



Canadian Fertilizer
Products Forum

Forum Canadien sur
les produits fertilisants



WORKING GROUP REPORT ON

REGULATORY EFFICIENCY



Prepared for the
Canadian Fertilizer
Products Forum





THE CANADIAN FERTILIZER PRODUCTS FORUM

The Canadian Fertilizer Products Forum (CFPF) was launched in the fall of 2006 to provide a forum for stakeholder input into the regulatory process for fertilizers and supplements. The CFPF brings together producer groups, industry representatives, non-governmental organizations and regulatory officials from across the country to provide recommendations to improve the regulatory system.

The CFPF recognizes that fertilizers and supplements are the most important crop input. Agricultural producers in Canada spend about \$3 billion on fertilizers and supplements per year, more than on pesticides, seeds, fuel, or any other crop inputs.

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Agriculture and Agri-Food Canada (AAFC) is pleased to participate in this project. AAFC is committed to working with industry partners to increase public awareness of the importance of the agriculture and agri-food industry to Canada. Opinions expressed in this document are those of the Canadian Fertilizer Products Forum and not necessarily those of AAFC.



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HIGHLIGHTS

- ☀ The Regulator Efficiency Working Group (REWG) is an open and accessible forum for fertilizer producers, regulators and (research and environmental) stakeholders operating within the Canadian marketplace and under Canadian regulations. REWG was commissioned by the Canadian Fertilizer Products Forum.
- ☀ During 2007, the full REWG met seven times by teleconference to consider issues of importance to its membership. To complete the work plan that the REWG had developed during the Canadian Fertilizer Products Forum (CFPF) conference in 2006, task teams were formed and met three times.
- ☀ REWG has been very successful at engaging the Canadian Food Inspection Agency (CFIA) in order to influence refinements to the fertilizer regulatory framework in a way that reduces operating costs to producers while maintaining the overall goals of the regulations. In particular, REWG has worked with the CFIA to:
 - streamline processes for novel supplement (fertilizers and inoculants) research approvals, in particular, provided suggestions and feedback on the application system, categorization of research authorizations, service delivery standards and map requirements
 - provide input on the requirements for a research application tracking system in order to monitor that progress of the different steps in the approval process to provide additional information in a timely if and when required and to ensure all the proper approvals are received in time for planting season,
 - identify the need for awareness and skills-based training for the development of research applications, and
 - develop a set of appropriate service standards that would achieve regulatory objectives and at the same time not negatively impact industry operations.



DESCRIPTION OF CONSULTATION PROCESS

Three approaches for consultation amongst stakeholders have been employed regularly:

- ☀ During the November forum Working Group members meet face-to-face to identify issues, develop and then execute a work plan. The work plan was developed by first of all ensuring a common definition of the REWG scope of practice and then brainstorming the range of regulatory efficiency issues facing the industry. Once members were satisfied that all the issues had been identified they were detailed so that there was a common understanding of the scope and elements of each issue. Then the issues were prioritized using a voting method. REWG members who are CFIA employees did not vote. The issues, listed below in priority, became the framework for the REWG annual work plan:

- Review efficacy data requirements
- Process for tracking status of applications
- Baseline study of economic impacts of current regulatory framework
- Events / training on regulation
- Develop standards for acceptability of industry research
- Improve consistency (national) of CFIA responses
- DACO Table – submission requirements
- Non-traditional products / combinations
- Conditional registration, similar to Pest Management Regulatory Agency (PMRA)
- 24% NPK rule review

These issues were used to guide the efforts of the REWG and were also included in the CFPPF strategic plan.

- ☀ Monthly meetings of the full Working Group were the major events to move the work plan forward. During these events actions were decided and responsibilities allocated or task teams struck. Meetings were held during the third Wednesday of each month. Agenda items were invited to be sent to the chairperson and facilitator by the first Monday of the month (see item “f”, below), the agenda was then finalized and distributed to members on the second Friday of each month. Where there were no agenda items brought forward the meeting was cancelled. Between January 2007 and October 2007 there were seven meetings of the full REWG and three task team meetings.

Meetings followed a standard agenda:

- Call to order and roll call
- Approval of meeting agenda
- Review of previous meeting minutes
- Status review of work plan items and required follow-up actions
- Overview of the preceding CFPPF Executive meeting
- Issues or items of interest to REWG
- Information items for Executive

Draft meeting minutes were provided to the Chairperson for review within three business days (typically) of the meeting. These were reviewed and any revisions incorporated, and then forwarded to the REWG for review and commentary within five business days.



- ☀ Where detailed follow-up research and discussion is required a task team was struck, consisting of the most impacted members to research an issue. Membership of the task teams was ad hoc in nature, based upon members' assessment of if, and how the issue under consideration affects their organization. Task teams were struck to look at the first two items of the REWG work plan.

REWG and its task teams made a commitment to work by consensus as much as possible and this goal was generally met to develop options and recommendations.

Recommendations were developed in two ways:

- the full REWG would provide input and advice during the monthly teleconference and follow-up e-mail circulations to the group, after which the facilitator would craft a proposed recommendation to the CFPF Executive for review by the Chairperson and the full REWG. After the review, recommendations were forwarded to CFPF for their review and submission to the Regulator, or
- a task team of REWG members was mandated to develop recommendations to address a specific issue. Once developed, these recommendations were circulated to the REWG, feedback received, revised and forwarded to the CFPF Executive by the REWG Chairperson, Peter McCann. These recommendations were then provided to the Regulator from the Executive.



ISSUES CONSIDERED

During the period November 2006 to October 2007 the REWG considered the following issues:

- ☀ The first issue that the REWG tackled was a review of efficacy data requirements. A task team was struck to deal with this issue, but during the very first meeting of the task team it became clear that the efficacy data issue was both broad and deep, and that it would not be resolved quickly. The task team chairperson therefore recommended that the task team be elevated to full working group status and be granted the same operating authorities and resources as other working groups. This was confirmed and the Efficacy Working Group was established by December 2007.

- ☀ Development of new fertilizer and inoculants is the life blood of the industry. Being able to meet the challenges of modern farming, gardening and horticulture operations in a timely way is the cornerstone of innovation and competitiveness in a global marketplace. The second priority on the REWG work plan was, therefore, to address the need for a research application tracking system to be employed by CFIA. This need arose from the frustration created by the uncertainty of obtaining research approval for new products and formulations in time for the upcoming planting season. Throughout the process, applicants were unaware of the status of their application and did not know what, if anything could be doing to move the process along. When REWG approached the Regulator on this issue, CFIA asked that the Working Group help to address the bigger issue; the overall structure of the research application / approval process.

The process by which new products and formulation are tested in the field is governed by Trade Memorandum T4-103. The memorandum lays out all of the processes for application, approval, transportation, requirements to ensure safe handling and post-research destruction of test crops. In November of 2006 CFIA agreed to a comprehensive review and revision of this document as part of their Strategic Action Plan.

The REWG was able to work with the Regulator during the winter and spring of 2007 to provide recommendations on all aspects of T4-103 and then again during the fall of 2008 to conduct a follow-up assessment on the results achieved. Important progress on this issue was made during discussions with the Regulator at regular monthly meetings; however, REWG also formed a task team that met with the Regulator three times, to deal specifically with this issue. Recommendations developed by the task team were made to the Regulator through CFPF Executive, as outlined in “Recommendations”, below.

- ☀ The Working Group’s third priority was to baseline the economic impacts of the current regulatory framework. REWG membership includes an economist at the George Morris Centre in Guelph. During discussions on this issue, the George Morris Centre identified a research proposal that it was preparing, which included an economic impacts component. The working group provided thoughts and insights into the research during working group conference calls. In addition, several members of the working group provided a list of potential interviewees for participation in the Centre’s research. A final version of the study will be released shortly to the study sponsors (CFIA).



- ☀ The fourth element in the work plan was training for industry staff in order to operate effectively and efficiently within a complex and changing regulatory environment. To this end REWG discussed and developed a proposal (see “Recommendations” below) to CFIA (through CFPF Executive) for on-going, “for cost” training delivered by the CFIA staff that would help regulatees understand the complex regulatory framework and to operate more effectively within that framework.

 - ☀ The four items listed above represent about half of the priorities measured during the votes cast at the November 2006 Forum planning session. Other items on the work plan were displaced by new and more pressing issues. These include:
 - The Micronutrient Fertilizer Association of Canada (MFAC) is a member of the REWG. Many MFAC members are also members of the CFPF within the REWG and in other working groups. On behalf of its membership this association is dealing with the regulatory and research requirements to certify the safety of heavy metals and guaranteed nutrient testing. The MFAC approached REWG to comment on a position paper they had drafted and were intending to submit to CFIA, proposing amendments to the testing requirements.

 - CFIA approached the REWG to comment upon and provide input to a set of draft service standards that were under development at the Agency. The service standard document basically outlines the nature of the working relationship between the Regulator and Regulatees and is a commitment on behalf of the Regulator to meet certain standards relating to the administration and enforcement of the Fertilizer Act. REWG members provided comments formally as part of a recommendation submitted to CFIA by the CFPF Executive, as outlined in “Recommendations” below.

 - The REWG was asked by CFIA to comment upon their work plan for modernization of the regulatory framework supporting the enforcement and administration of the Fertilizer Act, as outlined in the Plant Production Division’s Strategic Action Plan (SAP). Comments were provided directly to CFIA through their senior representative on REWG.

 - The REWG is currently working on a “re-registration” initiative that was referred to them from the Efficacy Working Group. The focus of the issue is to streamline re-registration of currently registered products and their labels. The Fertilizer Act stipulates that an application for previously registered products must be submitted to CFIA for review and re-registration at two-year intervals. This helps to assure the Regulator that no changes in formulation have been undertaken since the initial approval. The REWG does not contend the requirement, however, re-registrations are “batched” for review and approval along with new registrations. Since new registrations take considerable longer to review this is causing long delays for re-registration.
- All approvals are dealt with on a “first-come-first-served basis” and no additional resources are previewed by CFIA to deal with the backlog of both new and re-registrations. CFIA is, therefore, seeking to engage the Regulatee community to help resolve this issue and ultimately streamline the registration process.



RECOMMENDATIONS / OPTIONS PUT FORWARD

The REWG was able to work by full consensus during the previous year. Below are listed a number of recommendations developed by the REWG:

To CFIA through the CFPF Executive

- ☀ Incomplete or improperly completed application forms are problematic for both the Regulator and Regulatees. This slows the review and approval process and consumes government and industry unnecessarily. In order to ensure timely and thorough reviews the industry believed that an on-going, “for cost” training program, offered by the Regulator would be mutually beneficial. REWG provided a recommendation to CFIA to conduct training on submission preparation including research authorization applications.
- ☀ Regarding proposed changes to Trade Memorandum T4-103 (research application, review and approval process), the Regulatory Efficiency Working Group proposed that the CFPF Executive recommend to CFIA the following amendments:
 - That CFIA adopt a 90 day service standard for application results.
 - That field trial maps be submitted no later than 21 days after planting.
 - CFPF acknowledges that a 14 day submission period would be ideal and proponents should be encouraged to fax, mail or e-mail maps to CFIA within that period.
 - Where the 21day deadline can not be achieved, the proponent will contact CFIA prior to the 21 day deadline to request an extension.
 - A centralized process (such as a 1-800 fax line) for submitting trial maps would assist researchers in meeting their deadlines.
 - That the use of GPS technology to locate the corner points of field trial plots be phased in over a three year period by allowing the continued use of the existing process during that time.
 - The revised application form should include, as an attachment, detailed instructions and examples for locating trail plot corner (markers in some cases) using both the traditional and GPS-assisted methods.
- ☀ In their Strategic Action Plan for regulatory streamlining the Regulator developed a series of initiatives that are aimed at reducing time delays and associated costs. One such initiative is to develop a “service standard” which outlines the working relationship between companies in the industry and CFIA.



- ☀ Consensus comments on the CFIA proposed service standard in the following areas:
 - Premature timing to release Appendices A and B
 - Timeline commitments are too loose
 - Clearing the backlog of submissions as part of standard implementation
 - The need to commit to process streamlining
 - The need for full consultation and impact assessment on the final wording of the eventual Trade memorandum on Service Standards
 - Removal of the “full staffing” condition for the standards to be applied

- ☀ During the face-to-face REWG meeting, at the November 2006 conference, an item on the agenda was devoted to open and frank discussions with the Regulator. During this session the CFIA staff presented and responded to questions regarding their Strategic Action Plan. The theme of the session was for the industry to provide feedback to the Regulator on areas where they felt administrative requirements were overly burdensome and could be improved without diminishing the intent of the regulation. CFIA officials received this verbal feedback and eventually made adjustments to the priority and timeline of the research application and service standard items within their SAP.

To Other Members of the REWG

- ☀ To the George Morris Centre, on how to assess the economic impact of regulation on the fertilizer industry.

- ☀ To the MFAC, on how to best streamline the testing and certification requirements for heavy metals.

- ☀ To Milorgante, on how to approach the Regulator to institute a review and revise the upper limits of iron content in sewage sludge once it has been processed (the addition of ferric chloride removes phosphorus, but may result in residual iron that is difficult to quantify) into fertilizer products.



RESULTS ACHIEVED

Efficacy Data Requirements

The initial work of the REWG resulted in the establishment of a task team to deal with this issue. The task team was elevated to full working group status in December 2006. Please see the Efficacy Working Group for results achieved in this area.

Trade Memorandum T3-104

Ultimately the work of the REWG resulted directly in amendments to the application system, categorization of research authorizations, the service delivery standards and mapping requirements. In an informal survey of REWG members, during the October teleconference, members cited T4-103 as one of their biggest achievements over the year.

Economic Impacts of Regulation

REWG unsuccessfully petitioned CFIA to increase funding to the George Morris Centre study on regulatory impacts. Upon the encouragement of the REWG the Centre did, however, include additional interviews from the micronutrient and inoculants industries and were able to include this information within the scope of their study. The study has been forwarded to CFIA for review and it is anticipated that it will be released to the CFPF just prior to the November 2007 Forum.

Regulatory Framework Training and Awareness

CFIA agreed in principle that “for cost” comprehensive regulatory training would be an appropriate measure however the Regulator believes that development of a comprehensive package of training products can only be developed once all elements of the framework have been reviewed and updated, as outlined in the CFIA Strategic Action Plan. Based upon the REWG recommendation and encouragement the Regulator will host an event in Ottawa the day after the November Forum, called a Mid-Year Workshop on the Fertilizer Program Modernization. The event consists of two half-day sessions. The first session is a progress update and discussion session to seek stakeholder input on alternative delivery models. The afternoon session is a training session on research authorizations and the new T-4-103 process.

Formal recommendation on the top four REWG priorities were presented to the Regulator and concrete results were achieved which has streamlined the regulatory framework while preserving, and in the case of T4-103 enhancing, the objectives of the *Fertilizer Act*.



CONCLUSION / PATH FORWARD

The most pressing REWG issues identified during the November 2006 Forum have been addressed and resolved to the satisfaction of the REWG members and the Regulator. A new list of issues and residual concerns from the 2006 work plan remain to be dealt with, as outlined above.

The working group membership is strong and active. Working on a consensus basis has not been challenging to date and the participation and contributions of the Regulator members is highly valued by all members, both to receive clarification and to register concerns. Direct contact and two-way communication with the Regulator was rated as an important benefit of membership in an informal survey of members during the October conference call. Also rated highly was the on-going contact and exchanges with each other in a neutral and mutually beneficial forum. Members say that they have benefited from regular teleconference meetings, face-to-face meetings at the Forum and as part of issue-based task teams. They also say that discussions to clarify issue, development of actions to resolve problems and receiving timely communications about regulatory developments has been very helpful.

Members of the REWG intend to keep meeting in order to address residual issues on the work plan as well as to take on new challenges, including:

- ☀ the CFIA invitation to involve REWG members in modernization of the registration process, and
- ☀ marketplace monitoring has asked REWG to work with CFIA to help speed up their work relating to review and approval of label review / change progress



APPENDIX – WORK GROUP MEMBERS

Name	Company / Organization	Location
Punita Aneja	EMD Crop BioScience Inc	ON
Jennifer Armour	Fertilizer Safety Office, CFIA	ON
Suzanne Beattie	Agrium Advanced Technologies	ON
Joyce Borkhoff	Ciba Specialty Chemicals	ON
Jereleen Brydon	Micronutrient Fert. Assoc. of Canada	ON
John Burcombe	Mouvement au Courant	QC
Piran Cargeeg	Becker Underwood	SK
Chunquan Chen	EMD Crop BioScience Inc	ON
Achille Correggia	Agrium Advanced Technologies	ON
Kelly Devaere	MGS Horticultural Inc	ON
(Bob) R.J. Evans		SK
Allison Gallinger	Becker Underwood	SK
Rachel Geddy	CFIA	ON
Jennifer Hale	Plant Product Co.	ON
George Kanellos	Agrovchem	ON
Rigas Karamanos	Westco Alliance	AB
Irene Karas	Aquatrols	NJ
Warren Libby	EMD Crop BioScience Inc	WI
Peter MacIntosh	EMD Crop BioScience	WI
Ewa Madey	CFIA	ON
Javier Maldonado	CFIA	ON
Peter McCann	Brighton BioConsulting	ON
Haley McKinnon	CFIA Efficacy Evaluator,	ON
Kevin Moran	Yara Phosyn	UK
Peter Moutoglis	Premier Tech	QC
Louise Nelson	University of B C (Okanagan)	BC
Anthony Parker	CFIA	ON
Ginette Rambie	Ciba Specialty Chemicals	ON
Maureen Reilly	Sludge Watch	ON
Geneviève Roy	Premier Tech Biotechnologies	QC
Beth Sparling	George Morris Centre	ON
Tom Staples	Mosaic Company	MN
Dean Thome	Philom Bios Inc	SK
Jessica Walsh	Cantox Health Science Int.	ON