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

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Working Group on Pesticides

FOLLOW-UP TO THE EXPERT MEETING ON THE ELECTRONIC EXCHANGE OF PESTICIDES DATA (21-23 APRIL, 2008; US)

23rd Meeting of the Working Group on Pesticides

4-5 November 2008, Paris, France

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BACKGROUND

One of the main recommendations from the *Expert Group Meeting on the Electronic Exchange of Pesticides Data* that was held in the US, from 21 to 23 April, 2008 (see ENV/JM/PEST(2008)42) was the establishment of an *ad hoc* Expert Group, under the Registration Steering Group. The Expert Group would provide oversight of any work conducted by specialised subgroups below it (e.g., a subgroup on the harmonisation of methodologies for a common transport mechanism), as well as manage other activities as necessary. The main focus of the Expert Group would be the implementation of the recommendations from the April meeting in the US.

The establishment of the Expert Group was approved by the RSG at its last meeting in June, and WGP Delegations were invited on 16 July to send in nominations for the new Group. The Group currently includes 16 representatives from Australia, Canada, Germany, Japan, New Zealand, the US, EFSA and BIAC.

The Group held a conference call on 12 September, 2008 to review the recommendations from the April meeting, discuss on-going work, and prepare a draft Terms of Reference and an *initial* work plan. A draft of the Terms of Reference for the new group and the *initial* work plan can be found in the annexes to this document. A password-protected web site has been created for posting and retrieving documents. Please note that due to the limited amount of time during the call, only an initial work plan has been prepared. Based on the discussions at the WGP, and additional discussions within the Expert Group, a more detailed work plan will be developed in the coming months.

This document provides a summary of current work, and includes a draft of the initial Work Plan, and Terms of Reference for the group.

ACTION REQUIRED: ***The Working Group on Pesticides is invited to:***

(i) take note of the progress to date;

(ii) comment on the draft Work Plan; and

(iii) agree the Terms of Reference, amended as appropriate

INITIAL ACTIVITIES – Transport Subgroup

1. The most significant activity since the Expert Group was formed, was a meeting of the Transport Mechanisms Subgroup, which was held in Ottawa from 19-21 August, 2008. The meeting was chaired by Aaron Carswell (PMRA, Canada). This meeting dealt with the development of methodologies to promote common or fully convertible "transport" mechanisms. "Transport" systems are IT tools for submitting all the required dossier information for registering a pesticide in an electronic format and archiving and managing such information. The meeting was attended by representatives from Canada, the US and BIAC. (The draft report from the meeting is provided in Annex 4; the final report will be posted on the Expert Group's website.)

2. The focus of the meeting was on (1) identifying the required fields which are common to existing transport systems [e-Prism(US), e-Index Builder (Canada) and CADDY (EU)], (2) reaching a consensus on how to merge these fields, and (3) agreeing a process for developing a harmonized "overall" XML schema. (An "overall" XML schema refers to a schema for the organization of all data files in a dossier and monograph, as compared to the OECD XML schema, which refers to an individual schema associated with an individual OECD template for a study summary.)

3. At the conclusion of the meeting, the participants agreed next steps. One, the US will develop a data dictionary (in spreadsheet format) with field descriptions. The data dictionary will be distributed to all members of the subgroup for comment on the field descriptions, and suggestions for additional data fields. Two, Canada will develop a visual representation of the overall schema. This will also be distributed to the subgroup members for comment. Once these drafts have been agreed by the subgroup, they will be distributed to the full Expert Group for comment.

INITIAL WORK PLAN AND TERMS OF REFERENCE

4. The initial work plan (in Annex 1) describes the planned work for implementing the recommendations from the April meeting of the Expert Group. Annex 2 contains the draft Terms of Reference for the Expert Group.

Annex 1

EXPERT GROUP ON THE ELECTRONIC EXCHANGE OF PESTICIDES DATA

DRAFT WORK PLAN

Topic	Recommendations from the 21-23 April, 2008 meeting of the Expert Group	Planned Steps
1. Identify and address existing hurdles that hinder the efficient collection and exchange of pesticide information due to incompatible formats or IT systems/approaches	1. OECD should minimize making changes to existing templates and schema, and make clear (at a minimum on the public website) whether a template/schema is the original version or an updated one, and when the changes were made.	The Secretariat will explore the technical feasibility of including all templates/XML schema and XML schematron into a table on the public website, and including the version numbers (and date last updated) for each.
	2. Future templates/schema should be made compatible with the original.	The Secretariat, working with lead countries which will develop "pre-templates" for OECD templates that will be revised and the contractors responsible for the technical aspects of the templates, will aim to ensure compatibility. Members of the Expert Group are encouraged to participate on the CDG which reviews all templates to identify possible compatibility issues. Compatibility will also be considered during IUCLID development/modifications.
	3. A tool should be developed and made available to governments for verifying that an XML data file, based on the OECD XML schema, meets defined requirements and standards.	The OECD XML schema and schematron should be used as tools to verify that imported XML files meet requirements. The European Chemicals Agency (ECHA) has a stand-alone program that they use to verify the validity of XML files, and the Secretariat will explore with ECHA whether this could be provided more widely. Alternatively, it is possible to use the import function of IUCLID to verify the validity of XML files.
	4. An in-depth analysis should be conducted to determine the exact amount of disparity between the naming and numbering schemes used across countries	An example of such disparity is the different number systems for data on active substances – Appendix 6, parts 4 and 5, of the OECD Dossier Guidance. Canada and Bayer will lead this analysis. Input will be solicited from participants in joint reviews prior to and at the Lessons Learned Workshop (3-5 December; Bonn).

	5. EPA will investigate the separation of declarations from documents, look into resolving the 86-5 issues and provide an update on the potential 86-5 process changes, and develop smart documents as application-based data entry screens.	EPA has established a work group and is working to finalize the update to PR Notice 86-5 which is needed, as the Agency is able to accept applications electronically. The Agency is moving towards more harmonized requirements while not losing important information and conforming to U.S. statutes.
2. Determine how the joint review process will use the OECD templates	6. A "smart" Word document prototype should be developed that uses the established OECD XML schema and includes a mechanism for tracking technical errors during the Primary Review.	EPA initially will supply a prototype of the functionality for 5 of the 87 templates. This will include the "style sheet" output from the XML. Based on feedback from the Expert Group, EPA will then make modifications to the prototype prior to formal development of the other 82 schemas. Other relevant groups within OECD (e.g., IUCLID User Group Expert Panel) will be consulted on this work.
	7. The "lessons learned" workshop should include representatives with IT experience in order to ensure that this aspect of joint reviews is considered, and approaches developed for disseminating and managing joint review data electronically.	The workshop will include a presentation on the outcome from the April, Expert Meeting, and IT issues will be considered in one of the workshop breakout sessions
	8. The workshop should also consider whether existing template guidance is sufficient, and if there is a need for new or modified templates.	This will also be considered during the workshop.

3. Identify standard layout for rendering the OECD template XML	9. A redacted version of each of the DuPont study summaries should be made available for a workgroup to review as to the usefulness of the layout and whether it contains all of the elements in the OECD templates.	EPA will finalize the redacted version of the DuPont submission layout and provide it to OECD by 3 November, 2008.
4. Identify and review ways to harmonize methodologies for a common transport mechanism	10. OECD should standardize the term Dossier and other related terms (i.e., Decision, Submission) and provide data field definitions that explain the type of data that should be provided.	EPA will develop a data dictionary, in spreadsheet format, of field descriptions.
	11. Meeting participants recommended that a Transport Schema workgroup consisting of government and industry experts familiar with CADDY, e-Index Builder, e-PRISM Builder, and IUCLID be established.	The subgroup has been formed (and met from 19 to 21 August); all OECD Delegations will be invited to participate on this subgroup. Experts familiar with other relevant systems (e.g., IUCLID) will be invited to participate.
	12. EPA and the Transport Schema workgroup should investigate how CBI and non-CBI versions of a document are collected. EPA is to look into the legal issues, while the Transport Schema workgroup is to determine how CBI is currently being "physically" handled as well as how CBI should be handled using XML. Additionally, EPA is to adopt the use of a cross-reference field in e-PRISM (for studies only).	The Transport subgroup has identified how transport systems in Canada (e-PRS), the EU (CADDY) and the US (PRISM) currently collect/manage CBI versus non-CBI documents. The group will also identify how other countries do so. It will also consider how such documents could be flagged/managed in the "overall" schema.

5. Identify ways that the templates can use structured data for reporting summary information on field trails (e.g. XML-tagged cells within a table rather than text fields)	13. The Residue Chemist Expert Group should identify, during their 5-8 May meeting, what information that would be generated from crop field trials should be included in structured tables.	A draft of the template for field trials has been prepared, and is being reviewed by the RCEG. Work is underway to make the data reporting sections in the draft compatible with the template. The RCEG will review it for the final time during its 29-31 October meeting.
	14. Industry and governments should be consulted on whether: a. it is technically feasible to develop structured data tables for crop field trial data, and that such tables comply with the format and rules that apply to OECD templates, schema and schematrons b. governments can use data submitted in XML format c. companies are able to submit data in structured formats d. to begin now developing such structured tables, or wait until the next draft of the Crop Field Trial Test Guideline is available?	The Secretariat and lead for the crop field trial template will consult with the OECD contractor responsible for reviewing templates, and the contractor responsible for developing the schema and schematron to ensure technical feasibility Consideration will also be given as to whether it would be feasible to have the table used to upload the data incorporated into the final report. Thus, companies would only need to fill it out once.

Annex 2

Expert Group on the Electronic Exchange of Pesticides Data

DRAFT Terms of Reference

Objectives:

- Prioritise and implement the recommendations from the 21-23 April meeting of the OECD Expert Group on the Electronic Exchange of Pesticides Data (*see Annex 3)*
- Identify/address *additional* hurdles not discussed at the April meeting, if any, which hinder the efficient collection and exchange of pesticide information due to incompatible formats or IT systems/approaches.
- Identify and document government and industry best practices that would facilitate the electronic exchange of data and document
- Develop ways to harmonise methodologies for submitting:
  - documents to regulators using a common transport mechanism based on a harmonized, global XML schema.
  - pesticide information in OECD template/XML format and identify any needs for new OECD templates (e.g., for other pesticide dossier information besides OECD Test Guideline-based test study summaries).
- Develop an understanding of how global pesticide authorities intend to use the harmonized OECD XML templates within their review processes. Subsequently, industry and governments should develop a common transport mechanism for the submission of said XML templates.
- As feasible, provide input to the work of other groups (e.g., the Residue Chemistry Expert Group) which are developing enhanced templates for large structured data files, such as residue data, developed during crop field trials. The focus of this would be on how such data could be incorporated into pesticide transport systems.
- During the development of the new transport mechanisms, an overriding consideration should always be the avoidance of submitting redundant information (e.g. OECD/XML template file of phys-chem data as well as requirement to fill in online systems).

Approach

The Expert Group, with representation from member countries and other stakeholders will review the recommendations from the 21-23 April, 2008 Expert Group Meeting on the Electronic Exchange of Pesticides Data, and:

- Identify activities necessary to implement such recommendations
- Identify governments who will take the lead on these activities
- Develop a work plan and schedule for each activity
- Create specialised subgroups, as necessary
- Report to the Registration Steering Group
- Co-ordinate, as appropriate, with other sub-groups of the Joint Meeting responsible for IT and template activities

Participation

The Group will include representatives from OECD governments, industry and the Secretariat, with expertise in approaches and/or issues associated with IT systems and pesticide reviews (i.e., dossier and monograph preparation). Experts familiar with IT systems for industrial chemicals will be invited to participate on relevant work. Relevant groups within OECD (e.g., the IUCLID User Group Expert Panel) will be updated on the work of the Expert Group.

The Group will be chaired by the United States. Chairs of the subgroups will be selected.

Meetings

The Group will meet when necessary, but at least once-a-year. Where practical, these meetings should be held in conjunction with other OECD meetings. Teleconferences will be held between meetings. A password-protected website has been created by the Secretariat for posting and retrieving documents relevant to the group

Annex 3

RECOMMENDATIONS FROM EXPERT MEETING ON THE ELECTRONIC EXCHANGE OF PESTICIDES DATA
(21-23 APRIL, 2008; US)

Theme 1: ***Identify and address existing hurdles that hinder the efficient collection and exchange of pesticide information due to incompatible formats or IT systems/approaches***

Recommendations / Follow-up

1. OECD should minimize making changes to existing templates and schema, and make clear (at a minimum on the public website) whether a template/schema is the original version or an updated one, and when the changes were made.

2. Future templates/schema should be made backward-compatible with the original.

3. A tool should be developed and made available to governments for verifying that an XML data file, based on the OECD XML schema, meets defined requirements and standards.

4. An in-depth analysis should be conducted to determine the exact amount of disparity between the naming and numbering schemes used across countries. *Canada and Bayer will conduct such an analysis and provide a draft report in June, 2008*.

5. EPA will investigate the separation of declarations from documents, look into resolving the 86-5 issues and provide an update on the potential 86-5 process changes, and develop smart documents as application-based data entry screens.

Theme 2: Determine how the joint review process will use the OECD templates

Recommendations / Follow-up

6. A "smart" Word document prototype should be developed that uses the established OECD XML schema and includes a mechanism for tracking technical errors during the Primary Review. Such a document would allow a submitter to enter information using Word, but that information could, at a later point, be easily converted into XML. *Note: A "smart" Word document is similar to a style sheet, but is different as it does not contain the content and structure of a web page. Style sheets are discussed further in Theme 3 below.*

7. The "lessons learned" workshop should include representatives with IT experience in order to ensure that this aspect of joint reviews is considered, and approaches developed for disseminating and managing joint review data electronically.

8. The workshop should also consider whether existing template guidance is sufficient, and if there is a need for new or modified templates.

Theme 3: Identify standard layout for rendering the OECD template XML

Recommendations / Follow-up

9. A redacted version of each of the DuPont study summaries should be made available for a workgroup to review as to the usefulness of the layout and whether it contains all of the elements in the OECD templates. This should be compared with the layout of the IUCLID style sheets. *EPA would lead the workgroup that would also include OECD reviewers and industry representatives*. Once the study summary layouts are agreed, EPA will render them into style sheets. The necessary rendering characteristics to be included in the layout are: *bookmarks / links; each study beginning on a fresh page; continuous table numbers; figure numbers and appendices; locked title fields; complete (additional fields, if necessary); and separate physical files*. In addition, it was determined that reviews should be transferred back into XML format for sending to regulatory authorities and industry.

Theme 4: Identify and review ways to harmonize methodologies for a common transport mechanism

Recommendations / Follow-up

10. OECD should standardize the term Dossier and other related terms (i.e., Decision, Submission) and provide data field definitions that explain the type of data that should be provided.

11. Meeting participants recommended that a Transport Schema workgroup consisting of government and industry experts familiar with CADDY, e-Index Builder, e-PRISM Builder, and IUCLID be established. The workgroup would be responsible for comparing the fields in these transport systems, creating a data dictionary, and drafting guidance on the use/meaning of the fields. The group could meet over the next few months and report their findings back the OECD group.

12. EPA and the Transport Schema workgroup should investigate how CBI and non-CBI versions of a document are collected. EPA is to look into the legal issues, while the Transport Schema workgroup is to determine how CBI is currently being "physically" handled as well as how CBI should be handled using XML. Additionally, EPA is to adopt the use of a cross-reference field in e-PRISM (for studies only).

Theme 5: Identify ways that the templates can use structured data for reporting summary information on field trails (e.g. XML-tagged cells within a table rather than text fields)

Recommendations / Follow-up

13. The Residue Chemist Expert Group should identify, during their 5-8 May meeting, what information that would be generated from crop field trials should be included in structured tables.

14. Industry and governments should be consulted on whether:

a. it is technically feasible to develop structured data tables for crop field trial data, and that such tables comply with the format and rules that apply to OECD templates, schema and schematrons
b. governments can use data submitted in XML format
c. companies are able to submit data in structured formats
d. to begin now developing such structured tables, or wait until the next draft of the Crop Field Trial Test Guideline is available?

Annex 4

OECD Transport Mechanism Subgroup Meeting

Draft Meeting Report

Prepared by Dominique Rey-Carruth (US EPA)

MEETING LOGISTICS

Dates: 18 August 2008 through 21 August 2008
Location: Ottawa, Ontario, Canada
Host: Pest Management Regulatory Agency

OBJECTIVES

Representatives from the OECD Transport Mechanism Subgroup traveled to Ottawa, Ontario for a collaborative information technology conference at Canada's Pest Management Regulatory Agency (PMRA) to discuss an international transport mechanism and schema harmonization for jurisdiction specific pesticide regulation. The three day conference consisted of follow-up discussions on the development of a technical solution intended to support the joint review process. The EPA supports the harmonization with PMRA and other regulatory agencies within the scope of providing the transport of information. Further collaboration between OPP, PMRA and other regulatory agencies is necessary to establish a unified approach to information exchange between regulators and registrants. Once a joint transport and harmonized methodology is defined, EPA and PMRA will co-sponsor a proposal to OCED to encourage adoption by other international pesticide producing and regulating organizations. The discussion focused on two items: 1) to support the joint review process with a transportation mechanism for joint reviewed dossiers across agency jurisdictions and 2) standardization of a harmonized XML schema industry registrants can use to submit dossier packages across regulatory agencies. During the three days of meetings, the regulatory and industry workgroup continued to share information about these topics, identified common requirements for a universally harmonized schema and analyzed the potential a harmonized schema for a variety regulatory agencies.

GENERAL RECOMMENDATIONS

- Provide one universal packaging transport mechanism allowing industry registrants to transport compiled joint reviews information. It would improve registrant adoption, provide transparency across jurisdictions and allow for a reduction of redundant submission information across agencies.
- Define a harmonized XML schema that would support a flexible format and allow agencies to select fields according to agency requirements and further development of a data definition glossary.

TOPIC: ***TRANSPORT MECHANISM***

Background

In the past EPA has worked side by side with PMRA to reduce redundant registration activities in North America. The current tool used by PMRA assists companies in the creation of XML files and accepts XML schemas describing a submitted package's content. While this initial endeavor has proven helpful in reducing redundant registration activities in North America, further investigation is necessary to completely harmonize these two XML schemas. Additionally, exploration of European requirements from the CADDY system is necessary and support for global emerging market registrants with a harmonized schema would add additional design requirements to a transport mechanism.

Key Points

- Previous discussions centered on schema harmonization ahead of the transport of the information. The group deemed it necessary to define the criteria for the transport mechanism was necessary before addressing the document level schema.
- The EPA would use a tool similar to E-Index Builder (EPB). PMRA currently uses EPB to compile and transport information. The European Crop Protection Association (ECPA) uses a tool named CADDY to transport and view information.
- At the heart of all three regulatory agencies is a requirement to compile and transport information in a standardized format. It was deemed necessary that the universal transport schema would have 'compile' and 'transport' functions enabled. A 'view' function could be explored at a later date. Additionally, the universal schema should have a 'validation' function.
- A definitive set of commons terms would be necessary to assist in joint review activities. The lingual and semantic difference between PMRA, EPA and CADDY highlights challenges registrants could encounter. A data dictionary was deemed as an adequate resource.
- The present group discussed in high level terms that the information exchange process used to define industry applications for each new or existing product would be contained within a single dossier.
- The high-level process of completing a dossier could include one or more submissions that may be part of one dossier. One or many dossiers would be part of one product. Each dossier would represent one product from one registrant.
- Consistent nomenclature would be necessary for dossier identification in the transport mechanism during in joint reviews. Regulatory bodies could cross-reference company numbers generated by self designation.
- Once the challenges at the transport level were addressed a review of common dossier level elements collected by PMRA, EPA and EU regulatory bodies, highlighted the majority of outlier elements were in the CADDY system.
- The proposed structure of the dossier would be a flat file structure, currently used by EPA and PMRA. Again this distinction would adversely impact the CADDY system's current folder structure.
- Industry participants vocalized the strong desire to use the folder structure in conjunction with the joint review process since a majority of potential agencies would not be able to utilize a flat file structure due to a lack of technological resources.

- The EPA indicated it would implement a conceptual dossier (middle) level of the process and a Project ID number to differentiate each "dossier". EPA would support a dossier and harmonized schema initiative through further development of e-Prism Builder.
- The EPA indicated that since PMRA and the EPA do not have a vested interest in the folder structure set-up, a proposal indicating how this would affect the EPA's current consumption tool is necessary from another subcommittee member to provide.

Recommendations for Future Action

- Development of a new transport tool like the e-Index Builder that serves the needs of the EPA, PMRA, other regulatory agencies and registrant community with single and joint dossier submission capabilities.
- Revisit the potential need to further define dossier identification, version control, validation and potential level of effort for 'viewing' functionality for regulatory agencies not capable of in-house application management.

TOPIC: ***SCHEMA HARMONIZATION***

Background

The document level design was addressed after group consensus on the dossier transport mechanism methodology for pesticide regulation. The document level would be best served with a harmonized schema. To achieve a harmonized schema a consistent nomenclature would be needed. The harmonized schema should address common dossier level elements. In the past, EPA had utilized PMRA's schema for XML building tool. The conference group acknowledged this factor as a whole and it was widely agreed that the present challenge was separating the CADDY application constraints from the CADDY XML attribute sets. Only the necessary CADDY XML attribute would be incorporated into the universally harmonized schema. This harmonized schema would be utilized for joint review submissions. The anticipated participation of non-OECD countries like Brazil, Mexico, Japan and their potential requirements for a universal XML schema was mentioned as an additional challenge for creating a universally harmonized schema. The discussion developed into solutions focused on an EPA supported transport mechanism and its intent to produce a harmonized universal schema. It was further discussed the universal schema should be flexible to adequately meet various agency needs, geared toward reducing redundancies, contain version control abilities, enable documentation viewing, and smart documenting features.

Key Points

- The dossier was perceived as the most accommodating level for identifying whether a submission of packaged data from industry entity was for joint or single review. However, the requirement and type of details required at the document may still vary across agencies.
- The crosswalk of values from EPA, PMRA and the CADDY system were analyzed and viewed as a starting point to attempt harmonizing the document level.
- While the harmonization of the schema was being discussed it was clear that the EPA and PMRA requirements and values were in-sync. The complexity of the CADDY system and European industry participants list of regionally specific requirements requires further analysis to achieve a harmonized international standard.
- In all three current systems there are overlaps of data that required similar values or slightly modified data types. A data dictionary was viewed as helpful by all participants in moving forward to a harmonized schema reducing redundancy.
- One proposed mechanism for handling agency specific fields or values would be incorporated into the schema. The schema would allow an agency specific system to identify whether a field is required or to disregard the content in the field.
- The harmonized XML schema would support a flexible format and allow for insertion of agency specific fields.
- The group recognized that PDF/A documents should be the recommended form for submitting documents for review, but it will not be required.
- Industry subcommittee members raised the issue that the ability to attach several documents to one record instead of repeating that record is preferred at the document level.
- The harmonized schema should allow multiple CBI fields specified by country to indicate the CBI status across multiple regulatory bodies required when a joint review submission.
- The ability to link the MRID # from the EPA database to relevant documents was noted as a potential enhancement however, industry participants notated this may no longer be a requirement.

Recommendations for Future Action

- The EPA will review the deltas between the CADDY XML fields and those in the harmonized e-Index / e-PRISM schema. Then distribute a spreadsheet of the data dictionary to the subgroup members for comments on field descriptions and the possible addition of new data fields.
- PMRA will distribute a visual representation of the schema to the subgroup members.
- The harmonized schema, data dictionary and schema visual will be distributed to various EU representatives for comments.
- The EPA will analyze if MRID numbers are required on printed report submissions within a harmonized schema supported by a transport mechanism containing a project ID number.
- Sub-group industry members will reconvene on September 4, 2008 to discuss the work produced by the subcommittee. The conclusion from this meeting will result in recommendations submitted to the OECD for review and comments.

MEETING NOTES

19 August 2008

Attendees:
PMRA (Canada): *Joseph Mikhael, Alex Scholten*
IMSD (Canada): *Aaron Carswell, Phil Coyte*
EPA (US): *Quentin Jones, Dominique Rey-Carruth*
Guident (US): *David Rizzi, Millicent Smith, Nicole Carbonaro*
Bayer CropScience: *Bodo Stadtbaeumer, Dirk Fredrichsdorf*
BASF: *Bob Manfre*
Syngenta: *Debbie Corn Mahaffey*

1. PMRA opened with an explanation of the purpose for the meeting:
    a. The Transport Mechanism Subgroup was established by the OECD, and with the blessing of Industry participants, and was given the task of standardizing the Dossier submission process across global environmental agencies.
    b. The specific purpose of the group was to work toward the creation of a standard for a universal transport XML schema that can be used by Registrants to submit documents to any country, including non-OECD members.
    c. Emphasis was placed on identifying the required fields which are common to e-PRISM, e-Index Builder and CADDY and coming to a consensus on how to merge these fields
    d. It was also suggested that as a follow up to the process of merging common fields across schemas, that a data dictionary be built to define each of the fields in the newly designed and harmonized schema.
    e. It was in support of the transport mechanism the goal of the meeting would be to present a harmonized schema to the OECD and to obtain OECD approval of the process.

2. The representatives from Bayer CropScience proposed that some time be taken to discuss the high level differences between a submission sent to the EPA, PMRA and to CADDY and the following determinations were made:
    a. Each Agency views the process in three discrete steps. The first level in the process involves the submitting company sending in a registration package. This level is referred to as a Submission by the EPA and CADDY and as a Transaction by PMRA. There may be several iterations of the Submission/Transaction step in the process, as the submitting company attempts to provide all required information to the Agency.
    b. The second level in the pesticide registration process is called the Dossier level by CADDY, the Submission level by PMRA. This level does not currently have an EPA defined name, but it was indicated by an assigned Decision number and the EPA has discussed adopting the term Dossier to describe this stage of their process. This second level of the pesticide registration process is simply in place to help the agencies differentiate between multiple product registration requests. When a Submission/Transaction comes in the door, the agency must determine it relates to either a new or existing Dossier/Submission. This level may also have multiple iterations, as companies proceed to amend their products throughout the registration process.
    c. The final level of the pesticide registration process is the Product Level. This level indicates that the Dossier/Submission has been accepted by the agency and that the submitting company has received permission to market their product.

   d. The EPA proposed incorporating the Decision number into Documentum, which would then link documents that are part of the same Dossier together.
   e. In support of the transport mechanism all agencies should have a Dossier/Project number which is the same across organizations and that will be included in the metadata of the XML file.

3. Based on the discussion described in step 2 above, some discoveries were made regarding the creation of a Common Language for information exchange
   a. There are some linguistic differences between PMRA, EPA and CADDY in terms of what information is being exchanged/received/reviewed.
      PMRA: Many *transactions* may be part of one *submission*, many submissions may be part of one *product*.
      EPA: Many *submissions* may be part of one *decision*, many decisions may be part of one *product.*
      CADDY: Many *submissions* may be part of one *dossier*, many dossiers may be part of one *product*.
   b. Due to the shared terms between EPA and CADDY, and that fact that reviewers seem to already be using the CADDY language during Joint Reviews, such language could be part of the universal tool.

4. The EPA proposed a change in their process which would ensure that a document could only ever have one MRID number, regardless of whether or not it was part of a subsequent submission.

5. Would the schema contain fields that are common to each jurisdiction, or would there also be jurisdiction specific fields that are somehow identifiable using extra 'authority' fields?
   a. Industry argued that common fields reduce the regulatory burden on Registrants.
   b. From the Agency perspective, specific fields would allow the tool to be more useful to each jurisdiction.
   c. No final decision was made at this stage – but this will likely be revisited after a full analysis of the fields contained in each of the three tools.

6. What is the purpose of the transport schema?
   a. Currently, EIB and EPB are used to compile and transport information, and CADDY is used to transport and view information.
   b. It was raised that the view function is necessary in order for jurisdictions without their own internal databases to be able to manage the information that is sent.
   c. It was agreed that the universal transport schema may need all 3 functions: compile, transport and view. However, this is a long term goal and is outside the scope of this meeting.

7. When sending another Submission to a Dossier, what should that Submission contain? Only the new information or the new information along with the information that was in the previous Submission/Transaction?
   a. EIB and EPB currently only require the new information.
   b. CADDY currently requires the both the new information and the information that was included in the previous Submissions/Transactions.
   c. A proposed solution to this issue was that the new information along with the information in the previous submission should all be included in the XML, as it is in the CADDY system, however, each iteration of the submission should be assigned a version number within the XML. This would allow the EPA and PMRA to only consume the most recent section of the XML file, which would be indicated by the latest version number.

8. Dossier identification
    a. Currently, each jurisdiction assigns a unique dossier/submission/decision number when a one is submitted by the Applicant.
    b. Industry would like to assign their own dossier number, and they would refer to that number whenever they send in new submissions to the same dossier.
    c. Regulatory bodies can cross-reference that company assigned number to the number they generate in-house.
    d. The company would declare format. Eg: [3-letter company code] [2 letter ISO country code] [incremental number].
    e. Questions:
        i. Would we need to capture both, or only one of these numbers in the tool's XML schema?
        ii. Would the company dossier number only be needed for Joint Reviews, or can they also be used for other dossiers?
    f. This issue and questions were tabled for further discussion.

9. Plan for Day 2:
    a. 9-10am: A presentation is scheduled for Bayer Crop Science to present the CADDY system to EPA and PMRA.
    b. 10-11am: This time will be spent determining which dossier level information is common between all three systems and how to combine these identical fields into one in the harmonized schema.
    c. 11-12pm: This time will be spent distinguishing the dossier level elements from document level elements and designing a plan to merge these similar fields within the new harmonized schema.
    d. Afternoon: Return to topics listed in Agenda.

20 August 2008

Attendees:
PMRA (Canada): *Joseph Mikhael, Alex Scholten*
IMSD (Canada): *Aaron Carswell, Phil Coyte*
EPA (US): *Quentin Jones, Dominique Rey-Carruth*
Guident (US): *David Rizzi, Millicent Smith, Nicole Carbonaro*
Bayer CropScience: *Bodo Stadtbaeumer, Dirk Fredrichsdorf*
BASF: *Bob Manfre*
Syngenta: *Debbie Corn Mahaffey*

1. Presentations were held to review the common Dossier level elements collected by various Regulatory bodies. PMRA presented the elements that are collected via the Application Form and Secure Web Portal. PMRA uses an online PDF form to help registrants create the XML containing the form data and e –Index builder creates the XML containing the document data. E-Index builder was developed as a standalone Java application but this was a bit more complicated than industry wanted, so the PDF forms were created.
    a. PMRA collects the following elements:
        i. Product Name
        ii. Product Number
        iii. Registrant contact info

iv. Regulatory Contact info
v. Submission contact info
vi. Who to send acknowledgement of receipt to?
vii. Who is to receive formal correspondence?
viii. Type of application: (New, amendment, renewal, reinstatement)
ix. Type of Product
x. Proposed Classification: (Domestic, Commercial, Restricted, Manufacturing Concentrate, Technical, Integrated Systems Product)
xi. Type and size of container
xii. Submission type (24 options)
xiii. Proposed New User?
xiv. Declaration that the information in the application is true and complete.

b. Bodo presented what BVL (Germany) collects via their various forms and their secure web portal. The basic structure for the information they require is as follows:
    i. Administrative data:
        1. Type of product you want to register
        2. Trade Names
        3. Company Codes
        4. Type of application (new app, label extension, renewal of an expiring registration.)
        5. Address of the person submitting the application
        6. Person responsible on the EU level
        7. Name of the person distributing the product to the market.
    ii. Information related to the end use of the product and the active ingredient.
    iii. Information related to the intended use of the product.

c. The EPA indicated that the common elements they collect had already been discussed in detail throughout the e-Submission development process, and they are currently using those common elements in e-submission.
    i. As such, PMRA indicated that they will look at the lists of elements developed by Bayer Crop Science and the EPA in order to come up with a proposed set of common elements that should be found in the universal transport schema.
    ii. At the document level, most of the tags, such as CBI and Numbering Codes, will need to remain country specific.

2. PMRA proposed that one group take the initiative to put together a harmonized XML based on the data gathered by the end of the meeting, and present it to the group. This approach was agreed to by the group and it was determined the EPA would take on this task.

3. Submitting multiple documents for one record
    a. The issue was raised that it would be easier for industry to be able to attach several documents to one record instead of repeating that record.
    b. PMRA currently links those records together by allowing Applicants to identify those related documents using the 'Document Group' field in EIB. Once loaded into the database, those documents are set as 'cousins'. The EPA also uses the Document Group field to indicate that documents are related.
    c. It was proposed that a similar method be used to indicate related documents in the universal schema, but that something more specific than the Document Group field should be instituted.

4. Proposed methods for indicating the CBI content of submitted documents
    a. Canada and E.U. has 'Yes', 'No' flags for CBI, whereas U.S. has '0', '1', '2', '3' flags. Other jurisdictions likely have similar flags.
    b. Proposed that a universal approach be taken:
        i. The Registrant should be responsible for submitting the following:
            1. Submit the full original report
            2. Submit the redacted portion of the original report
            3. Submit the redacted version of the full report to each Agency or jurisdiction. Of course, each Agency may have different standards as to what needs to be segregated. This means that Industry would still need to be responsible for adhering to the CBI rules of each regulatory body and country.
        ii. CADDY would only use portion 1 of the report. The EPA would only use portions 1 and 3 and PMRA would use all three portions of the report for their review purposes.
        iii. It was proposed by Bayer Crop Science, that within the XML schema, only the option to indicate "Yes" or "No" for CBI status should be available. The EPA agreed to look into changing their approach.
        iv. Since the distinction of what is CBI and what is not tends to vary from country to country, it was also determined that the harmonized schema would need to allow for multiple CBI fields which would indicate the CBI status of a document across multiple regulatory bodies.
        v. Further distinctions between the documents can be made using specific Document IDs.

5. Location of the MRID # on submitted documents
    a. Since there will be a process in place that provides the ability to link the MRID # from the EPA database to relevant document, Industry questioned whether the MRID that is required to be printed on the cover page of each document is still necessary.
    b. The EPA agreed to look into this question and determine if the MRID still needs to be printed on each submitted report.

6. Relating Documents (cross-reference)
    a. Phil, of PMRA, proposed that there needs to be a process in place that can be used to relate complimentary documents to one another, and also a process in place to indicate which documents are simply subsequent versions of a base document. The committee agreed to this suggestion and Phil indicated that he would take the time to put together a proposed solution which he would send to the group for comments.
    b. Since this information is collected at the document level, it will be specific to each jurisdiction.

7. Hyper linking the Dossier
    a. Bayer Crop Science proposed that a field be added to the harmonized XML schema that would indicate if two documents were linked by hyperlinks. CADDY currently has the ability to create links between documents within a dossier and Industry was of the opinion that this would be a useful addition to the harmonized structure and that it will increase the efficiency of the review process.
    b. PMRA and EPA will investigate whether it is possible to carry-over those hyperlinks when those documents are loaded into their internal databases. If it is determined that this will not cause too much of a disruption to the current process, the EPA and PMRA will discuss instituting this practice.

8. Folder Structure within Zipped File
    a. The zipped file that is submitted to EPA and used in the e-Submission consumption tool and the PRZ file created by the EIB are 'flat' file structures. CADDY files, on the other hand, are organized into folders. The former method was used to allow for easier loading into the internal database. The latter method was used to allow organizations without certain technological tools to be able to logically order and view documents.
    b. It was proposed by Bayer Crop Science that a folder structure be adopted in the harmonized method, in order to more easily facilitate the joint review process among countries with a limited ability to interpret the flat file structure.
    c. The PMRA and EPA will investigate whether they can accept such structures and load them into their databases.

9. PDF vs. PDF/A
    a. PDF/A can provide many benefits because it does not rely on external technology to support its functionality. Therefore, it is a way of ensuring that the documents received can be archived for a long period of time and also that documents viewed on all computers around the world will look the same to the reviewer.
    b. The group proposed PDF/A documents should be the recommended form for submitting documents for review, but it will not be required.
    c. Bayer Crop Science pointed out that BVL (Germany) *requires* PDF/A. In such a case, whenever documents are being sent to BVL, PDF/A will be used.
    d. If a document is attached to a PDF that would be stripped when converted to PDF/A (such as a video), it was suggested that those attachments could be submitted as separate documents.
    e. Since different standards are often used to validate whether or not a document is PDF/A, it was proposed that the OECD agree on a standard. Industry suggested that this standard also include the ability to maintain hyperlinks between documents.
    f. The question of whether or not a field should be included in the XML to indicate PDF/A "Yes" or "No" was also raised and tabled for future discussion.

10. Validation of Dossier
    a. Since each of the transport schemas being used has a different method for validating the dossier, it was suggested that the universal schema have a standardized validation tools.
    b. Special emphasis was placed on the fact that there should be a flag added to the XML schema to indicate under which version of the OECD data dictionary the Dossier was created. This would mean that as the data dictionary inevitably evolves, the dossiers submitted in prior years will still be able to be interpreted and processed by the reviewers.

11. Plan for Day 3:
    a. Investigate ways to cross-walk between document identifiers: EPA Guideline Numbers, PMRA DACOs and OECD codes.
    b. Develop a Draft Data Dictionary
    c. Proposed change to file structure.

21 August 2008

Attendees:
PMRA (Canada): *Joseph Mikhael, Alex Scholten*
IMSD (Canada): *Aaron Carswell, Phil Coyte*
EPA (US): *Quentin Jones, Dominique Rey-Carruth*
Guident (US): *David Rizzi, Millicent Smith, Nicole Carbonaro*
Bayer CropScience: *Bodo Stadtbaeumer, Dirk Fredrichsdorf*
BASF: *Bob Manfre*
Syngenta: *Debbie Corn Mahaffey*

1. Cross-Walk
   a. The present group recommended that whenever a Joint Review is conducted, that the OECD document codes should be used. Registrants would also use country specific codes in addition to the OECD codes in Joint Reviews. For country-specific reviews, Registrants should use the country-specific codes, unless the regulatory body has the ability and willingness to cross-walk from the OECD codes.
   b. BASF proposed that the OECD put together a group to harmonize and accept the cross walks so that jurisdictions and industry can rely upon it. Secondly, the group would be responsible for analyzing the major gaps that exists between the lowest level node of OECD data points and the OECD templates.

2. Bayer Crop Science Revisited the PDF/A discussion
   a. Bayer Crop Science stated that if the PDF/A documents contain hyperlinks, the validation of the PDF/A should only show a warning if they are invalid. However, the validation step should not indicate that the PDF/A does not qualify, because the hyperlinks are only there for the benefit of the reviewing agency and if over time they become inactive, this would not affect the content of the document.
   b. This comment was taken into consideration and will be revisited in conjunction with the other points that were discussed relating to PDF/A.

3. Revisiting of Viewing options
   a. Industry revisited the idea of allowing a hierarchal folder structure within the submitted zipped file packages.
   b. The EPA indicated that since PMRA and the EPA do not have a vested interest in the folder structure set-up that some other group should put together a proposal indicating how this would affect the current consumption tool that is in place. After reviewing the proposal and coming to a more in depth understanding of the consequences of accepting a file with a folder structure, the EPA and PMRA will be in much better position about accepting this proposed change.

4. The EPA indicated that they will not be adopting an OECD universal authoritative level dossier set up. They will only be implementing a conceptual dossier (middle) level of the process and a Project ID number to differentiate each “dossier”. There are currently no discussions about or initiatives on the side of the EPA to be able to accept Dossier structured submissions.

5. Legacy MRID Numbers
   a. The EPA wants to be able to support the use of a Legacy MRID number. A Legacy MRID was described as an MRID that was included in a previous submission. Often times the same studies are included in subsequent submissions, and the EPA wants to prevent situations where they have multiple identical studies with varying MRID numbers.

6. Meta Data
   a. Bayer Crop Science questioned why metadata for documents should have to be repeated for supplemental documents, if this same information has already been provided in the XML for the core document. The validity of this question was agreed to by all, but was tabled for future discussion.

7. Data Dictionary
   a. A draft of the data dictionary was developed, and captured in a spreadsheet prepared by the EPA and a schema by IMSD. Both documents will be distributed to the group for comments, once they have been edited.
   b. Approximately 6 levels of details were agreed upon for the universal schema (5 if Contact Information is considered part of the Dossier level): System, Contact Information, Dossier, Submission, Document, and File.

8. Next steps
   a. Once finalized, the EPA will distribute a spreadsheet of the data dictionary to the subgroup members for comments on field descriptions and the possible addition of new data fields.
   b. Once finalized, PMRA will distribute a visual representation of the schema to the subgroup members.
   c. These two items, along with the minutes, will also be distributed to various EU representatives for comments.
   d. Sub-group industry members will also reconvene on Sept. 4 to discuss any changes.
   e. After all of the steps listed above have been completed, the work produced by the subcommittee will be submitted to the OECD for review and comments.