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THE BUSINESS CASE FOR THE JOINT EVALUATION OF DOSSIERS (DATA SUBMISSIONS) USING WORK-SHARING ARRANGEMENTS

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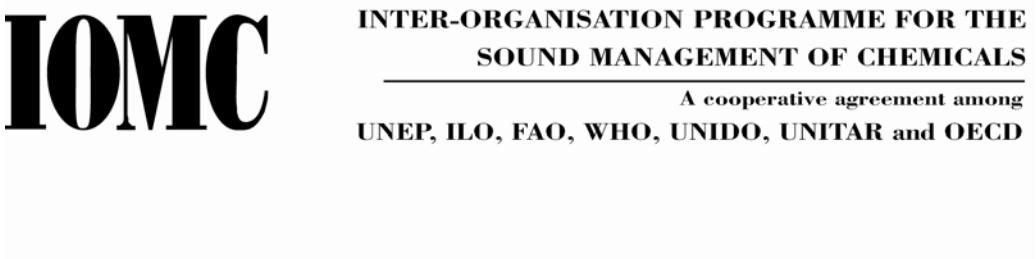
Series on Pesticides

No. 41

The Business Case for the Joint Evaluation of Dossiers (Data Submissions) using Work-sharing Arrangements



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The Environment, Health and Safety Division publishes free-of-charge documents in ten different series: Testing and Assessment; Good Laboratory Practice and Compliance Monitoring; Pesticides and Biocides; Risk Management; Harmonisation of Regulatory Oversight in Biotechnology; Safety of Novel Foods and Feeds; Chemical Accidents; Pollutant Release and Transfer Registers; Emission Scenario Documents; and the Safety of Manufactured Nanomaterials. More information about the Environment, Health and Safety Programme and EHS publications is available on the OECD's World Wide Web site (http://www.oecd.org/ehs/).

This publication was developed in the IOMC context. The contents do not necessarily reflect the views or stated policies of individual IOMC Participating Organizations.

The Inter-Organisation Programme for the Sound Management of Chemicals (IOMC) was established in 1995 following recommendations made by the 1992 UN Conference on Environment and Development to strengthen co-operation and increase international co-ordination in the field of chemical safety. The participating organisations are FAO, ILO, OECD, UNEP, UNIDO, UNITAR and WHO. The World Bank and UNDP are observers. The purpose of the IOMC is to promote co-ordination of the policies and activities pursued by the Participating Organisations, jointly or separately, to achieve the sound management of chemicals in relation to human health and the environment.

FOREWORD

In 2004, OECD countries agreed to a ten-year vision for the harmonisation of regulatory approaches for agricultural pesticides (chemical and biological) to facilitate and promote the sharing of work between regulatory authorities. The highlight of this "Vision" is that by 2014, OECD countries will routinely accept dossiers prepared by stakeholders in the OECD format; will routinely exchange "monographs" containing reviews of the data submitted; and will use OECD "monographs" as a basis for independent risk assessments and regulatory decisions for new and existing pesticides.

Over the last few years, the OECD Pesticides Programme has been working to harmonise approaches and establish the infrastructure that will facilitate such work sharing. Work sharing can be done by dividing up the review of each individual pesticide, with two or more governments reviewing different parts of the registration package. Work sharing can also be done by dividing up pesticides among two or more governments, with each government conducting the entire review of its assigned pesticide.

This document describes the benefits that will accrue to regulatory authorities, companies (registrants) and the general public as a result of joint evaluations of dossiers.

Mark Lynch, from the Pesticide Control Service in Ireland, was the lead author for this document. This document is published on the responsibility of the Joint Meeting of the Chemicals Committee and Working Party on Chemicals, Pesticides and Biotechnology.

THE BUSINESS CASE FOR THE JOINT EVALUATION OF DOSSIERS (DATA SUBMISSIONS) USING WORK-SHARING ARRANGEMENTS

Introduction

Building on progress achieved, the OECD in 2004 adopted the vision[1] that by the end of 2014, through the co-operation of OECD member countries working with relevant stakeholders, it will ensure that:

- The high level of protection afforded to human health, animals and the environment is further enhanced and the levels of risk arising for man, animals and the environment as a consequence of the marketing and use of agricultural pesticides, are minimised to the extent possible.

- The regulatory system for agricultural pesticides will have been harmonised to the extent that country data reviews (monographs) for pesticides prepared in the OECD format on a national or regional basis (*e.g.* EU or NAFTA) can be used to support independent risk assessments and regulatory decisions made in other regions or countries.

- The preparation of data submissions (dossiers) for pesticide active substances and for end-use products is co-ordinated globally by industry, to the extent possible, such that opportunities are maximised for work-sharing between the regulatory authorities of OECD member countries.

- Work-sharing arrangements between regulatory authorities in OECD countries take place as a matter of routine such that data submissions (dossiers) prepared by industry in the OECD format are accepted in all OECD countries and made available and used globally, notwithstanding the need for supplementary data submissions to address particular local/national conditions and issues, or country specific legal requirements.

- The generation of a single monograph for each active substance, serving the needs of the regulatory authorities in all OECD countries, has become commonplace, notwithstanding the need for separate independent risk assessments and regulatory decisions in each jurisdiction.

In relation to other inter-governmental organisations:

- Countries will ensure that the benefits derived from work-sharing and the experiences gained through the work of the OECD Working Group on Pesticides are taken into other relevant international fora (*e.g.* JMPR), thereby helping developing countries efficiently manage their pesticide regulatory systems.

It was envisaged that on implementation of the vision, registrants would benefit from minimization of the time, costs and uncertainty associated with registering new and defending existing products in re-registration programmes, and from earlier access to global market for new products.

Insofar as the Regulatory Authorities of OECD countries were concerned it was envisaged that on implementation of the vision, they would benefit from sounder scientific conclusions being reached *(that serve as basis for more timely regulatory decisions),* and a requirement for fewer resources for evaluation of data submissions and for peer review of monographs *(to be achieved through use of work-sharing arrangements)*.

[1] http://www.oecd.org/dataoecd/30/60/33854658.pdf

In the case of growers and other end users, it was envisaged that they would benefit from earlier access to new pesticide solutions and better access to pesticide tools to combat harmful organisms in crops.

Finally in the case of consumers/citizens, it was envisaged that they would benefit from a high degree of public confidence in the regulatory system.

Infrastructure

The OECD instruments for ensuring mutual acceptance of data (MAD) include three elements, the Decision of the Council Amending the Decision concerning the Mutual Acceptance of Data in the Assessment of Chemicals[2], the Decision-Recommendation on Compliance with Principles of Good Laboratory Practice[3] and the Decision on Adherence of Non-Member Countries to the Council Acts related to the Mutual Acceptance of Data in the Assessment of Chemicals[4]. Countries that signed up to MAD have decided that data generated in the testing of chemicals in an OECD Member country in accordance with OECD Test Guidelines and OECD Principles of Good Laboratory Practice shall be accepted in other Member countries for purposes of assessment and other uses relating to the protection of man and the environment. Those instruments developed to eliminate non-tariff trade barriers and to avoid duplicative testing by industry, form the cornerstone on which further infrastructure has been developed by the OECD Pesticides Programme to facilitate use of work-sharing arrangements by Regulatory Authorities in reviewing data submissions for agricultural pesticides.

Electronic templates have been developed by OECD to provide harmonised standard formats for reporting a summary of the results of tests and studies[5]. Through use of these templates, governments and industry can electronically exchange test study summary information.

In the context of the OECD Pesticide Programme, guidance has been developed for applicants wishing to have particular active substances approved, plant protection products registered or Maximum Residue Limits (MRLs) or Import Tolerances established[6]. The guidance provided specifies the format and presentation of the documentation to be submitted. The guidance developed facilitates compilation of data submissions to OECD countries by providing a common format and structure for their preparation, thereby reducing the need for resource-intensive re-formatting, re-structuring and re-writing for individual countries. The format specified facilitates use of electronic data submission systems, and the preparation of countries' review reports to a similar format and structure (monographs).

Guidance Notes to assist in the interpretation and transparent reporting of toxicological data on pesticides have been developed for repeat-dose toxicity studies[7] and for chronic toxicity and carcinogenicity studies[8]. Guidance has also been developed for use by regulatory authorities on the format and presentation of the documentation (Monographs) to be prepared by them, in the examination of applications for the approval of active substances, the registration of plant protection products, the

[2] C(81)30Final <http://webdomino1.oecd.org/horizontal/oecdacts.nsf/linkto/C(81)30>

[3] C(89)87Final <http://webdomino1.oecd.org/horizontal/oecdacts.nsf/linkto/C(89)87>

[4] C(97)114Final <http://webdomino1.oecd.org/horizontal/oecdacts.nsf/linkto/C(97)114>

[5] http://www.oecd.org/document/13/0,2340,en_2649_34383_36206733_1_1_1_1,00.html

[6] http://www.oecd.org/document/55/0,2340,en_2649_34383_33650359_1_1_1_1,00.html

[7] http://www.olis.oecd.org/olis/2000doc.nsf/LinkTo/env-jm-mono(2000)18

[8] http://www.olis.oecd.org/olis/2002doc.nsf/LinkTo/env-jm-mono(2002)19

establishment of MRLs or the establishment of import tolerances[9]. The guidance developed facilitates exchange of monographs between OECD countries and the sharing of the work necessary for the evaluation of plant protection products and their active substances.

The agreed arrangements for the mutual acceptance of data, together with the formats developed for the preparation of dossiers by industry, the guidance developed for the interpretation of toxicity studies, the guidance developed for the preparation of monographs by Regulatory Authorities, and the opportunities offered for closed meetings between Regulatory Authorities and individual companies in the margins of regular OECD meetings, facilitate development of arrangements for the joint review of dossiers using work-sharing arrangements for particular pesticides.

Current Status

The joint evaluation of dossiers submitted in support of applications for approval of new active substances and for the registration of products containing new active substances has become an accepted means of processing such applications in the OECD region. Currently some six separate joint reviews of new active substances are underway. Planning for the joint review of five further new active substances has commenced. In addition planning has commenced for the joint evaluation of dossiers submitted in support of applications to be made for the continued approval of two existing active substances. In all, joint reviews of some 13 active substances from some six separate international companies are either underway or are being planned.

Two pilot projects, involving the use of evaluations prepared by national authorities using work-sharing arrangements for the purposes of JMPR, have been completed[10]. Considerable savings were realised. JMPR found that the greatest impediment to the use of evaluations prepared by the Regulatory Authorities of OECD countries was the use of different formats for the preparation of evaluations, a constraint that will be overcome when the OECD Monograph format is used by all National Authorities.

Currently, no more than a quarter to a third of the dossiers for new active substances developed are being jointly evaluated using work-sharing arrangements. None of the medium or smaller companies have been persuaded to prepare dossiers containing data and information to meet global requirements in the OECD format, such that joint reviews using work-sharing arrangements could be undertaken.

While considerable progress has been achieved in the implementation of the vision, it is clear that much remains to be done to persuade key stakeholders of the benefits that will accrue on full implementation of the vision.

[9] http://www.oecd.org/document/12/0,2340,en_2649_34383_33650316_1_1_1_1,00.html

[10] JMPR Recommended that:

- a mechanism to identify available national and regional evaluations be established;
- that the text of OECD Monographs be incorporated into JMPR evaluations where acceptable;
- that Sponsors include all available evaluations sent to authorities and provide all relevant original studies which will continue to be the primary source;
- style and format be harmonized;
- as the benefits of work-sharing have been demonstrated, no further pilot studies are necessary.

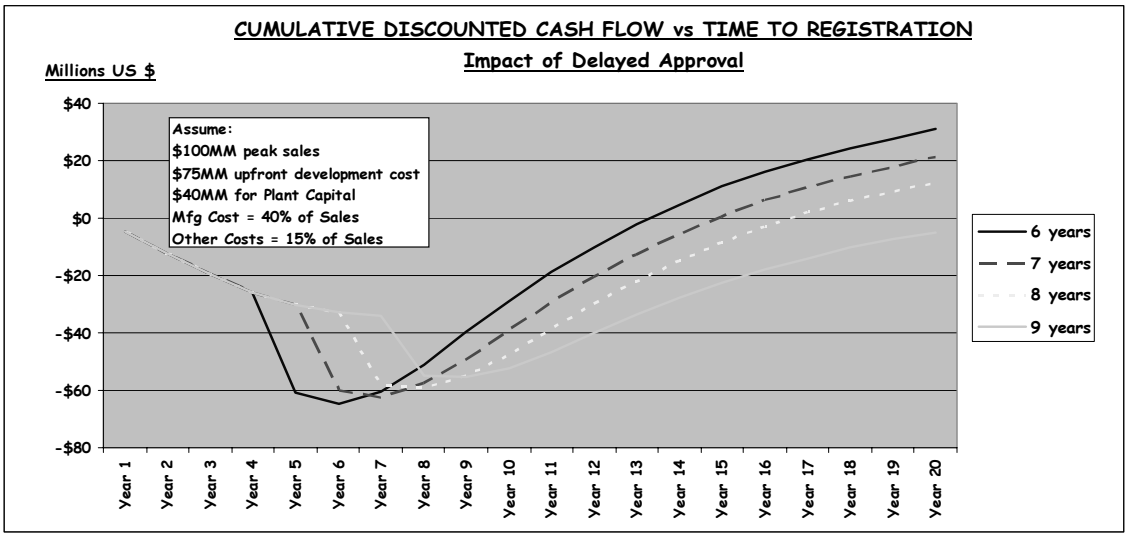
The Business Case for Registrants

Time to market and predictability of approval

Following the consolidation that has occurred over the past decade, the marketplace has become extremely competitive and the risks and costs of new product development have increased. This trend has led companies to carefully scrutinize new product opportunities in the light of both the costs likely to be incurred and the regulatory hurdles that need to be overcome. Major considerations in this analysis are the cost of development of a new product and the expected return on that investment. The former estimate can be obtained reasonably simply and is generally quite accurate. However, the latter estimate often contains a much greater level of uncertainty, due mainly to difficulty in accurately predicting regulatory review time, in some countries. As a result, for marginal business opportunities, this uncertainty can make the difference between proceeding, or not, with a new project.

A critical element in developing the financial model for a new product investment decision is the time it takes to develop and gain regulatory approval for that product. Application of project management techniques and software make it relatively easy to put together a project plan that captures the necessary elements that are needed to complete a full registration dossier. In addition, dependencies can be built into the model to facilitate an understanding of the impact of a variety of scenarios that could potentially delay the project. However, the time required for regulatory review and decision-making in some countries is the area of greatest variability and as a result, can create the most uncertainty for the viability of a project (Figure 1). A typical estimate for the financial impact of a delay of one year in regulatory approval is approximately 10% of the Net Present Value (NPV) of a business opportunity. Depending on the actual NPV this could translate into millions of dollars in lost revenue.

Figure 1 Financial Modelling of Key Elements - time to market



Closely related to the "time to market" is the predictability or lack of predictability, of the time taken for approval (Table 1). Businesses hate uncertainty, particularly when it is associated with the timing of the launch of a new product, because of the significant investment at risk. Product launches are the culmination of a number of planned events generally involving meetings with potential customers and

demonstration trials of the new product. These are generally timed to coincide closely with the market launch and first sales of a new product. Initiating those activities too early or too late in the launch process can have negative effects on both the launch and on customer interest in the new product. For example, failure to launch at the expected time generally can result in customer disappointment and subsequent loss of market share to competing products, making it very difficult to recover customer interest and lost sales (Figure 2). The median estimates provided in Table 1 although somewhat conservative are typical of the inputs that may be used by companies to estimate the financial value of projects. The staggered submissions between the various countries are a reflection of the time needed to fully develop the efficacy and residue packages for certain countries and regions. While it is true that in many cases regulatory reviews and decisions can be made earlier than noted in Table 1, it is equally true that those initial decisions may not be favourable and that the subsequent discussions and negotiations inevitably lead to delays.

The information included in Table 1 reflects crude but conservative estimates of the amount of time between submission of application and granting of market access but should not be equated to the net working time of the Regulatory Authorities in processing applications. The periods of time specified include periods where the Authorities await submission of additional information as well as periods during which additional data are being generated by the applicant to facilitate completion of evaluations undertaken. The periods specified also reflect delays arising from shortcomings in dossiers submitted. Thus the periods indicated are not performance measures for the Regulatory Authorities concerned.

Industry experience with work-share initiatives to-date has shown a great commitment on the part of the Regulatory Authorities to good project management discipline. Project plans are reviewed and updated on a regular basis to reflect new findings, or information that potentially could positively or negatively impact the overall approval timeline. New product registrants interested in participating in a work-share project are encouraged to meet at least two years prior to the submission of new product dossier. This recommendation together with the detailed project planning undertaken provides at least three major benefits: -

- The opportunity to discuss and revise product development strategies to address potential data development questions *e.g.* streamlining of residue field-testing.
- The opportunity to discuss potential issues arising during testing and to adjust testing plans to clarify or address those issues.
- The potential to more accurately predict regulatory review and approval timing and as a consequence to improve planning for manufacturing and launch activities.

Table 1 Typical sequence of submissions and time to approval by the Regulatory Authorities for critical markets [1], where submissions are prepared to meet national requirements *

Country	Timing of applications [2] (first application = year 0)	Time (months) between application and decision granting market access (includes periods of waiting for additional data)	
		Range	Median
Australia	0.5 – 1 year after first	15 – 18 months [3]	16.5 months [3]
Canada	0	21 -27 months	24 months
United States	0	16 – 24 months	21 months
France	1 year after first		27 months
Germany	0 - 1 year after first		28 months [4]
Italy	1 year after first		24 months
Spain	1 year after first		48 months
UK	1 year after first		24 months
Japan	0.5 – 1 year after first	22.7 – 60 months [5,6]	30.1 months[6]

* data provided by CropLife International

1 time between application and decision-making in the non-OECD countries Brazil and India range between 24 and 48 months

2 typical submission sequence for a broad spectrum insecticide (strategy would differ for other product types)

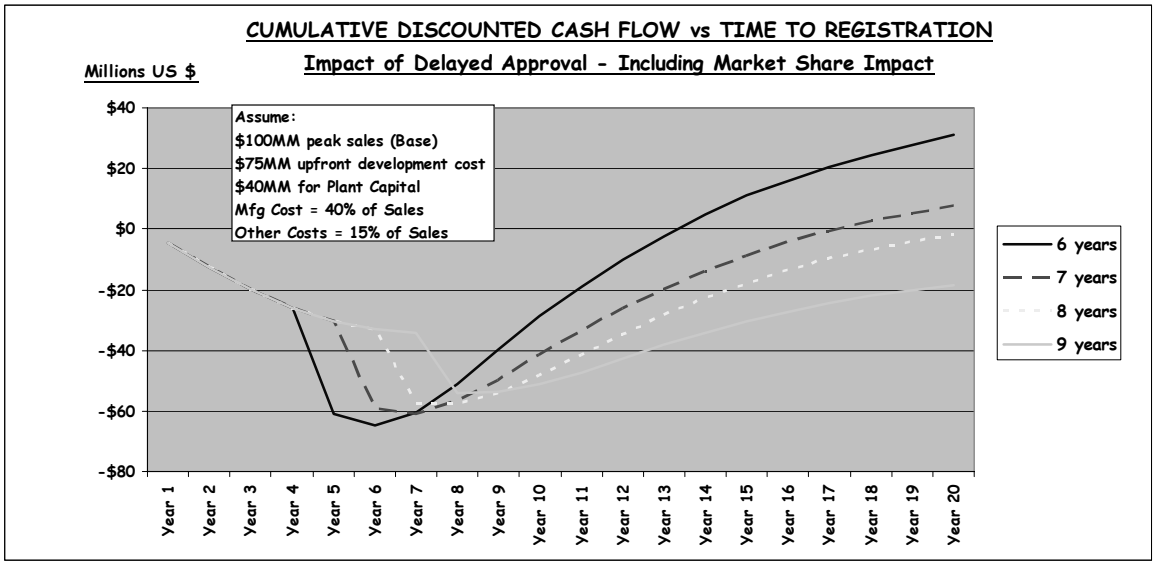
3 Corrected estimates provided by APVMA, reflecting timelines for assessment of complete dossiers

4 average of 2006, not median. The average evaluation time, excluding many of the periods of waiting for the dossier to be completed, was 13 months in 2006.

5 including time between request of risk assessment and initiation thereof

6 Japanese data for "Time (months) between application and decision granting market access" were provided by the Ministry of Agriculture, Forestry and Fisheries

Figure 2 Financial Modelling of Key Elements - time to market and potential to lose market share due to a competing product entering the market

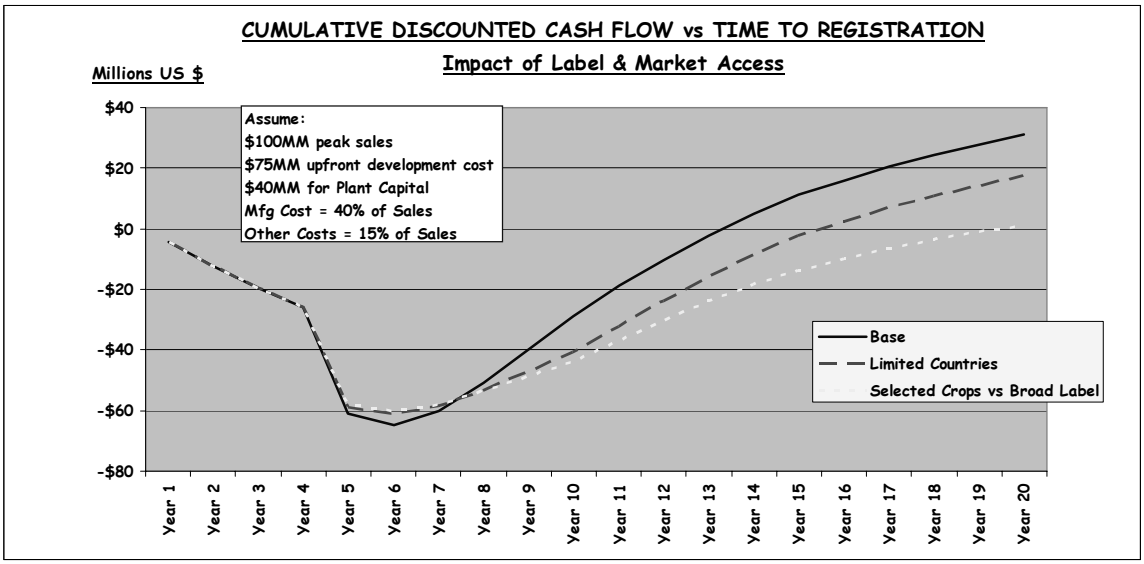


Where joint reviews, involving work-sharing arrangements for the examination of global dossiers prepared in the OECD format, are undertaken, experience has shown that regulatory decisions are made by the participating Regulatory Authorities within 13 to 16 months of submission of the complete dossier.

Maximization of label and market access

As companies evaluate strategies for the development of new products, one of the questions that needs to be addressed early in the process, is the breadth of the initial approved label. The broader the approved label the higher the potential for initial sales and broad market penetration (Figure 3). However, certain desired label uses may also be more problematic for a human health or environmental safety perspective. Thus, a company may choose to gain early market access by registering a few uses versus risking delayed approval due to questions that may arise from a broad label submission.

Figure 3 Financial Modelling – broad market access



From a financial standpoint, a broad label is highly desirable, as long as the additional sales revenue generated provides a reasonable return on the investment required to support those uses. While a particular use may be minor in some countries, it may be more significant in other countries. Minor uses in a number of countries or regions may on an aggregate basis constitute a viable market. In specialty crop markets, farmers growing tomatoes for example, are likely to cultivate a range of other specialty crops. Although the target crop may be tomatoes, it is important to have crops on the label that address the farmer's other cropping needs. Without such a label, farmers may be reluctant to buy the product, even though it may be the best product for tomatoes. With a label containing recommendations for only a few select crops, it will take much longer to gain peak sales and that those sales may be only 70-80% of the original sales potential. In contrast, approval in a limited number of countries may also delay peak sales but ultimately the product should attain 100% of the sales potential.

In addition, strategic decisions regarding the timing for entry into key markets need to be resolved. There are a number of judgments and opinions that need to be considered. For example, early approval in key agricultural markets may be accomplished but if the farmers in those countries are unable to export to the US and EU that will tend to limit initial sales. Thus provisions need to be made for approvals in key importing markets to enable the establishment of import tolerances and minimize non-

tariff trade barriers. Such early approvals have the dual benefit of maximizing global sales early in the product's launch while at the same time enabling the growers to have a broader market access for the crops that they produce.

The OECD work-share process has provided a venue to discuss and plan data development strategies to meet a variety of regulatory stakeholders' needs and to plan coordinated submissions in several countries, for a wide range of uses, at one time. Disharmony of MRL values, lack of accurate information on MRLs in various countries can contribute to as much as 10% loss of sales in certain markets. The work of the OECD Working Group on Pesticides and the Registration Steering Group highlights opportunities for harmonizing approaches to establish "Global MRLs" even where differences in the GAP exist. This is turn can set the stage for early adoption of Codex MRLs, thus facilitating trade between OECD member states and the rest of the world.

Reduction of overall costs

Recent estimates have shown that Crop Protection companies are on average investing more than $200 million on the development of each new active ingredient. The high cost of discovery and product development has lead to some companies abandoning their discovery research efforts. While it is difficult in most cases to envisage product development costs being significantly lowered as a result of work-sharing efforts, there are some areas where there is potential for some cost reduction.

Whereas most areas of a product submission dossier contain core information that is needed by all countries, there are areas where country-specific information is required. For example, laboratory data (*e.g.* toxicology, metabolism, ecotoxicology) required by countries is essentially the same. However, other data such as supervised residue trials and environmental field studies are generally conducted locally in accordance with the local GAP. The recently developed OECD Test Guidelines and Guidance for residue studies provide a basis for harmonization of study requirements and the mutual acceptance of data generated in various parts of the world. The leveraging of residue field data from one region to another based on their similar climatic conditions may result in further cost savings. Industry estimates that cost savings of 40% could be achieved for a major crop use and approximately 20% for a minor crop use. Work is ongoing that may result in similar opportunities in the area of environmental fate, through recognition and acknowledgement of the similarity of soils used to conduct studies in different regions.

The co-ordinating of the preparation of dossiers to meet the requirements of several different countries is a complex and demanding exercise for industry. Internal business processes and procedures must be changed to accommodate this new approach and, as with all new approaches, companies must adapt and adjust to meet the challenge. As companies become more experienced and adept at this way of working, the overall cost and time spent preparing one overall dossier will be less than that spent preparing multiple country dossiers. As yet it has not been possible to estimate the savings that will accrue. To further maximize the value of a "global dossier" of this nature, it will be important to broaden the impact of work-sharing to include non-OECD countries that are major agricultural producers, *e.g.* Brazil, China.

Conclusion

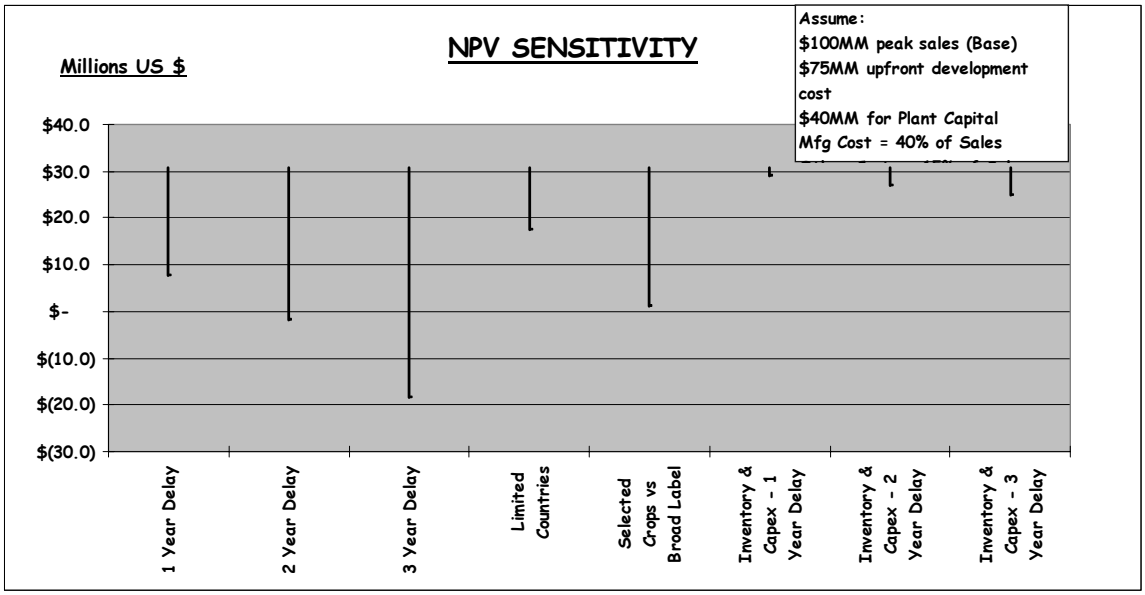
There are a number of factors that can affect the viability of a product development project. Among the most important of those are the following: -

- The time taken for product development and regulatory review and approval.

- The number of crops for which approval is sought in the original submission and the comprehensive nature of the product label.
- The predictability of the approval process and its influence on manufacturing start-up and product launch activities.
- The number of countries in which a product can be approved early in the product life cycle (*i.e.* the greater the market potential, the greater the viability of a product development project).

The degree to which each of these elements impacts upon the value of new venture can be seen in the analysis of Net Present Value and its sensitivity to these factors (Figure 4). It is clear that delays in approval and the breadth of the product label are the most important drivers determining whether a project is successful or not. This is closely followed by the number of countries that can be accessed early in a product launch.

Figure 4 Sensitivity of Net Present Value (NPV) Estimates – delays in registration, development costs, broad label and limited market access



Joint Reviews availing of work-sharing initiatives as championed by OECD and its member countries, because of the detailed nature of the process and planning involved, facilitate consideration of each of these critical elements in an optimal manner, facilitating maximal success in product development opportunities.

The overall financial impact of global work-sharing arrangements will vary depending upon each project's business potential. For a product that is projected to generate upwards of $150 MM in global sales, any significant reduction in the regulatory approval timeline that would result in an extra season or year of patent-protected sales would shorten the payback period on project development costs and positively impact the overall competitiveness of that business project.

The Business Case for Regulatory Authorities

Fewer Resources

Experience has demonstrated that the successful completion of joint reviews of active substances involving work-sharing arrangements with a number of Regulatory Authorities requires considerable management skill and an increased allocation of resources for project co-ordination. The increased investment required, however is more than offset by the savings realised though elimination of evaluative work by specialized experts. On the basis of experience gained and depending on the number of countries involved, it is clear that savings in the range of 33 to 40 %, accrue where joint reviews are undertaken using work-sharing arrangements (Table 2). Savings result from the elimination of duplicate evaluations by specialised experts (*e.g.* toxicologists, residues chemists, ecotoxicologists), but are partly offset by the increased cost of managing and co-ordinating a more complex regulatory system involving a number of Regulatory Agencies. Were 5 Regulatory Authorities to independently prepare Monographs for a particular compound, the cost to the authorities concerned would amount to €1.31 million, while working together the cost would be €0.82 million, giving a saving of some €490,000. If the cost of peer review is included the saving would amount to €1.06 million.

Table 2 Comparison of costs for evaluation of Dossiers, using national and work-sharing arrangements (joint review) for each participating Regulatory Authority [1]

Task	National Review		Joint Review (3 countries)		Joint Review (5 countries)	
	Working Days	**Cost**	**Working days**	**Cost**	**Working days**	**Cost**
Preparation of primary evaluations in monograph format						
Management, co-ordination, editing	36	€29,400	96	€78,400	96	€78,400
Expert evaluative work	285	€232,750	150 [2]	€122,900	105 [2]	€85,750
Peer review of primary evaluations prepared by other participating Authorities and decision-making						
Peer review (regulatory and expert work)	300 [3]	€245,000	160	*€130,670*	160	*€130,670*
Decision-making	30	€24,500	30	€24,500	30	€24,500
Total	**651**	**€531,650**	**436**	**€356,070**	**391**	**€319,320**
Saving			**≈ 33 %**		**≈ 40 %**	

1 source Pesticide Control Service, Department of Agriculture and Food, Ireland, January 2007. With further experience in conducting joint reviews it will be possible to refine (and differentiate) the estimated savings where 3 and 5 partners are involved.

2 the estimates reflect the need to evaluate geographically based data (*e.g.* residues and other field data) for sections of the Dossier for which another Regulatory Authority has primary responsibility for compiling the primary review

3 reflecting the time required for steering a Monograph through the EU peer review process – costs for regions other than the EU may vary

While it might be argued that three Regulatory Authorities are the optimum number to undertake a joint review using work-sharing arrangements, the involvement of a greater number of Regulatory Authorities in the peer review stages of a joint review can ensure the global relevance and acceptability of the Monograph produced.

Sounder Scientific Conclusions

The quality of Monographs produced, through the joint review of Dossiers by a number of Regulatory Authorities using work-sharing arrangements, can be assured through the peer review of the evaluations prepared by all of the Regulatory Authorities participating in the review. The active involvement of experts available to a number of Regulatory Authorities ensures a global scientific perspective and delivers more robust risk assessments to serve as a basis for decision-making. Divergences in interpretation that may be encountered can be properly explained and be placed in context, facilitating greater public confidence in the regulatory systems in place.

The Business Case for Citizens

Public and Environmental benefits

The joint evaluation of dossiers by the regulatory authorities of more than one country facilitates a more efficient and cost effective regulatory process. Duplication of evaluative work is avoided. As experts from several countries peer review evaluations completed, the public can have greater confidence in the scientific conclusions used as the basis for regulatory decisions.

The joint evaluation of Dossiers for agricultural pesticides s should make it possible for the more harmful pesticides to be withdrawn from the global market and replaced by less harmful ones more rapidly than if each country were to conduct the necessary evaluative work independently.

Concluding Remarks

It was recognized by the Working Group on Pesticides during its 21st Meeting in June 2007, that with the benefit of further experience in conducting joint reviews, it will be possible to further elaborate the benefits that accrue for all stakeholders, including those for farmers and growers. It will also be possible with further experience to refine the costing contained in the paper. Accordingly this paper will be reviewed and updated periodically.