TECHNICAL TRAINING ON RISK ANALYSIS FOR SAARC COUNTRIES
Delhi, India, June 17-21, 2013
FAO RAP, Bangkok, Thailand
Quality Council of India

Development of risk-based standard on aflatoxin in peanuts

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Bangkok, Thailand

Outline

- Risk analysis in the context of standard development
  - Risk assessment
    - Codex Alimentarius standards on Contaminants
    - Exposure assessment
    - Risk characterization
  - Risk management
    - Standard development on aflatoxin in Thai peanuts
    - Thai laws and regulations
  - Risk communication

Risk Analysis

-Risk evaluation
-Option assessment
-Implementation
-Monitoring/review

Risk assessment policy

Risk Assessor

-scientific based result
-uncertainties

Risk Manager

-hazard ID
-hazard characterization
-exposure assessment
-risk characterization

- consumer benefits
- impacts on economy and society
- stakeholder input

* Risk communication at all steps

Questions from risk manager

- Is there any significant risk from aflatoxin in agricultural commodities?
- Will it help reduce the risk if we reduce the maximum level from 20 ppb to 15 ppb as Codex's recommendation?
- Any other method to reduce the risk from aflatoxin?

Risk assessment

- Hazard identification
- Hazard characterization
- Exposure assessment
- Risk characterization

Codex standard for contaminants

JECFA: risk assessor

- Risk assessment/safety evaluation of food additives, processing aids, flavouring agents, residues of veterinary drugs in animal products, contaminants, natural toxins
- Exposure assessment
- Specifications and analytical methods, residue definition, MRL proposals (veterinary drugs)
- Development of general principles

CCCF: risk manager

- To establish or endorse permitted maximum levels or guidelines levels for contaminants and naturally occurring toxicants in food and feed
- To prepare priority lists of contaminants and naturally occurring toxicants for risk assessment by the Joint FAO/WHO Expert Committee on Food Additives
- To consider methods of analysis and sampling for the determination of contaminants and naturally occurring toxicants in food and feed
- To consider and elaborate standards or codes of practice for related subjects

Codex standard for contaminants

Definition of contaminants

- any substance not intentionally added to food
- Present in such food as a result of the production (including operations carried out in crop husbandry, animal husbandry and veterinary medicine), manufacture, processing, preparation, treatment, packing, packaging, transport or holding of such food or as a result of environmental contamination
- The term does not include insect fragments, rodent hairs and other extraneous matter

Codex General Standard for Contaminants and Toxins in Food and Feed (CODEX STAN 193-1995)

- Mycotoxins
  - **Aflatoxins, Total**
  - Aflatoxin M1
  - Ochratoxin A
  - Patulin
- Heavy Metals
  - Arsenic
  - Cadmium
  - Lead
  - Mercury
  - Methylmercury
  - Tin
- Radionuclides
- Others
  - Acrylonitrile
  - Chloropropanols
  - Melamine
  - Vinylchloride monomer

Aflatoxins, Total

1

AFLATOXINS, TOTAL

2

Reference to JECFA:	31 (1987), 46 (1996), 49 (1997), 68 (2007)
Toxicological guidance:	Carcinogenic potency estimates for aflatoxins B, G, M (1997, Intake should be reduced to levels as low as reasonably possible)
Residue definition:	Aflatoxins total (B1 +B2 + G1 + G2)
Synonyms:	Abbreviations, AFB, AFG, with numbers, to designate specific compounds
Related Code of Practice:	Code of Practice for the Prevention and Reduction of Aflatoxin Contamination in Peanuts (CAC/RCP 55-2004) Code of Practice for the Prevention and Reduction of Aflatoxin Contamination in Tree Nuts (CAC/RCP 59-2005) Code of Practice for the Reduction of Aflatoxin B1 in Raw Materials and Supplemental Feedingstuffs for Milk Producing Animals (CAC/RCP 45-1997) Code of Practice for the Prevention and Reduction of Aflatoxin Contamination in Dried Figs (CAC/RCP 65-2008)

Commodity/Product Code	Name	Level ug/kg	Suffix	Type	Reference	Notes/Remarks
SO 0697	Peanut	15		ML		The ML applies to peanuts intended for further processing For sampling plan, see Annex 1 below
TN 0660	Almonds	15		ML		The ML applies to almonds intended for further processing For sampling plan, see Annex 2 below
	Brazil nuts	10		ML		The ML applies to shelled ready-to-eat Brazil nuts For sampling plan, see Annex 2 below
	Brazil nuts	15		ML		The ML applies to shelled Brazil nuts destined for further processing For sampling plan, see Annex 2 below
TN 0666	Hazelnuts	15		ML		The ML applies to hazelnuts intended for further processing. For sampling plan, see Annex 2 below
TN 0675	Pistachios	15		ML		The ML applies to pistachios intended for further processing For sampling plan, see Annex 2 below
TN 0660	Almonds	10		ML		The ML applies to almonds "ready-to-eat" For sampling plan, see Annex 2
TN 0666	Hazelnuts	10		ML		The ML applies tohazelnuts "ready-to-eat" For sampling plan, see Annex 2
TN 0675	Pistachios	10		ML		The ML applies to pistachios "ready-to-eat" For sampling plan, see Annex 2

3

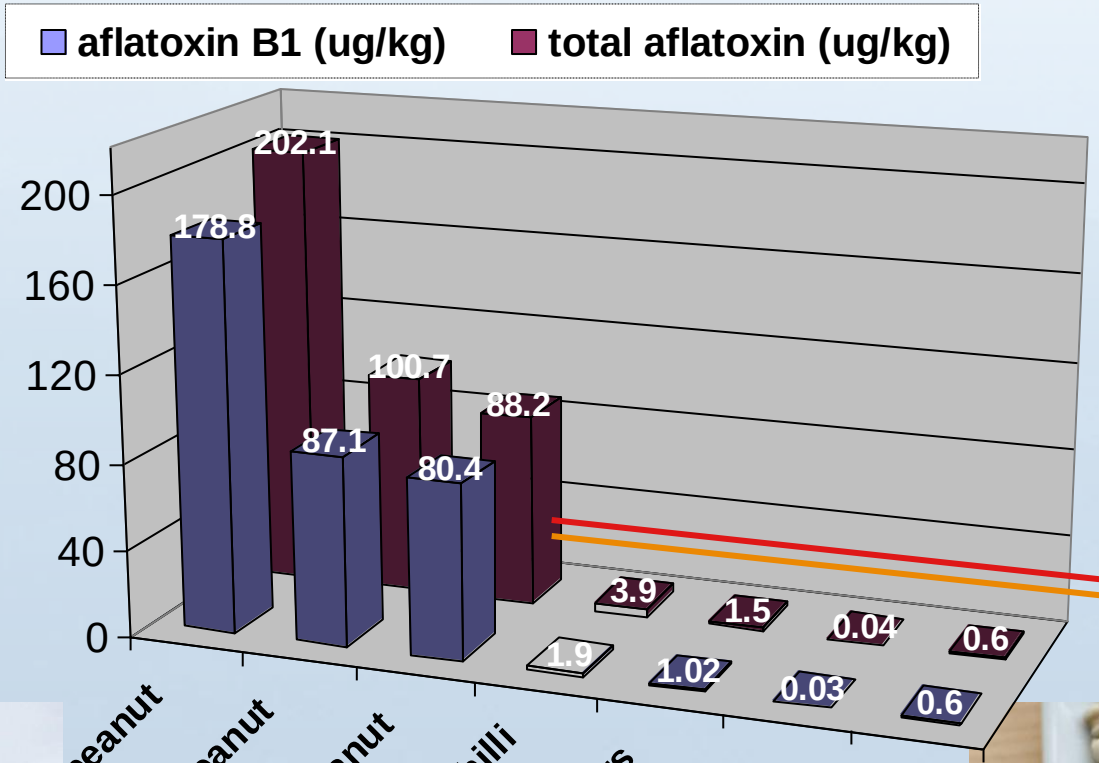
Aflatoxins are a group of highly toxic mycotoxins produced by fungi of the genus Aspergillus. The four main aflatoxins found in contaminated plant products are B1, B2, G1 and G2 and are a group of structurally related difuranocoumarin derivatives that usually occur together in varying ratios, AFB1 usually being the most important one. These compounds pose a substantial hazard to human and animal health. IARC (1992) classified aflatoxin B1 in Group 1 (human carcinogen) and AFM in Group 2B (probable human carcinogen). The liver is the primary target organ.

Reference to JECFA can be found at
http://www.who.int/foodsafety/chem/jecfa/publications/reports/en/index.html

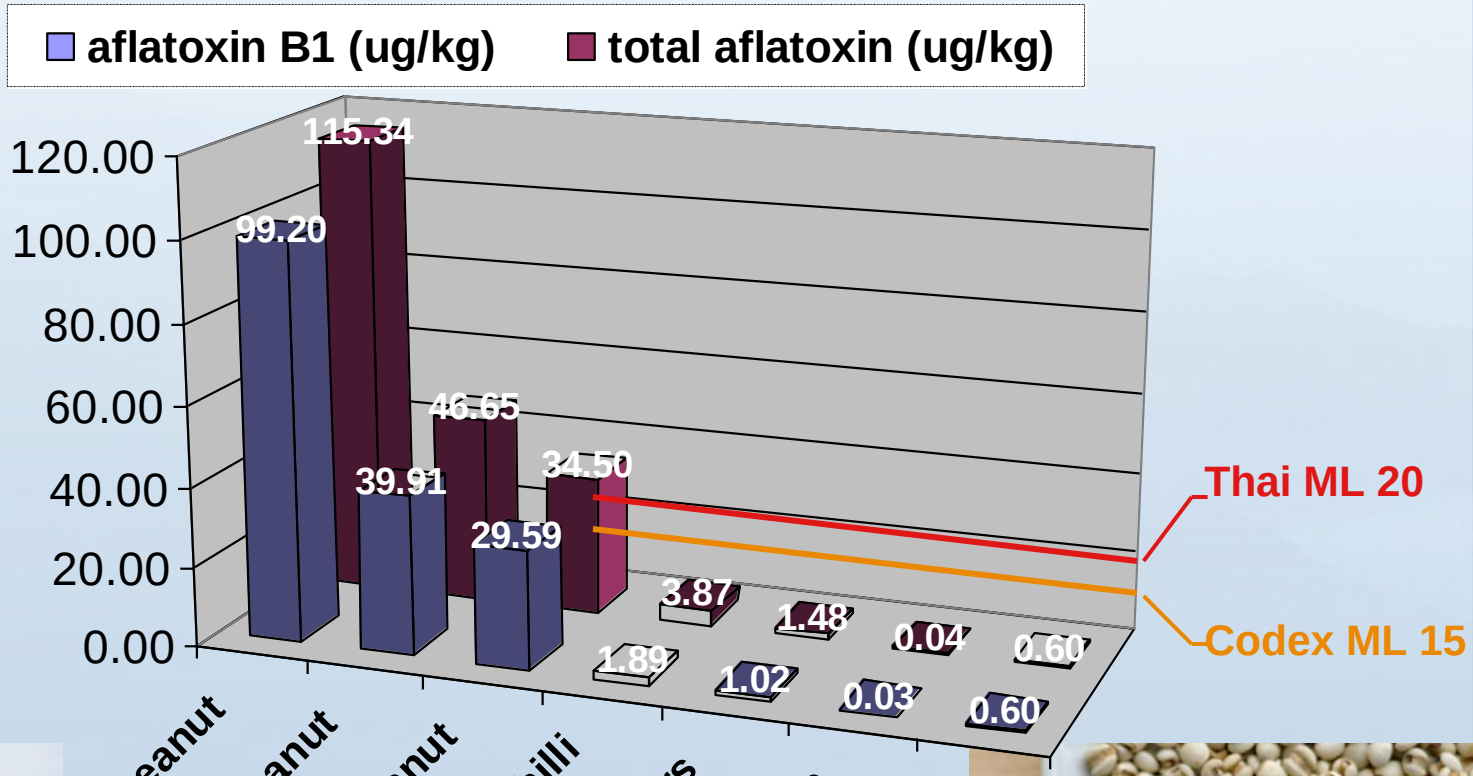
International Agency for Research on Cancer

- Group 1 Carcinogenic to humans
  - There is sufficient evidence of carcinogenicity in humans. Exceptionally, an agent may be placed in this category when evidence of carcinogenicity in humans is less than sufficient but there is sufficient evidence of carcinogenicity in experimental animals and strong evidence in exposed humans that the agent acts through a relevant mechanism of carcinogenicity.

Survey of average aflatoxin content in various foods during 2006-2007



Survey of average aflatoxin content in various foods during 2011



Exposure Assessment of Aflatoxin

Dietary Exposure

$= \sum$

Chemical level in a Food

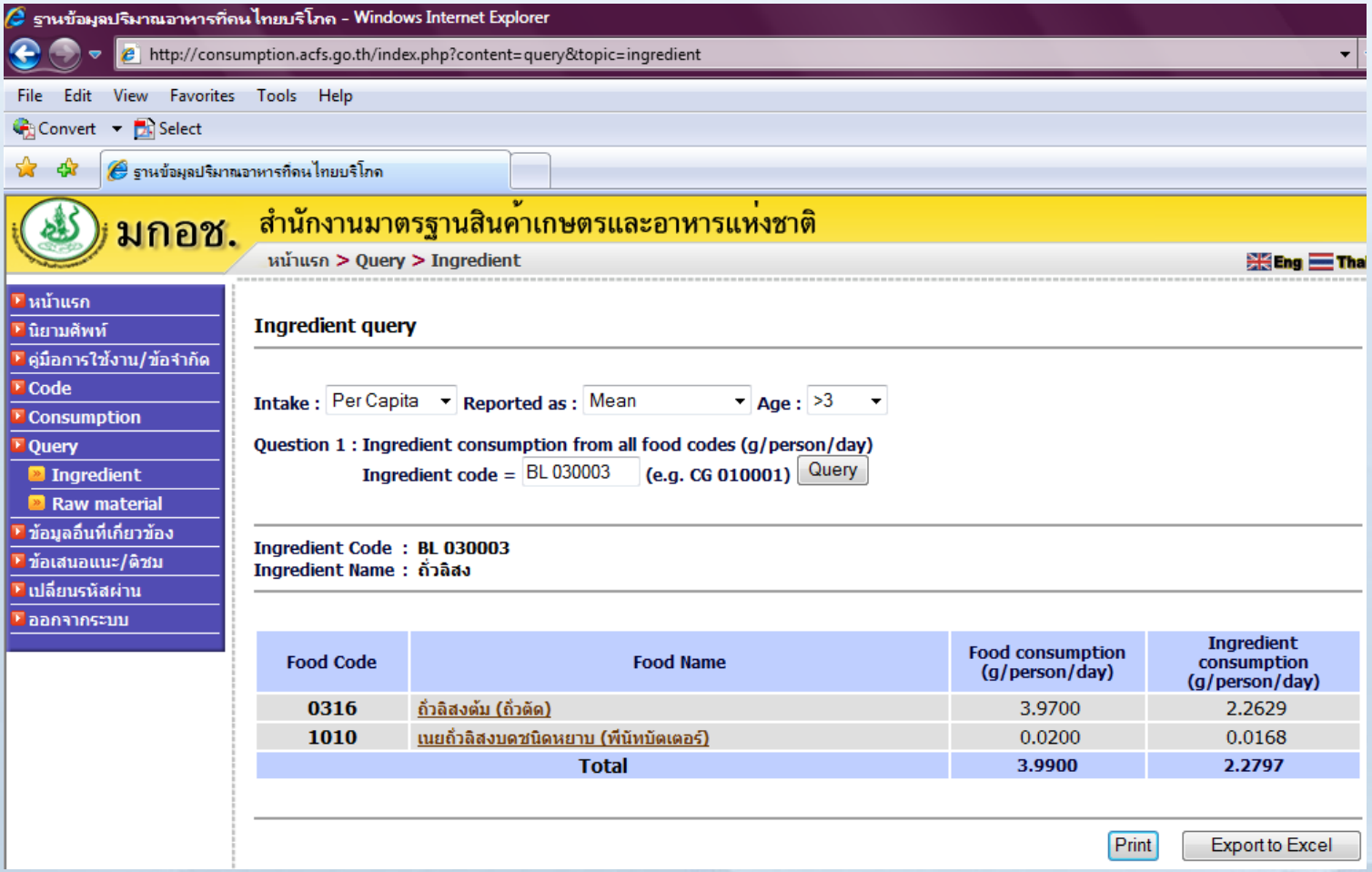
x

Consumption of a Food

ข้อมูลการบริโภคอาหารของประเทศไทย
FOOD CONSUMPTION DATA OF THAILAND

สำนักมาตรฐานสินค้าและระบบคุณภาพ
สำนักงานมาตรฐานสินค้าเกษตรและอาหารแห่งชาติ
กระทรวงเกษตรและสหกรณ์
ISBN 974-403-423-8

http://consumption.acfs.go.th/index.php

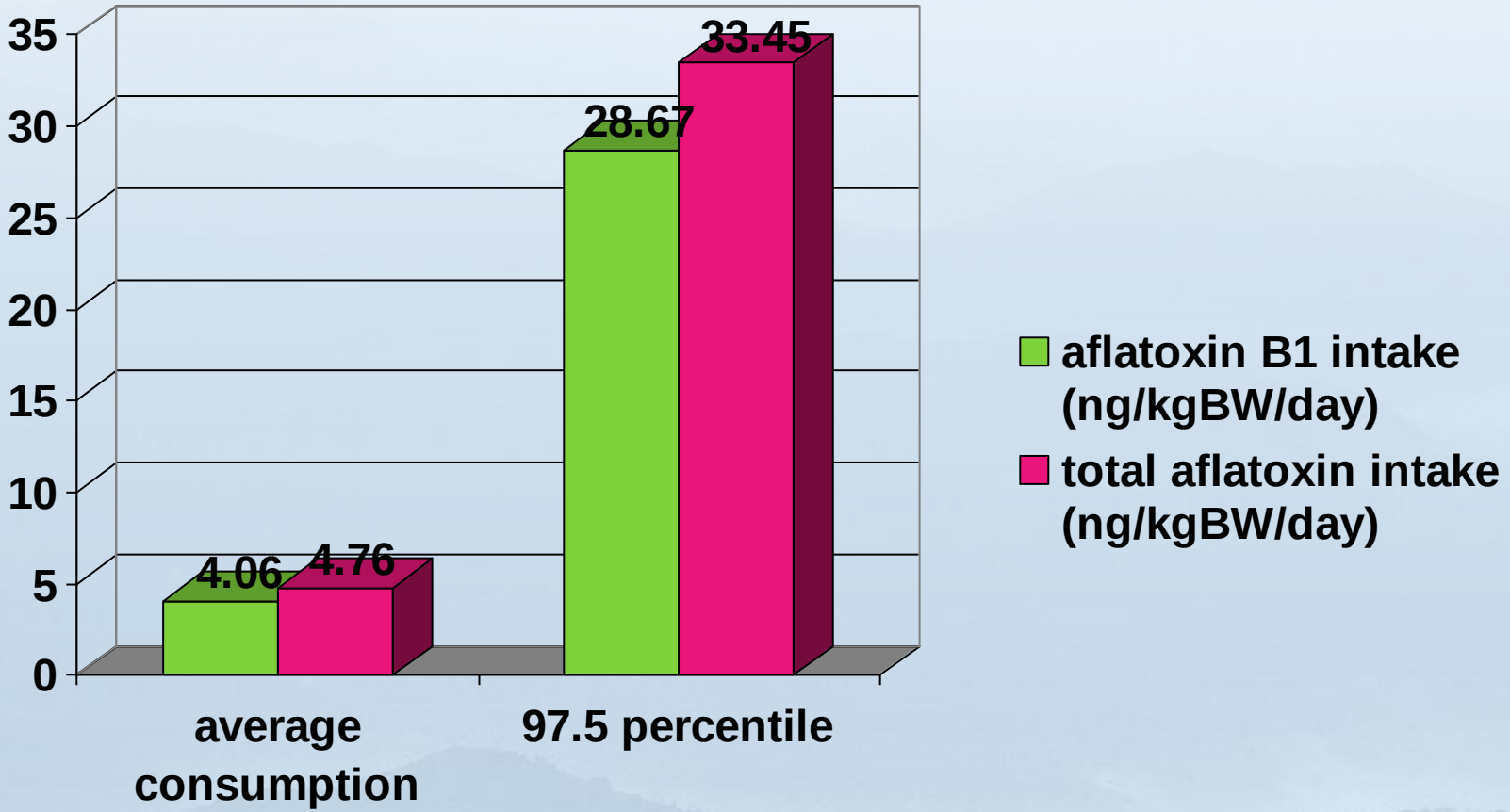


Dietary exposure

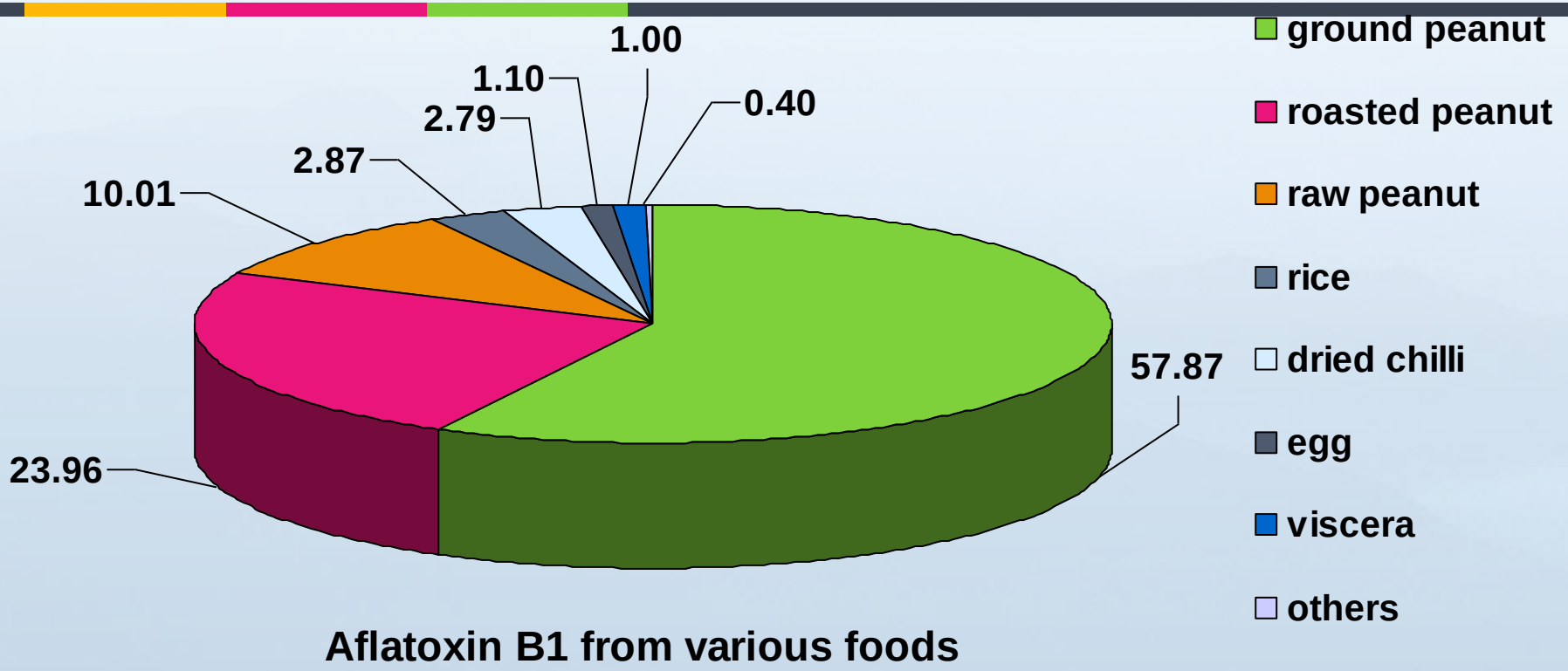
S17

	A	B	C	D	E	F	G	H	I	J	K	L	M	N	O	P	Q	R	S	T
1	ตาราง Dietary exposure ของอะฟลาทอกซินที่คนไทยได้รับ																			
2		ปริมาณบริโภคอาหาร		aflatoxin B1					total aflatoxin											
3	อาหาร	ปริมาณบริโภคอาหาร (g/คน/วัน)	บริโภคถั่วลิสงและผลิตภัณฑ์ที่ 97.5 perc (g/คน/วัน)	ระดับ aflatoxin B1 เฉลี่ย (ug/kg)	aflatoxin B1 intake (ug/คน/วัน)	% total intake	aflatoxin B1 intake 97.5 perc (ug/คน/วัน)	% total intake	ระดับ total aflatoxin เฉลี่ย (ug/kg)	total aflatoxin intake (ug/คน/วัน)	% total intake	total afla intake 97.5 perc (ug/คน/วัน)	% total intake		Intake (ng/person/day)			Intake (ng/kgbw/day)		
4	ถั่วลิสงดิบ	0.74	6.93	29.588	0.02190	10.08	0.20504	13.36	34.498	0.02553	10.01	0.23907	13.35			B1-ave	B1- 97.5P ถั่ว	B1-ave	B1- 97.5P ถั่ว	B1- 97.5 พริกแห้
5	ถั่วลิสงปน	1.28	8.08	99.201	0.12698	58.43	0.80154	52.21	115.343	0.14764	57.87	0.93197	52.04			217.30	1535.21	4.06	28.67	
6	ผลิตภัณฑ์ถั่วลิสง (คั่ว/ทอด	1.31	12.84	39.913	0.05229	24.06	0.51248	33.38	46.655	0.06112	23.96	0.59905	33.45		Cancer-HB+			1.218	8.602	
7	ข้าวสาร	203.5	203.5	0.034	0.00692	3.18	0.00692	0.45	0.036	0.00733	2.87	0.00733	0.41		per 100000					
8	พริกแห้ง	1.84	1.84	1.891	0.00348	1.60	0.00348	0.23	3.869	0.00712	2.79	0.00712	0.40		Cancer-HB-			0.041	0.287	
9	ลูกเดือย	0.38	0.38	1.024	0.00039	0.18	0.00039	0.03	1.480	0.00056	0.22	0.00056	0.03		per 100000					
10	ก่วยเตี๋ยวเส้นใหญ่	14.98	14.98	0.026	0.00039	0.18	0.00039	0.03	0.030	0.00045	0.18	0.00045	0.03		Cancer-total			0.158	1.118	
11	ไข่	31.25	31.25	0.077	0.00241	1.11	0.00241	0.16	0.090	0.00281	1.10	0.00281	0.16		per 100000					
12	เนื้อไก่	16.06	16.06	0.010	0.00016	0.07	0.00016	0.01	0.010	0.00016	0.06	0.00016	0.01		Cancer-total			103	727	
13	เครื่องในไก่	4.71	4.71	0.340	0.00160	0.74	0.00160	0.10	0.340	0.00160	0.63	0.00160	0.09		per population					
14	เนื้อหมู	54.83	54.83	0.005	0.00027	0.13	0.00027	0.02	0.005	0.00027	0.11	0.00027	0.02							
15	เครื่องในหมู	4.72	4.72	0.110	0.00052	0.24	0.00052	0.03	0.110	0.00052	0.20	0.00052	0.03							
16	Sum				0.21730	100.00	1.53521	100.00		0.25511	100.00	1.79092	100.00				4.76		33.45	
17	% Intake ของถั่วลิสง					92.6		98.9			91.8		98.8							
18	และผลิตภัณฑ์																			

Comparison of total intake between average consumption and 97.5th percentile consumption of Thai population in 2011

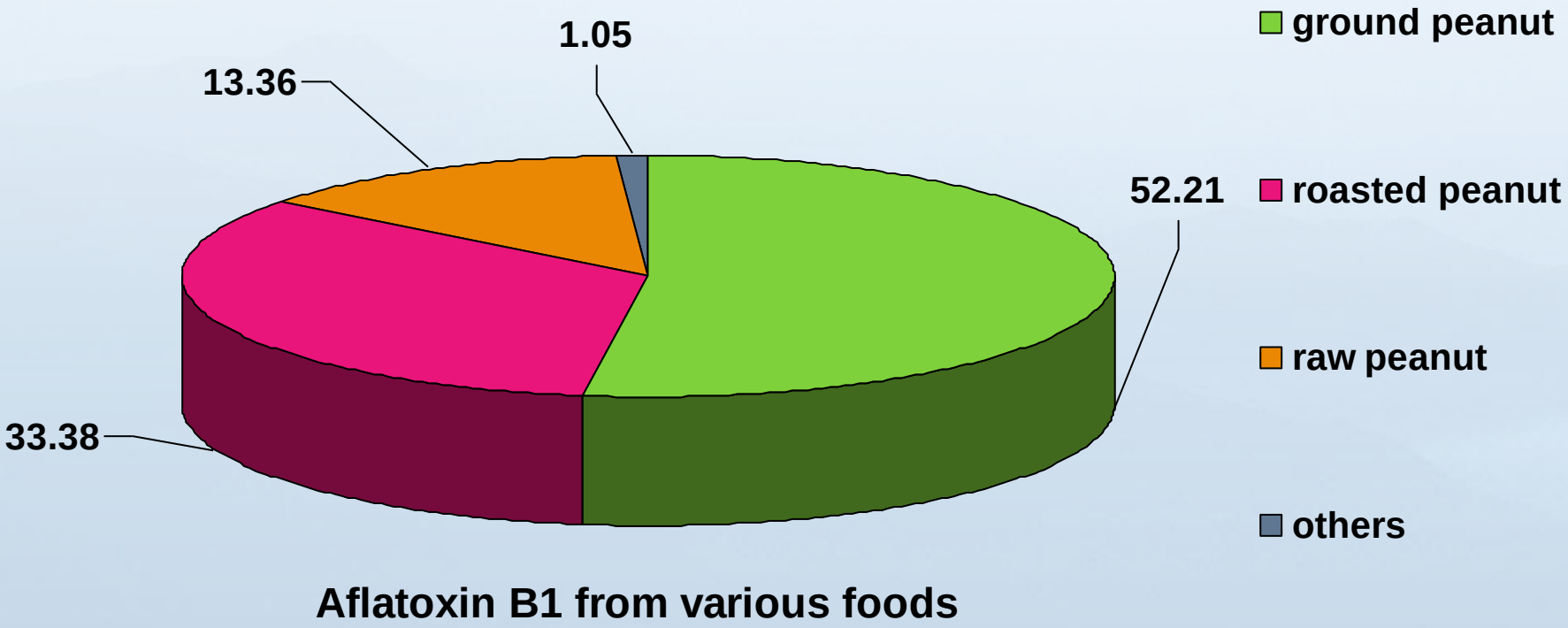


Ratio of Aflatoxin B1 (%) consumers received from average consumption of various foods



92.6% of aflatoxin intake comes from peanut

Ratio of Aflatoxin B1 (%) consumers received from 97.5th percentile consumption of various foods



99% of aflatoxin intake comes from peanut

Estimated risk of liver cancer in Thai consumers from Aflatoxin B1

- Estimated potency of liver cancer using JECFA model (1997)

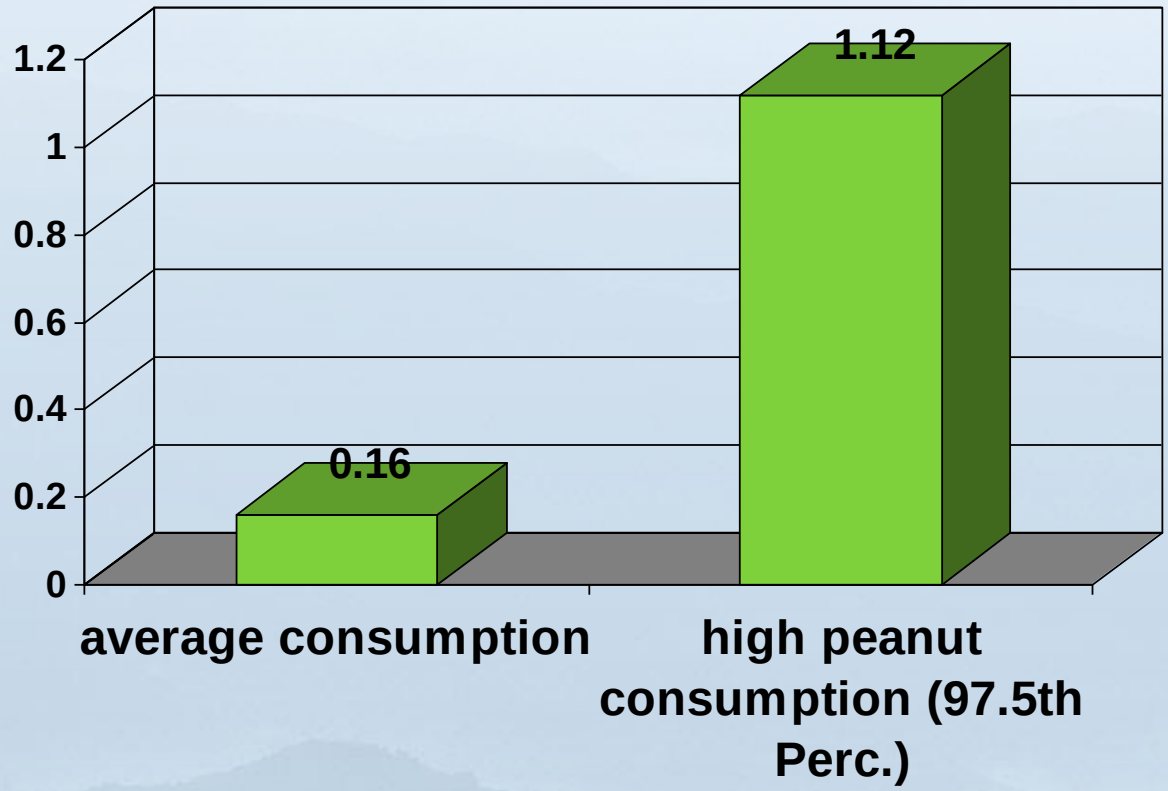
  Potency (cancer/year/100,000 people)

  = 0.01 x Aflatoxin B1 intake (ng/kgbw/day)
  for population without Hepatitis B surface antigen

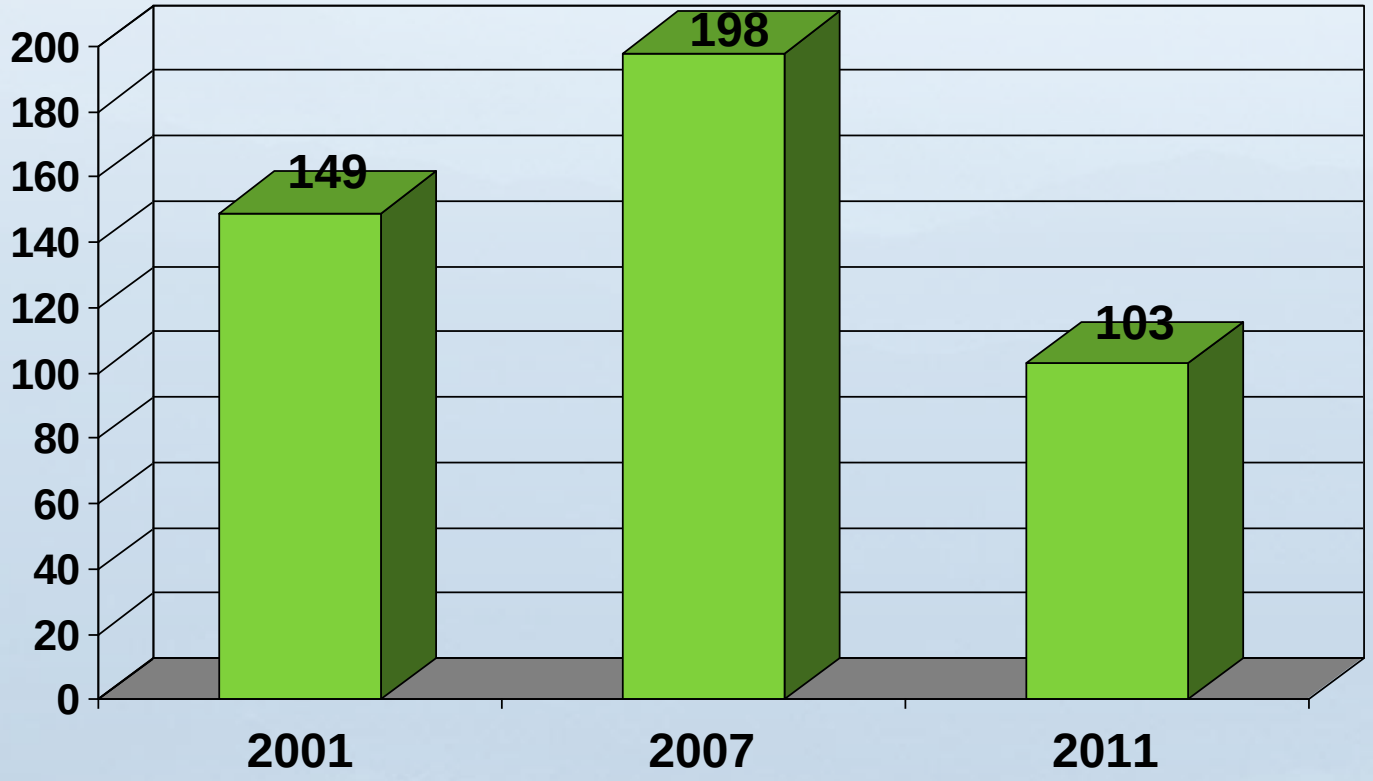
  = 0.30 x Aflatoxin B1 intake (ng/kgbw/day)
  for population with Hepatitis B surface antigen

http://whqlibdoc.who.int/trs/WHO_TRS_884.pdf

Estimated Potency of Liver Cancer in 2011 (cancer/year/100,000 people)

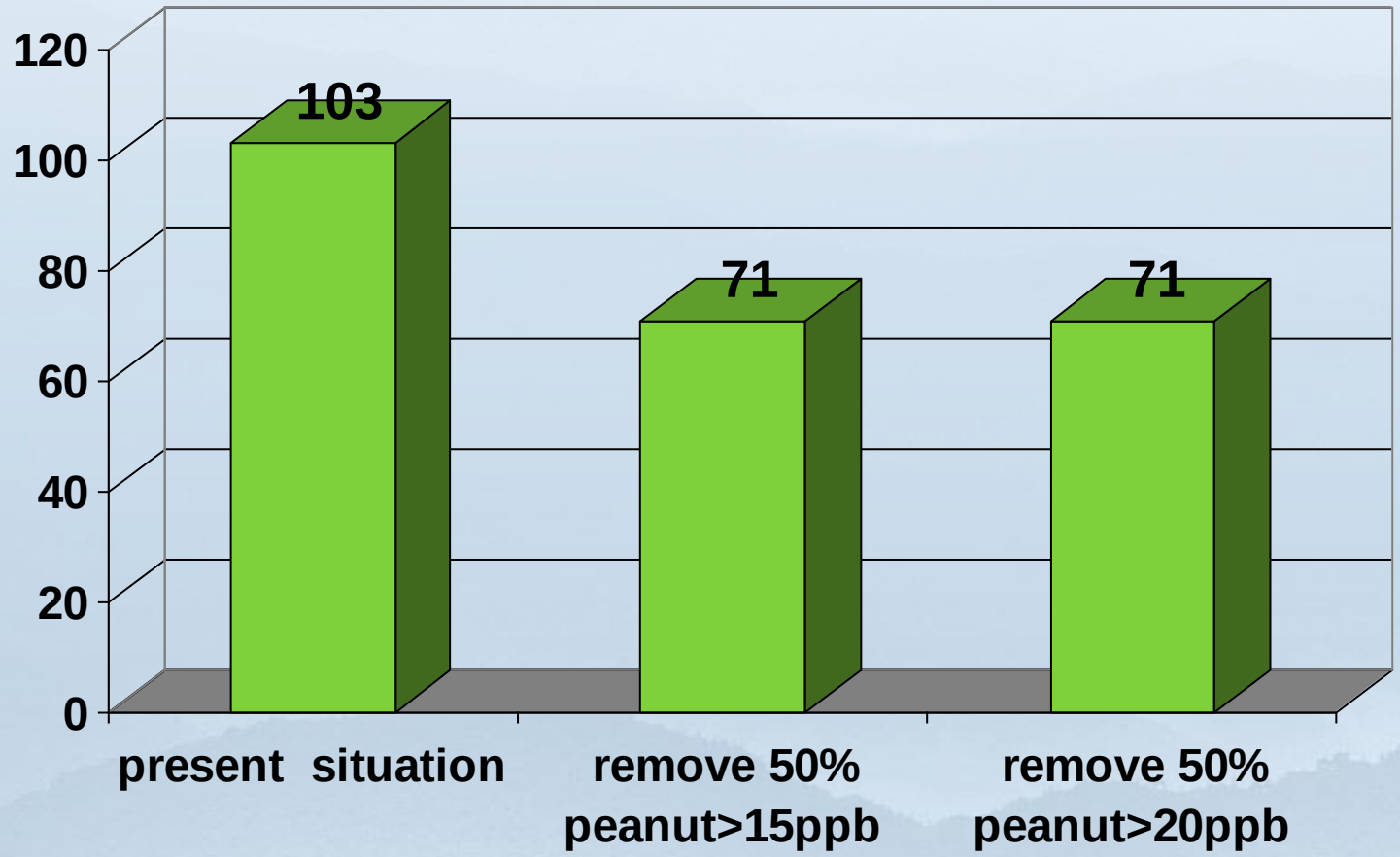


Estimated Potency of Liver Cancer from different years (cancer/year/Thai population)



Estimated Potency of Liver Cancer in 2011 (cancer/year/Thai population)

Comparison between present situation and removing of 50% peanut contaminated with Aflatoxin B1 at level higher than 15 and 20 ppb



Risk management

- Weighing policy alternatives, in consultation with all interested parties
- Considering risk assessment and other factors relevant to the health protection of consumers and for the promotion of fair trade practices
- Selecting appropriate prevention and control options

Standard development of aflatoxin in Thai peanuts

- Risk Assessment of Aflatoxin for Thai Population
- Cost-benefit analysis of all stakeholders--- farmer, trader, sheller, processor, consumer, competent authority, etc.
  - Change in productivity and replacement cost of farmers
  - Cost of sampling and lab analysis of the manufacturer
  - Cost of rejected materials of traders
  - Cost of illnesses of consumers
- Enforcement problems with small businesses

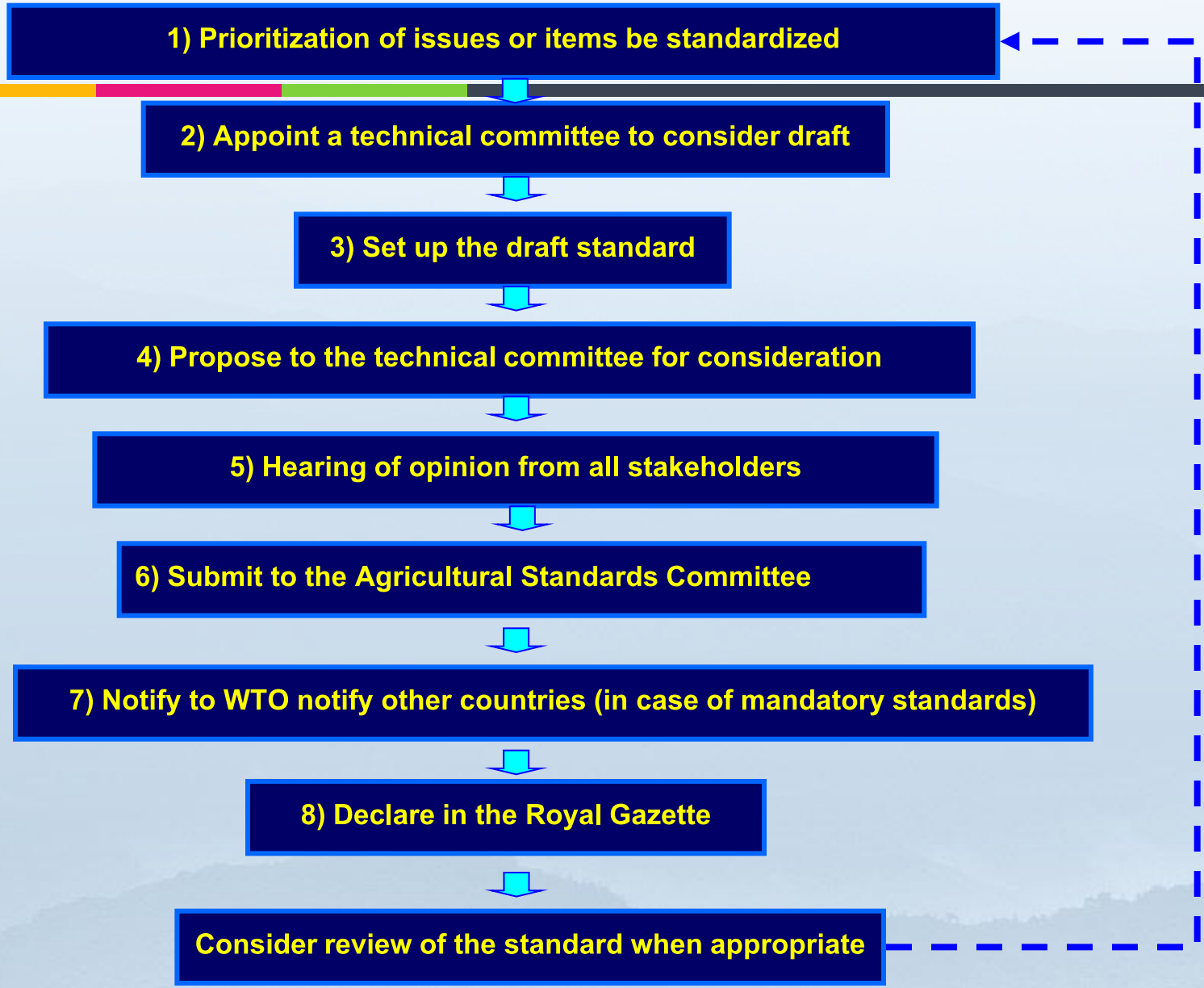
Cost – benefit analysis (million baht/year)

Stakeholders	Cost	Benefit
Primary producer		
70% of producer under GAP	Not applicable	1,130
50% of producer under GAP	Not applicable	810
Shelling plant and peanut manufacturer		
Collector, shelling plant	3	94-136
Manufacturer	1-4	Not applicable
consumer	Not applicable	81-117
Value of removed contaminated peanuts	28	Not applicable
total	1-35	175-250

How to resolve issues on aflatoxin?

- Establish standards for the whole food chain
- Promote standards to farmers, shellers, manufacturers, etc.
- Certify producers
- Certify products
- Educate consumers
- Anything else???

Elaboration of standard



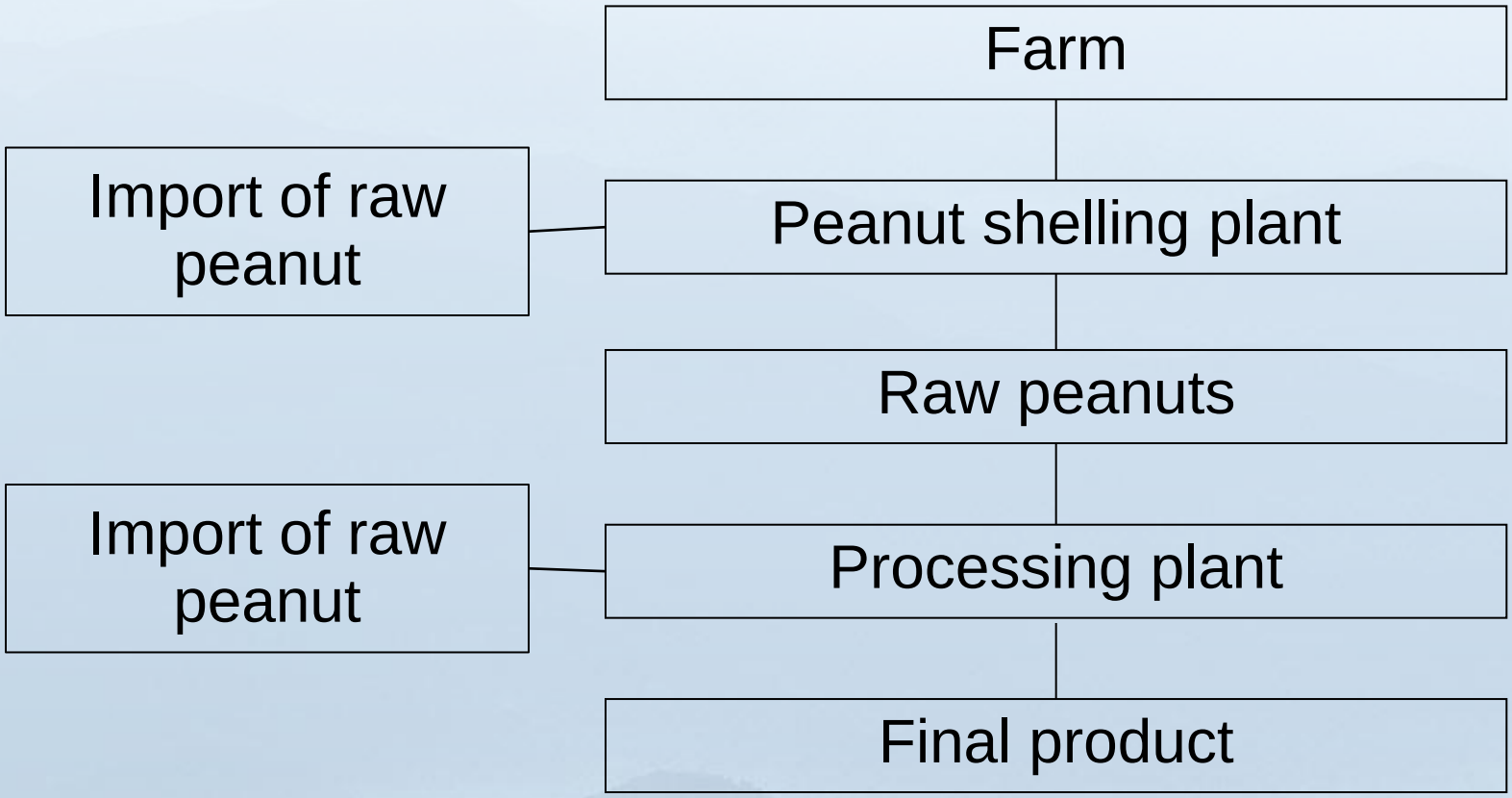
Codex: Code of Practice for the Prevention and Reduction of Aflatoxin Contamination in Peanuts

- Irrigation to ensure adequate soil moisture during the last 4-6 weeks of crop growth should minimize pre-harvest aflatoxin contamination of peanuts.
- It is very important to harvest the crop at optimum maturity, as excessive numbers of over-mature or very immature pods at harvest can be reflected in high levels of aflatoxin in the product
- Delayed harvest of already infected peanuts may cause significant increase in aflatoxin content of the crop.
- Sorting for quality removes a large part of the aflatoxin present at harvest.

Codex: Code of Practice for the Reduction of Aflatoxin B_1 in Raw Materials and Supplemental Feedingstuffs for Milk Producing Animals

- Feed production and disposition of AFB1 contaminated animal feeds
  - If aflatoxin B_1 is detected, consider one or more of the following options. In all cases ensure that the aflatoxin B_1 level of the finished feed is appropriate for its intended use (i.e. maturity and species of animal being fed) and is consistent with national codes and guidelines or qualified veterinary advice.
    - Consider the restriction of AFB_1 contaminated feed to a percentage of the daily ration such that the daily amount of AFB_1 ingested would not result in significant residues of AFM_1 in milk.
    - If feed restriction is not practical, divert the use of highly contaminated feedingstuffs to non-lactating animals only.

Establishment of standards for entire food chain



Setting up standards on peanut

1. Establishment of voluntary standards for entire food chain
   - Thai Agricultural Standard on Good Agricultural Practices for Peanut (TAS4900-2010) covers all steps in the primary production practiced by farmers especially the steps affecting the contamination of aflatoxin e.g. drying, pod sorting, storage, etc.

Setting up standards on peanut (cont.)

- Thai Agricultural Standard on Good Manufacturing Practices for Peanut Shelling Plant (TAS 4901-2012) covers all steps affecting the contamination of aflatoxin in the shelling plant e.g. raw material storage, shelling, sorting, etc.
- Thai Agricultural Standard on Dried Peanut (TAS4700-2011) covers minimum requirements/quality criteria including specification of moisture content and total aflatoxin, sampling and analysis of aflatoxin, etc.

Setting up standards on peanut (cont.)

2. Consideration of ways to promote/ enforce the standard on producers and consumers including certification of system and product
3. Development of **mandatory standard** on Peanut kernel: maximum level of aflatoxin

Control of moisture content and Sorting

Thai laws and regulations

- Ministry of Public Health (MOPH)
  - Bureau of Food, FDA,
    - Notifications under the MOPH or FDA
- Ministry of Agriculture and Cooperatives (MOAC)
  - ACFS
    - Thai Agricultural Standards under the Agricultural Standards Act B.E. 2551 (2008)
  - Department of Livestock Development (DLD)
    - Notifications under the MOAC

Main regulations on contaminants

- Notification under MOPH (No. 98) B.E. 2529 (1986) entitled Contaminants in Foods
  - Tin, Zinc, Copper, Lead, Arsenic, Mercury, Aflatoxin
- Notification under MOAC B.E. 2537 (1994) entitled Property of deteriorated feed
  - Aflatoxin

Some EU regulations---Commission Regulation (EC) No 669/2009

- the increased level of official controls on imports of certain feed and food of non-animal origin

Feed and food	Country of origin	Hazard	Frequency of physical and identity checks (%)
Spices, i.e. *Capsicum* spp., nutmeg, ginger, turmeric	India	Aflatoxins	50
Chilli, chilli products, curcuma and palm oil	All third countries	Sudan dyes	20
Vegetables, fresh, chilled or frozen i.e. yard long beans, aubergines, *Brassica* vegetables	Thailand	Organo-phosphorus pesticide residues	50

Risk communication

- Interactive exchange of information and opinions throughout the risk analysis process among risk assessors, risk managers, consumers, industry, the academic community and other interested groups
- Concerning hazards and risk, risk-related factors, risk perceptions, the explanation of risk assessment findings and the basis of risk management decisions.

The Rapid Alert System for Food and Feed (RASFF)

seeds for the third year in a row. This is related to the change of legislation in 2010 whereby the maximum levels for aflatoxins in almonds, hazelnuts, pistachios and Brazil nuts have been aligned with Codex Alimentarius maximum levels[16] and the significantly improved situation as regards non-compliance of certain commodities from certain countries (e.g. peanuts from Argentina). This was however counterweighted by a rise in notifications for aflatoxins in feed materials. This was mostly due to the recurrent findings of high to very high levels of aflatoxins in groundnuts for bird feed from India (106 notifications), of which 83 were reported by the United Kingdom as border rejections.

There were much less notifications about aflatoxins in spices given that the situation as regards the presence of aflatoxins in spices originating in India was much improved in 2011 (41 notifications) compared to 2010 (97 notifications). This significant improvement has resulted in reduction of the required control frequency at import. There was a further decrease in aflatoxins notifications for the product category nuts, nut products and

Table 5 – Aflatoxins

product category	aflatoxins	DON	fumonisins	ochratoxin A
cereals and bakery products	13	11	4	5
feed	119			1
fruits and vegetables	78			10
herbs and spices	51			17
nuts, nut products and seeds	320			
other	4			2
total	**585**	**11**	**4**	**35**

http://ec.europa.eu/food/food/rapidalert/docs/rasff_annual_report_2011_en.pdf

ACFS Early Warning

ACFS EARLY WARNING

ACFS Early Warning :

การเตือนภัยสินค้าเกษตรและอาหาร (**ACFS Early Warning**) เป็นหนึ่งในบริการข้อมูลที่ มกอช. ภูมิใจเสนอ เพื่อเป็นข้อมูลเตือนภัยว่าสินค้าเกษตรและอาหารที่เราจะผลิตส่งออกจำหน่ายทั้งในและต่างประเทศ มีข้อมูลอะไรบ้างที่ต้องพึงระลึกถึง ไม่ว่าด้านกฎหมาย ระเบียบ กฎเกณฑ์ใหม่ทางการค้า โดยเฉพาะอย่างยิ่ง กฎระเบียบด้านมาตรการสุขอนามัย สุขอนามัยพืช (**WTO / SPS**) ภายใต้เวทีองค์การค้าโลก (**WTO**) เพื่อให้เราจะได้หลีกเลี่ยงหรือทำตาม อันจะทำให้เราสามารถดำเนินการด้านการผลิต การส่งออก ได้อย่างมีประสิทธิภาพแข่งขันอย่างได้เปรียบและที่สำคัญท่านสามารถสมัครเป็นสมาชิกรับข่าวสารได้ฟรี ทาง **e-mail** คลิ๊ก เข้ามาที่นี้ ท่านจะได้รับ **e-mail** ที่ scan virus แล้วแทบทุกวัน

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- บทความ
- วารสาร
- งานวิจัย
- สารคดีเกษตร
- เว็บไซต์ที่เกี่ยวข้อง

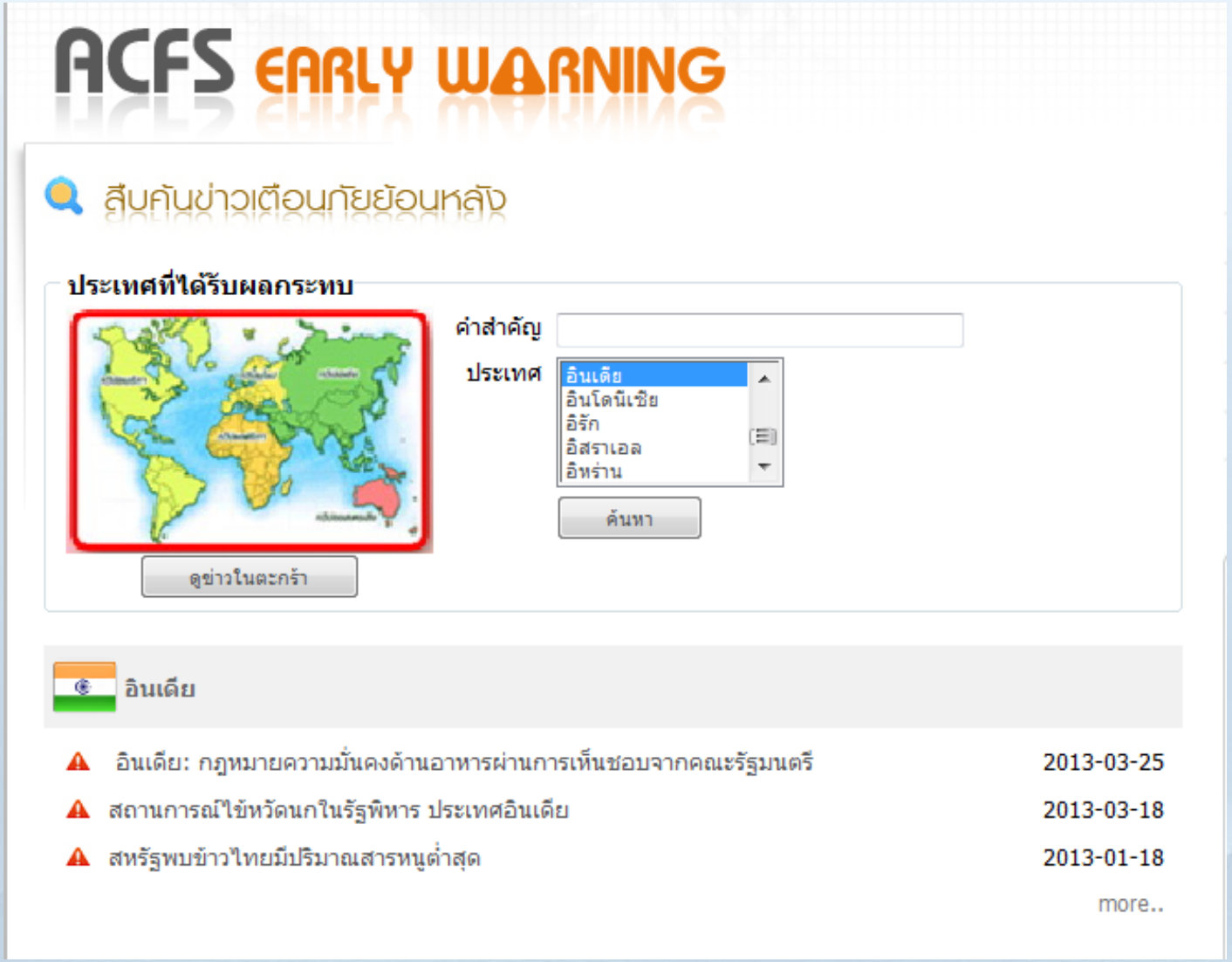
ปฏิทินข่าวเตือนภัย

<<	พฤษภาคม 2556					>>
อา.	จ.	อ.	พ.	พฤ.	ศ.	ส.
			1	2	3	4
5	6	7	8	9	10	11
12	13	14	**15**	16	17	18
19	20	21	22	23	24	25
26	27	28	29	30	31	

รับสมัครสมาชิกข่าว EARLY WARNING

สืบค้นข่าวเตือนภัยย้อนหลัง

ACFS Early Warning



Questions and comments ??

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