



Netherlands Food and Consumer  
Product Safety Authority  
*Ministry of Agriculture,  
Nature and Food Quality*

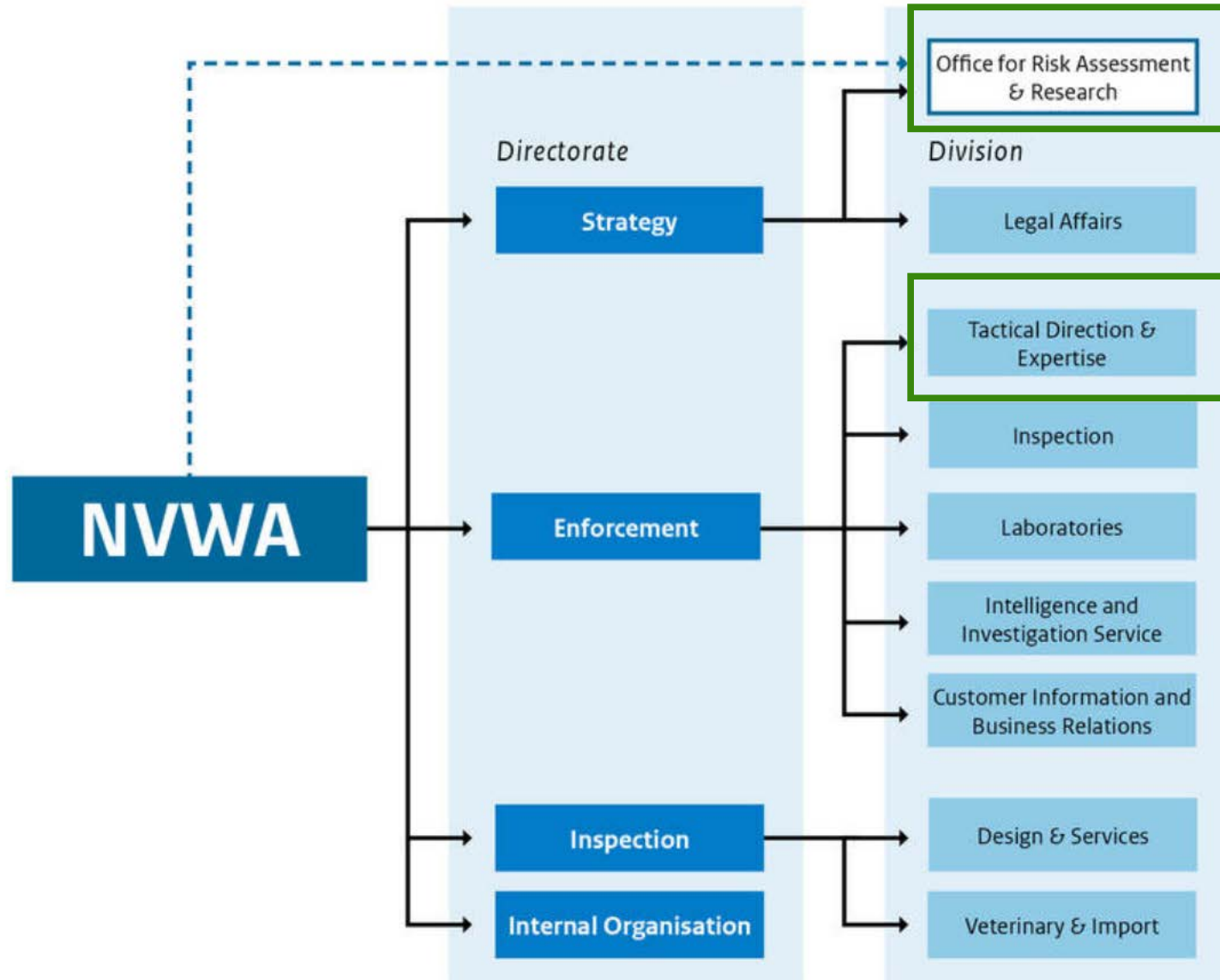
## Initiative on European level for classification pharmacologically active substances in food supplements

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Toxicologist (ERT) and risk assessor  
Office for Risk Assessment & Research



# Organisation chart





# Office for Risk Assessment & Research

Bureau  
Risicobeoordeling & onderzoek  
(BuRO)

- > BuRO provides independent advice to:
  - Inspector-General of NVWA
  - Dutch Ministry of Health, Welfare and Sport
  - Dutch Ministry of Agriculture, Nature and Food Quality
- > Upon request or upon own initiative



# Introduction

- › What are food supplements?
- › Involved risks
- › Examples
- › Legislation
- › HoA WG FS



# What are food supplements?

- › Directive 2002/46/EC defines food supplements as 'foodstuffs the purpose of which is **to supplement the normal diet** and which are **concentrated sources of nutrients or other substances with a nutritional or physiological effect**, alone or in combination, marketed in **dose form**, namely forms such as capsules, pastilles, tablets, pills and other similar forms, sachets of powder, ampoules of liquids, drop dispensing bottles, and other similar forms of liquids and powders designed to be taken in measured **small unit quantities**.'



# Different types of food supplements

- › Vitamins & minerals
- › Botanicals
- › Other substances



# Risk

- › Substance is not or not correctly declared on the label
- › Adverse health effects
  - Taking more pills than prescribed on the label
  - Interaction with medicines
  - Due to strenuous physical exercise
- › Positive doping test



# Shambala

“Find your inner  
guru”





# Shambala

- › Contains parts of two plants:
  - Caapi (*Banisteriopsis caapi*)
  - Bobinsana (*Calliandra angustifolia*)



# Shambala

- › Contains the  $\beta$ -carboline alkaloids: harmine, harmaline and tetrahydroharmine
- › Harmful effects can occur from a single use
- › Harmful interactions with other MAO inhibitors
- › [Risk assessments Front Office Food and Product Safety | RIVM](#)

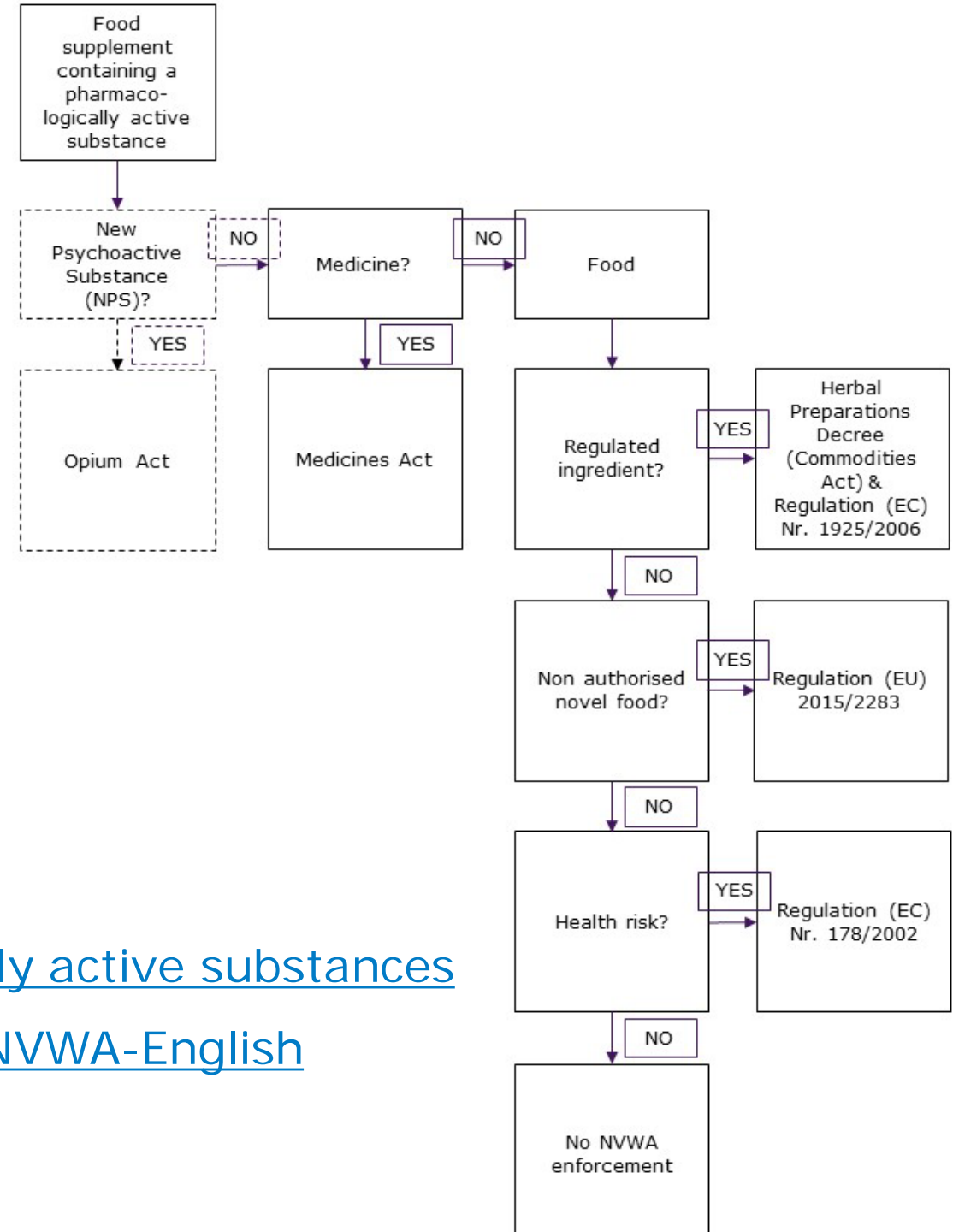


# Shambala

- › Retrieved from the Dutch market
- › Active communication to consumers

# Legislation & enforcement

- Status?
- National regulation
  - Positive or negative list
- Mutual recognition
- [Advice from BuRO on pharmacologically active substances in food supplements | Risk analysis | NVWA-English](#)





# European Commission

- › Portuguese presidency held a high-level conference on food supplements and concluded:
  - Revision of the current legislation is needed
    - Clear and enforceable legal provisions facilitating the implementation of common requirements and the harmonization of market conditions throughout the European Union.

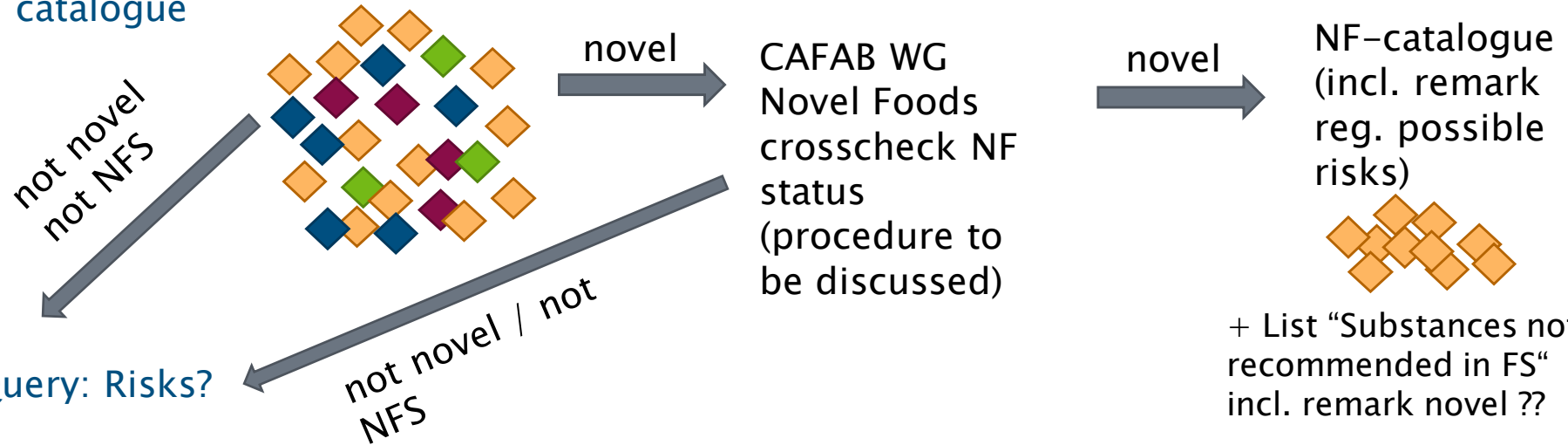


# HoA working group on food supplements

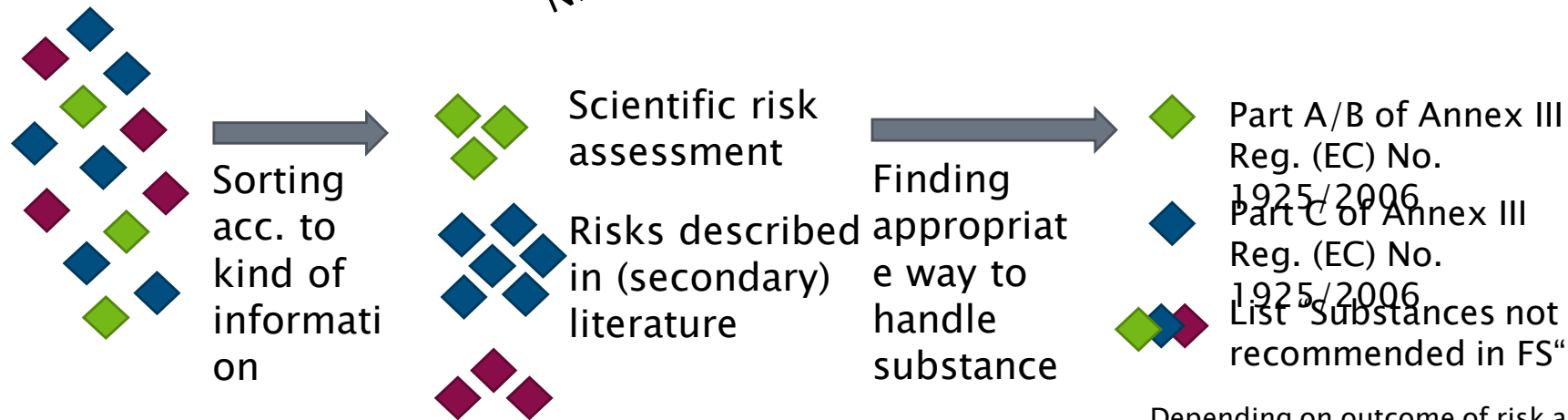
- › First meeting was in November 2020
- › Currently chaired by Germany and the Netherlands
- › Purpose: to establish a list of substances (botanicals) in food supplements that need to be forbidden or limited

# Visualization of procedure

1. Query: Novel or not? / Crosscheck D-A-CH with HoA WG and NF-catalogue



2. Query: Risks?



Depending on outcome of risk assessment, severity of risks and information available

## 3 UPDATES

### Risk assessors and risk managers will prepare a recommendation How to handle substances in FS with a potential risks for consumers

Known use in food before May 1997	Scientific risk assessment available	Recommended management of substances of concern
No	-	Novel food – Inclusion in the EU COM's Novel Food-Catalogue
Yes	Yes	Part A or B of Annex III Reg. (EC) No. 1925/2006
Yes	No	Part C of Annex III Reg. (EC) No. 1925/2006

#### Goal

- Reliable information for stakeholders
- to facilitate enforcement of “substances with a potential risk” by competent authorities.



# Questions?



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