Food Safety Risk Assessment without Animal Tests

Dawei Tang & Paul Hepburn

Unilever

About Unilever (关于联合利华)

EVERYDAY, 2.5 BILLION PEOPLE USE UNILEVER PRODUCTS

85% CONSUMER IN DEVELOPING AND EMERGING MARKETS

来自新兴市场的消费者占所有消费者的**85%**

2019 TURNOVER:
€52 BILLION
2019营业额520亿欧元

>190 COUNTRIES

我们的产品在190个国家有销售

169,000

EMPLOYEES WORLDWIDE 全球雇员

About SEAC (关于安全与环境保障中心)

We use **scientific evidence-based risk and impact assessment methodologies** (基于科学证据的风险和影响评估方法) to ensure that the risks / impacts of adverse human health and/or environmental effects from exposure to chemicals used in our products, processes & packaging are **acceptably low**.

APPLYING SCIENCE
应用科学

GOVERNANCE
监管

We provide scientific evidence to manage safety risks & environmental impacts for new technologies

ADVANCING SCIENCE
推进科学

NEW CAPABILITY
能力建设

We harness the latest science to create new tools to assess innovations of the future

SHARING SCIENCE
分享科学

COLLABORATION
合作

We partner with leading scientists from around the globe

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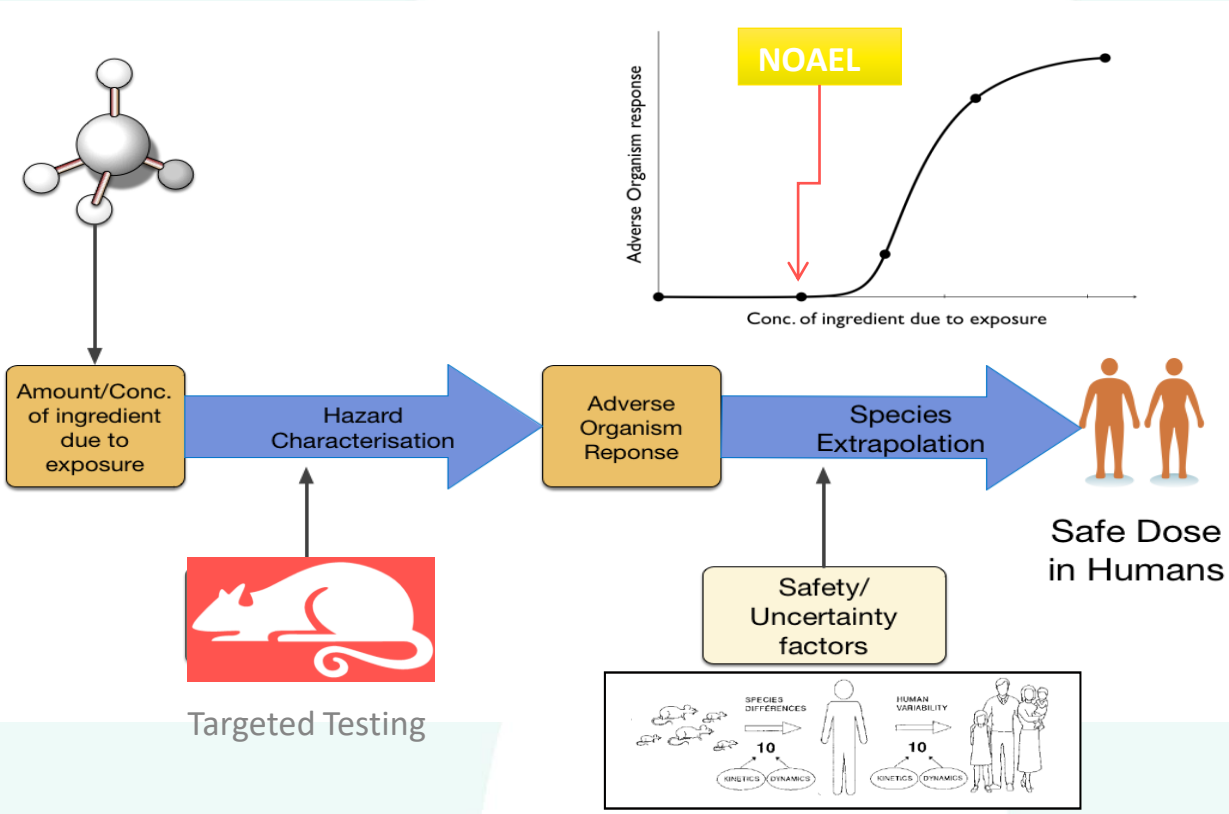
Traditional food Risk Assessment and its limitations
(传统风险评估方法以及其局限性)



ADI/TDI* = NOAEL ÷ 100

Exposure < ADI/TDI ☺

Exposure > ADI/TDI ☹

- Acceptable Daily Intake
- Tolerable Daily Intake

Limitations

- Value of animal test being challenged
- Lack of mechanistical understanding
- Consumer drive:
  - Not tested on animals
  - Vegan
- Advancement of science and technology

Vegan (纯素食)

A vegan food/beverage product

- Does not contain
  - Any products obtained from, or made by animals,
  - Milk and dairy products,
  - Egg and egg products,
  - Products from bees,

- Has not been manufactured using processing aids of animal origin.

- In addition,
  - No animal experiments have been carried out (不允许进行动物实验)

Registered in Europe, USA, Canada, Australia and India

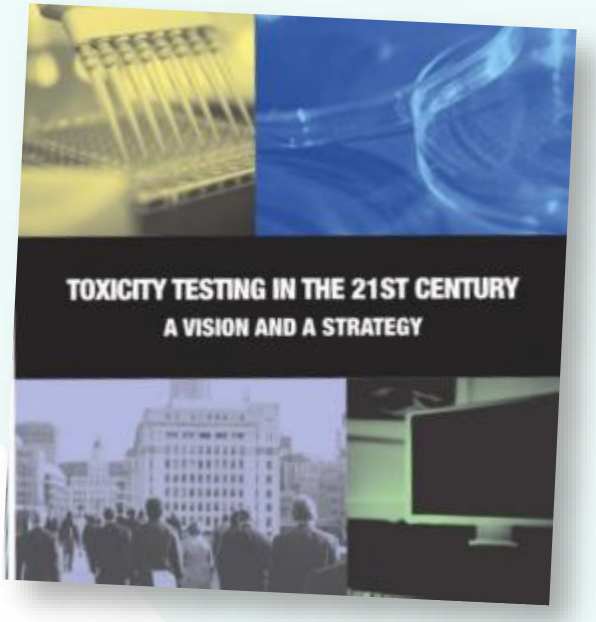
For companies in the US, Canada, Australia and New Zealand

Registered in Europe

Registered in the UK

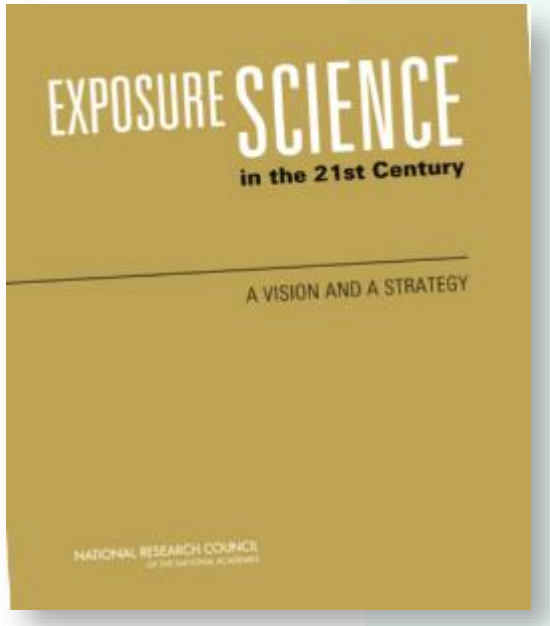
21st century safety sciences advanced greatly
21世纪安全科学取得了巨大进步

TT21C



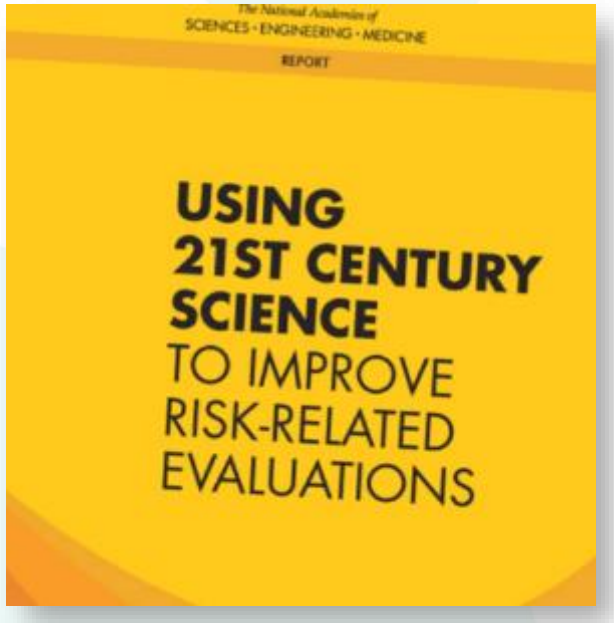
US National Academies of Science 2007
美国国家科学院2007报告

ES21C



US National Research Council 2012
美国国家研究委员会2012报告

21C Risk Assessment



US National Academies of Science 2017
美国国家科学院2017报告

Some Non-animal methods applied in food safety risk assessment (一些在食品安全风险评估中应用的非动物测试的方法)

- History of Safe Use (HoSU, 安全使用历史)
- Read across (交叉参照)
- Threshold of Toxicological Concern (TTC, 毒理学关注阈值)
- Quantitative structure–activity relationship (QSAR, 定量构效关系)
- Physiologically based pharmacokinetic modelling (PBPK, 基于生理的药代动力学模型)
- In vitro assays, such as bio-kinetics assay, high-throughput screening assay, Omics assay, etc (体外测试).

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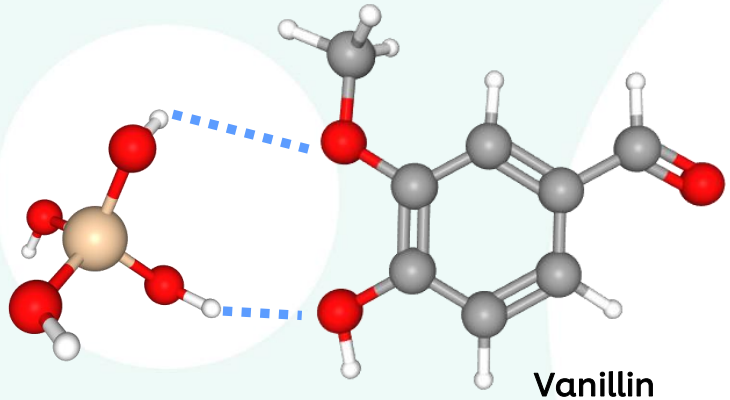
Orthosilicic Acid – Vanillin Complex (OSA-VC) (原硅酸-香兰素复合物)

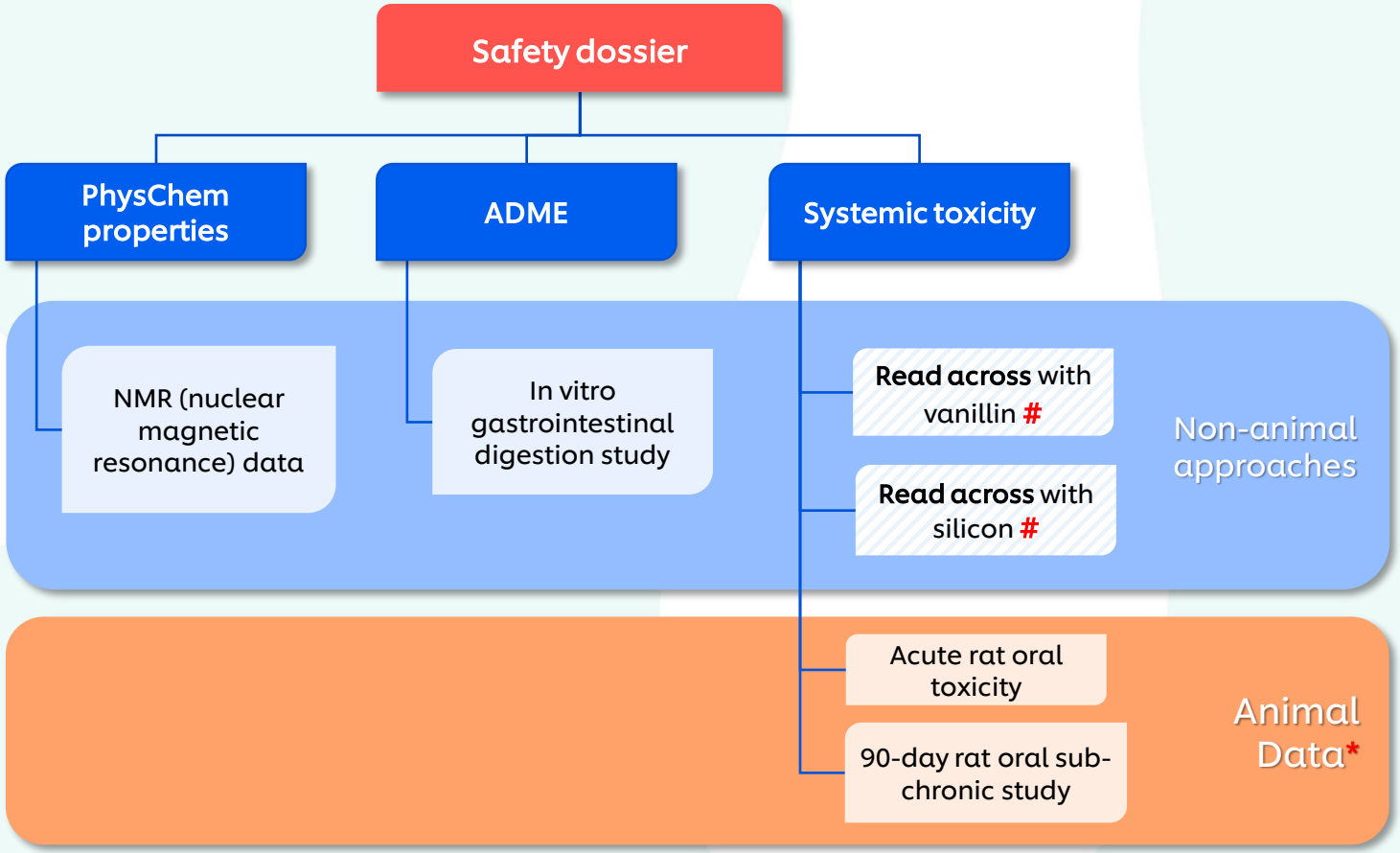
Novel Food Submission (2014)

efsa European Food Safety Authority

- **Identity of the food:** complex composed of orthosilicic acid [$Si(OH)_4$] and vanillin linked by weak hydrogen bonds.
- **Proposed use:** food supplement as a source of silicon (Si).



Orthosilicic acid — Vanillin



Key points

- *In vivo* studies on OSA-VC had severe limitations due to the technical difficulties with the solubility and dosing of the substance. (由于溶解度，以及物质剂量控制等因素，体内测试具有严重的局限性)
- Nevertheless, no additional toxicological data were required for the complex by EFSA (EFSA并没有要求提供更多的毒理学数据)

Ingredient-specific in vivo study could be considered unnecessary

(和具体成分相关的毒理学数据)可以被认为是没有必要的

existing *in vivo* data, not generated for the intended assessment

* Animal data is not Unilever data

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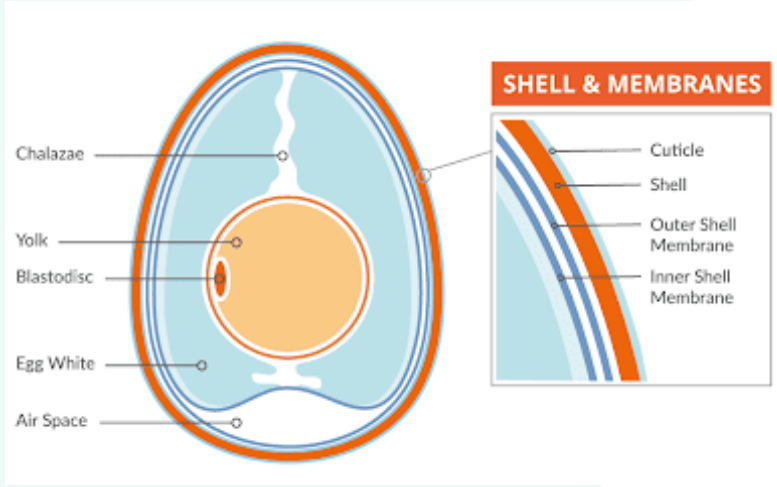
Egg membrane hydrolysate (蛋膜水解物)

Novel Food Submission (2016)

efsa European Food Safety Authority

- **Identity of the food:** a protein-based powder. Its main constituents are elastin, collagen and glycosaminoglycans derived from chicken eggs.
- **Proposed use:** food supplement.



CONTAINS ALLERGEN EGG

Safety dossier

Allergenicity	History of use	Systemic toxicity
RAST-inhibition assay	Occasionally consumed with boiled eggs	Open-label uncontrolled pilot human study
Egg Allergen Test	Post-market data	
Human allergen antibody assay	Negligible impact on total dietary protein intake	
Guinea pig sensitisation assay		Acute rat oral toxicity

Non-animal approaches

Animal Data*

* Animal data is not Unilever data

Key points

- A full toxicological assessment was not provided by the applicant and not deemed necessary by EFSA.
- (申请者并没有提供全套的毒理学测试，EFSA也认为全套测试没有必要)

Ingredient-specific in vivo data added little to the weight of evidence approach

(关于具体成分的体内数据并没有为整个风险评估提供什么额外的信息)

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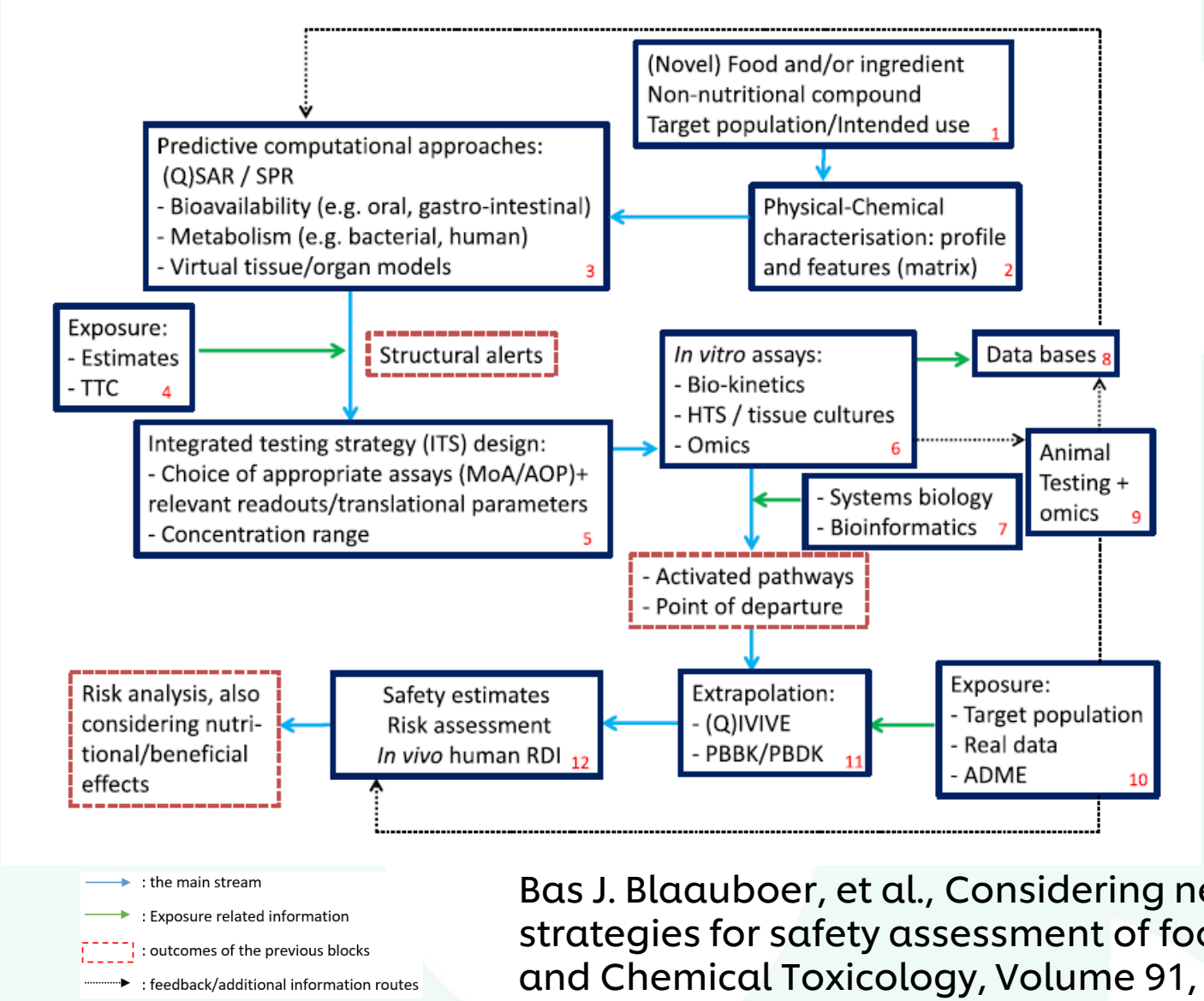
Food ingredient with History of Safe Use –Camomile in tea (具有历史安全使用历史的食品原料 – 洋甘菊茶)

- Considered as a new food ingredient in China
- Extensive use in range of food, cosmetic and medicinal preparation for a history of over 3000 years, across the world, including cosmetic use in China.
- Toxicological data:
  - **Acute toxicity (急性毒性)**: non-acute toxicant according to GHS
  - **Sub-chronic toxicity (亚慢性毒性):** no toxic effects from limited study available
  - **Genotoxicity (遗传毒性)**: no evidence of genotoxicity from the available studies
- Human data:
  - **Human studies (人体测试):** the available clinical data demonstrate a good safety profile for Chamomile preparations in adults, children and pregnant women
  - **Allergenicity (致敏性)**: rare reports of hypersensitivity reactions after exposure to Chamomile
- **Conclusion: Historical use of Chamomile infusion, combined with the existing toxicological and human data, supports its continuing use without further investigation (根据历史使用情况和已有的毒理学数据，我们认为作为茶饮的洋甘菊是安全的)**

Roadmap for safety assessment of novel food and ingredients (新食品原料的安全评估路线图)



Bas J. Blaauboer, et al., Considering new methodologies in strategies for safety assessment of foods and food ingredients, Food and Chemical Toxicology, Volume 91, 2016, Pages 19-35

Way forward (未来发展方向)

- Develop and apply strategies that avoid animal tests (e.g Blaauboer et al, 2016)
- Greater use of existing data and tools – e.g. History of Safe Use, read-across
- Exploit in vitro and in silico to generate more human –relevant data that can be used in risk assessment including mechanistic understanding
- Stakeholders need to be bolder in the use of non-animal approaches

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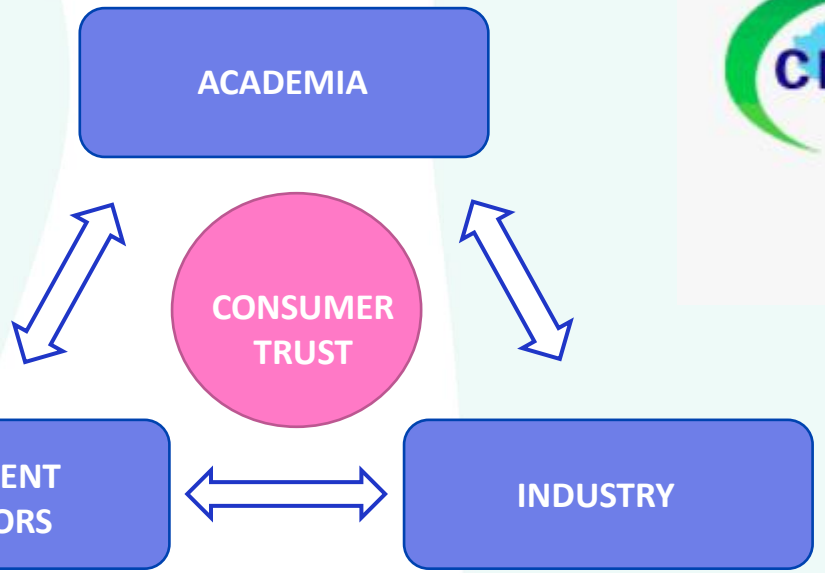
Important to collaborate and form stakeholder partnerships
(合作的重要性以及与食品安全相关方建立伙伴关系)

ILSI

南方醫科大學 Southern Medical University

CFSA 国家食品风险评估中心



中国毒理学会 Chinese Society of Toxicology

广东省疾病预防控制中心 Guangdong Provincial Center for Disease Control and Prevention

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UCCPSCC (联合利华消费者产品安全合作中心)

The Unilever China Consumer Product Safety Collaboration Center has been established at our Unilever Global R&D Center in Shanghai to partner with public and private stakeholders in China and to collaborate in key areas underpinning the safety of consumer products such as foods, personal and homecare products

Why this Centre? | Themes and Programs | Partners and Partnerships | Unilever Expert Resources | Calendar of Events | Contact and Directions

Unilever Global R & D Center (Shanghai), No.66, Linxin Road, Changning District, Shanghai, China / 联合利华全球研发中心 (上海), 中国上海市长宁区临新路66号，邮编：200335
www.unilever.com | www.unilever.com.cn