MIRC Risk Mitigation Subcommittee

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Acronym Training 101..

- **NGO** Non-Governmental Organization
- **FEMA** Flavor Extract Manufacturers Association
- **PSN** Produce Safety Network
- **IFRA** International Flagrance Association
- **IOFI** International Organization of the Flavor Industry
- **RIFM** Research Institute of Flagrance Materials
- **FSMA** Food Safety Management Act
- **GFSI** Global Food Safety Initiative
- **EPA** Environmental Protection Agency
- **FDA** Food Drug Administration
- **NMFS** National Marine Fisheries Service
- **REACH** Registration, Evaluation, Authorization and Restriction of Chemicals (EU)
- **CPG** Consumer Packaged Goods (Companies)
- **IARC** International Agency for Research on Cancer, part of WHO (World Health Organization)
- **CFR** Code of Federal Regulations
- **GRAS** Generally Recognized as Safe
- **ISO** International Committee of Essential Oils
- **CRISPR** Clustered Regularly Interspaced Short Palindromic Repeats
- **GMO** Genetically Modified Organism
- **ECJ** European Court of Justice
- **BAP** Biologically Active Principles
- **HS Code** Harmonized Commodity Description & Coding System (Harmonized System Codes)
- **MRL** Maximum Residue Limit
- **WDIVFT** Why Did I Volunteer for This…

MIRC – Risk Mitigation Sub-Committee

- **Purpose:** To collect and disseminate current regulatory, social and economic threats to the N. American mint industry preemptively. The Flavor and Fragrance Industry is increasingly under scrutiny by global regulatory bodies and Non-Governmental Organizations (NGO's).

MIRC – Risk Mitigation Sub-Committee

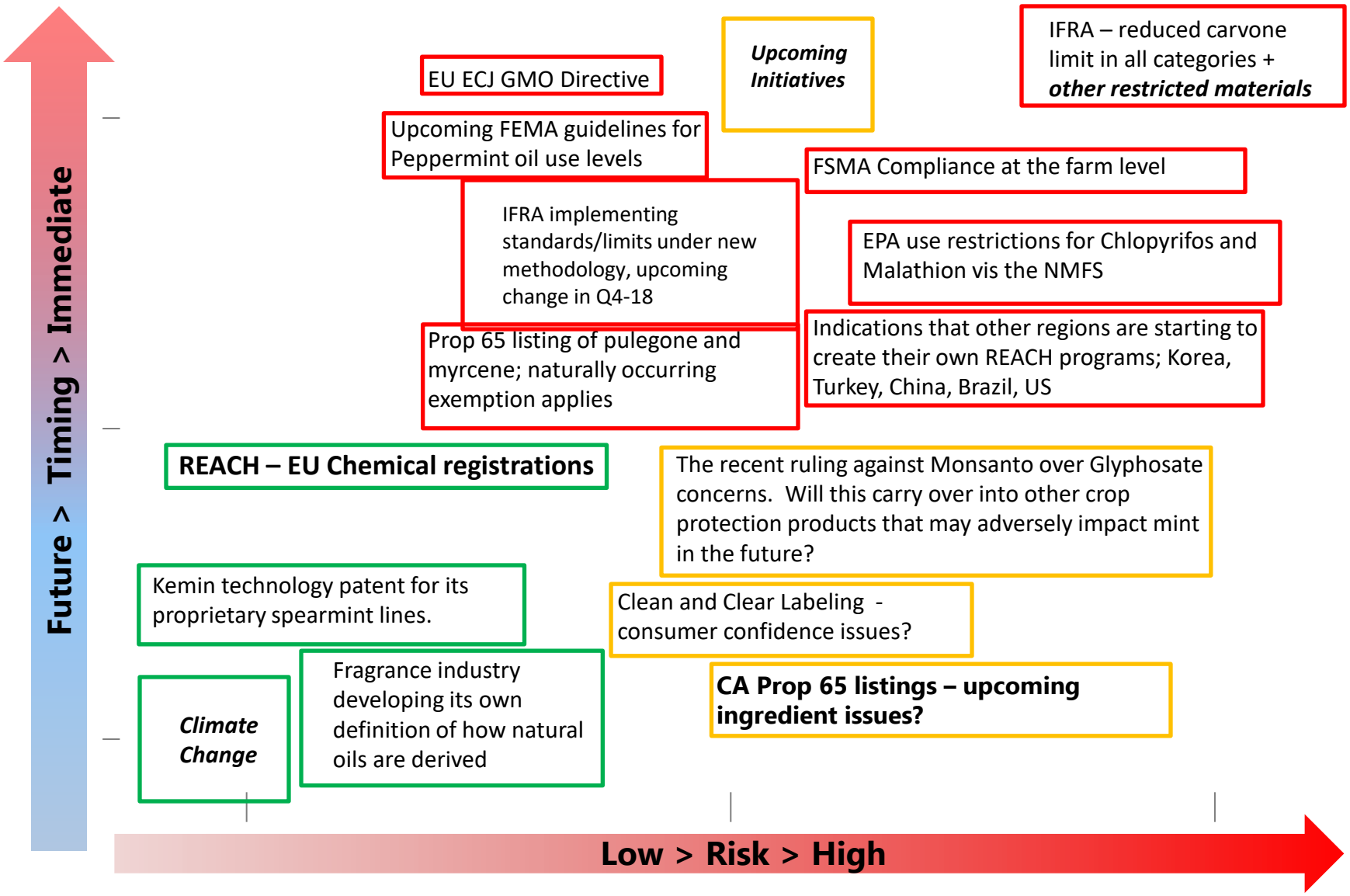
- **Objectives:**
- Interact and collect pertinent information related to current and proposed threats
- Inform the membership of the nature of the threats to our industry
- Interact with industry business associations that can provide input and assistance to the MIRC
  - FEMA (Flavor Extract Manufacturers Association
  - IFRA (International Fragrance Association)
  - IOFI (International Organization of the Flavor Industry)
  - RIFM (Research Institute of Fragrance Materials)
  - Other like organizations

MIRC – Risk Mitigation Sub-Committee

- Work with member companies to develop and recommend appropriate strategies to mitigate risk related to:
  - FSMA/GFSI
  - Social Trends
  - EPA - concerns
  - FDA – concerns
  - Global Regulatory Requirements
  - REACH
- Committee Members (should have regulatory experience)
  - CPG companies (End Users)
  - Dealer Member
  - Grower
  - Flavor House Member

Issues Mapping

Issues affecting the Mint Industry: Hot Spots map



Risk 1-3 (low , medium, high); Timing 1-2 (future to immediate)

Potential Risks at the Grower Level

FSMA (2.0, 1.8) – big potential impact, but lack of clarification at the grower level.

- Preventative vs. Food Safety
- Preventative controls
- FSMA overseen by FDA
  - Regulatory efforts pushed on to states

State(s) vs. Federal opinion on FSMA:

From our Regional PSN :

- "For your awareness, there was no consumption data on spearmint in the NHANES data sets, so it is indeed a covered commodity. They are eligible for the commercial processing exemption if the spearmint is being grown for its oil via a distillation process. As a result, the "stills" are under the PC rule."
- **Mintstills require FDA registration**
- **Hop Harvesting Facilities – Exempt from FSMA**
  - **Multi-Year Process**
    - **Grower Efforts**
    - **Legal Applications**
    - **Congressional Support**

Potential Risks at the Grower Level

- FDA – struggling with Farm "Definition":
  - What is a farm?
    - Mint Stills
      - Custom Distilling – *Defined as "Processing" per EPA*
- States: Distillation is a process, but common sense prevails.
  - **Some** states not thinking about licensing.
    - Promotes Confusion based on Farm Distillery Location
- **States must recognize FDA Regulations**
  - **However, these inspections are not a current priority.**
- Inspections ***if*** FDA asks for/provides funding.
- **Future clarification (and consistency) needed at the state level.**

Grower Sector Concerns:

7 FSMA rules:

1. Mitigation Strategies to Protect Food Against Intentional Adulteration (Food Defense)
2. Sanitary Transportation of Human and Animal Food
3. Accreditation of Third-Party Certification Bodies to Conduct Food Safety Audits and To Issue Certifications
4. Foreign Supplier Verification Programs for Importers of Food for Humans and Animals (FSVP)
5. Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption (Produce Safety)
6. Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Human Food (Preventive Controls for Human Food)
7. Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Food for Animals (Preventive Controls for Food for Animals)

Grower Sector Concerns: - FSMA

Potential risks

- Farms/businesses under/over doing what the law requires of them because the law is pretty convoluted (and they are making changes to the rule/laws).
- **Financial losses due to:**
  - Fines for non-compliance with the law
  - Unnecessary training (and employee costs associated with it)
  - Unnecessary Equipment Purchases (for testing purchases)
- Farms/Businesses staying small enough to avoid being under any FSMA ruling, thus undermining the entire system.
- Overkill on regulations/audits – (*General concern, not concentrated on FSMA*)
  - Each customer having their own standard they want their supplier to adhere to. Each customer will have their own audit they want performed, in addition to a GFSI audit (such as GLOBAL G.A.P.). Some are ok with piggybacking their audit onto a GFSI scheme, others want their own people to come out and audit.
- *Clarity within the law pertaining to differentiation of mint types:*
  - Peppermint is not subject to Produce Safety Rule; but Spearmint is.
  - Distillation = Kill Step for essential oils.

Loss of Crop Protection Assets

Potential risks

- **Impending loss of crop protection agents (2.7, 1.7):**

  - **Chlorpyrifos:**

  Lorsban – recent US Federal 9th district circuit court on order to ban with-in 60 days of August 9, 2018. Lorsban has uses on mint; concern with recent Vydate supply issues(resolved) and Mocap residual levels.

  - The EPA appealed the 2-1 ruling to a full panel of the 9th U.S. Circuit Court of Appeals.
    - **EPA, as of July 2019, says can remain on the US market (BUT, EU has banned…).**
      - **Denied all objections, available to use on Food Crops.**

  - **Malathion:**

  EPA considering restrictions (also includes Chlropyrifos mentioned above) via the NMFS and EPA. Comment period closed on 07/23/2018.

  - Elimination of use in watersheds considered habitat for listed salmon.
    - This could be huge determined by watershed definition and farm location.
    - Potential of imposing 1,000 ft. spray buffers for aerial applications and 500 feet for ground-based applications plus 20 ft. vegetative filter strips for all applications.

- **Glyphosate / Monsanto Ruling (1.7, 1.7)**– US 9th circuit court – will this action carry down to other crop protection assets?
  - Verdict partially overturned (Monsanto, Glyphosate)
  - Proliferation of lawsuits – "The World Is Against Them"
    - ***Social Media*** *– Resulting Impacts*

Risk Concerns - Domestic

Prop 65 (California)

- 2015 listed myrcene and pulegone (2.0, 1.3), *e*xempt if proven from a natural source – how does this affect the US mint industry?
- New list every year, as of current, no new material concerns for the North American Mint Industry.
- *900+ compounds currently listed*
- Glyphosate added July 7, 2017
  - Based on IARC conclusion “Glyphosate is “probably carcinogenic to humans”.
  - EPA disagrees with this conclusion.

Risk Concerns - Domestic

- **Clean and Clear Labeling (1.8, 1.3)**

  Food and beverage producers, for example, have adopted "clean and clear" labels to maintain customer confidence in their products.

  - The **Frank F. Lautenberg Chemical Safety for the 21st Century Act** in December 2015 provided much-needed updates to U.S. chemical safety laws, offering protection to consumers while encouraging manufacturers to remain globally competitive.
    - Administered by the EPA
    - Amends and updates the Toxic Substances Control Act
  - Much of the regulatory response has resulted from **consumer demand.**
  - Those consumers want natural, sustainable sources. This can be problematic given the vague definitions and lack of regulation for the word "natural."
  - Nevertheless, the fragrance industry is developing its own definition, based on how "natural" oils are derived;
  - those extracted with petroleum products, for instance, do not meet the minimum standards for that definition.
  - Fragrance manufacturers advise consumers not to be swayed by the use of "natural" on a product label, but to instead seek out products carrying the Natural Products Association seal guaranteeing ingredients from renewable resources with no petroleum compounds

Risk Concerns - International

- **IFRA**
  - Updates their standard every 2 years
  - -Current standards/limits under new methodology; upcoming change in Q4/2018 (2.0, 1.3)
  - Expect a reduced limit for Carvone in all categories (1.8, 1.3).
  - *Release of new restricted materials at the end of Q2 2019 (2.7, 1.7)*

- **Intellectual Property**
  - Kemin (1.0, 1.3) was granted a patent for a spearmint drying process that preserves polyphenols in KI110 and K142 spearmint lines (proprietary clonal lines with high rosmarinic acid levels). Polyphenols are extracted to produce Neumentix, which can be used in cognitive health positioned supplements or food.
- **Other**
  - Pulegone, menthofuran and beta myrcene regulatory issues (2.0, 1.3).
  - IFRA through FEMA
  - A recent study by FEMA updated the guidelines for use levels of peppermint oil in different food categories. Results have yet to be published (2.0, 1.3).
  - REACH – EU Chemical Registrations (1.3, 1.8)
  - IOFI/FEMA – essential oils GRAS re-evaluation initiative status

Risk Concerns - International Regulatory Issues

- Initiatives upcoming (1.7, 2.0):
  - ISO (International Committee of Essential Oils)
    - Late 2018 – Standards for Perfume and Cosmetics
  - FEMA, IOFI
    - Safety / Re-evaluation of essential oils concerning Mint Oils
      - Alicyclic Ketones, Ketals and Secondary Alcohols
      - Carvones, Menthols, Menthones, etc.

Risk Concerns - International

EU Issues

- European Court of Justice actions (2.0, 1.3):

- **CRISPR ramifications-** 25 July 2018, the European Court of Justice (ECJ) handed down a ruling to clarify applicability of existing GMO legislation to other gene-editing techniques (e.g. CRISPR). A French agricultural union representing small farmers brought a case in France against the EU's GMO law. The union had argued that new plant breeding techniques through so-called mutagenesis techniques should be covered by the GMO law, which has strict rules labeling and overseeing the products.

- In a surprising ruling (because it took the rare step to decide differently to the Opinion voiced by the ECJ Advocate General), the ECJ states that "Organisms obtained by mutagenesis are GMOs within the meaning of the GMO Directive, in so far as the techniques and methods of mutagenesis alter the genetic material of an organism in a way that does not occur naturally,(...)".

- The GMO directive requires a safety assessment by the European Food Safety Authority before an organism can be authorized to examine the risks to humans, animals and the environment. It also requires the products to be labeled as "GMO" which in Europe could effectively limit the commercial viability of any such product because most consumers do not want to eat a genetically modified food.

Risk Concerns - International

- European Court of Justice actions (2.0, 1.3): (Continued)

- The ECJ has however made clear that the Directive does not per se apply to certain mutagenesis techniques which have conventionally been used and that have a solid safety record – unfortunately, no examples are called out to bring definitive clarity. It is highly unlikely that CRISPR would fall under this exemption because it is a recent technique. In addition, even for these 'exemptions', Member States retain the right to apply the obligations of the GMO Directive. Experience in Member States tells us that in this context, it is likely that there would be a diversity of approaches throughout the EU, thereby reducing legal certainty and a level playing field in the EU.

- The ECJ decision is perceived as a major setback by some industry lobby groups (e.g. EuropaBio, representing biotechnology companies) when anti-GMO and anti Gene-Editing NGOs (e.g. Greenpeace, Friends of the Earth etc.) are satisfied.

- Although the European Commission had indicated that it would wait for the ECJ decision, certain declarations by public health and agriculture Commissioners were in favor of gene-editing not being subject to GMO legislation. Furthermore, a significant number of EU Member States were in favor of gene-editing not being subject to GMO legislation.'

Other Items of Interest

- Fragrance industry developing its own definition of how natural oils are derived (1.3, 1.0).
- REACH – Indications that other regions are starting to create their own REACH programs (2.0, 1.0):
  - Brazil, China, Korea, Turkey and possibly the US.
- Menthyleugenol added in newest EU Flavor regulation as one of the Biologically Active Principles (BAP), not to be added to food.
  - Suppliers are asked to declare contents of BAP's in raw materials, even if naturally occurring.
  - Also restricted via EC 1334/2008, Annex III Part A:
    - Isoeugenol,
    - Eucalyptol
    - carvacrol

Other items of interest

- Tariff Situation
  - Still in negotiations
  - HS Code 3301.25.00
    - Import rankings 3367/5832; export ranking 1742
    - 2017 China second largest source for exports.
    - 2017 India largest source for imports.
    - Hard to find information; federal shutdown(s) impacting sites.
- Tealeaf production concerns
  - Tealeaf production is a minor use
  - Pesticide Residues – ever lowering MRL's both regulatory or customer driven
    - Customer and regulatory agencies have unrealistic MRL's
  - FSMA requirements
  - Limited Herbicide availabilities

Climate Change (1.3, 1.0)

- What effect may this have on future N. American mint production and producing areas?
- How many times will outlooks change from now into the future?
  - Many varied opinions and outlooks
  - Political ramifications
  - Local weather variations versus long term trends
  - UN report 09/17/2018, using an 2050 endpoint
    - ❖Canada – Increase of Agricultural Production of 2.5%
    - ❖India – Decrease in Agricultural Production of -2.6%
    - ❖ **Overall, global food prices should remain relatively stable**

Climate Change (continued)

- **Impacts over the next 30-50 years:**
  - CO_2 concentrations will increase to roughly 450 ppmv.
  - CO_2 response will be higher on C3 species (includes peppermint, wheat, rice and soybeans)
    - C3 Plants will be quicker to respond to increasing CO_2 levels, but are more impacted by heat and drought.
  - Average Temps will increase by 1.0+C
    - Increased number of heat waves
    - Decreasing number of frost days
    - Longer growing season in temperate zones
    - Hydrological Concerns
      - More frequent and intense floods and droughts

Climate Change (continued)

- **2014 National Climate Assessment – Pacific Northwest**
- https://nca2014.globalchange.gov/report/regions/northwest
- Pacific Northwest
  - Rate of warming has generally increased; Precipitation has increased, but trends are within natural variability
  - Since 1950, Cascade range 04/01/XX SWC has decreased by 20%.
  - Groundwater concerns
  - Urban influences
    - Water transfer to Urban uses – Boise, ID area
    - Salmon recovery, Orca recovery
      - Loss of hydropower resources
  - Effects of forest fires/smoke on oil production and quality
    - 2017 and 2018 – Washington and Idaho
  - 2045 estimates, end of season river flows:
    - Yakima Basin -40%
    - Columbia Basin -10%
    - Idaho -20%

Climate Change (continued)

- Pacific Northwest (continued)
- Rapid urbanization will continue to see water transfer away from agriculture.
- Wildfire / Forest Fire
  - Increases in median annual area burned could quadruple by 2080 relative to the 1916-2007 time period.
- Precipitation should increase annually, but with much variability over the geographical areas. How to discern with natural cycles
- Projections of warming
    - 2070-2099: 3.3F to 9.7F
- **2014 National Climate Assessment - Midwest**
- https://nca2014.globalchange.gov/report/regions/midwest
- Midwest (upper)
  - Rate of warming has accelerated over the past few decades
  - Midwest growing season has lengthened by approximately 14 days since 1950, mainly due to earlier occurrence of last spring freeze.
  - Precipitation could increase by 10-20% annually by 2099.
  - Projections of warming:
    - 2045-2065: 3.8F to 4.9F
    - 2099: 5.6F to 8.5F

Climate Change – Conclusions?

- **Short Term**
  - Variable (natural) events are likely short term.
  - Growers have adapted well with irrigation improvements and are high users of new technology.
  - Improvements in management *should* cover short term climate impacts.
  - Mint Yields *may* increase further short term due to C3 ability and moderately higher temperatures.
    - Wildfire/smoke concerns
- **Long Term**
  - **Extremely hard to discern this far out….**
  - Global CO2 production growth will eventually decrease and most likely reverse by 2100 (or much earlier).
  - North American agricultural technological and grower adaptability advantages *should* be able to outpace most probable impacts.
  - Possible loss of foreign lower latitude growing areas.
  - Potential *movement* of growing areas to higher latitudes, especially outside the Pacific Northwest.

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