

Emerging Issues in Color: Growing International Challenge

2018 Global Color Conference

Arlington, VA

Kevin C. Kenny, J.D., LL.M.,
Chief Operating Officer
Decernis LLC

6 Nov 2018



Decernis: Research + Systems for Global Compliance

- Focus: **Food, Consumer- and Chemical Product Compliance**
- 6,000 users across 94 countries and 600+ clients
- Regulatory coverage of 212 countries
- Clients:
 - 50 Governments (e.g. US, EU, Health Canada, China, India, Japan)
 - 400+ Upstream manufacturers
 - 100+ Downstream manufacturers, processors & retailers
 - Others: Law firms, laboratories, associations, universities
- Founded 2003

Decernis Compliance Management Platforms



All tied together by our Risk Management Dashboard for easy access and seamless monitoring

Horizon Scanning

Daily Risk Monitoring:

Automatically tracks relevant, global regulatory notifications, scientific opinions, product recalls and warning announcements. Track substances, flag events and push info to others.

gComply

REGULATORY REFERENCE

Global Library:

Web-based regulatory reference database and library containing over 90,000 regulations across 212 countries.

gComply Plus

ENTERPRISE COMPLIANCE

Product Analysis:

Rule-based, intelligent, automated compliance analysis and reporting system; integrates with a company's PLM and ERP systems.

Supply Chain

Management

Supplier Risk Monitoring:

Manages all compliance documents including questionnaires, certificates, SDSs, lab results etc., to identify missing or out-of-date documents.

+ ACQUIRED FOOD FRAUD DATABASE IN 2018

Emerging Issues

1. **Global and Regional Harmonization & Challenges**
2. **Consumer Pressure**
3. **Blogs & interest groups replacing regulation**
4. **Enforcement challenges**
5. **Focus on “Natural”**

Food & Beverage Challenge:

- **200+ Countries**
- 40 Major Languages
- **3,172 Food Additive/Standards**
Regs/Drafts/Notices/ Amendments across 117
countries since 1 Jan 2018(!)
 - EU **471** (includes 194 EFSA reports and opinions)
 - USA **412** (includes warning letters and 243 recalls)
 - Canada **283** (includes 234 recalls!)
 - California **109**
 - Korea 121
 - China 108
 - UK 105
 - India 86

Taiwan 81
Australia 58
Hong Kong 55
Codex 53
Russia 47
Japan 46
Kenya 43
Thailand 43

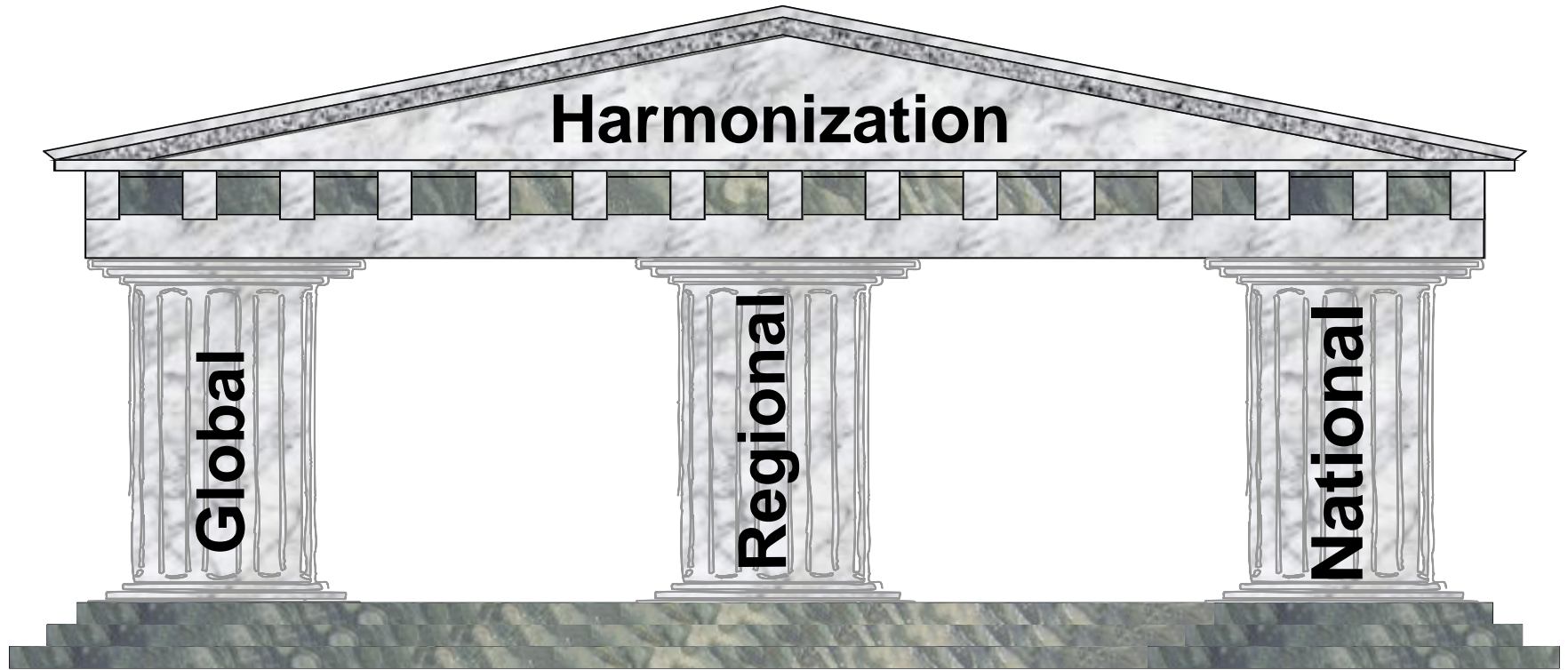
= Not Enough Harmonization

1. Harmonization

Why Harmonize Food Additives?

- Today: Lists, food categories, usages and specifications are non-harmonized making international trade of food-related products difficult & expensive.
- Major developed markets such as the EU, US and Japan have had detailed food regulatory systems in place for years: non-harmonized
- More “Mosaic” = Less Safety!

So, what does Harmonization mean?



Harmonization Efforts

- **Codex Alimentarius (116 Countries)**
- **European Union (52 Countries)**
- **Eurasian Economic Union (5 Countries)**
- **SIECA (8 Countries)**
- **Mercosur (6 Countries)**
- **GCC (6 countries)**
- **NOT YET: ASEAN (10 Countries)**



- **Established 1963 (FAO & WHO)**
- **Today:**
 - 187 Member countries + 1 Int. Org (EU)
 - 240 Codex Observers
 - 56 IGOs
 - 168 NGOs
 - 16 UN
- **Primary Goal: Develop harmonised international food standards, guidelines and codes of practice**





Acronym	Codex Committee	Id	Doc Ref	Host Country
CCCF	Contaminants in Foods	CX-735	CX/CF	NL
→ CCFA	Committee on Food Additives	CX-711	CX/FA	CN
CCFH	Food Hygiene	CX-712	CX/FH	US
CCFICS	Food Import and Export Certification and Inspection Systems	CX-733	CX/FICS	AU
→ CCFL	Food Labelling	CX-714	CX/FL	CA
CCGP	General Principles	CX-716	CX/GP	FR
CCMAS	Methods of Analysis and Sampling	CX-715	CX/MAS	HU
CCNFSDU	Nutrition and Foods for Special Dietary Uses	CX-720	CX/NFSDU	DE
CCPR	Pesticide Residues	CX-718	CX/PR	CN
CCRVDF	Residues of Veterinary Drugs in Foods	CX-730	CX/RVDF	US

JECFA

JECFA (**J**oint **FAO/WHO** **E**xpert **C**ommittee on **F**ood **A**dditives) is the scientific advisory body of FAO/WHO.

Responsible for:

- Establishing specifications for **identity** and **purity** of individual food additives
- Determining **safe levels** of use
- Setting standards of consumption and **acceptable daily intakes (ADIs)** for food additives specified in Codex Alimentarius (see **CSFA** below)



Additives

- Codex STAN 192-1995 General Standard for Food Additives

Labelling/Claims

- General Standard for the Labelling of Prepackaged Foods (CODEX STAN 1-1985)
- Codex Standard for Labelling of and Claims for Foods for Special Medical Purposes (CODEX STAN 180-1991)
- Guidelines on Nutrition Labelling (CAC/GL 2-1985)
- General Guidelines on Claims (CAC/GL 1-1979)
- Guidelines for Use of Nutrition and Health Claims (CAC/GL 23-1997)



Countries which directly follow Codex Additives (96)

Afghanistan	Cameroon	Iran	Nauru	Solomon Islands
Angola	Cape Verde	Iraq	Nicaragua	South Sudan
Anguilla	Cayman Islands	Ivory Coast	Niger	Sudan
Antigua & Barbuda	Congo	Jamaica	Nigeria	Suriname
Azerbaijan	Costa Rica	Jordan	Oman	Swaziland
Bahamas	Cuba	Kuwait	Pakistan	Syria
Bahrain	Curacao	Laos	Panama	Tanzania
Bangladesh	Dominica	Lebanon	Papua New Guinea	Tajikistan
Barbados	Dominican Republic	Libya	Paraguay	Togo
Belize	El Salvador	Macau	Peru	Tonga
Benin	Eritrea	Malawi	Qatar	Trinidad/Tobago
Bermuda	Ethiopia	Maldives	Rwanda	Turks and Caicos
Bhutan	Georgia	Mali	Saint Lucia	Turkmenistan
Bolivia	Ghana	Mauritania	Saint Vincent and the	UAE
Botswana	Grenada	Mongolia	Samoa	Uganda
British Virgin Islands	Guatemala	Mozambique	Saudi Arabia	Vanuatu
Brunei	Guyana	Myanmar	Senegal	Yemen
Burkina Faso	Haiti	Namibia	Seychelles	Zambia
Burundi	Honduras	Nepal	Sierra Leone	Zimbabwe
Cambodia				



If no local regulation for individual substance, follow Codex (20)

EXAMPLE - Argentina: Article 2 of Decree §2092/1991 states: "... all foods, condiments, beverages, or their raw material and food additives which are manufactured, fractioned, preserved, transported, sold, or exposed, must comply with the CAA requirements. ... GOA also considers products from countries which have food controls comparable to those of Argentina, or when they use the *Codex Alimentarius* (FAO/OMS) standards, to be in compliance with Argentine standards."

Algeria	Fiji	Peru	South Africa
Argentina*	Indonesia*	Philippines	Thailand*
CARICOM	Kazakhstan	Serbia	Uzbekistan*
Colombia	Kenya	SIECA	Venezuela
Ecuador	Morocco*	St. Kitts	Vietnam

* = If country does not regulate a substance which is approved by Codex, additive manufacturer must request and obtain permit approval before using.

Codex Step Process

Codex has an 8-Step Process with 8 = Adoption into GFSA

46 colors currently have draft status and/or final adopted provisions in GSFA:

MANY Colors are caught in either Step 4 or Step 7:

- **Step 4:** Draft text has been prepared, circulated to member countries and observers for comment, still awaiting review at Committee level before being sent to the Commission for review
- **Step 7** Additives already endorsed by Commission, agreed to be put forth for finalization = simply awaiting finalization by the Committee.



Colorants caught in Codex Step Process

INS 123 Amaranth

38 usage categories at **Step 7**

INS 160b(i) Annatto extracts, bixin-based

ca. 90+ usages at Step 4

INS 160b(ii) Annatto extracts, norbixin-based

ca. 90 usages at Step 4

INS 122 Azorubine (Carmoisine)

55 usages at **Step 7**

INS 162 Beet red

23 usages at **Step 7**

INS 151 Brilliant black (Black PN)

59 usages at **Step 7**

INS 155 Brown HT

58 usages at **Step 7**

INS 150a Caramel I – plain caramel

19 usages at **Step 7**

INS 150b Caramel II - sulfite caramel

Mostly at Step 4

INS 140 Chlorophylls

21 usages at **Step 7**

INS 100(i) Curcumin

68 usage categories at **Step 7**

Source: FA/50 INF/01 - Table One (Mar 2018)



Colorants caught in Codex Step Process

INS 161b(i) Lutein from <i>Tagetes erecta</i>	Mostly at Step 4
INS 160d(iii) Lycopene, <i>Blakeslea trispora</i>	Mostly at Step 4
INS 160d(i) Lycopene, synthetic	Mostly at Step 4
INS 160d(ii) Lycopene, tomato	Mostly at Step 3 & Step 4
INS 160c(ii) Paprika extract	Mostly at Step 2
INS 104 Quinoline yellow	57 usages at Step 7
INS 128 Red 2G	4 usages at Step 7
INS 102 Tartrazine	62 usages at Step 7
INS 171 Titanium dioxide	18 usages at Step 7
INS 161h(i) Zeaxanthin, synthetic	Mostly at Step 4



Codex is NOT intended as a Positive List:

GENERAL STANDARD FOR FOOD ADDITIVES

CODEX STAN 192-1995

Adopted in 1995. Revision 1997, 1999, 2001, 2003, 2004, 2005, 2006, 2007, 2008, 2009, 2010, 2011, 2012, 2013, 2014, 2015, 2016, 2017, 2018

P. 2 Footnote 1:

-
- ¹ Notwithstanding the provisions of this Section of the General Standard, the lack of reference to a particular additive or to a particular use of an additive in a food in the General Standard as currently drafted, does not imply that the additive is unsafe or unsuitable for use in food. The Commission shall review the necessity for maintaining this footnote on a regular basis, with a view to its deletion once the General Standard is substantially complete.



Advantages

- Brings everybody to the table
- Transparency: Freely, electronically available
- Arabic, Chinese, English, French, Spanish, Russian
- Makes it possible for less advanced countries to catch up in a hurry

Disadvantages

- Political
- Glaciers sometimes move faster
- Purely voluntary
- US, EU will never agree to drop 50 years of legislation

European Union: 27.5 Countries



EU 27.5 + other countries (24)



+ Candidate Members

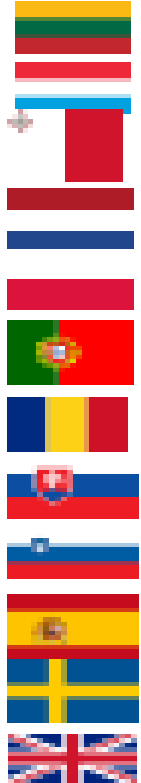
- Turkey + Albania, Iceland, Macedonia, Montenegro, Serbia

+ EEA Members

- Iceland
- Lichtenstein
- Norway

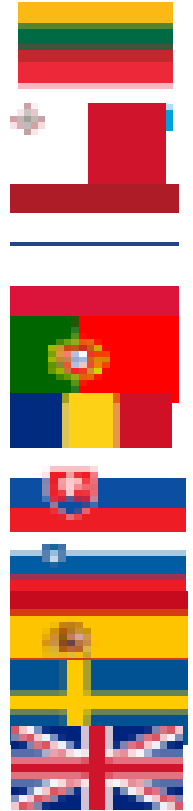
+ “Under the influence”

- EU: Bosnia & Herzegovina, Kosovo
- ES: Canary Islands
- FR: French Polynesia, French Guiana, Guadeloupe, Martinique, Mayotte, Reunion, Saint-Martin
- NL: Aruba, Curaçao and Sint Maarten
- PT: Azores, Madeira



Cornerstone Regulations

- **Additives**
 - Regulation (EC) No 1333/2008 on Food Additives
- **Labelling/Claims**
 - Regulation (EC) No 1924/2006 on Nutrition & Health Claims
 - Regulation (EU) No 1169/2011 on the Provision of Food Information to Consumers
 - [Public EU Register of Nutrition and Health Claims](#)



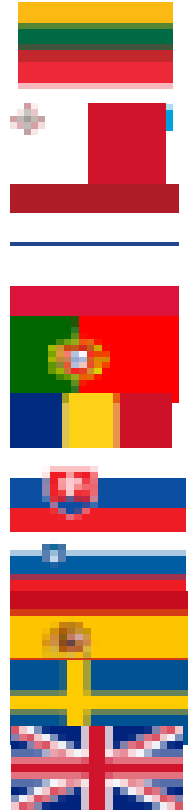
European Union

Advantages

- Directives -> Regulations = Single European Standard
- Absolute consistency in theory
- (Lex Britannia!)

Disadvantages

- Precautionary Principle – cf. hyperactivity
- Much more restrictive usages and maximum limits than US



Public Pressure

- Example: Southampton 6
- Headlines
- NGOs
- Bloggers
- “I want natural”

Hyperactivity – “A pattern of behaviour showing marked individual differences in the general population and comprises overactive, impulsive and inattentive behaviour.”

A wide range of contributing factors act in concert to increase the degree of hyperactivity shown by a child:

- Genetic influences
- Experiential influences
- Environmental influences

Do food colourants?

Southampton Six Case Study

- Commissioned by UK Food Standard Agency (FSA)
- Study carried out by researchers at University of Southampton, UK
- Published in 3-9 November 2007 issue of the Lancet:
 - Ⓜ Food additives and hyperactive behaviour in 3-year-old and 8/9-year-old children in the community: a randomised, double-blinded, placebo-controlled trial

Donna McCann, Angelina Barrett, Alison Cooper, Debbie Crumpler, Lindy Dalen, Kate Grimshaw, Elizabeth Kitchin, Kris Lok, Lucy Porteous, Emily Prince, Edmund Sonuga-Barke, John O'Warner, Jim Stevenson

Lancet 2007; 370: 1560-67

Southampton Six: Mix Contents:

E Number	US Label	Name of Additive	Mix A	Mix B
E102 Colour	Yellow 5 (FD&C)	Tartrazine	✓	✗
E104 Colour	Yellow10 (FD&C)	Quinoline yellow	✗	✓
E110 Colour	Yellow6 (FD&C)	Sunset Yellow	✓	✓
E122 Colour	14720 (CI#)	Carmoisine	✓	✓
E124 Colour	16255 (CI#)	Ponceau 4R	✓	✗
E129 Colour	Red40 (FD&C)	Allura Red AC	✗	✓
E211 Preservative		Sodium benzoate	✓	✓

The EFSA Journal (2008) 660, 1-53

European Food Standards Authority

“Panel concludes that the McCann et al. study provides limited evidence that the two different mixtures of synthetic colours and sodium benzoate tested had a small and statistically significant effect on activity and attention in children selected from the general population excluding children medicated for ADHD.....”

After its initial review of the study, EFSA issued an Opinion that this study gave no grounds for changing the ADI of any of the colors.

EFSA Finding: “There is no evidence to support that these substances cause hyperactivity.”

EU Commission overruled EFSA and imposed mandatory labelling “may have an adverse effect on activity and attention in children” – mostly because of the sensationalist press in the UK.

Results

Summary Interpretation: One or more of the artificial colours **or** a sodium benzoate preservative (**or both**) in the diet result in increased hyperactivity in 3-year-olds and 8/9-year-olds.

The Study was roundly criticized by Scientific Community. ID's Flaws:

- Done by sociologists, not food scientists
- Which ones actually caused hyperactivity? Impossible to tell.
- Maybe it was sodium benzoate?
- **Result:** Today using 'natural' additives sometimes with little data to validate safety

Headlines

Food Additives Drug Children

By eliminating the chemical preservatives and coloring commonly found in processed foods, Dr. Ben Feingold, a San Francisco specialist, has learned that he can cure some kinds of hyperactivity – a nervous condition which makes it difficult to concentrate.

Hyperkinesia – or hyperactivity – is no small problem. Feingold cites a California study which estimates that in the past 10 to 12 years the incidence of hyperactivity and learning difficulties rose from 2% to an average of 20-25% and in some cases, 40% of the entire school population.

If initial studies prove correct, a synthetic-free diet may, for many children, become an alternative to present methods of drug treatment. Feingold estimates that as many as 80% of the several million children now given drugs like Ritalin (a behavior modifier), amphetamines (commonly known as "speed"), or tranquilizers to control their behavior may be able to stop simply by restricting their diets to natural foods. Feingold points out that drug treatment is not a cure for hyperactivity, but only serves to mask the problem. And yet, he conservatively estimates that nationally at least two million of the approximately five million children labelled hyperactive are given drugs, but receive no other kind of therapy or treatment. One school official in Yolo County California says that nearly 16% of the children in his school are being given behavior modifying drugs.

In an adult, using Ritalin or amphetamines has the effect of making one more active. But in the case of hyperactive children, Ritalin seems to have the "paradoxical" reverse effect of slowing them down. The scientific explanation of this phenomenon is still conjectural, and some experts are now beginning to question whether the effect is in fact paradoxical.

These specialists point out that hyperactive children normally quiet down when put in stressful situations like visiting a doctor's office. Amphetamines and Ritalin, they hypothesize, could be putting the children under constant stress. Their ability to concentrate, however, might not have improved at all. And long term usage of stress-inducing drugs would have disastrous effects on the children's nervous system and general health.

Most hyperactive children, Feingold says, can probably be taken off drugs fairly quickly once they are on a careful diet. The problem is that it is nearly impossible to keep children away from the ubiquitous food additives. In one case, Feingold says, a child had been treated with Ritalin from the age of three and a half, and several years later he still couldn't calm down by himself. Two weeks after being

kept away from synthetic dyes and flavorings, his behavior became normal.

A few weeks after that, however, the boy was back in a hyperactive state. It turned out that he had eaten a donut



Are food additives harmful to children?

www.blueprintnutrition.ca



SCIENCE 2.0

Everything Is An Endocrine Disruptor, Claims French Activist

Researcher Barbara Demeneix



CHEMTrust
Protecting humans and wildlife
from harmful chemicals

From BPA to BPZ: a toxic soup?

Companies switch from a known hazard
to similar properties, and how regular

Boycott food with toxic additives

2014-10-21 04:51:23

What Are Phthalates—And Should We Be Worried?



You May Like



California Bill Would Prohibit Fluorinated Plastics in Fast Food Packaging

Danish group's testing finds cadmium and mineral oils in dark chocolate

By Joseph James Whitworth

06-Apr-2018 - Last updated on 06-Apr-2018 at 10:20 GMT



RISIS Ting Hsin oil allegedly contains Agent Orange

FDA determines tainted oil a health hazard

FOOD SCARE Tainted additives used for two decades

WIDENS

DEHP CANCER

Food safety fears

Plasticizers found in 10 food products in **CONTAMINATED**

Fraudulent oil firm raided

Meat probe

Adulterated

WEI DETAINED IN TING HSIN SCANDAL

Nine indicted over tainted starch case

Copper chlorophyllin found in 12 more oils

Food safety authorities on alert

Taiwanese 'gutter oil' scandal spreads to Hong Kong, Macau

Blogs

THE WORST FOOD ADDITIVES & how to avoid them



Worst Food Additives and How to Avoid Them
mindfulmomma.com



CREEPY FOOD ADDITIVES
where they like to hide, and how to find them



The Problem with Food Additives



5 Sneaky Food Additives To Avoid ...
blog.paleohacks.com

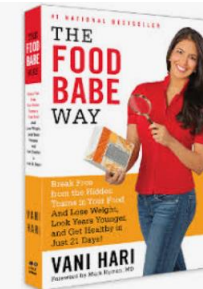
FOOD BABE

NOT ON THE TRAIL TO INVESTIGATE WHAT'S REALLY IN YOUR FOOD!

Vani Hari



Common food additives that you ...
foodbabe.com



Food Babe - Welcome to F...
foodbabe.com

Emerging Issues in Color



Related: What is a BAN?

Coloring agents can be found in almost any processed food: candy, mac and cheese, Cheddar-flavored crackers, Jell-O... the list goes on. Not all coloring agents are harmful, but some, including blue #1 and #2, yellow #5 and 6, and red #40, have raised specific health concerns, after research showed they can cause behavioral problems, cancer, birth defects, and other health problems in laboratory animals. Yellow #6, found in many boxed mac and cheese's, has also been shown to cause hypersensitivity in children. These artificial food dyes are banned in Norway and Austria, and the European Union requires a warning notice on most foods containing dyes.

Ragged University is a project where the community creates events in social spaces and we get to learn from each other in relaxed ways. ... The **Ragged University** project is about learning from all the traditions of free education and making them live through practice.

About Ragged... | Ragged University
<https://www.raggeduniversity.co.uk/about/>

<https://www.raggeduniversity.co.uk/2014/03/19/food-additives-banned-countries-alex-dunedin/>

G_Translate Pulse TRIS Netflix Kindle Verbs NFCU Dashboard JIRA Sites Jira Issues

RAGGED
University of the Ragged

'Education is not preparation for life, it is life itself'

Home About Us History What's On The Eclectic Talks Contact Resources

Food Additives Banned by One or More Countries

Due to requests I have produced this list of additives which have been banned by different countries. I have gone through the book '*E for Additives*' by **Maurice Hanssen** (Published 1987) and noted which ones have been singled out by governments for exclusion from the diet.

I have done this so that it makes clear that large bodies of educated people in the employment of governments around the world have surveyed the available evidence on the properties of these chemicals and have for one reason or another decided that these should not be allowed in the food chain. In short, there is compelling evidence as to these being poisonous to our health.

I have been contacted by someone who has brought critical reflections to this article and suggested that the legislative information which I have quoted needs updated. I am very appreciative of this and am at the moment working to incorporate the suggested points into this article. Key here is being able to reference reliable information resources so that informed decisions on what to exclude in the diet can be made.

Should you want to find other solid and dependable information on the toxicity of a substance (which is a good habit) I would recommend looking up the **Material Data Safety Sheet** on the chemical you are checking. Here is an example of one on Benzene:

Select Language
Powered by Google Translate

search

Subscribe to Blog via Email
Enter your email address to subscribe to this blog and receive notifications of new posts by email.
Join 12,183 other subscribers.
Email Address
Subscribe

The Sociology of Education: A Durkheimian View
The Importance of Music Within Society by Daniel Zambas
10th July 2018: Autism; The Plot Against Consciousness, Cognition and Language by Mike McInnes
Home
What are the Necessary Conditions of a

Science Lab.com
Chemicals & Laboratory Equipment

Material Safety Data Sheet
Benzene MSDS

Related: What is a BAN?

From: cecilie.svenning@mattilsynet.no [<mailto:cecilie.svenning@mattilsynet.no>]
Sent: Friday, December 08, 2017 4:04 PM
To: Larisa Bato <lbato@decernis.com>
Subject: Regulations on food additives - Kontaktskjema mattilsynet.no - 28112017 - 04:17:42

Dear Larisa Batotsyrenova

No food additive has been actively banned or prohibited in Norway since the EEA-agreement. Our legislation is fully harmonized with the legislation in the EU. Due to this we do not actively ban food additives that are authorized in the EU.

Yours Cecilie Svenning
Head office
Norwegian Food Safety Authority

Norway and Food Additives

Source: Norwegian Food Safety Authority
15/05/2006

 email  print

12 May 2006 - Norway used to regulate colourings, sweeteners and nitrite/nitrate different than the EC countries. In 2001 Norway implemented the EC Directives on food additives, and today there is no difference between the food additives legislation in Norway and the EC Member States.

Current situation

Norway has implemented all current EC Directives on food additives into our national legislation (regulation 21 December 1993 No 1378 on food additives for use in foodstuffs).

This means that all food additives authorised for use in an EU Member State are authorised for use in Norway as well. There is a delay whenever an amendment to the EC food additives legislation is adopted in the EC before it gets to be a part of the Norwegian legislation. This is due to procedure. The EC legislation must be adopted by the EEA Committee before it can be part of the Norwegian legislation.

There is however a difference in the structure of the legislation. The EC Directives are organized by substances whilst the Norwegian regulation is organized in food categories. The food categories are, with a few exceptions, similar to Annex B Food Category System - of the Codex' General Standard for Food Additives (CX STAN 192).

Before the implementation of the EC Directives the Norwegian Scientific Committee for Food reviewed the risk assessments and more recent studies for the food additives Norway where had some concerns. In general the EC legislation were considered to be acceptable. However, Norway asked for some exceptions and they are described later in this text.

Previous situation

Before the implementation of the EC Directives on food additives the Norwegian legislation deviated from the EC directives in four main areas; added/residual amounts, colourings, sweeteners and nitrite/nitrate.

Added/residual amounts

Norway regulated added amounts of food additives in food, whilst the EC legislation generally regulate the residual amounts in the final food. In general residual amounts in the food is more convenient both for the industry and the authority to manage, but not for nitrite/nitrate.

Colourings

Related: Natural

- **Consumers want NATURAL**
- **Chemicals sound dangerous!**
- **Misunderstanding GMP and need for additives**

Use of the term “natural color” is prohibited on an ingredient statement because, regardless of the source of the color, FDA regulations do not consider any added color to be natural unless the color is “natural to” the food product itself = ice cream using strawberry juice.

Common Exempt-from-Certification Color Additives

Annatto extract
Astaxanthin
Beet juice
Beta carotene
Beta-apo-8' caroteneal
Canthaxanthin
Caramel
Carmine/Cochineal
Dehydrated beets (beet powder)
Fruit juice
Grape color extract
Grape skin extract
Paprika oleoresin
Riboflavin
Saffron
Sodium copper chlorophyll
Spirulina extract
Synthetic iron oxide
Titanium dioxide
Tomato lycopene
Turmeric oleoresin
Vegetable juice

Figure 1

Enforcement

- **Regulators and Enforcement agencies are sometimes different**
- **Customs – skepticism toward colorants in food**
- **Non-Tariff Barriers masquerade as safety issues**
 - Local testing requirements
 - Standards of Identity
 - Artificially low limits
 - Conformance with Food Chemicals Codex
- **Religious issues pop up**

Chasing Zero

Today ultra small amounts of contaminants are traceable:

- 1 PPM = one word in all 7 books of Harry Potter
- 1 PPB = 1 second of time in 32 years

Dose-Response

Paracelsus (1493-1541)

"All substances are poisons; there is none which is not a poison. The right dose differentiates a poison from a remedy."

- Any substance, naturally occurring or man-made, is likely to produce some form(s) of harmful effect, if taken in sufficient quantity.



Thank you!

Kevin C. Kenny, J.D., LL.M.
Chief Operating Officer
Decernis LL.C.
1250 Connecticut Avenue NW, #200
Washington, D.C. 20036
Tel. +1 301-240-1800
US Mobile +1 (301) 535-2234
E-Mail: kkenny@decernis.com

**Thanks to Larisa
Batotsyrenova from
Decernis for assistance!**