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**ENVIRONMENT DIRECTORATE
JOINT MEETING OF THE CHEMICALS COMMITTEE AND
THE WORKING PARTY ON CHEMICALS, PESTICIDES AND BIOTECHNOLOGY**

**REPORT OF THE OECD WORKSHOP ON THE DEVELOPMENT OF HARMONIZED
INTERNATIONAL GUIDANCE FOR PESTICIDE TERRESTRIAL FIELD DISSIPATION STUDIES
AND CROSSWALK OF NORTH AMERICAN & EUROPEAN ECO-REGIONS**

**Series on Pesticides
No. 68**

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OECD Environment, Health and Safety Publications

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**Report of the OECD Workshop on the Development
of Harmonized International Guidance
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of North American & European Eco-Regions**

IOMC



INTER-ORGANIZATION PROGRAMME FOR THE SOUND MANAGEMENT OF CHEMICALS

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Paris 2012

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Report of the Pesticide Aquatic Risk Indicators Expert Group (2000)

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The Organisation for Economic Co-operation and Development (OECD) is an intergovernmental organisation in which representatives of 34 industrialised countries in North and South America, Europe and the Asia and Pacific region, as well as the European Commission, meet to co-ordinate and harmonise policies, discuss issues of mutual concern, and work together to respond to international problems. Most of the OECD's work is carried out by more than 200 specialised committees and working groups composed of member country delegates. Observers from several countries with special status at the OECD, and from interested international organisations, attend many of the OECD's workshops and other meetings. Committees and working groups are served by the OECD Secretariat, located in Paris, France, which is organised into directorates and divisions.

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FOREWORD

This report presents the results and 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, on 9-11 March 2011. The purpose of the workshop was to solicit OECD country experts’ input on issues related to harmonising guidance for pesticide terrestrial field dissipation (TFD) studies and to constructing an eco-region crosswalk. By sharing their views and expertise, the participants contributed to further progress harmonisation in pesticide scientific and regulatory areas among OECD countries.

The objective of the workshop was to advance a project of the OECD Pesticides Programme, that aims at developing:

- **harmonized international guidance for conducting pesticide terrestrial field dissipation (TFD) studies** (“Component 1”, led by US), and
- **a crosswalk between North American and European eco-regions** (“Component 2”, led by Canada). The crosswalk objectives are to i) identify similar eco-regions between North America and Europe, ii) provide a GIS-based decision support system to assist in the selection of regions for field study sites and iii) provide background information on pesticide use areas (crop-based), soils and climate.

The workshop overall objective for the participants was to provide solutions/recommendations to the OECD, member countries and stakeholders on options and next steps for developing, agreeing and adopting both above-mentioned project components.

This document includes summaries of the workshop discussions and recommendations, as well as background information about the OECD project and copies of experts’ presentations.

This workshop report was approved out-of-session by the Working Group on Pesticides by written procedure that was finished on 20 February 2012.

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, which has agreed that it be unclassified and made available to the public.

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1. Introduction and Overview

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The workshop was hosted by the Pest Management Regulatory Agency (PMRA) of Health Canada, and was opened by Dr. Richard Aucoin, PMRA Executive Director. Approximately 50 people attended. These included officials from OECD country regulatory agencies or international organisations, i.e. the European Commission (EC), the European Food Safety Authority (EFSA), the OECD Secretariat, as well as experts directly involved in conducting and assessing TFD studies, and representatives of pesticide manufacturers worldwide. The list of workshop participants is attached in [Annex 1](#).

2. Why this workshop? Background on the OECD Project

The workshop was organised in order to advance the OECD project that aims at developing:

- **harmonized international guidance for conducting pesticide terrestrial field dissipation (TFD) studies** (“Component 1”, led by US), and
- **a crosswalk between North American and European eco-regions** (“Component 2”, led by Canada). The crosswalk objectives are to i) identify similar eco-regions between North America and Europe, ii) provide a GIS-based decision support system to assist in the selection of regions for field study sites and iii) provide background information on pesticide use areas (crop-based), soils and climate.

The OECD project started in 2009 and is carried out by an *ad hoc* Project Expert Group, co-led by Canada and the US, and also comprising representatives¹ of Australia, the Netherlands, the EC and EFSA. Overall, this OECD project is part of the OECD Pesticides Programme (www.oecd.org/env/pesticides) and more specifically falls under the activities of the Registration Steering Group that aims at encouraging work sharing among pesticide regulatory agencies and promoting harmonisation in OECD countries and beyond. Both the guidance and the crosswalk, that will maximise the use of pesticide TFD studies, will eventually be available to regulatory agencies of all OECD and other countries, as well as to industry and other stakeholders.

This workshop was proposed by the Project Expert Group in order to discuss and resolve issues around the two components of the OECD project that would lead to further harmonisation.

¹ Representatives from the international pesticide manufacturer association, CropLife International, joined the Project Expert Group for the preparations of the workshop.

- First, concerning pesticide field dissipation, pesticide regulatory agencies worldwide require data on field dissipation/accumulation. The objective is to determine “what happens to a pesticide when it is used according to label directions in a representative use area and when all the factors of transformation and transport are acting together”. Depending on the country requirements, studies may account for fate and total dissipation, i.e., degradation, transformation, persistence, leaching, carryover, surface transport, volatilization, plant uptake, transformation products, etc. and also identify the major dissipation routes. So, given these parameters, how can TFD studies be harmonised?
- Second, concerning the eco-region part, site-specific conditions such as soil and climate play a major role in determining the fate and behaviour of a pesticide (in addition to vegetation, pesticide intrinsic properties and the use pattern). These environmental variables can be categorized into “eco-regions” and the fate and behaviour of a chemical is expected to be similar in eco-regions with similar environmental variables. So, how can eco-regions be characterised and the eco-region concept used at the international level?

Depending on the results of laboratory studies and extent of use, several TFD studies each costing hundreds of thousands of dollars are required. The use and acceptance of field studies conducted at foreign sites for national and global joint reviews would reduce economic and regulatory burdens for both registrants and regulators. However, in order to accept a foreign field study, two conditions still have to be met: first, the study objectives, protocols and methodology should be acceptable and second, the study site should be representative of the proposed use areas. Therefore, the specific goal of the project is that studies conducted in EU countries could be used to satisfy data requirements for North American countries and vice versa. An international harmonised TFD guidance document and an eco-region crosswalk capability or tool would help achieve this goal.

During its 2009-2010 activities and meetings/teleconferences, the Project Expert Group initiated work on the two project components.

- Regarding the TFD guidance component, the Group led by US-EPA collated a number of guidance documents available at the country/regional level in NAFTA and EU countries for conducting and using TFD studies for regulatory purposes. However, no internationally harmonized guidance for conducting a terrestrial pesticide dissipation/accumulation study/test was currently available.
- Regarding the eco-region crosswalk component, the Group, led by Canada-PMRA in collaboration with Agriculture and Agri-Food Canada, first considered the existing North American crosswalk that was developed between the US and Canada and then worked with the EC Joint Research Centre, Ispra, Italy, to obtain European databases on soils, climate, crops and to construct European eco-regions. Then the Group developed a computerised model to compare and identify similar eco-regions between North America and Europe (this “similarity” model was presented and discussed at the workshop.)

Two background/outlines papers about the specifics of each component were written for the workshop. These outlines compiled detailed information on the status of each component of the OECD project and listed references. They are included in [Annex 4](#).

3. Workshop Focus and Objectives

The OECD workshop focused on the two components of the OECD project:

- **Component 1: harmonization of guidance for conducting TFD studies,** and
- **Component 2: identification of similar eco-regions between Europe and North America.**

It addressed technical, scientific and policy/regulatory issues around these two components. The participants had the opportunity to share knowledge and experience with OECD country colleagues from governmental pesticide regulatory agencies and industry.

The workshop overall objective for the participants was to provide solutions/recommendations to the OECD, member countries and stakeholders on options and next steps for developing a harmonized guidance for conducting a pesticide TFD study and for considering and adopting a new eco-region crosswalk capability or tool.

In particular, the specific workshop objectives for the two project components were the following:

3.1 *For the guidance on conducting TFD studies*

- To review the progress made so far in identifying and comparing the existing North American and European guidance on pesticide field dissipation/accumulation studies
- To review the regulatory objectives of terrestrial field dissipation studies in North America and Europe and use of field study results in exposure/risk assessment in OECD countries, and to provide guidance on how the differences and needs for specific end-points can be addressed in a harmonized study guidance document
- To propose specific solutions/recommendations for contentious technical issues identified by the Project Expert Group in order to harmonize the guidance
- To provide recommendations on how to adopt and implement the new harmonized guidance.

3.2 *For the eco-region crosswalk*

- To review the progress made so far in identifying similar eco-regions between North America and Europe
- To assess the model and tool developed to compare and identify similar eco-regions
- To review the databases used in defining the eco-regions and the background information that the model provides on soils, climate and crops.

4. Workshop Organisation

The 3-day workshop was organised in alternating plenary and breakout sessions. The workshop programme is included in [Annex 2](#).

The plenary sessions provided a series of presentations on the main issues around each component of the OECD project. Copies of the presentations for each workshop day are listed in [Annex 5](#). Following each presentation, the floor was opened to all workshop participants for quick questions of clarification before splitting into the different break-out groups.

The break-out sessions, in which the workshop participants split into two or three smaller groups, allowed for more detailed discussion. Each break-out group (BOG) wrote a report summarising its discussions, and these reports are provided in [Annex 3](#). Slides of the BOG presentations by the respective Chair persons in plenary are also included in [Annex 5](#) (cf. “Day 3”).

5. Workshop Discussions and Recommendations

This section summarises, for each of the two project components, the discussions and recommendations reached by the workshop participants in break-out groups and in plenary session.

5.1. Terrestrial Field Dissipation (TFD) Guidance

5.1.1. Overview

The plenary presentations on the morning of Day 1 of the workshop first allowed for a detailed presentation of all aspects and issues related to the development of harmonised guidance for pesticide TFD studies. The topics of the presentations are listed below:

- 1/ Comparison of current NAFTA and EU guidance documents*
- 2/ Conceptual model/modular approach based on lab studies*
 - 2a. NAFTA*
 - 2b. EU*
- 3/ Experimental layout/sampling/analysis/results*
- 4/ NAFTA and EU use of results of pesticide TFD data in exposure and risk assessments*

The first presentation provided an overall comparison of the NAFTA and EU guidance documents and set the context of the workshop discussions. Specific aspects of the guidance, i.e. the NAFTA modular approach, the details of the study protocols and the use of the study results for risk assessment purposes, were provided in more detail by the next speakers.

The comparison of the NAFTA and EU guidance documents was organised around the following key steps:

- To identify current NAFTA and European guidance documents on TFD studies
- To compare triggers, purpose and role for NAFTA and EU TFD studies
- To determine similarities and differences in NAFTA and European guidance for conducting TFD studies
- To identify harmonization challenges for TFD studies

5.1.1.1. Current European and NAFTA guidance documents on TFD studies

- In NAFTA countries, the main document is the NAFTA Guidance 2006.
- In EU countries, both the Directive 91/414/EEC and the Regulation 1107/2009, SETAC Europe 1995 guidelines, along with some guidance documents such as the “FOCUS Degradation Kinetics” from 2006 and the EFSA proposed guidance from 2010, constitute the main documents on the conduct and evaluation of TFD studies. The NAFTA guidance (2006) is currently cited in the draft data requirements to be associated with EU Regulation 1107/2009.

Note: full references of documents are given in the Outline I (see [Annex 4](#)) and in the presentation itself (see [Annex 5](#)).

5.1.1.2. Triggers, purpose and role for NAFTA and EU TFD studies

The primary purpose for TFD studies under NAFTA and EU regulatory authorities is to determine the overall fate/dissipation/accumulation of the applied compound under actual field use conditions.

In NAFTA countries, TFD is based on a “conceptual model” that includes major modules (reflecting identified dissipation processes and routes) based on pesticide properties, formulation type and anticipated use patterns. In particular, TFD studies, that are required for all terrestrial and residential outdoor uses, should:

- answer the question “Where did the pesticide go after application?”
- demonstrate pesticide dissipation (transformation and transport) under actual/representative use conditions
- compare and contrast with laboratory data on the physiochemical, mobility, abiotic and biotic transformation of the pesticide
- validate and/or refine the relative importance of selected modules of dissipation such as soil abiotic/biotic processes and the processes of leaching, volatilization, run-off, plant uptake and others; and

- report a dissipation DT_{50} , DT_{75} and DT_{90} over the whole soil profile.

In EU countries, TFD studies are required when the laboratory soil degradation studies show that:

- DT_{50} lab > 90 days @ 10°C and pF 2 – 2.5
- DT_{50} lab > 60 days @ 20°C and pF 2 – 2.5

TFD studies conducted for the EU evaluate the fate of pesticides under representative use conditions. They measure degradation, formation of transformation products and dissipation by measuring residue concentrations in the upper soil depths over time. In terms of endpoints, the TFD studies should provide estimates of the time taken for *dissipation* of 50% and 90% (DT_{50} field and DT_{90} field) and if possible the time taken for *degradation* of 50% and 90% (Deg T_{50} field and Deg T_{90} field), of the active substance under field conditions. Where relevant, information on formation and decline of transformation products shall be reported. These studies are almost always conducted following a single application of the pesticide in order that the data can be used as inputs for environmental exposure modelling.

Therefore, the utility and relevance of the results and end-points derived from field dissipation studies in the risk assessment process varies to some extent between the pesticide regulatory authorities of NAFTA and EU.

5.1.1.3. Similarities and differences in NAFTA and European guidance for conducting TFD studies

A number of parameters dealing with the experimental layout, sampling, analysis, reporting were identified and compared. These included:

- Site selection and characterization
- Number of field sites
- Study design (plot size, controls, replicates)
- Field preparation and agricultural practices (e.g. bare soil vs. cropped plots, irrigation)
- Pesticide application
- Soil characterization
- Soil sampling and timing/frequency
- Analytical methodology
- Results and calculations
- Reporting requirements

5.1.1.4. Harmonisation challenges

NAFTA and EU guidance show no major differences in conducting TFD studies that cannot be harmonized. The following challenges for developing harmonised guidance were identified:

- The objective of the TFD studies in NAFTA countries is to demonstrate the fate and transport of applied pesticides under actual field conditions.
- The objective of the TFD studies in EU is to derive dissipation and/or degradation kinetics of parent and metabolites (also, the TFD studies can be used to derive model input parameters)

Therefore, it was concluded that the to-be-developed OECD harmonized guidance should satisfy the need for both NAFTA and EU partners. It should balance the need for harmonization for global joint reviews and provide the flexibility for the need for (some) different end points between OECD countries.

5.1.2. *Outcomes and recommendations for path forward*

Second, the break-out sessions in the afternoon of Day 1 of the workshop allowed for a detailed discussion of all aspects and issues related to the development of harmonised guidance for pesticide TFD studies. Three break-out groups (BOG) addressed the following topics:

- **BOG 1: Conceptual model/modular approach based on pesticide properties and lab studies**
- **BOG 2: Experimental layout, sampling, analysis, and results**
- **BOG 3: Use of TFD data for exposure/risk assessment**

[At this point, readers are referred to the original break-out group reports (in [Annex 3](#)) and to the slides of the presentations made in plenary (in [Annex 5](#)), which contain detailed aspects of the issues and discussions among the participants.]

During the break-out sessions, participants had the opportunity to gain a better understanding of the need for data for European and North American risk assessments. They worked hard to identify the similarities and minimize the differences among national/regional approaches, and were dedicated to resolve issues and to build consensus for developing a harmonized guidance. Interestingly, in many cases, discussions in different break-out groups reached the same conclusions. It is anticipated that the majority of the recommendations outlined below could be easily incorporated in the current NAFTA guidance to develop harmonized OECD guidance.

Recommendations regarding the development of harmonised TFD guidance

- **To address the different data needs for EU and NAFTA countries, it is recommended, in addition to the basic NAFTA module (i.e. dissipation on bare soil), to add a degradation module “degT₅₀” to satisfy the EU data requirements**
 - The degT₅₀ module would only be needed if there was an EU groundwater concern, a terrestrial risk assessment refinement need or an aquatic risk assessment refinement need (as a result of entry via drainage or run-off)
 - The degT₅₀ module would only consist of a single application, even if the adjacent TFD study evaluating behaviour according to representative use conditions has multiple applications
 - Running both modules (basic and degT₅₀) in parallel would create synergies, would potentially save time and resources, and would allow fewer sites for TFD studies than are currently conducted. Running both modules on the same site is likely to save time and effort involved in setting up, managing and sampling the experiments compared with setting up two separate sites. It was recognized, however, that the degT₅₀ module can also be run as a stand-alone study.
- **It was recommended that, with minor modifications, the 2006 NAFTA guidance could be used, for:**
 - Site selection (consider typical use conditions)
 - Bare ground study
 - Treated plots
 - Sampling
 - Field spikes and application verification
 - Depth of measurements in soil profile
 - Soil characterization
- **It was recommended to add additional text and guidance to accommodate EU needs regarding:**
 - Sampling frequency
 - continue sampling until 10 % of applied parent is reached
 - sufficient samples to allow calculation of DT₅₀ for metabolites, if necessary
 - Analytical aspects, LOQ and LOD
 - LOQ of parent and transformation products identified in the laboratory studies should be below 5% of initial concentration
 - Results and reporting
 - add example table showing what data need to be reported
 - Rate and frequency of application
 - add a separate module where single application is made
 - Low/non-persistent pesticides
 - Specify a reduced number of studies
- **It was also recommended:**
 - **to conduct separate studies for EU and NAFTA with single and multiple applications** (for representation of intended use and under actual conditions)
 - **to use representative formulations** (except for slow-release formulations such as granules)
 - to revisit the requirements of **irrigation schedule** of the NAFTA guidance that specifies application of 110% of the crop water demand to bare soils in arid climates where natural precipitation is low

- to determine the number of studies required in North America in situations when studies are not triggered in Europe (short half-life compounds)
- Regarding transformation products and given that EU and NAFTA have different criteria for selecting the metabolites of their interest, **it was recommended to conduct fewer experiments but to analyze all metabolites of interest to EU and NAFTA.**

5.1.3. *Next steps for the development of harmonised TFD guidance*

During the second half of 2011, the Project Expert Group will consider the workshop recommendations and will prepare draft guidance. This draft document will be reviewed by different groups in OECD, in particular the OECD Registration Steering Group and the OECD Working Group on Pesticides, as well as the OECD Working Group on National Coordinators for Test Guidelines. The approval process, including several rounds of comments, should eventually lead to the publication of the OECD Guidance on the conduct of pesticide TFD studies (expected in 2012-2013).

5.2. *Eco-region Crosswalk*

5.2.1. *Overview*

The plenary presentations on the morning of Day 2 of the workshop allowed for detailed presentations on all aspects and issues related to the development of an eco-region crosswalk. The topics of the presentations are listed below:

- 1/ *Criteria for acceptance of foreign pesticide field dissipation studies/eco-region concept*
- 2/ *Demonstration of GIS-based model for identification of similar eco-regions*
- 3a/ *Comparison of North American and European soil data/databases*
- 3b/ *Comparison of North American and European climate data/databases*
- 4/ *Eco-region delivery methodology*
- 5/ *When and how the eco-region tool is to be used (An example of comparison of North American and European eco-regions)*

The first presentation provided an overview of the eco-region concept and its objectives. The eco-region concept is based on the fact that the fate and behaviour of a pesticide depend on factors of:

- Soil, such as pH, organic carbon and soil texture; and
- Climate, such as air temperature and precipitation

These soil and climate parameters are collectively treated under “eco-regions” and based on these parameters the regions are classified into different regional units. If the regions are similar, then a pesticide is expected to behave in a similar way within those comparable regions. It is therefore expected

that for similar eco-regions, a TFD study conducted in Europe may be considered by the North American regulatory agencies and vice versa.

The OECD project has led to the development of a geospatial Eco-region Similarity Model (ESM) to compare, identify and visualise similar eco-regions between European and North American eco-regions. Soil, climate and other (e.g. agricultural land use, land cover) databases and frameworks existing on both sides of the Atlantic were reviewed (cf. presentations 3a/ and 3b/ for full references) and their variables were compared in order to select the databases/framework to be used in the ESM. Regarding the methodology, the proposed ESM is a parametric test of the soil and climate input variables (at the moment, data on crop and land use are not included in the ESM, but will be added to the system to refine assessments and queries). The geospatial model incorporates a mathematical similarity model (that compares the sum of the classed standard deviations of the normal distribution of each comparison parameter of the source eco-region to that of all the eco-regions of the target area and sums the classed differences in standard deviations to determine percent similarity). The percentage of “similarity” can potentially be adjusted and by default is currently set to 80%.

The second presentation allowed for a demonstration of the computerized eco-region crosswalk model/tool, showing the possibilities of the system, the user-defined input criteria (e.g. soil and climatic parameters, similarity threshold if not 80%) and how results/maps/graphs are reported. At the moment, as explained in the fourth presentation, the tool is desktop-based using commercial software. It was questioned whether this approach would be suitable for OECD needs and whether a web-based application using an open source software could instead be developed.

Finally, the last presentation provided an example run of the eco-region tool for comparing the sites of nine existing TFD studies, in North America and in Europe. The example revealed that using the tool at the planning stage could have reduced the number of studies and could have avoided choosing sites in separate locations that have essentially the same climatic/soil conditions. This example showed the possible use of the eco-region tool as a decision support system for site selection to help ensure an appropriate distribution of sites between regions.

5.2.2. Outcomes and recommendations for path forward

The break-out sessions in the afternoon of Day 2 of the workshop then allowed for a detailed discussion of all aspects and issues related to the eco-region crosswalk and model. Two break-out groups (BOG) addressed the following topics:

- **BOG 1: Criteria for Identification of Similar Eco-regions**
- **BOG 2: Comparison of NAFTA and EU Soil and Climatic Databases and Eco-region Crosswalk Model Delivery**

[At this point, readers are again referred to the original break-out group reports (in [Annex 3](#)) and to the slides of the presentations made in plenary (in [Annex 5](#)), which contain detailed aspects of the issues and discussions among the participants.]

During the break-out sessions, participants had the opportunity to gain a better understanding of the eco-region concept and of the data and methodology behind the similarity model.

Recommendations regarding the eco-region crosswalk

The workshop participants made a number of recommendations that addressed the following topics:

- Eco-region crosswalk model and tool
 - Databases and eco-region framework
 - Delivery
 - Governance and management
- **An eco-region tool was considered in principle useful to ensure an appropriate distribution of field sites between regions.** In addition, the GIS-mapping of similar site locations between North America and Europe was seen as a very powerful way of visualizing the data. However, the current version was seen as too broad and would not provide sufficient guidance for site selection and for acceptance of data among countries.
 - **It was recommended to clarify and further discuss the 80% threshold for similarity adequacy (and in particular in the regulatory context).** It was further suggested comparing input parameters individually (80%), rather than summed, and providing a rationale if 80% cannot be reached. It was also suggested revisiting the normal distribution assumption for each input variables.
 - **The following refinements and improvements for further tool development were recommended, e.g.:**
 - consider alternative parameters, such as available water and monthly weather data
 - keep high-level input data (i.e. soil and climate) in the model and provide various other data (e.g. crop, land cover) for better site selection
 - address weighting of parameters in the selection process (e.g. pH) for situations where substances demonstrate behaviour dependent on those parameters
 - consider switching from the “whole eco-region” approach to a “grid” approach, i.e. GIS mapping of all polygons that have a certain similarity to the polygon in which the study had been done.
 - develop guidance document, tutorials and training for users.
 - **The current soil and climate databases used in the model were considered acceptable.** The WWF eco-region framework was also found acceptable, although alternatives could be considered in the future.
 - **It was recommended, regarding the delivery of the tool, to keep the current approach (i.e. commercial software - ArcGIS - on desk-top), and to investigate open source and web-based options for the future.**
 - **Regarding governance and management aspects of the eco-region tool, it was recommended to determine ownership and responsibility and to clarify issues around resources for further tool development and long-term maintenance.** One break-out group agreed that Canada-PMRA should stay the lead of this project component and that mechanisms of contributions by other partners (e.g. EC JRC) should be investigated. PMRA indicated that it would consider possible financing of the project in 2012 depending on internal priorities.

- **It was recommended to set up a new OECD working group (or technical sub-group) to review, suggest improvements and manage the eco-region crosswalk development.**

Other points of discussion

As a matter of clarification, the developers of eco-region crosswalk tool indicated that the current version needed debugging before release.

Also the workshop participants agreed that the eco-region crosswalk and any software tool needed extensive testing and proper validation in order to be accepted in countries at the OECD level. No detailed discussion took place on the validation process itself but some participants suggested using existing trials.

5.2.3. Next steps for the development of the eco-region crosswalk

During the second half of 2011, the Project Expert Group will consider the workshop recommendations, to further develop and adjust the tool (to the extent possible given the available resources) and will finalise the first version of the crosswalk. This version should then undergo a commenting and validation process (to be determined) in cooperation with the OECD Registration Steering Group. This should eventually lead to the “publication” of the OECD eco-regions crosswalk, including the computerised tool and associated manuals/user guide.

5.3. Next steps of the OECD Project

In addition to what is outlined in sections 5.1.3 and 5.2.3 above, that describe the next steps for each component of the OECD Project, the recommendations developed by the workshop participants will also be forwarded to the relevant subsidiary bodies of the OECD Pesticides Programme, in particular the Registration Steering Group and the Working Group on Pesticides. These members will consider the workshop recommendations and agree on next steps for the overall project.

ANNEXES

ANNEX 1: PARTICIPANT LIST

OECD Workshop on the Development of Harmonized International Guidance for Pesticide Terrestrial Field Dissipation Studies and Crosswalk of North American and European Eco-regions

9-11 March 2011, Ottawa, Canada

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ANNEX 2: WORKSHOP PROGRAMME

OECD Workshop on the Development of Harmonized International Guidance for Pesticide Terrestrial Field Dissipation Studies and Crosswalk of North American and European Eco-regions

9-11 March 2011, Ottawa, Canada

Date	Time	Subject	Speaker
Day 1: PLENARY INTRODUCTION			
9 March 2011	8.30-8.45 AM	Welcome speech	Richard Aucoin (Canada-PMRA)
	8.45-9.00 AM	Introductory speech	Mary Mitchell (Canada-PMRA)
	9.00-9.15 AM	OECD, the Project and the Workshop	Beatrice Grenier (OECD)
	9.15-9.25 AM	Workshop details/plan/housekeeping	Raju Gangaraju (Canada-PMRA)
TERRESTRIAL FIELD DISSIPATION (TFD) GUIDANCE			
Moderator: Peter Delorme (Canada-PMRA)			
Rapporteurs: Gui Lai and Amber McCoy (Canada-PMRA)			
	9.25-9.55 AM	1. Comparison of current NAFTA and EU guidance documents	MAH SHAMIM (US EPA) Raju Gangaraju (Canada-PMRA) Andy Massey (UK CRD)
	9.55-10.15 AM	Discussion on objectives of the EU and NAFTA terrestrial field dissipation studies	All

Date	Time	Subject	Speaker
	10.15-10.30 AM	Health Break	
	10.30-11.00 AM	2. Conceptual model/modular approach based on lab studies 2a. NAFTA 2b. EU	MOHAMMED RUHMAN (US EPA) Ian Nicholson (Canada-PMRA) JOS BOESTEN (Netherlands-WUR)
	11.00-11.30 AM	3. Experimental layout/sampling/analysis/results	RAJU GANGARAJU (Canada-PMRA) Mah Shamim (US EPA) Christopher Lythgo (EFSA)
	11.30-12.00 noon	4. Use of TFD data for exposure/risk assessment	MARK EGSMOSE (EFSA) Faruque Khan (US EPA) Lizanne Avon (Canada-PMRA)
	12.00-1.00 PM	Lunch	
DAY 1 BREAK-OUT GROUPS			
	1.00-1.10 PM	Guidance for break-out groups	Peter Delorme and Raju Gangaraju (Canada-PMRA)
	1.10-2.40 PM	Group 1: Conceptual model/modular approach based on pesticide properties and lab studies	Chair: Andy Massey (UK CRD) Rapporteurs: 1. Ian Van Wesenbeeck (CLI) 2. Ian Kennedy (Canada-PMRA) Technical leads: 1. Mah Shamim (US EPA) 2. Ian Nicholson (Canada-PMRA) 3. Sabine Beulke (UK)

Date	Time	Subject	Speaker
		Group 2: Experimental layout/sampling/analysis/results	Chair: Christopher Lythgo (EFSA) Rapporteurs: 1. Bernhard Gottesbüren (CLI) 2. Lai Gui (Canada-PMRA) Technical leads: 1. Raju Gangaraju (Canada-PMRA) 2. Mohammed Ruhman (US EPA) 3. Adi Cornelese (Netherlands CTGB)
		Group 3: Use of TFD data for exposure/ risk assessment	Chair: Jos Boesten (Netherlands-WUR) Rapporteurs: 1. Ludovic Loiseau (CLI) 2. Ian Hardy (Expert) Technical leads: 1. Mark Egsmose (EFSA) 2. Faruque Khan (US EPA) 3. Ted Kuchnicki (Canada-PMRA)
	2.40-3.00 PM	Health Break	
	3.00-4.30 PM	Continuation of respective break-out groups	
	Immediately after 4.30 PM	Meeting of the Chairs, rapporteurs and technical leads	

Day 2: ECO-REGION CROSSWALK**Moderator: Ted Kuchnicki (Canada-PMRA)****Rapporteurs: Lai Gui and Ian Kennedy(Canada-PMRA)**

Date	Time	Subject	Speaker
10 March 2011	8.30-8.40 AM	Introduction to the day activities	Raju Gangaraju (Canada-PMRA)
	8.40-9.00 AM	1. Criteria for acceptance of foreign pesticide field dissipation studies/eco-region concept	RAJU GANGARAJU (Canada-PMRA) Mah Shamim (US EPA) Christopher Lythgo (EFSA)
	9.00-9.40 AM	2. Demonstration of GIS-based model for identification of similar eco-regions	DAVID KROETSCH (Canada-AAFC) Raju Gangaraju (Canada-PMRA)
	9.40-10.00 AM	Health Break	
	10.00-10.30 AM	3a. Comparison of North American and European soil data/databases	CIRO GARDI (EU JRC) Luca Montanarella (EU JRC)
	10.30-11.00 AM	3b. Comparison of North American and European climate data/databases	CIRO GARDI (EU JRC) David Kroetsch (Canada-AAFC)
	11.00-11.30 AM	4. Eco-region delivery methodology	DAVID KROETSCH (Canada-AAFC) Raju Gangaraju (Canada-PMRA)
	11.30-11.50 AM	5. When and how the eco-region tool is to be used (<i>An example of comparison of North American and European eco-regions</i>)	MOHAMMED RUHMAN (US EPA) David Kroetsch (Canada-AAFC)

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11.50-12.00 noon

Guidance for break-out groups

Raju Gangaraju (Canada-PMRA)

12.00-1.00 PM

Lunch

DAY 2 BREAK-OUT GROUPS

1.00-2.40 PM

Group 1: Criteria for identification of similar eco-regions

Chair: IAN HARDY (Expert)

Rapporteurs:

1. Richard Allen (CLI)
2. Amber McCoy (Canada-PMRA)

Technical leads:

1. Raju Gangaraju (Canada-PMRA)
2. Mah Shamim (US EPA)
3. Christopher Lythgo (EFSA)

Group 2: Comparison of North American and European soil and climate data/databases and model delivery methodology

Chair: DAVID KROETSCH (Canada-AAFC)

Rapporteurs:

1. Dieter Schaefer (CLI)
2. Lai Gui (Canada-PMRA)

Technical leads:

1. Ciro Gardi (EU JRC)
2. Denis Latremouille (Canada-AAFC)
3. Faruque Khan (US EPA)

2.40-3.00 PM

Health Break

3.00-4.30 PM

Continuation of respective break-out groups

Immediately after
4.30 PM

Meeting of the Chairs, rapporteurs and technical leads to prepare the reports

Day 3 AM: RECOMMENDATIONS - PLENARY SESSION

Date	Time	Subject	Speaker
11 Mar 2011	8.30-8.40 AM	Introduction to the day's activities	Raju Gangaraju (Canada-PMRA)

Break-out group reports**TFD Guidance****Moderator: Peter Delorme, Canada-PMRA****Rapporteurs: Ted Kuchnicki (Canada-PMRA) and Beatrice Grenier (OECD)**

8.40-9.05 AM	Guidance group 1 report	ANDY MASSEY (UK CRD)
9.05-9.30 AM	Guidance group 2 report	CHRISTOPHER LYTHGO (EFSA)
9.30-9.55 AM	Guidance group 3 report	JOS BOESTEN (Netherlands-WUR)
9.55-10.25 AM	Questions/discussion	
10.25-10.40 AM	Health Break	

Eco-region Crosswalk

Moderator: Ted Kuchnicki (Canada-PMRA)

Rapporteurs: Peter Delorme (Canada-PMRA) and Beatrice Grenier (OECD)

10.40-11.05 AM	Eco-region group 1 report	IAN HARDY (Expert)
11.05-11.30 AM	Eco-region group 2 report	DAVID KROETSCH (Canada-AAFC)
11.30-12.00 noon	Questions/discussion	
12.00-1.30 PM	Lunch	

Day 3 PM: PATH FORWARD

Moderator: Mary Mitchell (Canada-PMRA)

1.30-2.00 PM	Path forward for Harmonized TFD Guidance	MAH SHAMIM (US EPA)
2.00-2.30 PM	Path forward for use of eco-region model as a regulatory tool	IAN NICHOLSON (Canada-PMRA)
2.30-3.00 PM	Path forward for implementing guidance/eco-region model in the regulation process Next steps <ul style="list-style-type: none">• In EU countries• In OECD countries	MARK EGSMOSE (EFSA) BEATRICE GRENIER (OECD)
3.00-3.10 PM	Vote of thanks and closing remarks	DONALD BRADY (US EPA)

ANNEX 3: REPORTS OF THE BREAK-OUT GROUPS

TERRESTRIAL FIELD DISSIPATION (TFD) GUIDANCE

- **Report of Break-out Group 1** (Chair: Andy Massey, UK)
- **Report of Break-out Group 2** (Chair: Christopher Lythgo, EFSA)
- **Report of Break-out Group 3** (Chair: Jos Boesten, the Netherlands)

ECO-REGION CROSSWALK

- **Report of Break-out Group 1** (Chair: Ian Hardy, Expert)
- **Report of Break-out Group 2** (Chair: David Kroetsch, Canada)

TERRESTRIAL FIELD DISSIPATION (TFD) GUIDANCE

Report of Break-out Group 1

Chair: Andy Massey, UK

Conceptual model/modular approach based on pesticide properties and laboratory studies

The breakout group considered three questions proposed by the organisers of the workshop.

Question 1: Realizing that there are differences between NAFTA and EU objectives for the TFD studies, can the NAFTA modular approach to these studies accommodate both the EU and NAFTA? If not, what needs to be changed or adjusted in the respective study objectives to bring about harmonization? Would these changes/adjustments be feasible?

There was consensus within the group that the modular approach addresses the requirements of NAFTA countries. The basic NAFTA module (soil dissipation without a crop) also gives the option to calculate a dissipation endpoint (DisT50) which is equivalent to the European DisT50. However, there is no module within the current NAFTA guideline to provide a degradation endpoint (DegT50) and the latest European requirements are, therefore not fully satisfied.

Three options for addressing this issue were discussed:

Option 1: Adding a DegT50 module to the basic NAFTA module when appropriate.

The DegT50 module would consist of a field dissipation study where the parent compound is, for example, incorporated or watered in by irrigation relatively soon after application to minimise surface loss processes such as photolysis and volatilisation. The group did not discuss the likely experimental procedure or design of this module as this was not the task of the group. However, it was recognised that there may be some fundamental differences resulting from this approach between the DegT50 plot and the basic NAFTA plots. For example, it is recommended that only a single application should be made in the DegT50 plot even if the basic NAFTA module was undertaken with several applications. In this instance, it is necessary to use only a single application in order to facilitate a robust estimation of kinetic parameters. Some concern was expressed that the NAFTA requirement for multiple applications should not compromise the EU need for DegT50 calculation. However, it should be possible to run the NAFTA module using multiple applications and the DegT50 module using only a single application on separate but adjacent (or nearby) plots at the same site. It should not be necessary to conduct the DegT50 module on a plot that has the same scale as a NAFTA guideline for example. The DegT50 module could be conducted on a relatively small plot compared to the size of plot used in a typical NAFTA study, however the specific details of such a module design were not the remit of this group. (*Open point following the meeting – “Would the basic NAFTA module **with multiple applications** be acceptable as the DisT50 module for Europe, or would Europe require a separate single application DisT50 module?” This may require further discussion by the Workgroup.*)

The additional DegT50 module would be voluntary. The decision on whether or not to include this new module could be based on the results of first tier EU groundwater modelling (FOCUS modelling) or proposed new terrestrial risk assessment using laboratory derived kinetic end points. It was also recognised that this could be run as a stand-alone study if the other field dissipation requirements, i.e. clarifying fate and behaviour observed in the laboratory, had already been met.

It was also recognised that flexibility could remain in the guidelines to accommodate additional modules/processes that might be required by NAFTA countries on a case-by-case basis. Some synergies were anticipated from the proposed approach. The number of sites could potentially be smaller (e.g. the 4 DegT50 studies and 4 basic NAFTA modules could potentially be run on 4 instead of 8 sites in either Europe, the US or Canada, depending on a successful 'crosswalk'). Running the basic NAFTA module and the additional DegT50 module on the same site is likely to save time and effort involved in setting up, managing and sampling the experiments compared with setting up two separate sites. However, it was recognised that individual sites would be more expensive and complex (requiring more sampling and analysis) but hopefully overall cheaper than two separate sites since certain data such as soil characterization data and weather could be shared between the modules conducted at the same site. The additional information provided to NAFTA authorities could aid their interpretation of the results from the other modules. The direct comparison of a study with and without incorporation/irrigation would give valuable information on the importance of surface loss processes, this being of particular importance to the EU. Similarly, it would be beneficial for European authorities if the DegT50 study was complemented by information from the basic NAFTA module and any other modules that were set up for NAFTA countries. Whilst recognising that this additional information could be useful, some concerns were raised over how it could be used in regulatory decision making. It was suggested that additional guidance would be needed to aid this process, although development of guidance in this area was not a formal recommendation from the breakout group.

Option 2. Modification of the existing NAFTA module to allow degradation to be separated from other loss processes.

Although this is possible in principle, a number of group members considered that we currently do not have adequate modelling tools to separate all of the various processes from each other – in the EU at present, the lack of contribution of surface processes to dissipation tends to be argued in a qualitative manner on the basis of laboratory data on volatilisation, photolysis etc. Whilst there are tested modelling approaches to normalise degradation for variable temperature and moisture, there are currently no good models that describe volatilisation or photolysis. North American regulators expressed a lack of confidence in any existing models to separate out other loss processes at the present time. The contribution of loss processes other than degradation would therefore have to be accurately quantified. For example, in the case of volatilisation, it may be necessary to take measurements of air concentrations on the same site (i.e. combining the basic module and the volatilisation module). In order to calculate the losses by volatilisation from the measured air concentrations, models to simulate volatilisation would have to be developed and tested. (*Post meeting note: some participants noted that some models with better descriptions of volatilisation were already available, notably Consensus Pearl, CHAIN_2D, HYDRUS. However, these still may not be sufficient to quantify volatilisation losses accurately and would require further development and validation before they could be used for such a purpose.*) NAFTA guidance currently suggests that up to 10-20% unaccounted loss is acceptable. However, the estimation of the DegT50 could be sensitive to such unaccounted loss and compromise accuracy. This is particularly important in the leaching assessment which can be highly sensitive to DegT50. Thus, in conclusion, this option was not considered viable at this stage.

Option 3. Identification of criteria for accepting DisT50 as DegT50

If the dissipation observed in the field is only due to degradation within the bulk soil matrix and other loss processes are negligible, then the DisT50 derived from the basic NAFTA module is in effect a DegT50. It was discussed whether it would be possible to define criteria of accepting DisT50 values as DegT50 values. NAFTA have qualitative criteria and these could potentially be useful. However, on the basis of experience, some members of the group expressed the opinion that the criteria would only be met in exceptional circumstances as, in practice, there would generally be other loss mechanisms in operation as well, or at least their presence could not be easily excluded. Therefore this approach would not be very useful in practice. In particular it was noted that there are no established criteria for dismissing the contribution of photolysis.

Overall, the option of voluntarily adding a new DegT50 module was considered to be the most appropriate option and applicable in most situations and maintain the desired flexibility in the guideline.

Question 2: What are the modules that have to be included in the conceptual model to satisfy data requirements for NAFTA and EU?

Overall, the group considered that the common modules (or processes) to both NAFTA and EU requirements were:

- Dissipation, i.e. DisT50, including the processes of photolysis, abiotic/biotic degradation etc)
- Leaching (but not 'deep leaching' which is a separate and specific module in the NAFTA procedures)
-

The only EU specific module would be that of degradation in the bulk soil matrix, i.e. a DegT50 module. NAFTA specific modules required on a case-by-case basis were:

- Cropped field conditions (in cases where significant crop interception, uptake and/or shading effects would be expected, e.g. turf, application at advanced growth stages)
- Volatilisation
- Deep leaching
- Run-off

In relation to cropped studies, it was noted that unless the pesticide was systemic, there was generally very little crop uptake, but that shading effects influencing soil photolysis could be considerable in some cases. It was noted that after the cropping period, pesticide residues in cropped plots were often very similar to residues in uncropped plots. It was also noted that crop interception was only measurable if the crops were sampled and measurements converted appropriately.

Question 3: What would be acceptable module selection criteria for including any of the additional modules "other than the basic modules" in conducting the TFD studies?

The group considered that as the NAFTA conceptual model requirements would essentially remain unchanged in a new guidance document, the existing NAFTA criteria for, e.g. volatilisation, cropped plots, deep leaching and run-off, would also remain unchanged. New criteria would only be required for the DegT50 module for EU usage. In this case, it was considered that the criteria for the DegT50 module would be where one or a combination of groundwater assessment, terrestrial risk assessment or surface water risk assessment (where there was a significant route of exposure from soil via drainage or run-off)

failed using the laboratory derived DegT50 values and there was potential for refinement using field derived DegT50 values.

Additional discussions

The group considered some additional points that arose during the course of the discussion.

Leaching can be an interfering factor in attempting to evaluate an accurate DegT50 from TFD studies. It was suggested that it may be possible to infer how much substance had leached below the study depth using TFD data together with laboratory derived data on fate and behaviour and data on water balance in the soil. In order to be useful, the estimate would have to be very accurate. If the % unaccounted from the study was significant (a magnitude of 20% can potentially be accepted by the NAFTA guideline at present), this could have a significant influence on DegT50 estimation. It was noted that a very small percentage leached is sufficient to breach the EU threshold concentration of 0.1 µg/l, although a very small percentage lost by leaching may not have such a large impact on the DegT50 calculated. It was suggested that such information could only be used qualitatively, particularly as leaching simulations can be very sensitive to DegT50 value, thus if the leaching loss was poorly quantified, this could impact on the DegT50 estimation.

A further area of discussion was whether use could be made of small soil columns previously treated in the laboratory and 'transplanted' into the field. This would allow a very good quantification of the initial dose avoiding problems with variability of residues which are often encountered at the start of TFD studies, and could allow more precise control of surface processes compared with a typical NAFTA or EU TFD site. Concerns were raised that such disturbed soils might experience settling after exposure to field conditions resulting in pooling of water directly above the columns. There could also be inherent issues relating to the bottom boundary conditions relating to transplanting a soil column. These issues could result in water balance issues. Although these issues can be overcome, overall, the group considered that there was not enough experience with such approaches, and this would need further development to be a reliable option.

Participants in TFD BOG 1

Chair: **ANDY MASSEY (UK)**

Rapporteurs: Ian Kennedy (Canada)

Ian Van Wesenbeeck (CLI)

Technical Leads: Sabine Beulke (UK)

Ian Nicholson (Canada)

Mah Shamim (US)

Members: David Kroetsch (Canada)

Greg Malis (Canada)

Dieter Schaefer (CLI)

Ashok Sharma (CLI)

Bill Summers (CLI)

TERRESTRIAL FIELD DISSIPATION (TFD) GUIDANCE

Report of Break-out Group 2 Chair: Christopher Lythgo, EFSA

Experimental layout/sampling/ analysis/ results

Agreements reached

Experimental layout

Soil characterisation:

- NAFTA guidance is adequate, common taxonomic description will be required that is compatible with the databases in the ecoregion crosswalk project extension to include the EU.
- It would be good to have in the relevant appendix soil moisture characteristics in SI units (kPa as well as bars).

Site selection:

- Use NAFTA guidance that recommends to consider typical conditions in area of use (crop based) for site selection, registrant shall justify the consortium of selected sites based on the area of use
- NAFTA guidance: Bare ground study is the minimum (mandatory), cropped plots not required routinely, but only in specific situations (special cases)

Experimental conduct

- Follow NAFTA guidance with respect to use of field spikes and application verification.
- The guidance should specify the minimum set of meteorological data necessary. E.g. air or soil temperature, rainfall and solar radiation should be measured on site (other measurements needed will depend on the supplementary modules selected). Modelling approaches for soil temperature and moisture from air temperature and precipitation should be accepted and this should be indicated in the guidance
- Rate and frequency of application, NAFTA guidance to be followed but to address kinetics for EU (particularly for transformation products) may need a separate modular approach where only a single application is made even when label recommends more than one
- When EFSA DegT50 guidance is finalised a module that allows a strategy to eliminate surface processes should be accommodated

Actions identified

Sampling

Sampling times and sampling frequency:

- to work on paragraphs that fit with the EU requirements.
- to give examples i.e. indicating good practices regarding what is needed. i.e.
 - 1) to continue sampling until 10 % of applied parent is reached and/or transformation products no longer account for more than 10% of the molar mass of the initial mass of the parent or 2 growing seasons
 - 2) It is necessary to continue sampling until the DT50 for transformation products can be calculated if triggered by the EU requirements, if the requirement is being fulfilled with a study where a precursor to the transformation product of interest is dosed

Results reporting

- It will be necessary in the guidance to specify the results reporting that is needed by the different regulatory schemes to estimate the different DT rates and or qualitative assessment.
- Guidance should include an example table showing what data need to be reported. (e.g. mg/kg of each sample analysis, mass per unit area summing all core segments, 0-day % applied (measured immediately following application), transformation products reported on molar basis, etc.)

Record of the process and discussions that led to the agreements and actions identified

At the start of the group discussion, the objective agreed was:

- To agree on necessary actions to harmonise the guidance
 - during discussion or
 - further actions after the workshop,
- or
- To keep the guidance different where the different regulatory objectives require it to be different (options or modules)

Topics were selected by voting on the most important questions for each work group member.

The topics selected for discussion were:

(numbered questions originated from the slides in the presentation: Experimental layout/sampling/analysis/results).

- 1) site selection
 - 2) cropped plots
 - 3) irrigation schedule
 - 4) experimental layout e.g. no of sites, plots etc.
- New question: 1 Sampling times and frequency.
- 5) Field spikes & application verification
 - 6) Analytics: LOQ, LOD, Analytes to be considered
 - 7) Soil characterisation

- 8) Results + reporting
 - 9) Onsite meteorological data
 - 10) Rate and frequency of application
 - 11) Depth of measurement in soil profile
- New question: 2 Non-persistent substances, number of field studies necessary.

1) Site selection: Should we select a site with a worst case scenario based on concerns identified in conceptual model or a typical site in a region or both

- CropLife International: Important point of interest is the inherent variability of compound's behaviour in area of use rather than worst case.
- Canada-PMRA: Current NAFTA GD indicates typical use site, not the worst case. We (NAFTA) want to see if worst case e.g. with respect to leaching is covered so that no new study will be required for future user required minor use expansion (URMULE) registration.
- EFSA: worst case is different for different objectives
- Canada-PMRA: conceptual model determines what the worst case is
- CropLife International: a priori worst case site cannot be selected
- US-EPA: Conceptual model will determine what to analyse and which processes to be determined, but not the site selection
- US-EPA: sites in EU AND US will be preferred

CONSENSUS:

- Use NAFTA GD that recommends considering typical conditions in the area of use (crop based) for site selection
- Registrant shall justify the consortium of selected sites based on the area of use.

2) Is a crop plot site necessary? What are the criteria to determine plant uptake as a major route of dissipation? Is foliar dissipation to be included if crop plots are included?

- CropLife International: why cropped plots?
- Canada-PMRA: crops affect water balance and nutrient availability. Cropped plots are more realistic. Though such studies are preferred, they are difficult to conduct.
- CropLife International: some TFD studies in EU. Application are sometimes made onto bare ground, seedling emergence after the pesticide application, this can enable a more even (spatial) application being achieved, which is desirable as it should reduce spatial variability in results. Study on bare soil is probably the worst case.
- US-EPA: worries about crop effect on degradation led to the requirement (fast degradation in bare plots due to soil photolysis). Cropped plots are required when accumulation is studied through modelling with minimum samples.
- Many: Crop uptake of pesticides max. ~ 1-3 %

- Norway: we should concentrate on degradation in soil
- Specifics e.g. seed treatment shall be dealt with separately

CONSENSUS:

- NAFTA GD Bare ground study is the minimum (mandatory)
- Cropped plots routinely not required, only in specific situations (special cases)

3) Irrigation schedule?

- CropLife International: challenges 110 – 120 % of the crop demand also for bare ground studies. Particular problem for areas in which crop demand is much higher than natural rainfall
- Some general agreement in the group is that it seems to make sense to have the same excess of water in the bare plot soil compared to the cropped plot. So let's go for a minimum of 110 % of water excess based on bare ground evaporation for the bare plots

CONSENSUS:

- For irrigated crops where the study design is with bare soil, it was agreed that the basis to determine the irrigation volume should be based on evaporation from bare soil (minimum 110% of water surplus based on predicted evaporation from bare soil) and not according to crop requirements.
- For rainfed areas/crops it has to be assured that the precipitation (+irrigation) is equivalent to a minimum of 110% of 30 year average (this is in line with what is currently indicated in the NAFTA GD)
- In case of absence of equivalent rainfall, the first irrigation should take place shortly after application (e.g. 72h, 10 mm).
- Wording in the current NAFTA guidance Part E section 5 (irrigation) to be amended consequently. Suggested text indicated below (new text in *italics*):

It is essential that study design include sufficient water to meet the crop need in quantity and timing. If the use pattern includes irrigation to supplement water requirements of the plant then 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 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.

The range of 110-120% text has been removed in this proposal, as a study would not be rejected because of too much rain and this would be the consequence of including an upper limit such as 120%.

4a) How many treated plots are required?**4b) How many soil cores per replicate plot are required?****4c) How many composited samples are required for analysis per site?**

- Many voices: As draft data requirements to support EC regulation 1107/2009 refer to the NAFTA guidance then recommendations on the number of plots at each site, number of soil cores per plot and compositing per plot this should be in accordance with the NAFTA guidance.

CONSENSUS:

- For plots and sampling and compositing of samples follow NAFTA guidance.

New question 1 on sampling times / sampling frequency

- North American regulators were content to agree to update the requirements in line with EU data requirements rather than the current NAFTA guidance to reach a DT75

CONCLUSION:

- Continue sampling until 10 % of applied parent is reached and/or metabolites no longer account for more than 10% of the molar mass of the initial mass of the parent, or 2 growing seasons
Action to give examples i.e. graphs indicating good practice regarding what is needed.
- It is necessary to continue sampling until the DT50 for metabolites can be calculated if triggered by the EU requirements, if this requirement is being fulfilled with a study design where a precursor of the metabolite of interest is dosed.
Action to work on paragraphs that fit with the EU requirements.

5) Field spikes & application verification

- Many voices: Agreed it was important to verify application achieved and residue was not transformed during sample transportation (field spikes), so the options in the NAFTA guidance regarding these issues were appropriate.

CONCLUSION:

- Follow NAFTA GD with respect to use of field spikes and application verification.

6) Analytical aspects: LOQ, LOD, Analytes to be considered

- NAFTA: LOQ 1-2 times below EEC (= 1 – 10%)
- EU requirement: down to < 5% of initial concentration

CONSENSUS

- LOQ for dosed substance and transformation products (identified in lab incubations and photolysis investigations) should be < 5% of initial concentration (molar basis).

7) Soil characterisation

- Many voices: short discussion leading to consensus below.

CONSENSUS

- NAFTA GD is adequate, common taxonomic description will be required that is compatible with the databases in the ecoregion crosswalk project extension to the EU.
- It would be good to have in the relevant appendix soil moisture characteristics in SI units (kPa as well as bars).

8) Results + reporting

- EFSA: need to be consistent about the data that is to be reported to enable all parties to calculate / assess what is required for their exposure characterisations (DT values and or qualitative assessment)
- Action: Write down in the guidance what it is essential to report.

CONCLUSION

- Action: Update GD with an example table showing what data need to be reported (e.g. mg/kg of each sample analysis, mass per unit area summing all core segments, % initial applied, transformation products reported on molar basis, etc.)

9) Onsite meteorological data

- Are soil moisture measurements on daily basis absolutely necessary?
- CropLife International: prefers to simulate soil moisture and soil temperature, this is in line with EU FOCUS guidance.
- Other: questioned the added value of measured soil moisture.
- EC-JRC: minimum set of parameters in situ to be measured should be defined.
- US-EPA: does not think that very sophisticated instrumentation is necessary as long as accepted models can be used AND good basic data is measured on precipitation and air temperature to calculate the parameters e.g. soil moisture and temperature.
- Modular approach for specific measurements, e.g. wind speed and direction may be required for volatile compound.

CONCLUSIONS:

- Several key meteorologically related parameters can be calculated from other measurements rather than having to be measured directly (e.g. % soil moisture) - these approaches should be accepted and this should be indicated in the guidance

- The guidance should specify the minimum set of data necessary. E.g. air or soil temperature, rainfall and solar radiation should be measured on site (other measurements needed will depend on the supplementary modules selected).

10) Rate and frequency of application

- US-EPA: NAFTA- follows label also with respect to multiple application
- CropLife International: EU highest individual rate, single application is accepted.
- CropLife International: use modular approach, EU and NAFTA may not be compatible for a single field study, different plots may be required to fulfill both regulatory objectives; i.e. one with a single application and another with the label multiple application pattern recommended on the label.
- Canada-PMRA: prefer to follow the label.
- US-EPA: may be acceptable to consider some studies with single application; but some studies are required that follow the label.

CONCLUSION:

- NAFTA GD acceptable, but to address kinetics for EU (particularly for metabolites) may need a separate modular approach where single application is made.

New question: 2. Non-persistent substances, number of field studies necessary.

- As EU requirements do not trigger field studies for non-persistent compounds, it was discussed if less than 6 trial sites in N America might be proposed to EPA and PMRA.

New Action:

- NAFTA to consider if they could specify a reduced number of studies required for non persistent compounds.

11) Depth of measurement in soil profile

- It was discussed and agreed that the provision in the NAFTA guidance (regarding non detection and when deeper core segments did not have to be analysed) was appropriate.

CONCLUSION

- Follow NAFTA Guidance

Participants in TFD BOG 2

Chair: **CHRISTOPHER LYTHGO (EFSA)**

Rapporteurs: Bernhard Gottesbüren (CLI)

Gui Lai (Canada)

Technical Leads: Adi Cornelese (Netherlands)

Raju Gangaraju (Canada)

Mohammed Ruhman (US)

Members: Richard Allen (CLI)

Murray Belyk (CLI)

Ole Martin Eklo (Norway)

Brian Harvey (CLI)

Andrew Newcombe(expert)

Ciro Gardi (EC)

TERRESTRIAL FIELD DISSIPATION (TFD) GUIDANCE

Report of Break-out Group 3

Chair: Jos Boesten (Netherlands)

Use of TFD data for exposure/risk assessment

1. Introduction:

After a round table introduction of each participant to the break-out group, the questions prepared by the Chair, Rapporteurs and Technical leads were presented to the group. The group also had the opportunity to raise additional questions/points to be discussed. As a result, five main questions were raised and discussed:

1. Do you agree with the summary table? Suggestions for change (Note from the rapporteur: refer to the summary table of M. Egsmose, L. Avon & F. Khan – NAFTA and EU use of results of pesticide terrestrial field dissipation studies in exposure and risk assessments – slide # 20 inserted below)
2. Is it valid to incorporate pesticide to limit surface processes? (use of this study) – related to EFSA guidance (EFSA, 2010)²
3. What will happen to old studies with the new EFSA/NAFTA guidance? (re-review processes) – related to EFSA guidance (EFSA, 2010) and also NAFTA guidance
4. What endpoints are needed for NAFTA/EU today? How are they derived and used in the NAFTA\EU risk assessments? (keeping in mind current procedure: NAFTA parallel plots - incorporated and surface applied - and EU only surface applied)
5. What endpoints will be needed for NAFTA\EU in the future in view of developments? How will these be derived and used in the NAFTA/EU risk assessments?

2. Discussion report:

2.1. Question 1 - Do you agree with the summary table? Suggestions for change

The summary table as presented by M. Egsmose, L. Avon & F. Khan (slide # 20) was discussed point by point. Only the points which generate some discussions are reported.

² EFSA (2010) Guidance for evaluating laboratory and field dissipation studies to obtain DegT50 values of plant protection products in soil

Relevance of the Field Dissipation Results in Risk Assessments

Parameters	EU	NAFTA
Representation of intended use: •Applied as an end-use product •Under Actual Conditions •Representation of Pesticide use areas	Yes Yes Yes	Yes Yes Yes
Key Kinetic Parameters: •DisT ₅₀ and DisT ₉₀ •DegT ₅₀ and DegT ₉₀ •Utility of end-points	Yes Yes Yes	Yes No Yes
Identify Transformation Products	Yes	Yes
Exposure Assessment: •Ground Water •Surface Water •Soil Organism	Yes (Quantitative) Yes (Quantitative) Yes (Quantitative)	Yes (Qualitative) Yes (at refined tiers) Yes (Quantitative, PMRA), No (USEPA)
Relevance to Regulatory Decision	Yes	Yes (confirmation/weight of evidence)



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2.1.1. Representation of intended use – Applied as an end-use product

In EU, not all end-use products are tested for fate, only “representative” formulation(s). EU/PMRA/EPA agreed that the individual components of the formulation will not normally influence the fate of the AI, and that only a representative formulation needs to be tested. It was highlighted that it may be different for Granular formulations as the granular may affect the fate of this AI.

2.1.2. Representation of intended use - Under actual conditions

In NAFTA, TFD studies are conducted according to the exact GAP (as written on the label) to mimic the real use. For PMRA/EPA, the exact GAP is seen as necessary to evaluate carry-over due to a “long hard” winter and is considered as the highest Tier study. For multiple applications, PMRA and EPA calculate DisT50 starting from the last application. The field DisT50 is generally not used for modelling purposes by EPA/PMRA (laboratory DT50 are used).

In the EU, TFD are not necessarily conducted following the exact GAP (as an example if the label stipulated 6 foliar applications, the tested GAP in EU could be a single application with an application rate corresponding to the sum of the 6 individual application rates). It is not deemed to be necessary to apply the multi-applications as the aim is to derive a robust normalised DT50 and extrapolate from the few field studies to the “overall” EU with modelling.

The EPA/PMRA would interpret studies conducted with only one application as a study deficiency if the label recommends multiple applications. It would not necessarily mean rejection of the study and still

could be acceptable or supplemental if there are other data available (case by case situation). The method of applying the compound in the EU is driven by the need to simplify DegT50 and ffM (formation fraction of metabolites) calculations. It was highlighted that the EU prefers this approach as the statistical criteria in the kinetic fitting procedure for metabolites would not be met for multiple applications.

The question on how EFSA would evaluate kinetic parameters with multiple applications (as according to the GAP) was raised. No answer was provided.

As a potential solution/recommendation by the group to overcome this issue, it was proposed that:

- if the GAP is one application, there is no issue and the study can be used in NAFTA and EU directly
- for multiple applications GAP, both single and multi-applications studies would be needed for EU and NAFTA – single and multi-applications

2.1.3. Key Kinetic parameters

As a point of clarification, it was highlighted that to calculate DisT50 in EU/NAFTA the overall detected residues in the whole soil profile is taken into account.

2.1.4. Identify transformation products

In NAFTA, major metabolites on one hand and minor metabolites that have been identified as a concern in the human health review on the other hand need to be analysed in TFD [*i.e.*, residue of concern]. In EU, metabolites relevant for the risk assessment have to be analysed, but there is no strict requirement to analyse a metabolite that has a DT50 < 60d (but in practice is often done for the primary and secondary metabolites to facilitate kinetic model fitting).

The EU TFD analytics may not address all the requirements to support the NAFTA conceptual model (probably fewer metabolites are analysed in the EU and/or not the same). This could be seen as a deficiency by EPA/PMRA.

It was emphasised that the term “relevant metabolites” has a different meaning between NAFTA and EU. As a potential solution/recommendation by the group to overcome this issue, it was proposed that if there are fewer studies to be conducted (resulting from the crosswalk tool), then the studies may contain all metabolites of interest for NAFTA and EU.

2.1.5. Exposure assessment

As a point of clarification, it was highlighted that in EU the soil DegT50 was also used in the surface water exposure assessment via drainage and runoff. PMRA also indicates that it has started to evaluate the use of field DisT50 for higher tier soil organism risk assessment.

2.2. Question 2 - Is it valid to incorporate PPP to limit surface processes?

Some worries were raised regarding incorporation of the PPP in soil when incorporation is not the usual method of application. Is it scientifically valid to incorporate the compound that is surface applied? Would a soil incorporated study be acceptable to the EU level to cover the regulatory requirements when the EFSA PPR panel recommends incorporation? (EFSA, 2010)

As a potential solution/recommendation, parallel tests could be conducted. One test in which the compound is surface applied and one test in which the compound is incorporated. The incorporation test would be “artificial“ and done to eliminate surface processes so as to allow the calculation of a field DegT50matrix (specific value for a specific use). This was not seen as a problem by EPA as far as it is done in parallel to a surface applied application (module).

However, there were still worries that incorporation may produce artificially long DT50 values because the incorporation techniques may disturb the soil (disturbing the fungal activity as an example) and/or some product would be lost via surface process (“dose effect“). A proposal was made to quantitatively take into account surface process to correct the application rate for the incorporated test. However a surface applied test would need to be conducted to quantify the surface process and then correct the application rate for the incorporated test.

It was highlighted that incorporation is not the only way to overcome surface process issues, it is just one option. Surface applications can still be undertaken, but then it is necessary to follow the EFSA 2010 guidance in order to calculate the DegT50matrix.

How to take into account the surface processes in the risk assessment was raised. It is thought that the EFSA guidance clarifies this aspect (correct the application rate – refer to EFSA (2010)).

2.3. Question 3 - What will happen to old studies with the new EFSA guidance?

PMRA/EPA consider that such studies will still be accepted to confirm the conceptual model, but could be considered as deficient if they did not fully meet the new NAFTA guidance. However, they may not be adequate to derive field DegT50matrix for EU. Different DT50 values may be obtained as a result of the evolution of the kinetic parameters calculations (case by case). PMRA considers that the use of an old study depends if a new issue is raised. Just because a study is old does not automatically means that it is no longer acceptable.

2.4. Question 4 - What endpoints are needed for NAFTA\EU today? How are they derived and used in the NAFTA\EU risk assessments?

The discussions were captured in a table and are reported as such:

NAFTA today		
<u>What endpoints:</u>	<u>How are they derived:</u>	<u>How are they used:</u>
<ul style="list-style-type: none"> • PMRA/EPA = DisT50 + DisT90 + carry-over (% of the applied left at application the following year) • Depth of leaching and identity of metabolites • Maximum levels of metabolites 	<ul style="list-style-type: none"> • Total depth, PMRA (EAD tool that includes several kinetics similar to FOCUS), EPA (log-linear SFO). Discussions are ongoing between PMRA/EPA to harmonise • carry-over based on measurements prior to next year's application • Depth of leaching, down to depth <LoQ/LoD • Metabolites based on analytics - parent equivalent compared to max. measured parent 	<ul style="list-style-type: none"> • DisT50 Qualitative comparison with lab data (confirmation of conceptual model) • Carry-over: identify potential issue and mitigate on the label (if residue >30% of applied – restriction on the label) • PMRA, use the max level of metabolite from lab in modelling. Level from field study used to check/confirm modelling using lab data (field is higher tier). • EPA uses the max level from either lab or field (the worst one) for metabolites of concern
EU today		
<u>What endpoints:</u>	<u>How are they derived:</u>	<u>How are they used:</u>
<ul style="list-style-type: none"> • DisT50/90 + DegT50/90 parent and metabolites • Maximum levels of metabolites • Depth of leaching parent and metabolites (qualitative) 	<ul style="list-style-type: none"> • DisTx and DegTx according to FOCUS kinetic • Depth of leaching, down to depth <LoQ/LoD • Metabolites based on analytics - parent equivalent compared to max. measured parent 	<ul style="list-style-type: none"> • DisT50/90 used as trigger for accumulation assessment (calculate carry-over/accumulation or studies) and PECsoil calculation • DegT50 used in exposure assessment (modelling input) • Max level of metabolites used to calculate PECsoil • Depth of leaching is used in a qualitative way – with PECgw calculation

2.5. Question 5 - what endpoints will be needed for NAFTA\EU in future in view of developments? How will these be derived and used in the NAFTA\EU risk assessments?

The discussions were captured in a table and are reported as such:

NAFTA future		
<u>What endpoints:</u>	<u>How are they derived:</u>	<u>How are they used:</u>
<ul style="list-style-type: none"> PMRA = DisT50 at different depth (still discussion ongoing, 0-15cm, 0-7.5cm) for use in soil RAs 	<ul style="list-style-type: none"> PMRA (EAD tool) 	<ul style="list-style-type: none"> PMRA may use DisT50 for soil organism RA (discussion ongoing on the depth to calculate)
	<ul style="list-style-type: none"> Discussion between PMRA/EPA to harmonise DT50 calculations 	
EU future		
<u>What endpoints:</u>	<u>How are they derived:</u>	<u>How are they used:</u>
<ul style="list-style-type: none"> DegT50matrix Possibly aged sorption parameters Rapidly dissipated fraction 	<ul style="list-style-type: none"> DegT50matrix and rapidly dissipated fraction according to EFSA(2010) 	<ul style="list-style-type: none"> PECsoil PECgw,PECsoil, PECsw PECgw,PECsoil, PECsw

Participants in TFD BOG 3

Chair: **JOS BOESTEN (Netherlands)**

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Ludovic Loiseau (CLI)

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Faruque Khan (US)

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Kenneth Conroy (Ireland)

Roger Holten (Norway)

Amber McCoy (Canada)

Felix Meier-Manz (CLI)

Ralph Warren (CLI)

Denis Yon (CLI)

ECO-REGION CROSSWALK

Report of Break-out Group 1

Chair: Ian Hardy (Expert)

Criteria for Identification of Similar Eco-regions

Questions:

Of the original twelve questions suggested to the breakout group, three were prioritized (Q1, 3 and 9) as being the key ones to consider. Two additional questions were also suggested by the BOG and were designated Q13 and 14. Four questions (Q4, 5, 8 and 10) were also at least partly covered during the discussions. Questions 6 and 7 were considered more appropriate for BOG 2 and were not discussed by the group.

Q1. Field dissipation studies conducted at foreign sites are considered if the study sites represent similar environmental conditions, i.e., soil and climatic conditions represented by ecoregions. Is the ecoregion concept acceptable?

Q2. Are there any other criteria to be considered in accepting equivalent foreign pesticide field dissipation studies (other than study protocol)?

Q3. To identify similar ecoregions, soil parameters (pH, organic carbon and texture) and climate parameters (rainfall and temperature) are considered in the present model. Are there any additional parameters to be considered?

Q4. Should soil pH be excluded/included as a criterion for comparing and identifying similar ecoregions?

Q5. Should agronomic practices, microbial activity and soil moisture be included?

Q6. A GIS-based (ArcGIS 9.3) approach was used to compare and identify similar ecoregions. Is this the right software and approach?

Q7. Are these databases acceptable?

Databases used for ESM/ERX:

Soil: Harmonized World Soil Database (IIASA)

Climate: MARS FOODSEC ERA-Interim Meteoata (JRC)

Agricultural Land Use/Land Cover:

STATSCAN Census of Agriculture 2008 (Canada)

CENSTAT and STATSGO (USA)

CORINE (EU)

Framework:

– WWF Terrestrial Ecoregions of the World

Soil Regions map of Europe (published by ESNB, BGR and JRC)

Level II Terrestrial Ecoregions of North America (published by CEC)

Q8. Method of comparison: ESM uses mean and standard deviation to compute similarity between multiple ecoregions (parametric test) and estimates percent similarity. Is this methodology acceptable?

Q9. A similarity score of 80% is proposed to identify similar ecoregions, although the model allows selecting similarity score of 50-100%. Is 80% similarity threshold adequate to identify similar ecoregions?

Q10. The Model uses a query and filtering system based on user-defined criteria to select a field site. A site with a worst case scenario based on concerns identified by the conceptual model or a typical site can be selected. Is this methodology to select a site acceptable?

Q11. Do we prefer a site with a worst case scenario or a typical site or both?

Q12. The Model produces a map with similar ecoregions and comparison tables for soil pH, organic carbon, texture, taxonomic class, temperature and precipitation. What additional information is required in model output? (Taxonomic class, CEC, slope, bulk density, etc)

Q13. What is the link between the conceptual model and the ecoregion approach?

Q14. What validation is required? What are the criteria?

Five key topics were identified for discussion as follows:

1. *(Question 3) To identify similar ecoregions, soil parameters (pH, organic carbon and texture) and climate parameters (rainfall and temperature) are considered in the present model. Are there any additional parameters to be considered?*

The group discussed a number of topics.

- a) Is soil development/genesis a factor to be considered? Perspectives that were considered are:
- Does genesis influence pesticide behavior?
 - Does genesis influence water movement?
 - Does genesis cover soil sub-surface character?

The group concluded that the ecoregions themselves have been defined based partially on genesis (and ecology of the natural ecosystem) as soil parameters considered by the ecoregion comparison (texture, pH, %OC) are related to soil genesis. Therefore we concluded that this is not needed as a variable; however a comparison of soil taxonomy group could be a factor to consider in validation/evaluation of the tool.

b) Available water capacity could be a better indicator (parameter) for describing dissipation than texture. Values could be calculated with pedo-transfer functions (texture, organic carbon, bulk density). The break out group recommended that the project group consider this as a variable and to evaluate if this parameter adds value to the evaluation or is already correlated with existing soil parameters (partly covers Q5).

c) Selection of pH should be an optional factor for comparison depending upon the chemical of concern (covers Q4). Ideally the weighting of factors should be an option (Q10 and 13 partly covered) but selection of specific weighting factors would need to be justified (i.e. default weighting is 1 unless justified). Soil pH would only be included where the PPP is known to show pH-dependence.

d) Weather data – must be compared on a monthly time step rather than annual. Annual data can mask very different climate patterns and will cause erroneous comparisons. To widen the applicability to all OECD countries, an option to allow for an ‘offset’ to be used is needed in order to be able to compare data

from the Southern Hemisphere in the future – this will allow for seasonal variation between countries to be taken into account. There was a suggestion that this could be linked to crop timings.

2. (Question 9) A similarity score of 80% is proposed to identify similar ecoregions, although the model allows selecting similarity score of 50-100%. Is 80% similarity threshold adequate to identify similar ecoregions?

Before answering this question the group felt it needed to better understand how the ESM calculation was performed and what was meant by a ‘similarity %’. It was suggested to add in a detailed example calculation of the ‘similarity %’ approach to aid clarity.

Also the group questioned whether the assumption of a normal distribution for all parameters, especially climate, is appropriate (covers Q8). The soil texture parameter within an ecoregion as a parametric test is also rather meaningless. The project team should consider non-parametric statistical tests if appropriate.

The group felt that a similarity score should be provided for each parameter rather than just the cumulative % similarity. This would allow some flexibility in application, i.e. a score of 60% might be acceptable for some criteria if justified.

The project team should explain/justify why 80% similarity is appropriate. There may be a need to adjust as knowledge, experience and validation of the tool is developed. The choice of the final level (e.g. 80%) should be a regulatory decision.

(post-note: The 80% came from evaluation of a remote sensing project where it was assumed that remote sensing can accurately describe 80% of the landscape. But this should be better clarified).

The project team should develop a validation/ evaluation and ground-truthing exercise before an appropriate similarity score can be defined.

3. (Question 13) What is the link between the conceptual model and the ecoregion approach?

The group discussed if there was a link between the process of defining a conceptual model as used in the NAFTA terrestrial field dissipation study guideline and the ecoregion approach.

The discussion concluded that the conceptual model identifies the processes to be evaluated (including DegT50 for EU modeling input) and these then drive the parameters used as the critical components to select sites (but see Question 1 for further comment).

The ecoregion comparison tool and decision support system helps ensure an appropriate distribution of sites between regions. It can help to avoid doubling up of site conditions, i.e. avoids having 2 sites in separate locations that have essentially the same climatic/soil conditions.

However, the conceptual model and ecoregion approach are not directly linked together – the conceptual model identifies the important factors to be considered in the TFD study, whereas the ecoregion tool can help to identify and select sites that are suitable for use [and acceptable to several countries].

4. (Question 14) What validation is required?

Obviously the first point to address is what needs to be validated. The group decided that comparisons of results of dissipation studies (leaching/kinetics) would not be appropriate as intra ecoregion variability will most likely be as great as inter-ecoregion.

Rather validation that is focused on weather at the monthly time step, distribution of soils and crops within an ecoregion would be more appropriate. A set of TFD studies may be used to support the use of a PPP on multiple crops and this may need to be considered during the evaluations.

One proposal was to start with soil properties and weather from a number of soil dissipation studies conducted in North America and Europe and then to identify the ecoregions with a high % similarity. Then, within the ecoregion to evaluate the distribution of polygons with a high degree of similarity with respect to crops, soil type and climate. Expert opinion will also be needed in the ground truthing process.

The ESM model assumptions should also be validated (see Questions 8 and 9).

5. (Question 1) Field dissipation studies conducted at foreign sites are considered if the study sites represent similar environmental conditions, i.e., soil and climatic conditions represented by ecoregions. Is the ecoregion concept acceptable?

The BOG members discussed in detail ecoregion concept and recommended a two tier approach: Tier 1 to identify similar ecoregions based on a broad range of environmental parameters and Tier 2 site specific analysis (polygon/block level) for selecting a specific site based on pesticide properties and laboratory fate studies.”

The discussion concluded that the comparison of ecoregions is a Tier-1 evaluation that does not necessarily fully capture the objective to evaluate if an individual dissipation study location has equivalency/similarity in other regions.

A full Tier-2 evaluation of all the available polygons/blocks rather than aggregation by ecoregion would be ideal however this may require significant processing capacity – ‘grid’ approach.

In other words, the comparison of ecoregions (Tier-1) is a high level comparison of regions (region to region) with a broad range of values, whereas site specific parameters (field study sites) are specific values for further detailed analysis for site selection (Tier-2). Ecoregion comparison is not intended to identify individual dissipation study locations, rather it identifies similar regions with a broad range of parameters within which study sites are selected depending on pesticide properties and laboratory fate studies.

Once specific similar ecoregions have been identified then it would be extremely valuable to plot the polygons that have high similarity within that region.

GIS mapping of the ‘similarities’ of site locations between NA/EU is a very powerful way of visualizing the data, while the ‘grid’ approach described was thought to be a better way of evaluating the data than the ecoregion approach. The understanding is that the underlying data that would be required are already available from the development of the ecoregion tool. However, to provide a tool based on the ‘grid’ approach would take significantly more time and effort.

Another alternative suggested was to make the assessment in a stepwise manner. Firstly to identify polygons with a specific group of crops appropriate for the pesticide under evaluation. Secondly to select those polygons with similar climate and then thirdly to select equivalent soils.

The BOG agreed that the studies should be considered as acceptable if similar climatic and soil conditions were shown to exist between NA and EU (partly covers Q2 in that the BOG agreed soil/climate were the key drivers for comparison).

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ECO-REGION CROSSWALK

Report of Break-out Group 2

Chair: David Kroetsch, Canada

NA and EU soil and climatic databases and Eco-region crosswalk model (ERX) delivery

This OECD project was initiated to maximize the use of pesticide field dissipation studies by developing harmonized international guidance for conducting the studies and identifying comparable North American and European Ecoregions. There is a requirement for a delivery system accessible to all potential users that allow the selection of 'similar' Ecoregions between NA and EU. The fate and behaviour of a pesticide in an Ecoregion depends on factors such as soil (pH, OC, texture and classification) properties, climate and vegetation (crops). This geospatial model has been developed to identify comparable North American and European Ecoregions.

The databases used as source data for the Ecoregion Similarity Model and the Ecoregion Crosswalk Tool and attributes used are listed below:

DATABASES

- Soil: Harmonized World Soil Database (HWSD) v1.1(EU and NA) and Soil Regions Map for Europe v2 (EU)
 - pH, organic carbon and texture
 - Means and SD of normal distribution of each class calculated and % similarity calculated
- Climate: MARS FOODSEC Meteodata 2001-09 (EU and NA)
 - Climate: Precipitation and temperature
- Framework: World Wildlife Federation Terrestrial Ecoregions
- Land Use: Agricultural land use (pesticide use area):
 - Canada: SLC/STATSCAN Census of Agriculture 2008
 - USA: STATSGO (State Soil Geographic Data Base, USDA)
 - EU: CORINE/CAPRI

The Breakout Group considered three areas for discussion and recommendations:

- 1. DATA**
- 2. DELIVERY**
- 3. GOVERNANCE**

1. DATA

The breakout group considered three questions with respect to data requirements for the similarity model and querying proposed by the organisers of the workshop.

1.1. Are these databases acceptable?

The consensus of the group was that the current data which we defined as Tier 1 (soil (pH, texture, OC), climate (precipitation, temperature) are acceptable for high level (Ecoregion) analysis and similarity modeling. The discussion supported the idea that there is a need for Tier 2 data for refined assessments (i.e. crop distribution, bulk density, CEC, soil taxonomy (dominant soil). A group responsible for the development of this tool should decide about which data to be included at a later date along with who will be responsible. The Tier 2 data could help with site-specific analysis: how representative is the test site within an Ecoregion? For example if soil is not representative for an Ecoregion, you may need more detailed analysis. Basic rule: always use the latest data available.

Various options were discussed including showing the data layers that were used for the model and possibly indicating the level of similarity in the output maps by the depth of colours (graduated colours).

The BOG recommendations were:

- For the high-level (Tier 1) analysis the databases are acceptable
- Maintain current approach (with current Tier 1 data), but Tier 2 should be considered by separate working group, which will require further tool development and guidance documents for users

1.2. Is the current World Wildlife Fund Global Terrestrial Ecoregions framework acceptable or should it be changed to either the CEC North American Terrestrial Ecoregions / ESNB European Soil Regions framework?

It was discussed that the alternative to use European soil regions, which are similar in concept to NA Ecoregions and NA Terrestrial Ecoregions, could be an optional framework for comparison. The consensus was that WWF Terrestrial Ecoregion framework (vegetation biome based) has global coverage and more intuitive terminology and naming conventions than EU soil regions (soil/geology based).

Concerns were raised that the Ecoregion scale may be too coarse. Another option could be to run similarity analysis based on a grid (defined – but not too fine resolution geographic grid) framework, not Ecoregion based. This would allow reasonable comparisons i.e. map of region with pixels of all areas that are similar to the test site. The percentage of land in EU that is similar to study site in NA and vice versa could be calculated

Further comparisons of similar Ecoregions is required to compare the variability within an Ecoregion and between Ecoregions?

The Ecoregion approach works well within NAFTA; EU regulators (NLD) may accept NAFTA studies today if the case of applicant is reasonable (regarding soil and climate)

The BOG Recommendation was:

- leave the similarity model as it is now (based on WWF framework), but look at alternatives (i.e. grid approach)

1.3. Should crop data (land cover, land use or agricultural census) be included in the model, used for querying only, or within the similarity index?

It was the consensus of the group that land cover would not be appropriate to use for similarity modeling or for querying because the cover classes are too broad i.e. crop land versus pasture. Land cover has been used in North America to define the agricultural extent and this defines the limits for similarity mapping.

It was also determined that land use patterns and crop distributions are too different between NA and EU that comparisons would be very difficult and may not be correct. It was discussed that the number of similarity matches would decrease if restricted to target crop(s).

Any difference in dissipation between crops will be largely due to the climatic and soil conditions that are typical for this crop and these factors are already included in the similarity index. The crop type itself will not have a strong influence on dissipation.

The BOG Recommendations was:

- Land use should be used as a Tier 2 layer of data for refining of assessment or querying for scenario testing.

2. DELIVERY

The breakout group considered three questions with respect to delivery of the ERX Tool proposed by the organisers of the workshop.

2.1 Should the ERX Tool be delivered via a Desk-top application or a Web Mapping Service (WMS)?

The consensus of the group was that delivery of the tool via a WMS would ensure that all users would be using the same data, version of the tool and interface for similarity modeling and querying. There were concerns that a web-based tool may limit flexibility (not being able to add Tier 2 data) and speed.

Another alternative was suggested to make the tool accessible for distribution and downloading to the desktop via a webpage.

The BOG Recommendation was:

- To keep current approach (ArcGIS desk-top) but investigate open source and web-based options

2.2. Should this Tool (ERX) be delivered with Commercial off the Shelf Software (COTS) or Open Source GIS software?

The desktop version(s) have potential problems of compatibility with local (operating) systems and the need to run the version of ArcGIS in which the tool was developed. It was suggested that that the use of open source software could help limit that problem. It was also discussed that the OECD supports free, openly accessible data and applications.

The BOG Recommendation was:

- Keep current approach (ArcGIS desk-top) but investigate open source and web-based options

2.3. If a Web Mapping Service approach were used where would the ERX Tool be hosted and served from?

This was discussed as a Governance issue in the preceding section but a recommendation was developed by the group.

The BOG Recommendation was:

- Ownership of the tool and responsibility for maintenance and further development need to be determined at the appropriate level

3. GOVERNANCE

The breakout-group considered three questions with respect to the future Governance of the Ecoregion Crosswalk project and tool development proposed by the organisers of the workshop.

3.1. Should a Working Group be established to review, suggest improvements and manage the ERX project and tool development?

The consensus of the group was that PMRA (Health Canada) should stay in the lead of this project and that mechanisms of contributions by other organizations be investigated. It was also suggested that technical support for development and delivery of tool needs to be supported and options be determined.

The BOG Recommendation was:

- To have working group (technical) to review, suggest improvements and manage the ERX project and tool development under the umbrella of OECD: Expert Group open to OECD countries, stakeholders and NGOs, linked to the Pesticides Working Group.

3.2. Who has the responsibility for maintenance, updating and technical support for the ERX?

The group determined that adequate financial and technical resources are required for maintenance, updating and technical support of the ERX project and tool development. Other examples were presented such as the OECD MRL calculator, with ownership at EPA. A possibility for the delivery and development of the tool in the future as a working arrangement has been discussed informally with the Joint Research Centre of the European Commission.

The BOG recommended that an organization takes the responsibility for maintenance, updating and technical support. This could be PMRA. Further a technical group consisting of experts and future users of the tool from regulatory authorities and industry. This was suggested to ensure that the release of new versions are validated and agreed before the tool can be used for regulatory purposes.

3.3. How will the current and future versions of the ERX project and tool development be resourced?

The group determined that this was beyond the scope of this session.

The BOG Recommendations was:

- Ownership of the tool and responsibility for maintenance and further development need to be determined at the appropriate level. PMRA the current sponsor of the project will consider possible financing of the project in 2012 depending on internal priorities.

Additional discussions:

The break-out group considered some additional points that arose during the course of the discussion.

The group encouraged the preparation of a peer-reviewed scientific paper as part of validation to be led by AAFC/PMRA with contribution from others. There was further discussion with respect to the validation of the similarity model and the Ecoregion Crosswalk tool and the possibility of using a Post Doc or a Graduate student thesis was suggested.

The group also discussed and recommended the development of training sessions (or tutorials) for users/stakeholders, together with the preparation of guidance documents for the use of the ERX Tool and the Tier 2 Data set(s).

It was also suggest by the group that the working group investigate the possible extension of the tool to residues and efficacy assessments studies. It was suggested that the regulators discuss that use of the tool with responsible bodies within PMRA and EPA. Further discussions should happen through OECD for the future extension of the tool to other parts of the world.

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**ANNEX 4: OUTLINES OF THE OECD PROJECT
(FOR EACH COMPONENT)**

Outline I

Harmonization of Terrestrial Field Dissipation Guidance between North American and European Countries

&

Outline II

Crosswalk between North American and European Eco-regions

Outline I

**Harmonization of Terrestrial Field Dissipation Guidance
between North American and European Countries**

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Ottawa, Canada

March 9-11, 2011

INTRODUCTION

Pesticide regulatory agencies/departments worldwide require data on pesticide field dissipation/accumulation to determine “what happens to a pesticide when it is used according to label directions in a representative use area and when all the factors of transformation and transport are acting together.” Studies should account for fate and total dissipation, i.e., transformation, persistence, leaching, carryover, surface transport, volatilization, plant uptake, transformation products, etc and also identify the major dissipation routes.

The fate and behaviour of a pesticide depends upon its intrinsic properties, its use pattern and regional/site specific conditions such as soil, climate and vegetation. These environmental variables can be categorized into ecoregions. Depending on the results of laboratory studies and extent of use, several field studies required in North America and Europe could cost several hundreds of thousands of dollars. The use of field studies conducted at foreign sites for national and global joint reviews would reduce economic and regulatory burdens for registrants and regulators.

The major objective of this project is to develop a crosswalk for North American and European ecoregions and harmonized international guidance for terrestrial field dissipation studies. To achieve this objective, a project proposal on “Harmonization of Terrestrial Field Dissipation Study Guidance and Ecoregion Crosswalk” was presented at an OECD meeting in June 2008 to seek interest from member countries. A detailed OECD work plan was developed by US-EPA and Canada-PMRA and accepted as an OECD project with two components in November 2008. EPA will lead the Comparison and Harmonization of Terrestrial Field Dissipation Study Guidance (Component 1) and PMRA will lead the Construction of a Crosswalk between North American and European Ecoregions (Component 2).

For Component 1, preliminary comparison of North American and European Terrestrial Field Dissipation study guidance indicated significant differences in goals and objectives for these studies and how they are used for risk assessment purposes. Follow-up discussions with the European counterparts were planned to better understand the differences and work on the harmonization of goals and objectives for these studies. The project expert group recommended a workshop to help resolve these issues and the OECD approved it at its 25th meeting of the Working Group on Pesticides, 17-18 May, 2010, Paris, France.

Workshop Objectives

The OECD workshop will focus on the harmonization of guidance for conducting terrestrial field dissipation studies (component 1) and the identification of similar ecoregions between Europe and North America (component 2). The workshop will provide an opportunity to the participants to engage in discussion of technical/scientific issues and share knowledge and experience with OECD country colleagues. This outline will cover workshop objectives for component 1 on guidance. These include:

- Review the progress made so far in indentifying and comparing the existing North American and European guidance for conducting terrestrial field dissipation/accumulation study
- Review the regulatory objectives of terrestrial field dissipation studies in North America and Europe. Provide recommendations on how the differences could be addressed in a harmonized guidance for conducting terrestrial field dissipation studies and how the results from these studies could be used to satisfy the need for exposure/risk assessment in OECD countries

- Propose specific solutions/recommendations for contentious technical issues identified by the Expert Group in order to harmonize the guidance
- Provide recommendations on how to adopt and implement the new harmonized guidance

This guidance document will eventually be available to regulatory agencies of all member states of OECD and other countries, as well as industry and other stakeholders.

Existing guidance for Terrestrial Field Dissipation studies:

Although there are some guidance documents available at the national/regional level; however, there is no harmonized international guidance to assess the acceptance of a field study conducted at foreign sites. In North America, an ecoregion crosswalk as well as guidance for conducting a field study is fully harmonized and a study conducted in US in a similar ecoregion is accepted by the Canadian regulatory authorities and vice versa. The guidance documents include:

- EU directives provide objective and triggers for conducting TFD studies:
 - *Council Directive 91/414/EEC* – old data requirements
 - *Regulation 1107/2009* – proposed new data requirements
- EU directives cite these guidance documents for conducting TFD studies:
 - *SETAC-Europe Guidance, 1995*
 - *NAFTA Guidance, 2006* – cited in proposed new data requirements
- For Interpretation of the study results:
 - *EU Guidance on Persistence in Soil (Document 9188 VI/97, 2000)* – largely superseded by Focus guidance
 - *Guidance Document on Estimating Persistence and Degradation Kinetics from Environmental Fate Studies on Pesticides in EU Registration (Sanco/10058/2005, v 2.0, June 2005)* – ‘*FOCUS Kinetics*’
 - *EFSA Guidance for Evaluating Laboratory and Field Dissipation Studies to Obtain Deg T50 Values of Plant Protection Products in Soil (EFSA Journal 2010:8(12)1936* – proposed guidance, when finalized it would be used in conjunction with Focus guidance
- Some countries have country specific guidelines and their own data requirements, e.g. Germany
 - *BBA Guidelines for the official testing of plant protection products, Part IV, 4-1, 1986*
 - *Adi Cornelese and Werner Pol, Gewasbeschermingsmiddelen Hoofdstuk 6 gedragen lotgevallen in het milieu; gedrag in bodem; uitspoeling Versie 1.0. 2006*

Comparison of purpose, role and triggers for NAFTA /EU TFD guidance:

The NAFTA TFD guidance answers the question “Where did the pesticide go after application?” It is based on a “conceptual model” that includes major modules based on pesticide properties, formulation type and anticipated use patterns. It validates and/or refines the relative importance of selected modules of dissipation such as soil abiotic/biotic processes and the processes of leaching, volatilization, run-off, plant uptake and others. It also demonstrates pesticide dissipation (transformation and transport) under actual use conditions. It is used to substantiate laboratory data on the physiochemical, mobility, abiotic and biotic

transformation of the pesticide. The NAFTA guidance requires TFD studies for all terrestrial and residential outdoor uses.

For EU the purpose and role for TFD studies have evolved over time. The field studies are expected to generate data to assess degradation and formation kinetics in the microbially active upper soil layers. This provides rate of transformation and formation of transformation products in representative soils and under representative climatic conditions. The trial sites and study designs are selected to minimize losses by volatilization, photolysis at the soil surface, leaching and runoff. The sites are not cropped to minimize spatial heterogeneity that can make estimation of reliable decline rates difficult. The official trigger for conducting TFD studies is:

Laboratory Soil degradation studies:

- *DT_{50 lab} > 90 days @ 10 °C and pF 2 – 2.5*
- *DT_{50 lab} > 60 days @ 20 °C and pF 2 – 2.5*

Comparison of NAFTA/EU guidance for conducting TFD studies:

Although EU and NAFTA guidance show major differences in objective and use of TFD studies, there are no major differences in conducting TFD studies that cannot be bridged. This was based on comparison of site selection approach, number of field sites, plot size, field preparation and agricultural practices, pesticide application, soil sampling and inclusion of dissipation modules. The use of modules in the TFD studies represents one of the major differences between the NAFTA and EU guidance.

Harmonization of NAFTA and EU guidance:

These similarities and differences will be discussed in depth in the presentations and breakout groups planned for the OECD workshop. These include:

- Comparison of current NAFTA and EU guidance documents
- Conceptual model/modular approach based on laboratory studies
- Experimental layout/sampling/analysis/results
- Use of TFD data for exposure and risk assessment

The purpose of this workshop is to resolve differences between NAFTA and EU guidance and agree on a path forward to develop harmonized guidance for conducting these studies. As a follow-up of this workshop we plan to develop and publish position papers/reports on these discussions and integrate these documents to develop and implement OECD harmonized guidance for conducting TFD studies.

REFERENCES:

1. Harmonization of Guidance for Terrestrial Field Studies of Pesticide Dissipation under the North American Free Trade Agreement.
PMRA Regulatory Directive, DIR2006-01. (<http://www.pmra-arla.gc.ca/english/pdf/dir/dir2006-01-e.pdf>).
USEPA: Federal Register, August 11, 2006 (Vol 71, No. 155), DOCID: fr11au06-69
http://www.epa.gov/oppefed1/ecorisk_ders/terrestrial_field_dissipation_guidance.pdf.
(11th IUPAC International Congress of Pesticide Chemistry, August 6-11, 2006, Kobe, Japan. S15-6). Canada - US Geographic Information for Pesticide Studies (CANUS GIPS), June 1, 2000.
2. A GIS-based Decision Support System developed jointly by the PMRA, US EPA, AAFC and USDA under NAFTA to help identify comparable field study areas for assessing pesticide dissipation in the U.S. and Canada.
Proc. American Chemical Society, Aug 23, 1999 (CD and manual available upon request).
3. FOCUS (2006) "Guidance Document on Estimating Persistence and Degradation Kinetics from Environmental Fate Studies on Pesticides in EU Registration" Report of the FOCUS Work Group on Degradation Kinetics, EC Document Reference Sanco/10058/2005 version 2.0, 434 pp;
<http://focus.jrc.ec.europa.eu/dk/>
4. BBA guidelines for the official testing of plant protection products IV, 4-1, 1986.
(Schinke, K., H. Notting und J.R. Lunde. 1983. Verbleib von pflanzenschutz-mitteln boden – Abbau, umwandlung und metabolismus, vormals BBA-Merkblätter Nr. 36 und 56)
5. Mark R. Lynch, SETAC - Europe, 1995. Procedures for assessing the Environmental fate and Ecotoxicity of pesticides: Field soil dissipation. P 16-18.
6. Adi Cornelese and Werner Pol, Gewasbeschermingsmiddelen Hoofdstuk 6 gedrag en lotgevallen in het milieu; gedrag in bodem; uitspoeling Versie 1.0. 2006
7. European Commission, 2000. Guidance document on persistence in soil. VI B II.I. 9188/VI/97 rev 9, 12.07.2000.
8. EFSA Guidance for Evaluating Laboratory and Field Dissipation Studies to Obtain Deg T50 Values of Plant Protection Products in Soil. EFSA Journal 2010:8(12)1936

Outline II

Crosswalk between North American and European Ecoregions

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I. INTRODUCTION

This ecoregion crosswalk is a component of an OECD project to maximize the use of pesticide field dissipation studies by developing harmonized international guidance for conducting the studies and identifying comparable North American and European ecoregions.

Pesticide regulatory agencies/departments worldwide require data on pesticide field dissipation/accumulation to determine “what happens to a pesticide when it is used according to label directions in a representative use area and when all the factors of transformation and transport are acting together”. Studies should account for total dissipation, i.e., transformation, persistence, leaching, carryover, surface transport, volatilization, plant uptake, transformation products, etc., and also identify the major dissipation routes.

Under global joint reviews, field dissipation/accumulation data from studies conducted in foreign countries are submitted to regulatory agencies/departments, with a request to consider accepting them to satisfy country-specific data requirements.

The fate and behaviour of a pesticide in a region depends on environmental factors, such as soils and climate. If these environmental factors are similar between areas, then a pesticide is expected to behave in a similar way in those areas.

This has the potential of reducing the total number of terrestrial field dissipation/accumulation studies required for global joint reviews and registration, which strengthen regulatory decisions and reduce cost for both regulatory agencies and the pesticide industry.

II. OBJECTIVES

The objectives of the ecoregion crosswalk are:

- Identify similar ecoregions between North America and the European Union
- Develop a GIS-based Decision Support System to assist the pesticide industry and regulatory authorities in the selection of regions for field study sites
- Provide background information on pesticide use areas (crop-based), soils and climate including location

III. ECOREGION CONCEPT

Site specific characteristics of soil and climate play a major role in determining the behaviour and fate of pesticides introduced into the environment. Principle soil factors that influence the pesticide behaviour to a large extent are pH, organic carbon and texture, although other properties such as cation exchange capacity (CEC) play a role. Climatic parameters include precipitation and temperature.

These soil and climate parameters are collectively treated under ecoregions and based on these parameters the regions are classified into different regional units. If the regions are similar, then a pesticide is expected to behave in a similar way within those regions. A preliminary pilot project conducted by the Pest Management Regulatory Agency (PMRA) in collaboration with Agriculture and Agri-Food Canada (AAFC) indicated that similar ecoregions exist in North America and Europe (based on a defined set of criteria) and, for these similar ecoregions, a terrestrial field study of pesticide dissipation/accumulation conducted in Europe may be considered by the North American regulatory agencies and vice versa.

Previously, no methodology is available to assess the equivalency of European ecoregions to those of North America. This led to the development of the geospatial Ecoregion Similarity Model (ESM) to compare and identify similar ecoregions by PMRA and AAFC in association with the European Commission Joint Research Centre (JRC), Italy and U.S. Environmental Protection Agency (U.S. EPA).

Previously, a geospatial comparison approach using a Geographical Information System (GIS) was used to enable the identification of similar ecoregions between Canada and US under the North American Free Trade Agreement (NAFTA). In this case, existing North American Ecological Regions Level II (v3) map was used (Figure 1). There is no equivalent European ecoregion map available for comparison at the present time. There is, however, a map with three regulatory zones available (Figure 2).

The ESM utilizes ecological (soil) regions, geospatial soil databases, and climatic information, based on Harmonized World Soil Database (HWSD) and the MARS FOODSEC Meteodata climate data set with additional information from available Canadian, US and European soil and climate information systems.

The proposed ESM is a parametric test of the input variables. The model compares the sum of the classed standard deviations of the normal distribution of each comparison parameter of the source ecoregion to that of all the ecoregions of the target area and sums the classed differences in standard deviations to determine percent similarity. The threshold of percentage of similarity can potentially be adjusted.

In addition to identifying similar ecoregions between North America and the European Union, the ESM has other important features. It can be used to select field sites based on a worst-case scenario as identified by the conceptual model or a typical site in a region. For example, if a chemical has a potential to leach and contaminate groundwater, then the selected site should

provide ideal conditions for leaching, such as light-textured soil, high rainfall, shallow ground water table, etc., or if a chemical forms transformation products of importance under acidic conditions, then the study should be conducted in acid soils. In these cases, the model uses a query and filtering procedure to select pesticide use areas (crop areas) and a query to select soil and climatic parameters based on concerns identified from the conceptual model, i.e. the ESM selects polygons that meet user-defined criteria. In a future version of the model, land use/crop distribution data will be included to determine areas of crop distribution. The model can also be used to provide information on soils, climate and vegetation in a particular area.

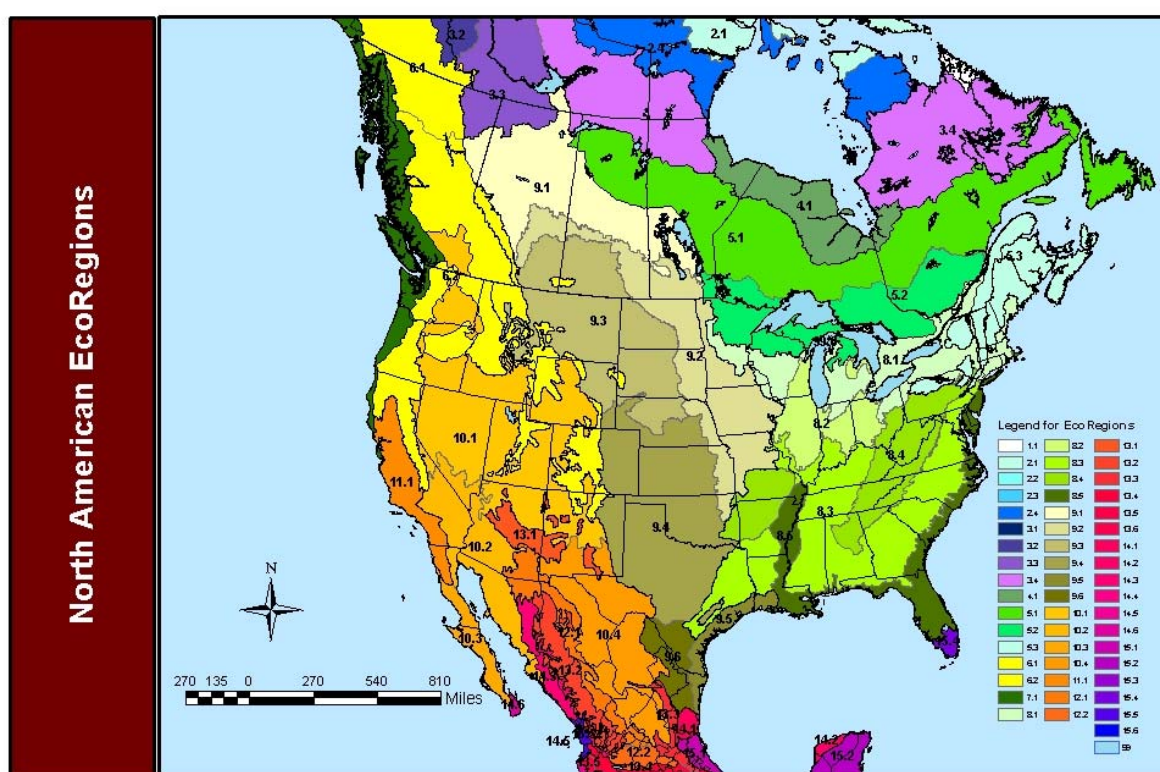


Figure 1 Map of the Level II North American EcoRegions (*Commission of Environmental Cooperation, 1997*).

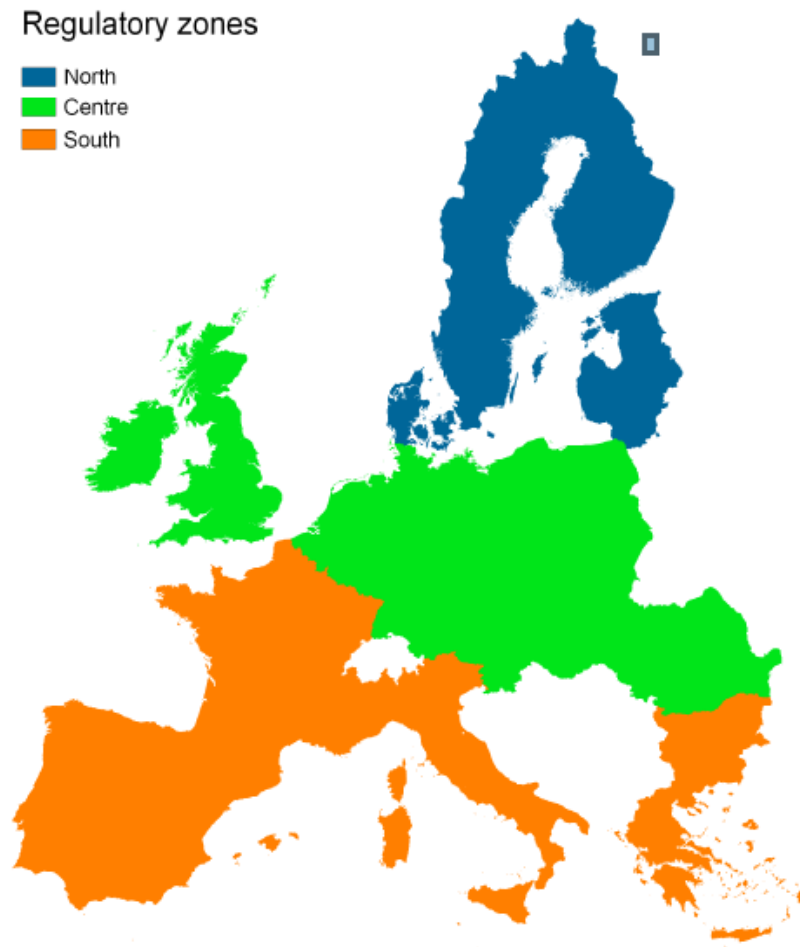


Figure 2 Map of European regulatory zones

IV. DATABASES

The following databases were used to obtain information on soils, climate and vegetation to compare and identify similar ecoregions.

North American Data:

Soil: HWSD (Harmonized World Soil Database) V1.1

Climate: MARS FOODSEC ERA-Interim Meteodata – 2000 to 2009

Agricultural Land Use: CANUS GIPS: NLWIS/STATCAN Census of Agriculture 2008 - Canada
CANUS GIPS: CENSTATS – USA

Framework: WWF – World Wildlife Fund Terrestrial Ecoregions

Framework: CEC Terrestrial Ecoregions Level II (Commission of Environmental Cooperation) will be used as the framework in the next version.

European Union Data:

Soil: HWSD (Harmonized World Soil Database) V1.1

Climate: MARS FOODSEC ERA-Interim Meteodata – 2000 to 2009

Land Cover: CORINE

Framework: WWF – World Wildlife Fund Terrestrial Ecoregions

Framework: Soil regions map of Europe v2 will be used as the framework in the next version.

DATA TYPE	DATA SPECIFICATIONS	CANADA	UNITED STATES OF AMERICA	EUROPEAN UNION
DATA TYPE	DATA SPECIFICATIONS	CANADA	UNITED STATES OF AMERICA	EUROPEAN UNION
SOIL	Name	HWSD	HWSD	HWSD
	Resolution	30 arc-seconds	30 arc-seconds	30 arc-seconds
	Source	IIASA – International Institute for Applied Systems Analysis, Luxembourg Austria	IIASA – International Institute for Applied Systems Analysis, Luxembourg Austria	IIASA – International Institute for Applied Systems Analysis, Luxembourg Austria
	Spatial Representation	Raster GRID	Raster GRID	Raster GRID
	Year	V1.1 March 2009	V1.1 March 2009	V1.1 March 2009
CLIMATE	Name	MARS FOODSEC – ERA INTERIM Meteodata	MARS FOODSEC – ERA INTERIM Meteodata	MARS FOODSEC – ERA INTERIM Meteodata
	Resolution	0.25 decimal degrees	0.25 decimal degrees	0.25 decimal degrees
	Source	European Commission - JRC	European Commission - JRC	European Commission - JRC
	Spatial Representation	Vector	Vector	Vector
	Year	2000-2009	2000-2009	2000-2009
ECOREGIONS	Name	WWF Terrestrial Ecoregions	WWF Terrestrial Ecoregions	WWF Terrestrial Ecoregions
	Resolution/Scale	-	-	-
	Source	WWF – World Wildlife Fund	WWF – World Wildlife Fund	WWF – World Wildlife Fund
	Spatial Representation	Vector	Vector	Vector
	Year	2004	2004	2004
LAND COVER/ LAND USE	Name	CANUS GIPS – NLWIS/STATCAN	CANUS GIPS – CENSTATS	CORINE - EUROSTAT
	Resolution/Scale	1:1,000,000	1:250,000	250m raster/1:100,000 vector
	Source	Agriculture and Agri-Food Canada; STATCAN (1971-2006 agricultural census data)	US National Atlas; CENSTAT; USDA Ag census crop acres	European Environmental Agency (EEA); European Commission
	Spatial Representation	Vector	Vector	Vector/Raster
	Year	V3.1 – Released 2008	2007	2000

Table 1 Data specifications table

V. METHODOLOGY

The geospatial Ecoregion Similarity Model (ESM) utilizes the mathematical model output (for a defined % threshold)) to display, identify, query and produce output reports and graphs at the region level.

The ESM is a parametric test of the input variables. It assumes that each variable in the input has a normal distribution. Where μ represents the mean of the root ecoregions distribution and σ represents the standard deviation of the root ecoregions distribution

Each variable is categorized as a class which is assessed by plotting the variable values against the distribution of the root ecoregion and determines within how many standard deviations from the mean the data lays. The variable is divided by itself, thus producing a value of 1 for which ever class it belongs in. Each class is summed independently and then divided by the total number of records (n) for that variable. The difference between these values is obtained and the absolute value taken. The differences for each class and variable are averaged to get the average difference between the root and the comparison ecoregion. To display this average difference as a percentage similarity, the difference is subtracted from one (1) and multiplied by 100. This calculation is performed for each ecoregion in the comparison continent.

ECOREGION SIMILARITY MODEL (ESM) FORMULA

$$ESS = (1 - ((SS + CS)/5)) \cdot 100$$

$$SS = TexS + OcS + pHS$$

$$CS = TempS + PrecS$$

$$TexS = (Tex1C1S + Tex1C2S + Tex1C3S + Tex2C1S + Tex2C2S + Tex3C3S + Tex3C1S + Tex3C2S + Tex3C3S)/2$$

$$OcS = (TocC1S + TocC2S + TocC3S + SocC1S + SocC2S + SocC3S)/4$$

$$pHS = (TpHC1S + TpHC2S + TpHC3S + SpHC1S + SpHC2S + SpHC3S)/4$$

$$TempS = (TempC1S + TempC2S + TempC3S)/2$$

$$PrecS = (PrecipC1S + PrecipC2S + PrecipC3S)/2$$

$$C1S = |C1Sr - C1Sc|$$

$$C2S = |C2Sr - C2Sc|$$

$$C3S = |C3Sr - C3Sc|$$

$$C1Sr = \left(\left(\sum_{i=r}^{n_r} \frac{\mu_r - \sigma_r < x_i < \mu_r + \sigma_r}{x_i} \right) / n_r \right)$$

$$C1Sc = \left(\left(\sum_{i=c}^{n_c} \frac{\mu_r - \sigma_r < x_i < \mu_r + \sigma_r}{x_i} \right) / n_c \right)$$

$$C2Sr = \left(\left(\sum_{i=r}^{n_r} \frac{\mu_r - 2\sigma_r < x_i < \mu_r + 2\sigma_r}{x_i} - C1Sr \right) / n_r \right)$$

$$C2Sc = \left(\left(\sum_{i=c}^{n_c} \frac{\mu_r - 2\sigma_r < x_i < \mu_r + 2\sigma_r}{x_i} - C1Sc \right) / n_c \right)$$

$$C3Sr = \left(\left(\sum_{i=r}^{n_r} \frac{\mu_r - 3\sigma_r < x_i < \mu_r + 3\sigma_r}{x_i} - (C1Sr + C2Sr) \right) / n_r \right)$$

$$C3Sc = \left(\left(\sum_{i=c}^{n_c} \frac{\mu_r - 3\sigma_r < x_i < \mu_r + 3\sigma_r}{x_i} - (C1Sc + C2Sc) \right) / n_c \right)$$

Where:

ESS represents the ecoregion similarity score expressed as a percentage match.

C1S, C2S, and C3S represent the class 1, class 2, and class 3 total counts respectively. Lowercase r and c represent the root and comparison ecoregion.

SS represents the soil score or the sum of the soil class differences

CS represents the climate score or the sum of the climate class differences

Tex represents the texture variable

Oc represents the Organic Carbon variable

pH represents the potential of Hydrogen variable

Temp represents the Temperature variable

Precip represents the Precipitation variable

μ represents the mean of the root ecoregions distribution

σ represents the standard deviation of the root ecoregions distribution

VI MODEL INSTRUCTIONS

STARTING THE APPLICATION

- Copy and paste onto C:\ drive. Double click on Ecoregion CrosswalkV102.mxd to open the project.
- Upon start up, the title page should appear, followed by the legal page.
- The project interface is available once the user clicks OK after reading the legal page.

Important: Please read the legal page before using the model. Not every ArcMap is set up the same so the interface layout may vary.

PROJECT INTERFACE

This is an example of the basic layout of the Ecoregion Crosswalk Tool (ERX) version 1.0.2 Figure 3). Please note that the project layout may differ for every user.

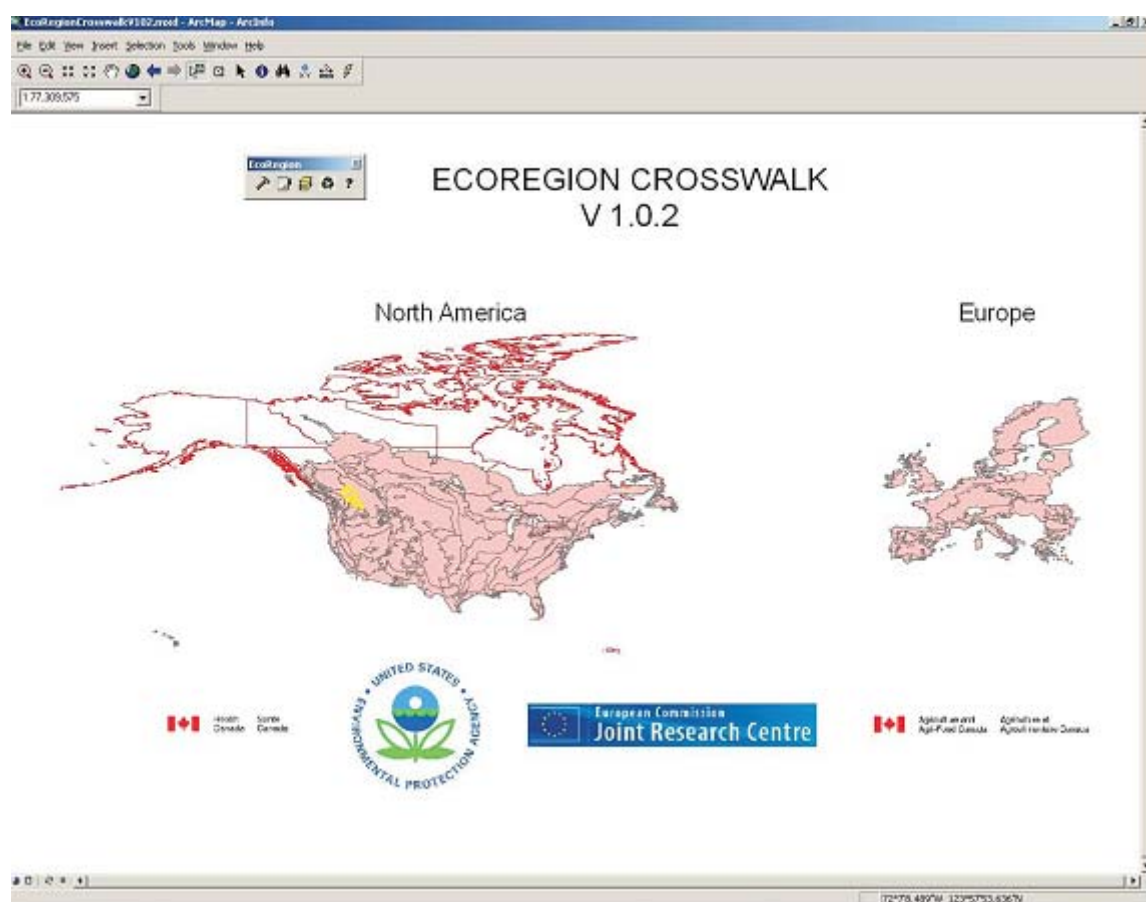


Figure 3 Ecoregion Crosswalk Tool Interface

If the user alters the project in any way that he/she cannot undo, he/she must close the project and choose NOT to save the project changes.

CUSTOMIZE INTERFACE

If the Tools Toolbar is not present in the EcoregionCrosswalkV102.mxd project, click on the Tools pull down menu from the main toolbar at the top of the project. Click on Customize. See Figure 4.

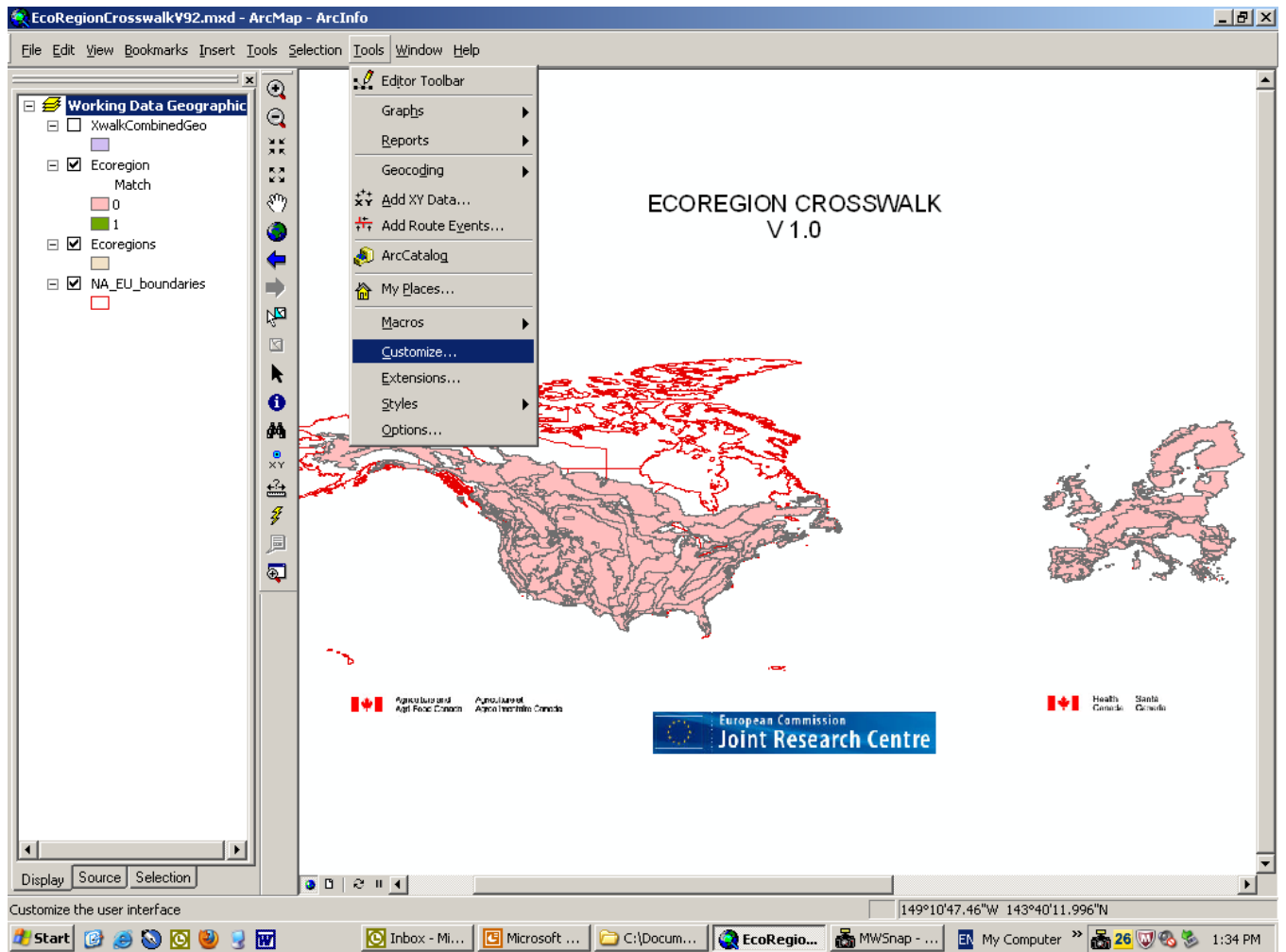


Figure 4 Customize Interface

ADD TOOLBARS

In the Customize window, scroll down and check the Tools toolbar. The Main Menu, Tools and Ecoregion Toolbar are the only toolbars that are essential to the project. See Figure 5.

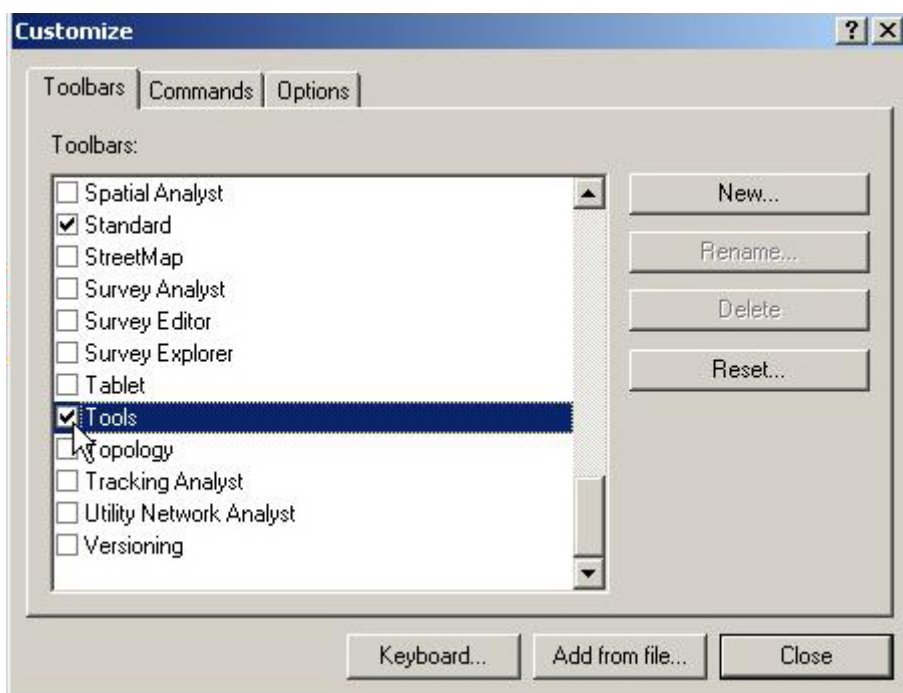


Figure 5 Customize toolbars

ECOREGION TOOLBAR

The following tools/buttons comprise the Ecoregion Toolbar. See

Figure 6.

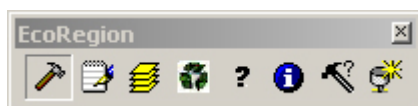


Figure 6 Ecoregion Toolbar



The **Run Model** button runs the model once a root ecoregion has been selected



The **Generate Report** button generates an HTML report that includes mean annual temperature (degrees Celsius), total annual precipitation (mm), Organic Carbon, pH, and Texture for the root ecoregion and the matching ecoregion(s)



The **View Report** button allows the user to recall the results in HTML form that were generated by the generate report tool



The **Reset** button allows the user to clear the reports and all selected ecoregions



The **Help** button provides access to the model's help documents. Included in these documents are images along with step by step instructions on how to successfully use the model



The **Identify** button allows the user to click anywhere on the map and view the location, climate and soil information for the ecoregion



The **Query Tool** button allows the user to query the data by inputting user-defined parameters



The **Similarity Results Tool** button allows the user to view the soil and climate results from the root and match ecoregion(s) in text or graph form

TOOLS TOOLBAR

The Tools toolbar contains helpful tools that allow the user to zoom in and out and select a root ecoregion. Please refer to the ArcGIS Desktop Help at the top of Main Menu for additional support using the buttons on this toolbar. See Figure 7.



Figure 7 Tools Toolbar

SELECT FEATURES TOOL

Use the Select Features tool to select the root ecoregion. To do this, click on the Select Features button. See Figure 8.



Figure 8 Select Features tool

SELECT ROOT ECOREGION

To select the root ecoregion, use the Select Features tool. Use the cursor to click on a location/ecoregion that will be the root ecoregion. The root ecoregion can be selected in either North America or the European Union. The selected ecoregion will be highlighted with a yellow border. This highlighted ecoregion will be used as the start point in identifying regions in the opposite continent that have a user-specified percent threshold match to the root ecoregion. If the user wants to choose a different ecoregion, then the Clear Selected Features button on the Tools Toolbar can be used to clear the selected ecoregion. See Figure 9.

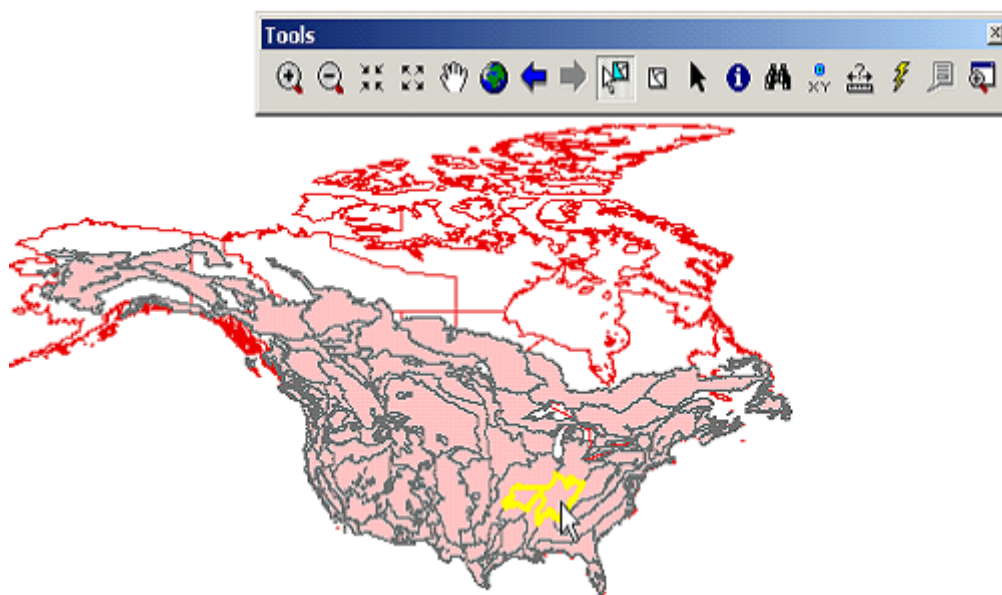


Figure 9 Use Select Features tool to select the root ecoregion

LAUNCH THE MODEL

Once the root Ecoregion has been selected, the Launch Model tool is used to run the Ecoregion Similarity Model (ESM) to calculate the matching ecoregions in the opposite continent.

To launch the model click on the Launch Model button on the Ecoregion Toolbar. See Figure 10.

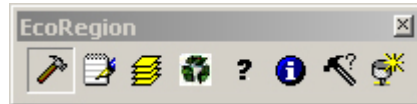


Figure 10 Launch Model button on the Ecoregion Toolbar

Clicking the Launch Model tool will prompt the Model Parameters box to appear, allowing the user to enter the percent similarity threshold value (Figure 11). Once the value has been entered, the ESM model will begin calculating to find suitable matches (Figure 12).

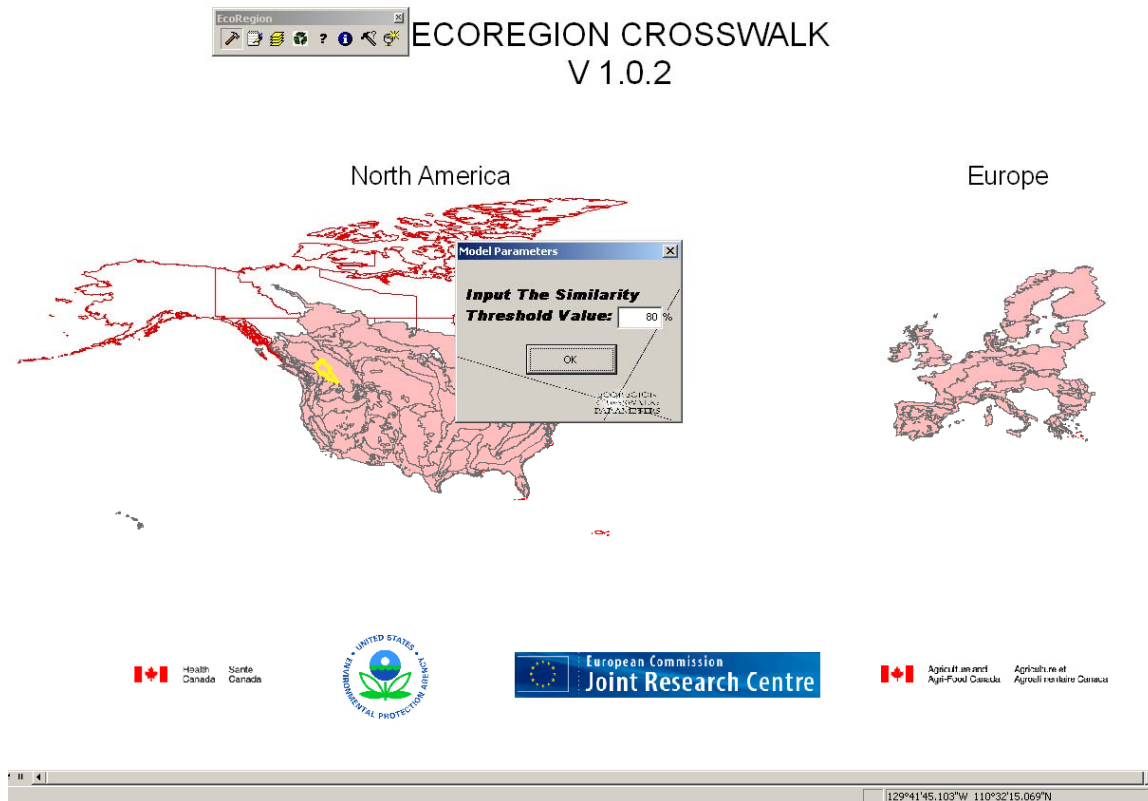


Figure 11 Percent similarity threshold value

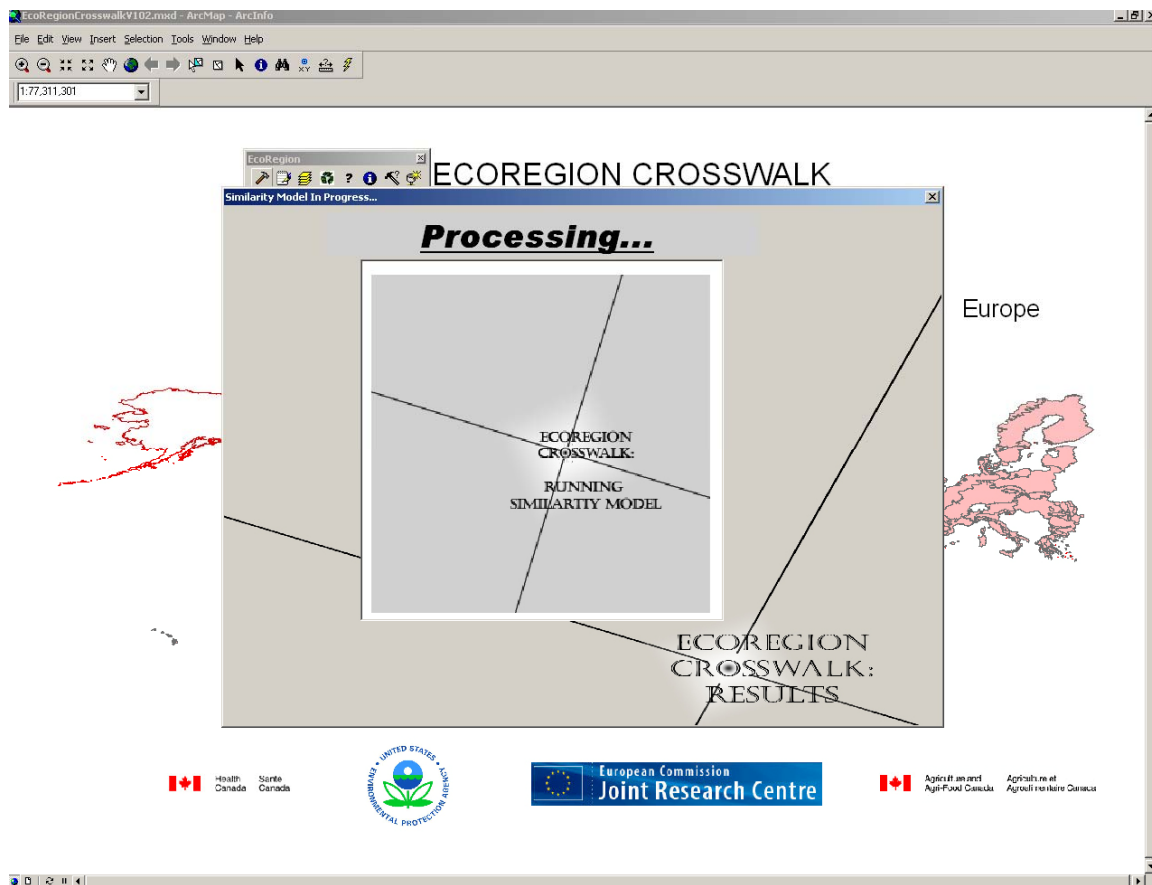


Figure 12 ESM Model Processing Interface

MODEL RUN COMPLETE

Once the matches have been calculated, a box will pop-up with the number of matches found. If no matches are found, '0 Matches Found' will appear in the box.

Click the OK button to close the match results box. See Figure 13.



Figure 13 Match Results with number of matches found

MATCHES DISPLAYED

The matches resulting from the calculations will appear in the opposite continent as the root ecoregion. They will be highlighted in green. The root ecoregion is coloured green with a yellow border (Figure 14).

If no matches are found, no ecoregions will be highlighted in green. This means that there are no ecoregions that match the chosen root ecoregion with a percent similarity threshold indicated.

At any time, the user can clear the selected ecoregions by using the Reset button that looks like a recycle symbol on the Ecoregion Toolbar. This will also clear any generated reports.

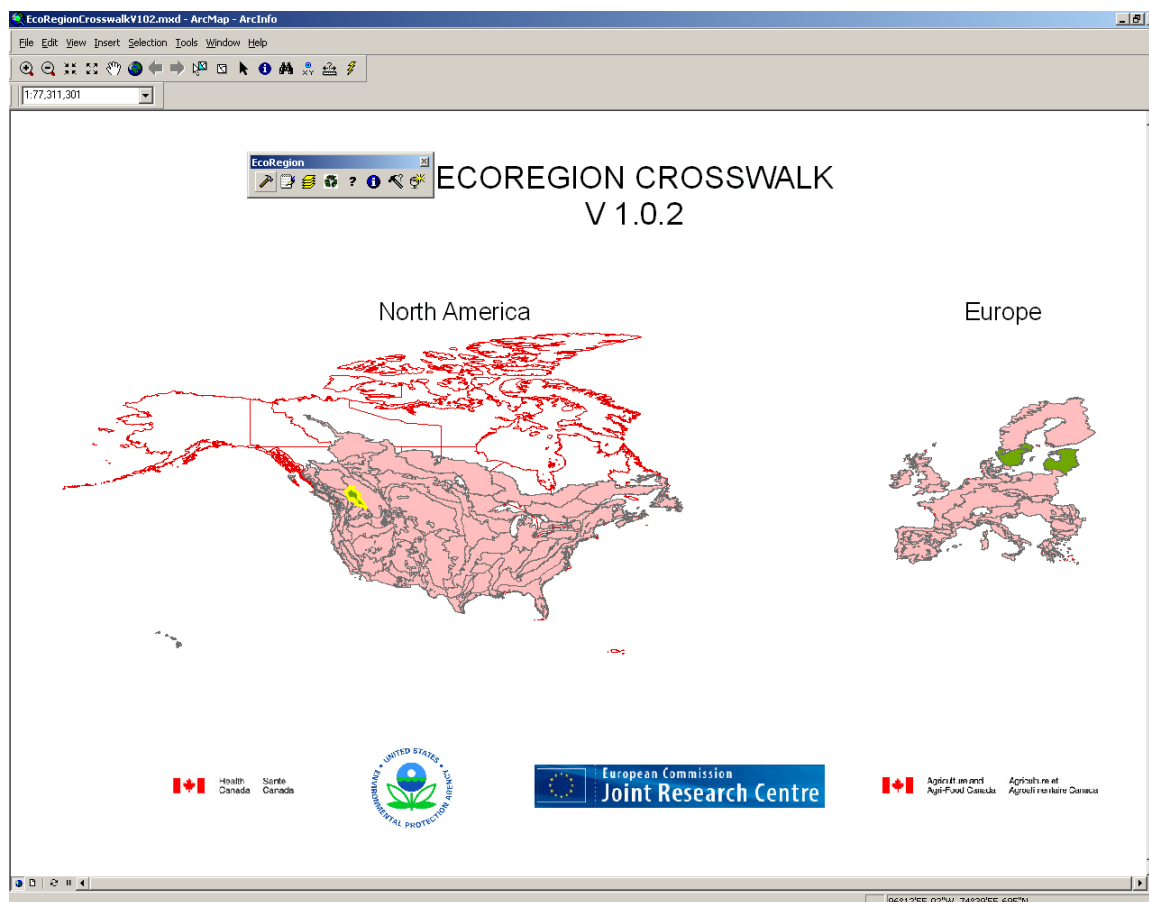


Figure 14 Matching ecoregions displayed in green

SIMILARITY RESULTS INTERFACE

The Similarity Results Interface allows the user to interactively preview the data of the matching ecoregion(s). Graphs of the data can also be viewed. Help documentation can be accessed through this interface. See Figure 15.

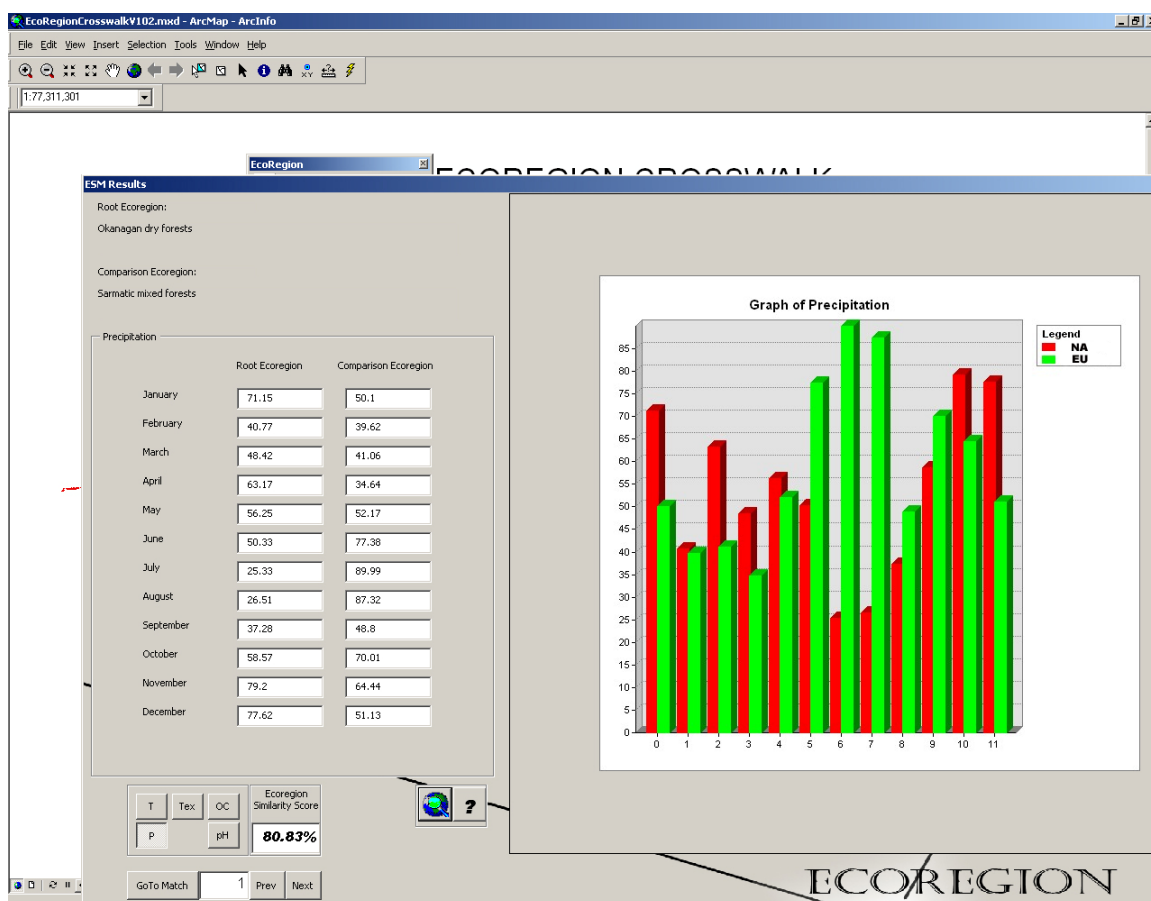




Figure 15 Similarity Results Interface

GENERATE REPORT

To generate an HTML report of the soil and climate properties of the root and match ecoregion(s), click on the Generate Report button  on the Ecoregion Toolbar. In order to run any of the Generate Results tools, the root ecoregion must have been selected and the ESM has to have been launched.

To view the report that was generated with the Generate Report button, click on the View Report button  on the Ecoregion Toolbar. The HTML Report Card is the output summary of the match results (See Figure 16). It compares the root ecoregion with the match ecoregions. The report created is an HTML report that can be viewed through any web browser (e.g. Internet Explorer). Once the report has been generated, the user has many options.

To print the results, go to File → Print in the web browser.

The table can also be exported to Excel in order to perform further calculations with the data.

To clear the report and all selected Ecoregions, click on the Reset button on the Ecoregion toolbar.

SIMILARITY REPORT

PRECIPITATION

MONTH	Root Ecoregions	Comparison Ecoregions										
	South Central Rockies forests	Rodope montane mixed forests	Iberian conifer forests	Euxine-Colchic broadleaf forests	East European forest steppe	Sarmatic mixed forests	Iberian sclerophyllous and semi-deciduous forests	Pontic steppe	Balkan mixed forests	Pannonian mixed forests	Carpathian montane forests	Tyrrhenian-Adriatic Sclerophyllous and mixed forests
	Percentage Match >>	89.06	88.53	88.46	88.26	84.73	84.00	83.53	82.33	81.33	81.33	81.26
January	42	61	50	74	34	54	56	36	53	48	48	89
February	39	63	49	78	37	65	57	38	56	52	48	90
March	32	42	49	54	31	63	54	30	40	44	45	84
April	39	39	40	41	44	69	35	39	40	51	58	45
May	36	41	23	27	52	74	16	40	40	69	87	20
June	35	51	21	32	66	73	13	45	51	74	102	11
July	58	72	44	44	79	56	34	58	69	87	114	19
August	58	71	62	46	62	44	52	49	66	71	89	33
September	42	55	53	47	45	39	50	36	49	49	59	49
October	40	49	51	46	29	35	51	28	41	36	40	62
November	34	47	42	48	30	31	47	30	40	36	38	68

Figure 16 HTML Similarity Report

IDENTIFY TOOL

The user can use the Identify Tool at any point to select an ecoregion on the map to view its soil, climatic and location information (Figure 17). Please note that the user does not have to run the ESM calculation before using the Identify Tool.

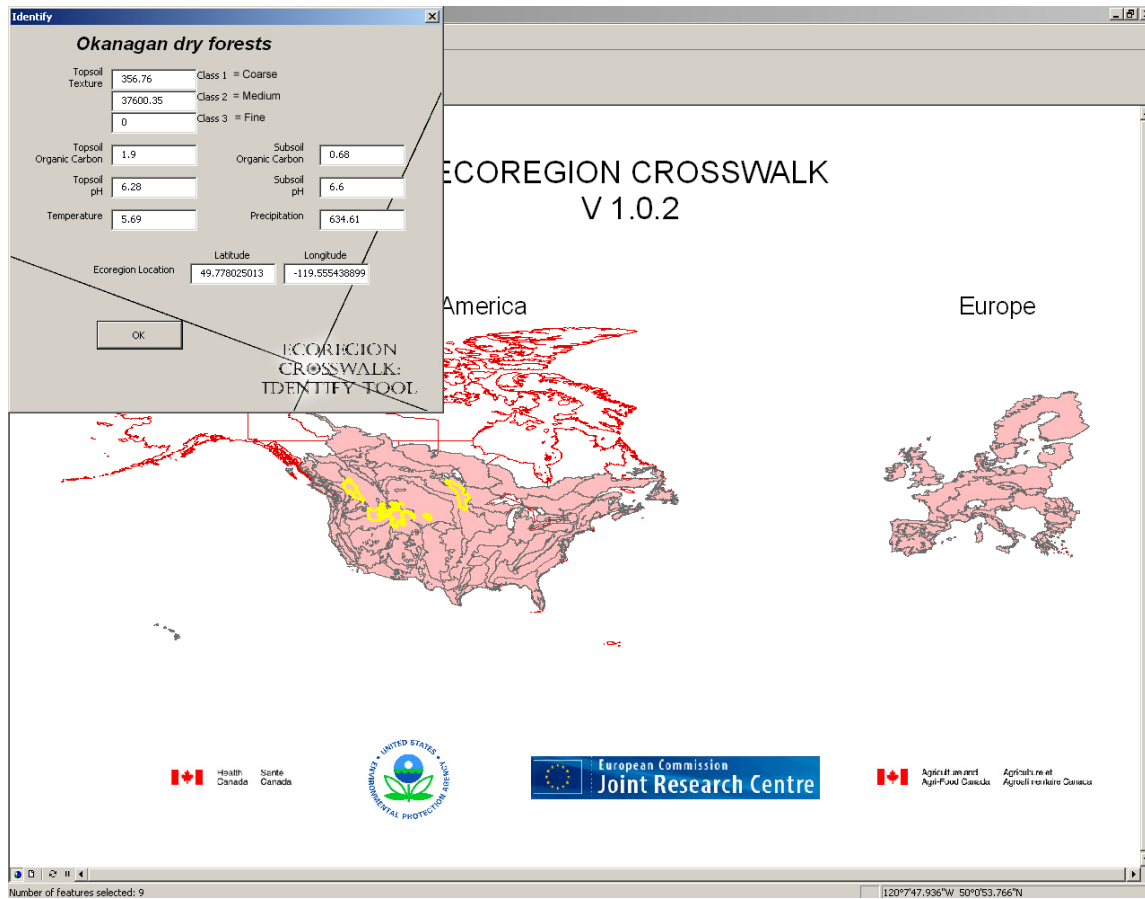
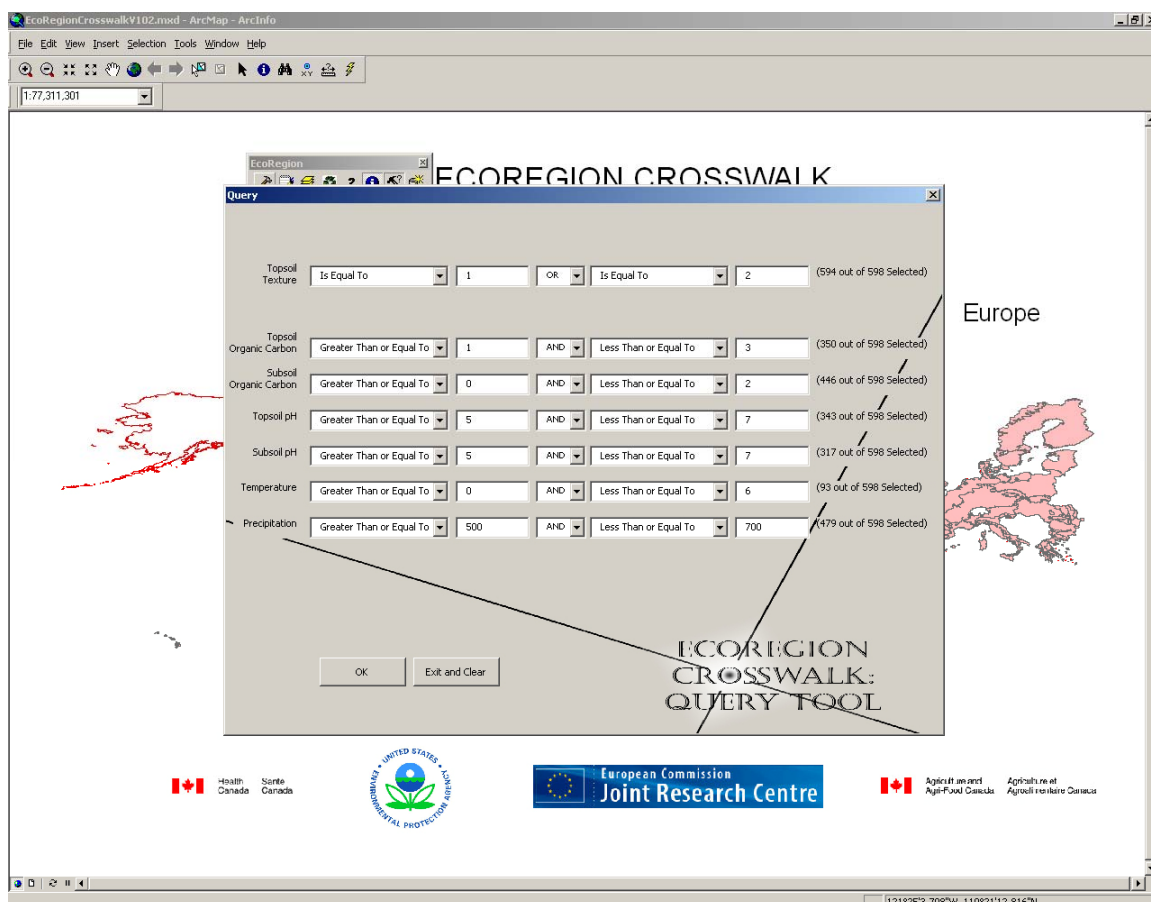


Figure 17 Identify Tool

QUERY INTERFACE


The Query Tool can be used to select soil and climatic parameters (Fig. 18), based on concerns identified from conceptual model (pesticide properties and fate studies). This tool will highlight any ecoregions that fit these parameters. The resulting highlighted ecoregions can be used to help the user in selecting a root ecoregion. Please note that the user does not have to run the ESM calculation before using the Query Tool.



Figure

18 – Query Interface

HELP INTERFACE

The Help Interface can be accessed by clicking on the  button on the EcoRegion toolbar or on the Similarity Results Interface (Fig. 49).

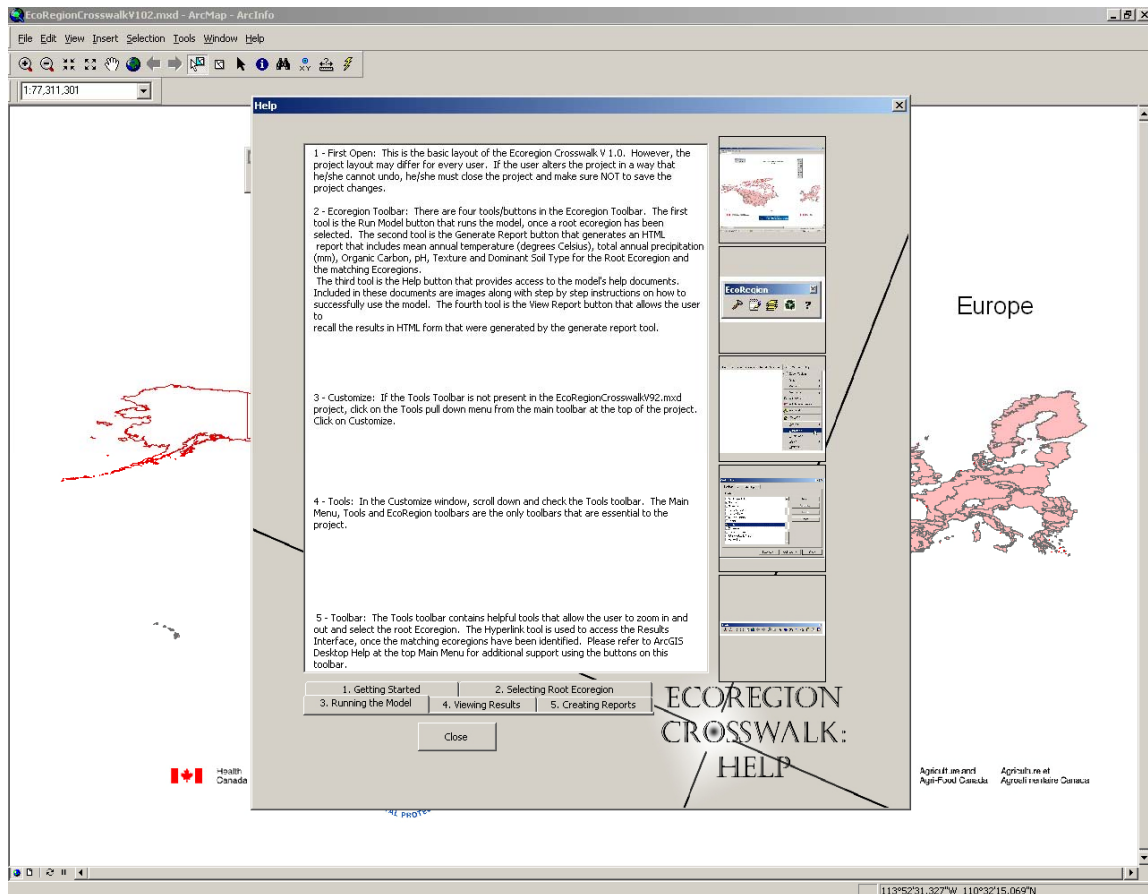


Figure 19 – Help Interface

VII SOFTWARE REQUIREMENTS

ESRI's ArcGIS version 9.2 or 9.3 (Please note that the model does not run in ArcGIS 10)

Microsoft Internet Explorer v 6.0

Python version 2.4 or 2.5.1 (Note: Python version is respective of the ArcGIS version you are running and will be installed when ArcGIS 9.x is installed)

APPENDIX 1 - LINKS TO SOURCES

1. NORTH AMERICAN AND EUROPEAN UNION SOIL DATA: IIASA (International Institute for Applied Systems Analysis) HWSD (Harmonized World Soil Database)
2. CANADIAN LAND USE DATA: NLWIS (National Land and Water Information Service) Interpolated Census of Agriculture to Soil Landscapes for years 1971 - 2006
3. UNITED STATES LAND USE DATA: USDA (United States Department of Agriculture) CENSTAT Agricultural Census Data 2007
4. EUROPEAN UNION LAND COVER DATA: CORINE – CEC (Commission of the European Communities) and EEA (European Environment Agency)
5. CLIMATE DATA: MARS FOODSEC Meteodata
6. NORTH AMERICAN ECOREGION DATA: WWF – World Wildlife Fund Terrestrial Ecoregion Data
7. EUROPEAN UNION SOIL ECOREGIONS DATA: Will be in next version
8. EUROPEAN UNION POLITICAL BOUNDARY DATA: CDC.gov
9. NORTH AMERICAN POLITICAL BOUNDARY DATA: CANUS GIPS data – provstate coverage

ANNEX 5: PRESENTATIONS* (SLIDES)

*The presentations can be found on the OECD website under Pesticides Publications, <http://www.oecd.org/env/pesticides>

DAY 1

OECD, the Project and the Workshop

By Beatrice Grenier (OECD).....

TERRESTRIAL FIELD DISSIPATION (TFD) GUIDANCE

1. Comparison of current NAFTA and EU guidance documents

By Mah Shamim (US EPA), Raju Gangaraju (Canada-PMRA) & Andy Massey (UK CRD).....

2. Conceptual model/modular approach based on lab studies

By Mohammed Ruhman (US EPA), Ian Nicholson (Canada-PMRA) & Jos Boesten (Netherlands-WUR)

2a. NAFTA (*Mohammed Ruhman (US EPA)*)

2b. EU (*Jos Boesten (Netherlands-WUR)*).....

3. Experimental layout/sampling/analysis/results

By Raju Gangaraju (Canada-PMRA), Mah Shamim (US EPA) & Christopher Lythgo (EFSA).....

4. NAFTA and EU use of results of pesticide terrestrial field dissipation studies
in exposure and risk assessments

By Mark Egsmose (EFSA), Lizanne Avon (Canada-PMRA) & Faruque Khan (US EPA)

DAY 2

ECO-REGION CROSSWALK

1. Criteria for acceptance of foreign pesticide field dissipation studies/ecoregion concept

By Raju Gangaraju (Canada-PMRA), Mah Shamim (US EPA) & Christopher Lythgo (EFSA).....

2. Demonstration of GIS-based model for identification of similar ecoregions

By David Kroetsch (Canada-AAFC) & Raju Gangaraju (Canada-PMRA)

3a. Comparison of North American and European soil data/databases

By Ciro Gardi (EU JRC) & Luca Montanarella (EU JRC).....

- 3b. Comparison of North American and European climate data/databases
By *Ciro Gardi (EU JRC), David Kroetsch & Erin Carnegie (Canada-AAFC)*.....
4. Ecoregion delivery methodology
By *David Kroetsch (Canada-AAFC) & Raju Gangaraju (Canada-PMRA)*.....
5. When and how the ecoregion tool is to be used (An example of comparison of North American and European ecoregions)
By *Mohammed Ruhman (US EPA) & David Kroetsch (Canada-AAFC)*

DAY 3

BREAK-OUT GROUP REPORTS

TFD Guidance

- BOG 1 report
By *Andy Massey (UK CRD)*
- BOG 2 report
By *Christopher Lythgo (EFSA)*
- BOG 3 report
By *Jos Boesten (Netherlands-WUR)*.....

Eco-region Crosswalk

- BOG 1 report
By *Ian Hardy (Expert)*.....
- BOG 2 report
By *David Kroetsch (Canada- AAFC)*.....

PATH FORWARD

- Path forward for Harmonized TFD Guidance
By *Mah Shamim (US EPA)*.....
- Path forward for use of eco-region model as a regulatory tool
By *Ian Nicholson (Canada-PMRA)*
- Path forward for implementing guidance/ecoregion model in the regulation process - Next steps
 - In EU countries: Update on Guidance for Evaluation Lab and Field Dissipation Studies for Obtaining DegT₅₀ Values, *by* *Mark Egsmose (EFSA)*
 - In OECD countries: Next Steps in OECD, *by* *Beatrice Grenier (OECD)*

*The presentations can be found on the OECD website under Pesticides Publications, <http://www.oecd.org/env/pesticides>