

Process: food safety law in action

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Would this be safe food? E-numbers

What can we do about it?

NL Plantaardige margarine.
Bevat 80% vet. **Ingrediënten:** plantaardige oliën en vetten*, water, 1% zout, emulgatoren (sojalecithine**, E471), droge melkbestanddelen, conserveermiddel (E200), voedingszuur (citroenzuur), aroma's, kleurstof (caroteen), 800 mcg Vitamine A en 7,5 mcg D3 per 100 gram.
* geproduceerd met genetisch gemodificeerde soja.
** genetisch gemodificeerd.

Geproduceerd in: Nederland.
Na openen koel bewaren.
art.nr. 5044009

Gemiddelde voedingswaarde
Energie
Eiwit
Koolhydraten

* Volgens de informatie verkregen van de partijen vóór aan de veldbezoeken van 20 vóór vóór worden geproduceerd. Daarom is de bronk op grond van een en registratie geproduceerd het product te een

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Overview

- Objectives
- Materials
- If food safety is the objective, what do you have to do to achieve it?
- Prevention
 - FBOs: Hygiene
 - Hygiene 1
 - Hygiene 2 food of animal origin
- Preparedness
 - FBOs: Traceability

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Objectives

- You:
- can appreciate the interaction between food hygiene prescriptions and self-regulation to implement them;
- have an insight in the structure and consequences of the requirement of traceability
- can apply this knowledge in a meaningful way.

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CJEU 13-11-2014 C-443/13 'Reindl'

- Inspectors find industry-brand turkey breast in supermarket
- Contaminated with salmonella
- Supermarket is fined
- Question: does EU law allow such fine?



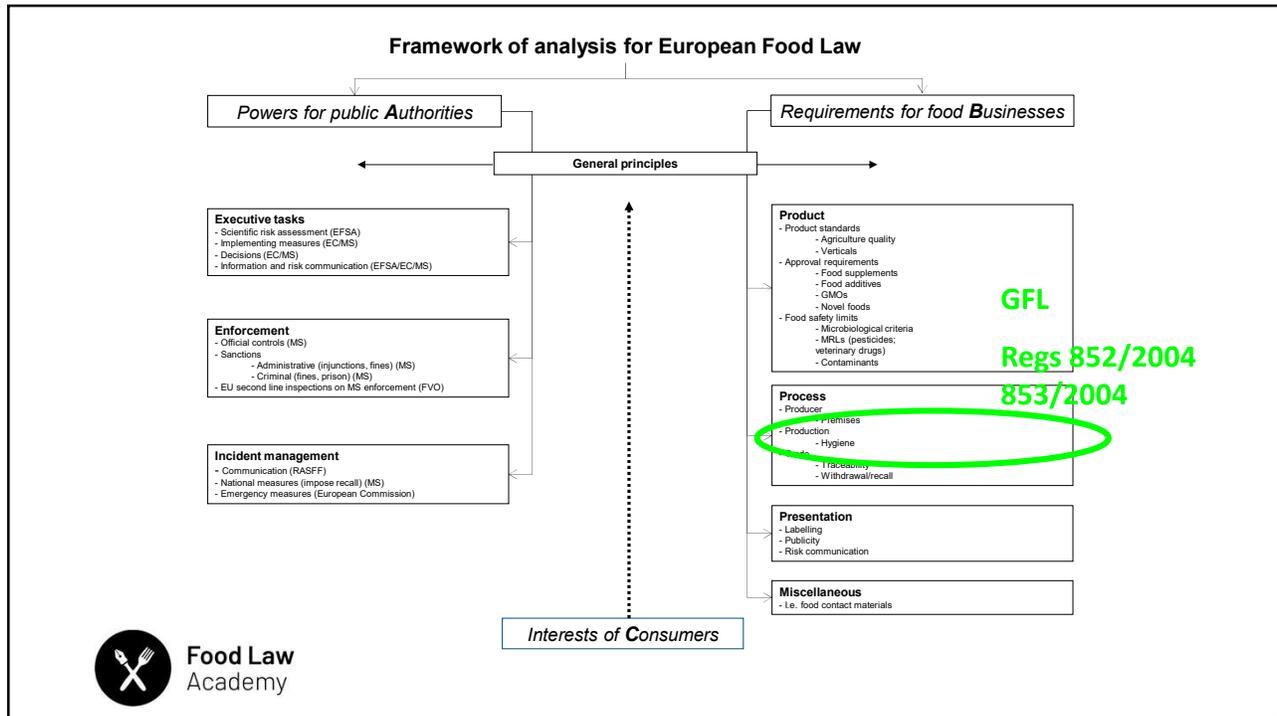
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Tools

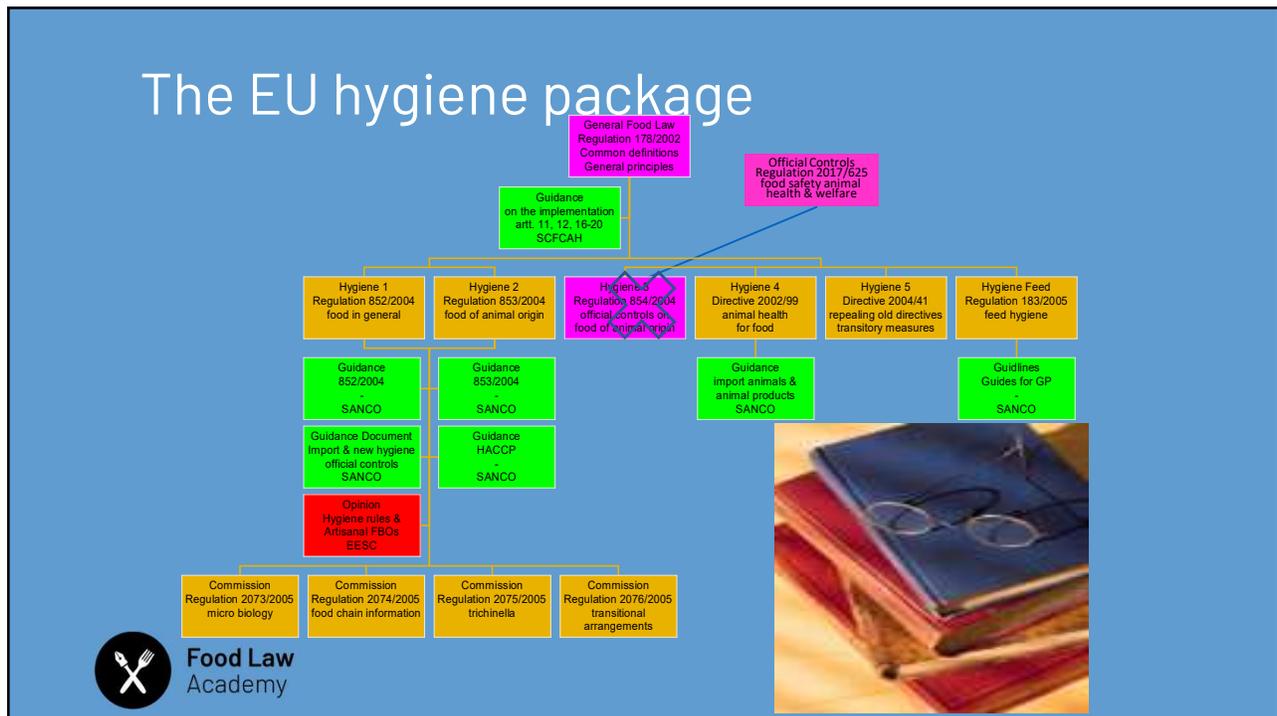
- Literature
 - Handbook chapter 12
- Sources
 - Hygiene 1 (852/2004)
 - ECJ 6 October 2011, Case C-382/10 hygiene



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Regulation 178/2002 (GFL)

- Definitions
 - Food
 - Food business operator

- General ban on unsafe food: Article 14
 - General sanction on non-compliance with food safety law → food may not be brought to the market

- Principles
 - Holism: feed & food from farm to fork
 - Apply international standards → Codex Alimentarius
 - Business is responsible for food safety → performance standards / process standards
 - Member States responsible for enforcement



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Food safety risks

- Article 3(9/14)GFL:

9. 'risk' means a function of the probability of an adverse health effect and the severity of that effect, consequential to a hazard;

14. 'hazard' means a biological, chemical or physical agent in, or condition of, food or feed with the potential to cause an adverse health effect;



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Risk management: responsibilities

- Article 6: risk management is based on scientific risk assessment
- Article 17(1) GFL: FBOs responsible for food safety
 - Prevention: hygiene
 - Preparedness: traceability
 - Response: recall
- Article 17(2) GFL: MS responsible for controls & enforcement
- Article 53 GFL: emergency measures by the European Commission



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Prevention - Food hygiene



- 'hygiene', means the measures and conditions necessary to control hazards and to ensure fitness for human consumption of a foodstuff taking into account its intended use
- **Achieve Article 14 GFL**
- **Achieve food safety objectives**
- Regulation 852/2004 Article 2(1)(a) Definitions

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Biological Safety: Food Hygiene

http://ec.europa.eu/food/safety_en

http://ec.europa.eu/food/safety/biosafety/food_hygiene_en

Commission and its priorities Policies, information and services

English EN

European Commission > Food, farming, fisheries > Food Safety > Food > Biological safety >

Food

BIOLOGICAL SAFETY

- Antimicrobial Resistance
- Crisis Preparedness & Management
- Food Hygiene**
- Legislation
- Guidance Platform
- Microbiological Criteria
- EU countries: approved food establishments

Food Hygiene

NEW: Revision of official controls on products of animal origin intended for human consumption: from 14 December 2019 on, Regulation (EC) 854/2004 will be replaced by the requirements in Regulation (EU) 2017/625, Commission Delegated Regulation (EU) 2019/624, Commission Delegated Regulation (EU) 2019/625, Commission Implementing Regulation (EU) 2019/626, Commission Implementing Regulation (EU) 2019/627 and Commission Implementing Regulation (EU) 2019/628 - [Read more](#).

Rules on hygiene of foodstuffs were **adopted in April 2004** by the European Parliament and the Council (Regulation (EC) No 852/2004, 853/2004 and 854/2004). They became **applicable on 1 January 2006**.

The 2004 rules **merged, harmonised and simplified** detailed and complex **hygiene requirements** previously contained in a number of Council Directives covering the hygiene of

RELATED LINKS

- [EU Register of National Guides to Good Hygiene Practice](#)
- [Food Hygiene related press releases](#)

QUICK LINKS

- [Rapid Alert for Food and Feed \(RASFF\)](#)
- [Health and food audits and analysis](#)
- [European Food Safety Authority](#)

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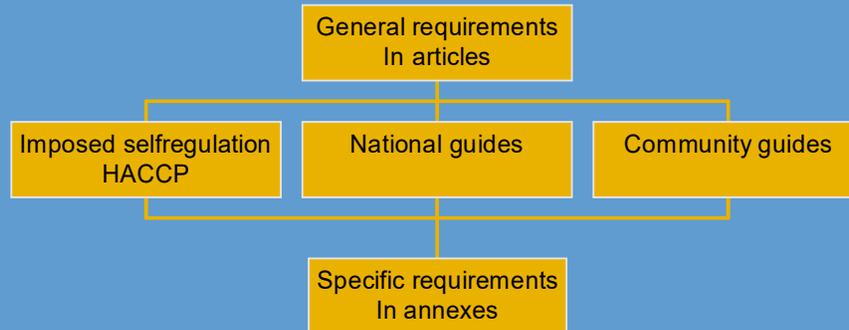
Hygiene 1(I)

- Regulation 852/2004
- General principles
 - Business responsible
 - Chain integration
 - HACCP
- Scope
 - All food (**including** animal origin)
 - All stages of production, processing, distribution
 - Except: primary production for private use, domestic preparation
- Definitions: GFL & specific

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Hygiene 1 (II) Structure



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Hygiene 1 (III)

- General obligations
 - Registration of establishments
 - Satisfy Regulation's requirements
 - Comply with applicable annex and Hygiene 2
 - Comply with criteria set by Commission
 - Implement and maintain permanent procedure based on HACCP-principles
 - Co-operate with authorities

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Hygiene 1 (IV) HACCP

Article 5(2) Hygiene 1

- A) Identify hazards
- B) Identify critical control points
- C) Establish critical limits
- D) Establish monitoring procedures
- E) Establish corrective actions
- F) Verification
- G) Documentation

Primary producers exempted
→ often corrected by private standards



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Hygiene 1 (V) Annexes

- Updated through Comitology
- Annex I: primary production
- Annex II: others
- Practical details
 - Sinks, personal hygiene
 - waste water, etc.

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ECJ 6-10-11 C-382/10: Responsibility

- At all stages of production, processing and distribution, food is to be protected against any contamination likely to render the food unfit for human consumption, injurious to health or contaminated in such a way that it would be unreasonable to expect it to be consumed in that state.

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ECJ 6-10-11 C-382/10: Resp. cont'd

- 20: FBO is responsible
- 22: It follows that (...) where the competent authorities do not appear to have concluded that there was actual contamination, it cannot be concluded that food business operators have infringed (...) on the basis only of the finding that a potential purchaser could conceivably have touched the foodstuffs by hand or sneezed on them, without **considering the measures** taken by those operators (...) in order to prevent, eliminate or reduce to acceptable levels the hazard which the contamination (...) may present and without **determining that the measures** taken in that regard were insufficient in the light of all the available relevant data.
- **I.e. check the system.**



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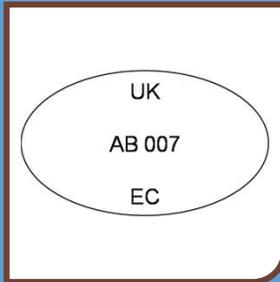
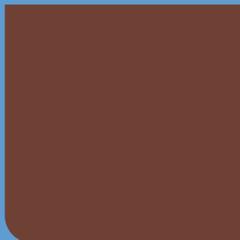
Cross compliance

- Primary sector receiving Single Farm Payment
- Regulation 73/2009 → comply with requirements mentioned in Annex
- Articles 14, 15, 17(1), 18, 19, 20 GFL businesses responsible to satisfy the food and feed safety requirements of food law → includes food hygiene legislation



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Hygiene 2

- Regulation 853/2004 laying down specific hygiene rules for food of animal origin
- Food of animal origin processed and unprocessed
 - Composite products excluded
- Health and identification marking
- Vertical rules in annexes: molluscs, fish, etc.



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Hygiene 4

- Council Directive 2002/99
- Animal health rules for human consumption
 - production, processing, distribution, etc.
- No spreading diseases
- Only use of healthy animals

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Hygiene feed

- Regulation 1831/2003
- Feed for food
- Feed hygiene &
- Traceability of feed
- Structure similar to H 1
 - Registration of establishments
 - Follow annexes
 - Implement HACCP




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(Acts whose publication is obligatory)

COMMISSION REGULATION (EC) No 2073/2005

of 15 November 2005

on microbiological criteria for foodstuffs

(Text with EEA relevance)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Regulation (EC) No 852/2004 of the European Parliament and of the Council of 29 April 2004 on the hygiene of foodstuffs⁽¹⁾, and in particular Articles 4(4) and 12 thereof,

(4) Microbiological criteria also give guidance on the acceptability of foodstuffs and their manufacturing, handling and distribution processes. The use of microbiological criteria should form an integral part of the implementation of HACCP-based procedures and other hygiene control measures.



European Institute for Food Law
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Food safety criteria

Microbiology of foods and animal feeding stuffs. Horizontal method for the detection and enumeration of *Listeria monocytogenes*

Viruses

Chapter 1. Food safety criteria

Food category	Micro-organisms/ their toxins, metabolites	Sampling-plan ¹		Limits ²		Analytical reference method ³	Stage where the criterion applies
		n	c	M	M		
1.1 Ready-to-eat foods intended for infants and ready-to-eat foods for special medical purposes ⁴	<i>Listeria monocytogenes</i>	10	0	Absence in 25 g		EN/ISO 11290-1	Products placed on the market during their shelf-life
1.2 Ready-to-eat foods able to support the growth of <i>L. monocytogenes</i> , other than those intended for infants and for special medical purposes	<i>Listeria monocytogenes</i>	5	0	100 cfu/g ⁵		EN/ISO 11290-2 ⁶	Products placed on the market during their shelf-life
		5	0	Absence in 25 g ⁷		EN/ISO 11290-1	Before the food has left the immediate control of the food business operator, who has produced it



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Food Safety in FBOs

- Preparedness
- (Response)



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GFL Food safety requirements

- EU food safety law applies to imports & exports
- Traceability
 - One step up, one down
 - Internal traceability?? → often corrected in private standards
- Withdrawal & recall
 - Food not in compliance with food safety requirements



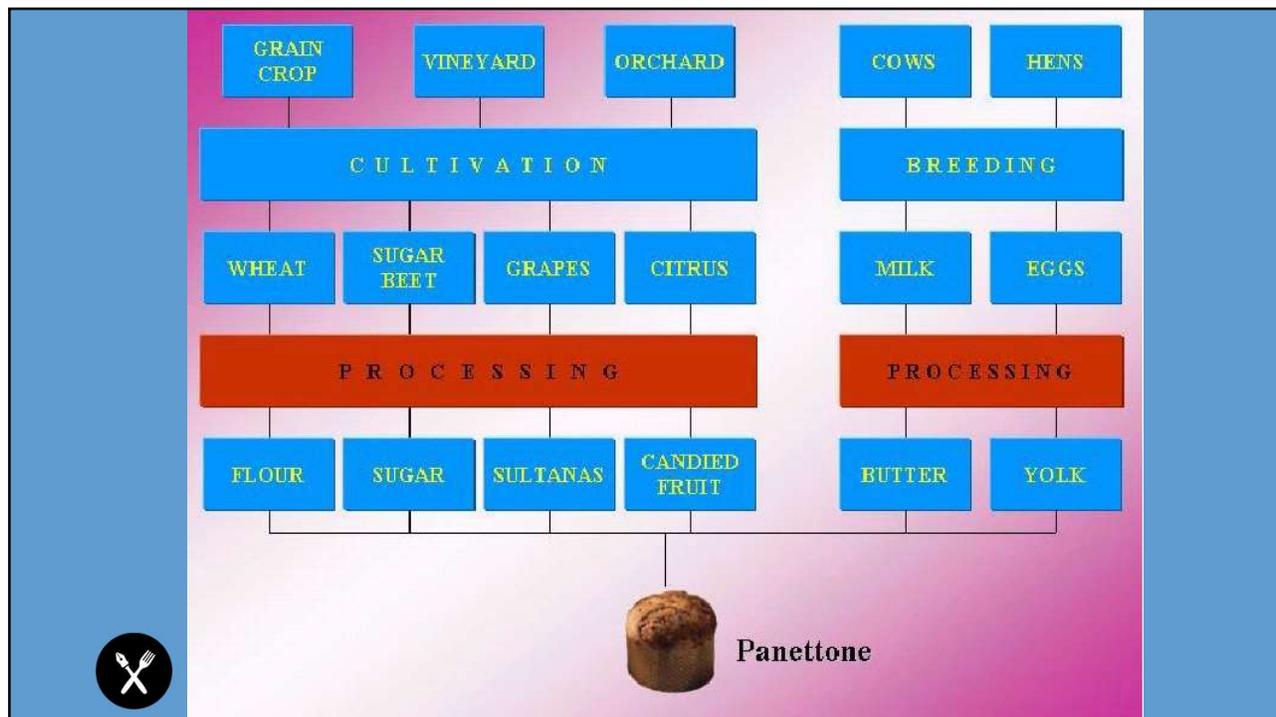
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Preparedness Traceability: aims

- Retrace origin of food safety problems
 - 'Normal' / Bio terrorism
 - Trace affected products of safety problems
 - Prepare recall
- information must be suitable to reconstruct the chain
- Other uses**
- Guarantee quality
 - inform consumers about invisible aspects (org. kosher, BRC, GM, origin, child labour, sustainable, etc.)
 - Identify liability (Reg. 1935/2005 on packaging)



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Traceability: responsibilities

- Food business operator
 - Have system in place
 - Decide on kind of system
 - Decide on batch size

The image shows a magnifying glass focusing on a barcode on a document, symbolizing traceability. The background is a blue gradient.

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Response

Identification of food safety problem

- Extent of the problem
 - Art. 14(6) GFL

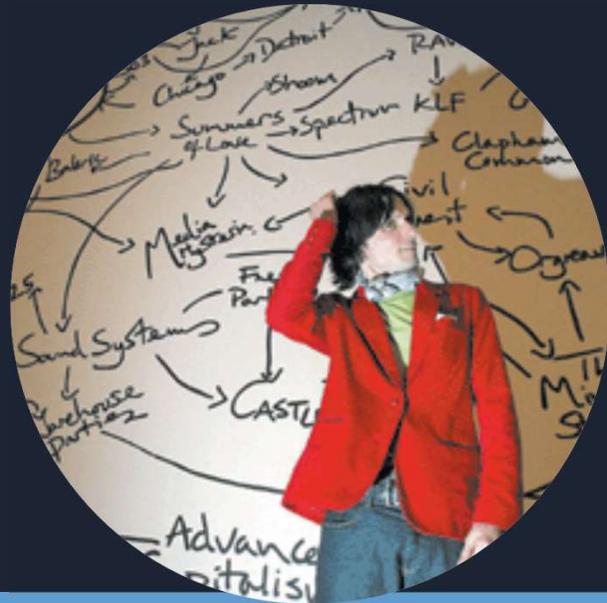
Where any food which is unsafe is part of a batch, lot or consignment of food of the same class or description, it shall be presumed that all the food in that batch, lot or consignment is also unsafe, unless following a detailed assessment there is no evidence that the rest of the batch, lot or consignment is unsafe.
- Where is the rest of the lot?
- Art. 18 GFL: traceability
 - One step up, one down
 - Information to authorities on demand



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What do I expect from you?

Analyse who is responsible for undertaking which actions to prevent food safety incidents



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Thank you
for your kind
attention

Q&A

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