submission will be made to determine how these aspects will be managed.

VI-C. Utility of Experimental Results

187. As with all field studies, the results need to be interpreted with care as they are only directly applicable to the climatic, pedological, agronomic (crop, timing, application rate etc.) conditions and spatial/temporal scales pertinent to the studies conducted. However, it may be that the studies cover what might occur in less vulnerable situations than those investigated. As a result, a modelling exercise on the results of these experiments may be necessary to give useful information on the meaning of the results in the context of potential groundwater exposure. This information is important because the duration and spatial scale of any experiment will rarely match the important temporal and spatial scale parameters that will drive actual groundwater concentrations, even in small unconfined vulnerable shallow aquifers.

VII. Plant Uptake Module

VII-A. Introduction

188. Cropped plot field studies may be needed when plants are an important factor in controlling field dissipation of a pesticide and plant uptake is an important route of dissipation. For systemic pesticides whose mode of action involves uptake through plant tissues (leaves and roots), this pathway may be a significant route of dissipation.

189. Plants influence the soil water balance and thereby affect leaching (EFSA, 2013), especially by macro pore-flow along the root channels and cracks. The presence of a well-developed crop canopy can be expected to greatly affect the pattern of water infiltration into the soil, especially row crops (Leistra and Boesten, 2010). Plants also influence the surface roughness and runoff.

190. In the modelling scenarios (PRZM, PRZM GW, PEARL, MACRO and PELMO), which are used for approval of pesticides and calculation of exposure of pesticides in surface and ground water, several parameters connected to plant uptake are needed. These models need input on foliar deposition, interception, volatilization rate, passive plant uptake via roots, foliar wash-off and dissipation rates.

191. Pesticide plant uptake is indirectly influenced by factors controlling the deposition of the pesticides on the plant such as spraying equipment, pesticide formulation and crop type. The pesticide residue in the crop is a multi-compartment system and is a function of deposition, volatilization, interception, translocations and degradation of the pesticides in the plant, deposition on soil from spraying, and wash off from plants after spraying and uptake by the roots.

192. The most reliable measure for interception is obtained if both deposition on the crop and on the soil underneath the crop are measured (van Beinum and Beulke, 2010). This method has also been accepted by FOCUS (Linders *et al*., 2000). Some of the systemic substances and pesticides with low sorption to soil will be available for plant uptake. Plants grown on soils containing bound residues may also have the ability to take up portions of these residues (Gevao *et al*., 2000).

193. The plant uptake via roots may be taken into account as this also can be important for the leaching assessment (EFSA, 2013). In this respect, it is important that assumptions used in the leaching assessment related to plant uptake via roots are robustly quantified. In the case of studies where the substance of interest is applied to the foliage, it could be difficult to distinguish the residue taken up via the soil from that taken up by the foliage. Therefore, any field study results that are used to provide evidence of plant uptake from the soil, particularly where application is made post-emergence of the crop, could be supported by laboratory or green house studies. At the time of writing, this is an area of development in the EU regulatory system, and applicants and regulators are encouraged to consult the latest guidance on the selection of the parameter (the transpiration stream concentration factor (TSCF) or the plant uptake factor (PUF) for regulatory exposure modeling. (See documents hosted on the FOCUS website: http://focus.jrc.ec.europa.eu/gw/index_with_doc.html).

VII-B. Study Design

194. Generally to study plant uptake, the cropped plot should be included as an additional plot in the basic field trial with non-cropped (bare ground) plot (Corbin *et al*., 2006). The cropped study is run in parallel to the bare study plot. The study should also include an untreated control plot. The study design should reflect normal conditions and practice and actual use of the test substance.

195. Cropped plots should be considered in the design of field studies when one or more of the following criteria have been met:

- Systemic pesticides, which are designed to move into and through the plant, are used. This type of pesticide is expected to become incorporated into the plant either through active or passive uptake.
- Foliar-applied pesticides applied at half to full canopy of the plant are expected to be predominantly deposited on leaf surfaces. Under these conditions, foliar dissipation is expected to be the dominant process in the field, although wash-off can lead to increased loadings to soil.
- Pesticides are applied to pasture, foliage crop, grass and turf and expected to strongly influence dissipation pathways of pesticides.
- High foliar wash-off fractions are evident or uptake of parent compounds (30-day emergency crop rotation interval) from rotational crop studies indicate plant processes may control pesticide dissipation. These studies should be conducted on the same crops as the TFD study crop(s).

VII-C. Pesticide Application

196. The pesticide should be applied to the crop corresponding to normal use of the substance as specified on the label. To provide a complete picture of the dissipation and plant uptake, information on the application method, type of spray equipment, pesticide formulation, meteorological conditions, stage of growth of the crops, and the crop type should be provided. At the time of spray application, an estimation of ground cover of the crop should be made to estimate the relationship between amounts of pesticide deposited on the soil.

VII-D. Sampling

197. Soil samples should be collected together with plant material to follow the deposition to soil just after application and wash off after rain events. If repeated applications are made, samples should be taken just before and after spraying. The sampling scheme should be designed to track the decline in pesticide residues from foliage with time, and foliage sampling should include a time zero residue level. Pesticide residues may also degrade abiotically (hydrolysis and/or photolysis), translocate into plant foliage, and volatilize from foliage more readily than from soil. If any of these processes from foliage are a likely route of dissipation, the study design should ensure that appropriate measurements are made. Samples need to be collected more frequently at the beginning of the study in order to adequately characterize foliar dissipation.

198. It may be appropriate to use existing laboratory and/or greenhouse plant studies as a substitute for a full scale field sampling of plant material. However, when relying on laboratory/greenhouse data to support a route of dissipation in the field study, the registrant needs to characterize any differences between the conditions under which the laboratory/greenhouse studies were conducted relative to the field dissipation study. These laboratory/greenhouse studies should be conducted using similar conditions as those present in the field study, e.g., plants, application, treatment, etc., if possible. The registrants should consider collecting a set of benchmark samples from the field study to determine how much of the pesticide was removed by the crop and for comparison with the laboratory/greenhouse studies.

VII-E. Analysis

199. Analyses of the data collected from the two-cropped and non-cropped plots should be similar except that plants should be sampled and analyzed for pesticide residues in the cropped plots. The separate collection, compositing and analyses of soil samples collected within and between the rows of the row crop(s) may also be necessary. Whole plant residues should be designed to capture either dissipation or accumulation in the plant. It is recommended that foliar wash-off half-lives, if available, and potential plant accumulation rates be considered for designing sampling frequency. Crop residues should be expressed as concentrations on both a dry weight and wet weight basis. Additionally, crop yields, expressed as the total crop mass (g)/unit area (m^2), should be determined at each sampling time. Recording crop growth stage and area coverage are important in the overall interpretation of the results

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200. Portions of pesticide residues in plants can be extractable residues, extractable conjugates bound to natural components of the plant or un-extractable or bound residues incorporated into the plant constituents (Kahn, 1982). Quantification of pesticide residues in the plant tissues will be defined by the nature of extractant and sampling preparation (Alexander, 1994).

201. Data generated from laboratory or greenhouse studies may be used to supplement or used instead of field data. However, the use of laboratory or greenhouse data will require an explanation of the conditions under which the data were collected and how any differences between conditions in the laboratory/greenhouse and the field study results and laboratory hypothesis may influence the evaluation of the field results.

VIII. PRINCIPLE, APPLICABILITY AND USE OF THE STUDY RESULTS

VIII-A. Principle of the Terrestrial Field Dissipation Study

202. With regard to the regulatory jurisdiction in which registration is sought, it may be necessary for each TFD study to be designed in the context of a suite of TFD studies that identify the route(s) and rate(s) of dissipation of the active ingredient and major degradates/transformation products when a typical formulation/end-use product is applied under field conditions representative of the significant area(s) where pesticides are used. The studies should quantify the pathways of transformation and transport as well as the distribution of the parent compound and its major transformation products in each environmental compartment. In short, the studies should address the dissipation and fate of the active ingredient and major transformation products in the environment. However, the applicant is advised to refer to the specific data requirements for TFD studies of the regulatory jurisdiction in which registration is sought, and if necessary, to discuss with the competent regulatory authority.

203. It may not be feasible or desirable to study each of the routes of dissipation, as identified by the pesticide-specific conceptual model at one field site. For example, testing conditions for the evaluation of pesticide runoff would not be appropriate for an assessment of leaching. In this case, a modular approach is recommended in which concurrent dissipation pathways are studied at one site, while non-concurrent pathways are evaluated in separate studies. The suite of field dissipation studies may, depending on the requirements of the regulatory jurisdiction, be conducted in an iterative fashion until the results:

- provide an integrated qualitative and quantitative environmental fate assessment that characterizes the relative importance of each route of dissipation for the parent compound and major transformation products (greater than 10% of applied) and/or toxicologically significant amounts of parent and transformation products. The study design should acknowledge that the relative importance of each route may be different depending on use pattern, formulation type and soil/climatic conditions;
- determine whether potential routes of dissipation identified in the laboratory are consistent with field results;
- characterize the dissipation rates of the parent compound and transformation products as well as decline of the major and/or toxicologically significant transformation products under field conditions;
- characterize the rates and relative importance of the different transport processes, including leaching, runoff and volatilization;
- establish the distribution of the parent compound and the major transformation products in the soil profile and determine the potential for leaching and ground water contamination;
- provide data on leaching if it is identified as a concern; include deep soil and groundwater sampling to determine groundwater contamination potential;
- characterize the persistence of the parent compound and major transformation products in soil, including retention and residue carryover in the soil to the following crop season;
- characterize foliar dissipation, if the compound is applied to plants, only when data collected meets certain conditions; and
- characterize the effect(s) of different typical pesticide formulation categories, where applicable.

VIII-B. Applicability of the Terrestrial Field Dissipation Study

204. TFD data are generally required by regulatory agencies to support the registration of an end-use product intended for outdoor uses and to support each application to register a technical grade active ingredient and manufacturing-use product used to make such an end-use product (US Code of Federal Regulations, Part 158 Title 40, *Protection of the Environment* in the USA; *Pest Control Products Regulation, Section 9* in Canada). In EU Regulation (EU) 283/2013 setting data requirements for active substances, the regulation requires TFD studies to derive degradation and dissipation values when the active substance and/or metabolites/transformation products meet certain persistence criteria. Dissipation and/or degradation values derived from TFD studies may subsequently be used in estimation of predicted environmental concentrations (PEC) in soil, groundwater, surface water and sediment.

VIII-C. Use of the Terrestrial Field Dissipation Study Results

205. The results of the TFD study are used to validate and/or refine the established hypothesis that the pesticide dissipates in accordance with the pesticide-specific conceptual model. Differences between field study findings and the established pesticide-specific conceptual model may suggest the need for revision of the pesticide-specific conceptual model and possibly the need for additional laboratory and/or field studies.

206. While this section provides examples of where the TFD study results may be used quantitatively, the value of this study in qualitative assessments should not be overlooked. A critical component of all risk assessments is the characterization of risk, in which the assumptions, limitations and uncertainties inherent in the risk assessment are captured and the potential effect of these factors on overall risk are explained. The TFD study results have been and will continue to be a critical element of the risk characterization component of the risk assessment; it is the only avenue by which the laboratory-based hypothesis and water model predictions of field behaviour can be tested.

207. Results of field dissipation studies can be used to estimate the field persistence of parent compound, formation and decline of transformation products, residue carryover, and leaching potential under representative actual use conditions. When other modules are included in the study, results of these tests may provide important information on major dissipation routes such as transformation, transport, volatilization, plant uptake and runoff. Although not specifically relevant to this technical guidance document, a brief discussion of how the TFD study results can be used in risk assessments deserves consideration. In addition to its value in characterizing the dissipation of a pesticide in an actual field environment, field dissipation study results can be used to evaluate the algorithms and input data for environmental fate models, and the results can be used to develop more refined ecological risk assessments. The following sections discuss some of the potential uses and limitations of using TFD results quantitatively.

1. *Use in Model Evaluation*

208. The results of TFD studies can be compared with pesticide estimations generated by Pesticide Root Zone Models (e.g., PEARL, PELMO, PRZM, PRZM-GW and MACRO) to evaluate how well the models perform. Although the current field study does not always track specific routes of dissipation and identify reasons for discrepancies, field dissipation studies can be designed to test hypotheses regarding routes of dissipation predicted by environmental fate models. Not only can modelling efforts be used to focus and interpret the results of field dissipation studies, but the study results can also be used to evaluate the model.

2. *Use as Input for Environmental Fate and Transport Models*

209. Environmental fate and transport models used in regulatory assessments typically require the use of bulk soil degradation rates rather than dissipation rates observed in TFD studies. Use of such dissipation rates in these models is incorrect when reported dissipation half-lives include the combined routes of dissipation (degradation/ transformation and transport) from the surface. A rapid field dissipation rate may be due to degradation, movement out of the surface soil, or both. Thus, the reviewer would expect a persistent, highly mobile chemical to have a short half-life ($t_{1/2}$) in the surface (provided rainfall or irrigation occurs) because it would move out of the surface. Therefore, it is important to distinguish bulk soil degradation from other dissipation processes which could have influenced observed disappearance in the TFD study.

210. Current models use inputs that represent the individual routes of dissipation (degradation half-life values, rate constants, sorption/partitioning coefficients, water solubility, vapour pressure/volatility) to simulate overall dissipation. Thus, use of a dissipation half-life in such a model would effectively treat movement out of the surface (and potentially into the compartment of interest, i.e., surface water or groundwater) as if it were degradation. For some specific assessments in certain regulatory jurisdictions, it may be possible to replace the route-specific model inputs with a combined dissipation rate determined in a field study under the following conditions:

- The sole focus of the modelling effort is to simulate runoff into a water body and, thus, requires only an estimate of the amount of chemical that is available at the surface and subject to runoff over time.

- The weight of laboratory and field evidence indicates that dissipation in the field can be confidently attributed solely to degradation/transformation (i.e., negligible loss by the other dissipation routes, such as leaching, runoff, volatilization and plant uptake).

211. It should be noted that EU countries routinely use degradation half-life values (DegT50 module) from the TFD studies for fate and transport modelling of parent and metabolites. The requirement for TFD studies to derive $DegT_{50}$ values are requested through the EU regulation (EU) 284/2013 for setting the data requirements for plant protection products in accordance with regulation (EC) 1107/2009. This OECD document contains guidance for the conduct of a TFD study module to specifically derive the $DegT_{50}$ parameter for active substances and metabolites. Use of such parameters in other regulatory jurisdictions would have to be discussed with the appropriate regulatory authority.

3. *Use in Terrestrial Exposure Assessment*

212. Although terrestrial field study results can be used to determine the potential for pesticide residues to remain in the soil from year to year, most of these studies do not provide adequate information on plant residue concentrations or residue concentrations in other food sources, such as seeds or insects, in a manner that can be used in refined terrestrial exposure assessments. However, when data are collected from foliage/food sources, they can provide estimates of residue concentrations over time under actual use conditions in refined risk assessments. In these cases, study results have been used in North America to calculate estimated exposure concentrations (EECs) in soil for buffer zone determinations in terrestrial habitats. Finally, results from TFD studies can be used to evaluate the potential for carry-over of residues (both parent and degradates) from one crop season to the following. This is particularly important for persistent pesticides used in colder climates where the potential for persistence is greatest. Evidence from TFD studies will have implications for long-term exposure to non-target organisms and may trigger additional studies (e.g., long term soil accumulation).

213. In EU countries, the dissipation half-life values (DT_{50}, basic study) are currently used as triggers for accumulation assessment and to calculate carry-over/accumulation in soil (PEC_{soil}) where maximum level of metabolites are used. The degradation half-life values ($DegT_{50}$ module), on the other hand, are used quantitatively as input parameters in simulation models for environmental exposure assessment (leaching to ground water, exposure to aquatic and soil organisms) within the EU.

4. *Use in Refined Risk Assessments (RRAs)*

214. Refined risk assessments produce a range or distribution of values instead of one fixed value produced in a deterministic approach. Current research is focused on refining risk assessment through the implementation of spatially and temporally distributed models and or advanced probabilistic models that look at multiple pathways for exposure and allow for sensitivity analysis to determine the significance of exposures to overall risk. Well-designed TFD studies can provide results that are useful for interpreting and providing feedback on model assumptions and results, and may even be considered as possible inputs for Monte Carlo analysis.

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APPENDICES

APPENDIX 1: SUGGESTED CRITERIA FOR MODULE SELECTION

Field Study Indicators

In deciding what modules to incorporate into a field study, the study sponsor should ask the following questions:

1. What is the potential for dissipation of the parent compound and major transformation by a given route (e.g., volatilization, leaching, runoff, etc.)?
2. Is the potential great enough to warrant measurement under field conditions representative of actual use?

In many cases, several criteria or a weight-of-evidence approach based on physicochemical properties of the test substance and laboratory fate and transport studies is the best way to answer these questions. No single laboratory study by itself can absolutely predict transformation, transport or dissipation in the field. Laboratory data can, however, provide quantitative or semi-quantitative indices of the inherent persistence and mobility under field conditions.

Volatilization Potential

Refer to the volatilization module (**Section V**).

Leaching Potential

The movement of a chemical through soil is dependent on several factors, including rainfall and irrigation and the properties of the chemical and the soil. In general, leaching is faster and more extensive in coarse-textured soils and soils that have low organic matter and clay content. An assessment of leaching potential at sites in specific use areas should also consider the likelihood of potential preferential flow through relatively large soil voids, e.g., cracks, root channels and Karst topography.

A mobility classification based on soil column leaching was developed by Guth[4] and Hörmann (1987)[5]. Monuron has been proposed as the reference compound.

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[5] Guth, J.A., and W. D. Hörmann. 1987. Problematik und Relevanz von Pflanzenschutzmittel-Spuren in Grund (Trink-) Wasser. Schr.-Reihe Verein WaBoLu, 68: 91–106.

Relative mobility factors (RMF) from soil column leaching studies and corresponding mobility classes for a variety of pesticides are presented in the table below (adapted from Guth and Hörmann, 1987):

RMF—Range	Compound (RMF)	Mobility Class
< 0.15	fluorodifen (< 0.15), parathion (< 0.15)	I immobile
0.15–0.8	profenophos (0.18), propiconazole (0.23), diazinon (0.28), diuron (0.38), terbuthylazine (0.52), methidathion (0.56), prometryn (0.59), alachlor (0.66), metolachlor (0.68)	II slightly mobile
0.8–1.3	monuron (1.00), atrazine (1.03), simazine (1.04), fluometuron (1.18)	III moderately mobile
1.3–2.5	prometron (1.67), cyanazine (1.85), bromacil (1.91), karbutilate (1.998)	IV fairly mobile
2.5–5.0	dioxacarb (4.33)	V mobile
> 5.0	monocrotophos (> 5.0), dicrotophos (> 5.0)	VI very mobile

The relative mobility factor is calculated as follows:

$$RMF = \frac{\text{leaching distance of test compound (cm)}}{\text{leaching distance of reference compound (cm)}}$$

Adsorption of a chemical to soil, expressed as the adsorption coefficients, K_d and K_{OC}, is a major determinant of leaching potential. The following mobility classification is based on the soil organic carbon adsorption coefficient, K_{OC}, and is best suited to non-ionic chemicals. (FAO, 2000)[6].

K_{oc}	Mobility Class
<10	Highly mobile
10-100	Mobile
100-1,000	Moderately mobile
1,000–10,000	Slightly mobile
10,000–100,000	Hardly mobile
>100,000	Immobile

Dissociation of ionic compounds in response to the ambient soil pH affects adsorption and, therefore, mobility in soil. Anionic species that have a negative charge at ambient soil pH are likely to have

6 FAO, 2000. Appendix 2. *Parameters of pesticides that influence processes in the soil*. In FAO Information Division Editorial Group (Ed.), *Pesticide Disposal Series 8. Assessing Soil Contamination. A Reference Manual.* Rome: Food & Agriculture Organization of the United Nations (FAO). http://www.fao.org/docrep/003/X2570E/X2570E00.HTM

a very high leaching potential. The effects of soil pH on the adsorption of acids and bases by soil is summarized by Tinsley (1979)[7].

Effect of pH on Adsorption of Acids and Bases by Soils (Tinsley, 1979)

Compound	Molecular/Ionic Species		pH Effect
	Low pH	High pH	
Strong acid	Anion	Anion	Small
Weak acid	Neutral molecule	Anion	Large effect: less adsorption at pH > pKa
Strong base	Cation	Cation	Decrease at very low pH
Weak base	Cation	Neutral	Increasing adsorption to pH = pK_a, decreasing with pH < pK_a
Polar molecule	Neutral molecule	Neutral molecule	Small effect
Non-polar molecule	Neutral molecule	Neutral molecule	Little effect

Other factors such as the compound's persistence affect its leaching potential. Cohen *et al*. (1984)[8] summarized the various physicochemical, transformation and mobility characteristics of a chemical that has the potential to leach under standard soil conditions:

Solubility in water > 30 ppm
K_d < 5 and usually < 1 or 2
K_{oc} < 300 to 500
Henry's law constant < 10^{-2} atm m^3/mol
Negatively charged (either fully or partially) at ambient pH
Hydrolysis half-life > 25 wk
Photolysis half-life > 1 wk
Half-life in soil > 2 to 3 wk

Note that all of these criteria should be considered together, not individually, in the assessment of leaching potential.

Gustafson (1989)[9] developed the following leaching potential index, based on persistence in soil and adsorption:

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7 Tinsley, I.J. 1979. *Chemical concepts in pollutant behavior*. John Wiley and Sons, New York.

8 Cohen, S.Z., S.M. Creeger, R.F. Carsel, and C.G. Enfield. 1984. Potential for pesticide contamination of groundwater resulting from agricultural uses. In R.F. Krugger and J.N. Seiber, (eds.). Treatment and Disposal of Pesticide Wastes. ACS Symposium Series No. 259. American Chemical Society, Washington, DC. pp. 297–325.

9 Gustafson, D.I. 1989. *Groundwater ubiquity score: A simple method for assessing pesticide leachability*. Environ. Toxicol. Chem. 8: 339–357.

$$GUS = \log_{10}(t_{½\ soil}) \text{ X } (4-\log_{10}(K_{oc}))$$

where: $t_{½\ soil}$ = 50% decline time in soil under field conditions

K_{oc} = soil organic carbon adsorption coefficient

This index is best suited for non-ionic compounds. More importantly, it is better to use laboratory soil metabolism/biotransformation values for $t_{½\ soil}$, as field values include decline via leaching (which is what is being assessed). In any case, based on the calculated GUS score, the leaching potential of compounds can be categorized as follows:

Classification system based on calculated GUS scores (Gustafson, 1989)

GUS	Leaching Potential
> 2.8	Leacher
> 1.8 and < 2.8	Borderline leacher
< 1.8	Non-leacher

The leaching potential of compounds with GUS scores > 1.8 should be investigated further.

APPENDIX 2: DEFINITIONS AND UNITS

50% dissipation time (DT_{50}): The amount of time required for 50% of the initial pesticide concentration to dissipate. Unlike the half-life, the dissipation time does not assume a specific degradation model (e.g., a first-order degradation).

Dissipation: Overall process leading to the eventual disappearance of substances from the site of its application or an environmental compartment. Dissipation comprises two main types of processes: transport processes, such as volatilization, leaching, plant uptake, runoff or erosion that transfer substances to different environmental compartments; and transformation processes such as microbial degradation, hydrolysis and/or photo-transformation that produce transformation products.

First-order kinetics: A model that assumes that the rate of degradation/dissipation is proportional to the concentration of the reactant and remains constant during the reaction time period.

The single first-order model is derived from the differential equation:

$$\frac{dM}{dt} = -kM \qquad M(0) = M_0$$

with

M = mass of the compound
M_0 = initial mass of the compound
k = rate constant for the compound

The integrated form of the above equation is a simple exponential equation with two parameters (*M* and *k*):

$$M = M_0 e^{-kt}$$

With

M = mass of the compound at time t

Half-life ($t_{1/2}$): The time required for a concentration of a pesticide to be reduced (i.e., degrade, metabolize or otherwise dissipate) to one-half. With each half-life period, half of the remaining concentration of pesticide will disappear from the system.
DegT50: Description of time taken for 50% of substance to disappear from a compartment as a result of degradation processes alone.

$DegT50_{matrix}$: For aerobic laboratory studies and tailored field dissipation studies with no significant influence of surface processes or aged sorption, this value relates to the time taken, assuming single first order kinetics for 50% of substance to disappear from the soil matrix as a result of degradation processes alone.

Half-life versus 50% dissipation time: When the reaction follows first-order degradation kinetics, the half-life will be equivalent to the 50% dissipation time. In this case, the reaction rate is proportional to the reactant concentration and constant over time. However, when the degradation rate is not first-order, the half-life and the 50% dissipation time will differ. In this situation, the half-life is usually greater than the 50% dissipation time. Discrepancies between the $t_{1/2}$ and the DT_{50} may suggest that pesticide degradation follows something other than a first-order reaction model.

Ideal application and planting techniques: The use of specially adapted application machinery to accurately apply a pesticide in small plot field trials in a manner approximating field methods.

Major transformation products: Degradation products/metabolites of the parent compound that are observed at any time in the laboratory or field studies at a level equal to or greater than 10% of the initial concentration of the parent compound. In addition, major transformation products may include other compounds of toxicological significance.

Pedon: The smallest unit or volume of soil that contains all the soil horizons of a particular soil type. It is the three-dimensional basic soil unit on which the classification of all soils is based.

Plot: A single experimental unit, e.g., a control plot, a treated plot.

Replicate plot: One of two or more plots treated in an identical manner at one site.

Site: Exact geographical location of a study.

APPENDIX 3: DATA SHEET TO CHARACTERIZE TEST SUBSTANCE PROPERTIES

This table contains the physicochemical properties of the test substance and the environmental fate laboratory studies necessary to design a TFD study.

Property/lab study	Values	Classification	Reference
Solubility (mg/L)			
Vapor pressure (Pa) Henry's law constant (atm·m^3/mol)			
Dissociation constant (pKa or pKb)			
n-octanol–water partition coefficient (K_{ow})			
Hydrolysis (half-life) Major transformation products			
Soil photolysis (half-life) Major transformation products			
Soil aerobic biotransformation (half-life and persistence) Major transformation products			
Soil anaerobic biotransformation (half-life and persistence) Major transformation products			
Adsorption/desorption (K_d and K_{oc}) Mobility class			
Others			

APPENDIX 4: ANALYTICAL METHOD REPORTING, QA/QC AND VALIDATION

Environmental chemistry information that is needed for the independent validation of analytical methods used in conducting field dissipation studies is listed below.

Documentation. A full description of the analytical methods used in all steps of the analytical protocol should be submitted, including the following information:
Name and signature, title, organization, address and telephone number of the person(s) responsible for the planning and supervision/monitoring and laboratory procedures/analyses

Analytical method(s) title/designation/date

Source of analytical method(s) [e.g., *Pesticide Analytical Manual* (PAM), Vol. II, scientific literature, company reports]

Principles of the analytical procedure (description)

Copy of the analytical method(s) detailing the following procedures:

- a) extraction
- b) clean-up
- c) derivatization
- d) determination and calculation of the magnitude of the residue

Reagents or procedural steps requiring special precautions to avoid safety or health hazards

Identification of the chemical species determined

Modifications, if any, to the analytical method(s)
Extraction efficiency

Instrumentation (e.g., GC)

- a) make/model
- b) type/specificity of detectors
- c) column(s) packing materials and size
- d) gas carrier and flow rates
- e) temperatures
- f) limits of detection and sensitivity
- g) calibration procedures

Interferences, if any

Confirmatory techniques

- a) other column packings
- b) detectors
- c) mass spectrometry
- d) nuclear magnetic resonance

Date(s) of sampling, extraction and residue analyses

Sample identification (coding and labelling information)

Residue results (examples of raw data, laboratory worksheets, stepwise calculation of residue levels, dilution factors, peak heights/areas, method correction factors applied [e.g., storage stability and method validation recovery values], standard curve(s) used, ppm of total residues and of individual components if they are of special concern, range of residue values, representative chromatograms, spectra of control and treated samples)

Statistical treatments of raw data

Other additional information that the study sponsor/researcher considers appropriate and relevant to provide a complete as well as thorough description of residue analytical methodology and the means of calculating the residue results

Quality Assurance/Quality Control. A complete description of the measures taken to ensure the integrity of the analytical results should include information on the following:

- Logbooks and/or record keeping procedures, representative instrument printouts, such as chromatograms, spectral analyses, etc.
- Sample coding
- Use of replicate samples and control blanks
- Use of written and validated analytical methodology for residue analyses involved in all test and analytical procedures, including modifications made
- Skills of laboratory personnel
- Laboratory facilities
- Use of high quality glassware, solvents and test compounds to ensure minimal contamination
- Calibration and maintenance of instruments
- Good laboratory practices in handling the test substance(s)
- Quality assurance project plan

Internal and external auditing schedule established by the study director using an independent quality assurance unit

Independent Laboratory Method Validation. A full description of the method validation procedures performed by an independent laboratory should be submitted and include the following information:

- Recovery level(s) of the test compounds from the soil (substrate) at various fortification level(s) using the residue analytical methodology
- A validated method sensitivity level
- Results of the study and statistical test applied, including a stepwise presentation of the procedure for calculating percent recovery from the raw data
- All the data/information necessary to independently verify the results
- Summary of the results
- Discussion and conclusions of the results

APPENDIX 5: SITE CHARACTERIZATION DATA SHEET

This table can be used to describe the pertinent site characteristics that can influence the dissipation of the test substance in terrestrial environments.

Parameter	Site Description	Information Source
Geographic coordinates Latitude Longitude Data Source FIPS Code for State, County		
Location within watershed		
Landforms		
Landscape position		
Land surface Slope gradient Slope length Direction Micro-relief Roughness Elevation Data source(s)		
Depth to groundwater		
Average rainfall (yearly/monthly)		
Average air temperature (daily/weekly/monthly) Minimum Maximum		
Average soil temperature (daily/weekly/monthly) Minimum Maximum		
Average annual frost-free period Dates Number of days		
Others		

APPENDIX 6: SAMPLE DESCRIPTION OF THE SOIL PROFILE (USDA

TAXONOMIC CLASS: Fine-loamy, mixed, thermic Aridic Paleustalfs; Amarillo Series

PEDON DESCRIPTION: Amarillo fine sandy loam—grassland. (Colours are for dry soil unless otherwise stated.)

A 0 to 11 inches; brown (7.5YR 4/4) fine sandy loam, dark brown (7.5YR 3/4) moist; weak fine granular structure; hard, very friable; many fine roots; many fine and medium pores; many wormcasts; mildly alkaline; clear smooth boundary. (5 to 19 inches thick)

Bt 11 to 27 inches; reddish brown (5YR 4/4) sandy clay loam, dark reddish brown (5YR 3/4) moist; moderate coarse prismatic structure parting to weak medium sub angular blocky structure; very hard, friable; many fine and medium pores; thin patchy clay films on faces of prisms; clay bridged sand grains throughout; common wormcasts; mildly alkaline; gradual wavy boundary. (8 to 25 inches thick)

Btk1 27 to 38 inches; yellowish red (5YR 4/6) sandy clay loam, moist; weak medium sub angular blocky structure; hard, friable; clay bridged sand grains; common films and threads of calcium carbonate on faces of peds; interiors of peds noncalcareous; moderately alkaline; gradual wavy boundary. (8 to 30 inches thick)

Btk2 38 to 56 inches; pink (5YR 7/3) sandy clay loam, light reddish brown (5YR 6/3) moist; weak medium subangular blocky structure; hard, friable; estimated 60 percent calcium carbonate equivalent; 30 percent by volume is concretions of calcium carbonate less than 1 inch in diameter; calcareous, moderately alkaline; gradual wavy boundary. (6 to 36 inches thick)

Btk3 56 to 85 inches; yellowish red (5YR 5/6) sandy clay loam, yellowish red (5YR 4/6) moist; weak very coarse prismatic structure parting to weak medium subangular blocky structure; slightly hard, friable; thin patchy clay films and clay bridging of sand grains; few, mostly vertical stringers of soft bodies of calcium carbonate are concentrated along faces of prisms; few calcium carbonate concretions less than 1 inch in diameter; calcareous, moderately alkaline; gradual wavy boundary. (8 to 50 inches thick)

Btk4 85 to 99 inches; light reddish brown (5YR 5/4) sandy clay loam, yellowish red (5YR 4/5) moist; weak very coarse prismatic structure parting to weak medium subangular blocky structure; hard, friable; thin patchy clay films and bridged sand grains; few soft bodies of calcium carbonate are concentrated in vertical columns along faces of prisms; calcareous, moderately alkaline.

APPENDIX 7: PHYSICOCHEMICAL PROPERTIES OF SOIL

Property	**Horizon**					**Method**
	H_1	**H2**	**H3**	**H4**	**H5**	
Depth						
Texture % sand % silt % clay Textural class (USDA)						
Bulk density						
Soil moisture characteristic 0 bar 0.1 bar ⅓ bar 1 bar 5 bars 10 bars 15 bars						
pH						
Organic carbon (%)						
Cation exchange capacity (meq/100 g) Base saturation (%)						
Clay mineralogy						
Specific surface						
Anion exchange capacity						
Others						

APPENDIX 8: METEOROLOGICAL HISTORY DATA SHEET

This table can be used to describe the pertinent meteorological factors that can influence the dissipation of the test substance in terrestrial environments.

Parameter	Site Description	Information Source
Average monthly rainfall January February March April May June July August September October November December		
Average minimum/maximum air temperature January February March April May June July August September October November December		
Average annual frost-free period Dates Number of days		
Others		

APPENDIX 9: SITE USE AND MANAGEMENT HISTORY FOR THE PREVIOUS THREE YEARS

Use	Previous Year	Previous 2nd Year	Previous 3rd Year
Crops grown			
Pesticide and fertilizer use			
Cultivation methods Tillage Irrigation practices			
Others			

APPENDIX 10: RUNOFF MODULE

Table 1: Site characterization data sheet (same as in basic study)
Table 2: Soil characterization data sheet (same as in basic study)
Table 3: Meteorological history data sheet (same as in basic study)
Table 4: Summary of site, soil and meteorological conditions that affect runoff

	Property	**Value**	**Interpretation**
Pesticide properties	solubility (mg/L)		
	adsorption K_d/K_{oc}		
Site	tillage		
	crop/vegetation		
	slope (%)		
	average rainfall		
Soil	texture		
	organic carbon (%)		
	CEC (meq)		
	permeability		
	infiltration capacity		
Meteorological conditions			

Table 5: Daily rainfall at the study site

Date	**Rain fall (mm)**			
	Gauge 1	**Gauge 2**	**Gauge 3**	**Total**

Table 6: Residue concentration in soil (mg/kg soil)

Date	**Subplot 1 (mg/kg soil)**	**Subplot 2 (mg/kg soil)**	**Subplot 3 (mg/kg soil)**	**Total (g/ha)**	**Comments**
(0 day)					

Table 7: Transport of residues in runoff water and sediment at each runoff event

Date	**Rainfall mm**	**Runoff L or cf/ha**	**Residues in water**		**Residues in sediments**			**Total water+sed mg/ha**
			Average µg/L	**Total g/ha**	**Suspended Solids %w/w**	**Average mg/kg**	**Total mg/ha**	

1 cubic feet=28.32 litres

APPENDIX 11: EXAMPLE OF DATA REPORTING TABLES

Application Methods and Test Substance

Summary of application methods and rates for [test substance]						
Field	**Application Method**	**Time of Application (Date and Start Time)**	**Amount [Test Substance] Applied (lbs)**	**Area Treated (acres)**	**Reported Application Rate (gal ai/acre)**	**Calculated Application Rate (lb ai/acre)[1]**
1	[#]	[#]	[#]	[#]	[#]	[#]
2	[#]	[#]	[#]	[#]	[#]	[#]
3	[#]	[#]	[#]	[#]	[#]	[#]
n	[#]	[#]	[#]	[#]	[#]	[#]

Application Schedule and Air Monitoring of Test Substance

Summary of [test substance] application and monitoring schedule				
Field/Plot	**Treated Acres**	**Application Period**	**Initial Air/Flux Monitoring Period**	**Water Sealing Period***
Field 1	[#]	MM/DD/YY between [##:##] – [##:##]	MM/DD/YY between [##:##] – [##:##]	MM/DD/YY between [##:##] – [##:##]
Field 2	[#]	MM/DD/YY between [##:##] – [##:##]	MM/DD/YY between [##:##] – [##:##]	MM/DD/YY between [##:##] – [##:##]
Field 3	[#]	MM/DD/YY between [##:##] – [##:##]	MM/DD/YY between [##:##] – [##:##]	MM/DD/YY between [##:##] – [##:##]
Field n	[#]	MM/DD/YY between [##:##] – [##:##]	MM/DD/YY between [##:##] – [##:##]	MM/DD/YY between [##:##] – [##:##]
* Water sealing may be required for highly volatile chemicals. Data for this column may not be appropriate for many pesticides				

Basic Soil Properties

Summary of soil properties for fields/plots							
Field	**Sampling Depth***	**Soil Textural Classification**	**Bulk Density (g/cm^3)**	**% Organic Carbon Content**	**% Sand Content**	**% Silt Content**	**% Clay Content**
[#]	[#] – [#]	[#]	[#]	[#]	[#]	[#]	[#]
[#]	[#] – [#]	[#]	[#]	[#]	[#]	[#]	[#]
[#]	[#] – [#]	[#]	[#]	[#]	[#]	[#]	[#]
[#]	[#] – [#]	[#]	[#]	[#]	[#]	[#]	[#]
* Also include plots of soil temperature (°C) and soil moisture (% of field capacity) measured throughout the study.							

Meteorological Sampling

Describe the meteorological instrumentation and vertical profile of measurements taken, if applicable. Details of the sensor heights and the meteorological parameters for which data will be collected are illustrated in **Table X-4**. The location of the meteorological equipment for each field needs to be presented in maps or graphics.

Summary of meteorological parameters measured in the field				
Field	**Minimum Fetch* (m)**	**Parameter**	**Monitoring heights (m)**	**Averaging Period**
1	[#]	Wind speed/Wind direction	Height [z_1], ….Height [z_n]	1 minute
		Ambient air temperature	Height [z_1], ….Height [z_n]	1 minute
2	[#]	Wind speed/Wind direction	Height [z_1], ….Height [z_n]	1 minute
		Ambient air temperature	Height [z_1], ….Height [z_n]	1 minute
		Solar radiation	Height [z_i]	15 minutes
		Precipitation	Height [z_i]	15 minutes
3	[#]	Wind speed/Wind direction	Height [z_1], ….Height [z_n]	1 minute
n	[#]	Ambient air temperature	Height [z_1], ….Height [z_n]	1 minute
		Ambient air temperature	Height [z_1], ….Height [z_n]	1 minute
*Only include for on-field flux air sampling.				

Determination of Flux rate

Field volatilization flux rates of [test substance or analyte]					
Sampling Period	**Date/ Time**	**Sampling Duration (hours)**	**Flux Estimate (µg/m^2-s)**	**Empirical Flux Determination Method***	**Notes**
1	MM/DD/YY [##:##] – [##:##]	[#]	[#]	[ID, AD, IHF, *etc*.]	[Include notes on missing data, or selection of reasoning used for flux determination method.]
2	MM/DD/YY [##:##] – [##:##]	[#]	[#]	[ID, AD, IHF, *etc*.]	[Include notes on missing data, or selection of reasoning used for flux determination method.]
3	MM/DD/YY [##:##] – [##:##]	[#]	[#]	[ID, AD, IHF, *etc*.]	[Include notes on missing data, or selection of reasoning used for flux determination method.]
4	MM/DD/YY [##:##] – [##:##]	[#]	[#]	[ID, AD, IHF, *etc*.]	[Include notes on missing data, or selection of reasoning used for flux determination method.]
5	MM/DD/YY [##:##] – [##:##]	[#]	[#]	[ID, AD, IHF, *etc*.]	[Include notes on missing data, or selection of reasoning used for flux determination method.]

Field volatilization flux rates of [test substance or analyte]					
Sampling Period	**Date/ Time**	**Sampling Duration (hours)**	**Flux Estimate (μg/m^2-s)**	**Empirical Flux Determination Method***	**Notes**
n	MM/DD/YY [##:##] – [##:##]	[#]	[#]	[ID, AD, IHF, *etc*.]	[Include notes on missing data, or selection of reasoning used for flux determination method.]
***Methods legend: ID = Indirect method, AD = Aerodynamic Method, IHF = Integrated Horizontal Flux.**					