Sicherheitsbeurteilung neuartiger Lebensmittel
Haslberger SS 2021

- Einführung, Sicherheit, Risiko, Hazard, WHO Codex
- Substantial equivalent, intended-, unintended Effects
- Geschichte, Ziele der Lebensmittelproduktion, Entwicklungen, Pflanzen, Tiere, MO
- Values in der Interaktion Mensch Umwelt
- Spezifische Aspekte GVOs, Gentransfer, Allergie, CRISPR, Klonieren
- Lebensmittel, -zutaten mit neuer Struktur, aus nicht traditionellen Rohstoffen, fremden Kulturkreisen, Neue technische Verfahren an traditionellen Lebensmitteln
- Regelungen, Novel food, traceability , labelling 2001/18, 1829/2013, 1830/2003
- Umwelt: Cartagena Protokoll, Trade regulations
- Sicherheitsbewertung, Risk assessment, Elemente, Toxikologie
- Health claim, fuctional food, personalised Nutrition, Epigenetic
- Vorträge zu Beispielen

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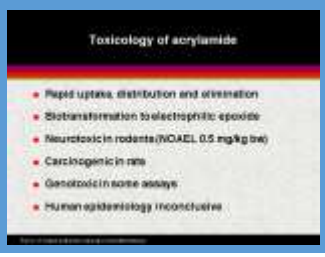
Food is not safe in principle (WHO) As safe as .....



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Blickweisen

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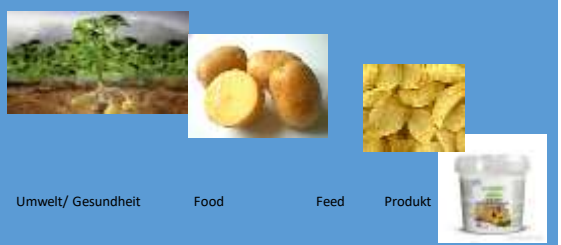
Was zu Regeln, wozu ?



Umwelt/ Gesundheit Food Feed Produkt

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Denkmodelle

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Wie zu regeln:
CODEX Alimentarius

Development of scientifically sound, international standards and norms for consumer health protection and fair food trade practices

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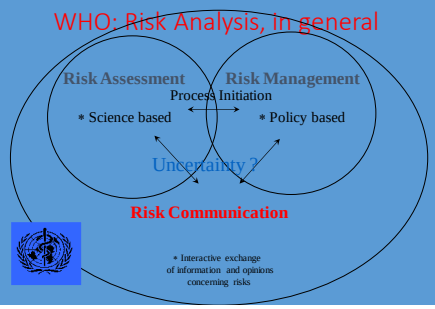
WHO: Risk Analysis, in general



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CODEX

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CODEX

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Definitionen

Hazard: Eigenschaften eines Stoffes oder Mischung von Stoffen, die bei der Herstellung, beim Gebrauch oder der Entsorgung negative Auswirkungen auf den Organismus oder die Umwelt haben können.

Risiko: Risiko ist die Möglichkeit, dass ein schädigendes Ereignis unter bestimmten Bedingungen aufgrund der Exposition chemischer oder physikalischer Stoffe auftritt oder die zu erwartende Häufigkeit des Auftretens eines schädigenden Ereignisses.

Hazard: qualitativer Begriff
Risiko: quantitativer Begriff

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Risk assessment

- Risikobewertung
- Strukturierter Prozess
- Ziel: Charakterisierung der Natur und der Wahrscheinlichkeit eines negativen Resultats
- basiert auf wissenschaftlichen Erkenntnissen
- transparent, objektiv, nachvollziehbar

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Risk assessment

- Identifikation der Gefahren
- Charakterisierung der Gefahren
- Expositionsabschätzung
- Charakterisierung der Risiken

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Prinzipien des Risk assessment

Hazard identification – Gefahrenidentifizierung

- Identifikation von bekannten oder unbekannten Gesundheitsgefahren in Verbindung mit einer bestimmten Substanz.
- biologische (Mikroorganismen wie z.B. Salmonellen, Listerien)
- chemische (Pestizide, Tierarzneimittel, Schwermetalle, usw.)
- physikalische Gefahren (Fremdkörper wie z.B. Steine, Glas

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Prinzipien des Risk assessment

Hazard characterisation – Gefahrencharakterisierung

- bestimmt Erreger und mögliche Nebenwirkungen
- qualitative und/oder quantitative Bewertung
- chemische Stoffe: dose-response-assessment
- biologische oder physikalische Stoffe: dose-response-assessment, wenn die Daten vorliegen
- Daten aus wissenschaftlicher Forschung, toxikologischen, epidemiologische Studien und Statistiken

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Prinzipien des Risk assessment

Exposure assessment – Expositionsabschätzung

- qualitative und/oder quantitative Bewertung des Ausmaßes eines Erregers
- gesamte aktuelle Exposition der Bevölkerung
- basiert auf der Verknüpfung von Verzehrsdaten bestimmter Lebensmittel mit dem Vorhandensein der Substanz in den betroffenen Lebensmitteln

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Prinzipien des Risk assessment

Risk characterisation – Risikocharakterisierung

Integration von hazard identification, hazard characterization and exposure assessment in einer Schätzung der Nebenwirkungen inklusive der auftretenden Unsicherheiten, die in der Population auftreten können.

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Biotechnology and Agriculture, development

Plant Selection

- Agriculture begins with the collection and planting of seeds from wild plants
- Occurs in 8 locations throughout the world between 7000 -12000 years ago
- Selections were made based on yield, seed size, and taste

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Landraces, Diversity

Refers to the particular kinds of old seed strains and varieties that are farmer-selected in areas where local subsistence agriculture has long prevailed. Landraces are highly adapted to specific locales or groups.

Definition :
modified by native and also immigrant farmers.

The term is usually applied to varieties of corn, squash, and beans that were domesticated by native farmers,

10

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GREEN Revolution

Term coined by U.S. Agency 1968)
Movement to increase yields by using:
. New crop cultivars
. Irrigation
. Fertilizers
. Pesticides
. Mechanization
A planned international effort funded by: Rockefeller Foundation
Ford Foundation
Many developing country governments
Purposed to eliminated hunger by improving crop performance Norman Borlaug (1970 Nobel price)

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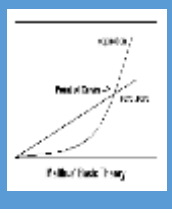
T. Malthus: 1766- 1834
Crisis in food production



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Models for population growth and food security:

Pessimistic or Alarmist Theory

Malthus - 19th century, Coale & Hoover (1958),
Paul Ehrlich (Population Bomb),
Meadows (Limits to Growth) – 1960s and 1970s.
Focus on population policy & fixed, non-renewable resources.

Optimistic Theory
Ester Boserup – 1960s – 70s (agric. Intensification)
Julian Simon – 1970s - 80s (human capital)

Neutralist or Revisionist Theory

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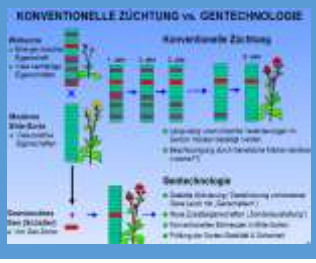
Pflanzenzüchtung
Breeding, yield, time for development



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Klassische Züchtungsmethoden

Auslesezüchtung/Selektionszüchtung
Die Auslesezüchtung fängt mit dem Anbau von Genotypengemischen (vorh. genetische Linien, auch Wildpflanzen) an. Aus dem nach gemeinsamer Abblüte erzeugten Saatgut werden Pflanzen mit vorteilhaften Eigenschaften ausgewählt (Zuchtwahl, Massenauslese).
Kombinationszüchtung
Die Kombinationszüchtung ist eine Kreuzung verschiedener Genotypen (Linien). Es entsteht ein neuer Genotyp

Heterosiszüchtung
In der Heterosiszüchtung werden bei Fremdbefruchtern (Mais, Roggen...) in mehrjähriger Züchtung aus Inzuchtzuchten Ausgangspflanzen nahezu homozygote Inzuchtlinien gezüchtet. Kreuzt man zwei solche Linien, tritt bei der F1 Generation oft eine auffallende Mehrleistung gegenüber der Elternformen auf. Dies nennt man „Heterosis-Effekt

Hybridzüchtung
Die Hybridzüchtung ist ein Beispiel für Heterosiszüchtung, zur Erzielung einer hohen markt- oder betriebsgerechten pflanzlichen Produktion durch Bastardwüchsigkeit. So werden bei der Hybridzüchtung geeignete, gesondert gezüchtete Inzuchtlinien einmalig miteinander gekreuzt (Einfachhybride). [1] Die Nachkommen der ersten Generation (F1) einer solchen Kreuzung haben gegenüber der Elterngeneration ein üppigeres Wachstum (Heterosiseffekt)
Für den Landwirt bedeutet dies jedoch, dass das Saatgut jedes Jahr wieder neu bezogen werden muss, wenn er den Ertragsvorteil gegenüber Nicht-Hybriden weiterhin erhalten will, da der Heterosiseffekt nur in der F1-Generation auftritt und danach wieder verloren geht.

Mutationszüchtung
Bei der Mutationszüchtung werden Samen Röntgen- oder Neutronenstrahlen, Kälte- und Wärmeschocks oder anderen Mutagenen ausgesetzt[2], um neue Eigenschaften durch Mutationen zu erzielen, die einen positiven Effekt aufweisen. Damit wird die Züchtung neuer Sorten erheblich beschleunigt.

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Hybridzüchtung, Heterosis

- Three Main Principles
  - Inbreeding
  - Hybridization
  - Heterosis
- Main Goals
  - Increase the homozygosity at all or specific loci in the plant genome
  - Produce a plant which breeds true
  - Produce uniform plants

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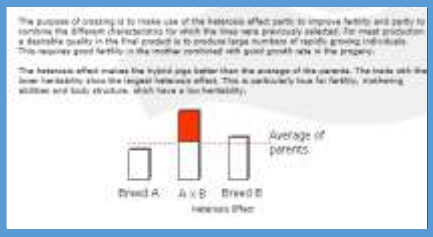
Hybrid: Heterosis effect



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Introducing new traits in a plant family:(Random) Mutation Breeding

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IAEA

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Breeding: Irradiation

Irradiator at Institute of Radiation Breeding Ibaraki-ken, JAPAN (http://www.irb.affrc.go.jp/)

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Mutation breeding

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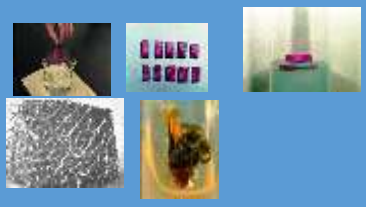
Tissue culture , Clones ?



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Somaclonal variation

- Production of a new variety of japanese butterbur using somaclonal variation.(upper:new variety, lower:native variety)

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Tomoffel

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Breeding using transposons

Ein Transposon ist ein DNA-Abschnitt bestimmter Länge im Genom, der seine Position im Genom verändern kann (Transposition). Man unterscheidet Transposons, deren mobile Zwischenstufe von RNA gebildet wird (Retroelemente oder Klasse-I-Transposon), von denjenigen, deren mobile Phase DNA ist (DNA-Transposon oder Klasse-II-Transposon).

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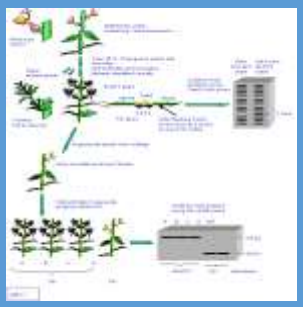

Transposon tagging

The molecular isolation of transposable elements now permits the cloning of genes in which the element resides. The major advantage of this system is that genes whose function is not known can be cloned

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Molecular marker directed breeding

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Bio-Technology ?
INTEGRATED Pest Management: A modern Way of Agriculture

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Cloning, Definition

Cloning is the process of making an identical copy of something

In biology, it collectively refers to processes used to

-- copies of DNA Fragments (molecular cloning)
-- cells (cell cloning)
-- organism

The term also covers when organisms such as bacteria, insects or plants reproduce asexually.

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DNA cloning:

To clone a piece of DNA, DNA is cut into fragments using restriction enzymes that recognize specific sequences of bases in DNA. The fragments are pasted into vectors that have been cut by the same restriction enzyme. Vectors (e.g., plasmids or viruses) are needed to transfer and maintain DNA in a host cell.

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Reproductive Cloning

Reproductive cloning is a technology used to generate an animal that has the same nuclear DNA as another currently or previously existing animal. Dolly was created by reproductive cloning technology. In a process called "somatic cell nuclear transfer" (**SCNT**), scientists transfer genetic material from the nucleus of a donor adult cell to an egg whose nucleus has been removed. The reconstructed egg containing the DNA from a donor cell must be treated with chemicals or electric current in order to stimulate cell division. Once the cloned embryo reaches a suitable stage, it is transferred to the uterus of a female host where it continues to develop until birth.

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Reproductive Cloning

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Therapeutic Cloning

Therapeutic cloning, also called "embryo cloning," is the production of human embryos for use in research. The goal of this process is not to create cloned human beings, but rather to harvest stem cells that can be used to study human development and to treat disease. Stem cells are extracted from the egg after it has divided for 5 days.
The extraction process destroys the embryo, which raises a variety of ethical concerns. Many researchers hope that one day stem cells can be used to serve as replacement cells to treat heart disease, Alzheimer's, cancer, and other diseases.

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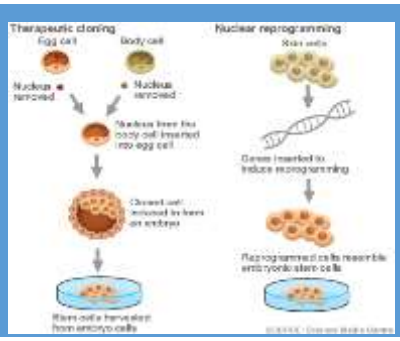

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Horticultural cloning

All plants which are originated from vegetativ reproductions are clones.
They have been derived from a single individual, multiplied by some process other than sexual reproduction.
Examples are bananas, grapes and potatoes.

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GM plants, Tranferring traits in ways which are not used in nature: GMOs

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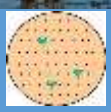
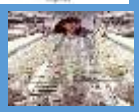
Agrobact. tumefaciens



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T DNA

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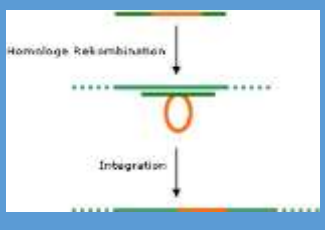
Homolog recombination



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Antibiotic resistance marker gene

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http://www.gmo-compass.org/

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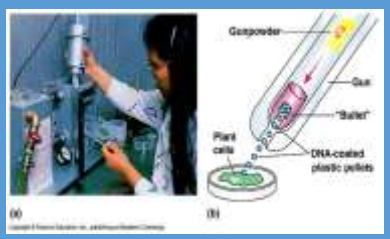
Gene gun



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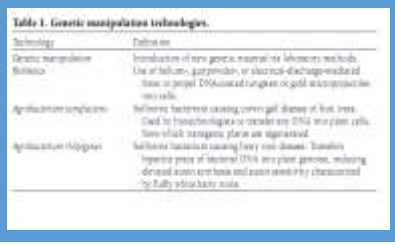
Methods, overview



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Herbicide tolerance, glyphosate

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Herbicide Resistant Soybean

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Herbicide Resistance: more or less herbicide? depending on local agricultural background

- Roundup Ready Soy, Corn, Canola
- Allows post-emergence herbicide spraying
- Increases yield
- Facilitates no-till farming
- 89% U.S. Soy crop (2006)

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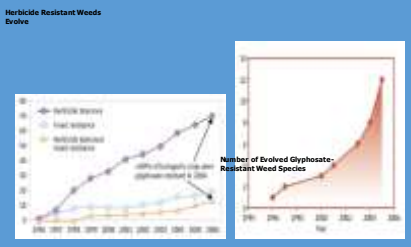
Old and new Problems: Resistance



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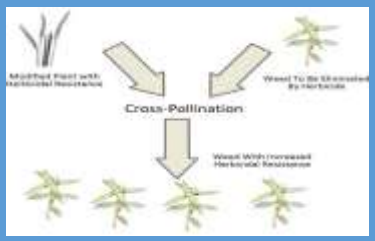
Herbizide resistance, gene transfer



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Gene flow: multiresistant Rape

Detection of feral transgenic oilseed rape with multiple-herbicide resistance in Japan

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Insect resistance, BT maize

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BT resistance: B. thuringiensis proteins

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Roundup ready, Monsanto

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Maiszünsler: wirtschaftlich bedeutendster Maisschädling

Es gibt mehrere Strategien zur Bekämpfung des Maiszünslers:

- **mechanisch durch Zerkleinern und Unterpflügen der auf dem Feld verbliebenen Pflanzenreste**
- **chemisch durch Einsatz von Insektiziden**
- **biologisch mit Hilfe von Trichogramma (Schlupfwespen)**
- **BT Toxin Präparate**
- **gentechnisch vermittelte Insektenresistenz besitzt (Bt-Mais)**

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Bt Corn

- Natural insecticide from *Bacillus thuringiensis*
- Non-toxic to humans
- Target insect: corn borer
- Potential to:
  - reduce insecticide use
  - reduce mycotoxins
- 40% U.S. Corn crop Bt (2006)

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Bt Concerns

- Bt pollen harms non-target species?
- Bt crops select for resistant insects
- Bt pollen can drift to organic fields
- Food system failed to keep BT Starlink corn out of human food products

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Insect Resistant Cotton

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Disease Resistance, viruses

Genetically engineered papaya resistant papaya ringspot virus

- **Cantaloupes**
- **Cucumbers**
- **Corn**
- **Rice**
- **Papaya**
- **Potatoes**
- **Soybeans**
- **Squash**
- **Tomatoes**
- **Wheat**

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Growth-enhanced fish

Salmon Growth hormone expressed in cold waters & unlinked from seasonal temp.

Auto-transgenic mud loach:β-actin promoter linked to GH gene.

(Devlin et al. 1994)

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GM Salmon

- Probleme der Lachsindustrie
- gv Lachs von Aqua Bounty
- Produktionssteigerung über Ernährung, Krankheitsresistenz

- Gefahr für die Wildlachspopulationen
- Abhängigkeit des Fischfutters
- Umweltverschmutzung durch Lachszucht

Kellner Anna
Stoll Christiane

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gv Lachs

- Atlantischer Lachs von Aqua Bounty
- **Wachstumshormon-Gen** des Chinook Lachs
- **Frostschutz-Protein-Gen**
- bessere Entwicklung in kalten kanadischen Gewässern
- Wachstum über das ganze Jahr
- normales Gewicht in der Hälfte der Zeit erreicht

BELFOND-CURIEUX, O.L et al.: Factors to consider before production and commercialization of aquatic genetically modified organisms: the case of transgenic salmon. Environmental Science & Policy 12: 170-189. 2009.

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Golden Rice

Goldener Reis,

Unter **Goldenem Reis** (engl. *Golden Rice*) versteht man eine gentechnisch veränderte Reissorte. Es wurden zwei artfremde Gene und damit ein mehrschrittiger Syntheseweg in das Genom eingefügt. Das Phytoensynthase-Gen (*psy*) stammt von der Osterglocke (*Narcissus pseudonarcissus*) und das Carotindesaturase-Gen (*crtI*) von einem Bakterium Namens *Erwinia uredovora* (neuer Name: *Pantoea ananatis*).

Dank dieser zwei Gene kommt es zur Bildung von Beta-Carotin (Provitamin A) im Endosperm der Reiskörner, die deshalb (gold-)gelb / orange gefärbt sind. Das Provitamin wird dann im Körper zu Vitamin A (Retinol) umgewandelt.

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GMO tobacco, expression of human proteins in plants

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GMOs in development: CLAIMED BREEDING OBJECTIVES

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CLAIMED BREEDING OBJECTIVES

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09.12.2008

Claimed breeding objectives

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BREEDING OBJECTIVES

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Breeding objectives

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GMO Trees

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GM FLowers

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To consider

Type of modification	Molecul. sequence	Epigenetic	Tox direct	Tox indirect	Environ ment,	Agric-ultural practice
Classic breeding						
Cross breeding						
Random mutation	??????????					
Cell culture, transposons	??????????					
Gene technology(bacteria, plants, animals, vaccines,..)		????????			??????	???????
Cloning, animals				???????	??????	

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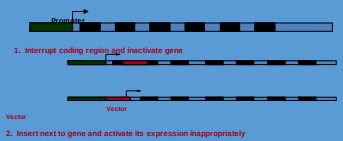
Safety: Random integration, Insertional mutagenesis



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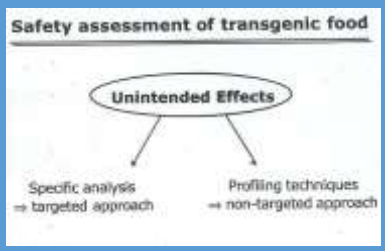

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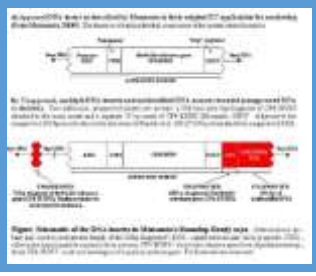

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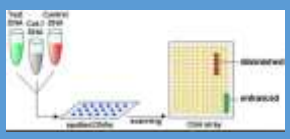
Detection of unintended effects in vitro, in vivo



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Toxicology Asessment: Difficulties Animal Feeding Studies Whole Foods

- Small doses to be fed (bulk, satiety)
- Nutritional imbalance of the diet
- Many confounding factors
- Small safety margins, if any
- Insufficient sensitivity for specific endpoints

85

GMO tests: PCR, primers, areas, array

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New Objectives

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Cas-9 (CRISPR associated protein 9)

- is an RNA guided DNA endonucleases enzyme.
- associated with CRISPR
- which plays an role in adaptive immunity system, found in bacteria Streptococcus Pyogenes.
- Involved in Type II CRISPR mechanism

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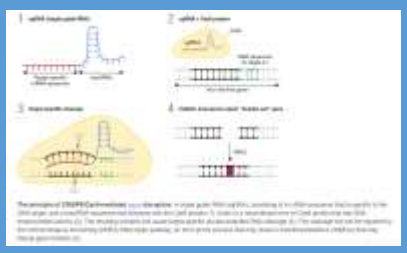
CRISPR/CAS9



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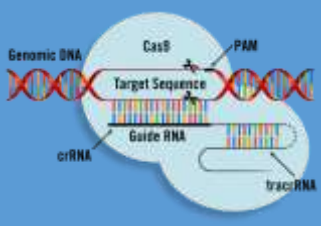

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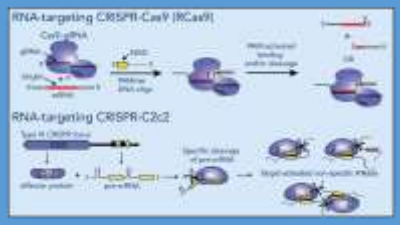
Targeting RNA



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CRISPR-Cas9

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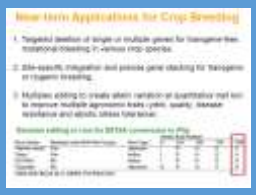
CRISPR-Cas9, applications



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Risk assessment , RNA interference?

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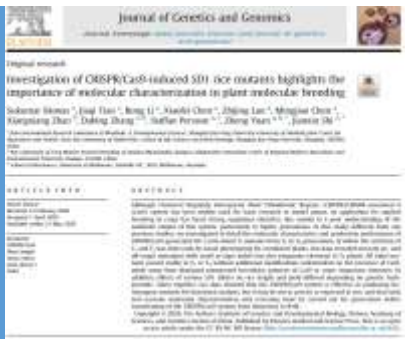

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CBD, Rio 1992

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CBD

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Umwelt Sicherheit LMOs

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Clearing House

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WTO

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Trade, WTO, SPS

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WTO trade TRIPS

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Trade Consequences

106

Codex standards and related texts are **voluntary** in nature. They need to be translated into national legislation or regulations in order to be enforceable.

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Risk assessment GMO
Codex Alimentarius Commission

TO PROVIDE A SUITABLE FRAMEWORK FOR UNDERTAKING RISK ANALYSIS ON THE SAFETY AND NUTRITIONAL ASPECTS OF FOOD DERIVED FROM MODERN BIOTECHNOLOGY

108

The Principles

- *Risk assessment:*
  Identification of hazard → *Nature and Severity*

Intended and unintended effects
New and altered hazards
Changes in nutrients relevant to human health

Data can be obtained developer, literature, scientists, technical bulletins, regulatory agencies

Data should be based on sound science, scientific peer review

- *Risk Management:*
  Should be proportional to risk identified
- *Risk Communication:*
  Should involve all stake holders, should be documented

Food labeling, conditional marketing approvals, post-marketing monitoring

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The Framework

Core considerations

Gene (s)
- Source (s)
- Molecular characterization
- Insert/copy no./integrity/ stability

Food/Feed Composition
- Proximate analysis
- Key nutrients/anti nutrients
- Animal performance

Protein
- History of safe use & Consumption
- Function/specificity/ mode of action
- Levels
- Toxicology & allergenicity

Environmental

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Molecular Characterization

- *Rigorous molecular characterization of each transgenic plant must be completed*

The following should be considered

The transformation system
- *(i) Agrobacterium mediated*
- *(ii) Microparticle bombardment*

Molecular characterization of the inserted DNA
- *(i) Insert number*
- *(ii) Insert composition*

Genetic stability of the introduced trait
- *(i) Segregation analysis*
- *(ii) Integron stability*

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Transformation system

- *A. tumefaciens mediated transformation is characterised by*
  - Low transgene copy number
  - Limited molecular rearrangements in the insert
  - Higher transformation efficiency

However it may show species specificity

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The information required…

- *All the genetic elements (promoter, leader, terminator, marker etc) transferred along with citation*
- *Detailed map of plasmid used as a vector indicating location, orientation, size etc of genetic elements*
- *Relevant restriction enzyme sites, location of primers used in PCR, regions used as a probe*

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Allergy : Some background

- *A specific adverse immune reaction to a protein*
- *Allergy*
  - *Immediate* → *IgE mediated*
  - *Delayed* → *Cell Mediated*
- *Most allergic reactions are caused by specific IgE antibodies*
- *The mechanism involved is development of IgE antibodies which upon re-exposure bind to mast cells and release histamines*
- *Occurrence ranges between 2-4% in adults and 4-8 % in children (US, Europe)*
- *Peanuts, milk, wheat, eggs, fish, soybeans, crustacean, tree nuts together accounts for over 90% cases (EU adds celery roots, mustard and sesame seeds)*
- *Disease management by avoidance*

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Three Questions

- *Is the novel protein an existing allergen ?*
- *Is the newly expressed protein going to cause allergic cross reactivity ??*
- *Is the new protein likely to sensitize and become an allergen ???*

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The Tests

- ***Bioinformatics***
- ***Specific serum testing***
- ***Searchable specific allergen databases***
  http://www.AllergenOnline.com
  (1313 in version 8.0 of known or putative allergens)
  NCBI (all sequences)
- ***Review scientific literature for evidence of allergenicity***

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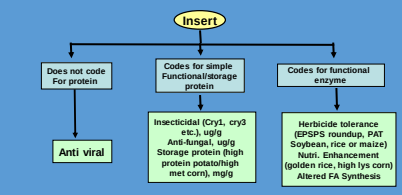
GM Product Classification



- *No significant sequence match with the aforementioned GM proteins as per data of major biotech companies around the world based on bio-informatics (no > 50% overall or > 35% identity in 80 aa match)*
- *Cry 1, 2, 3, CP4 EPSPS, NPT II and cry 1 F (except one 6 - mer match)*

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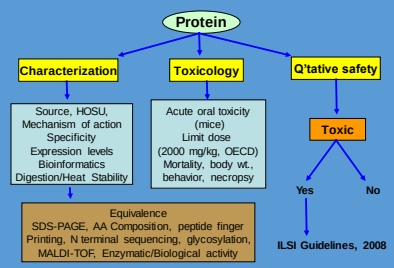
Acute Toxicity



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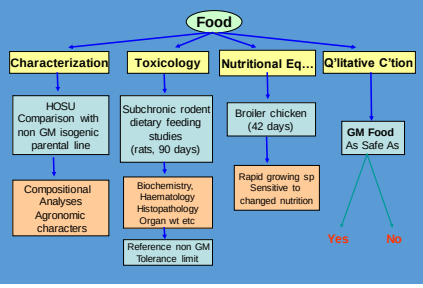
Food from GM plant



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Animal tests may not be warranted....

- ***Source not known to synthesize toxin protein (s)***
- ***The protein has a history of safe use***
- ***Amino acid sequence analysis lacks identity with known toxins***
- ***Protein is easily digested/degraded***
- ***Protein is unstable to heat and other processing***

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EU Regulatory framework on GMOs

DG Health and Consumer Protection
European Commission

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EU legislative framework in the 90s

- Directive 90/220/EC
  - On the deliberate release of GMOs
  - first GM products approved: maize, soy, oilseed r.
- Regulation (EC) N. 258/97 on Novel Foods
  - Notification of GM food and food ingredients
  - 7 oilseed rape, 4 maize, oil from 2 cottonseeds

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18 April 2004 – New legislative framework

Directive 2001/18 on the deliberate release of GMOs into the environment
Regulation (EC) No 1829/2003 on GM food and feed
Regulation (EC) No 1830/2003 on traceability and labelling of GMOs

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Directive 2001/18/EC

- Directive 2001/18/EC on the deliberate release into the environment of GMOs
  - Clear definition of GMO and relative techniq.
  - Scope: product containing GMOs or consisting of such organisms
  - The experimental release of GMOs into the environment (for example field trials)
  - The placing on the market of GMOs (for ex. cultivation, importation or transformation)

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One door one key principle

- For products containing/consisting of GMOs:
  - EITHER one single application under Reg. 1829/2003 covering both of food/feed use and the deliberate release of GMOs into the environment - in accordance with the criteria of Dir. 2001/18
  - OR the application — or part of the application — can be split and submitted separately under Dir. 2001/18 and Reg. 1829/2003 .
- GMOs likely to be used as food and feed can only be authorised for both uses ⇨after Starlink case

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New legislative framework

- Principles
  - Centralised and transparent authorisation procedure with a clear time frame
  - New rules on traceability and labelling
  - Applies on newly authorised and existing products
  - Clarifies what is currently on the market

126

The authorisation procedure (1)

- General overview
  - Risk assessment: European Food Safety Authority
  - Risk management: European Commission through a regulatory committee procedure

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The authorisation procedure (2)

- First step - Application
  - Submitted to the competent authority of a MS
  - The application dossier has to include:
    - definition of the scope
    - safety dossier with the indication of confidential parts
    - monitoring plan
    - proposal of a detection method
  - Receipt in 14 days and inform EFSA

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The authorisation procedure (3)

- EFSA – Risk assessment
  - GMO Panel – independent scientists
  - Both envir. risk and human and animal health
  - Timeframe: 6 months unless further information needed

Guidance documents: http://www.efsa.eu.int

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The authorisation procedure (4)

- Commission role – Risk management
  - Draft decision granting/refusing authoris. (3 months)
  - Justification if diverging from EFSA opinion
  - Proposal to be approved by a qualified majority in the SCOFCAH (Member States representatives)
  - IF No QM ⇨ Council of Ministers
  - IF Council no action or no QM ⇨ Commission adopts the decision (3 months)

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The authorisation procedure (5)

- Authorisation
  - Granted for 10 years
  - Renewable for 10-year periods
  - Subject to a post-market monitoring
- Authorised products shall be entered in the public register of GM food and feed

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State of play of new applications

- 14 applications received since full applicability of Regulation
- GM food and feed uses, import and processing, no cultivation
- Most of them maize (8), but also 3 cotton, 1 rice, 1 sugar beet and 1 potato variety

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Product	Applicant	Status	Current status clock
NK603 x MON810 / Z. Mays	Monsanto	Under completeness check	
1507 / Z. Mays (only food)	Pioneer Hi-Bred/Mycogen Seeds	Authorisation granted	03/03/2005
MON863 x MON810 / Z. Mays	Monsanto	Authorisation	Clock stopped on [illegible]
LLRICE62	Bayer CropScience	Authorisation	Clock stopped on [illegible]
1507 x NK603 /Z. Mays	Pioneer Hi-Bred / Mycogen Seeds	Authorisation	
MON863 x NK603 / Z. Mays	Monsanto	Authorisation	Clock stopped on [illegible]
MON863 x MON810 x NK603/Z. Mays	Monsanto	Authorisation	Clock stopped on [illegible]
H7-1 Roundup Ready Sugar Beet	KWS SAAT AG / Monsanto	Authorisation	
MON 531 x MON 1445 Cotton	Monsanto	Under completeness check	
MON 15985 and MON 15985 x MON 1445 Cotton	Monsanto	Under completeness check	
MIR604 maize	Syngenta Seeds	Under completeness check	
59122 / Z. Mays	Pioneer Hi-Bred/Mycogen Seeds	Under completeness check	
LLCotton25	Bayer CropScience	Under completeness check	
Amylopectin Potato Event EH92-527-1	BASF Plant Science	Under completeness check	

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Labelling rules

- GM products have to be labelled
- According to Reg. (EC) No. 1830/2003
  - "This product contains GMOs" or
  - "This product contains GM [name of the organism]"

  Pre-packaged ⇨ on a label

  Non pre-packaged ⇨on the display or in connection with the product

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Labelling rules

- According to Reg. (EC) No. 1829/2003
  - Compulsory GM labelling for food and feed indicating
    - "genetically modified"
    - "contains/produced from GM.[name of the organism]"
  - Labelling requirements apply regardless of the presence of modified DNA or proteins ⇨highly refined products and compound feed included
  - Not for products obtained from animals fed with GM feed or treated with GM medicines

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Thresholds

- Labelling and traceability requirements do NOT apply in case of adventitious or technically unavoidable presence IF
  - Traces of an authorised GMOs below the limit of 0.9%
  - Operators have to prove that they have taken adequate measures to avoid the presence

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Thresholds

- Adventitious presence (burden of proof to the operators) of an unauthorised GMO
  - Positive assessment by an EU Scientific Committee is necessary
  - The threshold is fixed at 0.5%

  Below labelling and traceability not enforced

  Above prohibition to put the product on the market

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Are there labelled products on the market?

- Recent discussion in a WG of national experts
- November 2004: 77 GM labelled products on the markets of 10 EU countries (mostly in France, Germany, the Netherlands and Czech and Slovak Republics)
- Strong resistance from the consumers' side

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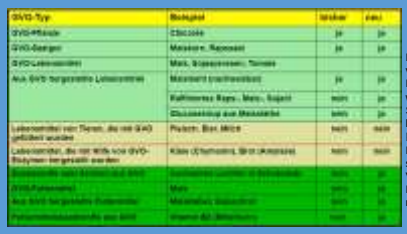
Kennzeichnung



Fleisch, Milch, Eier von Tieren, die mit gv-FuttermitteIn gefüttert wurden,
Sind weiterhin nicht kennzeichnungspflichtig
=> in tierischen LebensmitteIn
sind gentechnische Veränderungen aus FuttermitteIn nicht mehr nachweisbar

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Summary

- The new regulatory framework is implemented
- A transparent and timely authorisation procedure based on sound scientific assessment is in force
- The authorisation process has gained momentum
- GM foods and feed are already on the EU market although still the object of public resistance
- GM products have to be labelled according to the EU legislation

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More info

http://europa.eu.int/comm/food/food/biotechnology/index_de.htm

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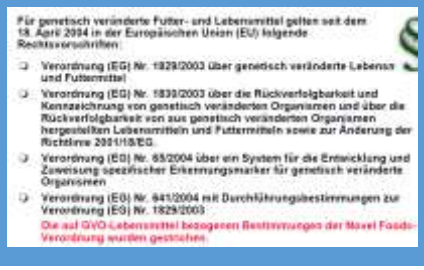
Post



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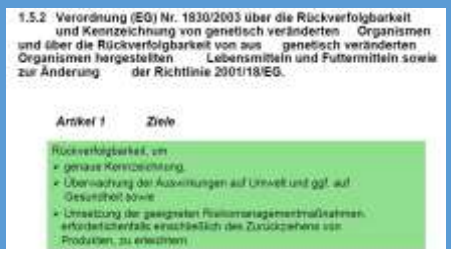
1830/2003 Rückverfolgbarkeit



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Rückverfolgbarkeit

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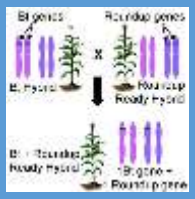
Rückverfolgbarkeit, Grenzen: genetische Stabilität , gene stacking ?

Zur Rückverfolgbarkeit von genetisch veränderten Lebens- und Futtermitteln

- muss jedem GVO ein spezifischer Erkennungsmarker zugeteilt werden;
- müssen von den am Inverkehrbringen Beteiligten Systeme und standardisierte Verfahren zur Erfassung der GVO und der daraus hergestellten Produkte etabliert werden;
- müssen die Informationen fünf Jahre lang gespeichert werden, um ermitteln zu können, wer wem wann welches Produkt geliefert hat.



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Statement by the Group of Chief Scientific Advisors

A Scientific Perspective on the Regulatory Status of Products Derived from Gene Editing and the Implications for the GMO Directive

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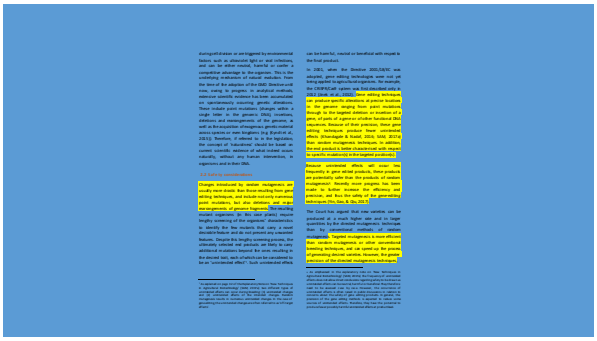

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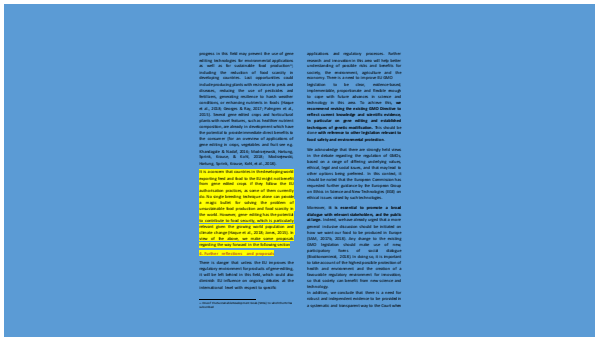

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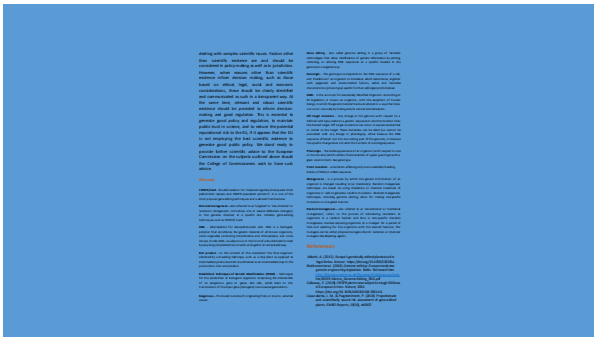

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Expanded categories of Novel Foods: The Novel Food definition describes the various situations of foods originating from plants, animals, microorganisms, cell cultures, minerals, etc., specific categories of foods (insects, vitamins, minerals, food supplements, etc.), foods resulting from production processes and practices, and state of the art technologies (e.g. intentionally modified or new molecular structure, nanomaterials), which were not produced or used before 1997 and thus may be considered to be as novel foods.

Generic authorisations of Novel Foods: Under the new Regulation, all authorisations (new and old) are generic as opposed to the applicant-specific, restricted novel food authorisations under the old Novel Food regime. This means that any food business operator can place an authorised Novel Food on the European Union market, provided the authorised conditions of use, labelling requirements, and specifications are respected.

Establishment of a Union list of authorised Novel Foods: This is a positive list containing all authorised novel foods. Novel Foods which will be authorised in the future will be added to the Union list by means of Commission Implementing Regulations. Once a novel food is added to the Union list, then it is automatically considered as being authorised and it can be placed in the European Union market.

A simplified, centralised authorisation procedure manged by the European Commission using an online application submission system.

Centralised, safety evaluation of the Novel Foods will be carried out by the European Food Safety Authority (EFSA). The European Commission consults EFSA on the applications and bases its authorisation decisions on the outcome of the EFSA's evaluation.

Efficiency and transparency will be improved by establishing deadlines for the safety evaluation and authorisation procedure, thus reducing the overall time spent on approvals.

A faster and structured notification system **for traditional foods from third countries** on the basis of a history of safe food use. To facilitate the marketing of traditional foods from countries outside the EU, which are considered novel foods in the EU, the new Regulation introduces a simplified assessment procedure for foods new to the EU. If the safety of the traditional food in question can be established on the basis of evidence of a history of consumption in the third country, and there are no safety concerns raised by the EU countries or EFSA, the traditional food will be allowed to be placed on the European Union market.

Promotion of innovation by granting an individual authorisation for five years based on protected data. Data protection provisions are included in the new Regulation. That means that an applicant may be granted an individual authorisation for placing on the market of a novel food. This is based on newly developed scientific evidence and proprietary data and is limited in time to 5 years.

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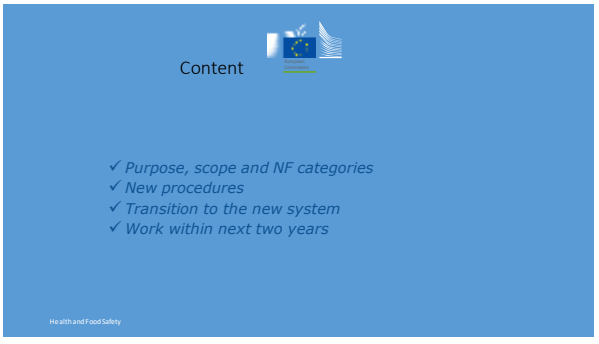

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Regulation (EU) 2015/2283 of the European Parliament and of the Council

Purpose

*"The purpose of novel food Regulation is to ensure the effective functioning of **the internal market** while providing a **high level of protection of human health and consumers' interests**."*

***NB!** The general concept of the "novel food" will not change!*

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Scope of the Regulation

foods

food enzymes

food additives

food additives

extraction solvents

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Not apply

It does not apply to

(a)genetically modified foods falling within the scope of Regulation (EC) No 1829/2003;

(b)foods when and in so far as they are used as:

(i)food enzymes falling within the scope of Regulation (EC) No 1332/2008;

(ii)food additives falling within the scope of Regulation (EC) No 1333/2008;

(iii)food flavourings falling within the scope of Regulation (EC) No 1334/2008;

(iv)extraction solvents used or intended to be used in the production of foodstuffs or food ingredients and falling within the scope of Directive 2009/32/EC.

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- Food with a new or intentionally modified molecular structure –
- Food consisting of, isolated from or produced from microorganisms, fungi or algae
- Food consisting of, isolated from or produced from material of mineral origin –
- Food consisting of, isolated from or produced from plants or their parts obtained by nontraditional propagating practices if significant changes in the composition or structure of the food affect its nutritional value, metabolism or level of undesirable substances –
- Food consisting of, isolated from or produced from animals or their parts obtained by nontraditional breeding techniques –
- Food consisting of, isolated from or produced from cell culture or tissue culture derived from animals, plants, microorganisms, fungi or algae –
- Food resulting from a new production process if significant changes in the composition or structure of the food affect its nutritional value, metabolism or level of undesirable substances –
- Food consisting of engineered nanomaterials –
- Vitamins and minerals and other substances used in accordance with Food Supplements Directive 2002/46/EC obtained by a new food production process or containing engineered nanomaterials –
- Food used exclusively in food supplements within the EU before May 15, 1997, intended to be used in foods other than food supplements

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Clarification of the categories

Food not used for human consumption to a significant degree before 15 May 1997 and that falls under at least one of the following categories:

(i) food with a new or intentionally modified molecular structure, where that structure was not used as, or in, a food within the Union before 15 May 1997;

...

(x) food used exclusively in food supplements within the Union before 15 May 1997, where it is intended to be used in foods other than food supplements as defined in point (a) of Article 2 of Directive

2002/46/EC;

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Cloning, Nano

Food from clones: Until separate legislation on cloning is adopted, food from clones but not offspring will continue to fall within the scope of the Novel Foods Regulation.

Engineered nanomaterials: Engineered nanomaterials require a novel food authorization before being used in food. Applicants will have to demonstrate the scientific appropriateness of the test methods used to test the nanomaterials for which they request an authorization.
The definition of engineered nanomaterials currently set out in the Food Information to Consumers Regulation 1169/2011 is transferred to the new Novel Foods Regulation.

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Engineered nanomaterials

Current situation

- ***Nano provisions in Regulation (EU) 1169/2011 on food information to consumers (FIC)***
  - *Definition and labelling requirement*

1 January 2018

- ***FIC regulation***
  - *Definition will be deleted from FIC Regulation*
  - *It will replaced by a reference to the definition set out in the new novel food Regulation*
- ***New novel food Regulation***
  - *The definition is included in the novel food Regulation*
  - *Empowerment for the COM to update the definition in light of the scientific and technical progress (Revision of the Commission Recommendation from 2011)*

Health and Food Safety

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https://www.efsa.europa.eu/en/press/news/180704

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The European Food Safety Authority has produced this Guidance on human and animal health aspects (Part 1) of the risk assessment of nanoscience and nanotechnology applications in the food and feed chain. It covers the application areas within EFSA's remit, e.g. novel foods, food contact materials, food/feed additives and pesticides. The Guidance takes account of the new developments that have taken place since publication of the previous Guidance in 2011.

Potential future developments are suggested in the scientific literature for nanoencapsulated delivery systems and nanocomposites in applications such as novel foods, food/feed additives, biocides, pesticides and food contact materials. Therefore, the Guidance has taken account of relevant new scientific studies that provide more insights to physicochemical properties, exposure assessment and hazard characterisation of nanomaterials. It specifically elaborates on physicochemical characterisation of nanomaterials in terms of how to establish whether a material is a nanomaterial, the key parameters that should be measured, the methods and techniques that can be used for characterisation of nanomaterials and their determination in complex matrices. It also details the aspects relating to exposure assessment and hazard identification and characterisation. In particular, nanospecific considerations relating to *in vivo*/*in vitro* toxicological studies are discussed and a tiered framework for toxicological testing is outlined.

It describes *in vitro* degradation, toxicokinetics, genotoxicity as well as general issues relating to testing of nanomaterials. Depending on the initial tier results, studies may be needed to investigate reproductive and developmental toxicity, immunotoxicity, allergenicity, neurotoxicity, effects on gut microbiome and endocrine activity. The possible use of read-across to fill data gaps as well as the potential use of integrated testing strategies and the knowledge of modes/mechanisms of action are also discussed. The Guidance proposes approaches to risk characterisation and uncertainty analysis, and provides recommendations for further research in this area.

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Case - Insects

Current NF Regulation (EC) 258/97
unclear as regards whole animals *e.g.* insects

Some EU States **tolerate** whole insects as food

New NF Regulation (EU) 2015/2283 **clarifies**

- insects are novel foods unless proven history of food use before 1997
- may qualify as traditional food in 3rd countries
- applicable from **1st January 2018**

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Case - Insects

A limited number of insects under discussion
for instance the Belgian list (http://www.favv-afsca.fgov.be/foodstuffs/insects/)

Acheta domesticus	House cricket
Locusta migratoria migratorioides	African migratory locust
Zophobas atratus morio	Superworm
Tenebrio molitor	Mealworm
Alphitobius diaperinus	Lesser mealworm
Galleria mellonella	Waxworm
Schistocerca americana gregaria	American dessert locust
Gryllodes sigillatus	Banded cricket
Achroia grisella	Lesser waxworm
Bombyx mori	Silkworm

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Insects from January 2018 onwards

Introduction of insects (whole, parts or processed) **from 3rd countries** to European food market through the notification procedure possible

In all EU MS insects to be used as food (whole, parts or processed) need authorization

EFSA guidance on dossiers for safety assessment

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Union list of authorised and new novel foods

- ***Conditions for inclusion***
  - ✓ *Safe, do not mislead consumer, no nutritional disadvantage*
- ***Generic authorisation, except if data protection granted for 5 years***
- ***Initial establishment of the Union list***
  - ✓ *Already authorised novel foods and the foods notified as being substantially equivalent (generic authorisation)*

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Novel Food Beispiel

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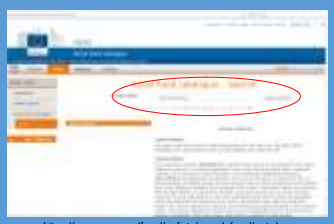
Novel Food Catalogue



https://ec.europa.eu/food/safety/novel_food/catalogue_en

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Novel Food Catalogue

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Centralised procedure

- *Applications/notifications to the Commission*
- *Applicant-Means a EUMS, non-EUMS or the interested party which may represent several interested parties*
- *Information to public-Summaries*
- *Evaluation by the European Food Safety Authority*
- *Authorisation by the Commission*
- *Time limits for each step*

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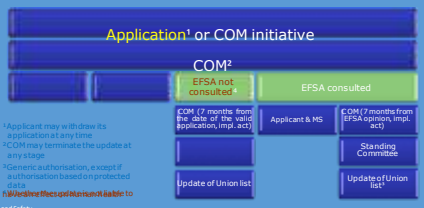
Authorisation process and updating the Union list of authorised novel foods



Health and Food Safety 175

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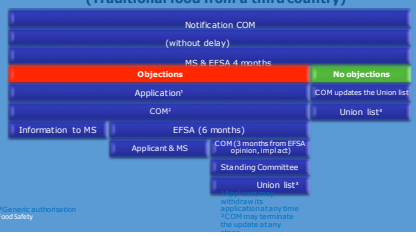
Authorisation process (Traditional food from a third country)



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Traditional food from a third country

Traditional food from a third country *is a novel food derived from primary production with a history of safe use in a third country.*

- *Traditional food can be*
  - ***Produced from plants/animals/micro-organisms etc.*** *(i.e. juice of the fruit of Morinda citrifolia L)*
  - ***From primary production*** *(i.e. chia seeds)*
  - ***Processed or unprocessed*** *(i.e. baobab dried fruit)*
- *Traditional food cannot be*
  - ***New molecules; from mineral origin; from a new process; from engineered nanomaterial; already authorised vitamins; minerals for which a new process has been applied or contains engineered nanomaterials; food used only in food supplements***

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Data protection

- *COM can grant the individual authorization for 5 years*
  - *Authorization holder indicated in the Union list*
  - *Does not apply to traditional foods from third countries*

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Beispiele und risk assessment

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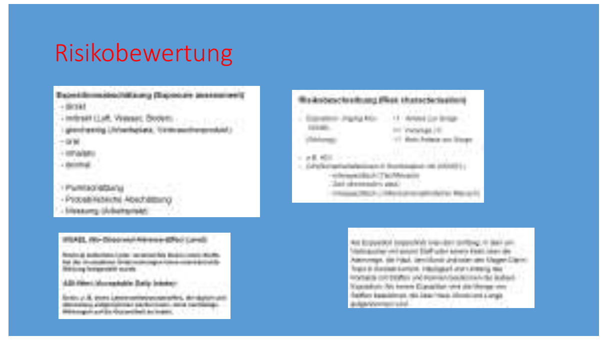

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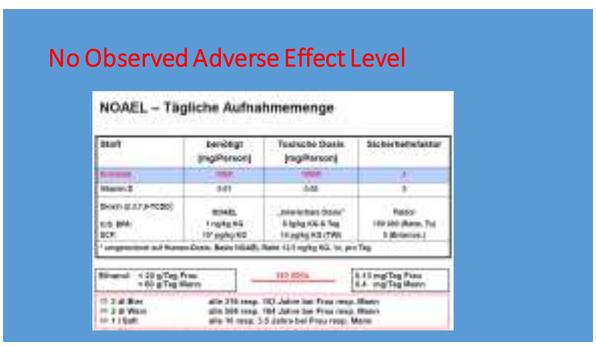

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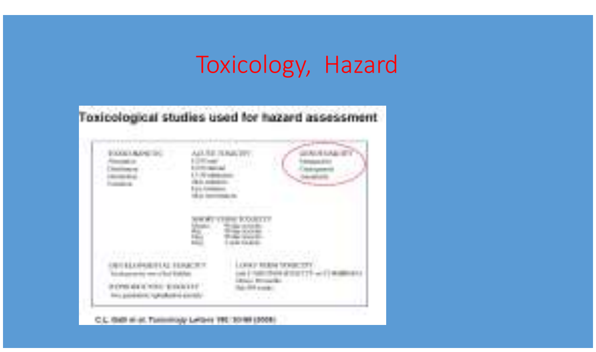

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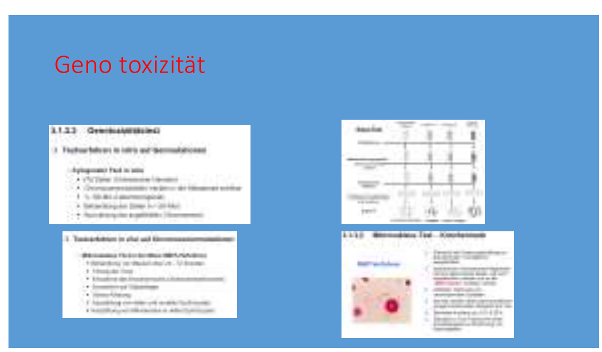

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Risko Nutzen

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Bewertung Neuartiger Lebensmittel

Notwendige Informationen für die Sicherheitsbewertung neuartiger Lebensmittel (NL)

Erforderliche Informationen:

- Spezifikation
- Herstellungsverfahren
- frühere Exposition des Menschen / Erfahrungen
- voraussichtliche Exposition
- ernährungswissenschaftliche Informationen
- mikrobiologische Informationen
- toxikologische Informationen

Einzelfallbetrachtung (case-by-case approach)

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Neuartige LM: Tox

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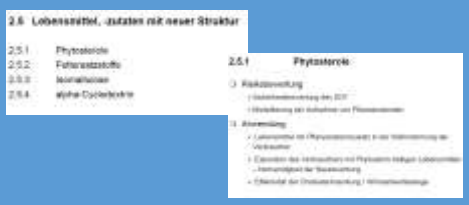
LM mit neuer Struktur



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Phytosterine , Beispiel

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Anträge

192

Sicherheitsbewertung

2.5.1 Phytosterol: Sicherheitsbewertung

- Keine Hinweise auf unerwünschte Wirkungen
- Kein Nachweis für Genotoxizität
- Sehr geringe Resorption
- No Observed Effect Level (NOEL): 9.6 g Phytosterinester / kg Körpergewicht / Tag
- Keine Wirkung auf das reproduktive System und keine estrogene Aktivität
- Keine Wirkung auf Darmflora (Keimzahl, Spezies, Enzymaktivitäten, pH-Wert, kurzkettige Fettsäuren) und Gallensäuren
- Bislang wurden am Menschen keine schädlichen Nebenwirkungen beobachtet, abgesehen von Menschen mit Phytosterolämie.

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Kritik

2.5.1 Phytosterol: Sicherheitsbewertung

Kritikpunkte

- Mögliches Risiko durch Dauereinnahme oder kumulierte Einnahme in verschiedenen Nahrungsmitteln
- Die maximale Menge an Phytosterolen / Phytostanolen soll 3 g pro Tag nicht überschreiten
- Mögliche Gefahr einer [illegible]
- Besondere Gefährdung
  - Patienten mit Phytosterolämie
  - Patienten, die cholesterinsenkende Medikamente einnehmen
  - Schwangere und stillende Frauen
- die genaue Zusammensetzung und Stabilität des Phytosterol-gemisches
- die mögliche Einnahme durch Personen, die keinen zu hohen Cholesterinspiegel aufweisen
- die Schwierigkeiten einer adäquaten Kennzeichnung

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EFSA zb Danacol

efsa

SCIENTIFIC OPINION

Danacol® and blood cholesterol

Scientific substantiation of a health claim related to a low fat formulated milk product (Danacol®) as richest with plant sterol/stanol esters and lowering/reducing blood cholesterol and reduced risk of (coronary) heart disease pursuant to Article 14 of Regulation (EC) No 1924/2006

"The Panel concludes that a cause and effect relationship has been established between the dietary intake of phytosterols and lowering of LDL-cholesterol.
The Panel considers that the following wording reflects the available scientific evidence: 'Phytosterols have been shown to lower/reduce blood cholesterol. High blood cholesterol is a risk factor in the development of coronary heart disease'.
The Panel considers that phytosterols should be consumed only by people who need and want to lower their blood cholesterol and that patients on cholesterol-lowering medication should only consume the product under medical supervision."

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Fettersatzstoffe

2.5.2 Fettersatzstoffe

- Einteilung, Anforderungen
- **Salatrim**
  - Spezifikation
  - Sicherheitsbewertung
- **Olestra**
  - Spezifikation
  - Sicherheitsbewertung

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Sicherheitsbewertung Salatrim

2.5.2 Sicherheitsbewertung Salatrim

Olestra: Sicherheitsbewertung

2.5.2 Olestra: Sicherheitsbewertung

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LM aus nicht traditionellen Rohstoffen

2.6 Lebensmittel aus nicht traditionellen Rohstoffen

- Lycopin aus Pilz Blakeslea Trispora
- Synthetisches Lycopin
- Lycopin-Oleoresin aus Tomaten
  - Sicherheitsbewertungen durch die EFSA
  - Anwendung
    Herstellmethoden von Nährstoffen / Probleme bei der lebensmittelrechtlichen Abgrenzung als Novel Food

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Zb Lycopin

Lycopin - Herstellung

- Mit Hilfe spezieller, lebensmitteltechnisch zugelassener Lösungsmittel wird Lycopin aus Tomaten (Lycopersicon esculentum L.) extrahiert. Ein Kilogramm Tomaten enthält etwa 20 mg Lycopin.
- Häufiger als der isolierte Farbstoff wird Tomaten-Extrakt eingesetzt. Er gilt, wenn nicht der enthaltene Anteil Lycopin gezielt erhöht wurde, als färbendes Lebensmittel. Wenngleich Tomaten-Extrakt keine E-Nummer trägt, ist er doch in der Zutatenliste aufgeführt.
- Lycopin kann auch chemisch-synthetisch hergestellt werden. Gemäß einer Stellungnahme des Wissenschaftlichen Lebensmittelausschusses der EU vom Dezember 1999 darf synthetisches Lycopin jedoch nicht als Zusatzstoff eingesetzt werden (SCF/CS/ADDICOL/100 Final). Dies wird damit begründet, dass das synthetische Präparat anders als das durch Extraktion gewonnene zusammengesetzt sei und entsprechende toxikologische Untersuchungen bisher fehlten.

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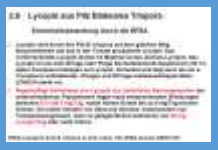

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LM ethnic

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Functional foods,additives
health claim regulation
Personalisationn

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- Lebensmittel vs. Arzneimittel?
  - Bei Pflanzen-Extrakten große kulturelle Unterschiede in den Mitgliedstaaten der EU
    Länder mit langer Tradition, aber sehr unterschiedlichen Handhabungen (pos. vs neg. Liste, LM vs. AZM)
- Neuartig (Novel Food) oder nicht?
  - Vielfältige und nicht konsistente Interpretation sowohl auf Mitgliedstaaten als auch EU-Ebene
  - **Folge** → große Unsicherheiten, eingeschränkte Entwicklungsmöglichkeiten

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Food improvement

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Safe level

Setting the "safe level"
As part of its safety evaluations of food additives EFSA seeks to establish, when possible (e.g. when sufficient information is available), an Acceptable Daily *Intake* (*ADI*) for each substance.

The ADI is the amount of a substance that people can consume on a daily basis during their whole life without any appreciable health risk. ADIs are usually expressed in mg per kg of body weight per day (mg/kg bw/day). The ADI can apply to a specific additive or a group of additives with similar properties. When re-evaluating previously authorised additives, EFSA may either confirm or amend an existing ADI following review of all available evidence.
When there are insufficient data for establishing an ADI, a *margin of safety* may be calculated to determine whether estimated *exposure* might be of potential concern.
In other cases, for example, for substances that are already present in the body or regular components of the diet or that did not indicate adverse effects in animal studies, there is no need to set an ADI.

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Green tea is produced from the leaves of *Camellia sinensis* (L.) Kuntze, without fermentation, which prevents the oxidation of polyphenolic components. Most of the polyphenols in green tea are catechins.
The Panel considered the possible association between the consumption of (-)-epigallocatechin-3-gallate (EGCG), the most relevant catechin in green tea, and hepatotoxicity. This scientific opinion is based on published scientific literature, including interventional studies, monographs and reports by national and international authorities and data received following a public 'Call for data'.
The mean daily intake of EGCG resulting from the consumption of green tea infusions ranges from 90 to 300 mg/day while exposure by high-level consumers is estimated to be up to 866 mg EGCG/day, in the adult population in the EU. Food supplements containing green tea catechins provide a daily dose of EGCG in the range of 5–1,000 mg/day, for adult population. The Panel concluded that catechins from green tea infusion, prepared in a traditional way, and reconstituted drinks with an equivalent composition to traditional green tea infusions, are in general considered to be safe according to the presumption of safety approach provided the intake corresponds to reported intakes in European Member States. However, rare cases of liver injury have been reported after consumption of green tea infusions, most probably due to an idiosyncratic reaction. Based on the available data on the potential adverse effects of green tea catechins on the liver, the Panel concluded that there is evidence from interventional clinical trials that intake of doses equal or above 800 mg EGCG/day taken as a food supplement has been shown to induce a statistically significant increase of serum transaminases in treated subjects compared to control.

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Health claim regulation

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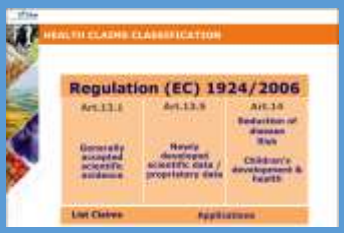
Health claim classification



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Examples 13.1

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Examples 13.5

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Problems of gut immune claims (eg probiotoics

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New developmements

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Spermidine

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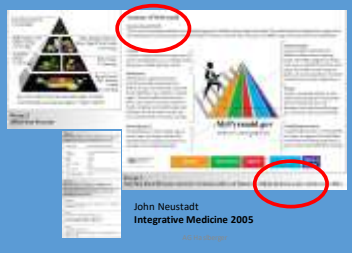
Basis: dietary reference values
1992 US USDA-Pyramide, an individualised approach, age, lifestyle (work)



John Neustadt
Integrative Medicine 2005

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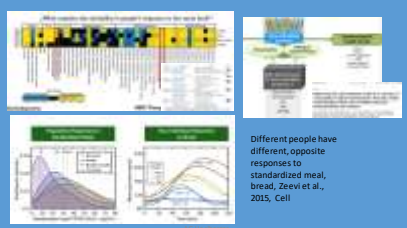
What explains the variability in responses to food ?
E.g. Highly different personal post- prandial glycemic responses



Different people have different, opposite responses to standardized meal, bread, Zeevi et al., 2015, Cell

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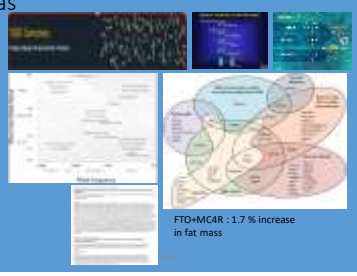
GWAs, SNPs, rare: common variants moderate, large effects; in different areas



FTO+MC4R : 1.7 % increase in fat mass

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The penetrance of SNPs,
DTC genetic testing for nutritional advice

For diseases controlled by 1000 loci of mean relative risk of only 1.04, a case-control study with 10,000 cases and controls can lead to selection of ~75 loci that explain ≥50% of the genetic variance. The 5% of people with the highest predicted risk are three to seven times more likely to suffer the disease than the population average, depending on heritability and disease prevalence. Whether an individual with known genetic risk develops the disease depends on known and unknown environmental factors.

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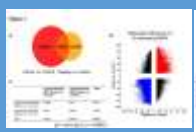
Missing heritability: what is missing to understand a phenotype, a person: gene- environment interactions epigenetics ?

225

Methylation of CpGs established as marker in nutrition, Agouti mouse: nutrition modulated: interaction nutrition- microbiome-epigenome



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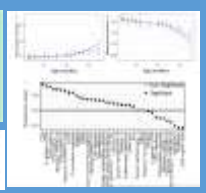
Epigenetic clock, CR, nutrition



Intrinsicage: horvath multiple tissues.
Extrinsic: Hannum, bloodcell

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Epigenetic miRNAs: food borne, marker for mechanisms, phenotypes, disorders

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Individual diversity of gut microbiota reflects nutrition and lifestyle, mediates individual different energy extraction, and different metabolisation

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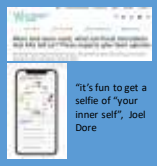
Individual glucose-responses mediated by microbiota structure, personal nutrition predictor, advise



"it's fun to get a selfie of "your inner self", Joel Dore

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Personalisation: obesity: only 30-40 % linked to mendelial variation, role for gene- environment (epigenetic?) interactions

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Personal different responses to nutriton affect personal different developments of hallmarks of aging, types of aging, ageotypes

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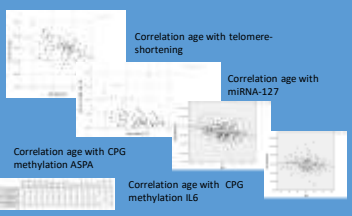
Faces of personal aging: correlations age with telomers, miRNAs, CPG-methylation, inflammation



Correlation age with telomere-shortening

Correlation age with miRNA-127

Correlation age with CPG methylation ASPA

Correlation age with CPG methylation IL6

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Consequences personalised nutrition, EU- Food4me Study,

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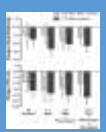
EU- Food4me study results prove „personal nutrition does better than on size fits all",
J. Mathers



Changes of dietary intake after personalised advice Healthy eating index

Changes in a dposity markers were greater in participants who were informed that they carried the *FTO* risk allele (level 3 AT/AA carriers) than in the nonpersonalized group

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Definition of metabotypes from biochemical, genetic-, microbiota- based information, (air-)digestion trackers; Consequences

Triacylglycerol (TAG), total cholesterol (TC), HDL cholesterol, and glucose
Metabotyping seems to be a promising tool to simplify the delivery of effective advice.

Metabotype cluster 3 with the highest occurrence of diseases and risk factors, generally advised to reduce the relatively high consumption of meat and to increase the relatively low consumption of vegetables and physical activity compared to clusters 1 a nd 2.

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Consequences of metabotyping, example

237

health/aging. Use of supplements, functional foods which address specific mechanisms „ Achilles Fersen Concept“

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Aging: Increase of senescent cells in tissues, senolysis enables re-juvenation

Senescence-Associated Secretory Phenotype

Domhnall McHughand Jesús Gil, JCB 2017

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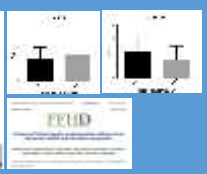
Functional foods, food additives, and precision nutrition Sirt activation drink mimics certain effects of fasting/CR in the area of healthy aging and balances microbiota.



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Importance of good biomarkers, the way to precision medicine, especially cfDNA Precision Nutrition

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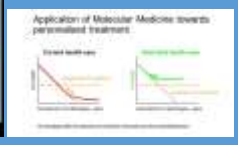
intervention:
personal or precision medicine,
synonyme?
personal or precision nutrition,
nyme?



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Precision, personalised nutrition,
where we are, where to go

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Precision-, personalised nutrition,
the way we may go

Mobile apps and wearable devices facilitate real-time assessment of dietary intake and provide feedback which can improve glycaemic control and diabetes management.

By integrating these technologies with big data analytics, precision nutrition has the potential to provide personalised nutrition guidance for more effective prevention and management of complex metabolic diseases

(D. D. Wang & Hu, 2018).

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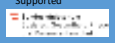
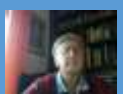
Many open questions
remain …

www.alexander-haslberger.at
www.my-personal.health

Supported





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