



# ECDC programs and projects for blood safety

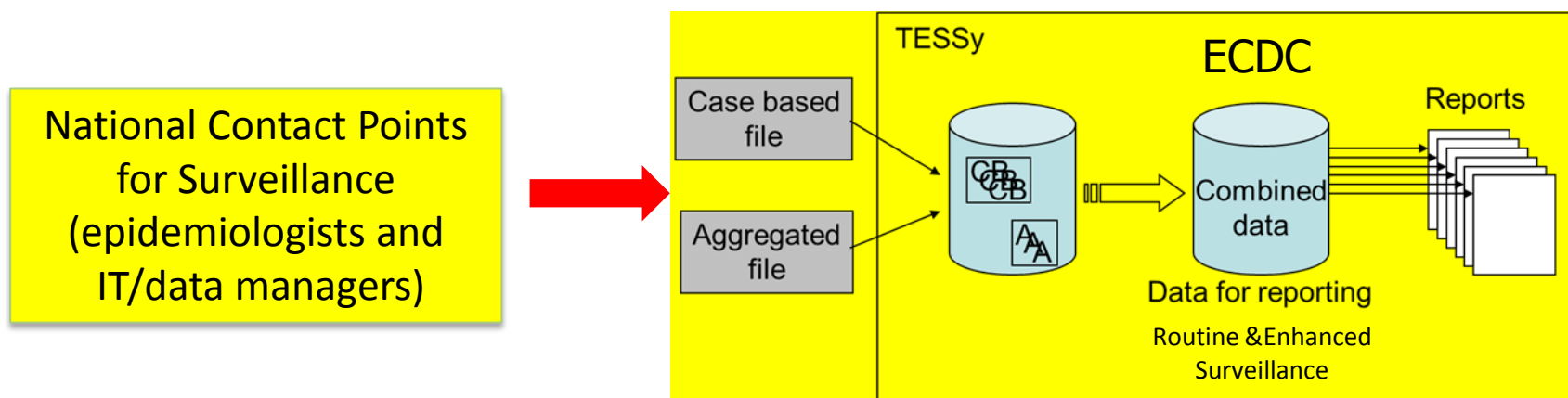
**Dragoslav Domanovic**  
**ECDC Stockholm**

# Areas Related to Blood Safety

- **Surveillance**
- **Preparedness**
- **Scientific advice**
- **Outbreak management support**
- **Epidemiology of donor derived infections**
- **International collaboration**



## The European Surveillance System (TESSy)



The legal framework:

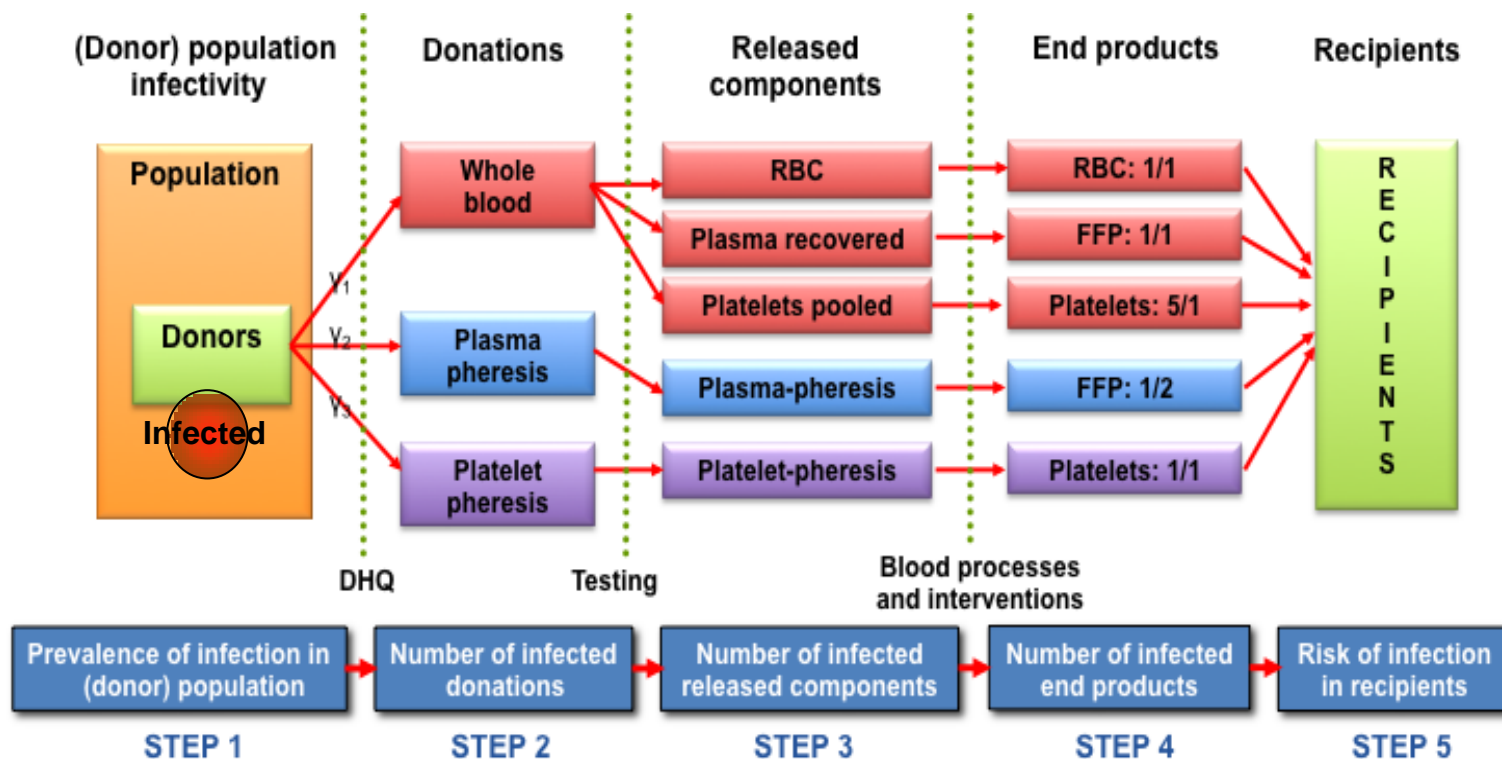
Decision No 2119/98/EC of the European Parliament and of the Council of 24 September 1998 setting up a network for the epidemiological surveillance and control of communicable diseases in the Community OJ L 268/1; 03.10.1998

# Preparedness

- Developing of tools
  - Euftrat tool
  - WNV tool
- Preparedness plans
  - WVN preparedness plan
  - Disease prioritisations
  - Risk assessments
  - Mapping
- Knowledge library



# The European Up-Front Risk Assessment Tool (EUFRAT) – Risk model scheme



# Mapping

## Reported cases of West Nile fever for the EU and neighbouring countries

Transmission season 2013; latest update: 06/11/2013



# Prioritisation of ABD

| Prioritised ABD Disease           | Final rank |
|-----------------------------------|------------|
| WNV fever                         | 1          |
| Dengue                            | 2          |
| Malaria                           | 3          |
| Chagas disease                    | 4          |
| Chikungunya                       | 5          |
| Leishmaniasis                     | 6          |
| Usutu virus fever                 | -          |
| Tick-Borne encephalitis           | -          |
| Babesiosis                        | -          |
| Crimean Congo Haemorrhagic fever* | -          |
| Borreliosis*                      | -          |

# Risk assessments and prevention of transmission of WNV, malaria, dengue thorough SoHO

| <u>Substances</u>          | <u>Subgroups</u>  | <u>Tissue characteristics</u> |                     |                          | <u>Processing characteristics</u> |                 |   |                                 |                     |                               |                     | <u>Storage conditions</u>  |                                      |  |
|----------------------------|-------------------|-------------------------------|---------------------|--------------------------|-----------------------------------|-----------------|---|---------------------------------|---------------------|-------------------------------|---------------------|----------------------------|--------------------------------------|--|
|                            |                   | <u>living/PM donation</u>     | <u>viable cells</u> | <u>Blood/body fluids</u> | <u>Washing</u>                    | <u>Cultured</u> | <u>Filtration/centrifugation/purification</u> | <u>Chemical/enzym treatment</u> | <u>AB treatment</u> | <u>Radiation Gamma/E beam</u> | <u>freeze dried</u> | <u>preservation fluids</u> | <u>storage temp. MT/Cry/VT/RT/BT</u> |  |
| blood system derived cells | Perifere Blood SC | L                             | Y                   | Y                        | Y                                 | N               | Y   | N                               | N                   | N                             | N                   |                            | MT                                   |  |
| Skin substitutes           | Epidermis         | PM                            | Y/N                 | N                        | Y                                 | N               | N   | Y                               | Y                   | N/Y                           | Y/N                 | N/Y                        | MT/Cry/RT/VT                         |  |
| Neural tissue              | Corneas           | PM                            | Y                   | N                        | Y                                 | N               | N   | N                               | Y                   | N                             | N                   | Y                          | BT                                   |  |
| Musculoskeletal tissue     | bone              | L/PM                          | Y/N                 | Y/N                      | Y                                 | N               | N   | Y                               | Y                   | G/E                           | Y/N                 | N                          | Cry/RT                               |  |
| Cardiovascular tissue      | heart valves      | PM                            | Y/N                 | Y                        | Y                                 | N               | N   | Y/N                             | Y                   | N                             | N                   | Y                          | VT                                   |  |
| ART                        | Sperm             | L                             | Y                   | Y                        | Y                                 | N               | N   | N                               | N                   | N                             | N                   | Y                          | VT/RT                                |  |
| organs                     | kidney            | L/PM                          | Y                   | Y                        | Y                                 | N               | N   | N                               | N                   | N                             | N                   | Y                          | MT                                   |  |
| blood                      | erythrocytes      | L                             | Y                   | Y                        | N                                 | N               | Y   | N                               | N                   | N/YG                          | N                   | N/Y                        | MT                                   |  |

Autologous SOHO is excluded

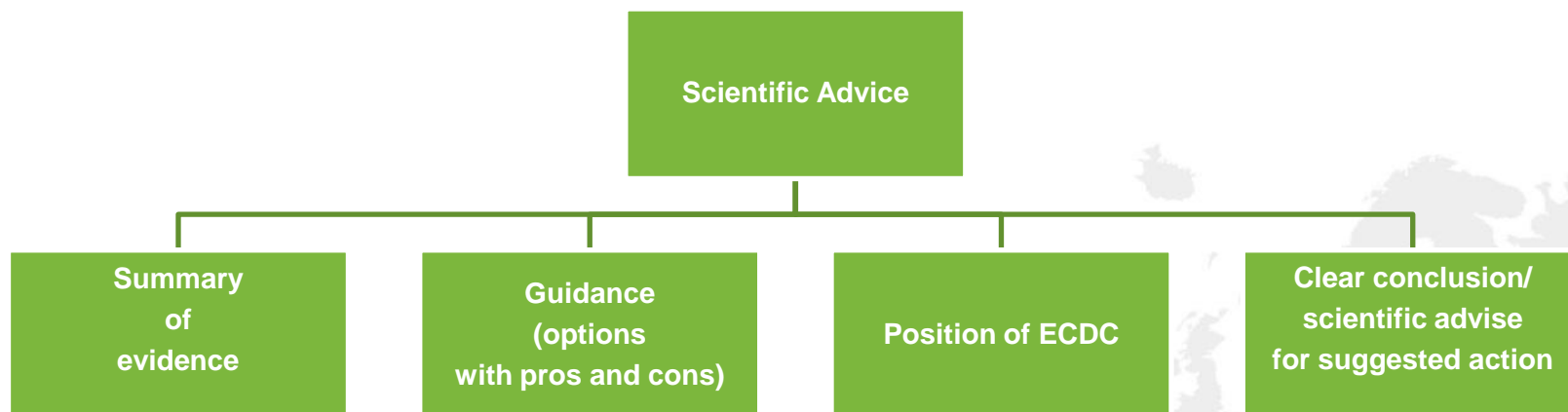
Relevant donor/material testing or i.p.control not i

|     |                  |             |
|-----|------------------|-------------|
| VT  | Vitrification    | >130 C      |
| CRY | Cryopreservation | >50 < -80 C |
| MT  | melting water    | 1-4 C       |
| RT  | Room temp        | 20-25 C     |
| BT  | Body temp        | 35-37 C     |



## Working Definition Scientific Advice

*"A conclusion of an expert evaluation and/or judgment, taking into account scientific evidence and acknowledging uncertainties"\*.*



\*adapted from: Provision of Scientific Advice to Codex and Member Countries. Report of a Joint WHO/FAO Workshop, Geneva, Jan 2004

# Scientific Advice

## Rapid Risk Assessment

- Viaspan contamination

## Risk Assessments

## Opinions

- Risk areas terminology
- Spatial definition of areas affected by malaria
- Laboratory screening of blood donors in areas affected by malaria

## Guidance



# Rapid Risk Assessment - example



## Autochthonous dengue cases in Madeira, Portugal

10 October 2012

### Source and date of request

ECDC internal decision, 4 October 2012.

### Public health issue

Risk for the EU associated with autochthonous transmission of dengue virus in the Autonomous Region of Madeira.

### Consulted experts

ECDC internal response team: Dragoslav Domanovic, Romit Jain, Lara Payne, Jas Mantero, Laurence Marrama, Emmanuel Robesyn, Herve Zeller, Denis Coulombier.

Portuguese team: Francisco George, Graça Freitas, Ana Nunes, Ana Clara Silva, Maurício Melim, Ana Leça, Kamal Mansinho, Paula Vasconcelos, Cristina Abreu Santos, Isabel Marinho Falcão.

World Health Organization: Jukka Pukkila (WHO EURO), Mikhail Ejov (WHO EURO), Raman Velayudhan (WHO HQ).

External experts: Paulo Almeida, Carla Sousa, Maria João Alves.

# Risk areas of arthropod-borne diseases terminology and classification

Eurosurveillance, Volume 17, Issue 20, 17 May 2012 Editorials

## HOW TO DEFINE AN AREA WHERE TRANSMISSION OF ARTHROPOD-BORNE DISEASE IS OCCURRING?

D Domanovic (Dragoslav.Domanovic@ecdc.europa.eu)<sup>1</sup>, J Giesecke<sup>1</sup> European Centre for Disease Prevention and Control (ECDC), Stockholm, Swede

### TABLE

Terminology and classification of the risk areas where an arthropod-borne disease is occurring

| Risk area type | Criteria                |                       |                           |                         |
|----------------|-------------------------|-----------------------|---------------------------|-------------------------|
|                | Conditions <sup>a</sup> | Pathogen <sup>b</sup> | Transmission <sup>c</sup> | Recurrence <sup>d</sup> |
| Predisposed    | +                       | -                     | -                         | -                       |
| Imperiled      | +                       | +                     | -                         | -                       |
| Affected       | +                       | +                     | +                         | -                       |
| Endemic        | +                       | +                     | +                         | +                       |

<sup>a</sup> Environmental conditions favouring transmission of arthropod-borne diseases to human.

<sup>b</sup> Presence of the pathogen in vectors and/or animals.

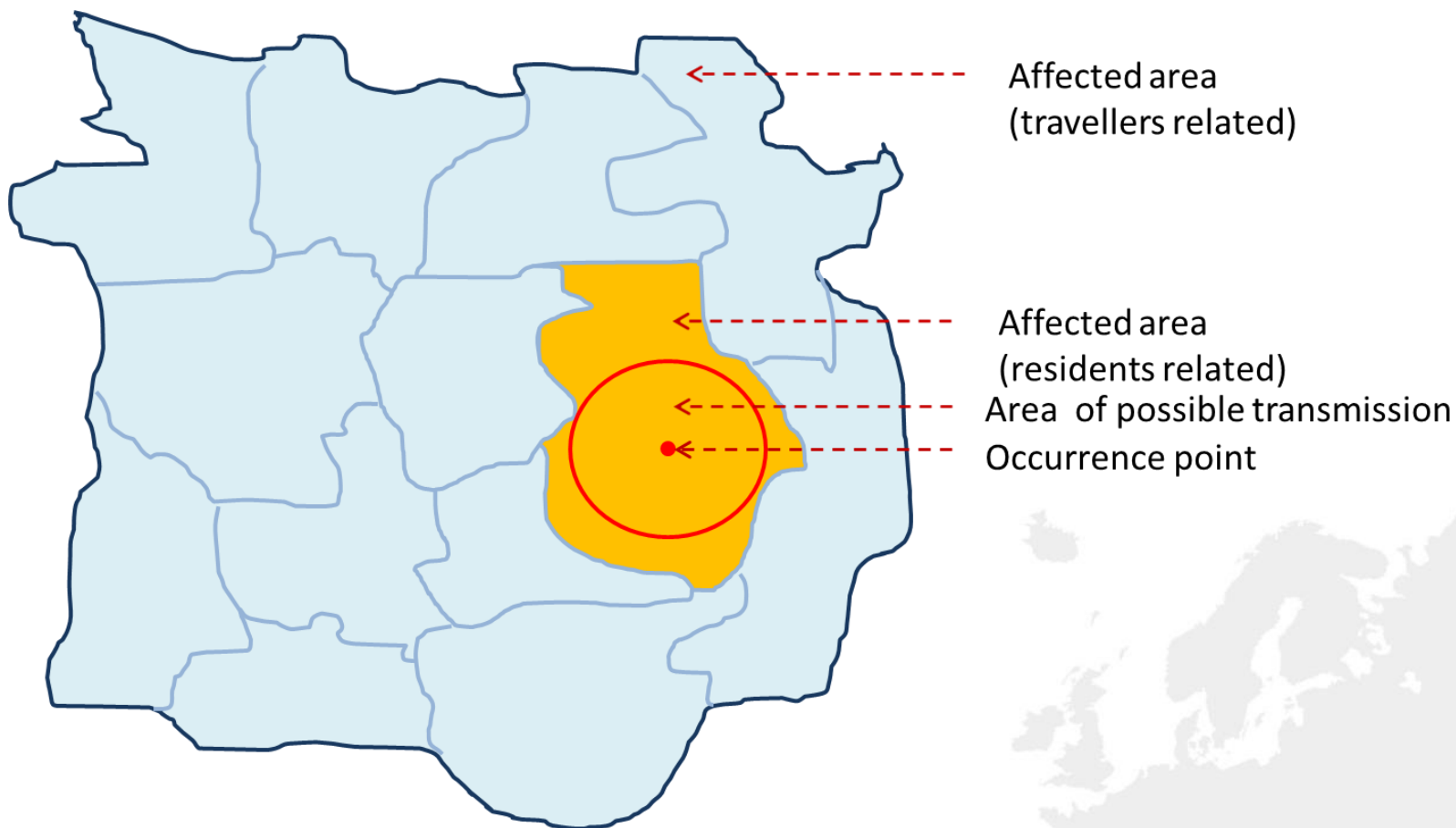
<sup>c</sup> Transmission of arthropod-borne diseases to human

<sup>d</sup> Seasonal recurrences of arthropod-borne disease transmissions to human.

# Spatial characteristics of mosquito borne outbreaks

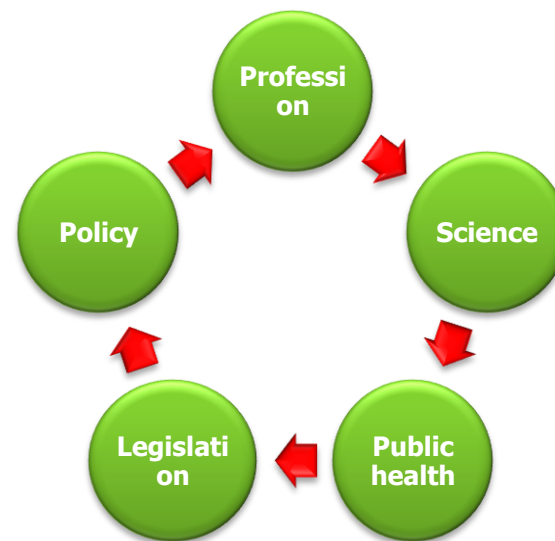
| Disease outbreak   | Year | Country   | Affected Areas (NUTS3) | Total NUTS3 | % Affected |
|--------------------|------|-----------|------------------------|-------------|------------|
| <b>Chikungunya</b> | 2007 | Italy     | 4                      | 107         | 4%         |
| <b>WNV</b>         | 2010 | Greece    | 11                     | 51          | 22%        |
|                    |      | Hungary   | 3                      | 20          | 15%        |
|                    |      | Italy     | 3                      | 107         | 3%         |
|                    |      | Romania   | 18                     | 42          | 43%        |
|                    |      | Spain     | 1                      | 59          | 2%         |
|                    |      | Total (5) | 36                     | 279         | 13%        |
| <b>WNV</b>         | 2011 | Greece    | 10                     | 51          | 20%        |
|                    |      | Hungary   | 3                      | 20          | 15%        |
|                    |      | Italy     | 6                      | 107         | 6%         |
|                    |      | Romania   | 5                      | 42          | 12%        |
|                    |      | Total (4) | 24                     | 220         | 11%        |
| <b>WNV</b>         | 2012 | Bulgaria  | 1                      | 28          | 4%         |
|                    |      | Greece    | 12                     | 51          | 24%        |
|                    |      | Hungary   | 9                      | 20          | 45%        |
|                    |      | Italy     | 8                      | 107         | 7%         |
|                    |      | Romania   | 6                      | 42          | 14%        |
|                    |      | Total (5) | 36                     | 248         | 15%        |
| <b>Malaria</b>     | 2009 | Greece    | 2                      | 51          | 4%         |
|                    | 2010 | Greece    | 3                      | 51          | 6%         |
|                    | 2011 | Greece    | 4                      | 51          | 8%         |
|                    | 2012 | Greece    | 5                      | 51          | 10%        |

# Spatial definition of areas affected by malaria



- **Laboratory screening of blood donors in areas affected by malaria**

# Outbreak Management Support

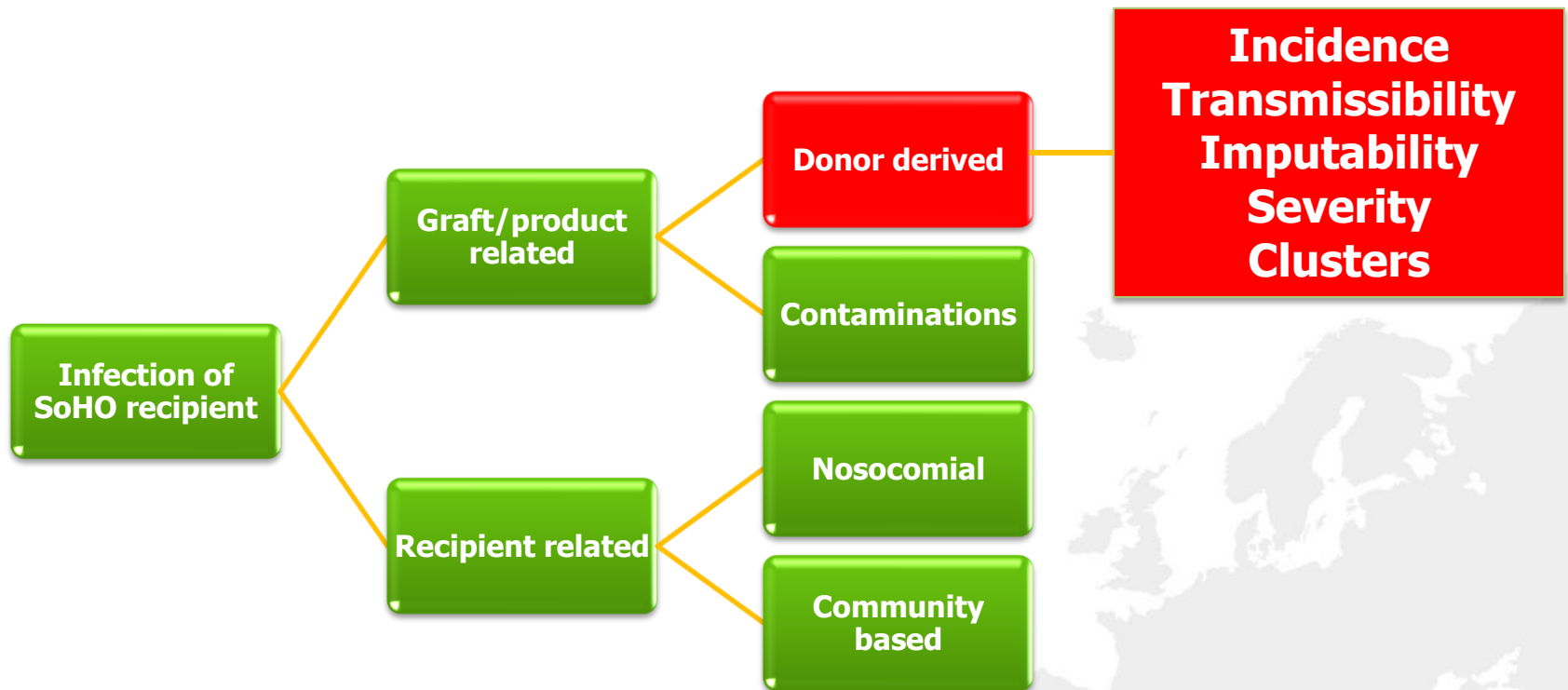


## Country visits/ advice

- Preparedness
- Detection
- Response
- Evaluation

# Epidemiology of Donor Derived Infections

-infections that are present in a donor and have the potential to be transmitted to at least 1 transfusion/transplant recipient\*.



\*Ison MG, Nalesnik MA. An update on donor-derived disease transmission in organ transplantation. Am J Transplant 2011; 11: 1123.



# Pre-donation qualification of new blood donors

**Commission asked ECDC (along with AT, IT, SE and CoE), to look into “performing an HIV risk assessment, which will, in particular, evaluate the use, including cost effectiveness, of ‘qualified’ donors. ECDC will also discuss with CoE on how to best conduct the risk assessment”.**

## Objectives

- 1. Obtain the evidence**
- 2. Risk reduction of and cost benefit analyses.**
- 3. Develop recommendation**

# Regulators

## Competent Authorities for blood

- EPI - updates
- Briefing
- RA system for blood
- Knowledge library

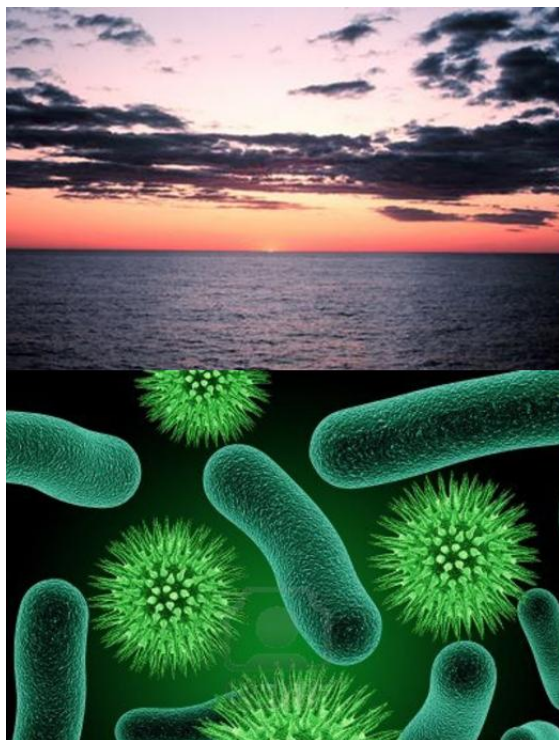


**Commissione  
europea**

# International collaboration & horizon scanning

## Collaboration

**WHO - Notify library; EBA; ISBT, CDC, AABB,**



- (i) HS as intelligence-gathering activity
  - a) Epidemiological intelligence
  - b) Surveillance
- (ii) HS for priority setting of
  - a) Research
  - b) Regulations & Guidance
  - c) Legislation
- (iii) HS for benchmarking
- (iv) HS for organisational learning

# Instead of conclusion

- ECDC is becoming a recognized authority in providing Member States and EU Commission with the scientific advice and infectious risk assessments in relation to SoHO.
- Final tuning of ECDC activities on communicable diseases with an impact on blood safety should be discussed with DG SANCO, EMA and CAs.
- Collaboration with professional organisations should be improved