Do we need rapid alert and early warning to increase safety in blood transfusion and donation?

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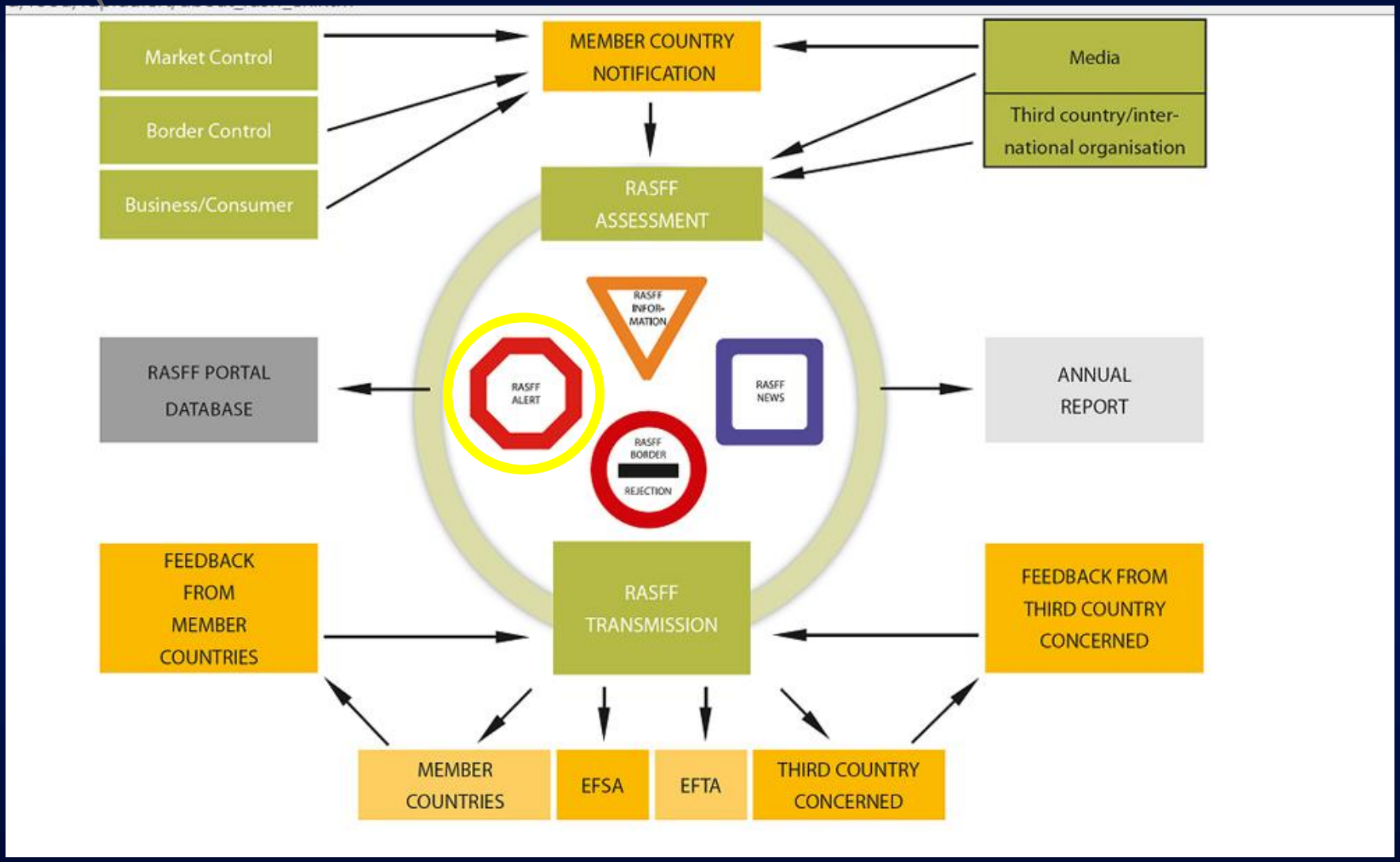
Irrational debate on a “real” problem
political interference, slow response

- **Rapid Alert System for Food and Feed (RASFF)** is a system for reporting food issues within the European Union.

The Rapid Alert System for Food and Feed (RASFF) was put in place to provide food and feed control authorities with an effective tool to exchange information about measures taken responding to serious risks detected in relation to food or feed. This exchange of information helps Member States to act more *rapidly* and in a coordinated manner in response to a health threat caused by food or feed.

RASFF: complex and fastidious



Directive of the European Parliament and of the Council **2002/98/EC** (08.02.2003, OJEC)

setting standards of quality and safety for the collection, testing, processing, storage, and distribution of human blood and blood components and amending Council Directive 2001/83/EC

Chapters I. to X., 34 Articles, 4 Annexes

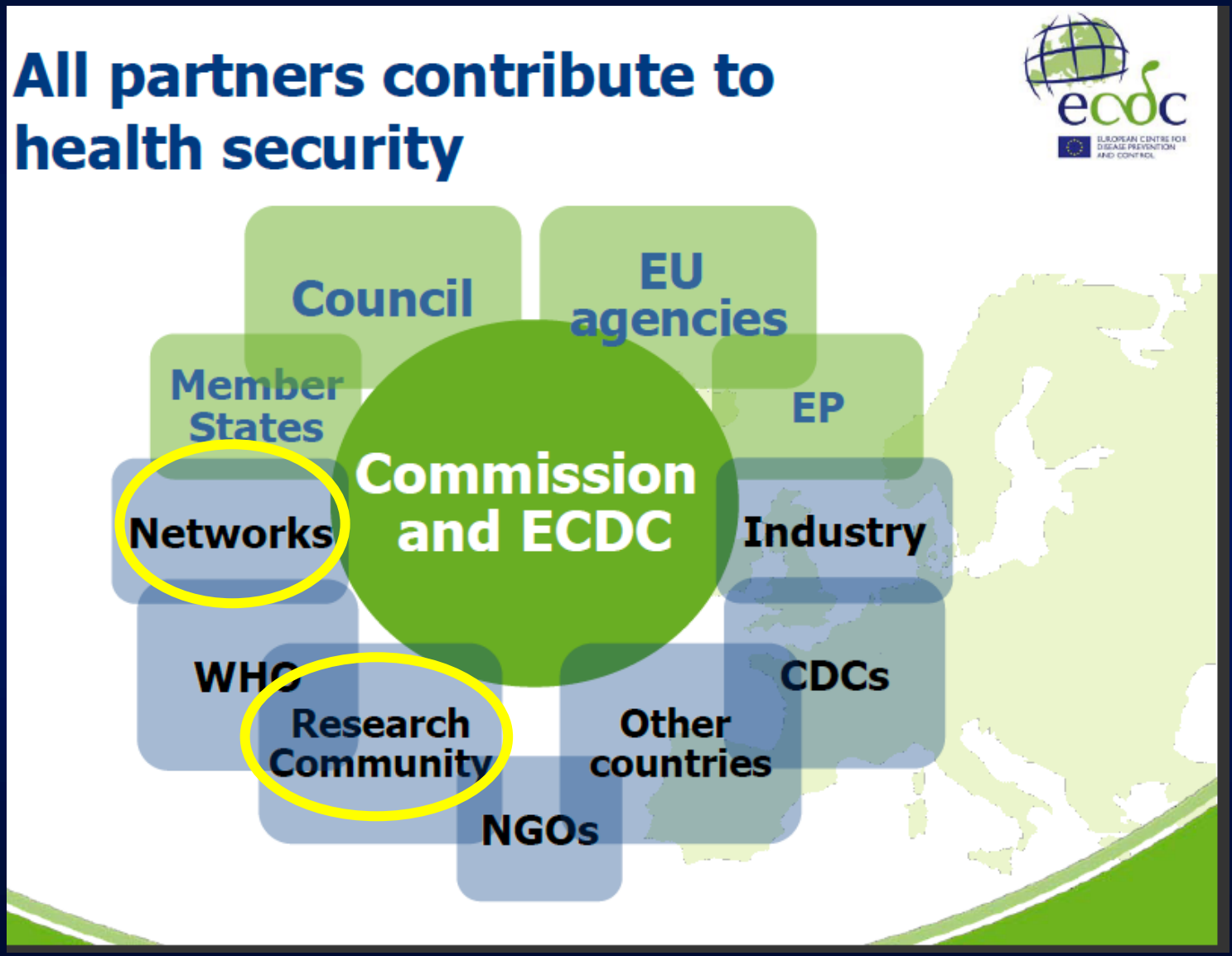
(33 Whereas, 9 Technical Requirements according art. 29. a.-i.)

Chapter V. HAEMOVIGILANCE

- article 14. on traceability
- article 15. on notification of serious adverse events and reactions

N.B. NOT a single word about rapid alert or early warning

ECDC: …timely detection of communicable disease threats



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- Health communication
- Public health microbiology programme

The European Surveillance System (TESSy)

The European Surveillance System (TESSy) is a highly flexible metadata-driven system for collection, validation, cleaning, analysis and dissemination of data. Its key aim is to provide the basis for high quality data analysis and interpretation to provide evidence for public health action. All EU Member States (27) and EEA countries (3) report data on communicable diseases as described in Decision No 2119/98/EC to the system. TESSy was launched in 2008 and, apart from routine surveillance, it has incorporated all the data collection systems that were in place for the Dedicated Surveillance Network (DSN) projects and now provides experts with a one-stop-shop for EU surveillance data. Prior to May 2005 when ECDC was established, there were 17 DSNs that collected data on a variety of diseases but also using different file specifications.

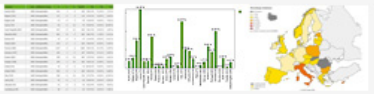
National Contact Points for Surveillance (epidemiologists and IT/data managers)

In order to ensure solid working relationship with the Member States in surveillance matters, each Member State has identified individuals who are the main Contact Points for bilateral communication with the ECDC. These epidemiologists and IT/data managers are also the main counterparts responsible for data submission to ECDC.

Data collection

- A common set of variables is defined for all diseases. This common set is applicable to all diseases.
- For selected priority diseases or disease groups 'enhanced surveillance' is needed. This consists of an additional set of variables that enables a more detailed level of analysis to be carried out.
- The technical transport protocol (file format and data submission) supports both the CSV and XML file format.

INTERACTIVE TESSY DATABASE



Online databases with public access

- Influenza database
- Antimicrobial resistance database

Access TESSy

- The European Surveillance System

Access to TESSy data

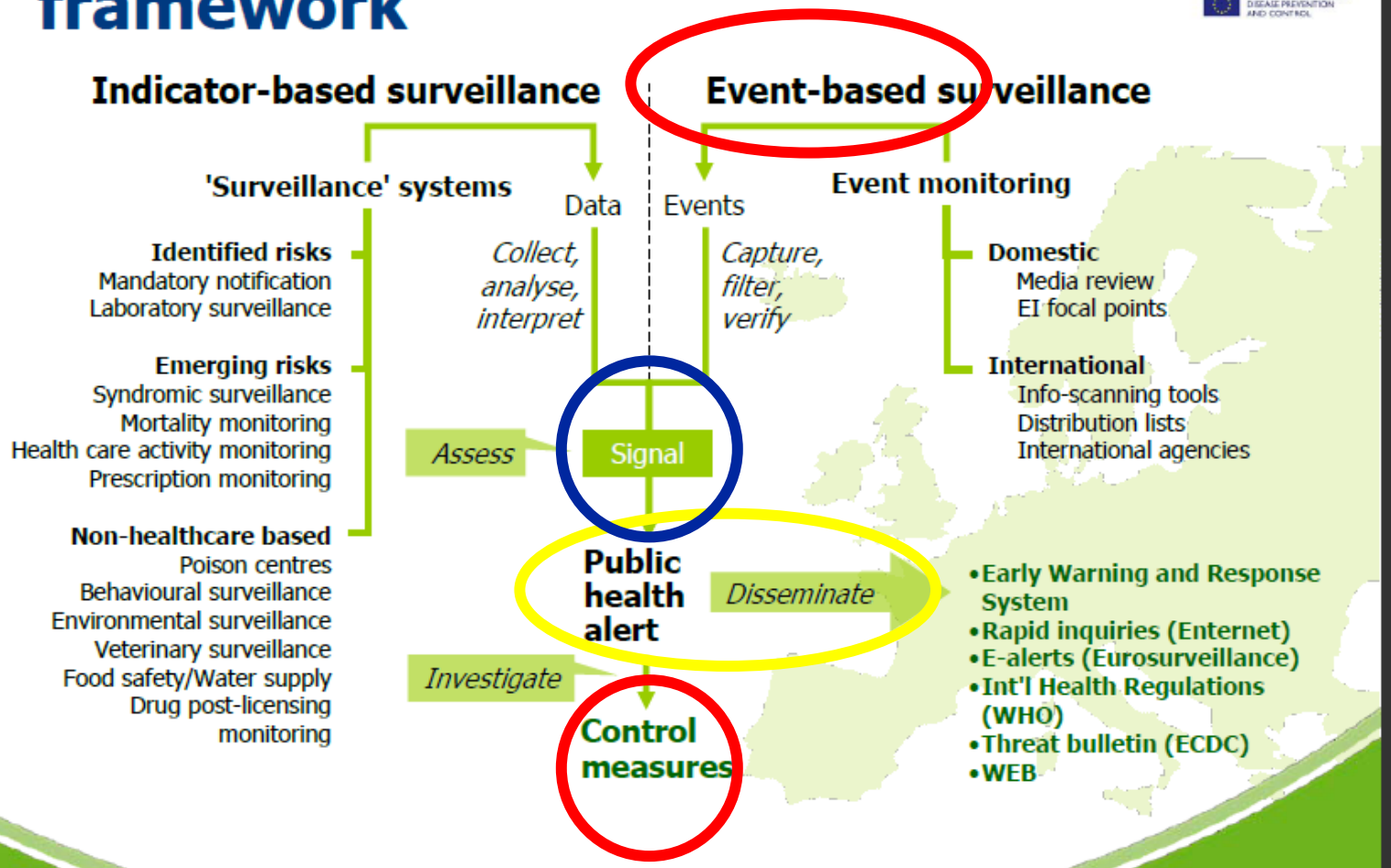
- How to request access to TESSy data

DOCUMENTS

- Commission decision of 22 December 1999 on the communicable diseases to be progressively covered by the Community network under Decision No 2119/98/EC of the European Parliament and of the Council
- Commission decision of 18 December 2007 amending Decision No 2119/98/EC of the

*The Commission's Health Security Initiative includes a requirement for them to **notify all types of threats** at EU level, not only communicable diseases.*

ECDC's threat detection framework



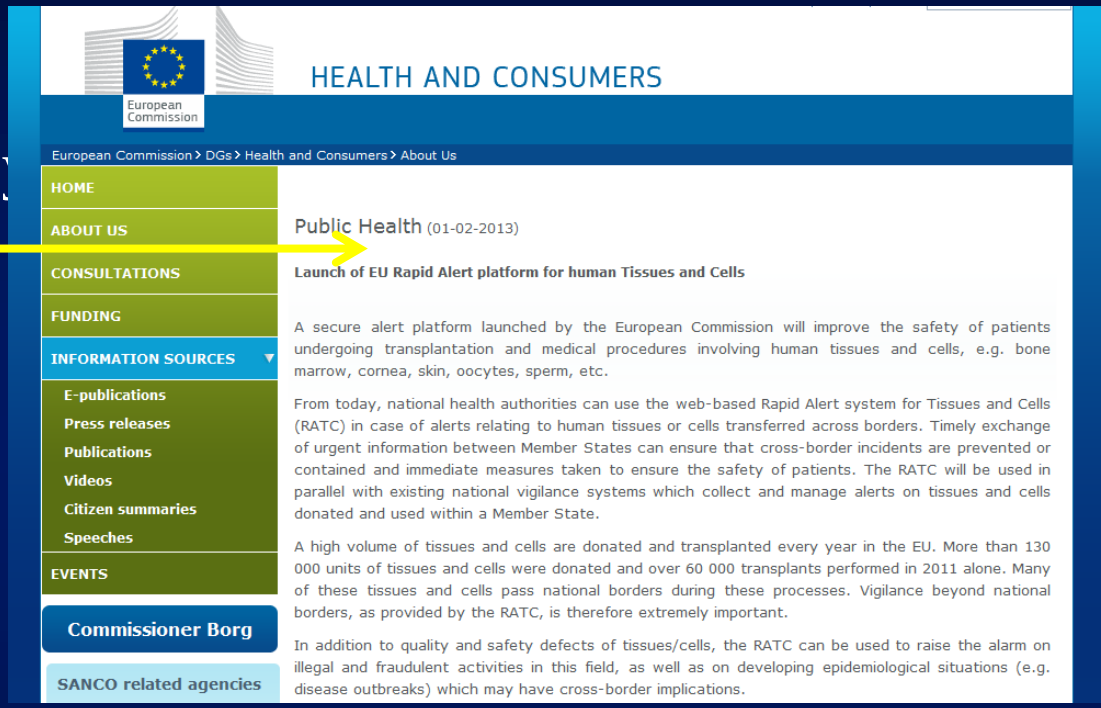
Rapid Alert for human substances (SOHO)

- EC/SANCO
- Alert system for MD
- ECDC (infectious-TESSy)
- RATC:

Rapid alert for tissues and cells

- RAB:

Rapid alert for blood



…the EU has established a number of mechanisms for a **coordinated, Europe-wide response** in the following areas:

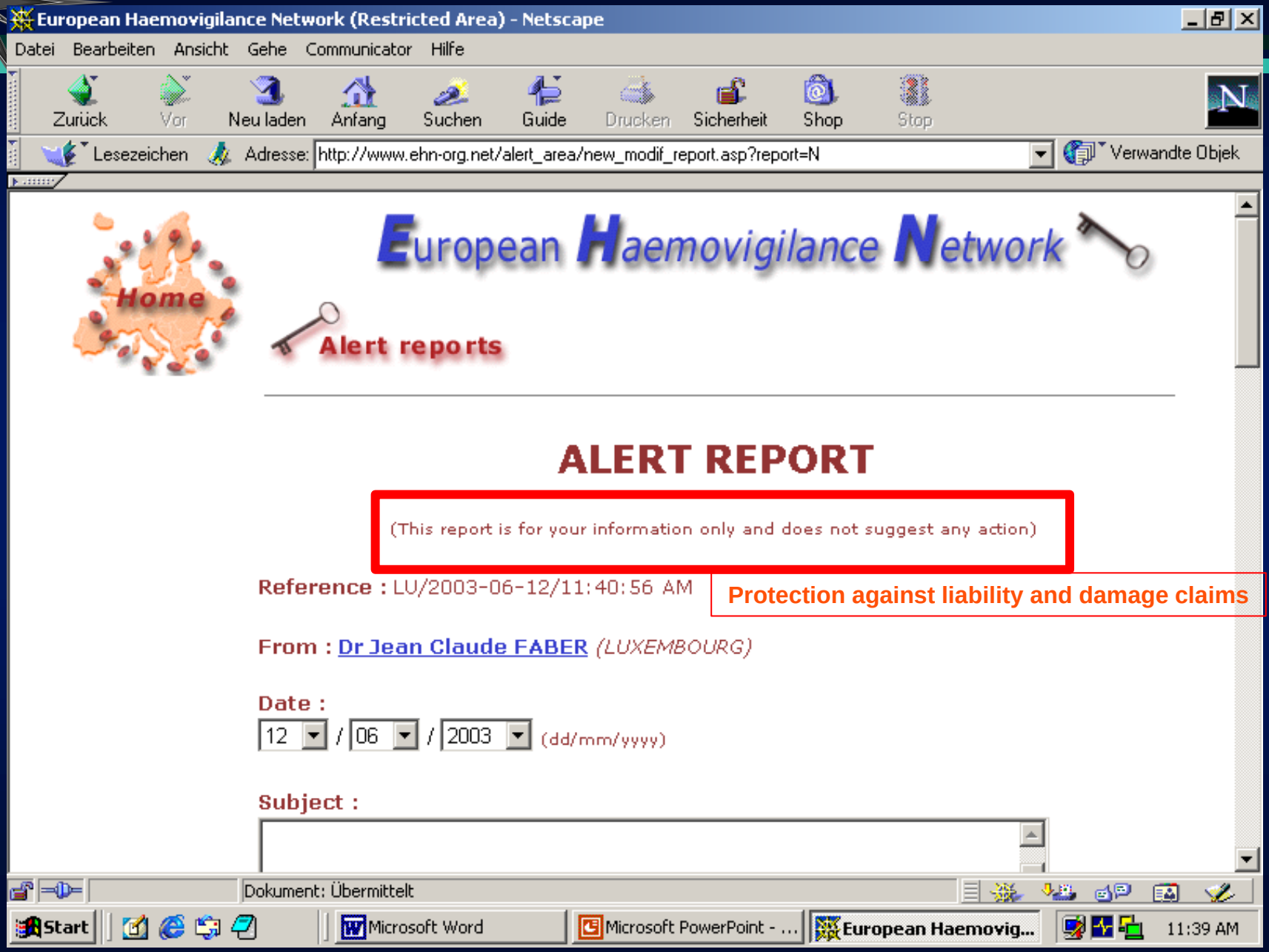
Preparedness
Risk assessment
Risk management
Risk communication
International cooperation

EHN: Rapid Alert (RAS), starting in 2002

Rapid Alert / Early Warning:

- quick and safe **transmission**
- of precise and correct **data**
- to competent (official) contact **persons**
- deciding on possible **action** in order to maintain or improve **safety** (corrective or preventive action -CAPA).

Rapid Alert System (RAS) is the validated construction to pass this information from one actor to another.


European Haemovigilance Network (Restricted Area) - Netscape
Datei Bearbeiten Ansicht Gehe Communicator Hilfe
Zurück Vor Neu laden Anfang Suchen Guide Drucken Sicherheit Shop Stop
Lesezeichen Adresse: http://www.ehn-org.net/alert_area/new_modif_report.asp?report=N
Verwandte Objek
Home
European Haemovigilance Network
Alert reports
ALERT REPORT
(This report is for your information only and does not suggest any action)
Reference : LU/2003-06-12/11:40:56 AM
Protection against liability and damage claims
From : Dr Jean Claude FABER (LUXEMBOURG)
Date :
12 / 06 / 2003 (dd/mm/yyyy)
Subject :
Dokument: Übermittelt
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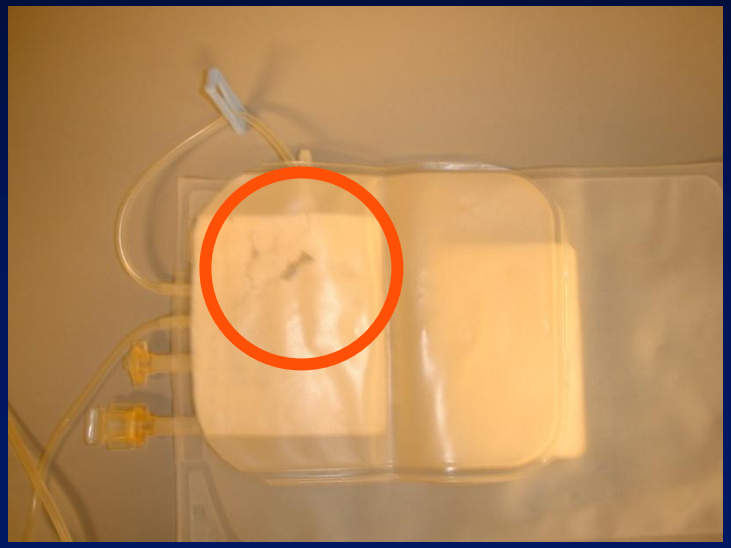
We work in a ***globalized, complex and vulnerable*** world: things can go wrong …even if regulated, controlled and managed



Blood establishments/centers work under robust QMS

Commission Directive 2005/62/EC - art. 11: QS for BE

- (a) Quality management and change control
- (b) Personnel and organisation
- (c) Premises, including mobile sites
- (d) Equipment and materials
- (e) Documentation
- (f) Donor session
- (g) Processing
- (h) Storage and dispatch
- (i) **Quality monitoring**
- (j) **Quality control** and laboratory testing
- (k) Contract management
- (l) **Deviations**, complaints, adverse events or reactions, **recall, corrective / preventive actions**
- (m) Self-inspection, audits and improvement

EHN: Rapid Alert (RAS)

RAS may be used in the case of a « signal »:

- a **proven** problem / defect
- a **potential** problem / risk
- a justified **doubt**

(f.ex. defective lots not used; batches returned to manufacturer because they failed to pass validation,...)

N.B. It is all about the threshold of the alarm trigger!

IHN: Rapid Alert (RAS)

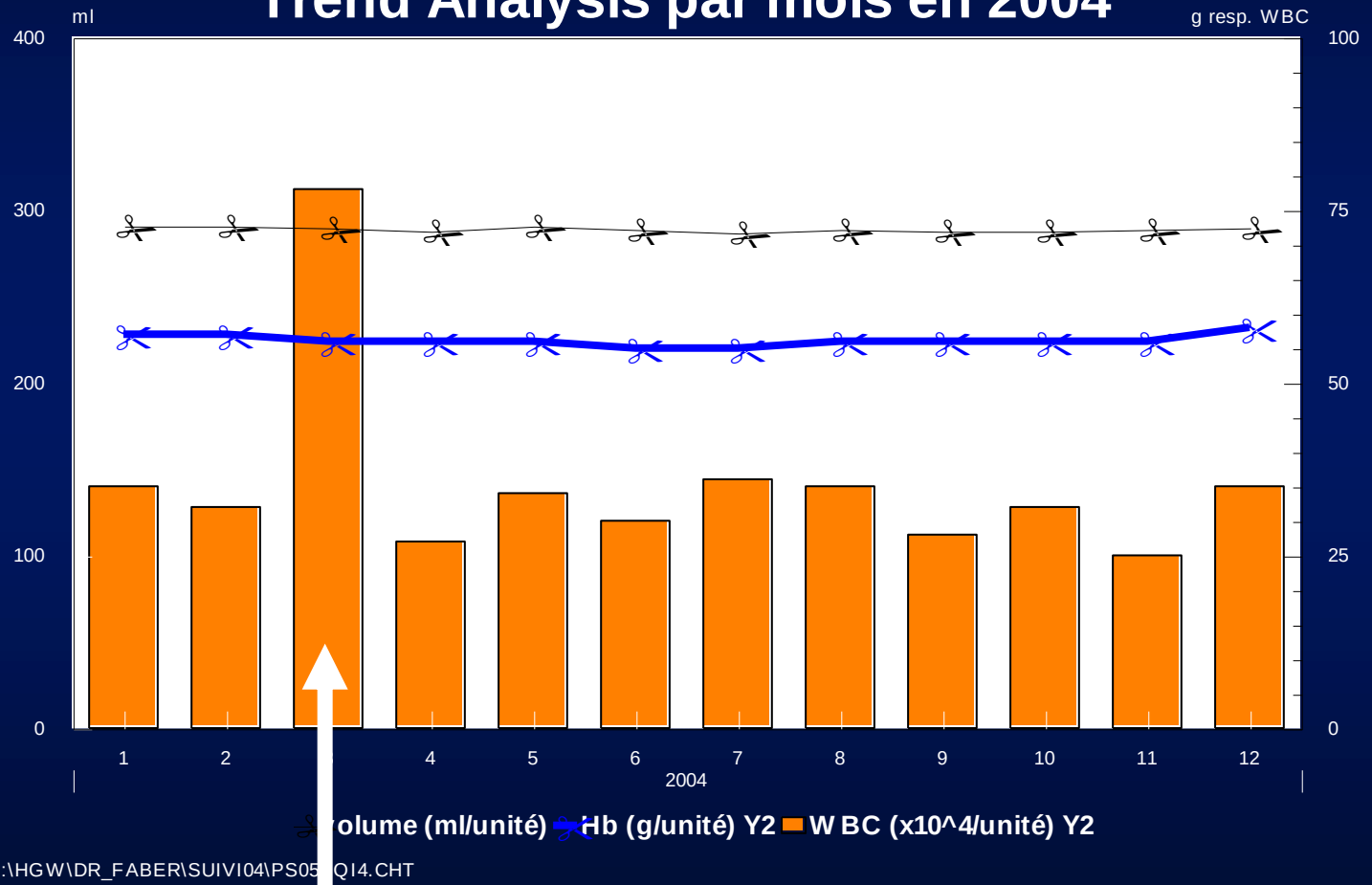
IHN-RAS has been used on different occasions:

- appearance of clusters of clinical signs / symptoms / adverse reactions during or after transfusion
- hidden or apparent defects of disposable material / MD used in donation, production and transfusion transfusion (like, leakages of filter housings, holes in collection bags, defects in apheresis material,…)
- problems with equipment / instruments
- deficiencies with reagents (for example, ELISA tests producing false negative results - sensitivity problem; or giving high numbers of false positive results - specificity problem; blood grouping antisera failing to give the correct phenotype; immuno-haematological in vitro diagnostics failing to detect weak allo-antibodies,…)

QMS: QC on incoming material – follow up / trend analysis

PS05-2BC: Quality Indicators Q.I.

Trend Analysis par mois en 2004

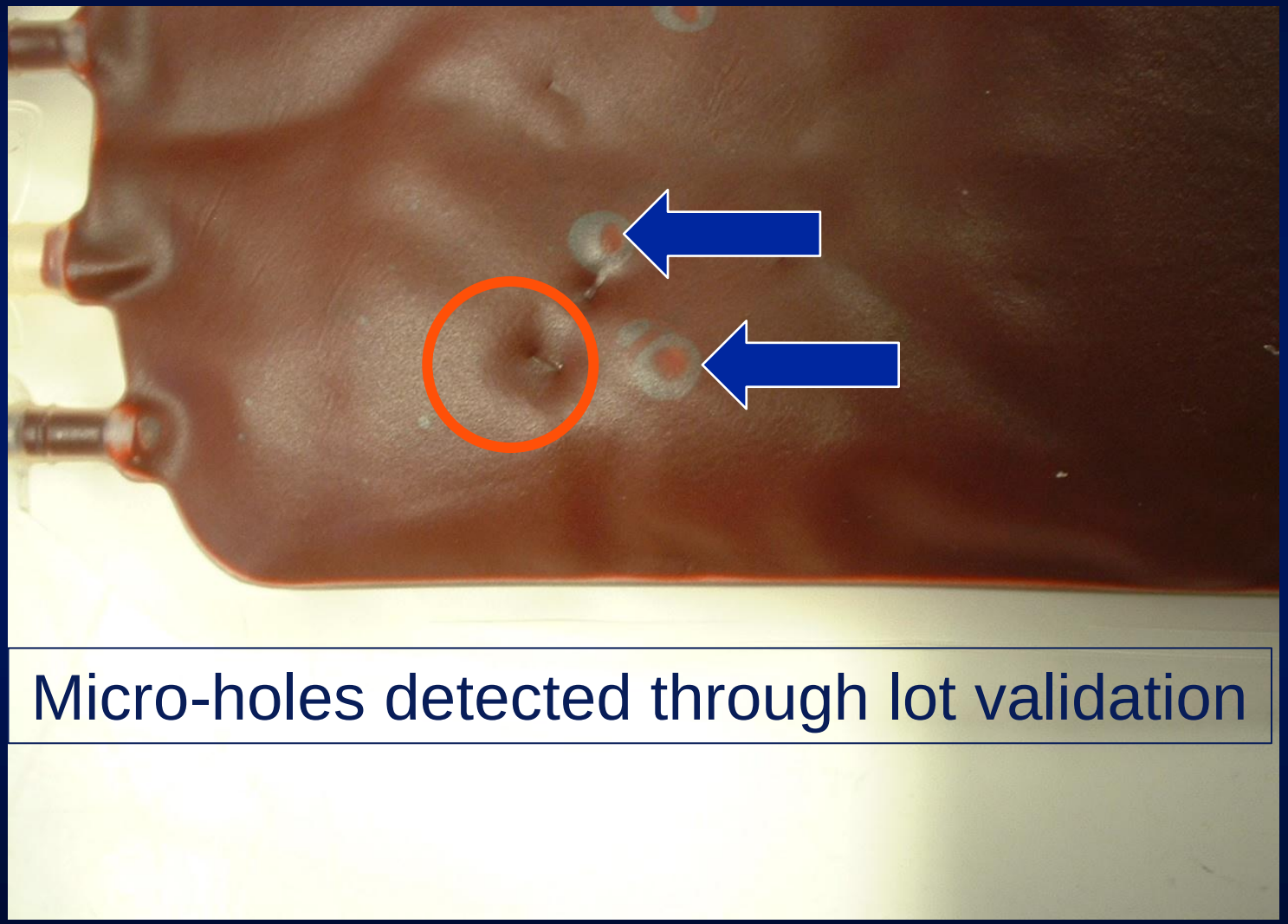


new lot of filters

CAPA: defective batch returned; lot validation introduced

Alerts triggered by the field

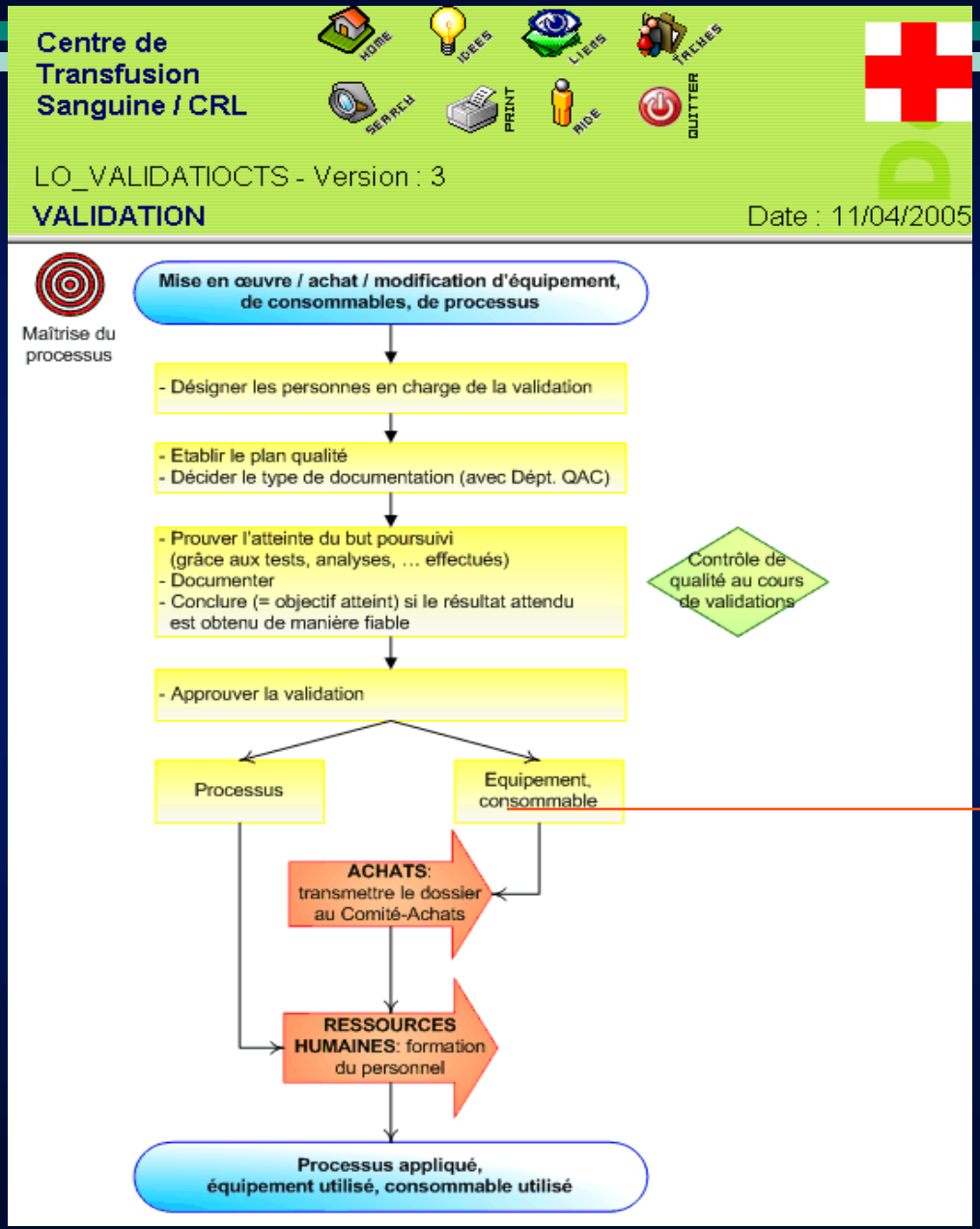
Early warning approach – application of precautionary principle



Micro-holes detected through lot validation

QMS: CAPA – quick response

Key materials:
- blood bags,
- apheresis kits,
- production disposables,
- reagents,
- etc…



lot validation failed: disposable returned to manufacturer

RAS

Ultimate goal: HV is a quality tool for continuous improvement of quality and safety in the blood chain

Deming
Q cycle
- **P**lan
- **D**o
- **C**heck
- **A**ct

Q + S ↑ in tx

BEs: reply, response and reaction - ***narrow Q cycle***

For effective vigilance: ***Comprehensive*** vs. splitted approach ***Pragmatic*** vs. official character

In some countries, lBC are MP (→PhV)

… but there is only an obligation to notify side-effects that are not yet known

In other countries, some lBC are MP (like FFP or "treated" FFP →PhV), others are not (→ HV)

Medical devices influence the quality of BP/BC;
if AR/AE appear are they to be reported into HV, PhV or materiovigilance?

What matters?

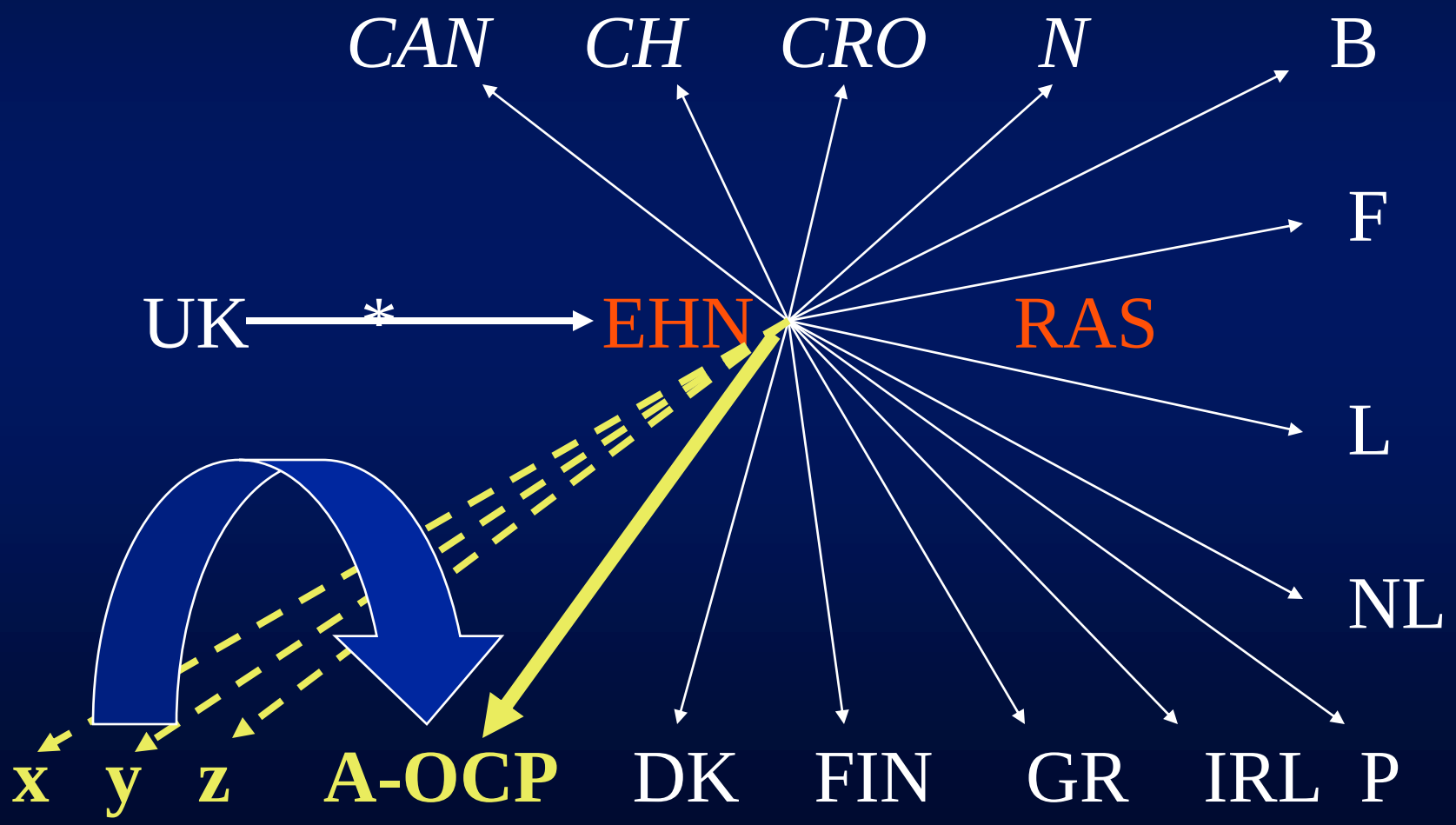
Responsiveness vs. competency, verification, validation

FR: ANSM – ex-AFSSAPS: **8 Vigilances**

- la **pharmacovigilance** pour les médicaments à usage humain et les matières premières à usage pharmaceutique
- la **pharmacodépendance** ou addictovigilance pour les substances psychoactives dont les stupéfiants et les psychotropes
- l'**hémovigilance** pour l'ensemble de la chaîne transfusionnelle du prélèvement du donneur au suivi post-transfusionnel du receveur de produits sanguins labiles
- la **matériovigilance** pour les dispositifs médicaux et les produits thérapeutiques annexes
- la **réactovigilance** pour les dispositifs de diagnostic in vitro
- la **biovigilance** pour l'ensemble de la chaîne de greffe du prélèvement du donneur au suivi post-greffe du receveur d'organes, de tissus, de cellules d'origine humaine excepté le sang et les gamètes, et pour les produits thérapeutiques annexes
- la **cosmétovigilance** pour les produits cosmétiques
- la **vigilance des produits de tatouages** pour les produits de tatouages

RAS / Rapid Alert in IHN (32 members): ½ are not EU

International networking



Why we need IHN-RAS:

Field triggered (through BEs)

Early warning approach

Precautionary principle

Quick reply and response time

Effective reaction (implementation of CAPA)

Comprehensive approach (not compartimented)

Pragmatic character (not official, regulatory)

International networking (inclusive)

→it helps to increase safety and improve quality of the entire blood chain

Bon appétit for tonight!