

# Novel Food Navigation Tool

June 2021



Smart Regulatory Solutions



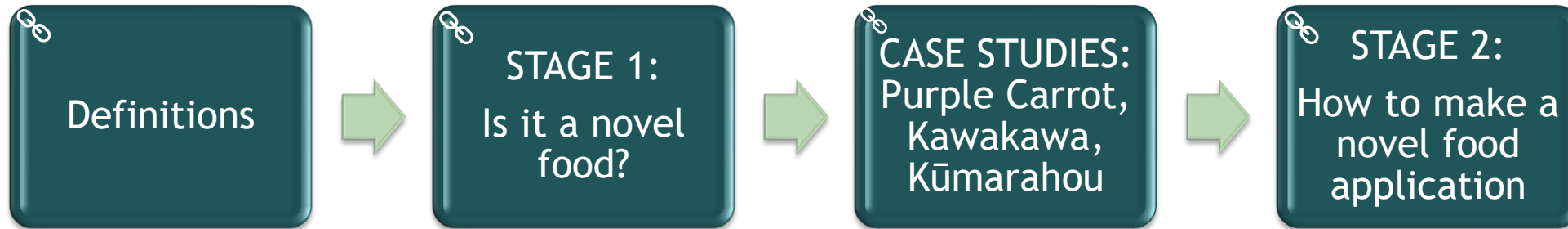
National  
**SCIENCE**  
Challenges

HIGH-VALUE  
NUTRITION

Ko Ngā Kai  
Whai Painga

- ❖ *Prepared by Michelle Cubitt, Smart Regulatory Solutions*
- ❖ *With the support of Riddet Institute*
- ❖ *Funded by High Value Nutrition*

# Novel Food Navigation Tool



Click links for more details

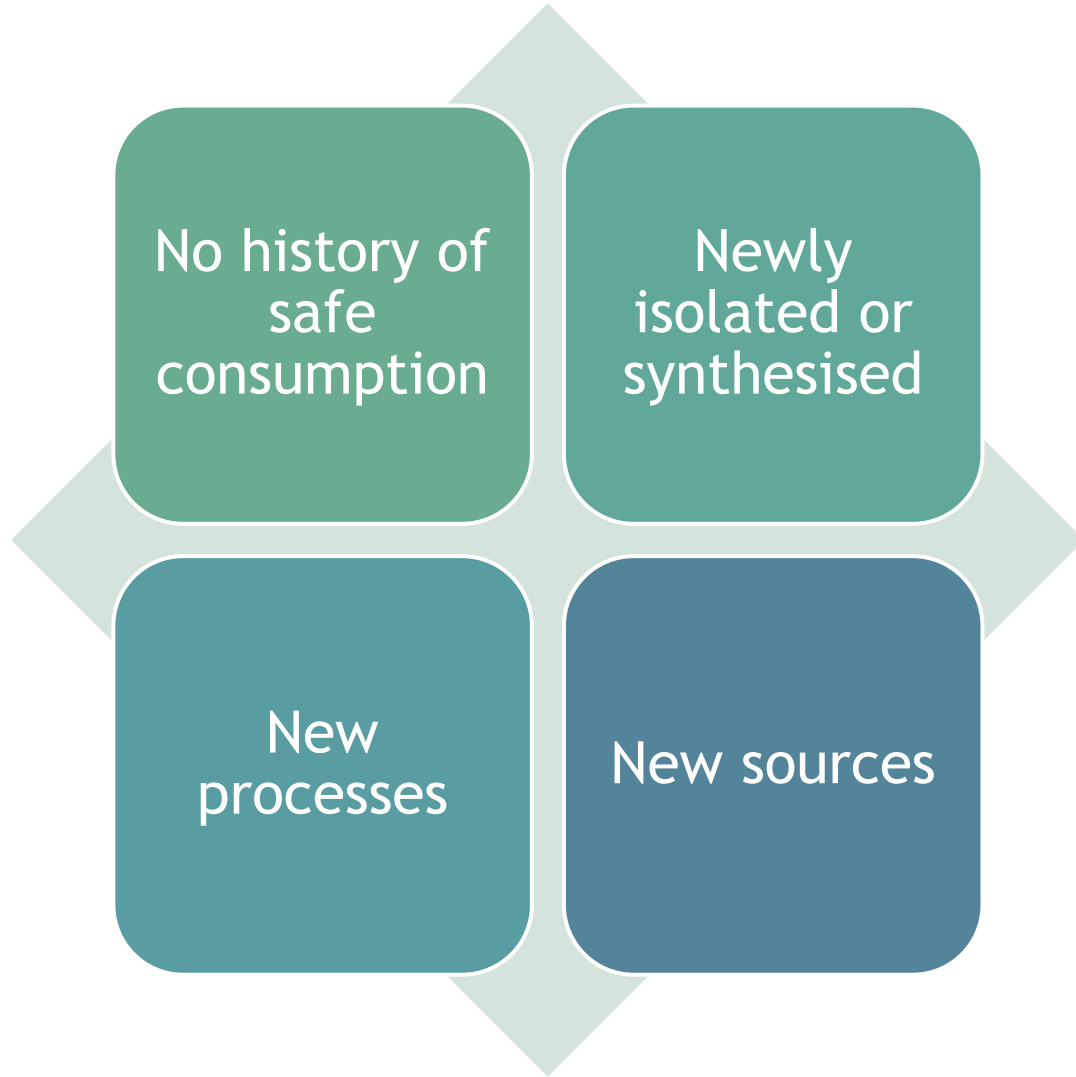
# What does novel mean?

Novel Food - a food or food ingredient that have not been used for human consumption or do not have a long history of safe use.

This means:

Has it been consumed safely as a food or part of a food for multiple generations?

# What makes it a novel food?



Key factors that can influence novel food classification.

# What is traditional use?

## Duration

- Number of years or generations

## Extent

- Worldwide
- General population
- Sub-population

## Quantity

- Amount consumed
- Frequency

## Purpose

- Regular diet
- Ceremonial
- Medicinal

Foods or food ingredients with long history of use in large populations where it is consumed frequently as part of the regular diet will be traditional foods.

# How to demonstrate traditional use

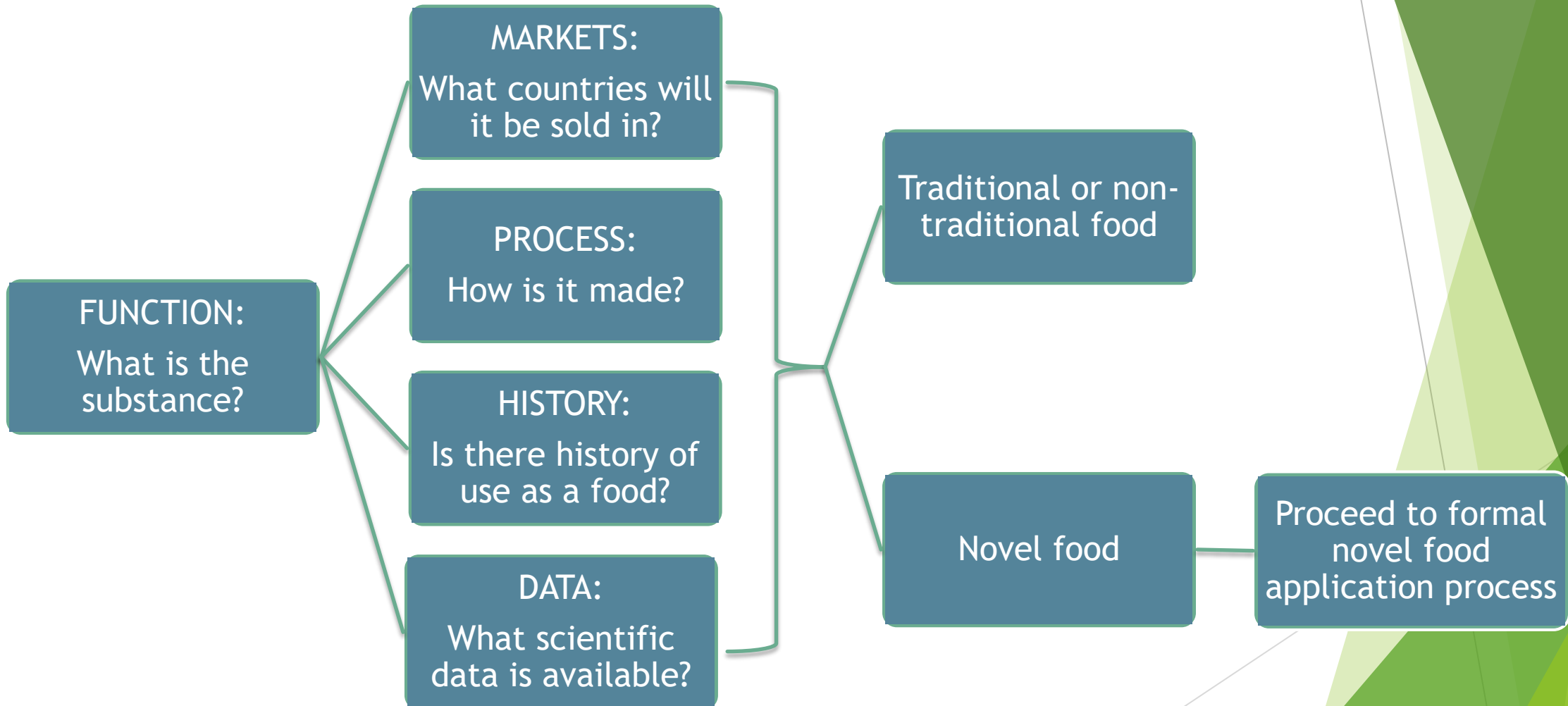
- Verbal accounts or interviews with traditional consumers
- Scientific or non-scientific publications
- Cookbooks
- Books on the history of food culture
- Information from reputable authorities
- Patents

The background features abstract, overlapping geometric shapes in various shades of green, ranging from light lime to dark forest green. These shapes are primarily located on the right side of the frame, creating a modern, layered effect.

**STAGE 1:**

**Is it a novel food?**

# How to decide if it is novel





# What can make something a novel food?

## Markets

What are the countries of interest?

## Function and Process

What is the purpose of the substance?

Is it an additive e.g. flavour or sweetener?

Is it providing a nutritive or health benefit?

What manufacturing process technology is used to create the substance?

## History of Use

Has the substance historically been used as a food?

Which markets has the substance been historically used – origin country or target market?

Is the function different to how it was used historically?

Is the manufacturing process different to historical processes?

## Data

Have any regulatory agencies published a view on the status of the substance?

What published literature is available on the safety of the substance?

## Status

If there is no history of use, a new use, new source material, new manufacturing technology or there are safety concerns – proceed to **novel food application roadmap**

If there is sufficient history of use and/or no safety concerns – not a novel food and **no further action required**

# NZ/Australia: Advisory Committee on Novel Food (ACNF)

*Service to help understand the traditional or novel status of a food or food ingredient in New Zealand and Australia*

## WHO

- ACNF = Advisory Committee on Novel Foods
- FSANZ, representatives from Australian states/territories, and NZ Ministry for Primary Industries (MPI)

## WHAT

- Provide recommendations (not legally binding) on whether substance is novel or not
- Recommendations published under “Record of views formed in response to inquiries”

## HOW

- History of consumption - traditional or non-traditional food
- Public health and safety considerations - novel food or not

## WHERE

- Guidance tool - <https://www.foodstandards.gov.au/industry/novel/Pages/default.aspx>
- Application form - send to [acnf@foodstandards.gov.au](mailto:acnf@foodstandards.gov.au)

# CASE STUDIES: Purple Carrot Extract, Kawakawa, & Kūmarahou

Case studies are indicative status only developed based on available information and regulatory definitions of traditional and novel foods. These opinions do not constitute definitive decisions from regulatory authorities. For more information on regulatory definitions of novel foods refer to the Resources section at the end of this tool. Any proposed use or research activity that involves taonga species or associated mātauranga must only be undertaken with prior informed consent and mandate of Māori, and with IP and benefit-sharing arrangements agreed in advance.

# Case Study: Purple Carrot Extract (Daucus carota)

## Markets

New Zealand, Australia and South Korea

## Function and Process

Purified and concentrated anthocyanin extract from purple carrots

## History

Carrots have documented traditional use as food  
Anthocyanin extract has significantly different composition – no history of consumption

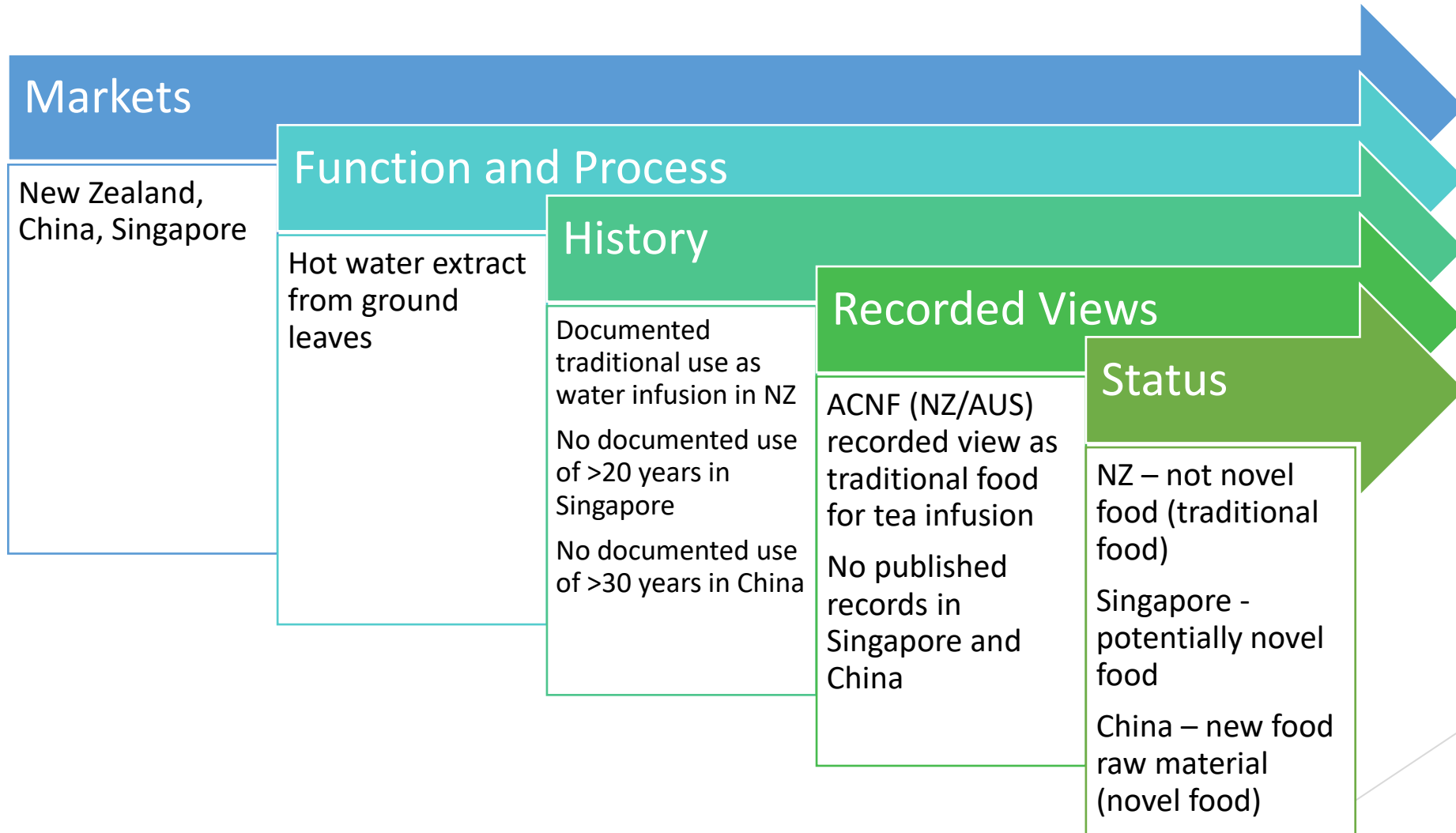
## Recorded Views

No record in NZ, Australia or South Korea of consuming highly purified and concentrated carrot extract

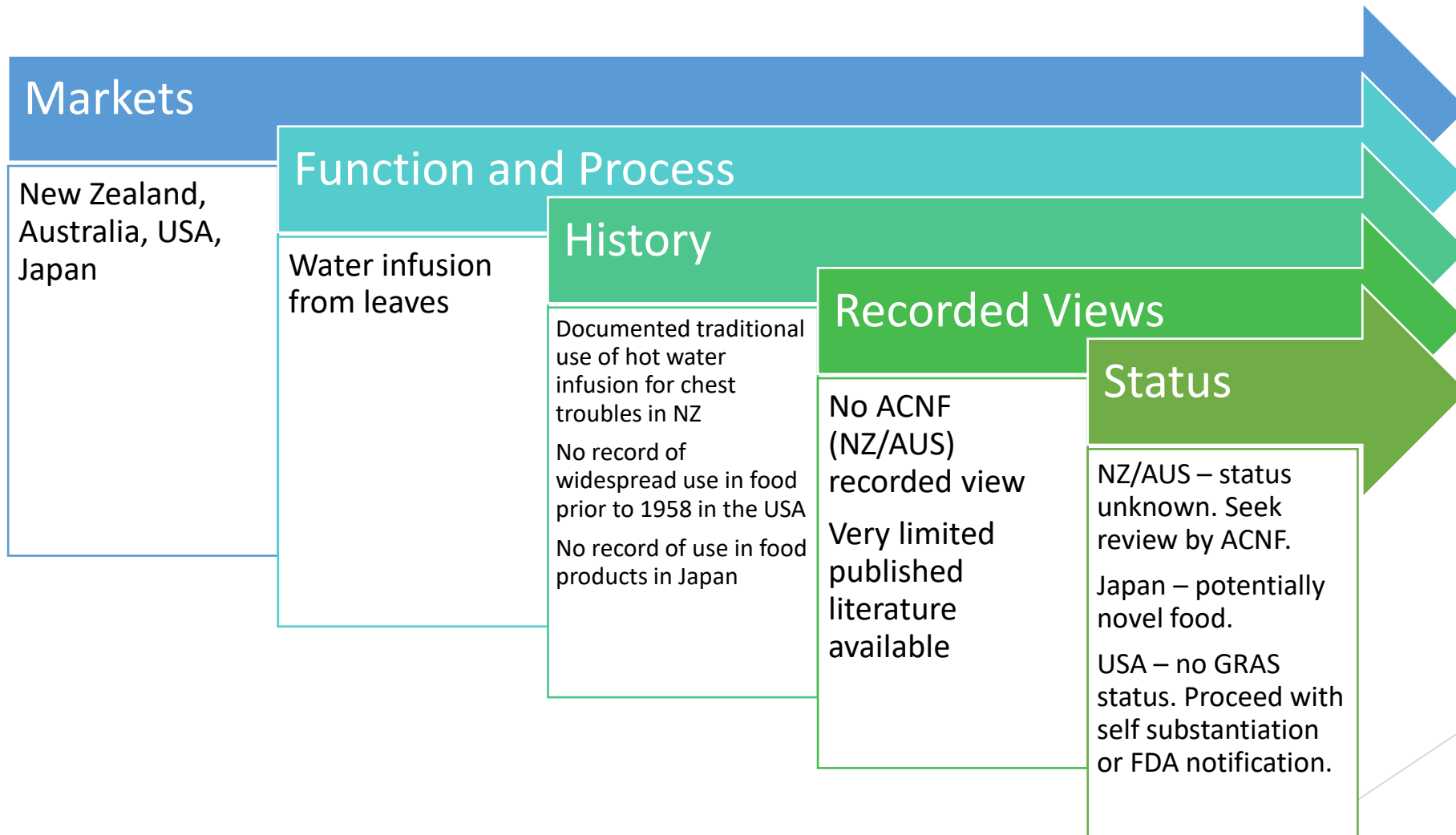
## Status

All markets – potential safety concerns due to no history of safe consumption. Potentially a novel food.

# Case Study: Kawakawa (*Piper excelsum*)



# Case Study: Kūmarahou (Pomaderris kumeraho)



# Summary of Indicative Status

	<b>Purple Carrot Extract</b>	<b>Kawakawa</b>	<b>Kūmarahou</b>
<b>New Zealand / Australia</b>	Carrots are a traditional food globally. Purified, concentrated extracts with very high levels of anthocyanins do not have history of safe consumption.  Seek ACNF view for purified, concentrated purple carrot extract.	ACNF recorded view – water infusion from leaves is a traditional food. No view on other preparations or parts of the plant.  Seek ACNF view for any preparation that is not water infusion from leaves.	No ACNF recorded view. Limited published data available about non-medicinal use as a food.  Gather additional data on traditional use as a food in New Zealand and seek ACNF view.
<b>USA</b>	<b>Not GRAS</b> - No record of widespread use in the USA prior to 1958. Required to self-substantiate GRAS or submit FDA GRAS notification.		
<b>Singapore</b>	<b>Potentially novel food</b> – no history of use in food in Singapore for >20 years.		
<b>China</b>	<b>New food raw material</b> – no record of use in food in China for >30 years.		
<b>Japan</b>	<b>Potentially novel food</b> – no record of widespread use in food in Japan.		
<b>South Korea</b>	<b>Potentially novel food</b> – no record of widespread use in food in South Korea.		



# STAGE 2:

## How to make a novel food application



START

### GAP ANALYSIS

Engage with regulatory agencies and third parties to assess potential data gaps



### PREPARE APPLICATION

Collate data and prepare application. Ensure all standard application forms are used. Check application language requirements.



USA:  
Simplified Roadmap  
for FDA GRAS

### SUBMIT APPLICATION

Submit application directly with government agency or through nominated representative acting on behalf



### FORMAL ASSESSMENT

Regulatory agency formally assesses application



### FORMAL DECISION

Regulatory agency formally accepts or rejects application and publishes result. Legal framework updated if application is accepted.



### AGENCY RESPONSE

Regulatory agency requests more data (refer back to generate data) or accepts application and proceeds with formal assessment



### GENERATE DATA

Conduct testing to generate missing data identified in gap analysis. Use suitably qualified service providers.



### INITIAL ASSESSMENT

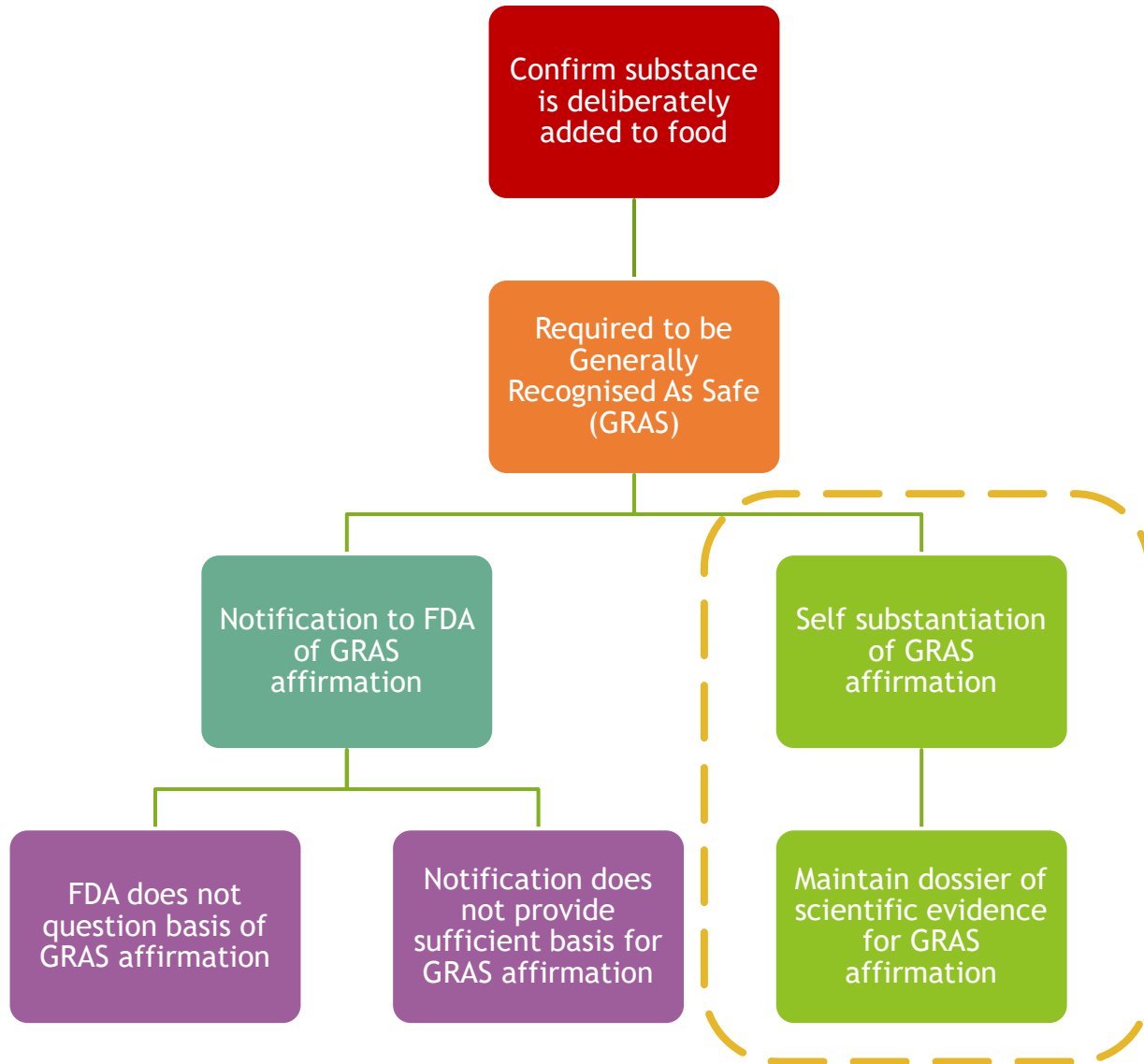
Confirm substance meets definition of novel food



# Novel Food Application Roadmap Overview

FINISH

# Simplified Roadmap for FDA GRAS

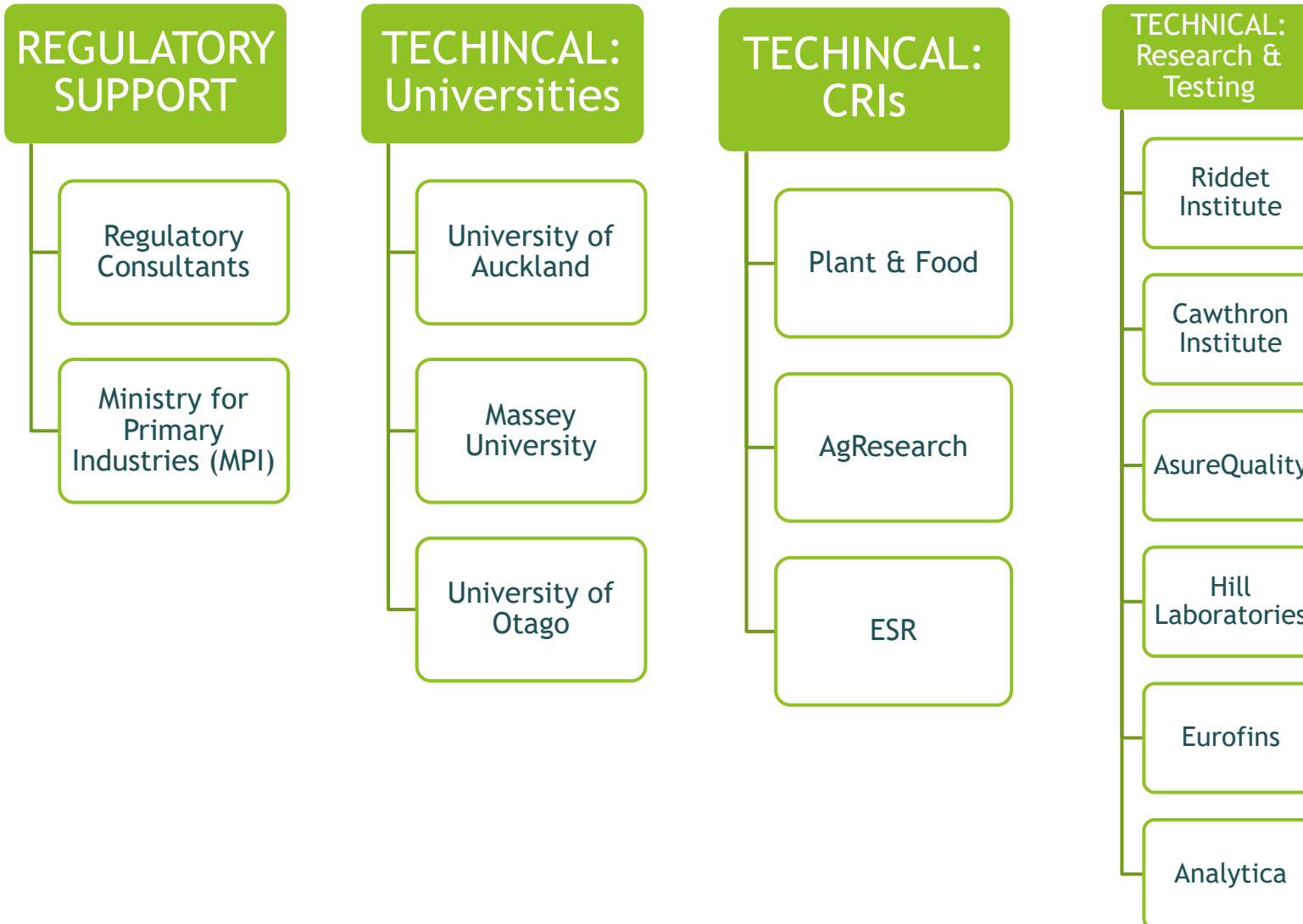


FDA GRAS process allows for the option to self-substantiate. Once **GAP ANALYSIS** and **GENERATE DATA** have been completed, there is the opportunity to follow self-substantiation route. This is an alternative to standard pathway in Novel Food Application Roadmap

# Novel Food Application: Technical Data Requirements

<b>INFORMATION</b>	<b>REQUIREMENTS</b>
<b>Identification</b>	Scientific/Latin name, common names, part(s) used, geographical origin
<b>Manufacturing Process</b>	Detailed production process from cultivation to finished substance
<b>Composition</b>	Detailed compositional analysis with focus on presence of possible substances of concern in botanical material e.g. naturally occurring substances that maybe be of concern for human health
<b>Stability</b>	Demonstrate stability under normal conditions and address possibility of presence of harmful substances due to degradation
<b>Specification</b>	Tests and limits for key parameters that characterise identity of novel food and relevant physiochemical, biochemical and microbiological parameters
<b>Dietary Intake and Use Level</b>	Target population, anticipated daily intake, other potential sources of intake of the novel food, estimated exposure to undesirable substances.
<b>Nutritional Information</b>	Data to demonstrate novel food is not nutritionally disadvantageous for consumers under proposed conditions of use, potential precautions or restrictions for use.
<b>Toxicological Information</b>	<p>Genotoxicity (start with basic in vitro), acute and subchronic toxicity (90 day rodent study).</p> <p>Depending on initial toxicity results may also require chronic toxicity, carcinogenicity, reproductive and developmental toxicity tests.</p> <p>Human data – can include relevant safety assessment information from human clinical trials e.g. physical examination, blood chemistry, monitoring of adverse events.</p> <p>Allergenicity</p>

# Where to go for help



# Resources



## New Zealand / Australia

- [Regulation of Novel Food](#)
- [FSANZ Application Handbook](#)
- [Pre-Application Assistance](#)

## USA

- [Determining the Regulatory Status of a Food Ingredient](#)
- [How U.S. FDA's GRAS Notification Program Works](#)
- [FAQs About GRAS for Substances Intended for Use in Human or Animal Food](#)
- [Regulatory Framework for Substances Intended for Use in Human Food or Animal Food on the Basis of the Generally Recognized as Safe \(GRAS\) Provision of the Federal Food, Drug, and Cosmetic Act](#)
- [Guidance for Industry Considerations Regarding Substances Added to Foods, Including Beverages and Dietary Supplements](#)

## Singapore

- [Requirements for the Safety Assessment of Novel Foods](#)

## Japan

- [Food Safety Commission of Japan Novel Food Evaluation Reports](#)

## China

- [New Food Raw Material Regulation Summary](#)