



**Budapest, 29-30 March 2007**



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Director General

# The Croatian Food Agency (CFA)

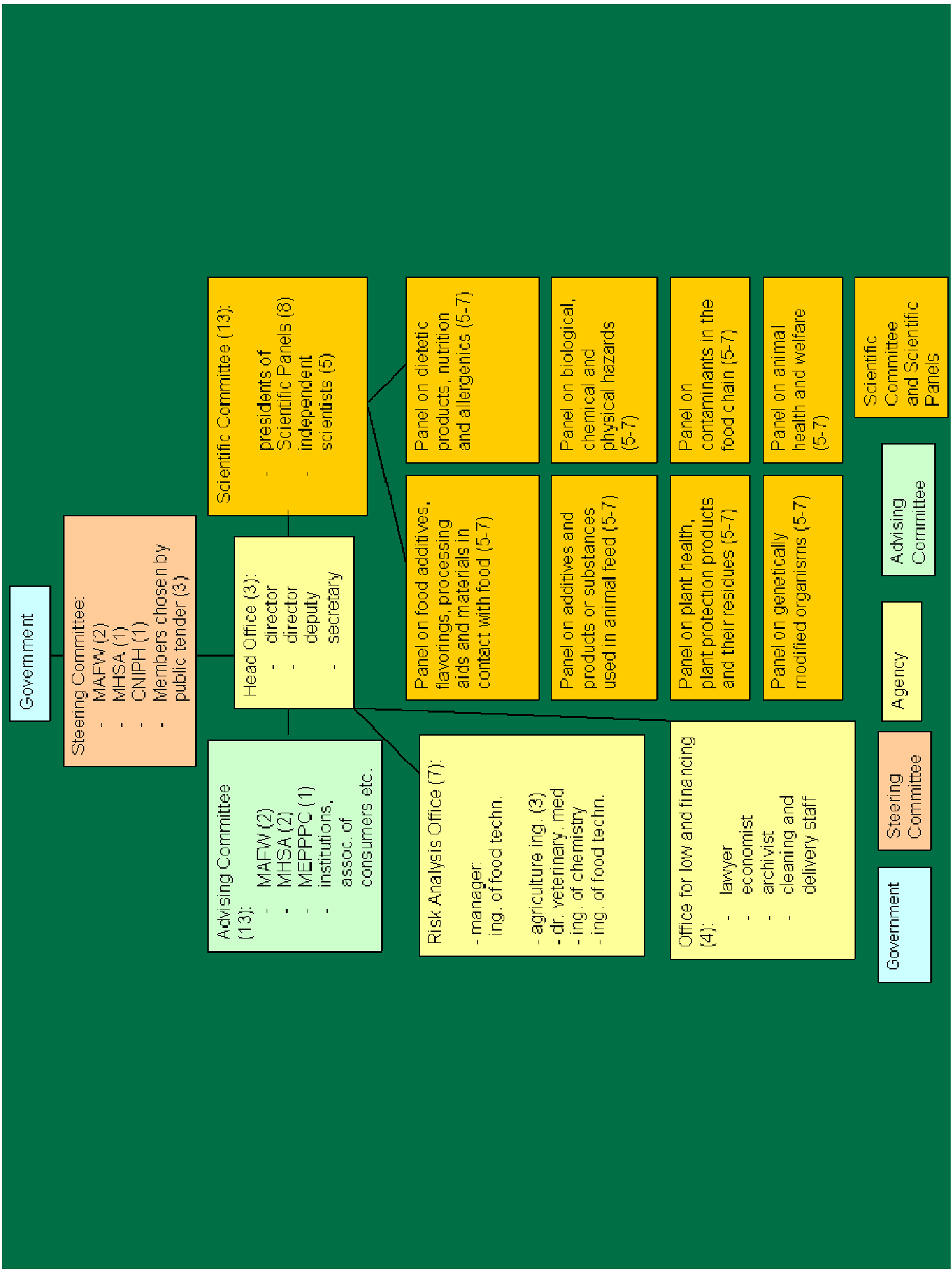
- is a legal body with rights, obligations and responsibilities written in **Food Law** (Official Gazette No. 117/03; 130/03; 48/04);
- was established by the Republic of Croatia and the **Government** has the rights and duties of the establisher.



# Why was the Agency established?

- **Consumers'** protection;
- **Risk analysis framework** in the field of food safety and hygiene;
- Connection between **legal authorities** (ministries, institutes, laboratories...);
- Accession to the **EU** (legislation, inspections, EFSA).





# How do we see food safety issue?

## Consumers

- food safety
- sensor characteristics
- proper labeling

## CFA

### Public health

- food safety
- food hygiene
- regulations

### Food safety

### Quality

## Producers

- food safety
- recognizable quality
- competitiveness

# Activities of the Agency (1)

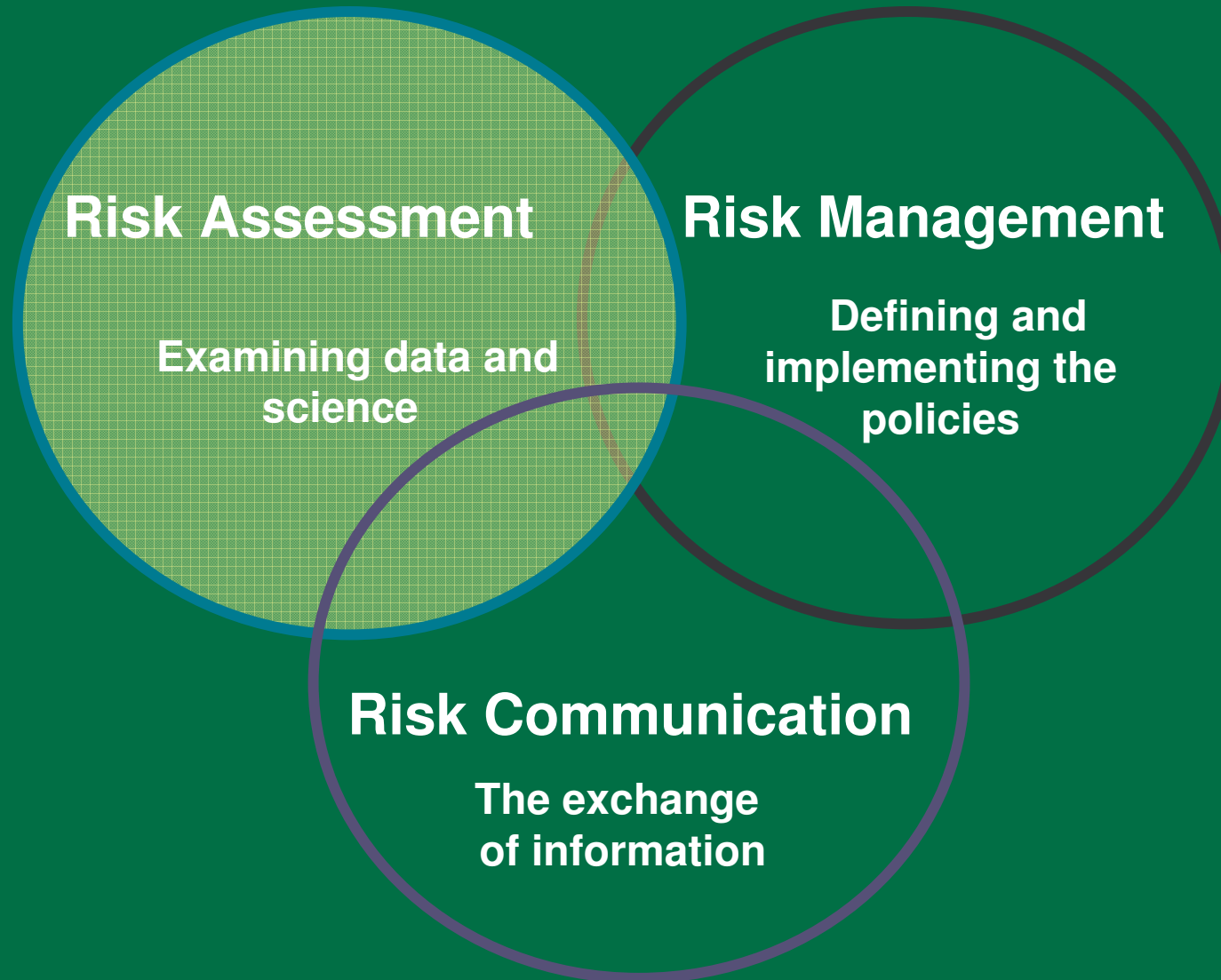
- requiring, **gathering and analyzing scientific and technical data** needed for enforcement of Risk Analyses;
- in coordination with the Croatian National Institute of Public Health, the Croatian Veterinary Institute and other competent authorities, is **monitoring** food and feed safety;
- undertaking activities for **identification and characterization of risks** concerning food and feed safety;
- carrying out **scientific studies** necessary for improvement of risks assessment in the field of food and feed safety.

## Activities of the Agency (2)

- **connecting** all institutions in Croatia that deal with food hygiene and food safety in one **Central Information System**;
- launching new **HR RASFF Project** - start 1th January 2006.



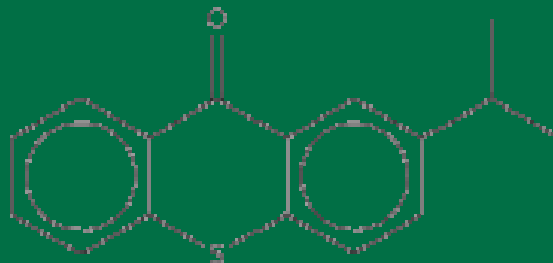
# RISK ANALYSIS: THE PRINCIPLES





# ITX

## (Isopropyl thyoxanthone) in food



# Firstly, ITX was found in baby food on EU market

- in autumn 2005 competent authority in Italy found out that this substance has migrated through packaging into food, and, therefore, 30 millions liters of milk was withdraw from the market;
- during December 2005 ITX was also found in other food in Italy.



## Standing Committee on the Food Chain and Animal Health

### Section Toxicological Safety

#### Conclusions of the meeting of 30 November 2005

The Standing Committee met on 30 November 2005 to assess the situation with respect to the presence of isopropylthioxanthone (ITX) in milk for babies and other products.

1. Recent notifications under the Rapid Alert System for Food and Feed (RASFF) have shown the migration of ITX from packaging of milk for babies.
2. At the request of the European Commission, the European Food Safety Authority (EFSA) is carrying out a risk assessment on ITX. EFSA will provide preliminary advice on 7 December 2005 and expects to deliver its final opinion on ITX no later than March 2006.
3. On 24 November 2005 EFSA has issued a press statement indicating that "on the basis of the very limited data available today, the presence of ITX in food could be considered undesirable but it is not likely to present a health risk at the levels reported".
4. On the basis of the knowledge available today, the Standing Committee agreed that there is no need to take any measures at EU level such as withdrawal of the concerned products from the market.
5. The Standing Committee took note that Tetra Pak has ceased to use ITX in packaging for baby milk at the end of September 2005. It also took note of the commitment of Tetra Pak to cease to use ITX in packaging for fatty products by the end of December 2005 and for other concerned products by the end of January 2006.
6. The European Commission will continue to raise awareness of industry at EU level with respect to their responsibilities of ensuring that the food they produce is safe in all Member States. Member States will do the same at national level.
7. The European Commission and Member States will re-evaluate the situation in the light of the forthcoming EFSA advice and will evaluate whether there is a need for any harmonized measures at EU level.



European Food Safety Authority

de | en | fr | it

- **the Scientific Panel** on food additives, flavorings, processing aids and materials in contact with food (AFC) of the **European Food Safety Authority (EFSA)** was asked to carry out risk assessment. Following the scientific opinion of EFSA, **Member States are free to take their own measures on their market.**



The EFSA Journal (2005) 293, 1-15

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**Opinion of the Scientific Panel on Food Additives,  
Flavourings, Processing Aids and Materials in Contact with Food  
on a request from the Commission related to**

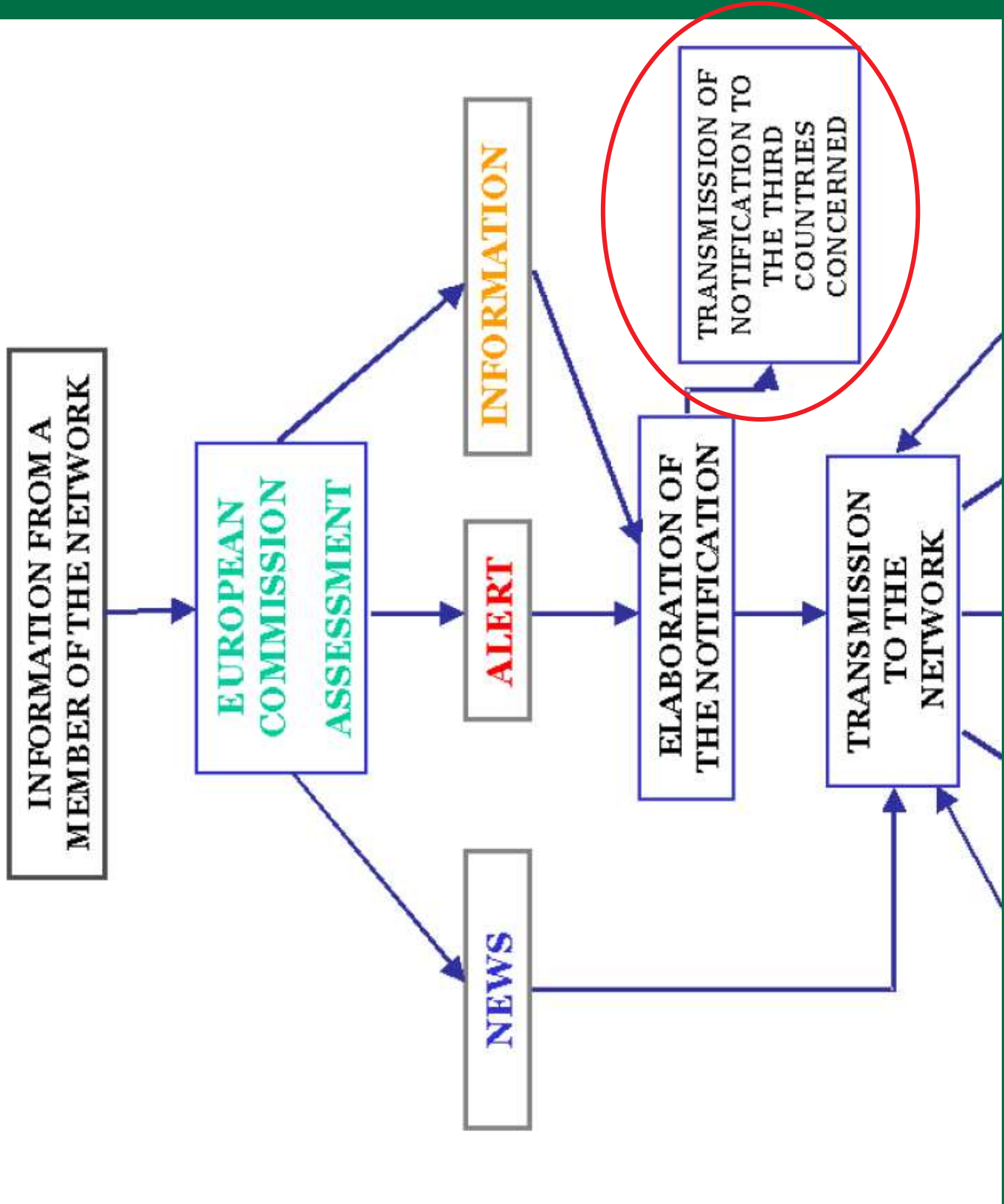
**2-Isopropyl thioxanthone (ITX) and 2-ethylhexyl-4-dimethylaminobenzoate  
(EHDAB) in food contact materials**

**(Question numbers EFSA-Q-2005-240 & EFSA-Q-2005-241)**

**Adopted on 7 December 2005**

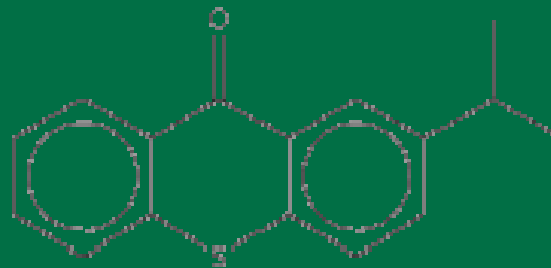
# Conclusion of EFSA Opinion on ITX

- ITX was tested with contradictory results in limited genotoxicity studies *in vitro*; however, clearly negative results were obtained in two adequate *in vivo* studies. In conclusion, the existing *in vivo* genotoxicity studies do not indicate a genotoxic potential for ITX. No other toxicity data on ITX are available;
- In view of the lack of other toxicity data no further comment on the safety of ITX can be made.



# ITX case in Croatia

- through EU RASFF system, Croatian Food Agency received at the end of year 2005 an alert notification on chemical substance ITX (isopropyl thioxanthone) in some fruit juices, also present on Croatian market.



22.12.2005.

**FOOD**

**VERY URGENT - TRES URGENT**

**ALERT NOTIFICATION: 2005.930-add01**

**ADDITIONAL INFORMATION**

**SUBJECT: MIGRATION OF ISOPROPYL THIOXANTHONE FROM  
PACKAGING OF MULTIFRUIT JUICE FROM AUSTRIA**

**PAGES: COVER PAGE (1) + 2**

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**HTTP://FORUM.EUROPA.EU.INT/**

**outcome of investigations in ITALY**  
**Distribution to Croatia**





Range Company Information Semifinished goods Services FAQ Contact/jobs

- Fruit juice
- > Apple
- > Orange
- > Pineapple
- > Multivitamin
- > ACE
- > BCE
- > Green Apple
- > Blood Orange
- > Peach
- > Grapefruit
- > Pear
- > Blackcurrant
- > Apricot
- > Lemon Lime
- Iced Tea
- Wellness
- Exclusive
- Gastronomy
- PET-Fruit
- New products



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start

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Inbox - Microsoft Out...

Startseite - Microsoft...

http://www.pfanner....

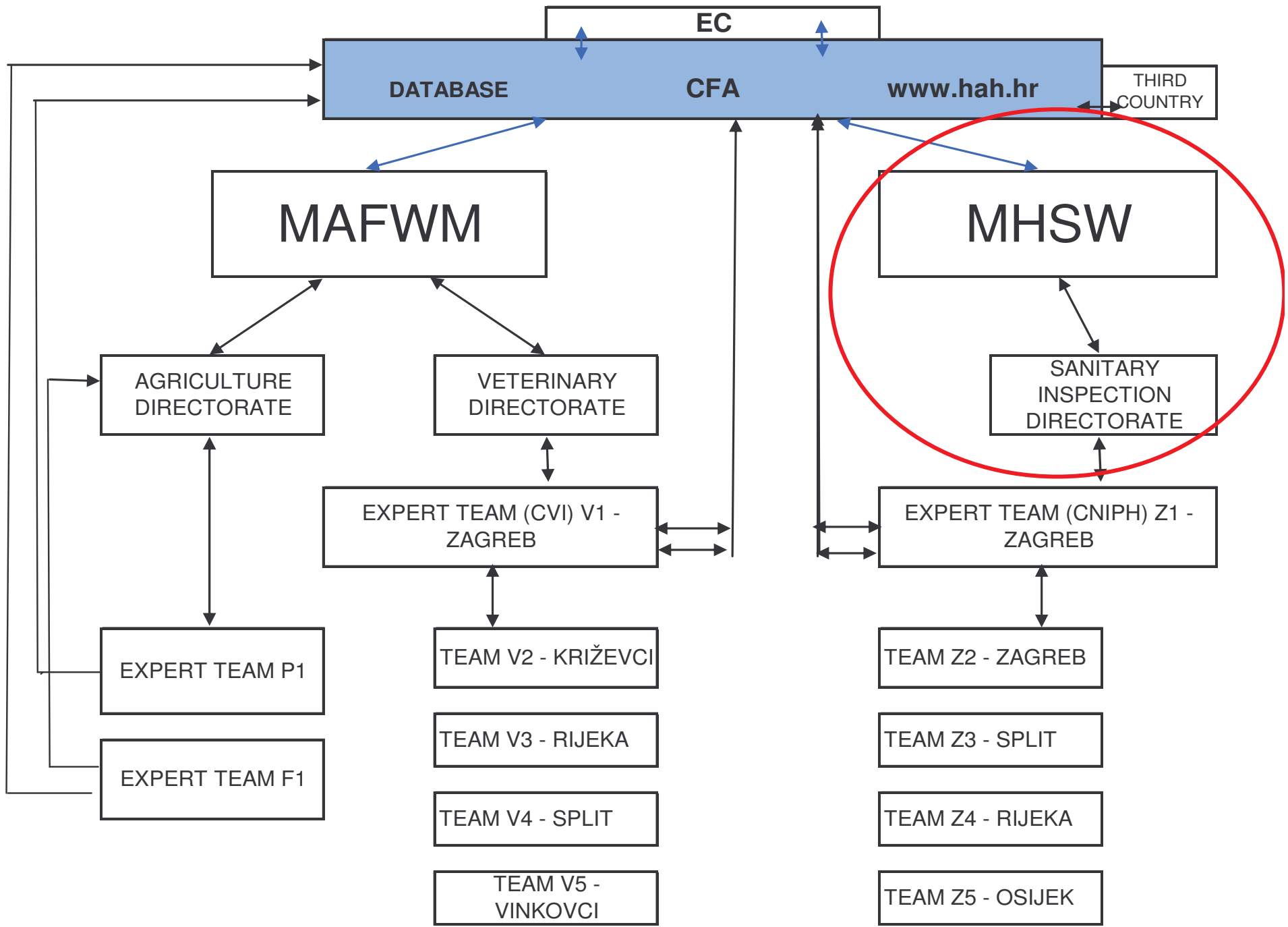
Internet

HR

13:57

- packaging producers use UV-cured inks containing ITX as **photo initiators** for cartons used for food packaging;
- inks applied to **food packaging materials are not covered by specific European legislation**;
- however, materials and articles intended to come into contact with food **should comply with the general criteria laid down in Regulation (EC) No 1935/2004**;
- this framework regulation specifies that food contact materials **should be safe and should not transfer their components into food in unacceptable quantities**;
- since ITX is not intended to be used as food color, its presence in food **can be considered accidentally and undesirable**.





# Steps

- Sanitary inspection in Croatia **increased market control**, according to CFA HR RASFF notification;
- Sanitary inspector **took samples of few fruit juices** from different producers that were given to laboratory for testing;
- laboratory result proved **the presence of ITX in two samples of juices from Austria**;
- on the basis of Article 8. of Croatian Food Law (Official Journal No. 114/03, 130/03, 48/04), that gives directive on precautionary principle, juices were **temporary withdrawn from the market**;
- ITX in food was **the first information forwarded through HR RASFF system** that started with its functioning from 1 January 2006.

## OBRAZAC A.

RASFF - RAPID ALERT SYSTEM FOR FOOD AND FEED			
<b>GENERAL INFORMATION: OSNOVNI PODACI</b>		RASFF 2006. Br.	siječanj
			2
OBAVIJEST PREMA STUPNJU ŽURNOSTI :	uzbunjujuća obavijest		
VRSTA NADZORA / KONTROLE:	službena		
OBAVIJEST DOBIVENA OD :	Sanitarna inspekcija grada Zagreba		
DATUM :	28.12.2005.		
<b>HAZARD: OPASNOST</b>			
ŠTETNA TVAR / NEPRIKLADNOST ZA KONZUMACIJU:	Isopropyl thioxanthone (ITX)		
REZULTAT ANALIZE:	utvrđena prisutnost		
UZORKOVANJE:	DATUM:		05
	BR. UZORAKA:		1
	METODA:	službeni uz	
LABORATORIJ:	Zagreba		
METODA ANALIZE:			
BROJ OSOBA KOJE SU UGROŽENE:			
TIP BOLESTI / SIMPTOMI:			
<b>PRODUCT: PROIZVOD</b>			
GRUPA I PODGRUPA PROIZVODA:	KOD 14. Sokovi i bezalkoholna osvježavajuća pića, gazirana i negazirana PODGRUPA 14.1.1.2. Negazirani voćni sokovi		
NAZIV PROIZVODA:	Miješani mutni voćni sok iz koncentrata više vrsta voća i pirea 12 vrsta voća obogaćen sa 8 vitamina i provitaminom A		
BROJ PROIZVODA:	MULTIVITAMINSKI NEKTAR		
<b>CONSIGNMENT: PREPOZNAVANJE POŠILJKE / LOTA</b>			
BROJ POŠILJKE:	B6 2181		
POSREDOVAČKI CERTIFIKAT O ZDRAVSTVENOJ ISPRAVNOSTI:	BROJ:	DATUM:	
ROK UPOTREBE:	hipermarketi COOP		
OPIS POŠILJKE:	BR. KOMADA:	UK. TEŽINA:	
<b>ORIGIN: PODRIJETLO</b>			
ZEMLJA PODRIJETLA:	Austrija		
PROIZVOĐAČ:	NAZIV:	Hermann Pfanner Getranke Ges.m.b.H.	
	ADRESA:	A-6923 Lauterach, Austrija	
	BROJ OBJEKTA VET.AP-N:		
DISTRIBUTER / IZVOZNIK:	Proizvođač		

**HR RASFF notification regarding ITX in fruit juices**

http://www.hah.hr/pdf/tjedan01h.pdf - Microsoft Internet Explorer

Datoteka Edit Idi na Favoriti Pomoć

Nazad Pretraži Favoriti

Adresa http://www.hah.hr/pdf/tjedan01h.pdf

Save a Copy Select 122% Search Web Y! Adobe Reader 7.0

### RASFF HRVATSKA 2006/1

TABLICA 1: OBAVIJEST O OPASNOSTI  
Obavijesti ispisane plavim slovima

DATUM:	MJESTO UZORAKA	RAZLOG OBAVIJESTI:	ZEMLJA PODRIJETLA:
28.12.2005		otpuštanje izopropil tioksantona sa pakiranja u voćni sok	Austrija
28.12.2005	002/06	otpuštanje izopropil tioksantona sa pakiranja u voćni sok	Austrija

1 of 1

Done Nepoznata zona

start HR RASFF 1.2006 RASFF HRVATSKA... Microsoft PowerP... Hrvatska agencija... http://www.hah.h... HR 9:04

**HR RASFF web notification regarding ITX in fruit juices**

# FORMING THE WORKING GROUP

- Based on request from Ministry of Health and Social Welfare and basic activities of the Agency, **special working group was formed** on behalf of Scientific Committee on biological, chemical and physical hazard in order to **make scientific opinion** related to ITX in fruit juices found on Croatian market.



# SCIENTIFIC OPINION

- ✓ **Scientific Committee on biological, chemical and physical hazard** of the Croatian Food Agency on 13th meeting held in Zagreb on 20 April 2006 accepted the Scientific opinion on 2-isopropylthioxanthone in food **demande d from Ministry of Health and Social Welfare;**
- ✓ They concluded that based on **the lack of adequate scientific studies for genotoxicity** of ITX they are **not able to make full risk assessment** so **the presence of ITX in concentrations higher or equal than 5mg/l is considered unacceptable, therefore presents risk for human health.**

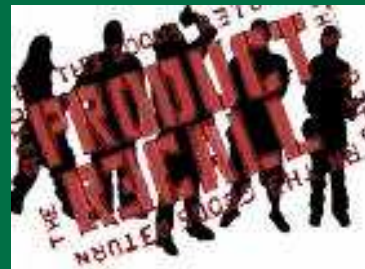
## **REASONS FOR DIFFERENCES:**

1. It contains substance that is not toxicologically evaluated, checked and safe for human consumption;
2. It has cumulative effect of mutagenesis;
3. Children are more exposed to ITX due to their body weight.



# RECALL OF THE PRODUCT

- Based on scientific opinion conclusion, which was forwarded to Ministry of health and social welfare, debatable product was recalled from the market.



# Thank You for attention

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