



EAT Forum, 2019



# **Towards safe innovations: nutrивigilance and post-market monitoring for novel proteins**

Dr. Alie de Boer | Maastricht University

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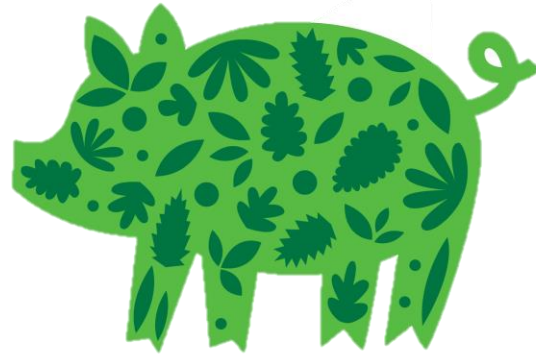
# Maastricht University's Food Claims Research Centre

- Multidisciplinary research centre studying nutrition and food science & food law
- How is scientific evidence generated and used in food policy and legislation?
- Food information to support **safe, healthy and sustainable** food choices





# MoSIN: Monitoring the safe introduction of novel foods







# Aims of MoSIN

- To gain knowledge on **how allergies develop** and what the impact is of demographic factors
- To provide clear guidance for food business operators how to **collect, verify and analyse adverse reactions to (novel) foods**
- To develop a best practice for (novel) **food allergen labelling** and providing food allergen information



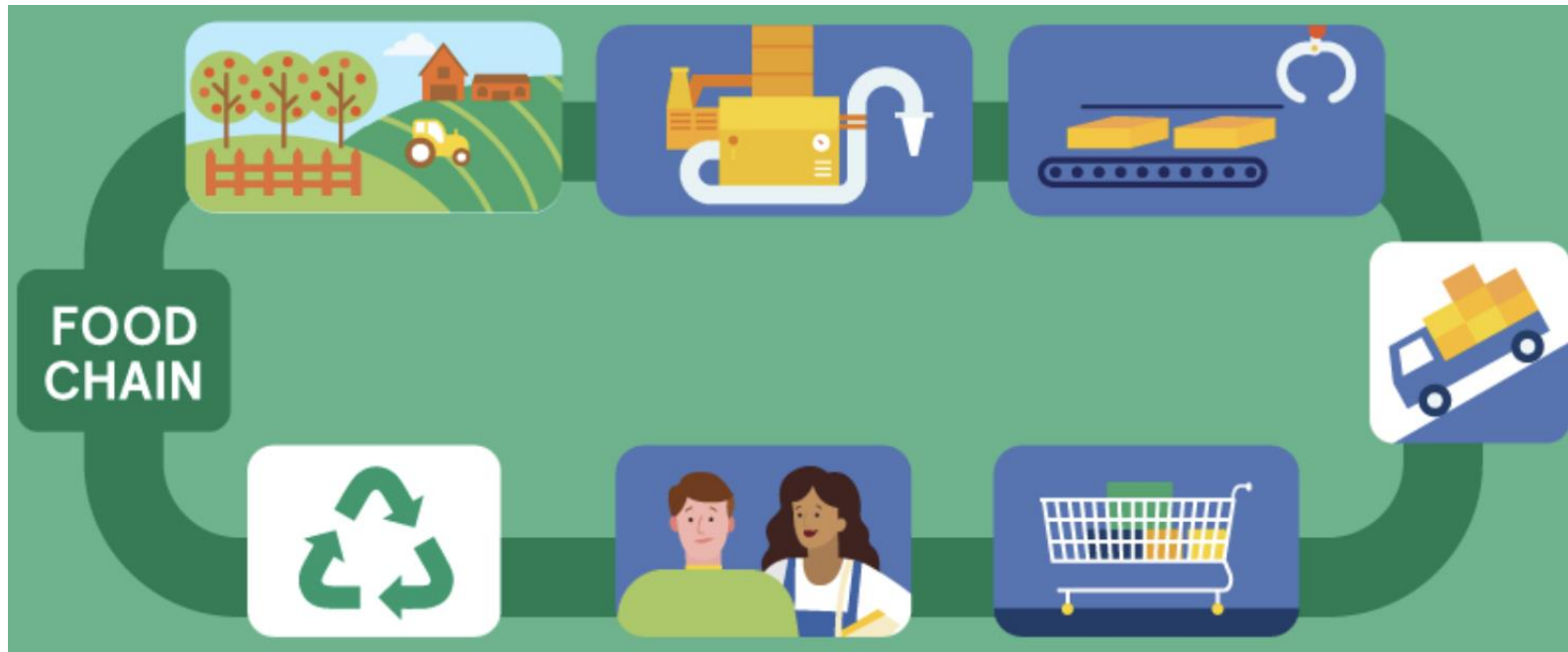
# Collect, verify and analyse: vigilance

- Pharmacovigilance: collect and analyse adverse events related to pharmaceutical products
  - Legal requirement in EU
- Vigilance (WHO, 2006): Science, system and activities related to detecting, assessing, understanding and preventing adverse reactions associated with the intake of pharmaceutical products
- Foods: should be safe



# Food safety: legal requirements

- EU General Food Law (Regulation No 178/2002)



EUFIC, 2014



# Food safety?

Regulation 178/2002, Art. 14:

1. Food shall **not be placed** on the market if it is **unsafe**.
2. Food shall be deemed to be unsafe if it is considered to be:
  - a. **injurious to health**  
Acute, short & long term effects on consumers and offspring;  
potential cumulative toxic effects; possible particular sensitivities
  - b. **unfit for human consumption**  
Depending on normal conditions of use & information provided to consumers





# Pre-market authorisation

## **New nutrient source**

- Added nutrient source: Reg 1925/2006
- Special Groups: Reg 609/2013
- Supplement: Dir 2002/46/EC

## **Novel food (ingredient)**

- Reg 2015/2283
- Traditional foods: Reg 2017/2468
- Art 10: Reg 2017/2469

## **Foods for special groups**

- Reg 609/2013
- Infant formula: Reg 2016/127
- Special medical groups: Reg 2016/128

## **Food improvement agents**

- Reg 1331/2008
- Additives: Reg 1332/2008
- Enzymes: Reg 1333/2008
- Flavourings: Reg 1334/2008

## **GM foods and crops**

- Directive 18/2001/EC
- Reg 1829/2003
- Reg 503/2013

## **Health claims**

- Reg 1924/2006

**GFL: all foods should be safe for the general population**



# So: foods are safe?





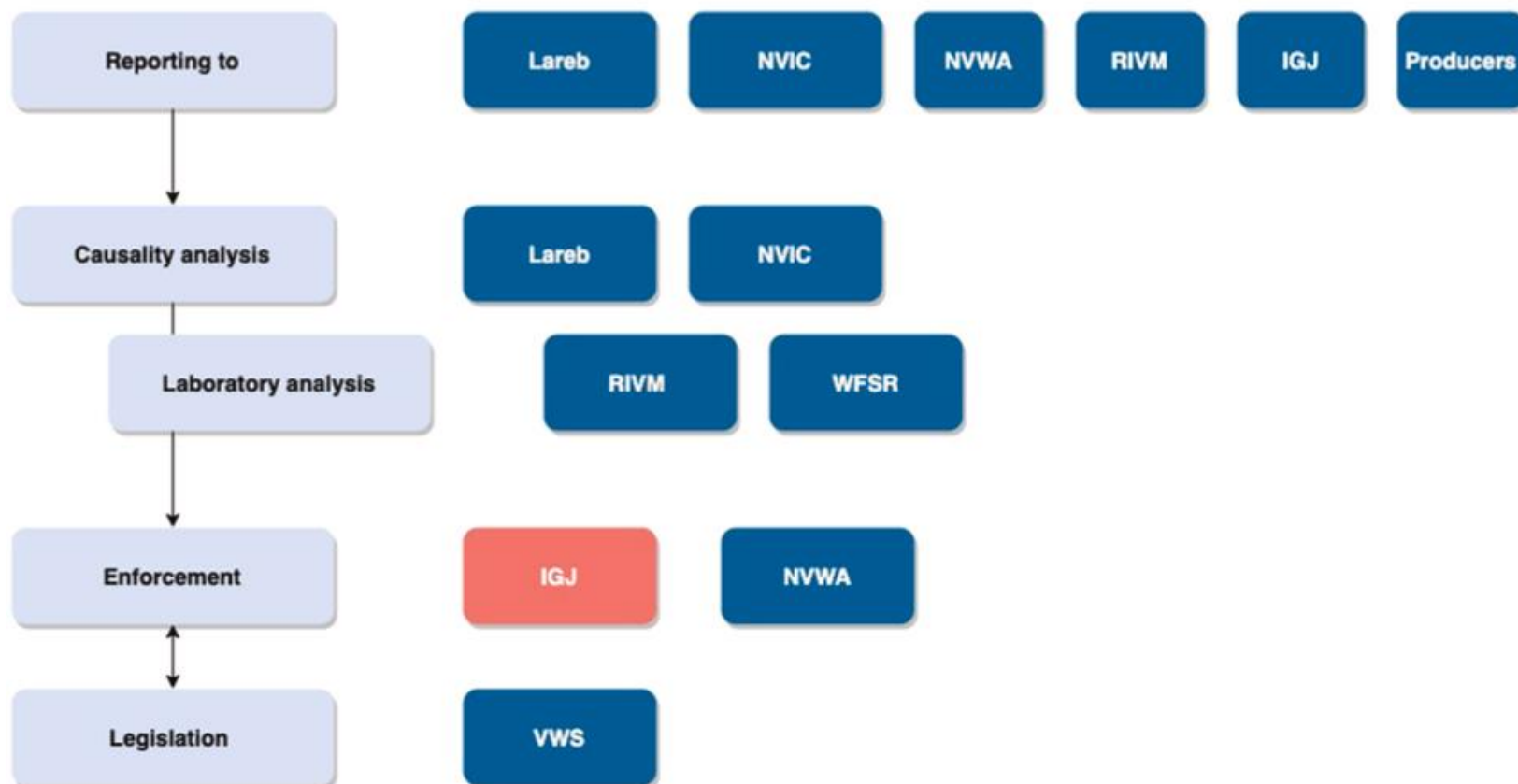
# Reporting adverse events

- Various EU countries: nutrivigilance systems
  - France: ANSES (Agency for Food, Environmental and Occupational Health & Safety)
  - Italy: ISS (Italian National Institute of Health)
- Collecting & reporting adverse event reports
  - Focus on dietary supplements, herbs and botanicals, fortified foods and sometimes novel foods



# In the Netherlands (de Boer et al., 2022)

- Reports received at various organisations
- Since 2021: Lareb point of contact for supplements & herbal products

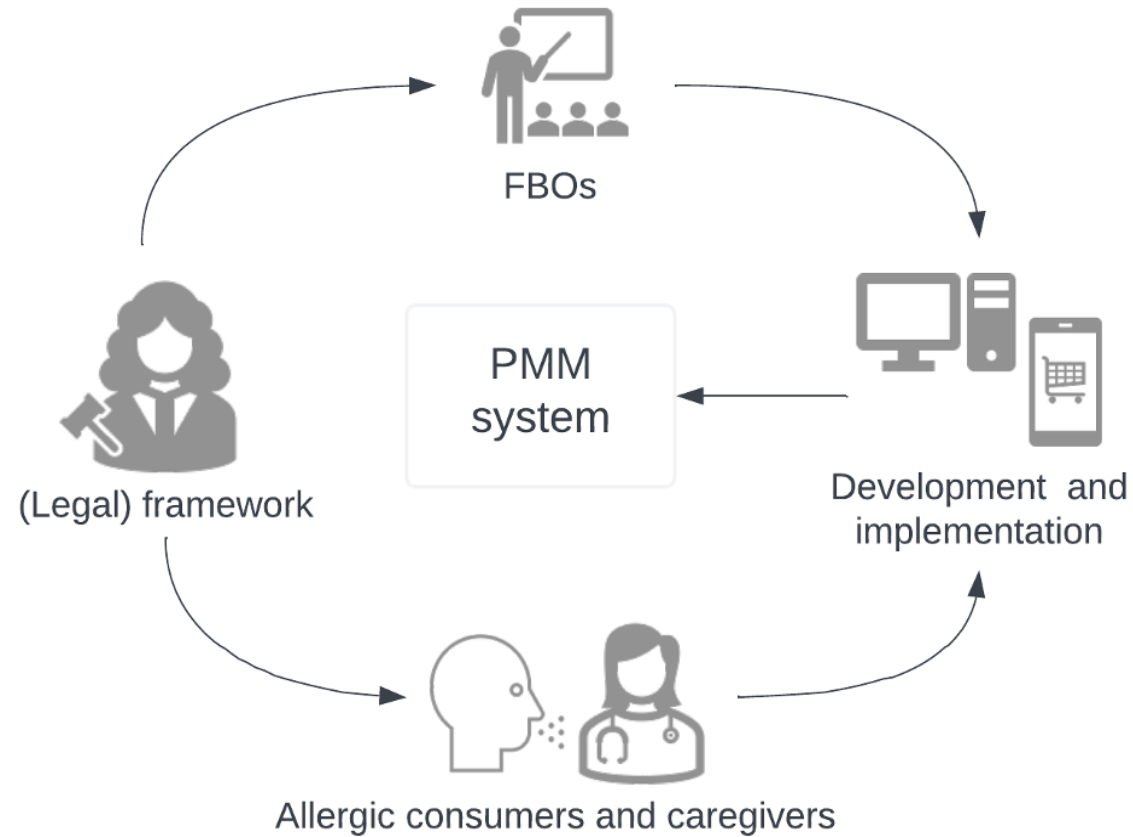








# MoSIN: post-market monitoring







# First MoSIN findings

- Increasing (unharmonised) activities across Europe
- Limited reports received at (Dutch) food businesses
- Quality managers report:
  - Highly varied **need** for post-market monitoring system
  - Very **positive effect** of system on **food safety**



# Join our efforts!

- Share your insights in our first survey
- Approach us for more info on the project
- Follow us on [www.mosin-kic.nl](http://www.mosin-kic.nl)





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