



AURORA[®]

Cannabis Pesticide Residues: Regulatory Overview in Canada

2019 MRL Harmonization
Workshop
May 29, 2019

Disclaimer

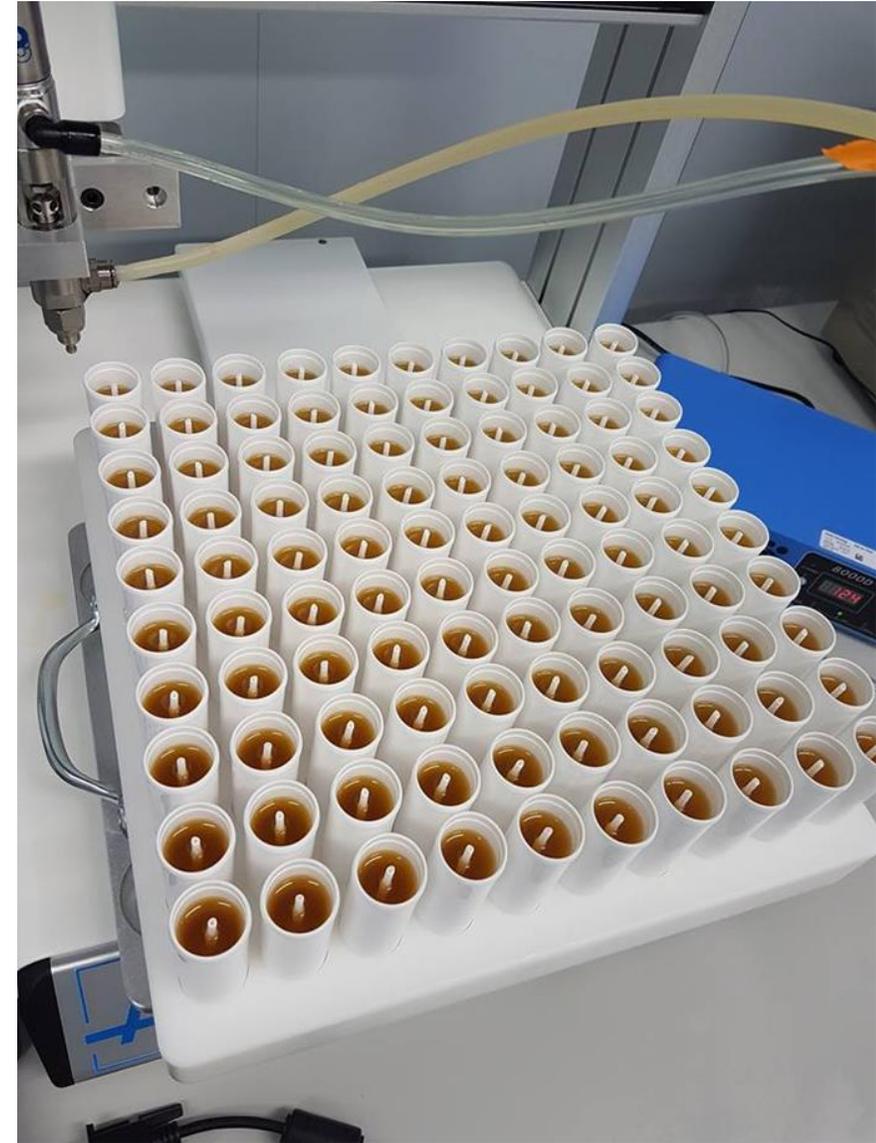
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Cannabis Market

- Cannabis is **rapidly undergoing change** in its regulation, production and use in various jurisdictions – **here to stay**
- Cannabis is arguably now the **fastest growing agricultural sector in the world** with new and innovative products entering the market or in development.
- The global cannabis market is expected to reach a value of **\$70+ US billion per year by 2025**
- Canada is now the **largest federal seller** of cannabis in the world



Aurora:

Mission: “To develop and sell world class quality cannabinoid products to patients and consumers globally”

Vision: “Define the future of cannabis globally”



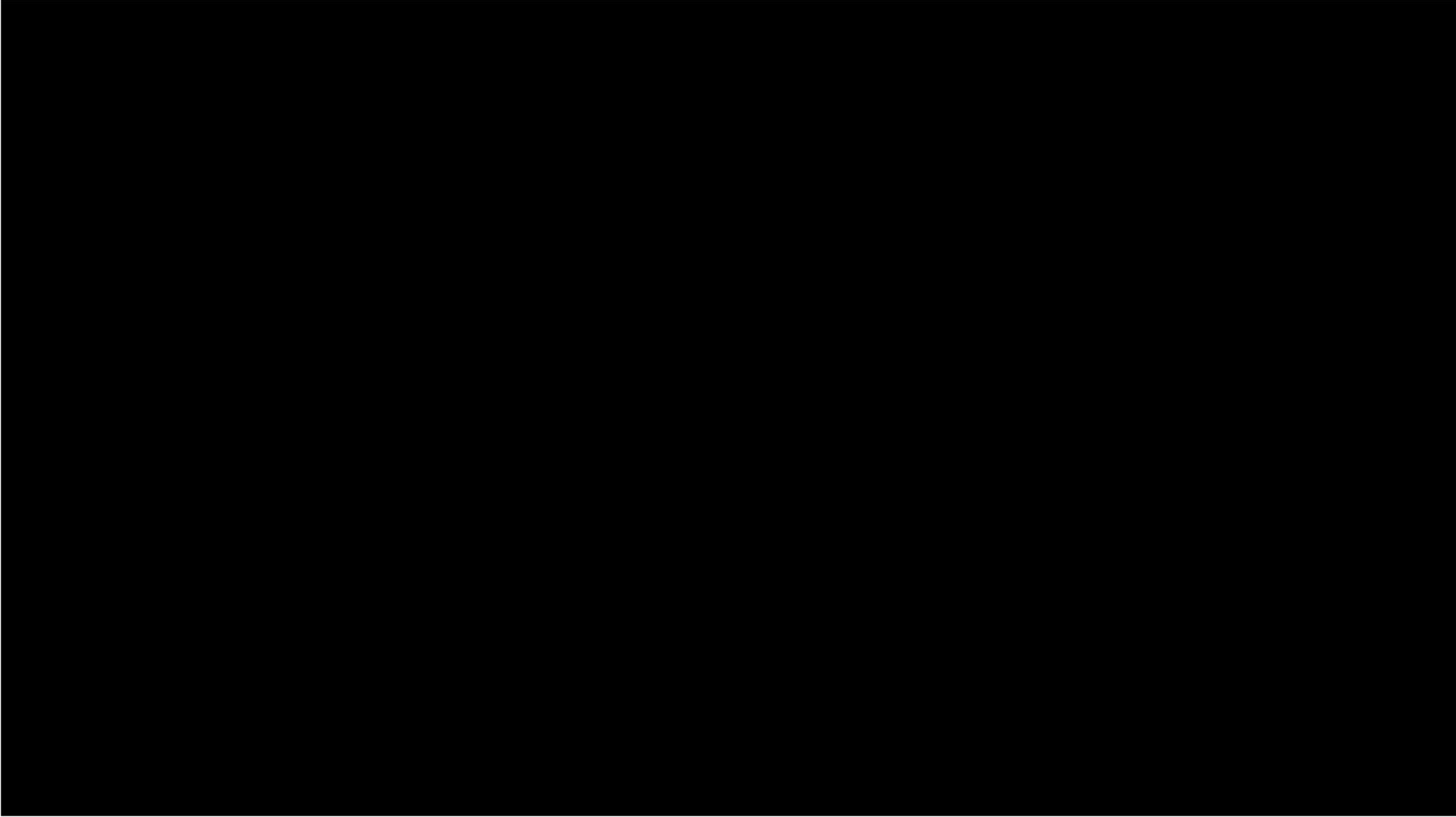
AURORA AT A GLANCE

- A Leader in the Global Cannabis Industry
- Sector Leader in Technology Across Operations and Product Development
- Active in **5** Continents and **24** Countries, **2,400+** staff
- Leading Medical Market Share in **Europe** and **Latin America**
- **17** Global Production Facilities⁽¹⁾ with **3 EU GMP** Certified⁽²⁾
- **15** Strategic Acquisitions Across the Value Chain since August 2016
- **40** Clinical Studies Underway or Completed⁽³⁾ and over **83,000** medical patients being served

1. Excludes facilities from the recently closed ICC Labs acquisition.

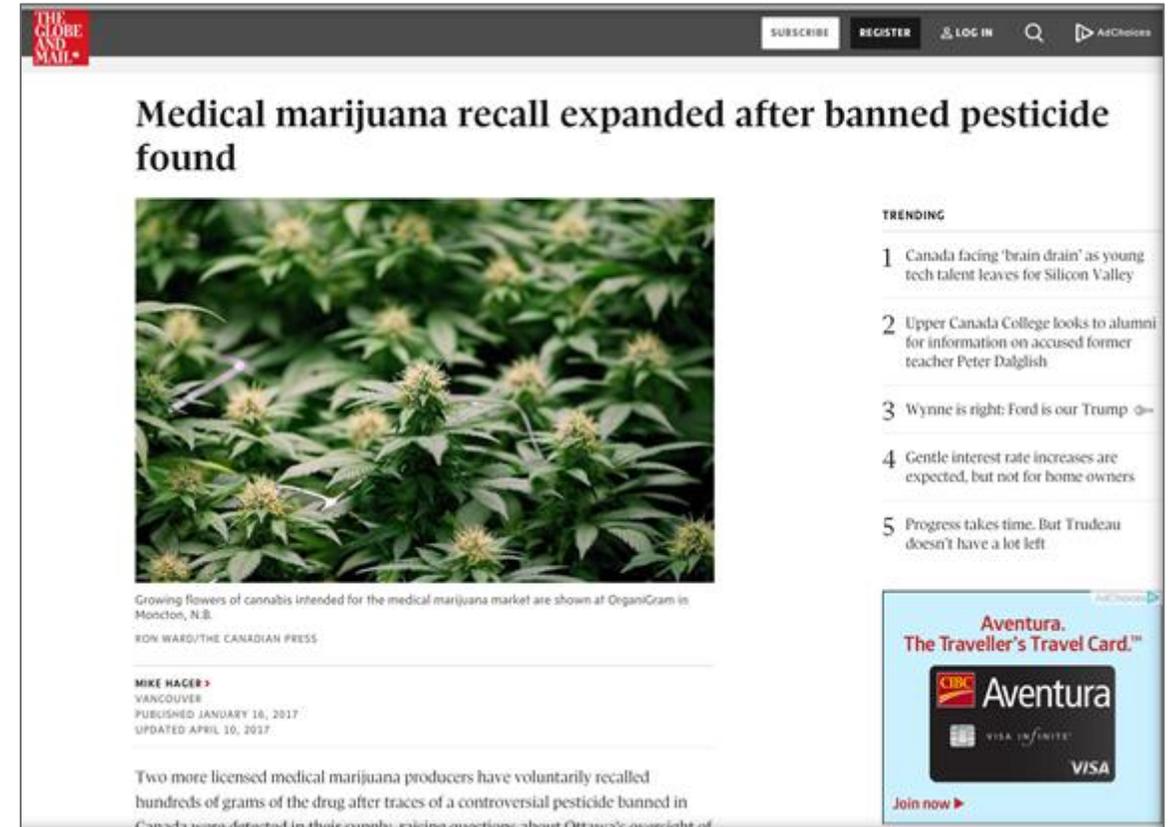
2. Includes 2 production facilities in Canada and 1 European distribution center.

3. Studies include randomized clinical trials and observational studies in addition to several case studies.



Plant Health Protection is Important

- High media attention
- Larger production levels
- Outdoor Growing now allowed: increased use of plant protection products likely & drift
- Greater final product ranges (edibles, etc.)
- Increased Imports and Exports
- Home grow has no inspection or enforcement



The screenshot shows a news article from The Globe and Mail. The headline is "Medical marijuana recall expanded after banned pesticide found". Below the headline is a photograph of cannabis plants. The article text indicates that two more licensed medical marijuana producers have voluntarily recalled hundreds of grams of the drug after traces of a controversial pesticide banned in Canada were detected in their supply. The article is by Mike Hager, published on January 16, 2017, and updated on April 10, 2017. On the right side of the page, there is a "TRENDING" section with five items, and an advertisement for the Aventura Visa Infinite credit card.

THE GLOBE AND MAIL SUBSCRIBE REGISTER LOG IN Ad Choices

Medical marijuana recall expanded after banned pesticide found



Growing flowers of cannabis intended for the medical marijuana market are shown at Organigram in Moncton, N.B.
KON WARD/THE CANADIAN PRESS

MIKE HAGER VANCOUVER
PUBLISHED JANUARY 16, 2017
UPDATED APRIL 10, 2017

Two more licensed medical marijuana producers have voluntarily recalled hundreds of grams of the drug after traces of a controversial pesticide banned in Canada were detected in their supply, raising questions about Ottawa's oversight of

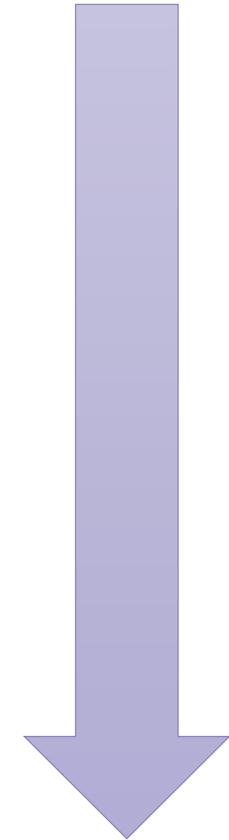
TRENDING

- 1 Canada facing 'brain drain' as young tech talent leaves for Silicon Valley
- 2 Upper Canada College looks to alumni for information on accused former teacher Peter Dalglish
- 3 Wynne is right: Ford is our Trump
- 4 Gentle interest rate increases are expected, but not for home owners
- 5 Progress takes time. But Trudeau doesn't have a lot left

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Canada: Brief History

2013



Today

- HC sets zero tolerances for unapproved pesticides but no testing requirements (MMPR: **regs 2013**)
- HC fails to define zero for pesticide testing & HC tells LP to define zero and reporting limits themselves
- News media on LP pesticide recalls and Some LPs implement voluntary pesticide testing (**Late 2016**)
- HC/PMRA undertakes pesticide testing on random LPs (**March, 2017**) without validated testing method or sampling SOPs
- HC uses 10 ppb as “action level”/ “zero” (no consultation with industry)
- HC consults with industry on pesticide policy (one day session, **June 2017**)
- HC publishes draft pesticide policy in **January 2018** for comment
- HC announces plans for \$1M fines for use of unapproved pesticides use in cannabis
- HC publishes pesticide policy, effective **Jan 2, 2019** – strictest in the world

Canada vs California

Canada

Not treated with pest control product unless the product is registered for use on cannabis under the *Pest Control Products Act* or is otherwise authorized for use under that Act

California

Must be exempt from US EPA's residue tolerance requirements

AND

FIFRA 25b exempt

OR

Label must be broad enough to include cannabis

	Canada	California
Mandatory testing	96	66
Limits	Very low	low
Limit Policy	Quantification	Health Risk

Approved Pest Control Products in Canada:

Registration Number	Registrant Name	Product Name	Registration Status
26854	AEF GLOBAL INC*	BIOPROTEC CAF	REGISTERED
27115	BIOWORKS INC.*	ROOTSHIELD HC BIOLOGICAL FUNGICIDE WETTABLE POWDER	REGISTERED
27886	W. NEUDORFF GMBH KG*	NEUDOSAN COMMERCIAL	REGISTERED
28095	BIOWORKS INC.*	MILSTOP FOLIAR FUNGICIDE	REGISTERED
28146	OMEX AGRICULTURE INC.*	OPAL INSECTICIDAL SOAP	REGISTERED
28820	DANSTAR FERMENT AG	PRESTOP	REGISTERED
29320	LAM INTERNATIONAL CORPORATION	BOTANIGARD ES	REGISTERED
29321	LAM INTERNATIONAL CORPORATION	BOTANIGARD 22 WP	REGISTERED
29508	BIOSAFE SYSTEMS, LLC*	ZEROTOL BROAD-SPECTRUM ALGAECIDE/FUNGICIDE	REGISTERED
29890	BIOWORKS INC.*	ROOTSHIELD(R) WP - BIOLOGICAL FUNGICIDE	REGISTERED
30110	AEF GLOBAL INC*	LACTO-SAN	REGISTERED
30199	MARRONE BIO INNOVATIONS INC.	REGALIA MAXX BIOFUNGICIDE LIQUID CONCENTRATE	REGISTERED
30345	GREENSTAR PLANT PRODUCTS INC.*	AGROTEK VAPORIZED SULPHUR	REGISTERED
30459	AEF GLOBAL INC*	CYCLONE	REGISTERED
30539	BIOWORKS INC.*	ROOTSHIELD® PLUS WP BIOLOGICAL FUNGICIDE	REGISTERED
30692	AEF GLOBAL INC*	INFLUENCE LC	REGISTERED
31091	AEF GLOBAL INC*	SIROCCO	REGISTERED
31231	ANATIS BIOPROTECTION INC.*	BIO-CERES G WP	REGISTERED
31433	W. NEUDORFF GMBH KG*	KOPA INSECTICIDAL SOAP	REGISTERED
31989	BIOWORKS INC.*	BW240 WP BIOLOGICAL FUNGICIDE	REGISTERED
32408	W. NEUDORFF GMBH KG*	VEGOL CROP OIL	REGISTERED
32425	AEF GLOBAL INC*	BIOPROTEC PLUS	REGISTERED
32819	753146 AB LTD. O/A ULTRASOL INDUSTRIES	DOKTOR DOOM FORMULA 420 PROFESSIONAL USE 3-IN-1 CROP & PLANT RESCUE CO	REGISTERED
33347	INTELLIGRO	PURESPRAY FX	REGISTERED

Pesticide Testing Limits in Cannabis:

3.0 Limits of quantification of the mandatory testing for pesticide active ingredients in cannabis products

Active ingredient	Limits of Quantification in parts per million		
	Fresh cannabis and plants	Dried cannabis	Cannabis oil
Abamectin	0.25	☒	0.25
Acephate	☒	0.020	0.050
Acetamiprid	0.050	0.10	0.050
Acequinocyl	☒	☒	☒
Aldicarb	0.50	1.0	0.50
Allethrin	0.10	0.20	0.10
Azadirachtin	0.50	1.0	0.50
Azoxystrobin	0.010	0.020	0.010
Benzovindiflupyr	0.010	0.020	0.010
Bifenazate	☒	0.020	0.010
Bifenthrin	0.10	☒	☒
Boscalid	0.010	0.020	0.010
Buprofezin	0.010	0.020	☒
Carbaryl	0.025	0.050	0.025

Case Study:

- HC allowed plants to purchased from MMAR system
- Mother plants kept for several years due to severe space constraints and up to 6 months plus for licence amendments
- Health Canada refused to provide guidance
- No HC validated methods for testing different matrices
- Voluntary testing established at 4 times less than lowest global regulatory level with lab that tested the most pesticides (50 PPB)
- HC tested live plants (including mothers): results 11 to 23 PPB
- No Health Risk Assessment completed
- Type III Recall (because that is what HC did prior)
- New HC policy would mean 90% of recall not required

Lessons:

- HC fell into the regulatory policy trap of “zero tolerance”
- HC cannot “test” themselves out of this issue
- Current approach is unsustainable
- Label changes are the only long term solution



Proposal:

- For Canada label owners need to be open to adding cannabis to label
- PMRA needs to prioritize User Requested Minor Use Label Expansions (URMULE) for cannabis
- AAFC and PMRA need to make cannabis pest management a priority for the Minor Use Pesticides Program (MUPP) (2017 AAFC Minor Use Pesticide Priority Setting Workshop refused to make medical cannabis a priority as “wasn’t legal”)
- Pesticide and cannabis industry organizations will need to coordinate efforts
- Joint development of specialized plant protection best practices program for cannabis industry

Thank you / Merci

Questions?

twitter  @DrShaneMorris