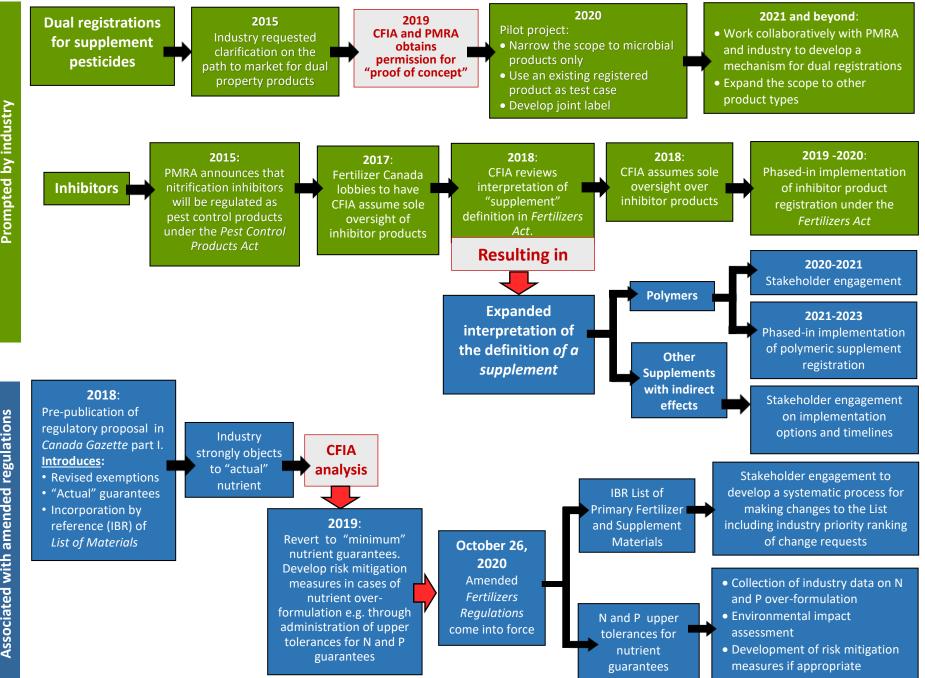
Drivers, historical perspective and interdependencies between the various Fertilizer Initiatives



Fertilizer Program updates

CFIA Fertilizer Regulatory Workshop February 2, 2022



Outline

- Covid-19: impacts and adjustments
- Service delivery standards and file statistics
- Updates





Covid-19: impacts and adjustments

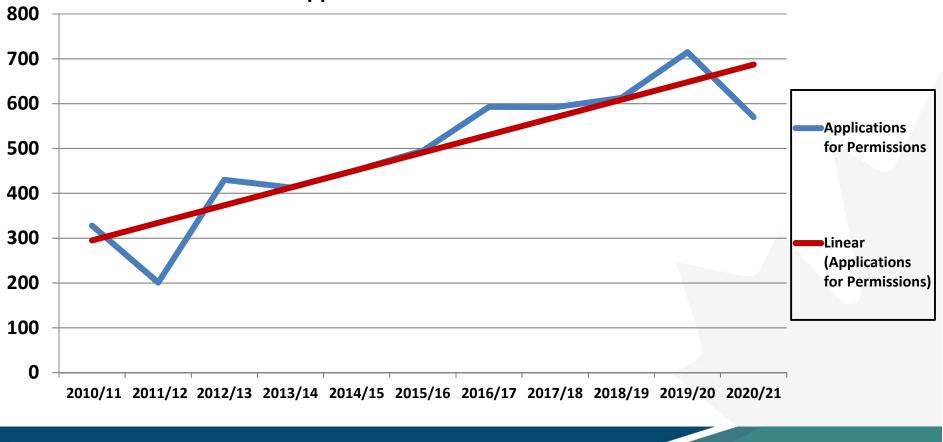


- The Fertilizer Safety Program has historically been a paper-based program, physical applications being stored in a secured file room in Ottawa.
- **Covid-19**: March-April 2020 brought a rapid shift to working remotely.
- Limited access to physical files and the workplace significantly slowed reviews until processes could be adapted to adjust to the new norm.
 - Files stored on site
 - Access to worksite through bookings to reduce contact between employees.
 - Evaluators notified one another as they completed their reviews and returned files to the file room. With multiple evaluators on each file, this introduced significant delays to the file review process.
- Over the course of the pandemic, systems were upgraded, new tools were brought online and internal processes were adapted to facilitate remote work.
 - Increased network capacity, MSTeams, e-signatures, progress towards digitizing new applications received through legacy channel.
 - MyCFIA online applications platform identified as critical.



Service Delivery Standards

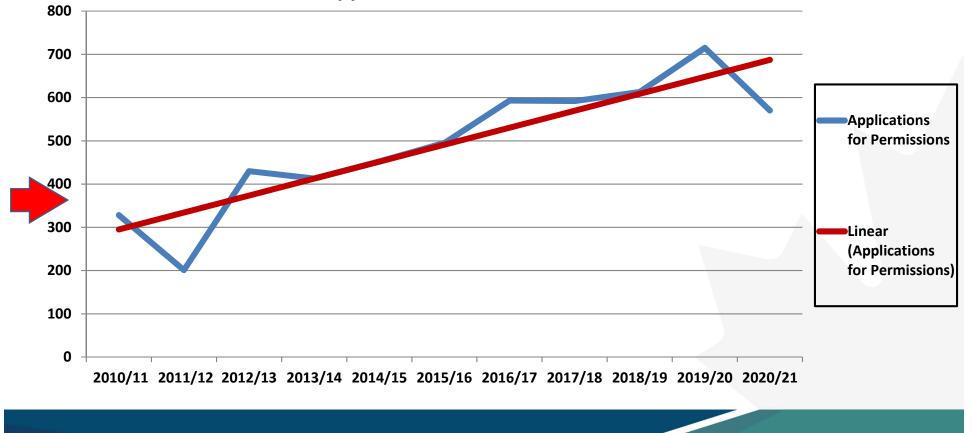
• SDS were established in 2008 assuming a baseline of 350-400 applications per year (steady increase since).



Applications for Permissions

Service Delivery Standards

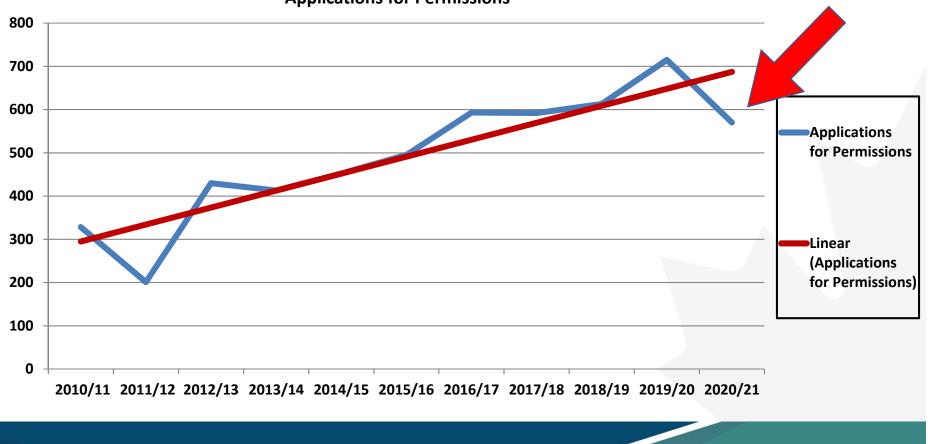
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Applications for Permissions

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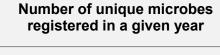


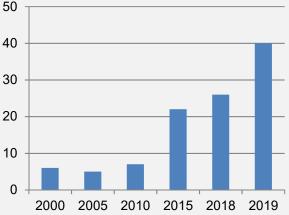
Applications for Permissions

Trends in active submissions

- Long-term impact of regulatory modernization will be until the transition period is over and the full benefits of the new exemption scheme can be realized.
- Increasingly complex and innovative product formulations (e.g. multiple active ingredients and new materials entering the fertilizer stream).

Requests to register supplements containing genetically modified bacteria are becoming more common. Associated safety assessments are much more time consuming and scientifically demanding.

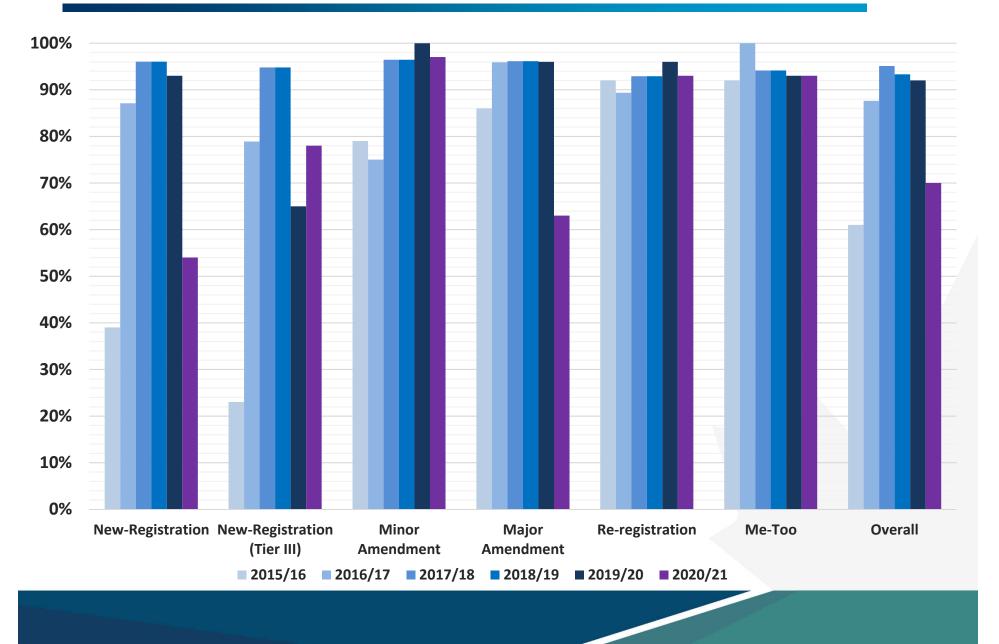




 Ongoing growth and diversification of sector of products marketed for hydroponic use, some of which would have formerly been "specialty fertilizers".

Fiscal Year	10/11	11/12	12/13	13/14	14/15	15/16	16/17	17/18	18/19	19/20	20/21
Total # of Active Files	544	592	386	544	905	685	743	803	977	1,119	1,089
# of Files Meeting SDS	540	568	377	465	544	498	651	751	941	1,035	758
Meeting SDS	99%	96%	98%	85%	60%	73%	88%	94%	96%	91%	70%

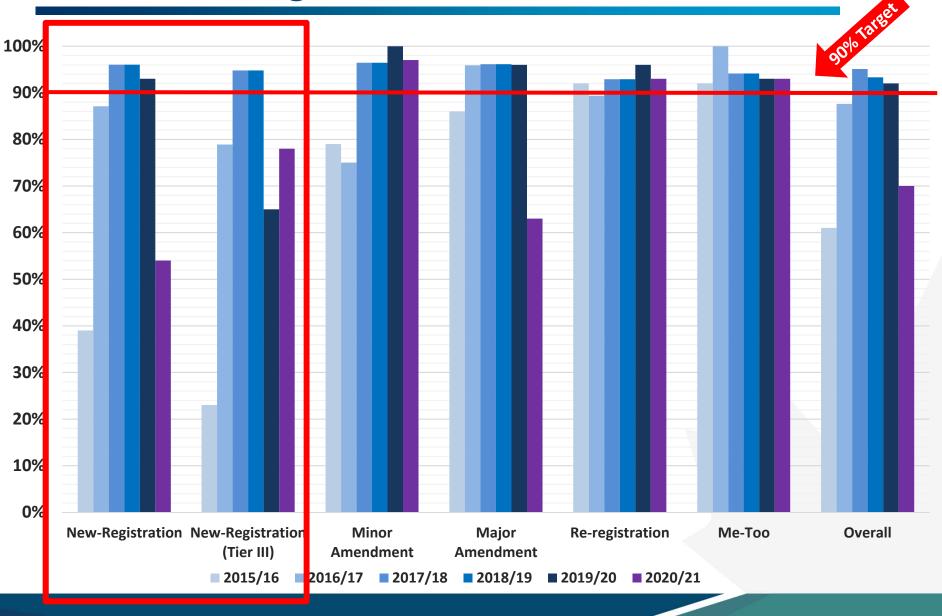
Performance against SDS

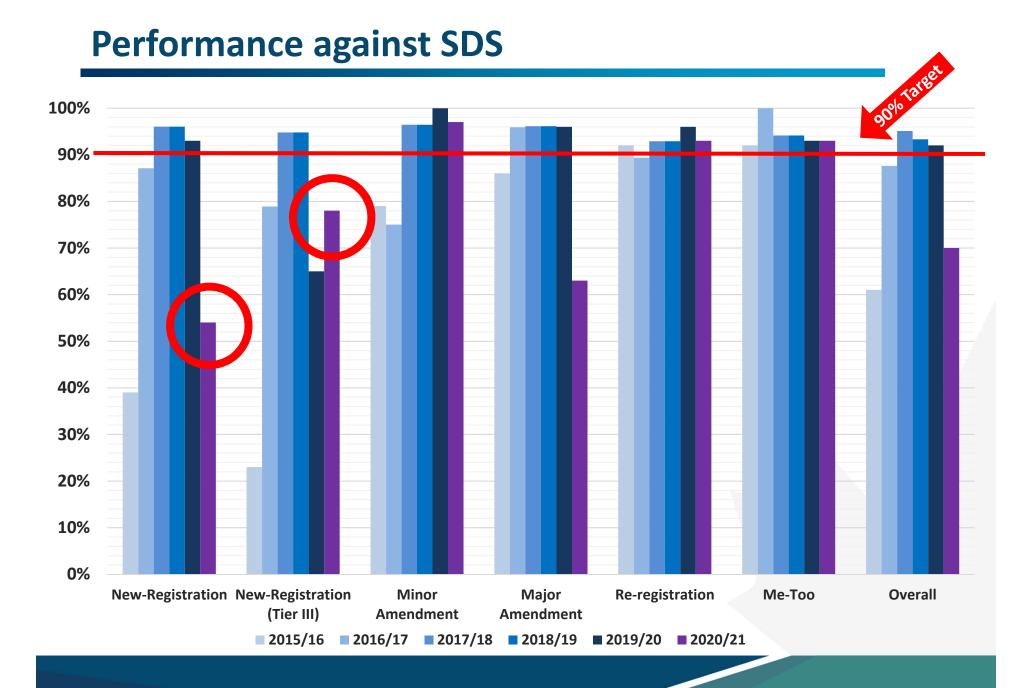


Performance against SDS 100% 90% 80% 70% 60% 50% 40% 30% 20% 10%

0% New-Registration New-Registration Minor Major Re-registration Me-Too Overall (Tier III) Amendment Amendment 2015/16 2016/17 2017/18 2018/19 2019/20 2020/21

Performance against SDS





Performance against SDS 100% 90% 80% 70% 60% 50% 40% 30% 20% 10% 0% **New-Registration New-Registration** Minor Major **Re-registration** Me-Too **Overall** (Tier III) Amendment Amendment

■ 2015/16 ■ 2016/17 ■ 2017/18 ■ 2018/19 ■ 2019/20 ■ 2020/21

Efforts continue

- Ongoing efforts to streamline file review processes and to digitize "legacy" submissions to better support remote work.
- Continuous improvement to user experience in the MyCFIA platform, both internal and external
 - Internal: remove duplication and automate where possible.
 - Bug fixes where issues have been identified by external users.
- Tweaks to industry guidance documentation in response to requests for clarification on modernized regulations + internal and external training material.
- Strict adherence to submission requirements & closing incomplete packages and/or incomplete responses to identified data deficiencies.
- Clear warnings that fees for rejected applications will not be refunded.
- Note: as all files are processed in the order they are received, the quality and completeness of the applications ahead of yours in the queue affect the start time of the review and the processing time.





Ongoing challenges

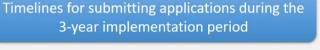
- Incomplete* submissions and deficiencies in the data/information received by the CFIA protract the registration process
 - ➤ (3 reviews vs. 1) → 195 vs. 315 days (CFIA time) for Level I & II New Reg.
- Quality of submissions remains highly variable, with those submitted through MyCFIA generally being poorer than those submitted through legacy channel.
- MyCFIA submissions platform structures submissions and includes links to guidance that explain what is required in each field but applicants don't appear to be following guidance.
 - CFIA is working on implementing WalkMe software
- Frequent on "hold" requests and "extensions" from applicants who do not have key information in advance of applying for registration (e.g. access to 3rd party information) cause delays.
- Changing/revealing new info on product formulations mid-way through the CFIA's review process can invalidate completed review work such changes may result in file closures.
- Operating under two sets of regulations simultaneously. Applicants are asked to ensure they transition to the new regulations as quickly as possible rather than waiting until the old regulations are expiring. We want to avoid a surge of last minute applications when the option to follow the former regulations is about to expire.





A VERY busy year

- Modernized Fertilizers Regulations published on Oct 2020, progress towards full transition continues.
- Ongoing updates to guidance material
 - Implementing ListServ for notifications of each update.
- Polymers: making progress towards conversion of "DS" holders.
 - >80% have submitted applications to register, with ~60% now registered.
- Phosphite: cannot be represented as a <u>fertilizer</u> in Canada
 - Generally regulated as a pesticide under the Pest Control Products Act (regulated as a fertilizer-pesticide under Fzr Act).
 - Phosphite in fertilizers identified as the likely cause of multiple shipments rejected by EU.
 - Undeclared presence in fertilizers has significant trade implications.
 - Ongoing focus of CFIA marketplace monitoring





Exports of pulse crops to EU in 2021							
Сгор	Metric Tonnes	Value (CDN)					
All Pulses	265,589	\$300,769,325					
Beans	138,035	\$174,201,632					
Lentils	88,382	\$97,011,480					
Source: Global Trade Tracker							

Source: Global Trade Tracker

MyCFIA progress

- Work on the electronic submissions platform began in 2017 and continues.
- As Covid19 forced a transition to remote-work, work on MyCFIA intensified.
- MyCFIA Fertilizers live in Oct 2020, supporting modernized Fertilizers Regulations.
 - First stage of release limited to applications for new registrations and research authorizations under the modernized regulations.
 - Work to onboard remaining permission types continued.
- Uptake has been slow:

November 1, 2020 - November 30, 2021	Adoption rate			
Applications for New Registrations	50%			
Research related applications	49%			
All permissions	50%			



- Partial launch of fertilizer service platform is cited as a major cause
- MyCFIA updates:
 - Electronic applications for renewals and amendments NOW LIVE!
 - E-billing changes (on-account transaction floor being removed)
 - Guidance for consultants pending publication.
 - WalkMe mentioned earlier

Contacts and Questions

http://inspection.gc.ca/eng/1299165827648/129 9165914316

Pre-market Application Submissions Office

Canadian Food Inspection Agency 59 Camelot Drive Ottawa, Ontario K1A 0Y9

E-mail: <u>cfia.paso-bpdpm.acia@canada.ca</u> Phone: 1-855-212-7695 Fax: 613-773-7115

