Tried and True:

The Case for Reinstituting Efficacy Testing for Non-Fertilizer Supplements

National Farmers Union

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Canada's NFU is a direct-membership national organization. Founded in 1969, and with roots going back more than a century, the NFU represents thousands of Canadian farm families, farm units, and farm workers from coast to coast, and also enjoys the support of many non-farmer Associate Members. The NFU embodies the principle that all farmers share common problems and that all farmers must come together, and work with non-farmer allies, in order to address those problems. Our organization believes that agriculture should be economically, socially, and environmentally sustainable. Food production should lead to enriched soils, clean water, a more beautiful countryside, adequate and stable farm incomes, jobs for non-farmers, thriving rural communities, healthy natural ecosystems, diverse habitats for all species, and Canadian tables arrayed with diverse, delicious, nutritious foods.

The NFU's governance structures are democratic, participatory, and progressive. A farm unit membership gives equal participation rights to all family members over the age of 14

To learn more about the NFU, go to our website: www.nfu.ca. **Please join the NFU, as a farm family or farm unit, as a farm youth member, as a farm worker member, or as a non-farmer Associate Member.** The NFU has a place in our organization for every Canadian concerned about farms, food systems, justice, the environment, and the future.

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Executive Summary[1]

Non-fertilizer supplements ("supplements," hereafter) are products other than fertilizers that, by a wide variety of means and modes of action, improve soil physical condition, aid plant growth, or increase yields. They include biostimulants such as microbial inoculants; humic/fulvic acids; and seaweed extracts; and soil amendments such as biochar, compost tea, manure, and lime. Supplements can offer many benefits, including: direct nutrient contributions; enhanced plant physiological responses to stress; stimulation of plant growth not related to nutrition; disease protection; increased fertilizer use efficiency (and attendant reduced GHG emissions); and alterations to soil physical, chemical, and biological properties.

Many supplements have been used safely and effectively in agriculture for centuries. However, given that supplements can have multiple active ingredients and modes of action, they are best defined based on their claimed benefits to agriculture; it is therefore essential that these claims be tested and the data be made publicly available, so that farmers can make informed choices.

Until 2013, Canada had a science-based, federally regulated system for determining whether non-fertilizer supplements were delivering on their label or marketing claims. To demonstrate the validity of each benefit claimed on a product label, companies were required to conduct replicated field trials across multiple sites and years (including laboratory and greenhouse trials where appropriate). They would then submit their trial and test results to the Canadian Food Inspection Agency (CFIA) for validation and, once granted, their product could be registered for sale in Canada. This system was so highly respected that companies based in other countries used to register their products in Canada, as it would increase their market acceptance abroad to say that it passed Canadian standards of efficacy. The CFIA's efficacy testing requirements for non-fertilizer supplements were not repealed because they were not working; they were repealed by the federal government as part of cuts to CFIA's budget and mandate.

The NFU strongly recommends that Canada's former efficacy testing (ET) regulations be reinstituted.

To facilitate the smooth reintroduction of ET, we further recommend that the number of CFIA Efficacy Evaluators be increased (a total cost of <$1 million per year); and products now on the market be allowed to remain on the market, with existing labelling and claims, for a period of 2 or 3 years, while ET can be conducted; i.e., the reintroduction of ET will not reduce farmers' access to products currently on the market.

Reintroducing ET will be inexpensive for companies. Reputable companies are already conducting their own field trials and lab tests—to assess effectiveness and underpin usage recommendations and label, website, or marketing claims. Moreover, if CFIA processing fees under a renewed ET system are like those of the past, fees will be very low: just a few hundred dollars per claim.

Though costs are low, benefits will be large:

- Farmers will have independent validation and quantification of claimed benefits, enabling them to make cost-benefit decisions and purchase products with confidence;
- Non-performing products will be removed from the marketplace, increasing trust in the entire supplements sector;

1 Note: all information referenced in the Executive Summary is paraphrased from the report's main body; any information requiring references contains citations in the main body.

- Some products will provide alternatives to fertilizers, enabling some farmers to reduce the use of these costly inputs;
- By providing alternatives to fertilizers, supplements will provide competitive options for farmers, potentially helping discipline fertilizer prices, a benefit to even the farmers who choose not to try supplements;
- Products that demonstrate the ability to reduce fertilizer use (or decrease emissions in other ways) could potentially qualify for government subsidies, making them even more affordable to farmers, increasing adoption and sales;
- Increased sales and use could accelerate the development and commercialization of promising *new* supplements and supplement types; and
- A wide range of farmers could gain important new production options, including farmers who want to take a lower-input approach, organic farmers, those seeking more resilience or to regenerate soils, and those who prefer to farm in ways that rely more on biological inputs and less on chemical and industrial ones.

There are many precedents for government-administered and -validated ET around the world: the European Union, the United States, Brazil, and many other major food-producing countries and regions all require scientific testing to justify the claims on supplement labels, websites, or marketing materials. Such jurisdictions have maintained their ET regimes to ensure that their farmers have products they can trust, and Canada should be no exception.

Reinstating Canada's ET systems for non-fertilizer supplements is a crucial step toward fostering a more resilient and sustainable agricultural sector. By restoring the robust system of scientific validation that once distinguished Canadian standards, we can ensure that farmers have access to proven, effective products that genuinely support soil health and plant growth. This approach will not only enhance the credibility of the supplement industry but also facilitate greater adoption of innovative, environmentally friendly alternatives to conventional fertilizers. As a result, Canadian agriculture will benefit from improved nutrient management, reduced emissions, and more competitive pricing, ultimately advancing the country's net-zero goals. Embracing a science-based framework for ET will align Canada with global best practices, providing farmers with the confidence and tools needed to drive sustainable agricultural practices forward.

Introduction

There is growing interest in the use of alternative soil amendments and biostimulants in agriculture. These products cover a wide range of uses, and differ greatly in their abilities to overcome soil constraints and improve plant growth. Referred to collectively as "non-fertilizer supplements" in Canada, such products have the potential to improve plant performance and soil structure and biodiversity, and to reduce costs and emissions associated with synthetic fertilizer use. With the exception of legume inoculants—whose nitrogen-fixing benefits have been well-documented—most supplements are not independently verified in their effectiveness. Moreover, many supplements work differently on different crops and soil types, in different climatic conditions, and when used for multiple years or in combination with other products (e.g., fertilizers or other supplements).[2] It is therefore difficult to identify the appropriate supplements to address local soil conditions with certainty and without introducing risks. This adds up to create a confusing and overwhelming market for farmers to navigate alone, and leaves them vulnerable to advice from companies making unverified claims.

The solution to the problem of untested and unverified claims for supplements is efficacy testing (ET)—for governments to require supplement makers to conduct multi-year, multi-site tests and submit those tests to governments for scrutiny and independent verification and certification of claims on labels, websites, or marketing materials. Canada had just such a system of efficacy testing until 2013, when cuts to the Canadian Food Inspection Agency (CFIA) mandate and budget caused ET to be terminated. Non-fertilizer supplements could provide many environmental, financial, and emissions-reduction benefits to Canadian farmers, but independent scientific testing and government certification is required to ensure that farmers do not pay the price for ineffective supplements.

Supplements, verified by testing, may be able to help reduce fertilizer use and emissions

Agricultural emissions make up about 10% of total Canadian GHG emissions. In spite of emissions-reduction targets and programs, agricultural emissions have continued to rise (Figure 1), mostly driven by an increase in crop-production-related emissions.[3]

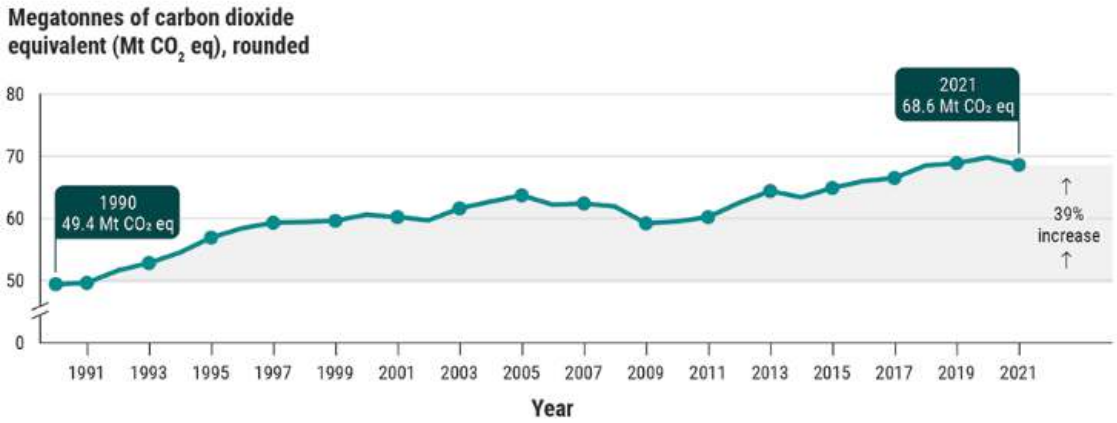


Figure 1: Agriculture sector greenhouse gas emissions in Canada, 1990 to 2021.
Source: Adapted by the Office of the Auditor General (Report 5, 2024) from Canada's National Inventory Report 1990-2021: Greenhouse Gas Sources and Sinks in Canada, ECCC 2023.

2 Abbott, L.K., Macdonald, L.M., Wong, M.T.F. et al. "Potential roles of biological amendments for profitable grain production—A review." *Agriculture, Ecosystems and Environment.* 256, (2018): 41.

3 Office of the Auditor General (OAG), *Report 5—Agriculture and Climate Change Mitigation—Agriculture and Agrifood Canada.* (Government of Canada, 2024). Accessed May 14, 2024. https://www.oag-bvg.gc.ca/internet/English/att__e_44477.html

Synthetic fertilizers have played a crucial role in Canadian agriculture, and it would be difficult to sustain current yields without them. However, the application of nitrogen (N) fertilizer results in nitrous oxide (N_2O) emissions both directly (following application) and indirectly (later and often in distant locations, via leaching and volatilization).[4] N_2O is of particular interest to climate scientists, as it has a warming potential nearly 300 times than that of CO_2 and stays in the atmosphere for more than 100 years. In 2021, the agricultural sector accounted for 75% of Canada's N_2O emissions, primarily from fertilizer use.[5] Figure 2 shows the doubling and redoubling of N fertilizer tonnage.

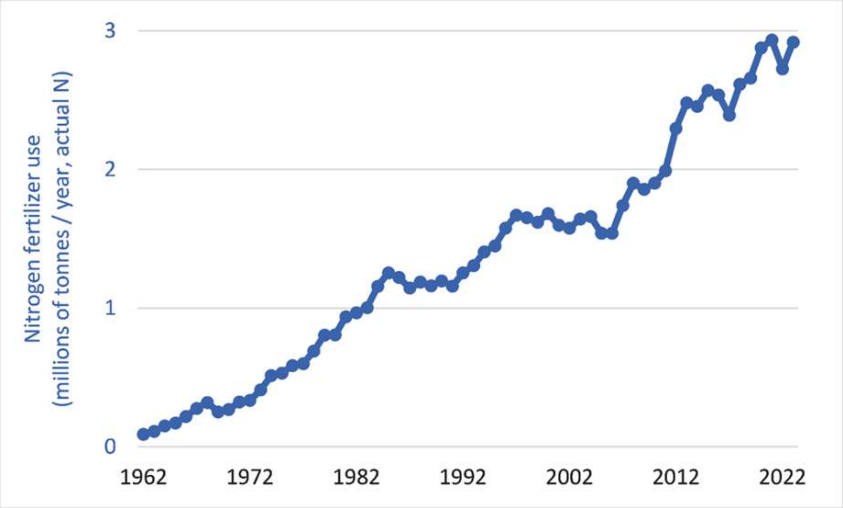


Figure 2: Nitrogen fertilizer use in Canada, 1962 to 2022, measured in millions of tonnes per year of actual N. Sources: Statistics Canada Tables 32-10-0037-01 and 32-10-0274-01; and Korol et al., Canadian Fertilizer Consumption, Shipments and Trade 1997/1998 (AAFC 1999)

As fertilizer use has gone up so, too, has the cost to farmers. In 2023, Canadian farmers spent over $8.9 billion on fertilizer and lime, compared to $5.7 billion in 2015.[6] Increased costs of inputs—including fertilizer, pesticides, fuel, and farm machinery—have eroded farmers' profit margins for decades.[7] A wider array of affordable biological alternatives could slow the rate of increase of N fertilizer application, contributing to reduced crop-related emissions and reduced input expenditures for farmers.

Supplements are defined broadly in Canada, as "products other than fertilizers that improve the physical condition of the soil or aid plant growth or yields."[8] Most supplements can be grouped into one of two categories—soil amendments or biostimulants. Soil amendments are products added to the soil to improve its physical qualities, such as fertility and structure, and include biochar, compost tea, manure, peat, lime, and vermiculite. Biostimulants are a more amorphous category, due to their numerous, sometimes living, ingredients, and many definitions have been suggested. To address this complexity, some scientists have proposed the following definition for biostimulants: "a formulated product of biological origin that improves plant productivity as a consequence of the novel or emergent properties of the complex of constituents and not as a sole consequence of the presence of known essential plant

4 Agriculture and Agri-Food Canada. *Discussion document: Reducing emissions arising from the application of fertilizer in Canada's agricultural sector.* Last modified Oct. 4, 2022. https://agriculture.canada.ca/en/department/transparency/public-opinion-research-consultations/share-ideas-fertilizer-emissions-reduction-target/discussion

5 OAG, *Report 5*, 1-2

6 Statistics Canada. *Table 32-10-00049-01 Farm operating revenue and expenses, annual* [Data table]. (Statistics Canada, 2024). Accessed May 15, 2024. https://www150.statcan.gc.ca/t1/tbl1/en/tv.action?pid=3210013601

7 Qualman, *Tackling the Farm Crisis,* 10.

8 Canada Food Inspection Agency (CFIA), *Fertilizer or supplement registration: Overview*. (Government of Canada, 2023). Last modified October 25, 2023. https://inspection.canada.ca/en/plant-health/fertilizers/overview-0

nutrients, plant growth regulators, or plant protective compounds."[9] Examples of biostimulants include microbial inoculants, humic acids, fulvic acids, amino acids, and seaweed extracts.

Non-fertilizer supplements can offer many benefits in the areas of direct nutrient contributions; plant physiological responses to stress; stimulation of plant growth not related to nutrition; protection against plant disease; and alterations to soil physical, chemical, and biological properties (Figure 3).[10]

In addition, non-fertilizer supplements have the potential to reduce emissions associated with crop production. They can reduce N_2O emissions by replacing or displacing an amount of N fertilizer, like inoculants that help plants fix their own N. Via another mode of action, application of non-fertilizer supplements with N fertilizer can also improve the nutrient use efficiency of soil bacteria and enzymes digesting the fertilizer, thereby potentially reducing associated emissions. Nitrification and urease inhibitors are examples of products in the latter category.[11] Other products, like complexing compounds, claim to increase the amount of plant-available phosphate by preventing it from being immobilized in alkaline soils. This could theoretically lead to reduced P fertilizer usage, but remains inadequately researched.[12]

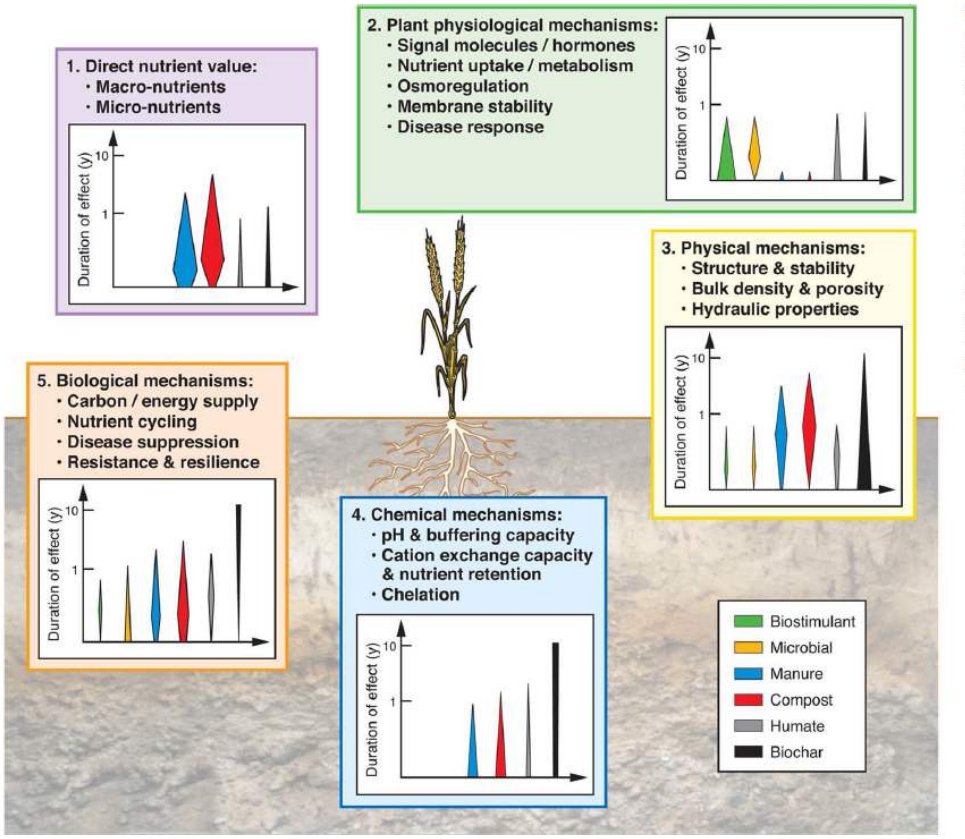


Figure 3: Potential benefits from the application of biological amendments in agriculture.
Note: The width of bars signifies intensity or response and the length indicates duration of response in years (y).
Source: From Abbott et al., 2018.

9 Yakhin, O. I., Lubyanov, A. A., Yakhin, I. A., and Brown, P. H. "Biostimulants in Plant Science: A Global Perspective." *Frontiers in Plant Science*. 7:2049 (2017), 7. https://doi/10.3389/fpls.2016.02049

10 Abbott, "Potential," 35.

11 CFIA. "T-4-127 – Regulation of nitrification and urease inhibitors under the Fertilizers Act and Regulations." Last modified October 26, 2023. https://inspection.canada.ca/en/plant-health/fertilizers/trade-memoranda/t-4-127

12 Degryse, F., Ajiboye, A. Armstrong, R.D., McLaughlin, M.J. "Sequestration of Phosphorus-Binding Cations by Complexing Compounds is not a Viable Mechanism to Increase Phosphorus Efficiency." *Soil Science Society of America Journal*. 77, no. 6. (2013), 2058. Accessed July 5, 2024. https://doi.org/10.2136/sssaj2013.05.0165

Not all supplements replace fertilizers or reduce emissions. Some enhance soil structure, crop health, yield, and/or build up plants' resilience to environmental (abiotic) stress. The Senate's 2024 report on soil health clearly identifies Canada's pressing need to improve soil health and carbon sequestration as a crucial pillar of its climate change and agricultural strategy,[13] and non-fertilizer supplements have a lot to offer in that regard.

Farmers have always been eager and willing to do their part to combat the climate crisis and adopt innovations. Widespread adoption of no-till in the Prairies and of cover-cropping in Ontario are testaments to that.[14] But there is a hurdle complicating farmer adoption of non-fertilizer supplements and that is the all-important question: "Do they work?"

Non-fertilizer supplements: A promising but untested solution

Non-fertilizer supplements have always existed and many, such as manure, compost, peat, and seaweed, were used in agriculture long before the invention of synthetic fertilizers.[15] However, in contrast to most other agricultural inputs, research into their effective use is inconsistent and can be contradictory in its findings.[16] For example, one product containing plant-derived amino acids was found to stimulate plant growth, while another containing amino acids of animal origin depressed plant growth and negatively affected plant iron levels.[17] Further, a review of multiple studies into the effect of humic substances on plant growth found both positive and negative impacts, depending on the source and rate of humic substances applied, along with plant type and growing conditions.[18] As rainfall and temperatures become more inconsistent and extreme due to climate change,[19] any product that aims to stabilize yields will be of great interest to farmers. However, without independent verification that supplements work consistently and beneficially, their adoption will be delayed.[20]

Certain biostimulants have also been found to enhance plant root growth, nutrient uptake, and stress tolerance. For instance, scientists in Italy determined that chitosan—a natural compound that can be applied to crop plants via foliar spray—can protect bean plants against pathogen attacks and reduce stomatal opening and transpiration within 24 hours of treatment, thus improving plants' responses to abiotic stress.[21] When biochar from maize and wood was added to acidic soils in Zambia, soil pH increased from 4-6 to 6-7, and cation-exchange capacity increased by 30% to 100%.[22] Moreover, studies into the GHG emissions reduction potential of biochar find it could contribute to decreases in N_2O

13 Senate of Canada. *Critical Ground: Why Soil is Essential to Canada's Economic, Environmental, Human, and Social Health*. (Government of Canada, June 2024). https://sencanada.ca/en/info-page/parl-44-1/agfo-critical-ground/

14 Morrison, C.L., and Y. Lawley. *2020 Ontario Cover Crop Feedback Report*, Department of Plant Science, University of Manitoba. (2021). https://gfo.ca/agronomy/soil-leadership/

15 Calvo, P., Nelson, L., Kloepper, J.W. "Agricultural uses of plant biostimulants." *Plant Soil* 383. (2014): 4, 11. https://doi.org/10.1007/s11104-014-2131-8

16 Abbott, "Potential," 35.

17 Cerdan, M., Sanchez-Sanchez, A., Jorda, J.D., Juarez, M., and Sanchez-Andreu, J. "Effect of commercial amino acids on iron nutrition of tomato plants grown under lime-induced iron deficiency." *J. Plant Nutr. Soil Sci.* 176, (2013). https://doi.org/10.1002/jpln.201200525

18 Rose, M. T., Patti, A. F., Little, K. R., Brown, A. L., Jackson, W. R., and Cavagnaro, T. R. "A meta-analysis and review of plant-growth response to humic substances: practical implications for agriculture." *Adv. Agron.* 124, (2014). https://doi.org/10.1016/B978-0-12-800138-7.00002-4

19 Intergovernmental Panel on Climate Change (IPCC). *Climate Change 2007: Synthesis Report Contribution of Working Groups I, II and III to the Fourth Assessment Report of the Intergovernmental Panel on Climate Change* [Core Writing Team, Pachauri, R.K and Reisinger, A. (eds.)]. (Geneva, Switzerland: IPCC, 2007): 7. https://www.ipcc.ch/site/assets/uploads/2018/02/ar4_syr_spm.pdf

20 Yakhin, "Biostimulants," 9.

21 Iriti, M., Picchi, V., Rossoni, M. et al. "Chitosan antitranspirant activity is due to abscisic acid-dependent stomatal closure." *Environmental and Experimental Botany*. 66, (2009): 495. https://doi.org/10.1016/j.envexpbot.2009.01.004

22 Cornelissen, G., Martinsen, V., Shitumbanuma, V. et al. "Biochar Effect on Maize Yield and Soil Characteristics in Five Conservation Farming Sites in Zambia." *Agronomy*. 3, no. 2, (2013): 270. https://www.mdpi.com/2073-4395/3/2/256

emissions of up to 54% in field tests (and 91% in lab tests). However, other such studies have produced contradictory results, and further testing in a variety of soil zones is needed to understand the emissions reduction potential of this amendment.[23]

Given the inherently complex nature of biological systems, and that many non-fertilizer supplements contain multiple components (some with unclear origins and modes/mechanisms of action), it is perhaps not surprising that many products are ineffective or inconsistent in response to various soil, climatic, and crop conditions. Nevertheless, there is considerable independent evidence documenting the benefits of some supplements,[24] and market growth data demonstrates that there is a good deal of support for these products within agricultural producer communities.[25] However, without comprehensive testing and regulation around supplement efficacy, the supplements industry faces five significant risks, each building upon the preceding:

1. Farmers will not try supplements at all, dismissing them as too risky;

2. A farmer could try a particular supplement once and, if they do not see the expected results, never try another;

3. No matter what a farmer's one-time experience with supplements, without verified and public baseline data, they have no way of knowing if their results align with others, or are simply the result of random chance or error (perhaps the farmer chose the wrong product for their needs, made an error during application, or the products' benefits require more than one season to become evident);

4. Leaving a product's efficacy up to farmer trial-and-error is inefficient and creates duplication: many individual farmers could simultaneously be wasting time and money trying out the same ineffective supplements with no way of knowing; and

5. Farmers will have fewer supplement options if lack of ET and confusion and doubt around product effectiveness erodes confidence in supplements overall, depresses sales, and thereby slows growth of the supplement market and slows new-product development.

N-fixing legume inoculants are a prime example of ET at work. Legume inoculants have been sold in Canada for over 50 years, and we no longer think of them as supplements at all. Rather, because of their consistent and well-documented performance over time, legume inoculants are now considered as common a cropping input as fertilizer, and a requisite component for growing legume crops by conventional and organic farmers alike.[26] But it wasn't always this way. Legume inoculants were once regarded with the same distrust as many supplements are today, and the reason was simple: they did not always work as promised, or even contain the promised amount of key ingredients. In 1973, a survey of Quebec retailers found that 80% of inoculants contained fewer than the claimed amounts of rhizobium per gram, spurring the federal ministry of agriculture to begin the Canadian inoculant testing program in 1975.[27] The program tested for the presence of viable microorganisms and, from 1992 onward, published their product test results annually in the "Canadian Legume Inoculant and Pre-

23 Muñoz et al. 2016. "Use of biochar as a soil amendment: a brief review." *Chilean J. Agric. Anim. Sci.* 32, special issue no. 1, (2016): 40. https://revistas.udec.cl/index.php/chjaas/article/view/6181/5789

24 Abbott, "Potential," 35.

25 Yakhin, "Biostimulants," 21-22.

26 Sessitsch, A., Howieson, J.G., Perret, X., Antoun, H., and Martinez-Romero, E. "Advances in Rhizobium Research." *Critical Reviews in Plant Sciences.* 21, no.4, (2002); Saskatchewan Pulse Growers, *Inoculant Options for Pulse Crops* [Report]. March 2024. https://saskpulse.com/resources/inoculant-options-for-pulse-crops/

27 The Canadian Food Inspection Agency (CFIA) took over the inoculant testing program when it was formed in the mid-1990s.

Inoculated Seed Product Testing Report." This report listed all products analyzed by cross inoculation group, manufacturer, brand, sampling location, carrier type, and test result.[28]

Initial test results for viable microbes were quite poor when the program first began, with only about 50% of inoculants delivering on their label guarantees. By the time it was dismantled in 2013, however (along with the rest of Canada's ET program), the pass rate was around 95%.[29]

In its 38-year duration, Canada's inoculant testing program evaluated approximately 220 products per year, assisted in the development of strict industry standards, and contributed significantly to the adoption of legume inoculants in Canadian crop production. A 1994 analysis of this program credits it with "a rapid and significant increase in the quality of inoculant products offered to the Canadian farmer."[30] Another says, "It is now well established and documented that the introduction of standards and quality testing services has improved the situation regarding inoculants in at least Australia, Canada and the UK."[31]

Similar products exist that would help non-legume plants fix their own nitrogen (without first forming a symbiotic relationship with the plant, as *Rhizobium* species do with legumes) but they are not nearly as well researched and their performance remains inconsistent. With asymbiotic or biological N-fixing products, bacteria infect the soil surrounding plant roots and fix N from the air. This would mean that a wider variety of crops could fix their own nitrogen, reducing the need for synthetic N fertilizers. In the United States (where such biologicals are inconsistently regulated) some products claim to reduce fertilizer N by as much as 50 lbs applied N per acre (23 kgs). This could reduce emissions by 125.16 kg CO_2e/acre and save farmers approximately $50/acre (assuming fertilizer prices of $1/lb actual N)[32]—if these products work.

Midwestern extension universities including Michigan State collaborated on joint tests of three such products—two of which are also for sale in Canada. They included multiple N rates with and without asymbiotic N-fixing products Envita, Utrisha, and ProveN 40, and found no yield improvement with the addition of these products ($p<0.05$) compared to N rates alone (Table 1).

N rate, Pounds N/acre	Corn Yield, bushels per acre			
	No additive	Envita	Utrisha	ProveN 40
60	130 bcd	148 ab	120 cd	119 d
110	154 a	148 ab	152 a	137 abc
180	160 a	145abc	139 abcd	154 a
Mean	148NS	147	137	137
Check	128 d			

Table 1: Michigan State University corn yield trials with no additives vs. biological N-fixing products.

Similar trials on corn, spring wheat, sugar beets, and canola were conducted at other universities across the upper Midwest.[33] They found that, for all but two of the 61 combined site-years, biological N-fixing

28 Olsen et al., 1994, p. 128.

29 CFIA, personal communication, July 23, 2024.

30 Olsen et al. 1994, p. 130

31 Day, 1991 (from Olsen)

32 https://www.canr.msu.edu/news/can-biological-products-substitute-for-fertilizer-nutrients https://www.canr.msu.edu/soilfertility/Files/Bulletins/Performance%20of%20Selected%20Commercially%20Available%20Asymbiotic%20N%20fixing%20Products%20in%20the%20North%20Central%20Region.pdf

33 Franzen, D., et al. *Performance of Selected Commercially Available Asymbiotic N-fixing Products in the North Central Region* [Report]. North Dakota State University Extension. (April 2023). https://www.canr.msu.edu/soilfertility/Files/Bulletins/Performance%20of%20Selected%20Commercially%20Available%20Asymbiotic%20N%20fixing%20Products%20in%20the%20North%20Central%20Region.pdf

products demonstrated no yield increase over the N fertilizer rate individually. Michigan mandates efficacy testing of soil amendments, but not biological fertilizer products such as these.[34] However, the potential cost and emissions savings from these products certainly warrant further research and testing. Were such testing mandatory, companies could work out the inconsistencies of under-performing products and improve their effectiveness, thereby increasing their adoption—similar to legume inoculants in the 1980's and '90's.

In Canada, such testing was once mandatory for all supplements—not just legume inoculants. Canada's *Fertilizer Act* and *Regulations* stated that "A fertilizer or supplement shall have such chemical and physical composition as to be efficacious for every purpose for which it is represented or sold."[35] The CFIA laid out guidelines for proper scientific testing in Trade Memoranda, which included replicated tests across various locations and multiple years in the agricultural regions for which the product was intended to be sold.[36] Companies would then test their products according to these guidelines and submit their results to the CFIA to be verified by its team of Efficacy Evaluators—trained scientists with an MSc or PhD in the relevant field.

For instance, for the benefit claims reproduced in Figure 4, the manufacturer would need to demonstrate that, in at least 60 percent of trials, its product "stimulated growth and development" of crop plants, leading to "higher yields and quality" compared to plants grown without the supplement. If tests revealed that a product stimulated plant growth but did not produce higher yields compared with an untreated control, then the product's label or marketing materials could only claim that it stimulates plant growth, not that it increases yields.

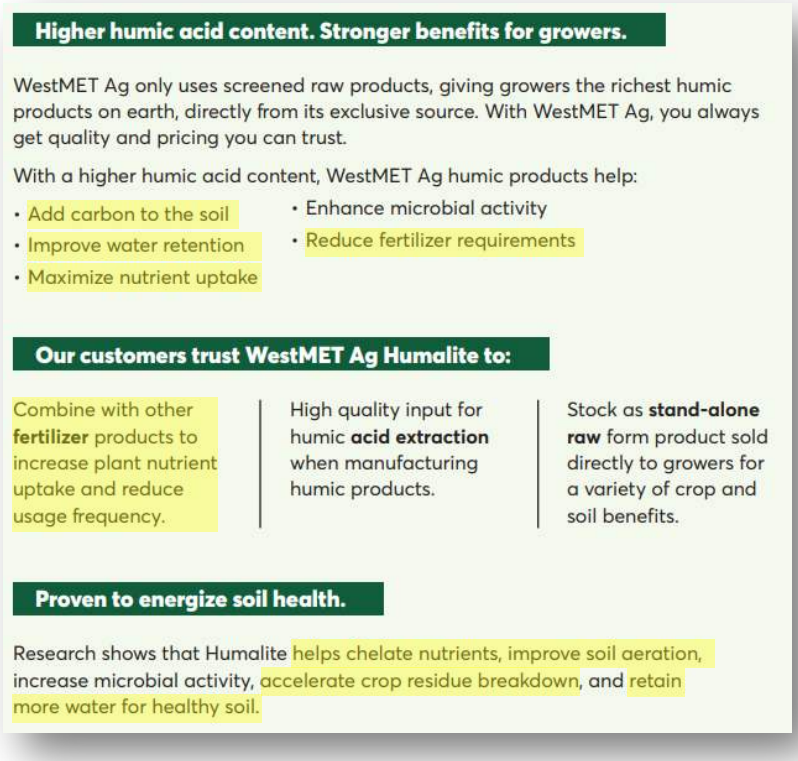
Canada's former ET standards were highly regarded internationally; companies with little Canadian market for their product would still register them in Canada, as it offered market access benefits elsewhere in the world.[37] Until 2013, this science-based system protected farmers from companies making false claims; in that year, it was repealed following federal cuts to the CFIA's budget.

34 Michigan Department of Agriculture & Rural Development, "Fertilizer & Soil Conditioner License / Registration Application", accessed on May 16, 2024, https://www.michigan.gov/mdard/-/media/Project/Websites/mdard/documents/pesticide-plant-pest/feedsafetyandfertilizer/fert_app_form.pdf?rev=e48ab95c27f3469ba0c9cb4e4a9b5400&hash=50797A92C3419BFC3ABE068EE1D4A195

35 Government of Canada. *Fertilizers Regulations* 11.2 [Repealed, SOR/2020-232, s. 8]. Accessed May 29, 2024. https://laws-lois.justice.gc.ca/eng/regulations/c.r.c., c. 666/FullText.html

36 The former system is explained in more detail in the final section of this report: Precedent.

37 CFIA official, personal communication. May 28, 2024.



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- Improve water retention
- Maximize nutrient uptake
- Enhance microbial activity
- Reduce fertilizer requirements

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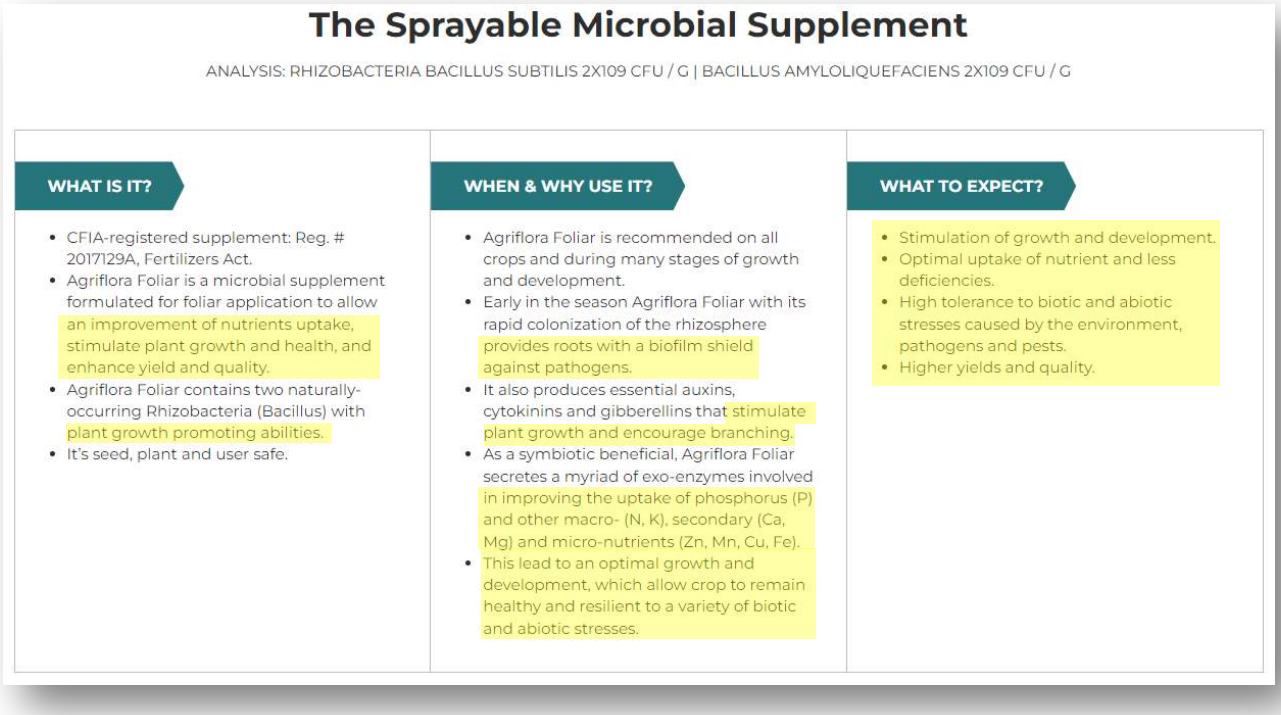
High quality input for humic **acid extraction** when manufacturing humic products.

Stock as **stand-alone raw** form product sold directly to growers for a variety of crop and soil benefits.

Proven to energize soil health.

Research shows that Humalite helps chelate nutrients, improve soil aeration, increase microbial activity, accelerate crop residue breakdown, and retain more water for healthy soil.



The Sprayable Microbial Supplement

ANALYSIS: RHIZOBACTERIA BACILLUS SUBTILIS 2X109 CFU / G | BACILLUS AMYLOLIQUEFACIENS 2X109 CFU / G

WHAT IS IT?

- CFIA-registered supplement: Reg. # 2017129A, Fertilizers Act.
- Agriflora Foliar is a microbial supplement formulated for foliar application to allow an improvement of nutrients uptake, stimulate plant growth and health, and enhance yield and quality.
- Agriflora Foliar contains two naturally-occurring Rhizobacteria (Bacillus) with plant growth promoting abilities.
- It's seed, plant and user safe.

WHEN & WHY USE IT?

- Agriflora Foliar is recommended on all crops and during many stages of growth and development.
- Early in the season Agriflora Foliar with its rapid colonization of the rhizosphere provides roots with a biofilm shield against pathogens.
- It also produces essential auxins, cytokinins and gibberellins that stimulate plant growth and encourage branching.
- As a symbiotic beneficial, Agriflora Foliar secretes a myriad of exo-enzymes involved in improving the uptake of phosphorus (P) and other macro- (N, K), secondary (Ca, Mg) and micro-nutrients (Zn, Mn, Cu, Fe).
- This lead to an optimal growth and development, which allow crop to remain healthy and resilient to a variety of biotic and abiotic stresses.

WHAT TO EXPECT?

- Stimulation of growth and development.
- Optimal uptake of nutrient and less deficiencies.
- High tolerance to biotic and abiotic stresses caused by the environment, pathogens and pests.
- Higher yields and quality.

Figure 4: Example of product claims from two randomly-chosen supplements from the CFIA's Registered Products List. Note: Claims that would seem to require efficacy testing and verification are highlighted in yellow.
Sources: WestMETAg Humic Products product guide, https://www.westmetag.com/wp-content/uploads/2023/10/5586_WESM_2023_Product-Guide_v14-LR.pdf; and Omex, Agriflora Foliar, https://omexcanada.com/products/specialty/agriflora-foliar/#:~:text=Agriflora%20Foliar%20is%20a%20microbial,with%20plant%20growth%20promoting%20abilities

Today's supplement market can best be described as "farmer buy-and-try." The only efficacy testing the CFIA now requires is for supplements claiming environmental or safety benefits (e.g., reduced nitrogen leaching, volatilization or runoff; or emissions reductions). The remainder of supplements are only required to prove that they contain the stated amounts of active ingredients,[38] and it is up to farmers to discover whether a product actually works for their operations—whether the benefits described on the label, website, or marketing materials are real. In some cases, companies may conduct their own testing, or partner with government or university research stations to ensure their products achieve their claimed benefits in their target crops and regions. However, such results are seldom published and are therefore not available for most products.[39]

Many more companies expect farmers to rely on observational and/or anecdotal data, or to do their own testing—sometimes requiring the purchase of expensive specialized equipment. This is a barrier in an industry where profit margins can be slim. Moreover, it can take multiple years to see changes to soil structure, bulk density, and carbon sequestration.

The landscape of non-fertilizer supplements presents a complex terrain of potential benefits, costs, risks, and uncertainties. While some products show promise in enhancing plant resilience and reducing input costs and environmental impacts, the lack of regulated ET leaves farmers exposed to ineffective or inconsistent products, which slows the adoption of effective and beneficial ones. The historical success of regulated ET, exemplified by the widespread adoption and positive perception of legume inoculants, underscores the value of rigorous scientific evaluation in establishing trust and maximizing the benefits of agricultural innovations. By fostering a regulatory environment that prioritizes transparency and efficacy, Canada has the opportunity to cultivate a more informed and resilient agricultural sector poised to meet the challenges of a changing climate and evolving market demands.

38 "Canadian Food Inspection Agency to Fous on Fertilizer Safety" [News Release]. Last modified May 25, 2012. https://www.canada.ca/en/news/archive/2012/05/canadian-food-inspection-agency-focus-fertilizer-safety.html

39 Abbott, "Potential," 35.

The Solution: Bring Back Federally Regulated Efficacy Testing

The NFU strongly recommends a return to Canada's former ET requirements, conducted by supplement manufacturers and validated by the CFIA. Testing should be consistent with best experimental practices in the agronomic sciences, and be able to withstand independent scrutiny. This would not only enhance product reliability, but would give farmers verified information with which to make sustainable and profitable choices.

By requiring regulated and comprehensive testing, and making test results publicly available, Canada could keep ineffective products off the market, encourage under-performing or inconsistent products to improve, and increase the adoption of beneficial supplements by strengthening trust in the industry as a whole. Canada's former legume inoculant testing program had a tremendously positive impact for the inoculant industry, supporting its meteoric rise and incorporation into mainstream agricultural production. If Canada's federally-regulated ET system was reinstated, other supplements could come to be regarded with the same level of trust.

The proposed ET framework should ensure comprehensive (multi-year, multi-site) testing of each benefit claimed on a supplement's label or marketing material, and the public reporting of test results. For supplement companies, this would include a minimum of six trials per year for two years, with at least two trials per year in each agronomic region for which the product is intended for use (e.g., Prairies, Ontario and Quebec, Atlantic Canada). The test data should be from Canadian sites, as international sites with comparable climates may not recreate the conditions of actual use, and likely have different soil microbial communities, influencing product performance.[40] In fact, for products that improve nutrient availability (usually via microorganisms), soil types and soil conditions can be more relevant than crop type when designing trials.[41] Companies claiming on-seed survival of their microbes within a certain planting window should also provide data verifying these claims. We recommend that, as in the past, the CFIA conduct spot-checks of products on retailer shelves to confirm that active ingredients, such as microbes, remain active and in consistent numbers for the entirety of the period claimed on the label.

Under controlled conditions (greenhouse or laboratory), we recommend the confidence level for statistically significant results be set to 95%, and 90% for field trials (consistent with agronomic literature). Such statistical significance should be demonstrated in at least 60% of trials for a product to be sold in Canada, as was previously the case. And where test results indicate inconsistencies in product performance, supplement manufacturers should explain the reasons for such inconsistencies when submitting their trial data to the CFIA, and add similar explanations to their product instructions so users have accurate information on a product's expected performance, and the conditions under which optimal and consistent performance is most likely. This level of transparency and scientific rigor will provide farmers with the tools they need to make prudent decisions aligned with their specific conditions and requirements. This represents a promising model, following precedent in the Canadian system for its governance.

The NFU recognizes that if these standards were implemented immediately, most supplement products would have to be pulled from the shelves to await testing, review, and registration, which would hinder farmers in the short-term. To avoid this, the NFU recommends allowing products to be released with a

40 Lyseng, R. "Farmers urged to be alert when buying soil supplements." *The Western Producer*. (January 17, 2019). https://www.producer.com/crops/farmers-urged-to-be-alert-when-buying-soil-supplements/

41 Ricci, M. Tilbury, L., Daridon, B. Sukalac, K. "General Principles to Justify Plant Biostimulant Claims." *Frontiers in Plant Science*. 10:494, (2019): 2.

registration exemption until testing is complete. This would help curtail regulatory backlog and provide farmers with continued access to products that are not yet tested and certified under a future ET system. There is precedent for such a provision in Canada's former ET guidelines, which are discussed in greater detail in the Precedent section of this report.

A recent unpublished survey of the fertilizer industry, government, academics and producers conducted on behalf of CSA Group found that respondents were nearly unanimous on the need for and importance of efficacy standards (94%) and composition standards (100%) for agricultural biostimulants (supplements) in Canada.[42] 91% of participants agreed that efficacy and composition standards would play a significant role in future innovations and 87% agreed that these standards would enhance the credibility of biostimulant products.

The government is in the best position to manage and mandate the provision of this data. The CFIA administered the previous efficacy evaluation system and maintains the bureaucratic infrastructure needed to run it, including data, offices, and laboratories, as well as a working knowledge of regulations governing other agricultural inputs that could be mixed or combined with supplements. Moreover, as a federal agency, it is an independent third party committed to scientific rigor and the public good, with no vested interest in the results of testing.

By maintaining transparency through independent verification and public reporting of data, Canada can cultivate a marketplace where confidence in agricultural supplements is bolstered, fostering innovation and resilience in the face of evolving agricultural, climate, and emission-reduction challenges. Allowing products a registration exemption pending testing and certification strikes a balance between regulatory rigor and farmer access, ensuring that beneficial supplements can enter the market swiftly without compromising scientific integrity in the medium term. Ultimately, embracing these standards not only enhances product reliability but also paves the way for a more robust agricultural sector that prioritizes environmental stewardship and farmer welfare.

42 Lemay, M.A. (2024). Scoping Standards for Agricultural Biostimulants in Canada. CSA Group (Canadian Standards Association), Toronto, ON.

The Benefits of Efficacy Testing

Efficacy testing of non-fertilizer supplements presents low hanging fruit for addressing rising fertilizer costs, seeking emissions reductions in agriculture, and removing the risk of unsubstantiated claims from the market for non-fertilizer supplements. Moreover, it can be cost effective for farmers and the government, and could open paths to climate incentive programs. Three sequential benefits underpin the wider advantages of a comprehensive ET structure.

A. Products that do not deliver on their claims will be identified and documented. This means farmers can omit inefficacious products from their list of options, and the market will be cleared of non-performing, money-wasting products.

B. From the products that remain, farmers will be able to make confident, data-supported cost-benefit comparisons to underpin purchasing decisions. This could result not only in the adoption of fertilizer alternatives, but the adoption of cheaper alternatives, and therefore positive returns for farmers.

C. Of the affordable non-fertilizer supplements that prove to be efficacious, emissions assessments can be made to quantify reductions, offering farmers the potential to reduce emissions at a low cost per tonne or even a *negative* cost per tonne—reducing emissions while increasing profits.

Improved farmer confidence would expedite the adoption of non-fertilizer supplements in Canada, which in turn could contribute to improved soil health and reduced emissions, while also increasing the input options available to farmers.

Cost-effective for farmers and for government

As fertilizer costs rise, including the costs associated with enhanced efficiency fertilizers, and governments seek to reduce emissions, there are a number of ways that ET can lead to decreased costs.

1. Farmers can save directly when relatively lower-cost supplements can enable reduced fertilizer purchases while still maintaining yields.

2. Giving farmers alternatives to conventional fertilizers can discipline the prices of those fertilizers, creating savings even for farmers who do not use supplements.

3. Even if supplements are more costly than the fertilizers they may replace or obviate, the incremental cost may be small relative to the tonnes of GHG emissions reduced. In such cases, incentives to farmers could tip the balance toward supplement use, reducing emissions at a low per-tonne cost. In this way, ET opens the door for supplements' inclusion in government incentive programs (see next section).

Emissions reduction incentives

If products are determined to be efficacious and emissions-reducing, yet are still less affordable than fertilizer, farmers and industry could take advantage of emissions-reduction incentive programs like the On-Farm Climate Action Fund (OFCAF). Subsidizing farmers' purchase of such products via programs such as OFCAF could bring them into the affordable range and stimulate adoption.

ET could be a win-win for farmers and supplement producers, as emissions-reduction incentive money for some products could spur very rapid uptake. Additionally, increased adoption of non-fertilizer supplements could stimulate a reduction in cost over time, increasing their affordability. These advantages are wholly inaccessible to non-fertilizer supplement providers without ET, as it would make little sense for the government to incentivize unverified products.

Why farmers cannot be responsible for efficacy testing

With the 2013 termination of government-verified ET, the expectation emerged that farmers would conduct tests themselves. An article in the Canada Gazette announcing the amendment to the *Fertilizer Act and Regulations* repealing ET stated: "It is generally understood that the quality and efficacy of a product are the responsibility of its manufacturer and through their choices, consumers have a means of rewarding these manufacturers who present an efficacious product."[43]

The federal government's de facto decision to foist testing and evaluation onto individual farmers overlooks several critical points.

1. Farmers cannot conduct tests that are statistically significant. Such testing requires multiple sites and multiple years. A result from a single year and one or two fields may produce a false positive or false negative.

2. Farmers will not test multiple products. One or two bad results will cause most farmers to cease trying new supplements—concluding that supplements "don't work."

3. Most farmers do not have the sensitive equipment needed to conduct tests, e.g., harvest equipment that can quantify small yield changes or lab equipment to analyze soil changes.

4. Even if farmers can generate comprehensive, statistically significant results, those results are not available to other farmers, forcing each farmer to do their own on-farm test of every product, creating redundancies and huge inefficiencies.

5. Many products make claims that are impossible for farmers to assess, e.g., "a biofilm shield against pathogens." Such claims require laboratories and scientists to assess.

Farmer-buy-and-try is no substitute for statistically significant, government-verified and certified testing and data publication. Efficacy testing for supplements and data publication are public services and necessary components of Canada's national climate change and agricultural sustainability strategies. Thus, ET should be immediately restored as part of CFIA's mandate under the *Fertilizer Act* and *Regulations*.

Why industry self-certification is not the right approach

In the absence of government-verified ET, and acknowledging the pressing need for some way for farmers to know if a product is effective, some companies and industry associations are exploring voluntary, industry self-certification. This idea is still in its early stages and no structure has yet been proposed, so it is difficult to know what self-certification in the supplement industry would look like. However, we can gain a rough idea by examining the structure of quality management systems more generally. According to the International Accreditation Forum, "For a quality management system (QMS)

43 Canada Gazette May 2013, p. 1254 https://gazette.gc.ca/rp-pr/p2/2013/2013-05-08/pdf/g2-14710.pdf

to be considered certified, the certificate must be received from an independent, accredited certification body upon completion of an assessment against specific documented criteria."[44] In some scenarios, if supplement companies wanted to self-declare as being compliant with an industry-determined set of standards, that would involve each supplement company conducting its own internal audit and determining that it believes it is compliant with the requirements articulated by an industry body.

Regardless how industry-certification may work, there are many reasons why such voluntary systems would fall far short of what farmers need, and far short of what pre-2013 government-delivered verification provided:

1. In most scenarios, there is no independent, objective, scientifically rigorous body that *actually scrutinizes* the data and has incentives to hold companies to account.

2. Farmers may have little trust in a system created by product sellers.

3. The system will be opaque. For farmers to have confidence in industry self-certification, farmers would have to spend time investigating the certifying body and what scientific measures it uses to determine efficacy. Farmers may be ill-equipped to assess scientific methods or rigor.

4. Because it is voluntary, not all products will be certified.

5. It is unlikely that voluntary, industry self-certification will meet government standards for being included in programs of incentives for emissions reduction, etc., slowing product uptake.

Voluntary, industry self-certification is far, far inferior to government-run ET and independent scrutiny of data and claims. The latter is no more costly than the industry proposal, but provides far greater benefits.

Self-regulation in the Canadian organics industry

Proponents of industry self-regulation argue that there is a precedent in Canada's organics sector. This is false. Organic farmers do not self-certify, and instead are subject to third-party on-site inspections, audits, etc. Moreover, in Canada, the CFIA participates in organic certification in several ways:

1. Administration and setting standards: The Canadian Organic Standards, which specify the requirements for organic production and labelling, are developed and maintained by the Canadian General Standards Board in collaboration with industry stakeholders, and are administered by the CFIA.

2. Accreditation of certification bodies: The CFIA accredits certification bodies that are responsible for certifying organic operations, reviewing documentation, and conducting inspections.

3. Monitoring and enforcement: The CFIA oversees the organic certification system to ensure compliance with the Canadian Organic Standards. This includes auditing certification bodies to verify their adherence to accreditation requirements and the proper application of organic standards.

The CFIA ensures that organic products sold in Canada meet recognized standards and expectations and it maintains the integrity and credibility of the organic label.

44 Robitaille, D. "Self-Certification Is Not a Real Thing." *International Accreditation Forum*. (October 19, 2017). https://iaf.nu/en/news/self-certification-is-not-a-real-thing/

Efficacy Testing Costs

In terms of total cost to farmers and companies, it is probable that an ET system once again administered and verified by the CFIA will be the least costly and most efficient.

Before it was repealed in 2013, the CFIA's fee for ET was $250. If a product also required safety testing ($500) and a registration application ($350), the cost of the combined fees was capped at $1000.[45] Given that most companies would be conducting their own testing to ensure product performance and simply sending the results to the CFIA, it is difficult to understand how saving $250 per product makes any difference to their bottom lines, and how establishing a voluntary regulatory body from scratch is a lower-cost solution. If supplement makers believe in the importance of ET, as survey results suggest, they should be willing to support federally-regulated testing.

A renewed ET system within CFIA may have slightly higher costs than was the case in its pre-2013 form. Any potential worries about backlogs or delays could be alleviated by employing more Efficacy Evaluators than the three that were in place before 2013. Doubling that complement to six might cost an additional million dollars per year (all salaries, offices, equipment, transportation, etc. included) but this is a tiny incremental expenditure in the context of a farm sector that spends tens-of-billions of dollars per year on inputs.

While the idea for a voluntary, industry-run certification body is still in the research phase and no formal structure has yet been proposed, it is very hard to believe that such a system could be put together at a cost that is less than a few hundred dollars per product. Regardless of how a theoretical industry self-certifying body would be structured, it will almost certainly cost supplement companies much more than federally regulated ET did.

The existing infrastructure and institutional knowledge within the CFIA provide a solid foundation to revive ET without substantial additional costs. By modestly expanding the CFIA's staff to manage efficacy evaluations, the agricultural sector can again benefit from reliable, scientifically validated product assessments without the need to establish and fund a new industry body from scratch. This pragmatic approach not only ensures regulatory oversight but also maintains affordability and accessibility for farmers while upholding rigorous standards crucial for product reliability and consumer trust in the agricultural supplements market.

Precedents

In this section, we examine past and present ET regimes for fertilizers and supplements. We first detail the program that existed in Canada up to 2013. We then turn to other jurisdictions in the United States, Europe, and beyond to understand how they incorporate ET into their regulatory frameworks. In this overview, we are guided by three questions: what products require testing, what does that testing consist of, and who conducts the testing.

45 CFIA Fee Schedule, provided on request

How efficacy testing used to work in Canada

Prior to its repeal in 2013, Section 11 of the *Fertilizer Act and Regulations* read as follows: *A fertilizer or supplement shall have such chemical and physical composition as to be efficacious for every purpose for which it is represented or sold.*

This meant that any supplement (defined as "products other than fertilizers that improve the physical condition of the soil or aid plant growth or crop yields") claiming to have an advantageous effect compared to cropping without that product would require testing. If a product made multiple claims, or was intended for use with more than one crop, it would need to test each claim with each crop and provide its results to the CFIA for assessment and verification.

The T-4-108 Trade Memorandum outlining efficacy data requirements for supplements regulated under the *Fertilizer Act* describes the testing requirements in detail.[46] It defines efficacy as "the ability of a fertilizer or supplement to fulfil any label claims and to produce a desired or intended result based on the labelled guarantees and directions for use" and includes "the ability to clearly demonstrate a benefit to the end user from the application of the product." It further states that "The purpose of an efficacy assessment is to evaluate product performance in order to establish appropriate label claim(s), active ingredient guarantee(s), and usage pattern(s)."

The testing was conducted by the company who produced the product, and requirements varied depending on which of Canada's three agricultural regions the product was intended to be used: Western/Prairies, Central (Ontario and/or Quebec), or Atlantic. If a product was intended for use across Canada (national registration), the company was required to provide results from 12 tests conducted across two years (six trials per year). How these trials were dispersed across the three regions would be determined by the percentage of crop production in each region, with more trial sites placed in regions with a greater share of national production. If a product was only intended for use in one "primary" region, the company was required to provide results from at least three sites across two years, totaling six trials or site-years overall.

Trial sites were required to be representative of the climatic and soil conditions intended for the end use of the product, and companies had to provide analyses of the sites' soil characteristics to the CFIA. When selecting trial sites, applicants were encouraged to choose locations that spanned the environmental conditions, geographic regions, seasonal variations, soil zones, and agricultural production regions in which the product/crop combinations would be used, and to explain their selections.

For a product to be approved for registration by the CFIA, a minimum of 60% of trials across all site-years needed to demonstrate a statistically significant benefit at 95% probability. Companies could also request that the threshold be lowered to 90% probability, as is common in the agronomic sciences where environmental factors like weather and topography make controlling variability a challenge. Companies could also apply to have certain trial site-years removed from consideration if extenuating circumstances (incl. extreme weather, drought, lodging, or human error) negated the results of the trial.

Accelerated trial requirements

Companies had the option to conduct all efficacy trials in a single year but, if they chose that option, they were required to complete at least sixteen trials (rather than twelve) for national approval, and eight trials

46 Canadian Food Inspection Agency. "T-4-108 Efficacy Data Requirement for Fertilizers and Supplements Regulated under the Fertilizers Act." Government of Canada, August 2008.

for regional approval (in the primary region), and four trials for secondary region approval. They were also required to demonstrate that these trials were adequately spatially distributed within the relevant production region(s), so as to capture a range of environmental conditions in a single year of testing.

Amending a product's registration

The CFIA also provided a shortened registration pathway for companies looking to amend or expand the performance claims of a product, or to support the registration of a similar product to one that was already registered. The company could do so by providing bridging data, which was defined as "[t]he use of a reduced number of trials or laboratory studies to support expanded, or amended performance claims." This would be accepted in cases where the company could demonstrate an appropriate amount of initial supporting direct or indirect evidence, in which case only one year of testing was required, consisting of three trials for regional registration and six trials for national registration.

The CFIA lists some examples in which bridging data may have been appropriate:

- new formulation but same active ingredient(s);
- co-formulation of two or more registered/approved products;
- change in application method, rate, technique, or volume;
- change in fertilizer/supplement constituent(s);
- change in carrier; or
- addition of a crop species.

International testing

International testing was accepted for a maximum of 50% of trial data under Canada's ET regime. However, the same trial information was required, and companies would have to provide a rationale detailing the similarity between the foreign sites and Canadian agricultural production areas with respect to climate, soils, agronomic conditions, and other parameters relating to the product's mode of action, usage pattern, and intended crop species that may affect its efficacy.[47]

Efficacy testing precedents in Canada: conclusion

As demonstrated above, Canada's former ET regime was comprehensive, science-based, rigorous, and realistic. It included provisions for extreme weather, accelerated testing, international testing, and bridging data to streamline the process when needed. Furthermore, in the event that efficacy data for a product did not exist, companies could apply for an exemption from registration to carry out research.[48] A return to this streamlined, scientifically-sound system would provide farmers with an expanded range of trusted input products and may provide less-costly alternatives to conventional fertilizers.

Efficacy Testing in Other Jurisdictions

Canada was not the only country to have a system of ET for supplements. The European Union (EU) and numerous US states have ET laws in place, along with many other nations and jurisdictions. In the following section, we explore a few case studies of agricultural jurisdictions with ongoing ET requirements.

47 Canadian Food Inspection Agency. "T-4-108 Efficacy Data Requirement for Fertilizers and Supplements Regulated under the Fertilizers Act." Government of Canada, August 2008.

48 Canada Gazette p. 1249-50. https://gazette.gc.ca/rp-pr/p2/2013/2013-05-08/pdf/g2-14710.pdf

European Union

The EU represents over 40% of the global biostimulant market and has rigorous laws for testing claims.[49] EU regulations adhere to a claims-based definition of plant biostimulants, and stipulate (similarly to Canada) that a biostimulant "shall have the effects that are claimed on the label for the plants specified thereon."[50] The European Committee for Standardization is developing standards for how applicants must provide data in conformity with this requirement.[51] Guiding principles proposed by the European Biostimulant Industry Council (EBIC) outline a system very similar to that of pre-2013 Canada.[52] They recommend that all claims should be demonstrated for every one of the four categories in the EU Fertilizing Products Regulation that they relate to: improving nutrient use efficiency, tolerance to abiotic stress, crop quality traits, or availability of confined nutrients in the soil. As each of these claimed benefits could conceivably lead to increased yields, such yield benefits must also be demonstrated if they are claimed on a product label. They outline a data-collection system centering around field trials with multiple sites, years, and replicates, but also allow for the submission of data from peer-reviewed studies, international trials in similar geo-climatic conditions, and greenhouse and laboratory trials when they are better suited to test a certain claim (e.g., abiotic stress, which needs to be simulated in a controlled environment). They state that manufacturers need the flexibility to design studies in such a way that the variety of possible effects, crop types, and growing conditions can be captured, and note that efficacy trials "will become ever more crucial as the industry trends toward the development of complex, multi-component products."

France's national system requires supplement producers to submit data on the efficacy of "fertilizers, fertilizer adjuvants, and growing media", unless they qualify for an exemption (e.g., if the product is already registered under the EU framework).[53] Applicants must substantiate label claims with the results of at least four efficacy trials in soil and climatic conditions comparable to France.[54]

Spain requires ET for biostimulants.[55] Applicants must submit independently produced data from trials in Spain that clarify the soil and crop types employed.[56]

United States

In the U.S., government and industry also support the development of consistent regulation and labelling for plant biostimulants that is harmonized between states and internationally.[57] Currently, plant biostimulants do not have a regulatory definition at the U.S. federal or state level, which complicates companies' abilities to make defined product claims; rather, biostimulants are defined and regulated

49 Yakhin, "Biostimulants," 21. The next largest share of the global biostimulant market is North America, at 21.5%.

50 "Regulation (EU) 2019/1009 of the European Parliament and of the Council," March 16, 2023, http://data.europa.eu/eli/reg/2019/1009/2023-03-16

51 European Committee for Standardization, "CEN/TC 455 - Plant Biostimulants," accessed May 16, 2023, https://standards.cencenelec.eu/dyn/www/f?p=205:7:0::::FSP_ORG_ID:2279055&cs=113EEA26EFA977A752425C21498AD4298

52 Ricci, "General principles," 3-7.

53 Agence nationale de sécurité sanitaire de l'alimentation, de l'environnement et du travail, "Marketing authorisation of fertilisers, fertiliser adjuvants and growing media," May 1, 2023, https://www.anses.fr/en/content/marketing-authorisation-fertilisers-fertiliser-adjuvants-and-growing-media

54 Ministère de l'agriculture et de l'alimentation, "Guide Relatif à l'évaluation des Dossiers de Demandes d'autorisation de Mise sur le Marche et de Permis des Matières Fertilisantes, des Adjuvants pour Matières Fertilisantes et des Supports de Culture," 2020, https://www.mesdemarches.agriculture.gouv.fr/spip.php?action=acceder_document&arg=849&cle=538b5634d20f9343a5d7761f3fb6069b2ef49e14&file=pdf%2FGuide-evaluation-MFSC_2020-07.pdf

55 Seipasa, "The European Fertilizing Products Regulation: what you need to know to understand the new EU 2019/1009 regulatory framework," July 19, 2022, https://www.seipasa.com/en/blog/the-european-fertilizing-products-regulation/

56 Ministerio de la Presidencia y para las Administraciones Territoriales, "Real Decreto 999/2017, de 24 de noviembre, por el que se modifica el Real Decreto 506/2013, de 28 de junio, sobre productos fertilizantes," November 24, 2017, https://www.boe.es/eli/es/rd/2017/11/24/999

57 USDA. *Report to the President of the United States and United States Congress on Plant Biostimulants Submitted by the United States Department of Agriculture (USDA) in Consultation with the Environmental Protection Agency (EPA).* (December 2019): 4. https://agriculture.house.gov/uploadedfiles/usda_report_on_plant_biostimulants_12.20.2019.pdf.

based on their "mode of biological action" (e.g., acting as a pesticide, nitrogen fixer, etc.). Given the multitude of known (and unknown) microbes operating in some biostimulants, each with multiple possible modes of activity, this is much more difficult to demonstrate than proof of efficacy and safety. Consequently, U.S. supplement regulation is variable and complicated, and plant/soil amendments require an average of three to five labels per product.[58] At the federal level, the Environmental Protection Agency (EPA), the Food and Drug Administration (FDA), and the United States Department of Agriculture (USDA) all have some authority in regulating non-fertilizer supplements. If a company's product does not fall under any of these federal jurisdictions, it must seek state-by-state approval under a variety of distinct product labels and categories, including soil amendment, plant amendment, plant inoculant, beneficial substance (which is defined in only 13 of 50 states), or fertilizer, which can be complex and confusing for companies, regulators, and users.[59]

Requirements for ET are determined at the state level and vary depending on the level of resources (funding and staff) available and the types of supplements each state recognizes. Currently, some U.S. states only require the claims of soil amendments or "conditioners'' to be tested (like biochar, compost tea, manure and lime) and not biostimulants (like inoculants, humic acids, and seaweed extracts), while some states require both.[60]

A joint government-industry working group convened in 2018 to report to Congress on the status and regulatory review of plant biostimulants. The working group reported that current state regulatory frameworks for biostimulants "limit the benefit claims product developers can make," and recognized the need "to develop clear guidance in order to evaluate efficacy and safety concerns consistent with risk management."[61] Their report cites the EU's similar efforts towards regulatory clarity and harmonization, and states that federal regulation of biostimulants would present industry with numerous benefits, including a unified label and federally recognized class of products, as well as increased efficiency, speed to market, and reduced redundancy in the validation process.

Kansas

In 2021, Kansas had the seventh largest agricultural output in the US by dollar value and was the leading wheat-producing state.[62]

As part of the registration process, Kansas requires submission of efficacy data for all soil amendments, defined as "any substance which is intended to improve physical, chemical or other characteristics of the soil, or improve crop production."[63] There are exemptions for commercial fertilizers, compost, and some other products.

The specifications are similar to those in Canada before 2013. They require two years of trials in three locations (at least one of which must be in Kansas) that represent three different common soil types in the state. Applicants must submit data demonstrating statistically significant results at a 90% confidence

58 USDA, "Report to the President of the United States…."

59 USDA, "Report to the President of the United States…."

60 Biostimulant Industry Working Group, Biological Products Industry Alliance, and The Fertilizer Institute. "United States Biostimulant Industry Recommended Guidelines to Support Efficacy, Composition, and Safety of Plant Biostimulant Products," February 28, 2022. http://www.bpia.org/wp-content/uploads/2022/02/Biostimulant-Efficacy-Comp.-and-Safety-Claims-022822.pdf.

61 United States Department of Agriculture, and Environmental Protection Agency. "Report to the President of the United States and United States Congress on Plant Biostimulants," December 20, 2019. https://agriculture.house.gov/uploadedfiles/usda_report_on_plant_biostimulants_12.20.2019.pdf.

62 U.S. Department of Agriculture Economic Research Service, "Cash receipts by commodity State ranking," February 7, 2023, https://data.ers.usda.gov/reports.aspx?ID=17844

63 Kansas Department of Agriculture, "GUIDELINES FOR CONSIDERING SOIL AMENDMENTS FOR REGISTRATION AND PROOF OF EFFICACY", accessed on June 13, 2024, https://www.agriculture.ks.gov/home/showpublisheddocument/1260/638451532669026831

level. This data must be generated by land grant universities, [the] USDA, and other reputable research organizations. Once received by the Kansas Department of Agriculture, the application is forwarded for review to experts at Kansas State University. This system works to ensure that efficacy data is generated and reviewed by qualified experts at arm's-length from the companies themselves.

Other states with similar legislation include Oklahoma and Michigan.[64]

Iowa

In 2021, Iowa had the second largest agricultural output in the US by dollar value and was the leading state in terms of corn production.[65]

Iowa adopts a middle ground between Canada's previous and current systems. The State does not require data on efficacy for all applications but "reserve the right to ask for 2 years of efficacy data using the product in like soils and the Iowa crops that the product is intended for."[66] When requested, data must be from "at least three Iowa crop reporting districts in accordance with standards for ET."[67] The results of testing are then reviewed by the state Secretary of Agriculture's pesticide and fertilizer advisory committee, a nine-member team composed mostly of Iowa State University experts and two persons representing the general public.[68] The model used in Iowa empowers reviewers to request the data they need to assess novel products and label claims.

Other states with similar legislation include California and Texas.[69]

Other jurisdictions

Many countries require some form of ET prior to product registration for fertilizers and other related products. The World Bank produced a report in 2017 which compares fertilizer regulations around the world.[70] They found that field tests for at least some products were mandatory in many major agricultural producing nations, including Ukraine, Russia, India, and Brazil.

Canada broke with best practices in 2013 by ceasing efficacy testing, and would join agricultural powerhouses such as Kansas, Iowa, Ukraine, and Brazil by reinstituting it. Such jurisdictions have maintained their ET regimes to ensure that their farmers have products they can trust. Their models, along with Canada's previous system, provide templates for a renewed system of ET in our country. By restoring comprehensive, government-administered and -verified ET, Canada can take tangible steps towards a more resilient and lower-emitting agricultural sector.

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64 Oklahoma Department of Agriculture, Food and Forestry, "Directions for Application of Soil Amendment Registration," accessed on May 16, 2023, https://ag.ok.gov/wp-content/uploads/2020/11/Printable-Registration-for-Soil-Amendment.pdf; Michigan Department of Agriculture & Rural Development, "Fertilizer & Soil Conditioner License / Registration Application", accessed on May 16, 2023, https://www.michigan.gov/mdard/-/media/Project/Websites/mdard/documents/pesticide-plant-pest/feedsafetyandfertilizer/fert_app_form.pdf?rev=e48ab95c27f3469ba0c9cb4e4a9b5400&hash=50797A92C3419BFC3ABE068EE1D4A195

65 U.S. Department of Agriculture Economic Research Service, "Cash receipts"

66 Iowa Department of Agriculture and Land Stewardship, "Distributing a Fertilizer or Soil Conditioner in Iowa," accessed on May 16, 2023, https://iowaagriculture.gov/sites/default/files/grain/Forms/DistributingFertilizerOrSoilConditionerInIowa.pdf

67 Iowa Legislature, "Iowa Administrative Code 21—43.21(200)," May 17, 2023, https://www.legis.iowa.gov/docs/iac/chapter/05-17-2023.21.43.pdf

68 Iowa Legislature. "Advisory committee created – duties." *Pesticides, 206.23*. Accessed June 10, 2024. https://www.legis.iowa.gov/docs/code/206.23.pdf

69 California Department of Food and Agriculture, "Guidelines for Substantiation of Product Efficacy Claims," accessed May 16, 2023, https://www.cdfa.ca.gov/is/ffldrs/pdfs/EFFICACY_DATA_GUIDELINES.pdf; Texas Legislature, "Texas Administrative Code Title 4 §65.17," accessed May 16, 2023, https://texreg.sos.state.tx.us/public/readtac$ext.TacPage?sl=T&app=9&p_dir=N&p_rloc=182664&p_tloc=&p_ploc=1&pg=3&p_tac=&ti=4&pt=3&ch=65&rl=17

70 World Bank Group, "Enabling the Business of Agriculture 2017," February 7, 2017, https://eba.worldbank.org/en/eba

Conclusions

Canada's former efficacy testing (ET) system exemplifies a robust and rigorous framework grounded in science and pragmatism. A reinstatement of this system would significantly benefit Canadian agriculture across the value chain, offering benefits to farmers as well as industry and government.

Industry should support a return of a government-administered ET system, because:

1. It is the least-cost option for testing, costing just a few hundred dollars per supplement product;

2. Verification of efficacy on any products that can substitute for chemical fertilizers opens the door for government to subsidize their purchase, through programs like OFCAF; and

3. Verified efficacy plus government incentives/cost-sharing could mean a multiplication of product use—a huge upsurge in sales.

Government should support this because:

1. It is a potential source of low-cost per-tonne emissions reduction in the agricultural sector;

2. It diversifies input options and multiplies resilience-supporting products; and

3. Governments have a responsibility to regulate markets and minimize misleading claims.

Farmers should support this because:

1. They won't have to sift through unproven products and can focus instead on finding the right one for their conditions;

2. They gain options to potentially reduce their fertilizer use;

3. Proven-effective products could qualify for government funding, potentially reducing farmers' input costs;

4. A proliferation of reliable non-fertilizer options can discipline fertilizer prices, benefiting even those who choose not to use supplements; and

5. Organic farmers gain additional production options.

Comprehensive, government-administered and -verified ET promises to foster a more resilient national agricultural sector, better equipped to meet environmental challenges while supporting sustainable farming practices and economic prosperity for all farmers.

The NFU strongly recommends that Canada's former government-administered and -verified efficacy testing system be reinstituted.