

HIGH-VALUE  
NUTRITION

Ko Ngā Kai  
Whai Painga

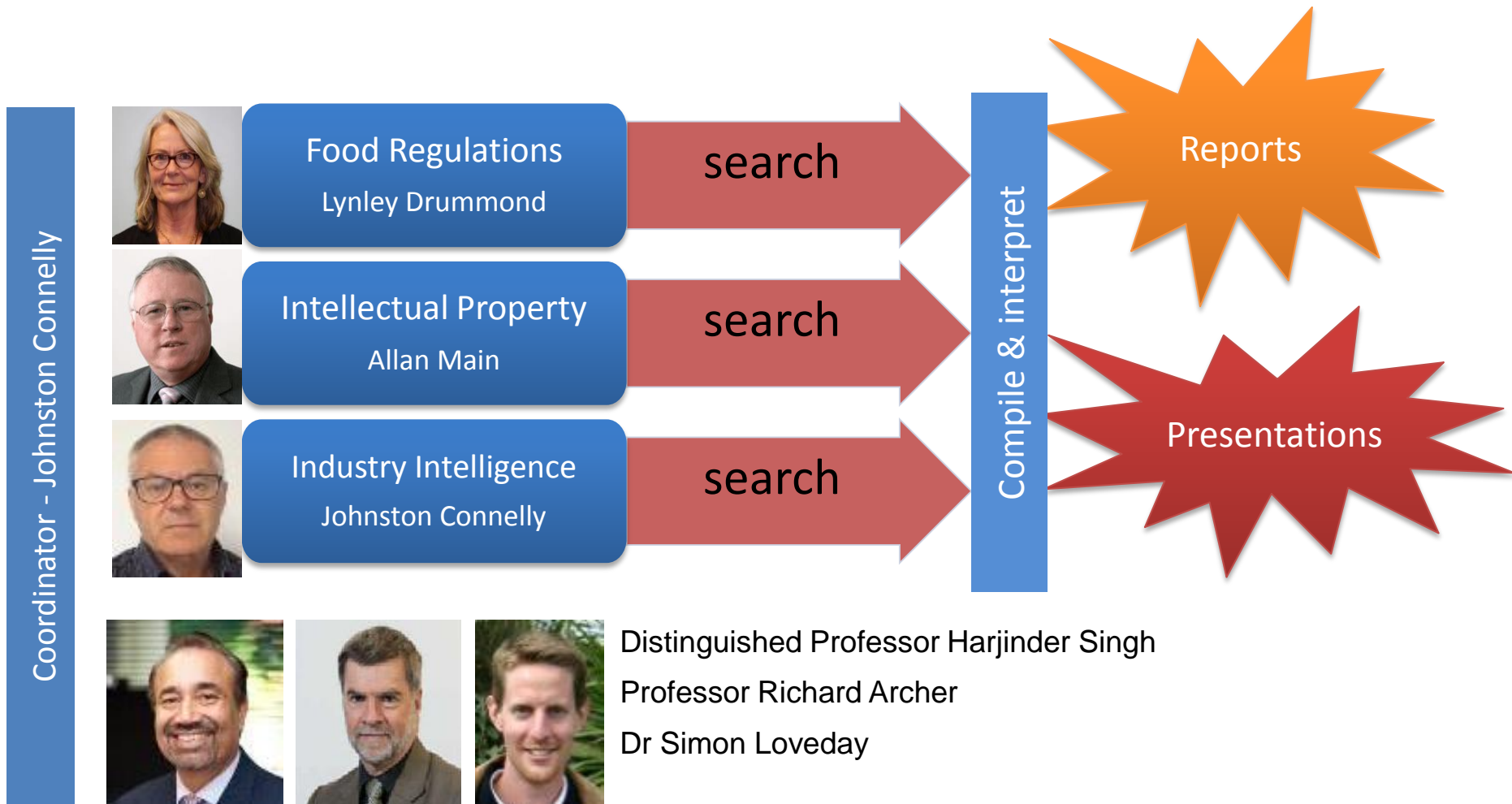
# Opportunities, competition and freedom-to-operate for New Zealand

## Dist. Prof. Harjinder Singh

Host Institution



# Scanning the Horizon



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## Scanning the Horizon Regulatory Workstream

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# Purpose of the Regulatory Workstream

**To provide a roadmap of the regulatory environment and related topics for the HVN Platform Programmes in a user friendly format**

KPI's for the HVN Platform programmes include “*regulator-approved evidence dossiers or dossiers submitted to FSANZ demonstrating consumer health benefits*” by 2018

## **Deliverables**

### **Regulatory Roadmaps:**

- Clarity of requirements and processes for Platform Programmes to deliver on KPI's
- Toolbox to assist programmes work through regulatory requirements

### **Case studies**

**Specific topic reports identified as valuable support to the HVN Programmes**


# Regulatory Roadmap

HVN Target Jurisdictions		Influencer Jurisdictions
Au /NZ	South Korea	European Union
China	Indonesia	FDA
Taiwan	Philippines	Canada
Hong Kong	Malaysia	Japan
Singapore	India	CODEX Alimentarius
Thailand	Vietnam	
Russia		

Interactive Roadmap developed

- Outlines key requirements for health claims which may be made across 17 regulatory jurisdictions
- Provides an overview of the procedures to make health claim applications
- Provides links to relevant legislation and guidance documents in each jurisdiction
- Copies of key documents provided country files accompanying the Roadmap
- Roadmap complements MPI “Global Regulatory Environment of Health Claims on Foods” document

# Example of Roadmap – South Korea

SOUTH KOREA		
REGULATIONS	GUIDANCE DOCUMENTS	COMMENTS and USEFUL LINKS
<p>The Korean Health Functional Food Act (HFFA) □ and Health Functional Food (HFF) Code were introduced in 2004. Certain products in the form of tablets, capsules, powders, granules, pastes, gells, jellies, bars were covered by the Act, and the scope was extended to include conventional foods and other diet supplements by the revised act in 2008.</p> <p>The Code has since been updated <a href="#">Korea Functional Food Code (2010)</a> □ . The Code provides extensive detail on a wider range of substances with approved claims and conditions of use.</p>	<p>The <a href="#">Korean Ministry of Food and Drug Safety</a> (MFDS) is responsible for execution and enforcement of HFF regulations</p> <p>MFSD is the authority that reviews and approves functional ingredients and foods with health claims. All health claims must be scientifically substantiated (safety and efficacy).</p> <p>There are 37 pre-approved Generic HFF ingredients. All new ingredients must undergo pre-market approval.</p> <p>A flowchart of the Approval procedure is provided on the <a href="#">MFDS</a> site</p>	<p>Korea has a highly structured, well documented and progressive regulatory environment for health claims</p> <p>KFDA (Korean Food and Drug Administration) is the principle government agency for the administration, amending &amp; promulgation of food regulations. The KFDA mission statement for functional foods is stated as "Overlooking manufacture, importation, and the distribution of food and health functional foods and their safety".</p> <p>In Korea both manufacturers and retailers of HFF must be approved.</p>
<p><b>Relevant laws and regulations</b></p> <p><b>ACT</b></p> <ul style="list-style-type: none"> <li>• <a href="#">Health Functional Food Act</a> □ (05/18/2015)</li> </ul> <p>The Health Functional Foods Act provides legal basic for Health Functional Food ranging from manufacturing, authorization, health function claim of the products. Health Functional Foods Act provides legal basic for Health Functional Food ranging from manufacturing, authorization, health function claim of the products.</p> <p><b>ENFORCEMENT DECREE/RULES</b></p> <ul style="list-style-type: none"> <li>• <a href="#">Enforcement Decree of Health Functional Food Act</a> □ (05/18/2015)</li> <li>• <a href="#">Enforcement Rule of Health Functional Food Act</a> □ (05/27/2015)</li> <li>• <a href="#">Health Functional Food Code</a> □ (12/30/2014)</li> <li>• <a href="#">Health Functional Food Labeling Standards</a> □</li> </ul>	<p>Health claims are defined as:</p> <ul style="list-style-type: none"> <li>• <b>Nutrient function Claims</b> relates to any physiological role of the nutrients in growth, development and normal functions of the human body.</li> <li>• <b>Other function claims</b> relates to any positive contribution to health to the improvement of a function, or to modifying or preserving health in the context of the total diet.</li> </ul> <p><b>Disease risk claim</b> relates to the reduced risk of developing a disease or health-related conditions in the context of the total diet.</p>	<p>HFF products approved by MFDS under the Health Functional Foods Act can be labelled with certain health claims with the symbol of "HFF".</p>  <p>A graded system for "Other function claims" exists which allows potential early entry for new HFF</p> <p>Grade 1 (Convincing): "Can have a beneficial effect on..."</p> <p>Grade 2 (Probable): "May improve / increase / decrease..."</p> <p>Grade 3 (Insufficient): "May improve / increase / decrease... but the scientific evidence on human study is insufficient."</p>

# Case Studies

- > A set of 6 case studies were prepared to provide examples of successful and unsuccessful health claim applications in different regions
- > The studies highlight:
  - The level of research sitting behind applications and health claim initiatives
    - Human data, animal studies & *in vitro* studies
    - Development of putative mechanisms
    - IP background
  - Timelines to develop the evidence base prior to preparation of health claim applications





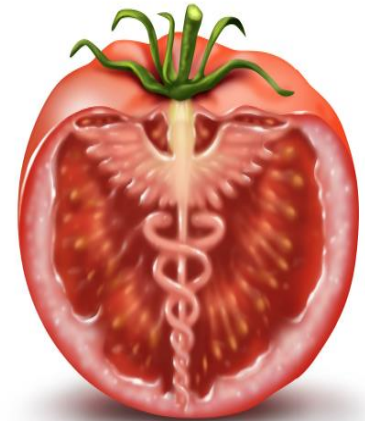
# Claims Across Jurisdictions

- Consistency of information required
  - Characterisation of material and delivery
  - Safety/toxicity
  - “Dose”
  - Putative mechanism (at least)
  - Well designed human studies to demonstrate the health outcome
- Processes required for health claim registration varies
- Many countries have updated health claim regulations in the past 5-6 years and continue to amend. These changes have meant the requirements are more aligned across the regions

# Regulatory Report -Selected Topics

- Critical aspects to consider when establishing evidence to support a food health claim
  - Clinical trial design
  - Publication
  - Links to and references key documents and guidelines
- Detailed review of the new regulations and requirements for China
- Update on the new health claim legislation in Japan

## Selected Regulatory and Related Topics for Health Claims for Food-Health Relationships



# Scanning the Horizon

## Industry Intelligence Workstream

# Industry Intelligence

## Monitoring emerging and growth trends in markets

- Achieved through searching and monitoring databases, literature, social media
  - Intel GNPD (Global New Products Database)
  - New Nutrition Business
  - Nutra-Ingredients
  - Trade literature
  - Company activity through press releases / social media (Facebook / Twitter / LinkedIn)

# New Product Launches in the Food and Beverages Categories

- Countries / Regions
- Functional Claims
- Ingredients
- Demographics
- Company

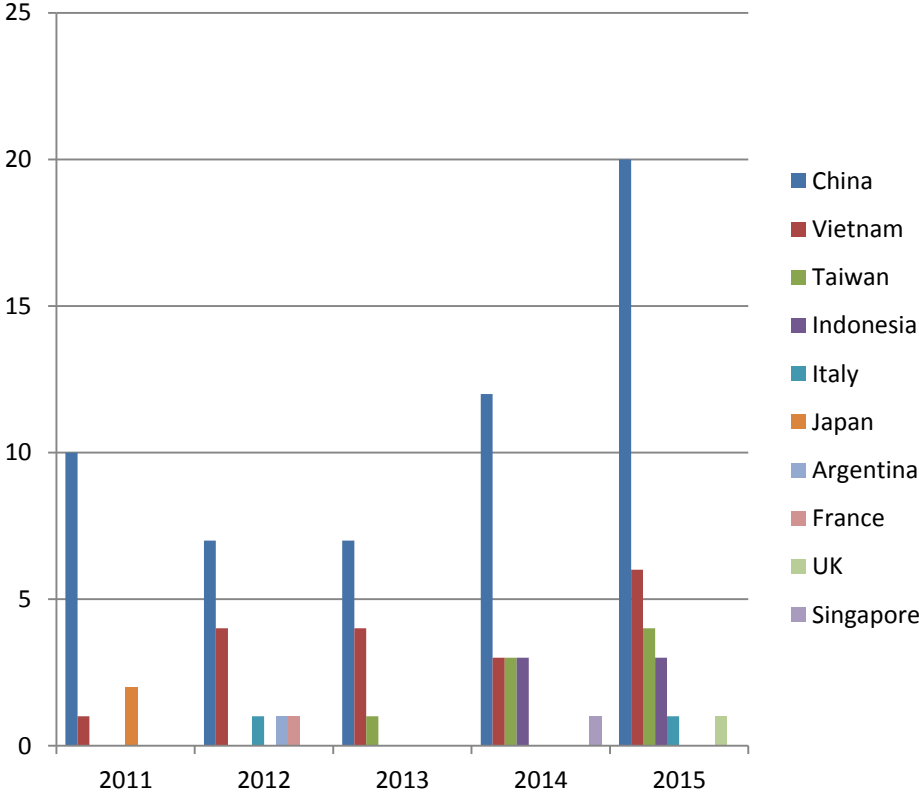
Food

<input type="checkbox"/> Baby Food Show Sub-Categories	<input type="checkbox"/> Bakery Show Sub-Categories	<input type="checkbox"/> Breakfast Cereals Show Sub-Categories	<input type="checkbox"/> Chocolate Confectionery Show Sub-Categories
<input type="checkbox"/> Dairy Show Sub-Categories	<input type="checkbox"/> Desserts & Ice Cream Show Sub-Categories	<input type="checkbox"/> Fruit & Vegetables Show Sub-Categories	<input type="checkbox"/> Meals & Meal Centers Show Sub-Categories
<input type="checkbox"/> Processed Fish, Meat & Egg Products Show Sub-Categories	<input type="checkbox"/> Sauces & Seasonings Show Sub-Categories	<input type="checkbox"/> Savoury Spreads Show Sub-Categories	<input type="checkbox"/> Side Dishes Show Sub-Categories
<input type="checkbox"/> Snacks Show Sub-Categories	<input type="checkbox"/> Soup Show Sub-Categories	<input type="checkbox"/> Sugar & Gum Confectionery Show Sub-Categories	<input type="checkbox"/> Sweet Spreads Show Sub-Categories
<input type="checkbox"/> Sweeteners & Sugar Show Sub-Categories			

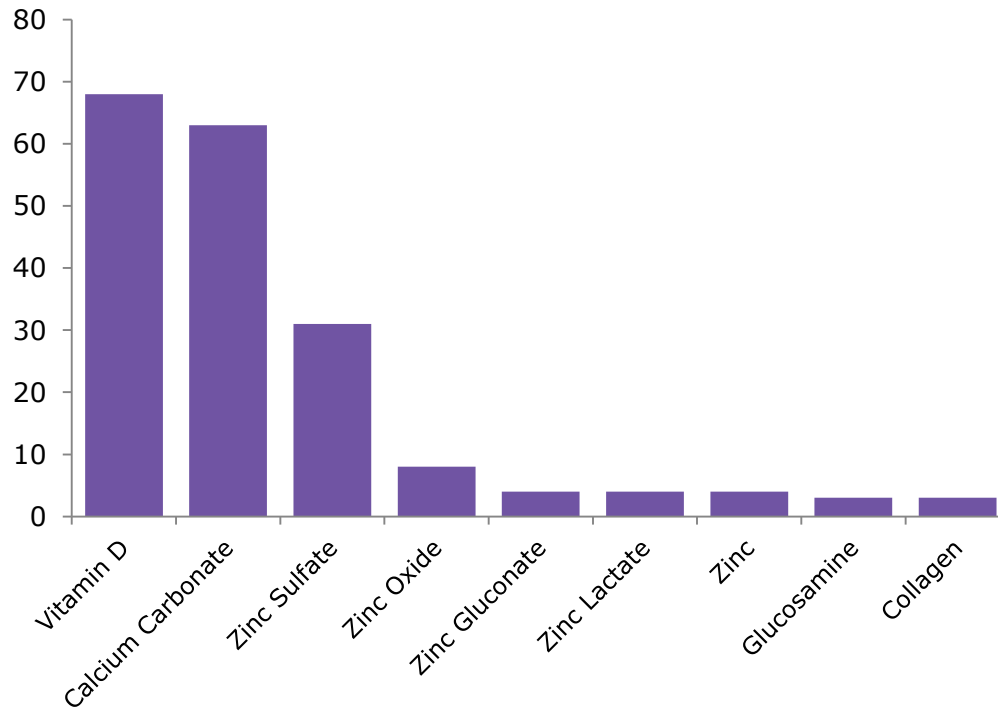
Drink

<input type="checkbox"/> Alcoholic Beverages Show Sub-Categories	<input type="checkbox"/> Carbonated Soft Drinks Show Sub-Categories	<input type="checkbox"/> Hot Beverages Show Sub-Categories	<input type="checkbox"/> Juice Drinks Show Sub-Categories
<input type="checkbox"/> Other Beverages Show Sub-Categories	<input type="checkbox"/> RTDs Show Sub-Categories	<input type="checkbox"/> Sports & Energy Drinks Show Sub-Categories	<input type="checkbox"/> Water Show Sub-Categories

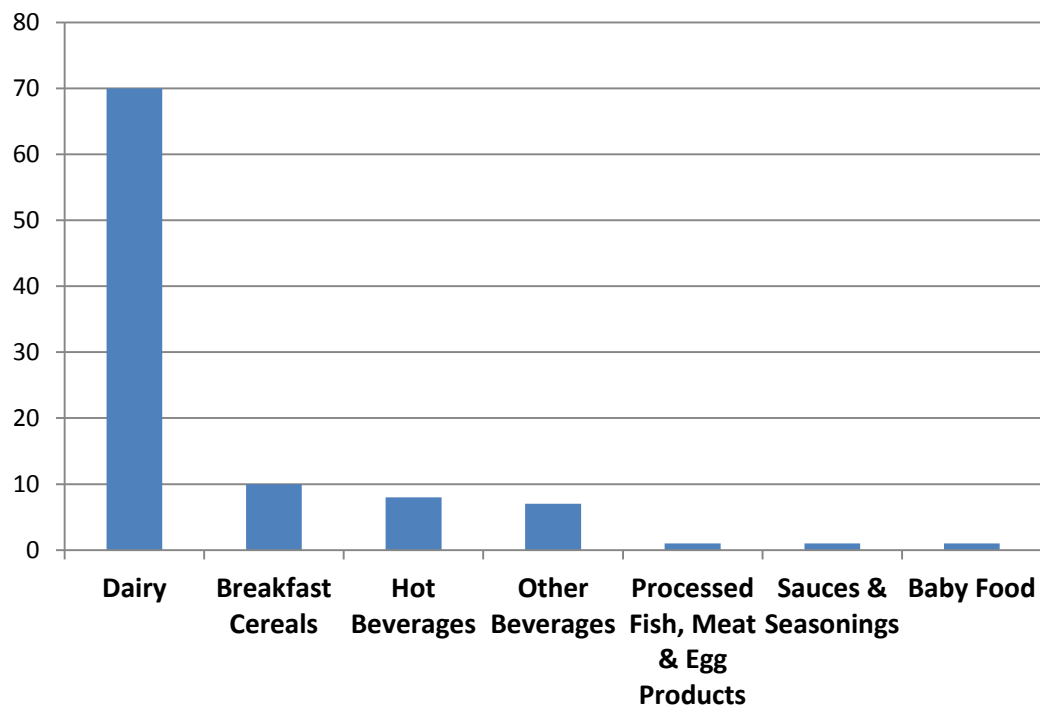
# Bone Health Products for Seniors (+55) Country



# Bone Health Products for Seniors (+55) Ingredient Claim

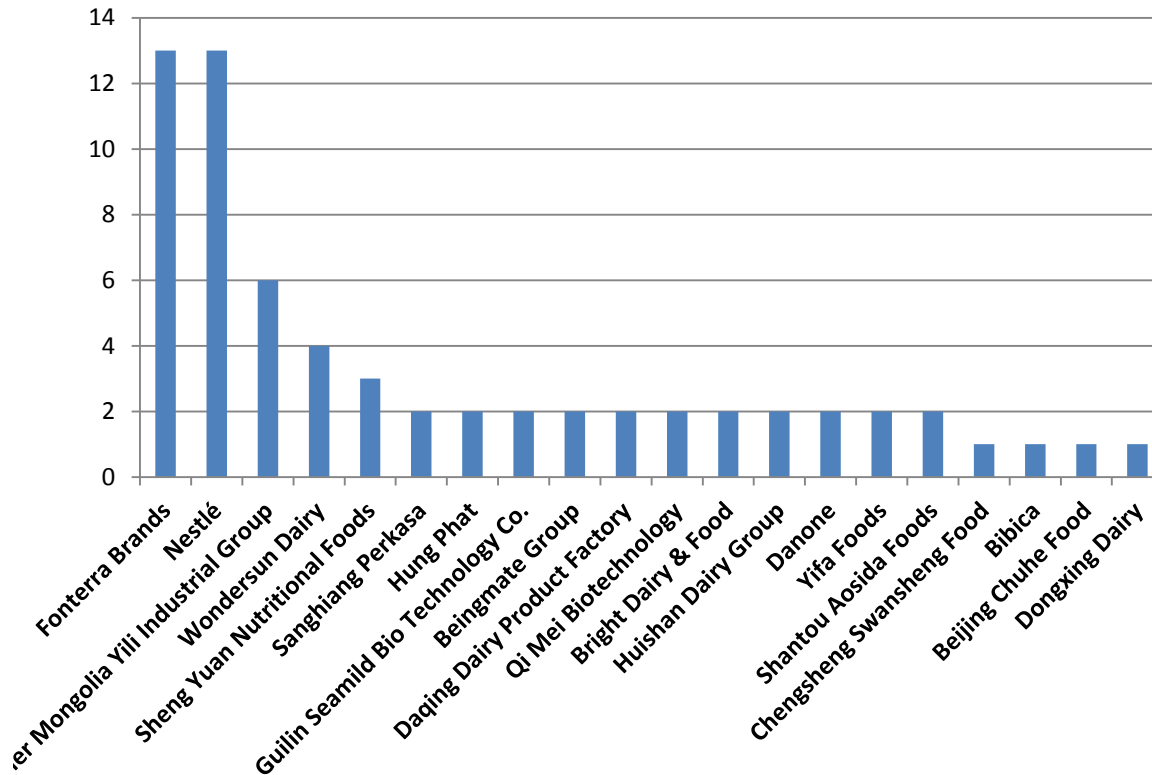


# Bone Health Products for Seniors (+55) Category





# Bone Health Products for Seniors (+55) Company



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## Scanning the Horizon

# Intellectual Property Workstream

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# IP Workstream: Purpose

## > Patent databases to inform research plans:

- Closer to market than science publications (supplement science literature)
- Insights to
  - technologies (established, emerging, trends ...)
  - participants (key players, established and new; their tech strategy; possible collaborators, rivals, targets...)

## > Provides context to future commercialisation:

- IP risk to manage?
  - Minefields – cluttered spaces with high FTO risk
  - Goldmines – technologies and/or geographies with low patent densities
- Opportunities for own IP?
  - Low patent density “white space” indicates potential IP opportunities
  - Opportunity for zone-of-exclusion
- Freely available technologies
  - Expired patents provide content free-for-public-use with assured FTO

# Boundaries to Patent Research

- > **Three HVN themes, scope for each defined by the health platform teams**
  - **IMMUNE**: oral interventions that offer ...  
“enhanced influenza vaccine response; manage irritant-driven respiratory inflammation”
  - **METABOLIC**: oral interventions that offer ...  
“metabolic syndrome management through targeting the obesity link to diabetes and dyslipidaemia”
  - **ELITE GUT**: oral interventions that offer ...  
“avoiding gastrointestinal discomfort with irritable bowel syndrome as a clinical target”

# Boundaries to Patent Research (Contd)

## > “Oral Interventions”

- Foods: primary target for HVN research opportunity
- Traditional Medicines: indicators of food-compatible targets
- Oral Pharma: identify potential intervention biological pathways to target

## > “Research Tools”

- Biomarkers: individual biomarkers or biomarker suites identified as response variables
- Research regimes: protocols for investigating response to interventions

# IP Workstream: Outputs

- > **A report for each theme focussing on INSIGHTS derived from patents, patentees, and parallels (ie non-food aspects)**
  - Current food solutions;
  - Technology trends over time;
  - Key players;
  - Approaches in non-food orals transferrable to food;
  - Hot zones (minefields) and cold zones (goldmines)
  
- > **Around 100 pages each (additional appendices give patent content detail):**
  - Proximity maps
  - Text heat mapping
  - Text networks
  - Innovator activity clocks
  - Player strategic profiles

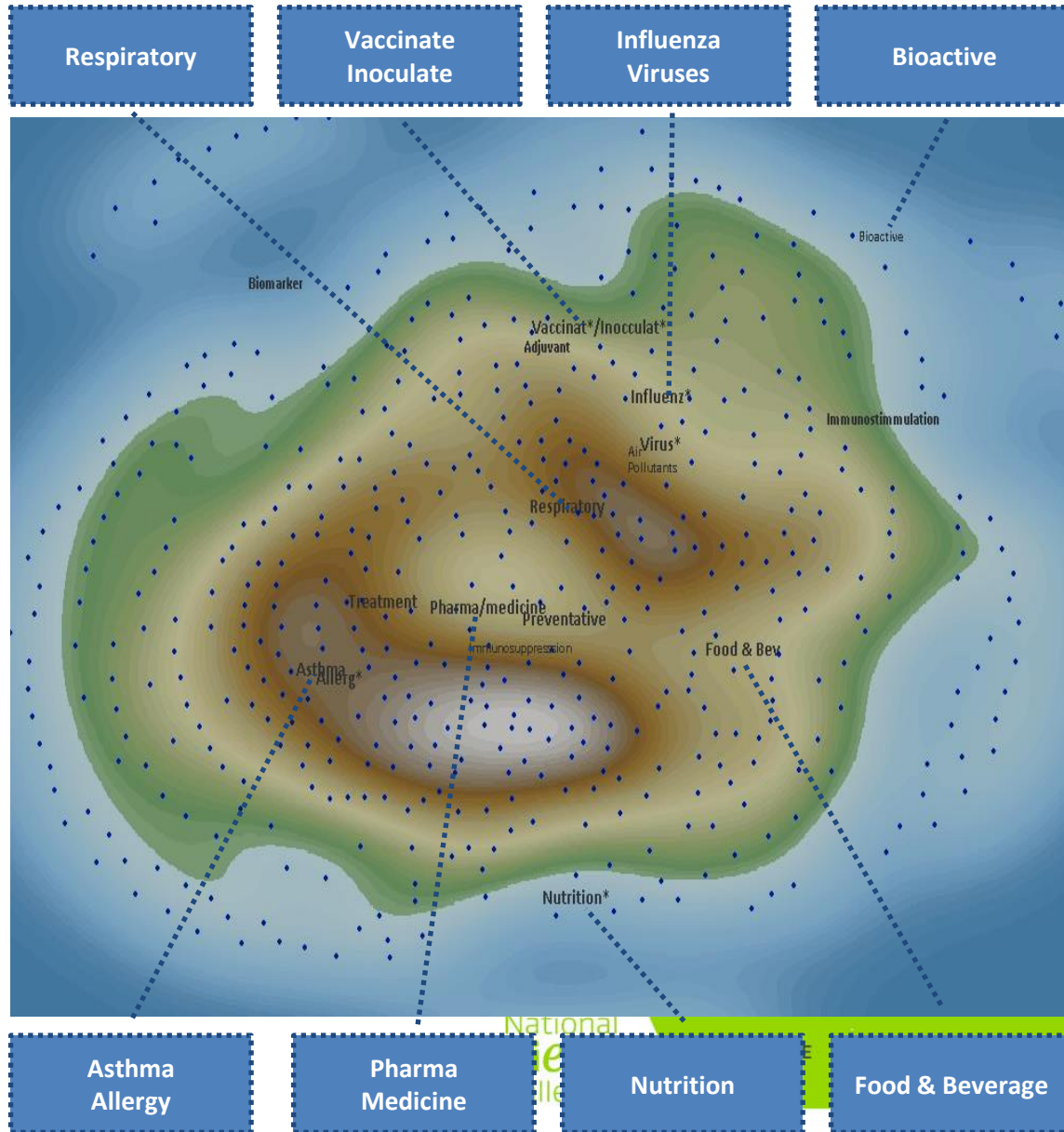
# Content Example: Proximity maps

In PROXIMITY LANDSCAPING patents are organized based on their similarity with one another.

- Each DOT locates a single patent family;
- Distance between two dots indicates their similarity in content;
- Keywords (examples in call-outs plot) at the geographic centre of all patents aligned to that concept;
- Maps are drawn as contoured islands, with concept density reflected as altitude;
- Useful to assess what are the hot topics (and conversely empty spaces) in the dataset.

## Immune Report. Some impressions:

- Patent density around ASTHMA/ALLERGY and RESPIRATORY;
- Relatively vacant concepts are PRO-IMMUNE NUTRITION and BIOACTIVES SUPPORTING IMMUNITY



# Content Example: Text Heat Mapping

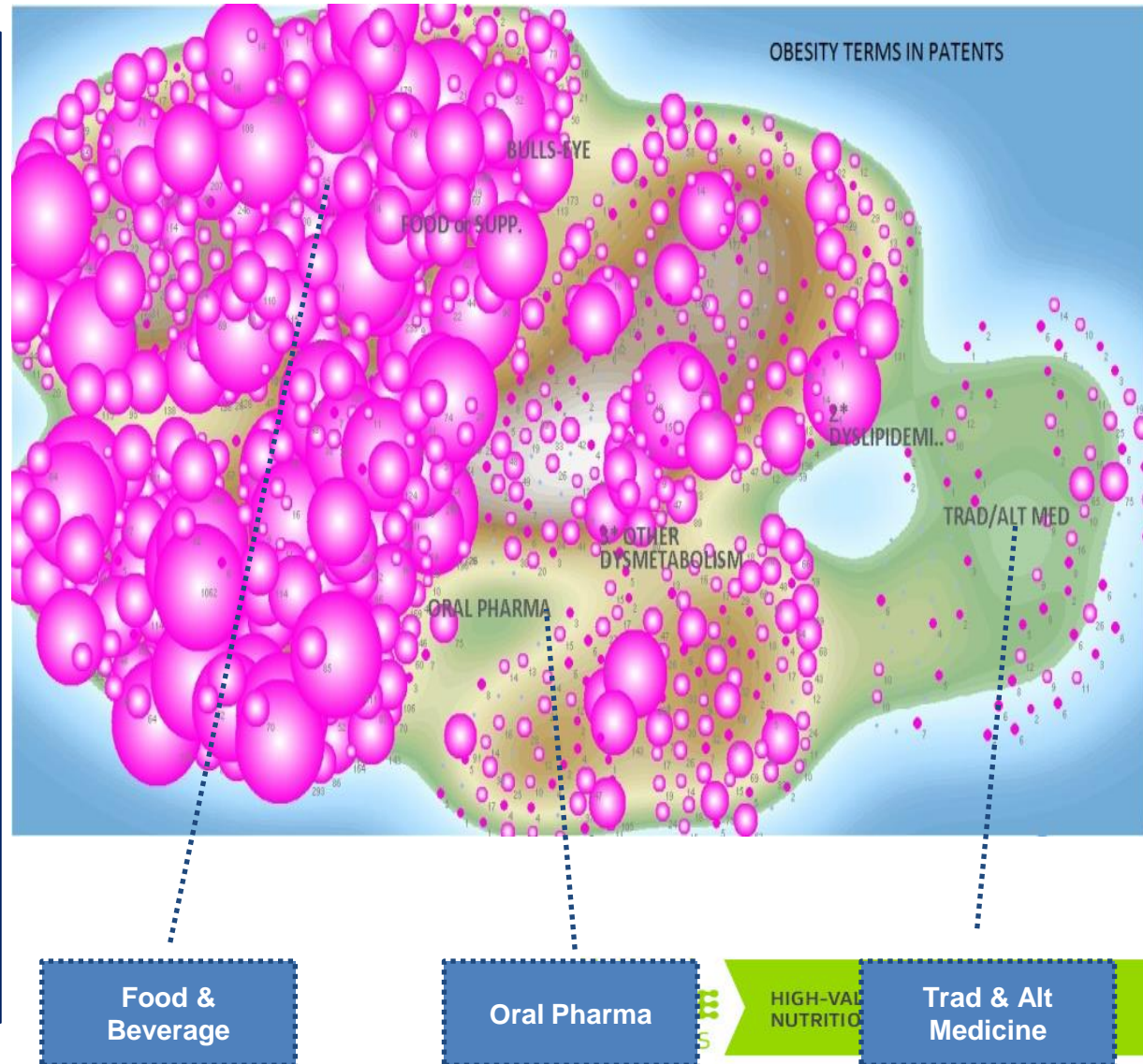
In **TEXT HEAT MAPPING** a further dimension is added to the proximity map by conducting text intensity analysis.

- Each **BUBBLE** locates a single patent family;
- **SIZE** of the bubble correlates to the frequency of the terms mined in that patent text.
- Useful to assess what are the associations between base concepts plotted on the proximity map and specific ideas of interest in the dataset.

Here we show the text intensity for **OBESITY** terms in the **METABOLIC** dataset taken from the **Metabolic Report**

## Some impressions:

- **OBESITY** is a strong target for Food & Beverage, a moderate target for Oral Pharma and weak target for Trad/Alt medicine.

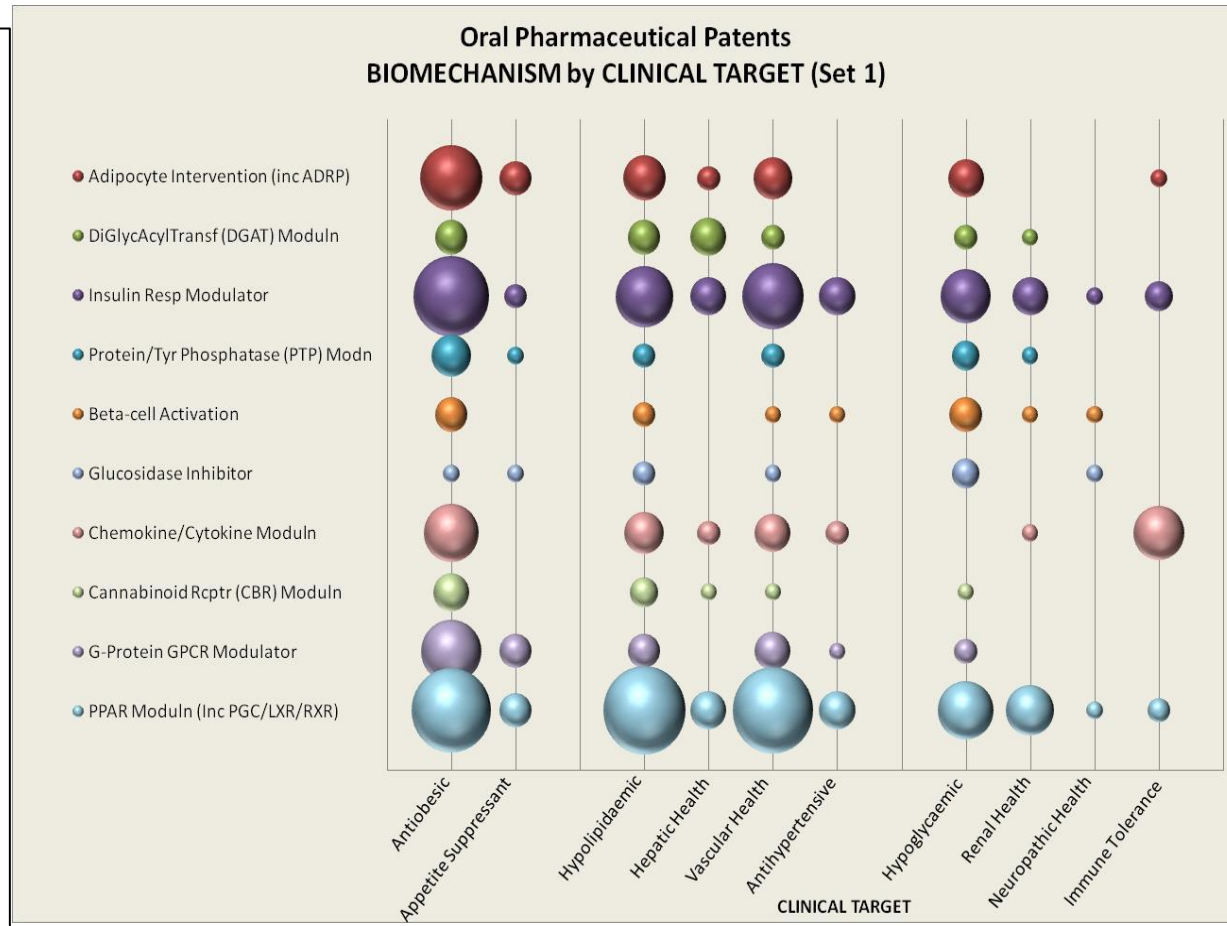




# Content Example: Mechanistic Clues


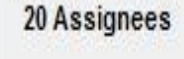










For this aspect we plot BIOMECHANISM against the CLINICAL TARGET with a bubble graph where the size of the bubble reflects the frequency of that association.

**Interplay between ORAL PHARMA BIOMECHANISMS and METABOLIC CLINICAL TARGETS** in a bubble graph taken from the HVN Metabolic Report provided to give researchers some insights to what biomechanisms may be responsive to a food intervention.



# Content Example: Operator Strategy

**PATENT PORTFOLIO STRATEGY PROFILE FOR LEADING OPERATORS** across the full oral intervention spectrum (Example for IMMUNE)

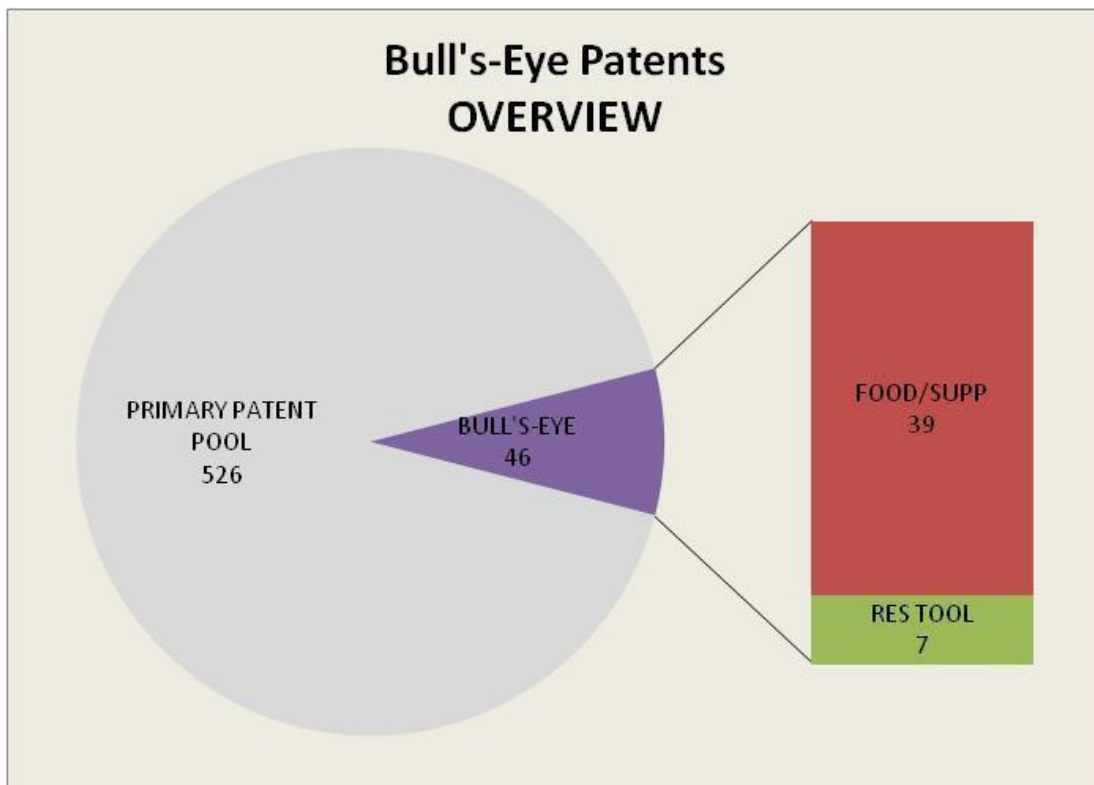
Patent Owner	Total No. of Families (% of full set)	Filing Trend (Absolute) 	No. of Filings in last 5 yrs vs Average of Top 20 Assignees 	Filing Year Range	TERRITORIAL COVERAGE (Inc Equivalents)										FORMAT			ACTION					
					US	EP	WO	JP	CN	KR	TW	HK	SG	AU	NZ	Food or Supplement	Oral Pharma	Trad Medicine	Research Tool	Innate Immune Treat/Mediate	Symptoms Preventative/Suppressant	Vaccine	Stimulant/Adjuv
NESTLE SA	26 (4.3%)			2001-2015	19	23	26	8	19	2	5	1	11	18	0	25	0	0	1	24	1	0	0
WYETH	14 (2.3%)			1991-1992	13	6	3	6	0	1	0	0	0	6	1	0	14	0	0	0	13	1	0
HAO ZHENRONG	12 (2%)			2013	0	0	0	0	12	0	0	0	0	0	0	0	0	12	0	0	12	0	0
GLAXO-SMITHKLINE PLC	9 (1.5%)			1995-2014	6	7	5	8	3	2	2	1	2	6	3	0	9	0	0	0	3	4	2
ABBOTT LABS	8 (1.3%)			1993-2015	7	7	8	6	3	2	3	0	1	6	2	5	3	0	0	5	0	3	0

# Defining a “BULL’S-EYE” PATENT

- Patents that most closely align with at least one core interest of the HVN Health Platform
- The set of published patents that:
  - has the best potential to inform research plans
  - should be kept in sight for managing freedom to operate risk
- Bull’s-eye patents are described in the reports.



# METABOLIC BULL'S-EYE PATENTS



- Total bull's-eye patents = 46 (8% of eligible pool)
- Providing useful FOOD INTERVENTIONS = 39
  - For OBESITY = 27
  - For DYSLIPIDAEMIA = 12
- Providing on-point RESEARCH TOOLS = 7
  - For OBESITY = 5
  - For DYSLIPIDAEMIA = 2

# REPORTS

1. Gut Health – Industry Intelligence
2. Gut Health – Patent Landscape
3. Metabolic Health – Industry Intelligence
4. Metabolic Health – Patent Landscape
5. Immune Health – Industry Intelligence
6. Immune Health – Patent Landscape
7. Food-Health Relationship – Regulatory Overview

# Patent Insights – IMMUNE

- Concept 1: Food interventions to enhance immune response to (flu) vaccination
  - Not totally new idea, 18 patents directed to this
  - Broad range of actives cited as effective
  - Oral actives included probiotics (x4), prebiotics (x2), specific peptides (x2), SCFA's, CLA, particular lipids, glycosides, poly-gamma-glutamic acid, glucosamine, glucans, proteases, a specific mushroom and a kiwifruit extract (!!)
- Concept 2: Food interventions to cope with respiratory inflammation from environmental airborne irritants (incl asthma):
  - Far less active, but not unknown with just 5 patents found
  - Nestlé hold 2 of the set directed to immune enhancement with probiotic (for infants) and sialic acid prebiotic (for elderly)
  - A third patent also combines pre- and probiotic for this effect
  - The remaining patents claim peptides and Actinidia (kiwifruit, again) as actives
- Trad & Alt Med patents provide most explicit interventions for pollutant irritants :
  - Predominantly rely on food-acceptable extracts like ginkgo, kelp, liquorice, konjac, so should be assessed for functional food use;
- Other points of note:
  - Infant immune stimulation patents far outweigh immune stimulation for adults and elderly
  - Nestle (CH) with a portfolio of 26 patent families is the top patent filer across all sectors
  - Other food companies with strong immune patent portfolios are Abbott (US, 8), Gervais Danone (FR, 8) & Mead Johnson (US, 7).
  - Designing regulatory acceptable claim validation protocols for pollutant irritants will be a challenge as there seems to not yet be standard and recognised models to adopt “off the shelf”.

# Patent Insights – METABOLIC

- Recent trend in focus of metabolics patents is away from obesity and lipid dysmetabolism to re-emphasise sugar dysmetabolism, esp serum glucose management.
  - Rapid rise to 2005, then plateaued.
- Metabolic development hot-houses (by % first filings):
  - US (30%), JP (20%), CN (18%), KR (15%)
  - EU only 5% first filings
- Sector focus:
  - Asian countries (JP, KR, CN) dominate food interventions and trad/alt med patent filings (mostly CN);
  - Western countries dominate pharma filings
- Dominant food actives claimed as active against lipid dysmetabolic conditions
  - Natural extracts, esp saponins/polyphenols (rutin notable); protein-peptides-FAAs; lipids-phospholipids.
  - Pre- & probiotics less impactful in this area
  - Feedback from the Metabolic lead scientist that rutin was “a focus of interest” led to a report exclusively on rutin IP, particularly directed to management of metabolic hyperglycaemia.
  - Rutin now a hot prospect for further study by science team for metabolic obesity management
- Key players
  - Nestlé (again) top of food league chart (12 patents), but 3<sup>rd</sup> overall and sole Western player of significance.
  - Other strong food players are Kao Corp (JP), Fancil Corp (JP), Genmont Bio (TW), Kaneka (JP), Yakult Honsha (JP), Megmilk (JP)
  - Asian (esp KR) universities strong too

# Patent Insights – ELITE GUT

- Patent filing trend for foods targeting gut comfort conditions shows long-run growth
  - 10% sustained annual growth since 1999
- Balance shifting from pharma solutions to food solutions
  - Key pharma players AstraZenica, MSD, have retired from the field, whereas food cos have increased activity
- Innovation hot-houses (by % of first filings):
  - CN (27%); US (26%) neck-and-neck (but US wins quality stakes)
  - Also runs are JP (12%); KR (7%) and EU (7%).
- Leading territories for gut comfort food innovations:
  - JP and EU each file well over 50% of their patents in the field as food sector solutions;
  - US shows a lower proportion (ca 40%) but higher count.
- Dominant food actives claimed as active against gut discomfort
  - A heavy dominance of probiotics (present in 32% of relevant patents) and prebiotics (24%) in foods promoting gut comfort; probiotics especially associated with foods for IBS
  - Otherwise strong representations of protein-peptides-FAA's (20%), Complex CHO's (12%) and phytochemicals (12%)
  - Insoluble fibre shows notably low presence; the focus has very much shifted to soluble fibre (Prebiotics).
- Key players:
  - Food companies show high presence in oral interventions to gut discomfort with top 4, and 6 of top 10 being food companies
  - Nestlé (CH) top dog (again) with 36 patent families, 4 times the count of runner-up Gervais Danone (FR)
  - Ajinomoto (JP) and Nutricia (NE) make up the top 4 with Yakult Honsha (JP) and Ironwood (US) making top 10.