leatherhead food research
part of SAGENTIA REGULATORY

sagentia REGULATORY
formerly TSG CONSULTING

sagentia INNOVATION

From MAHA to Market: Understanding the Implications

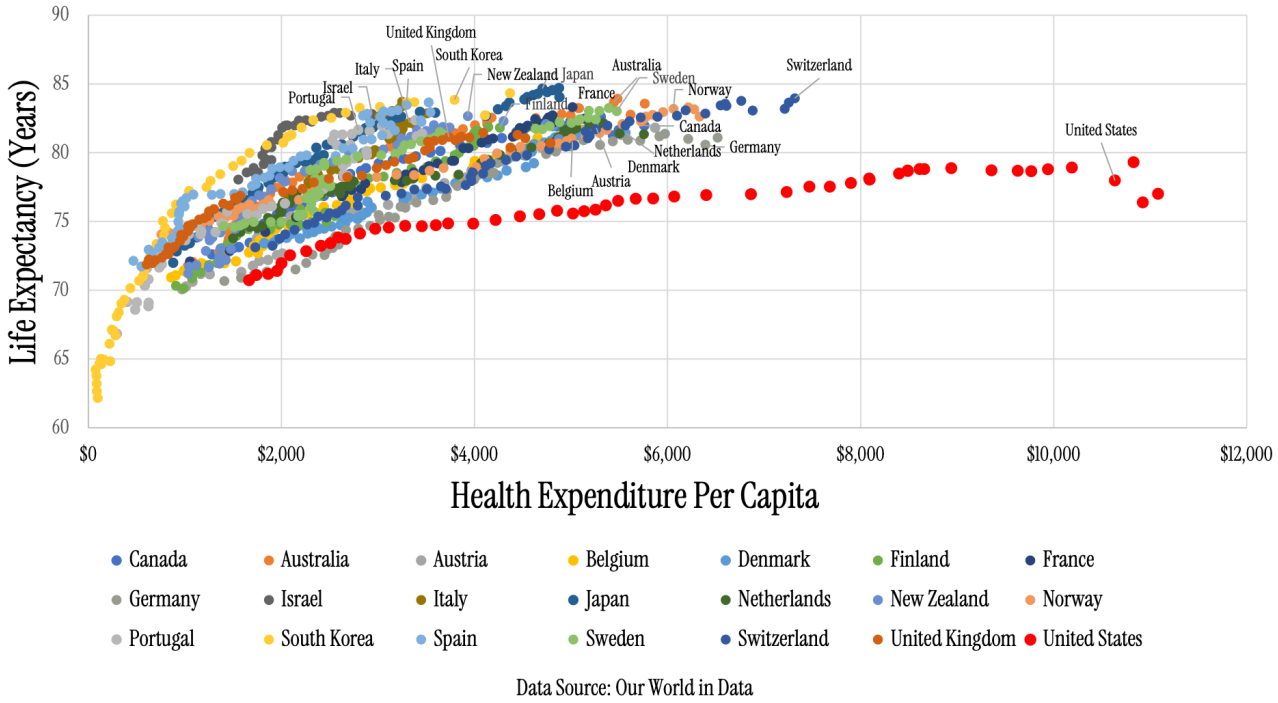
Abigail Wacek, Managing Director, Sagentia Regulatory North America
Mariko Kubo, Global Head of Regulatory & Operations, Leatherhead Food Research
Ankita Singal-Sareen, VP Consumer, Sagentia Innovation

Agenda

- Introduction and current state of MAHA
- Key regulatory areas: UPF, post-market chemical review, and GRAS reform
- How to prepare

Making America Healthy Again

Life Expectancy and Health Expenditure Per Capita By Country (1970-2023)



Data Source: Our World in Data

THE WHITE HOUSE
WASHINGTON

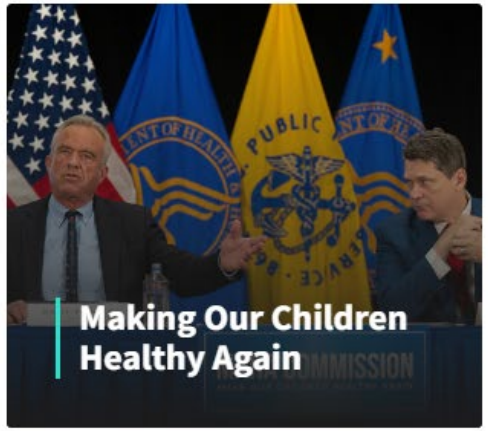
THE MAHA REPORT

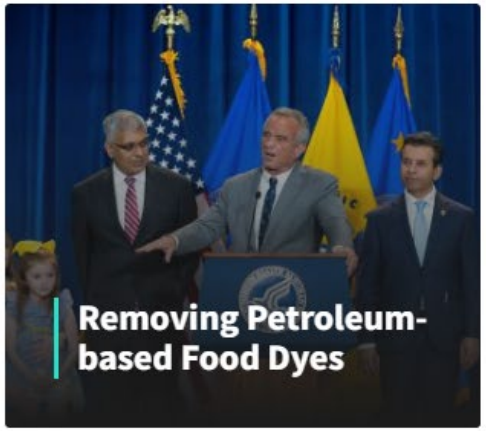
End childhood chronic disease

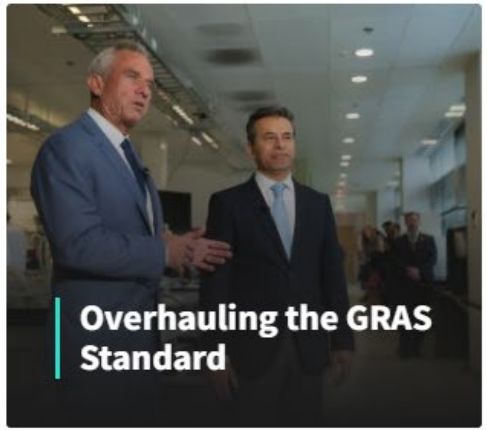
The MAHA *Report* and the MAHA *Strategy*

The Report identified four drivers of childhood chronic diseases:

1. Poor diet
2. Chemical exposure
3. Lack of physical activity and chronic stress
4. Overmedicalization



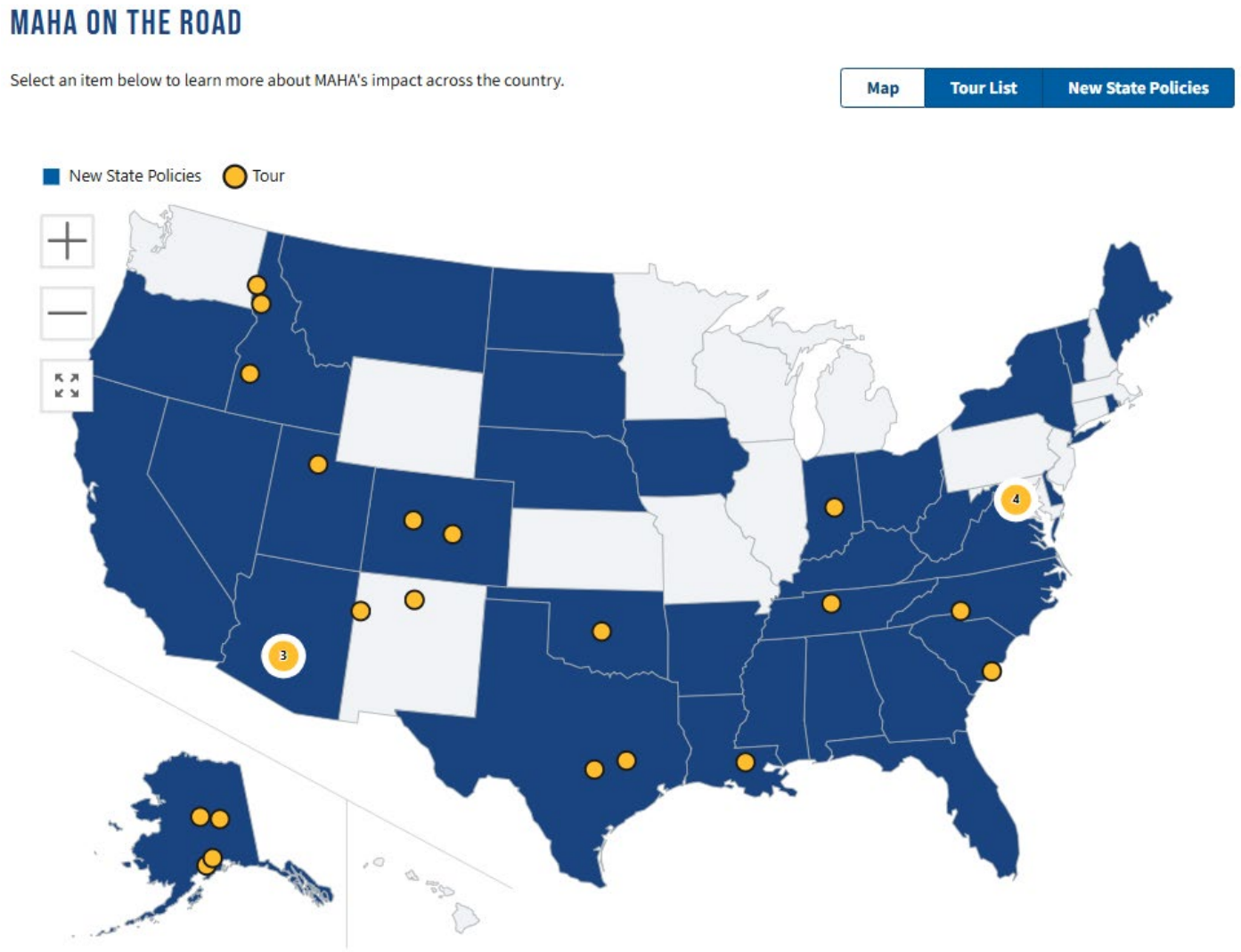




"Over 60% of children's calories now come from highly processed foods, contributing to obesity, diabetes, and other chronic conditions."

– MAHA Strategy

Change is already underway



Source: [Make America Healthy Again (MAHA) | HHS.gov]

*"We are asking, as an administration, American food companies to remove these petroleum-based food chemicals and replace them with natural ingredients for American kids**, just as they have already done for kids in Europe and Canada**."*

- Food and Drug Administration Commissioner Dr Marty Makary

leatherhead food research
sagentia REGULATORY
sagentia INNOVATION

Chemical Classes and Common Exposure Pathways

Heavy Metals

- Lead, Mercury
- Exposure: Legacy paint, pipes, dust

Air Pollutants

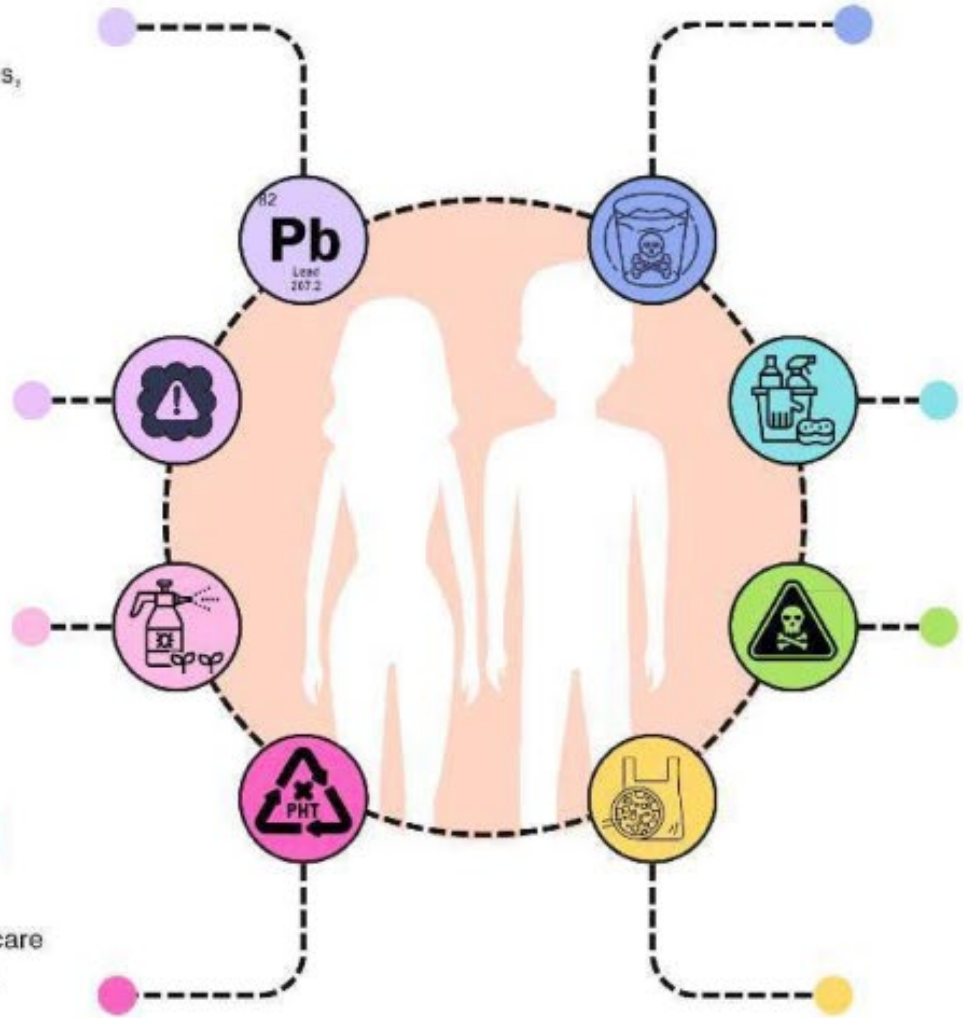
- CO, O_3, Particulate Matter, NO_2, SO_2, ETC, PAHs
- Exposure: VOCs, smog, wildfires

Pesticides

- Atrazine, Chlorpyrifos, Glyphosate
- Exposure: Food, water, dust, lawn treatment, household sprays

Endocrine-Disrupting Chemicals

- Phthalates, BPA, PBDEs
- Exposure: Plastics, personal care products, packaging, textiles, dust



Waterborne Contaminants

- PFAS, Nitrates, Fluoride
- Exposure: Drinking water, agricultural runoff

Industrial Residues

- Formaldehyde, Cleaning Products, Cosmetics
- Exposure: Home surfaces, building materials, cosmetics, cleaners

Persistent Organic Pollutants

- PCBs, Dioxins, PBDEs
- Exposure: Dust, food

Physical Agents

- EMR; Microplastics
- Exposure: Wi-Fi, mobile phones, 5G; food, water, air

Source: MAHA Assessment

Navigating the food regulation landscape

Emerging regulatory shifts in food safety and nutrition: five critical frontiers to watch

Ultra-processed foods

USDA, HHS & FDA working on a unified definition to guide research and policy

Post-market chemical review

FDA to enhance evidence-based review of chemicals in food (additives, GRAS, packaging, contaminants)

Front-of-pack nutrition labels

FDA reviewing public input and upcoming dietary guidelines to finalize labeling rules

GRAS reform

FDA to close loopholes, require mandatory notifications, and improve transparency

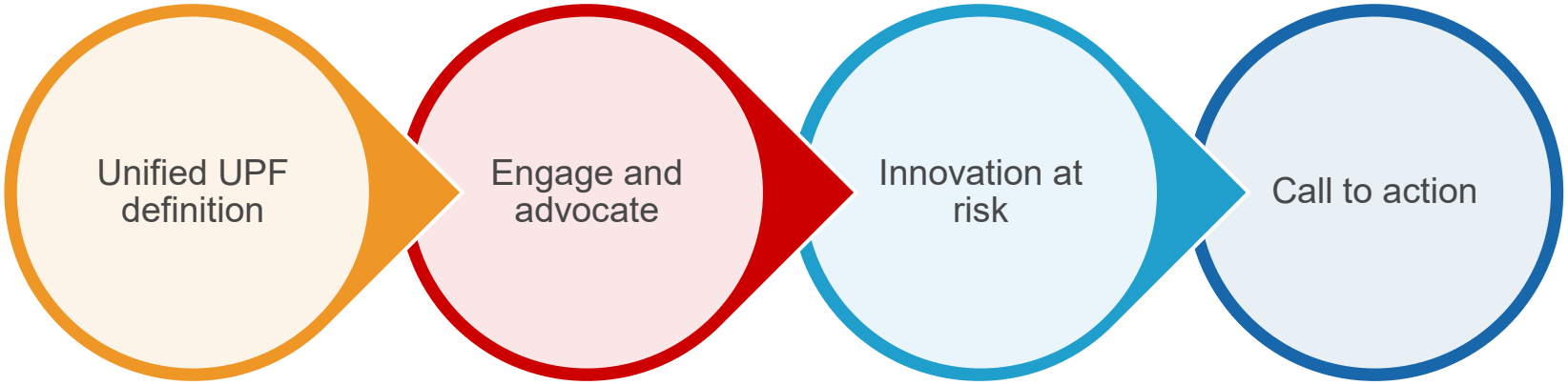
Food allergies

FDA to issue guidance on diagnostics/ treatments and improve ingredient disclosure (e.g., gluten, allergens)

Ultra-processed foods: why the definition matters

Ultra-processed foods

USDA, HHS & FDA working on a unified definition to guide research and policy



Preparing for UPF definition

Evaluate product portfolios against potential UPF definitions

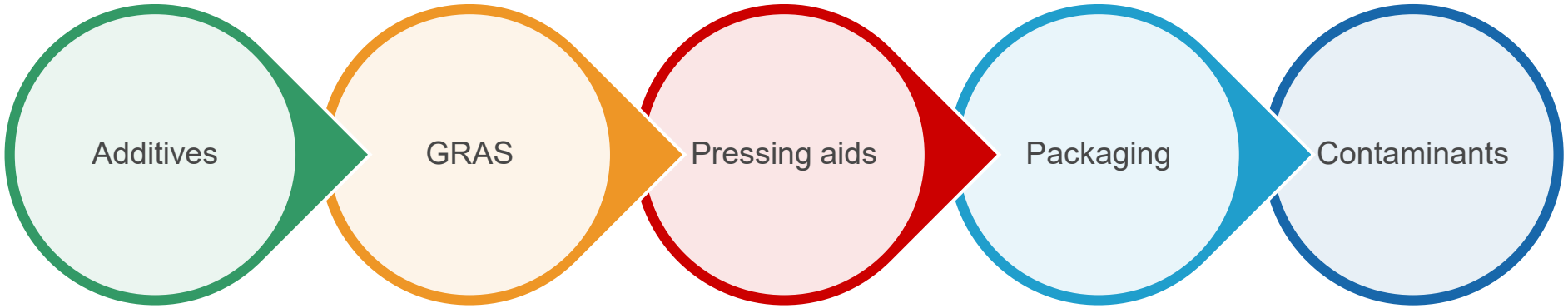
Prioritize products with both high regulatory risk and significant commercial impact

Externally, collaborate with suppliers

From GRAS to glass: FDA's science-driven review of food-related chemicals

Post-market chemical review

FDA to enhance evidence-based review of chemicals in food (additives, GRAS, packaging, contaminants)



From risk to opportunity: global strategy for food innovation

Identify the chemicals that have raised concerns in other markets, and evaluate how your product portfolio, addresses or mitigates and ensure your project portfolio is future-proofed

Ensure your innovation efforts in the U.S. also deliver value in other key markets

GRAS reform: closing loopholes

Closing the GRAS loophole

The FDA will eliminate the **self-affirmed GRAS pathway**, which currently lets companies declare substances safe without FDA oversight

Mandatory GRAS notification program

Companies will be required to **notify the FDA** when they intend to use a substance under GRAS status. This aims to ensure **regulatory oversight and accountability**

Increased transparency

The FDA will improve **public access to information** about substances in the food supply, including those with GRAS status. This includes publishing more detailed data and safety evaluations

Review of existing GRAS substances

The FDA may re-evaluate substances already in use under GRAS, especially those linked to health

Preparing for GRAS reform

Internal readiness & compliance

Audit all ingredients
Update internal protocols
Prepare for FDA notification
Adjust product development timelines and budgets

External engagement & transparency

Monitor regulatory developments
Enhance supply chain communication
Prepare for public disclosure
Advocate and collaborate

R&D

How are innovators responding?

Raw materials and supply chains

Alternative ingredients *(e.g. colour/dye, sweeteners – likely? exposure? solutions?)*

Supply chain dynamics *(agricultural practices, contaminants)*

Consumer reaction *(ingredient differentiator)*

Processing challenges

Minimal processing vs UPF *(high P, T)*

Challenges *(scale up, cost, energy/sustainability quality & safety)*

Consumer impact *(e.g. sensory, nutrition)*

Product innovation

Reformulation, renovation vs innovation *(resource allocation)*

Portfolio management *(impact analysis, options)*

Maintaining/gaining competitive edge

Packaging innovation

Alternative packaging materials *(options? functionality)*

Recycled materials challenges *(contaminants)*

Packaging design *(e.g. format, adhesives, coatings, printing inks)*

Strategy

Assessment of overall risks & opportunities

Organisational structure

Ecosystems – collaboration is key

Building holistic value proposition

Strategy to validate a mathematical model for predicting risk from a crop pathogen

Our client asked:

Our client identified a crop pathogen that significantly impacts key supply chains and, therefore, production. They also identified a published academic model of the pathogen in a different setting. They wanted to know how to determine whether the published model could apply to their situation and provide commercially valuable insights.

The project story:

Sagentia Innovation provided a strategy for model validation that holistically considers a range of factors.

- We interviewed key decision-makers within the client organization to determine performance criteria for a model. We identified how accurate and how early model predictions need to be to have commercial value
- We identified the types of data required to validate the model, including weather patterns, crop growth data and harvest metrics
- We wrote a guide detailing the appropriate statistical tests to assess the model predictions against the data
- The amount of data required to validate the model will depend strongly on how correlated pathogen contamination is in neighbouring regions, so we developed a strategy for the client to assess this prior to committing to a full data collection programme

Client benefit:

Sagentia Innovation provided a detailed technical plan for model validation, including how to approach uncertainty in the availability and quality of the required data. The client used the plan to secure approvals for project progression.

Preservative-free beverage formulations with natural sweeteners

Our client asked:

The client wishes to succeed in the well-being and stimulation market by introducing novel branded drinks with mood-state effects for the US and Aus/NZ markets and wanted Sagentia Innovation to provide an understanding of the impact on the taste of their beverage formulation if their current sweetener is replaced with an alternative natural sweetener.

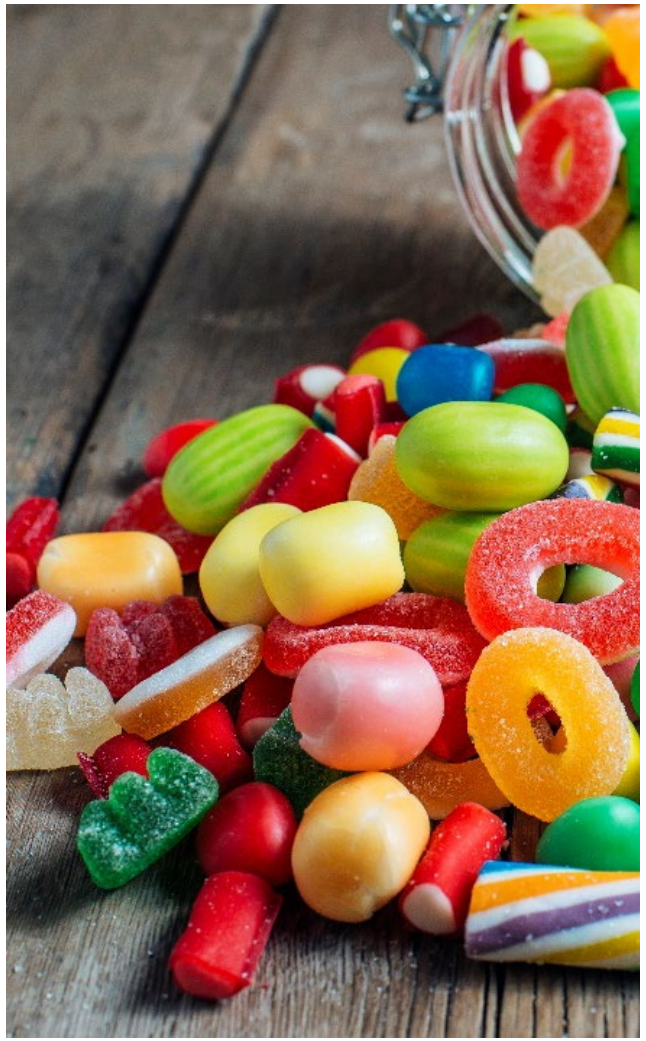
The project story:

- Sagentia Innovation conducted a sweetener search and regulatory review to identify UK-approved natural sweeteners that can be trialled and tasted
- An experimental plan was developed considering the most promising sweeteners and their regulatory limits in the target markets
- Selected ingredients were trialled in prototype formulations over multiple experimental rounds to explore the effect of inclusion levels, supplemental sweeteners and flavour enhancers, bitterness masking flavourings and bitterness-blocking agents, and acidity levels to control sourness
- Prototypes were tasted by a small internal panel to identify the effect of formulation on taste attributes
- Analysis and recommendations were presented to the client based on experimental findings and the estimated cost of each sweetener

Client benefit:

We delivered a report that outlines details of identified ingredients, experimental approach, experimental findings and analysis, recommendations and next steps.

Reinventing a confectionery product using only natural ingredients



Our client asked:

Our client, a global confectionery company, approached us to re-invent confectionery products using only natural, sustainable and clean-label ingredients. Competitive formulations are not perceived as giving the consumer the same sensorial qualities as the product made with artificial ingredients.

The project story:

- Sagentia Innovation identified natural functional materials that could provide suitable chemical, physical and textural properties for use in the product
- Formulation concepts were generated that theoretically could deliver the target sensorial and textural attributes
- The naturally based formulations were then created in a kitchen environment and evaluated for performance using tailor-made in-vitro methodologies and an expert sensory panel

Client benefit:

Our formulation performed on par with the predicate (artificial) formulation, enabling the client to take development on internally to scale-up tasks.

Product successfully launched.

Questions?

leatherhead
food research

part of SAGENTIA REGULATORY

For further information visit us at: leatherheadfood.com

Email: help@leatherheadfood.com

Follow us on LinkedIn: @leatherheadfoodresearch

Epsom

Great Burgh
Yew Tree Bottom Road
Epsom
Surrey
KT18 5XT
UK

Cambridge

Harston Mill
Harston
Cambridge
CB22 7GG
UK

London

First Floor
17 Waterloo Place
London
SW1Y 4AR
UK

Washington

1150 18th Street NW
Suite 475
Washington
DC 20036
USA

Disclaimer

The information contained in this document is believed to be accurate, but no representation or warranty, express or implied, is made by Leatherhead Food Research as to the completeness, accuracy or fairness of any information contained in this document. Any opinions expressed in this document or during the course of the work described in it are those of the individual author and not those of Leatherhead Food Research or its group. Except where limited by law, neither Leatherhead Food Research nor its group shall be responsible for any actions taken or not taken as a result of such opinions and you agree to indemnify Leatherhead Food Research, its group and/or personnel against any liability resulting from the same.