

Cannabis Edibles Research & Development Discussion

ON-LINE ROUND TABLE HELD SEPTEMBER 17, 2020

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This round table was a collaboration between Prairie Research Kitchen and Bioscience Association Manitoba as an effort to bring interested stakeholders together to build a robust and active cannabis research community. The intention is to ensure industry knows about the resources available and the researchers understand the needs of the industry. We look forward to building these relationships and building on the strengths of our bioscience community in Manitoba.

We would like to thank Kelley Fitzpatrick, NutriScience Solutions and Leanne Tibbatts, Manitoba Agriculture & Resource Development for their help with this session.

Keynote speaker, Sid Hathiramani, CCI Deloitte, provided an overview of the Cannabis Edible market at the start of the session. His presentation is also available for distribution to the participants of this round table.

Purpose of the Session

- Discuss the current state of the cannabis edibles industry
- Facilitate information sharing related to cannabis edibles research and development
- Identify available equipment / resources within Manitoba
- Discuss areas that could accelerate industry growth
- Brainstorm next steps to leverage opportunities, engage other stakeholders and capitalize on strategies to make Manitoba the province of choice for cannabis edibles research and development
- Roundtable is a follow-up to a February 2019 meeting which focused on R&D and commercialization capacity in Manitoba.

Manitoba Ag and Resource Development Funding and Resources

**Manitoba Agriculture and Resource Development
Business Development Specialist
Food and Agri Product Processing
Shauna McKinnon (Shauna.McKinnon@gov.mb.ca)**

- We are part of the Department of Agriculture and Resource Development
- We are experienced business advisors located across Manitoba
- Our services are free: provide training, regulatory path-finding and resources to agri-food and agri-product (cannabis/hemp) entrepreneurs, processors and organizations
- The Government of Manitoba has made the processing hemp and cannabis an economic development priority
- The Economic Growth Committee of Cabinet has developed a Provincial Cannabis Strategy
- Agriculture and Resource Development (ARD) is leading the initiative
- One of our current initiatives is a lobby effort, working with industry associations and the other provinces, to have Health Canada loosen the regulations around CBD and its sale and processing
- ARD's diversification centres are conducting variety trials to develop high CBD hemp strains
- ARD provides access to funding programs for market development and capital equipment purchases

Ag Action MB for Agri-Processors

- Provides grant funding (non-repayable) for:
 - Capital assets and equipment
 - Equipment related to extraction or value-added processing of hemp and cannabis products
 - Equipment related to preparing, producing, or packaging product
 - Expenses related to getting the equipment to your location: freight, physical and professional installation, and training
 - 2 funding streams – projects over and under \$1.0M
 - Maximum 25% cost share to maximum \$500K depending on project size

Market development

- Supports activities related to entering a new market
- Cost Share: 50:50
- Funding Cap: \$20,000 per year
- Minimum Project Size: \$3,000

Overview of Manitoba Research Capacity Presentations

Prairie Research Kitchen

Red River College

Mavis McRae mmcrae30@rrc.ca

- Industries Served: Food Production & Food Service
 - Product ideas & prototypes
 - Formula and process optimization
 - Ingredient utilization
 - Food styling & photography
 - Consumer trials
 - Specialized training
- Chef-driven, Science-backed
 - The chefs in the labs will work on food product development for cannabis edibles, including “prototyping” and clinical trials.
 - Access to 16 chefs & bakers within the culinary school
 - Access to scientists on staff and in RRC Life Science department
- Affordable research
 - student participation
 - benchtop prototypes
- Access to college specific grants
- Cannabis Research License applications (pending)
- Culinary research lab
- Processing trials, extracts (bench scale)
- Prototype development in edibles and topicals
- Test method development
- Genetic analysis

The Food Development Centre (FDC)

Alphonsus Utioh Alphonsus.Utioh@gov.mb.ca

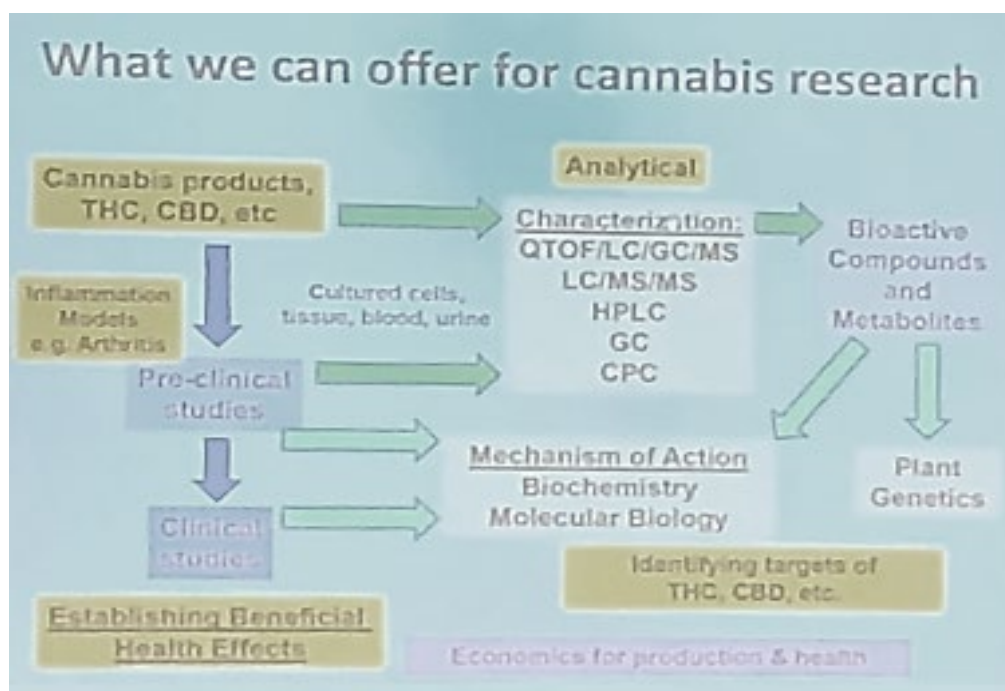
- The Food Development Centre (FDC) has a Canadian Cannabis License for Research Use Only
- FDC has had Industrial Hemp License since 1999
- Focus on using existing supercritical fluid extraction suite for the extraction of cannabinoids, terpenes, oils, waxes and other plant material
 - Anticipate doing extraction work on cannabis and hemp. It is a small unit that uses CO2 and can handle 5kg of material at a time. We use this to verify the chemical components and process to extract the desired component.
- Develops capabilities in cannabis processing co-products into higher value added products, particularly with the biomass generated from CBD oil extraction
- Development of edibles with CBD oils based on existing capabilities in conventional food development will be included in FDC services
- FDC will liaise with Health Canada on cannabis edible regulations
- Health Canada license allows the facility to hold a maximum of 1000 grams of both raw material feedstock and finished extracted ingredient for research.

Canadian Centre For Agri-Food Research in Health & Medicine
(CCARM)

Food & Nutritional Sciences at University of Manitoba

Dr Michael Aliani

- Research offered:



- Link plant bioactives with their biological effects and determining their potential for improving health
 - Analytical Expertise: QTOF LC/QC/MS, NMR, LC/MS/MS, HPLC, GC/MS, CPC
 - Cell Culture & Animal Models: Obesity, Diabetes, Cardiovascular disease (CVD), Renal disease, Fatty liver disease, Inflammation
 - Biological Tools: Biochemical, Molecular, Immunological
 - Food & Human Trials: Flax – Blood pressure & CVD; Lentils – CVC; Peas – Diabetes; Beans – CVD; Canola - Obesity
- St. Boniface:
 - Basic Research Lab (Albrechtsen Research Centre)
 - Asper Clinical Research Institute

Research:

- Mass spec database contain over 250,000 compounds
- NMR database with over 1700 compounds for use in analysis
- Sensory evaluation of Cannabis edibles (UMB License in progress)
- Analysis of 14 Cannabinoids by MS and NMR
 - important to know how they are modified in the body and bioactivity in edibles.
- Metabolomics Studies of Cannabinoids and THC-Related Compounds in urine, tissues and blood samples

The Richardson Centre for Functional Foods & Nutraceuticals (RCFFN)

Dr. Michael Janzen

- The core capacities of dry fractionation, tableting, capsule filling and human nutrition testing are performed within the Centre at both lab and pilot scale.
- The remaining core capacities of food ingredient functionality, protein quality, oilseed extraction and extrusion cooking flow through University Faculty members research labs, either here at the RCFFN or within the Department of Human and Nutrition Sciences; these tests are typically performed at the laboratory scale.
- The Dry Fractionation Facility at the RCFFN is an 800 sq ft² room.
- We have both lab-and pilot-scale equipment; 3 lab-scale mills – ball mill, centrifugal mill and a rotor beater mill
- Pilot scale equipment - Satake debranner, prater impact mill with 4 different screen sizes such that flours with differing particle size distribution can be milled; prater air classifier which can generate protein concentrates with increased protein content.
- The Centre has tableting and capsule filling capacity
 - have the capacity to assist in formulation development (for example in selecting binding agents, gliding agents or flavouring agents) and then to manufacture on a small to medium sized scale for further R&D purposes.
 - capacity to manufacture capsules containing a food ingredient. We have the capacity to manufacture 2 different capsule sizes '0' and '00'.
 - '0' capacity: depending on ingredient density – 450 to 800 mg
 - '00' capacity: depending on ingredient density – 300 to 500 mg
- The Centre has expertise in cardiovascular health, body composition, post-prandial glycemia, appetite, food intake & endurance testing. Dr. Semone Myrie Lab
- Food Functionality Testing. Rotimi Aluko Lab
- Protein Quality Testing. James House Lab
- Food Ingredient Extraction & Testing - Usha Thiyam-Holländer & Trust Beta Labs
- Extrusion Cooking. Filiz Koxsel Lab
- RCFFN is unique for innovative R&D works on food products (fundamental scientific research plus bench to semi-pilot plant scale) complementing the activities of FDC and RRC.

Roundtable Poll Questions

13 responses per question

a. What are the 3 biggest challenges facing the Canadian cannabis edibles industry today?

- Consumer misinformation 2
- Overconsumption/safety 0
- Regulations 9
- Taste 2
- Quality control 2
- Black market 4

b. Do you feel Manitoba is in a position to be a leader in the cannabis market?

- Yes 6
- Not sure 7
- No 1

c. What are the top priorities moving forward?

- Regulations 8
- Research capabilities 2
- Clinical trials 1
- Quality control 0
- Commercialization 2

Roundtable Discussion: Key Points and Recommendations

The group was divided into 3 breakout sessions. Moderators included Mavis McRae, Kim Kline and Kelley Fitzpatrick who lead the group through a series of questions. Key points and overall recommendations are captured here.

RECOMMENDATIONS

These recommendations include key highlights from the discussion of questions that follow under “**LOOKING AHEAD**”.

- What resources should be added to the provincial capacity?
- What do other provinces offer that we need to consider?
- What are you sourcing from other provinces? Why?
- What is holding back the cannabis industry in Manitoba to capitalize on new opportunities?

Provincial Consortium

- Establish a provincial consortium of producers through to retailers including key researchers and consumer groups, to drive legislative change in the province. Act as a quasi-lobby group that would provide policy advice in such areas as challenges with licensing, standardization, capital, funding etc.
- Include research recommendations as well as lead and inform on distribution and logistical challenges and opportunities for beneficial changes to regulations at the provincial and federal government levels, to aid industry growth and development.
- Consortium could be structured within a trade association or through one of the Chambers of Commerce. Consortium could work with similar groups nationally to drive change with federal government legislation.

Action Items for Consortium:

- Develop a strategy for cooperation at all levels of the industry, research and consumers.
 - a. Include priority research areas for potential funding applications.
- Encourage policy initiatives necessary to provide a level playing field for allowable CBD **levels** in various product formats.

- Determine the potential of a processing license to support small scale production as part of commercializing efforts.
- Work with the provincial authorities to develop a comprehensive database to inform industry as to how to capitalize on opportunities and with governments at all levels to better understand the industry and its needs. Map out the funders, scientists, industries, organizations etc. and their role and support mechanisms.
 - a. A summary of the municipal processes required (zoning, consultation, etc.) and a roadmap of funding/grants available to provide some direction to those interesting in entering the market would be helpful

Regulations

- Work with Health Canada to update and relax regulations recognizing advances in public safety to encourage the legitimacy of the legal market and discourage consumer purchase from the illegal back market.
- Encourage mechanisms for supporting and developing consumer education, without the threat of illegal medical information being used for claims.

Research

- Industry requires scale-up facilities for developing products from basic CBD extractions where various formulations can be developed and assessed prior to scaling to large production.
- Encourage collaboration by developing potential collaborative research activities which could serve as the basis of a focused research application and /or formal initiatives for cannabis.
- Across all areas of priorities from production through product development, commercialization and consumer education, seek funding for high priority areas of benefit to the MB industry. This kind of initiative can also provide more credibility for the industry as it seeks research funding, capital and investments overall.
 - Collaborative applications with a number of research entities and industry players is more attractive to funders and investors than individual applications.
- Consider a model similar to the former (provincial government funded) MB Agricultural Research Health Network to facilitate networking and outreach of the research community with industry in MB. This entity would work with the consortium and act as an information conduit for all stakeholders involved in cannabis in MB.
- Capitalize on the strengths MB research capacities, the capital that has been invested and the expertise of the industry through communications to government and consumers.

Clinical

Provide / encourage support for

- Adequate funding for collaborative research projects
- Connections between agricultural research, fundamental research and clinical trials
- Multi-disciplinary approaches to all aspects of research into edible cannabis products
- Further dialogue with researchers and industry.

Quality

- With provincial government support, industry and research community working together to establish quality standards for products – from production through to retail and end-user.
 - A model similar to the United States Pharmacopeia which develops and publishes standardized test methods, to reduce differences between the labs and facilitate the development of high-quality edibles.

Commercialization

- Consortium to work with edibles Manitoba LGCA for improvements in distribution and logistics. Use examples from jurisdictions that have more industry friendly regulations.

ROUNDTABLE DISCUSSION SUMMARIES

REGULATIONS

- What concerns or questions do you have with regard to regulations?
- Are regulations a barrier or an advantage in marketing cannabis products?

Advantages:

- Retail transparency provides an opportunity to educate consumers and a barrier to entry to low quality products.
- Creating a high barrier to entry to convince the consumer that this is a safe product and they can be comfortable with using it.
- Biggest differentiator between the legal and illicit market, and the advantage the legal market has, is transparency. You know product potency, the ingredients, etc. You know that if something goes wrong, there are insurers behind these companies that can provide compensation if appropriate.

Issues:

- Regulations are a barrier and a challenge.

- The amount of CBD and THC allowed in different edible product formats is inconsistent and far too low – offering limited efficacy and potency.
 - Forcing consumers to purchase many products to achieve effect – however this is often cost prohibitive
 - You would need to consume 5 beverages to meet recommendations – contrary to other CBD products
 - Limited to purchase five drinks and not be able to buy any other cannabis products at the same time
 - Consumers constrained with the number of (low potency) products that they can purchase – becomes price prohibitive and makes black market items more attractive.
- Regulations a huge bottleneck right now due to concerns from Health Canada with regard to overconsumption, safety, etc. Health Canada created a very complicated schedule of the different types of cannabis products, including edibles with a number of different subcategories.
- Regulations are not meant for consumer protection because five two mg drinks, drank at once, would equate to ten milligrams. Whereas if you were to buy a green or organic infusion powder, a 10-milligram potency powder, which comes in a little sachet the size of a sugar packet, there seems to be no limit to the number you can buy.
- It seems that Health Canada has equated the weight of the product to the dry grams of cannabis which is a mistake.
- Because of these inconsistencies, black market is still an issue (around 50 percent of the cannabis consumed is still coming from the black illicit market).
- Producers are challenged with very high fees by Health Canada which makes the products too expensive and difficult to achieve a competitive price point for the consumer. It's very important to grow high quality production to yield high quality products.
- Marketing restrictions are definitely very hard for individual producers and individual cannabis companies to deal with in terms of differentiating the products and consumer education.
 - Some companies seem to have been more creative in pushing the boundaries and where gray areas exist.
- Maybe more potential internationally when it comes from a marketing of product – a company should think globally and while ensuring safety, quality and purity. However, regulatory authorities in different countries can be challenging.
- Adhering to many of the regulations requires a lot of expertise – almost to the level of biopharmaceutical which is limited in Manitoba.
- Health Canada in some regard took the worst of different regulatory regimes, i.e. marketing restrictions from tobacco packaging, consumption etc. with the guise of public safety, in order to limit marketing and communications. Need to have such a different approach for cannabis than tobacco or alcohol, for example.

- Regulatory approvals are very lengthy to receive for companies and from the research standpoint.
- A challenge with research license is the limitation that Health Canada places on the amount of product, one kilogram of biomass, for use in extraction. The amount of CBD or THC that is allowed in the research license is too tight.

RESEARCH CAPABILITIES

- What research capabilities should be added in Manitoba to support industry?
- Are there research capabilities in other provinces that you access and/or that should be available in Manitoba?

Advantages:

- Overall MB has excellent RD capability in product development, prototypes, clinical, test methods, quality, sensory, formulation.

Issues:

- Industry requires more early stage processing RD capability
- FDC has been able to provide the extraction of CBD
 - Need for an intermediate scale facility to allow development of products beyond the extraction process (formulation, taste etc.)
 - Require enough quantity for companies to be able to use in applications-based testing and market research
 - Once the initial research is completed, there is no facility to refer companies for further testing and product development (there is one company in Alberta that does this).
- Underdeveloped mechanisms to link research community with the industry
 - Need to coordinate the research activities in the province.
- Barrier is lack of info and data on the MB market landscape – would benefit industry to have market landscape data
 - i.e. entry data such as min, max pricing of products, retail locations, consumer demographics, sensory analytics, maximum CBD, THC for various product types? What is selling in different retail stores across the province? Who are primary processors, edible manufacturers, retail stores? What do the consumers want in terms of a format of cannabis as well as potency and different strains?
- For producers, there is limited genetics x environment data for quality, quantity - research around different environmental conditions, microclimates to understand what's suitable to grow and where.
 -

- Better understanding of what the retailer wants in a strain and a better way to connect all these variables to provide a better feedback communication system for a superior experience for the consumer.
- Taste is a huge issue and there is a lot of room for improvement
 - Bitterness is very important, quite difficult, very challenging to mask. Masking agents may negatively impact the stability, efficacy and functionality of the cannabis through interfering with the chemical structure of the compound of interest.
- Very limited sensory testing available – often done by companies with own employees, which is not adequate, and many not able to reformulate based on sensory results.
- Several MB research facilities have not received a research license from Health Canada.
- Further research on the by-product of CBD extraction, what can be developed from the hemp flower, leaves, etc. What are the economics of developing by-products.?

CLINICAL TRIALS

- Is there a desire from industry to have clinical trials in Manitoba?
- What challenges face those that wish to conduct clinical trials in Manitoba? How can they be addressed?
- Are there collaborative clinical trials or research areas of interest to the industry in general? E.g. impact of cannabis on insomnia

Advantages:

- MB has capacity of clinical trials.
- There is a desire from industry to conduct clinical trials in MB
- Unique clinical research capabilities at the University of Manitoba and at St. Boniface
 - St. Boniface can perform clinical studies on sick patients in a hospital setting, whereas the RCFN can do trials on both healthy and unhealthy populations – both of which to determine the efficacy of these products
 - However, the industry needs further clarification on the strengths of each facility
 - Also, when working together there is more credibility when holding industry funds.
- There is encouraging data being generated in pre-clinical trials regarding the beneficial impacts of CBD on reducing the side effects of chemotherapy (vomiting, nausea)
- Some safety clinical data is available, but efficacy seems to be a bit lacking.

- An extensive health related database exists in MB existing health with over seventy-five hundred individual electronic medical records, which is a gem for research in cannabis and for the industry, not just nationally but globally. This is a resource that the medical community would like to work with provincial stakeholders to capitalize upon.
- Nano emulsions are a technology that industry is looking toward to stabilize effects of CBD in the body i.e. providing a gradual release of the CBD following consumption of a product. This is a positive step from a pharmacokinetic standpoint, may help mitigate some risk associated overdosing, etc.

Issues:

- Funding severely lacking for longer term research including financial support from industry especially for clinical studies.
- Research community in health and medicine not fully engaged, few clinicians are trained or knowledgeable about CBD.
- The retail market is driven by THC and CBD – a lot of unknowns in terms of the secondary cannabinoids and their therapeutic utility
 - Require research on effects/actions of different formats of CBD in edibles as well as in comparison to vape; what happens to efficacy when its digested in a different form. It might interact in the body in a different way – need a better understanding of food and CBD /THC interactions
 - We need to better ensure that patients understand which cannabinoids they should be taking for what type of indication, whether its chemotherapy induced nausea, vomiting, Type two diabetes, appetite control, etc.
- Very expensive with limited IP available due to the history of cannabis. Competitors can use your research findings without IP protection
 - Limited utility to clinical trails as medical claims not allowed on CBD.
 - Very limited in the type of information that can be provided to a customer and must be very cautious as to providing any type of medical advice. Some stores have close proximity to medical clinics that can assist with consumer education– this is an advantage that many retailers do not have access to.
- Is a new class of drugs necessary to make CBD related claims? A “cannabis class of drugs”, where medical claims may be allowed
 - Perhaps a separate pathway similar to a natural health product that would at least allow Health Canada to approve health related claims supported by research.
- Require research on the endocannabinoid system in the body and the levels/types of CBD and THC in the plant and product

- i.e. two different strains of cannabis that are both 20 percent THC yet produce different effects because of the other cannabinoids present.
- Need more data on interactions of different types of products, different cannabinoids, different profiles and terpene profiles for various conditions
 - I.e. some of those clinical studies use oil as a whole even though not all CBD oil are the same; need to understand the characteristics of the fractions.
- Formulation will affect the chemistry and thus the efficacy of various CBD and THC in an edible.
- Challenge is recruiting people. Ideal if license holders have patient populations available for clinical studies.

QUALITY CONTROL

- Are you experiencing issues related to quality in edibles and topicals?
 - e.g. consistency, formulation
- What tools can be used to mitigate risks related to quality?

Issues:

- Edibles can have significant challenges with stability which can be related to quality control. In part this is because of the “newness” of the category and the lack of information available and being provided to stores on stability data, storage, temperature controls, packaging effects on compounds and on stability, etc.
- Need high quality product to start with for processing
 - Unfortunately, this new area is a quick way to profit for some without considering things like pharmacokinetics, taste profiles, stability, etc.
- Quality consistency in formulation, are the levels of CBD on the label actually in the product?
 - One reason to have disciplined quality control.
 - Batch to batch inconsistencies can be a problem
- There are lot of gaps in the quality management systems of many companies. They've tried to do so many things too quickly. The onus is on the license holder to make sure that they've mitigated their supply chain risk.
 - Perhaps using specialized third-party risk management, supply chain risk quality agreements to mitigate quality risks.
- Need for industry-wide standardized methods.

COMMERCIALIZATION

- Are there barriers in the commercialization of cannabis products?
- Consider the challenges, roadblocks, or threats that need to be addressed or solved (in Manitoba and globally).

Background (Manitoba) Liquor Gaming Cannabis Authority (LGCA) Regulatory Framework

- Provincial agency responsible for licensing and inspecting retail stores and for public and retail employee education and training.
- Licensing retail cannabis stores, conduct due diligence, inspection of premises
- Manitoba has control over the number of retailers in the space
- Manitoba is the only province without a cannabis secretariat

Issues:

- MB distribution and logistics system is a barrier and challenge
 - LGCA doesn't have the capacity to review registration requests or to list products – huge barrier to commercialization
- Multiple cannabis companies have noted that is very difficult to enter the Manitoba market, to have their products listed with retailers and provide retailers the opportunity to purchase them.
- Manitoba regulations require producers to ship directly to every single retail store (only about 30 stores at present)
- Once there are a hundred plus stores, many producers will not be able to service the MB market simply because they don't have the logistics to ship (many have to ship daily in some cases).
- Other provinces allow / have central distribution systems which can help; smaller producers to enter and remain in the market
- Look at SK logistics – appealing model
- Allows stores to deal directly with the producer of product
- Far more difficult in MB and it makes producers want to deal Saskatchewan instead of the distribution system here
- A summary of the municipal processes required (zoning, consultation, etc.) and funding/grants available to provide some direction to those interesting in entering the market would be helpful
- A processing license to support small scale production as part of commercializing efforts would also be helpful
- Market landscape document / report would be helpful (retail list)
 - Ontario provides this info to suppliers, producers

- Retail environment for the consumer can be overwhelming and as noted earlier, there is limited medical advice allowed.
- Lending bias towards cannabis by financial lenders, even though it's federally legal. I.e. Federal CAP requires a building and six months of sales before they will consider support, even though capital and infrastructure are touted as part of the program.
- Access to capital, particularly now after COVID-19, is a huge challenge.

