Canadian Fertilizer Products Forum | Forum Canadien sur les produits fertilisants

WORKING GROUP REPORT ON

EFFICACY TASK FORCE

Prepared for the

Canadian Fertilizer Products Forum

Canadian Fertilizer Products Forum

Forum canadien sur les produits fertilisants

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.

ACKNOWLEDGEMENTS

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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 inputs industry and farm groups alike have identified a need to increase access to new fertilizer and supplement products. During meetings of the Canadian Fertilizer Products Forum (CFPF), it has been noted that Canada is falling behind in new technology that offers environmental and productivity benefits. Existing efficacy rules are seen as the primary impediment to national competitiveness in this area.

Within the Forum, discussions have not resolved the value and desirability of having regulatory requirements for efficacy. However, there was unanimity on the need to improve the existing regulations, procedures and methods used to review fertilizer, fertilizer products and supplements. To tackle these questions, a special Efficacy Task Force was established. The mandate of this Task Force was not to resolve the need for efficacy testing on any specific product or group of products. Rather, the Task Force was asked to provide recommendations on how to more efficiently conduct efficacy testing for any products that require the submission of efficacy data as prescribed under the Fertilizers Act and Regulations.

The Task Force has not included recommendations on which products should be regulated for efficacy; however, it does provide specific suggestions on better micronutrient regulations as this has been a particularly problematic area.

- Recommendations include:
- Triggering Efficacy
- Number of Trials and Standards of Significance
- Requirements for Greenhouse or Growth Chamber Data for Fertilizer Registrations
- Efficacy guidelines for registering micronutrients in Canada. These are the only product-specific recommendations.

DESCRIPTION OF CONSULTATION PROCESS

Initially, a New Products Working Group (NPWG) was created and began working on its mandate. However, at the CFPF Forum in November 2006, issues concerning efficacy testing were brought to the forefront and the work of the NPWG was suspended in favor of the Efficacy Task Force. Membership to the Task Force was extended to all participants in the CFPF but more broadly to any stakeholders affected by the Fertilizers Act and Regulations.

The Task Force was chaired by Dean Thome of Philom Bios. Meetings were held via conference calls approximately once a month beginning in February 2007. Members volunteered to draft technical papers on the issues noted in Section A above. Drafts of all recommendations were presented to the Task Force and decisions made by consensus. The results are detailed, specific recommendations on ways to improve the regulation of efficacy.

The list of members is contained in Appendix A.

Meeting Dates

- September 7, 2007
- July 25, 2007
- June 27, 2007
- May 17, 2007
- April 24, 2007
- March 15, 2007
- February 8, 2007

ISSUES CONSIDERED BY WORK GROUP

1. **What triggers efficacy** – The group expressed concern that full efficacy testing is required even for minor formulation changes. It reviewed what triggers efficacy requirements such as reformulations, altered carriers, altered use patterns, etc. Recommendations are noted in Section D below.

2. **Acceptance of private data** – A draft document was developed and discussed by the group. The document is contained in Appendix B. The group concurred that scientifically sound data is welcome from many sources and elements of this discussion were incorporated into subsequent recommendations.

3. **Acceptance of international data** – See Appendix B for the draft document noted above. The discussions and points noted within this document were incorporated into other formal recommendations.

4. **Schedule II** – The Forum and Task Force both explored the role of Schedule II in exempting some products from efficacy testing. The Canadian Food Inspection Agency (CFIA) clarified that Schedule II does not necessarily mean a company is exempt from providing efficacy data, and gave a summary of what Schedule II actually encompassed. The group decided not to pursue this matter.

5. **Standards of significance** – See recommendations that follow.

6. **Greenhouse trials** – See recommendations that follow.

7. **Micronutrients position paper** – See recommendations that follow.

8. **Tax Credit Policies** – Companies wanted to know what portion of work and testing is subject to the tax credit for research and development. A summary of the criteria for investment tax credits is available on-line, and rules were discussed.

RECOMMENDATIONS MADE BY WORK GROUP

Triggering Efficacy

To avoid redundant testing, it is recommended that full efficacy data only be required when there is a new active ingredient, a major new claim for an active, or a combination of fertilizer with a pest control product. Bridging data requirements would be required for changes in formulations. These rules would apply only to those product categories subject to efficacy testing.

Definition of Terms

- **Full efficacy data** refers to a maximum of 2 years of field data conducted to the newly agreed standards.
- **Bridging data** refers to a maximum of 1 year of field data conducted to the newly agreed standards and/or lab data for certain quantitative changes such as compatibility and shelf life.

Proposals

1. A new active will require full efficacy data.
2. A novel activity claim will require full efficacy data.
3. An extended label claim for a registered product (e.g. extension of use to a new crop, new application rate, new application methods, use with a registration exempt product to extend a label claim, changes to expiration date/shelf life), will require bridging data.
4. A new formulation for a registered active or a slightly different active (for example, a new strain for a registered carrier) will require bridging data for the same use pattern, demonstrating the same statistical benefit as the positive control.
5. A minor re-formulation for a registered active will require bridging data.
6. Formulation/selling two or more *Fertilizers Ac*t registered products as a single product will require bridging data.
7. Formulation/selling a *Fertilizers Act* registered product with a *Pest Control Products Act* (*PCPA*) registered product as a single product will require full efficacy data to satisfy both the Canadian Food Inspection Agency (CFIA) and Pest Management Regulatory Agency (PMRA).

Number of Trials and Standards of Significance

The CFPF Efficacy Task Force recommends that:

1. For a National Registration, a registrant needs 3 field trials per year per region for two years, for a total of twelve (12) efficacy trials. This number can be reduced to as few as eight trials in total where the majority of the crop is grown in one region and only a small percentage is grown in the second region. Please see Recommendation #4 below.

    - **Rationale**: PMRA requires only 3 trials in total for insecticides and fungicides (DIR 2003-04). In addition, the CFIA has already been seriously considering a similar change.

    - **Currently**: CFIA requires 4 field trials per region over two years, for a total of sixteen (16).

2. Of the twelve required trials, a maximum of 50% can be from a non-Canadian source provided the climatic conditions are similar.

    - **Rationale**: CFIA has indicated verbally (Guelph conference) it would be comfortable with the use of up to 100% foreign data, if the conditions are similar enough.

    - **Currently***:* Officially, no USA data is allowed but under some circumstances a small amount can be used to support a registration. Data from countries other than USA is rarely allowed.

3. To expedite the process, companies could elect to complete 8 trials in one year instead of 6 over two years (per region). Again 50% can be from a non-Canadian source.

    - **Rationale**: If the two year requirement is to try to gain experience under a number of growing conditions, then more trials in one year, if placed in geographically distinct areas, could achieve similar results. Also, placing trials over two years but with the same researcher does not guarantee a good level of diversity, especially if the researcher uses a single research farm. The onus would be on the registrant to substantiate that a good level of cropping diversity was achieved with the eight trials done in one year.

    - **Currently**: Registration required efficacy data generated over two years.

4. Where >85% of the crop area is in one region (e.g. corn in E. Canada), only two trials in one year are required in the smaller region to expand the registration into that secondary region. USA data can be used for up to 100% of the data for this secondary region. However, 60% of the trials must still be statistically significant. Therefore, if the trials for the smaller, secondary region were submitted at a different time than the trials for the primary region, then both trials would need to be statistically significant. If the trials for both the primary and secondary region were submitted at the same time, then the 60% statistical rule would apply to the total number of trials submitted.

    - **Rationale**: Companies will not be able to financially justify placing 4 trials per year for two years into regions where there is only a small area of the target crop. As such, farmer in these areas will be at a disadvantage.

- **Currently***:* Officially, a national registration requires the generation of 4 applicable data points in each of the two regions, regardless of the size of the crop area in each region.

5. Label claims must be supported by scientific data that has been statistically analyzed and is statistically significant at the 90% confidence level.

    - **Rationale**: Previously agreed to.
    - **Currently***:* 95%.

6. For a major label claim (e.g. increased yield), 60% of the trials in total should be statistically significant at the 90% confidence level. Alternatively, multi-location analysis can be used to group sites but a 90% level of significance is still required.

    - **Rationale**: Framers are already accustomed to having access to products where the benefit is demonstrated at a statistical level at least 60% of the time. It was widely agreed that in some cases it might be better to group sites for analysis rather than treating them individually.
    - **Currently**: 60% of trials per year must be statistically significant.
    - **Currently**: multi-location analysis is not officially accepted.

7. After first supporting the major label claim (e.g. yield), registrants can make secondary or soft claims, if 50% of the trials are statistically significant for that secondary claim. The label language would need to reflect the softer claim. (e.g. “has been shown to help promote increased plant vigour”). Registrations will not be granted on soft claims alone. Only after major claims have been proven with the normal statistical data can soft claims with reduced data requirements be added to the label.

    - **Rationale**: Farmers may be willing to pay for some of the softer benefits from technologies but any such claims need to be clear so that expectations are reasonable. The PMRA uses a similar system whereby “control” refers to >80% control and ‘suppression” refers to 60%-80%. Often pesticide labels have a list of controlled pests and a second list of suppressed pests.
    - **Currently**: there is no special provision for secondary “soft” claims. All label claims currently require support from eight statistically significant field trials over two years and 60% of all trials completed must be statistically significant at the 95% level.

Requirements for Greenhouse or Growth Chamber Data for Fertilizer or Supplement Registrations

1. All work must be randomized and replicated in a statistically valid format.

2. Environmental conditions must be recorded. Range of environmental conditions must be within those that are typically seen in Canadian crop growing areas.

3. Lighting should be supplied through the use of lighting systems typically used in growth chambers (e.g. fluorescent “grow lights”).

4. Planting media, where soil type is relevant, should include a soil media that is applicable. For soil-applied products seeking registration, the soil medium may not be soil-less or hydroponic unless the registrant is seeking a registration for soil-less or hydroponic uses. (See supplement details below.)

5. For soil applications, the product must be tested on a minimum of two soil types.

6. For foliar applications, the product must be applied using delivery technology that reasonably matches the technology that is to be used in the labeled use pattern (i.e. through sprayer nozzles if applied through farm sprayer).

7. All conclusions should refer to relative differences to an untreated control. Reference to a currently registered product may also be included in addition to the untreated control. Data should be evaluated using a significance level of 10%.

Specific Supplement Growth Chamber Recommendations:

1. Depending on the nature of the experiment, data collected to substantiate claims can include, but not necessarily be limited to:

    a. Above ground biomass (shoot dry weight)
    b. Root biomass (root dry weight)
    c. Nutrient content of shoots (N or P)

2. Applications rates should be comparable to the commercial rates noted on the proposed label. Seed applications of biological material should be recorded as cfu or viable cells/seed.

Growth chamber data is meant to supplement field data, not replace the need for replicated field trials. Since environmental conditions can be variable, field testing sometimes results in statistically non-significant data. In these cases, it would be appropriate to supplement this data with growth chamber results.

We would recommend that growth chamber results could be used to supplement the required field data. At most, two sites of field data could be supplemented with growth chamber data (assuming two different soil types have been used) in order to be granted registration under the *Fertilizers Act*.

Recommendations for Efficacy Guidelines for Registering Micronutrients

The particular needs of the micronutrients sector were also reviewed by the Task Force, which endorsed proposals flowing from the Micronutrient Fertilizer Association of Canada.

Executive summary

- Requirement for 6 station years of data for all products, with the potential to perform some of these trials in growth chambers and some of the trials outside of Canada.

- Requirement for 4 out of 6 trials to show that the proposed treatment performs better than an untreated check.

There is a need to develop a system of reviewing data that will allow reviewers to handle workloads and make registrations in a predictable, expeditious fashion. By accomplishing this, registrants can formulate business plans and realistically manage the entry of products into the Canadian market.

There is a need to make sure that the registration system does not disincentivize innovation by slowing down new technology to a point where there is no longer a business case to develop new products in Canada.

There is a need to treat incumbent micronutrient products that were registered in Canada in past years, and new products that are making their way through the registration system now, with an even-handed regulatory approach.

The key elements for this strategy are twofold. Firstly, we must leverage the fact that simple micronutrient nutrition, micronutrient behaviour in soils, and behaviour in plants is not a new science but rather is well known in the literature. Given this, there is an opportunity for an approach that will ensure efficiency and clarity in the system. The proposed way forward in this regard is to require companies to use a formulaic approach to trailing requirements and to require CFIA reviewers to adhere to predictable service guidelines.

Rules for submissions

1.1 There must be 6 station years of data submitted. It is up to the registrant as to whether the station years are structured so that all trials are performed in one year or in multiple years. There are no requirements to spread these trials over political boundaries or regions. More than one soil type must be represented in the data package. The aim of the trials will be to demonstrate that the product delivers the benefit that the registrant will be claiming. Methodology could include tissue testing, yield testing, analysis or tracking of products in plants or soils, with specific methods including stabilized isotope nutrients.

1.2 The six station years may take the form of (a) growth chamber trialing, (b) trials performed in any OECD country, with 50 percent of trials to be done in fields in Canada. Growth chamber environment may be any temperature, humidity regime at which crops grow, and growing media may be any soil type found in Canada or materially similar to any soil in Canada. The registrant may use any crop as long as the Genus and species is grown in Canada. For non-Canadian trialing, registrants must ensure that the trial was conducted on soil types/crops that are similar to Canadian soil types and ensure that the crop used in the trial is of the same genus and species as any crop grown in Canada.

1.3 The 6 trials must be designed in such a way that randomization and replication are essential elements. Within this framework, any standard statistical test and post test means separation may be used (e.g. t-test, RCBD, CRD, contrasts). The treatments proposed for registration must be applied in the same use pattern as being proposed for the label (i.e. soil applied for soil applied registration requests, foliar applied for foliar registrations)

1.4 For trials involving single elements, the registrant must satisfy one of the following two requirements

1.4.1 At least 4 of the 6 trials must show that the proposed treatment is better than a check to a pH level of 0.1. The check shall be an appropriate untreated check.

1.5 For trials involving multiple elements, the registrant must satisfy one of the following two requirements

1.5.1 At least 4 of the 6 trials must show that the proposed treatment is better than an untreated check to a soil pH level of 0.1.

1.5.2 Where a soil applied treatment that contains elements that are less available in high pH, and where the product is to be marketed on soils with a pH of more than 7, at least 3 of the 6 trials should be performed on soils with pH>7. Where the registrant has performed 3 or more trials on soils with pH>7 with these products, the registration will apply to soils of all pH ranges regardless of political boundaries in Canada.

1.6 If a registrant wishes to register a treatment on all crops, at least 2 of the 6 must be on dicot crops and at least 2 of the 6 must be on grass crops. If statistical hurdles as noted above are met for both the broadleaf and the grass crop(s) chosen, then the registration will apply to all crops for the use pattern used in the registration package.

AREAS FOR FUTURE CONSIDERATION

Efficacy or No Efficacy – that is the question

- The Forum strongly supports CFIA's role in monitoring safety of products.
- Current regulations in the area of efficacy are creating market barriers for some products to enter the marketplace.
- Requirement for efficacy data is seen as the source of a particular backlog of registration processing and a disincentive for innovation by slowing down new technology to a point where there is no longer a business case to develop new products in Canada's relatively small market.
- The market opportunity in Canada for some products does not really support the expense of extensive field trialing for the purposes of registration.
- There are outstanding questions regarding the need for efficacy data:
  - What types of products require efficacy data, which do not, and why?
  - Is it still possible to provide a scientific rationale (i.e. scientific papers) as evidence of efficacy, rather than data? What are the guidelines for providing a scientific rationale?
  - Do all labels require claims about performance?
- Member opinion is mixed as to whether it is worthwhile to retain efficacy requirements.
  - This should be discussed in the context of specific products (i.e. fertilizers, micronutrients, supplements)

Product Category Decisions

- CFIA should indicate what products are subject to efficacy testing in a manner which is clear, consistent, and understandable. This applies not only to product categories such as micronutrients, macronutrients, inoculants, and supplements, but also products within these categories. For instance, some micronutrients do appear to require efficacy testing and others do not. Although CFIA supplied information to help clarify this point, some Forum members still report issues.

- The recommendations on triggering efficacy are meant to make it easier to identify when efficacy data are needed.

Micronutrients

- It is noted that the Micronutrient Fertilizer Association (MFAC) supports the attempt of the Efficacy Task Force to make the efficacy process understandable and more transparent. However, the Association indicates there is still a lot of room to make the process easier for registrants.

- MFAC has also submitted a specific set of suggestions on the need for efficacy regulations for micronutrients. This document (outlined in Appendix C) has not been discussed or endorsed by the Efficacy Task Force and it provided for informational purposes only.

PATH FORWARD

As previously noted, the work of the New Products Work Group of the Forum was suspended to allow the Efficacy Task Force to focus on efficacy regulations. As the Task Force has completed its work, the New Products Work Group should be reconvened to address questions such as:

- What constitutes a new product
- Environment for innovation
- Support for R&D in fertilizer and supplement products
- Harmonization of new product approvals, especially with OECD countries
- Product Standards

APPENDIX A – WORK GROUP MEMBERS

Membership List

Company	Member
Aquatrols Corporation	Irene Karas
Becker Underwood	Piran Cargeeg
Becker Underwood	Allison Gallinger
Brett Young	Manas Banerjee
CFIA	Anthony Parker
CFIA	Samielle Hynes
CFIA	Kathleen Dickenson
EMD CropBioScience Canada Inc.	Warren Libby
EMD CropBioScience Canada Inc.	Punita Aneja
EMD CropBioScience Canada Inc.	Chunquan Chen
Floratine Ag Solutions	Bill Zimmer
Issues & Insights	Robynne Anderson
Issues & Insights	Kelly Green
Mosiac	Tom Staples
Philom Bios Inc.	Dean Thome (Chair)
Plant Products Co. Ltd.	Jennifer Hale
Premier Tech Biotechnologies	Dominique LeQuéré
Premier Tech Biotechnologies	Geneviève Roy
Quadra Chemicals	Walter Banas
Soil Conservation Council of Canada/Alberta Conservation Tillage Society	Josie Van Lent-Staden
Soil Conservation Council of Canada/Eastern Canada Soil And Water Conservation Centre	Gordon Fairchild
Wolf Trax	Geoff Gyles
Wolf Trax/Micronutrient Fertilizer Association of Canada	Mark Goodwin
Yara Phosyn	Kevin Moran

APPENDIX B – PRIVATE AND INTERNATIONAL DATA

Available International Standards for Efficacy Data to Support New or Novel Fertilizer Product Registration

Introduction

This analysis and the concluding recommendations are based upon information taken primarily from the European Community (EC Fertilizer Directive) but also from India (Fertilizer Control Order) and individual registration requirements for the United States of America (based upon AAPFCO Publications).

Also I have sought assistance and commentaries from appropriate colleagues within Yara Phosyn Ltd (formerly Phosyn plc) and Yara International (formerly Hydro-Agri Fertilizers) who each have long experience in the development, testing and registration of new fertilizer products in international markets.

References as well as names, qualifications, specific responsibilities and experience will be provided if required.

Analysis Overview

Firstly, in the regulations of the countries/regions reviewed it is essential to note that categories and lists already exist which define acceptable fertilizer materials, including micronutrients, which do not require registration, simply because they are not viewed as new or novel fertilizers, or combinations thereof (for instance see: Annex 1 to Regulation EC No 2003/2003; OJ L 304, 21.11.2003).

New or novel fertilizers, or combinations thereof, which contain materials not found or listed in the categories within say Annex 1 of the EC Directive are required to be submitted with a supporting Technical File to the Commission's Working Group on Fertilizers to enable it's evaluation for entry into Annex 1 and eventually designated as an "EC Fertilizer" which can be sold without hindrance anywhere in the Community (see: Guide to the Compilation of a Technical File: 2005/C 250/02*).

*(**Please Note**: The EC Fertilizer Directive was the only source I found that contained written requirements for registration of new or novel fertilizers which is why this is the only source I have referenced in this analysis.)*

Regarding the specific requirement in the EC for efficacy data, this is defined in one of the five sections of information which must be provided in the Technical File: item 3.2.3. Efficacy in 2005/C 250/02*. Although, in my opinion, it is explicit that some quality experimental data and information are required there is no expansion on structure of trials nor the degree of statistical significance required nor whether the trials are conducted under controlled environment (glass-house) or in field conditions, nor the location (region or country) where they are carried out.

The experience of my colleagues in Yara is that all the information available on the new or novel fertilizer product is acceptable for the review, and may include some replicated trials which may show statistical significance, and that generally speaking discretion is widely used in decision-making. It has never been the case that a Working Group has asked that more trials data be supplied, statistically significant or otherwise.

Finally, I emphasise again that the EC Fertilizer Directive was the only regulatory device that I could find that went as far as providing any written guidelines such as those found in the 2005/C 250/02* document.

Recommendations

In order that I can turn this analysis into a proposal for a way forward on efficacy data requirements I feel that I must now make a "leap of faith".

I will draw from the previous section the word "quality" and I believe that his is where the focus should be in trying to identify a solution or at least a good compromise by applying the following rationales:

- The development, testing, manufacturing and distribution as well as the marketing and selling of Yara Phosyn (YP) products are all governed by at least ISO 9001 Quality Assurance Accreditation.

- The Quality Policy Statement (O2A.1); Operating Procedure 04: *Design and Development of Products*; Operating Procedures 08: *Control of Non-Conformances, Audit, Customer Complaints*; amongst others; all place an obligation upon YP with respect to the supply and use of their fertilizer products in every market – and this is clinically and externally audited twice annually.

- Irrespective of the Quality Systems the simple and real fact of the matter is that the businesses are not sustainable in any market if fertilizer products are not efficacious for their intended purposes.

- It is also mandatory on all Business Managers that they must submit an audit on product performance (particularly newly introduced ones) and/or non-conformance with their Monthly Market Reports submitted to Senior Management including the Quality Systems Manager (who coincidentally and appropriately is also the Senior Agronomist at YP).

Therefore my recommendation is that any Manufacturer who submits a new Fertilizer Product for registration is able to demonstrate that they have, or run, an independently audited and accredited Quality Assurance System at, or equivalent to, the ISO 9001 standard.

In this case the submission is much more likely to be supported by quality trials and/or experimental data and information on efficacy for intended purpose which should be, by qualification, assured and reliable.

Replicated trials with some having statistical significance, to say no more than the 5% level, would be preferred. Trials conducted in controlled environmental (glasshouse) conditions and/or field sites from any source or country should be eligible for the efficacy review to allow registration of new or novel fertilizers, or combinations thereof.

I am still a firm believer that farmers everywhere, with the pressures they are under on costs, are quick and ruthless in sorting out the money-spinners from the money-wasters in their inputs, including new fertilizers.

Therefore I further recommend that, by using a quality-assured in-market monitoring of all new or novel fertiliser products which qualify with the above requirements, then they could be given a two year provisional registration from the CFIA and that this may represent a way forward for all the stake-holders concerned – Regulators, Manufacturers and perhaps most important of all Canadian Farmers – it would also involve the latter in the assessment and control of the most appropriate fertilizer products which is a move I believe they would be tuned into right now.

I will be delighted to enlarge upon the observations and recommendations made in this analysis.

Dr Kevin Moran
Director of Technical Services
Yara Phosyn Ltd (formerly Phosyn plc)
Part of Yara International ASA
February 2, 2007

APPENDIX C – MFAC POSITION PAPER

Micronutrient Fertilizer Association of Canada
Position Paper
March 2007

Members of the Micronutrient Fertilizer Association of Canada (MFAC) have adopted the following position on issues relating to the regulatory system for micronutrient fertilizers in Canada:

It is the position of MFAC that:

1. **Efficacy data for micronutrient fertilizers is not necessary as a requirement for registration in Canada.**

    a. Canada is the only jurisdiction that requires efficacy data for micronutrient fertilizers. In effect, this requirement acts as a trade barrier, reducing access to technology and the ability of Canadian farmers to compete.
    b. The registration requirement for efficacy data is not applied consistently across all micronutrient products, and thus creates an unlevel playing field within the industry.
    c. Consistent labeling should be applied and used to better ensure efficacy by directing use only under conditions of deficiency.
    d. MFAC supports the continued emphasis on safety and environmental impact data within the regulatory review process.

2. **Removing the need for efficacy data as a requirement of registration is a policy change, not a legislative change.**

    e. Micronutrients are different from supplements as defined by the Fertilizer Act, and should not be treated similarly regarding regulation, or registration requirements.
    f. MFAC acknowledges that making these regulatory changes will take some time. If necessary, MFAC will provide resources to aid in developing policy change, such as financial support of contract help for a literature review, or providing scientific literature as needed.
    g. Removing the need for efficacy data as a requirement of registration would remove the subjectivity and vagueness of current policy outlined in Trade Memorandum T-4-11, Section 1.6 which states:

> "If applicable, statistically significant efficacy data that supports the claims being made regarding the benefits of the product. (This is rarely required for micronutrient fertilizers; please feel free to contact the Plant Products Division for discussion of the applicability of this item to a specific product."

3. **Timelines for registration application review need to be defined within the regulation.**

    h. MFAC acknowledges that the CFIA Modernization initiative is working to establish delivery standards and applauds and supports this initiative.

4. **Regulatory harmonization with other recognized jurisdictions (Europe, US) should be pursued.**

    i. Acceptance of U.S. and international testing, data and regulatory acceptance should be acknowledged within the Canadian regulatory system.
    j. Standards and protocols should be developed that would lead to the acceptance of company-generated, internal data for regulatory review.

5. **The current practice of requiring four sets of heavy metal and guaranteed nutrient analysis is impractical and should be changed to streamline the process.**

    k. MFAC is willing to work with CFIA to develop more reasonable recommendations.
    l. Acknowledgement of quality manufacturing processes that are in place by individual companies should reduce need for several samples.

6. **The MFAC supports the development of the Canadian Fertilizer Products Forum (a permanent consultative body for the fertilizer sector).**

    m. MFAC will support this body with a representative to communicate and represent concerns of the Canadian micronutrient industry.