

# FRENCH VIGILANCE ORGANISATION

FROM A BIRD'S POINT OF VIEW...

*“At the national level, States Parties are required to assess all reports of urgent events within their territories within 48 hours by applying a specific algorithm”* International health regulations (2005)  
WHO

Félix FAUCON  
General Inspector  
General Inspectorate for social affairs  
and health



# The scope of vigilance

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- Human, animal and vegetal health,
- Products on the market and out of the market (mushrooms collected in the forest, kitchen gardens, private orchards...),
- Practices (use of medical equipment emitting ionising radiation...),
- Not only for patients or users, or consumers, but also for providers

# A growing concern

## La grippe aviaire est arrivée en France



PLAINTES

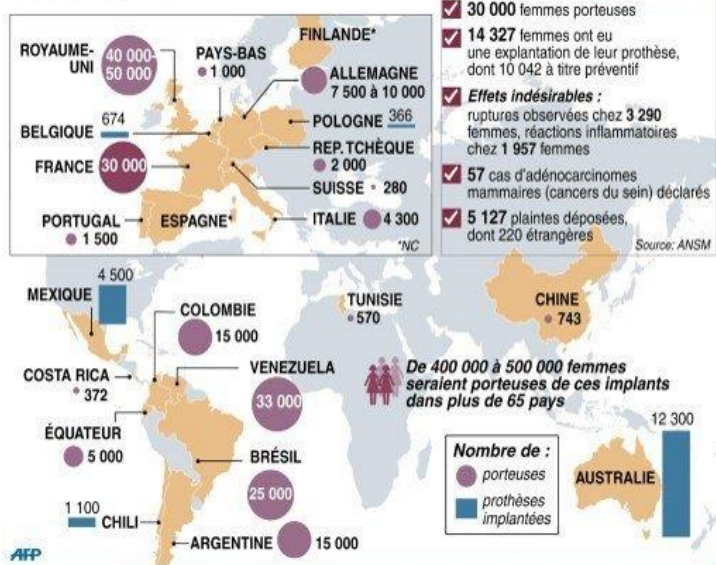
14/12/2012 à 13h26

## Pilule de troisième et quatrième génération : le scandale atteint la France

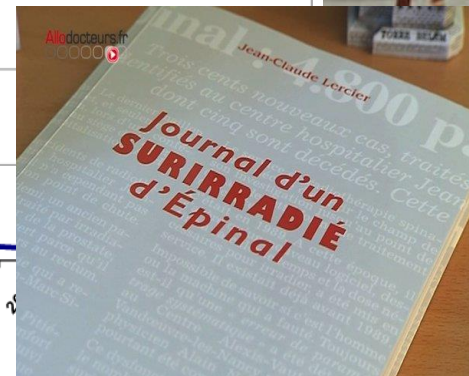
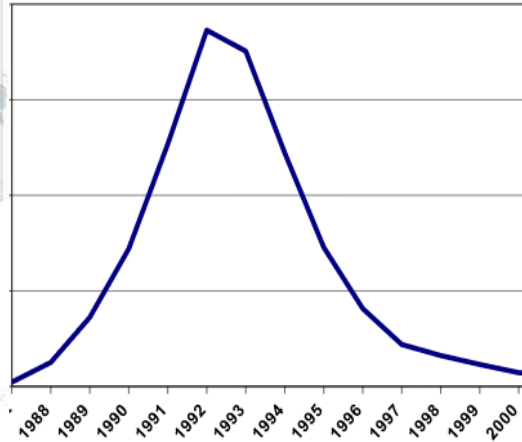


## Le scandale des prothèses mammaires PIP

Un procès hors normes aura lieu du 17 avril au 17 mai à Marseille



## Nombre de cas d'encéphalopathie spongiforme bovine (ESB) signalés au Royaume-Uni (1987-2008)



# Health monitoring building blocks

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- **Routinely collected data (monitoring via specific surveillance):** priority and well known risks; population health status (reportable diseases, incidence threshold crossing), living environment (concentration of a pollutant in the air), various zoonotic infections (avian mortality, equine encephalitis...)
- **Systems able to collect signals of all kinds and origins (vigilance via non specific surveillance)** concerning different types of threat: abnormal clinical profile, complaint from a neighbouring resident of a polluted site, disease peak in a community etc...

# Examples of diseases surveillance networks

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- Specific mortality and morbidity; notifiable diseases; hospital acquired infections;
- Medical test laboratories: gonococcal infection; chlamydia; haemophilus influenza; HCV; HIV; rubella; streptococcus; pertussis etc.
- Hospital services: paediatrics; asthma; influenza; Creutzfeldt-Jacob...
- National centres of reference (44) and associated laboratories
- Environmental surveillance: heatwave; poisoning (lead, carbon monoxyd...)

# Examples of diseases surveillance networks

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- Sentinel / GPs under the umbrella of the INSERM (national institute of health and medical research): seasonal surveillance (influenza, acute diarrhoea), and permanent surveillance on an annual program basis (currently 8 diseases);
- Regional surveillance: West Nile, Lyme disease, dengue fever, leptospirosis...
- Sentinel / occupational physicians: specific diseases
- European and international networks: legionnaires (ELDSNET), antimicrobial resistance (EARSS), influenza (EISN), vaccine preventable diseases...

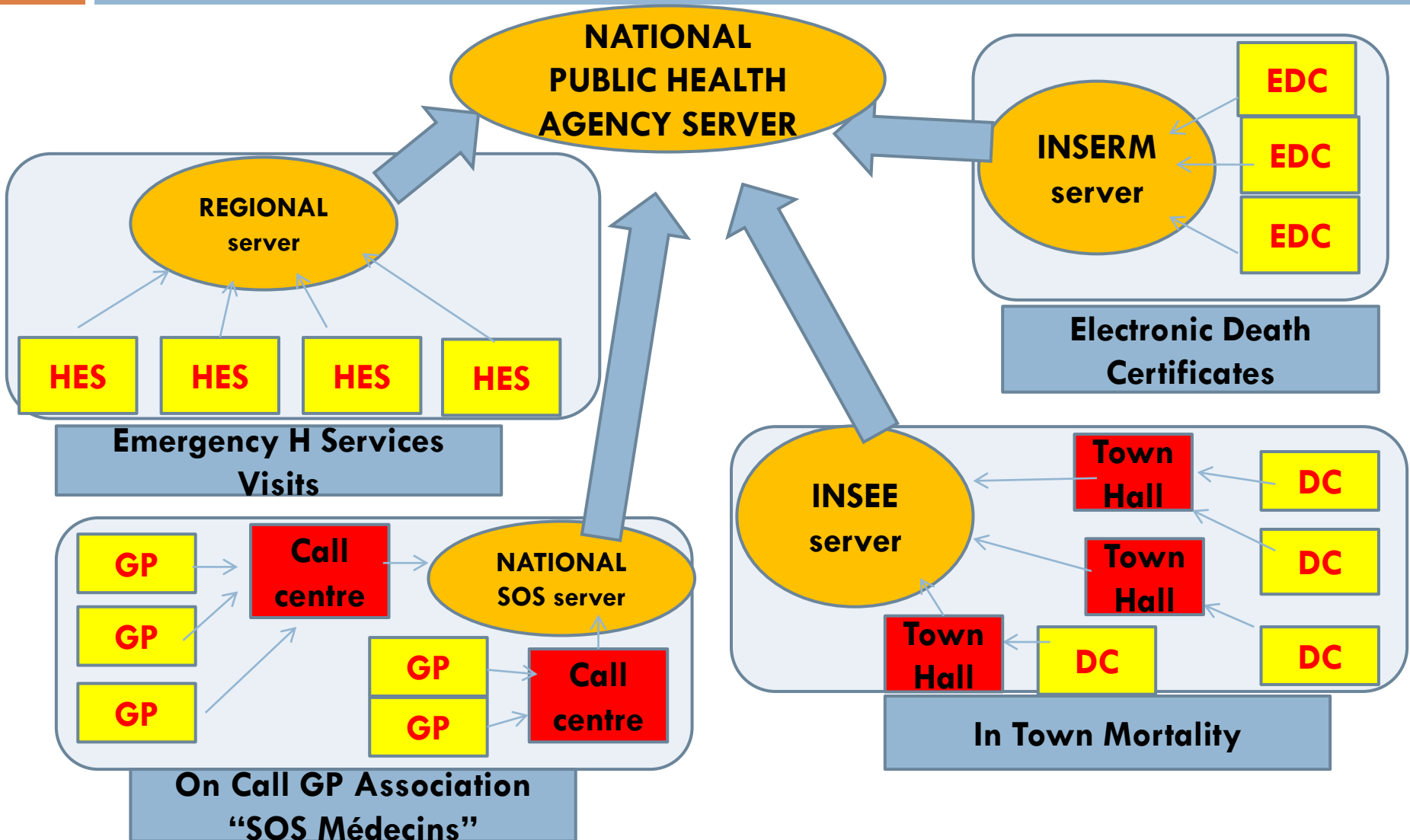
# Examples of risk exposure indicators (surveillance networks)

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- Quality of drinking and human uses water
- Quality of bathing water
- Quality of the air
- Radioactivity
- Aerobiological inspection
- Weather events
- Phytosanitary products exposure
- Sectoral or general exposure matrix for occupational risks

# Emergency and death surveillance information system architecture

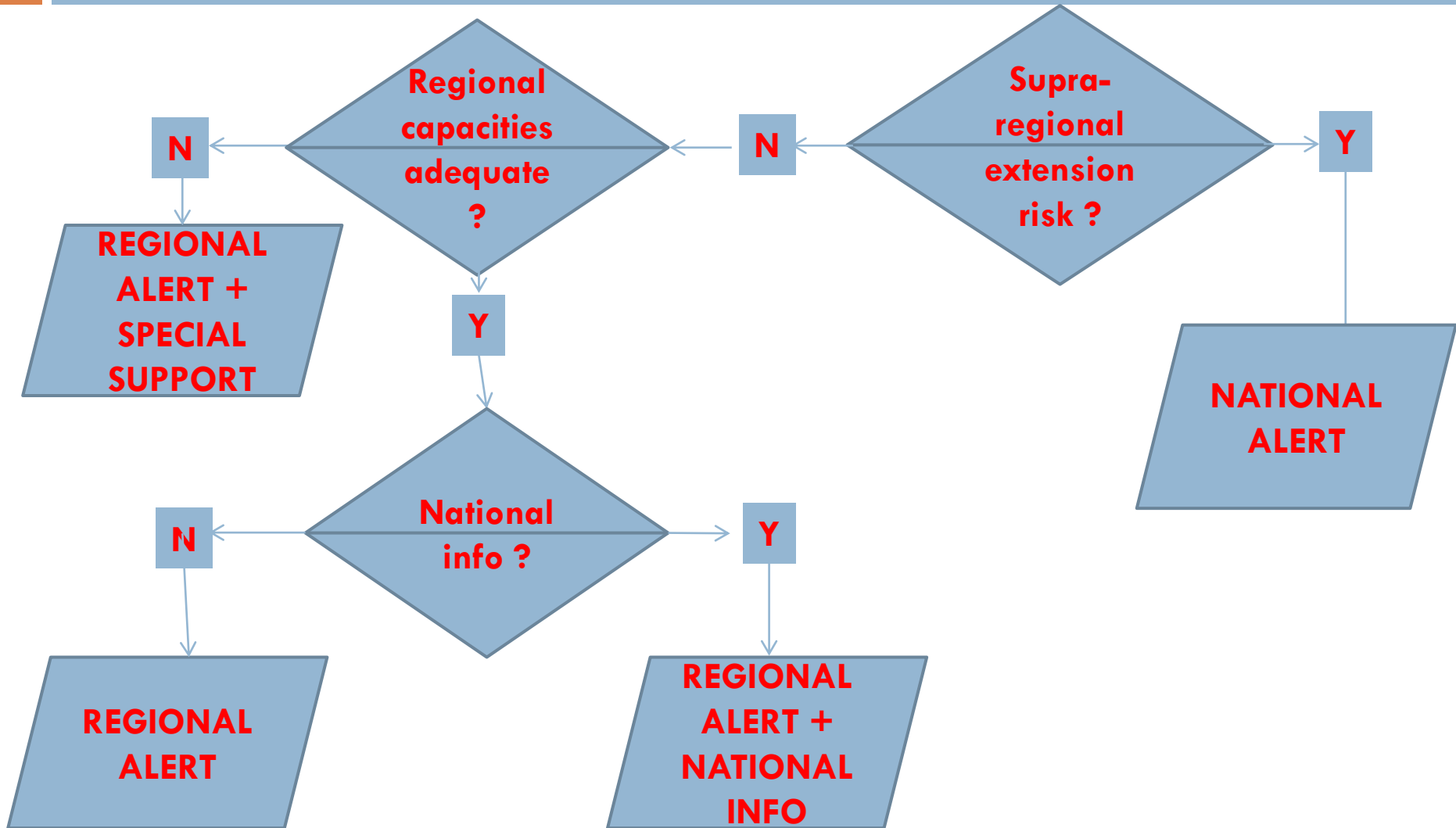
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# Assessment of an alert

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# A gradual construction of a legal framework...and a complex system

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- Born out from public health crisis (HIV contaminated blood, mad cow crisis, asbestos contamination...)
- And sentences against the State because of its deficiencies: Like all kinds of safety, sanitary safety is a State responsibility
- Then, a lot of legislators' interventions from 1993 to now (last law in 2016)
- Each crisis brings its specific agency; and some have since been merged

# Players of the health monitoring system

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**The DGS / General Directorate for health** (Ministry of Health) in charge of:

- Health monitoring
- Alert response
- Sanitary crisis management in cooperation if necessary with the Ministry of Interior (inter-ministerial role of the Prefects)

It includes the national operational centre for sanitary and social emergency responses

IHR (2005) Focal point for WHO

# Players of the health monitoring system

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**6 thematic national agencies** (some having regional offices)

**Overarching principle: risk assessment done by the agencies; risk and crisis management done by the State (regional and/or national level);**

Exceptions: health products (human and veterinary uses) decisions on behalf of the State done by the CEO (ANSM or ANSES)

- **HAS** (National authority for health): vigilance related to drug prescription and dispensing assistance softwares

# Players of the health monitoring system

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6 thematic national agencies:

- **ASN** (nuclear safety authority): vigilance related to radioprotection significant incidents
- **ANSP** (public health national agency): transversal action closely linked with the DGS; epidemiological surveillance; prospective watch on sanitary risks; preparation and response to health threats, alerts and crisis;
- **ABM** (biomedicine agency): biovigilance (organ, cell and tissue implantation), vigilance related to medically assisted reproduction;

# Players of the health monitoring system

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6 thematic national agencies:

- **ANSM** (medicine and health products and devices agency): pharmacovigilance; medical device vigilance; hemovigilance; reagent vigilance; addictovigilance; cosmetovigilance; tattoo product vigilance; biomedical trial vigilance
- **ANSES** (Food, environment and occupational health agency): toxicovigilance; food vigilance; veterinary pharmacovigilance (effects on humans); agrochemical product vigilance (effects on humans);

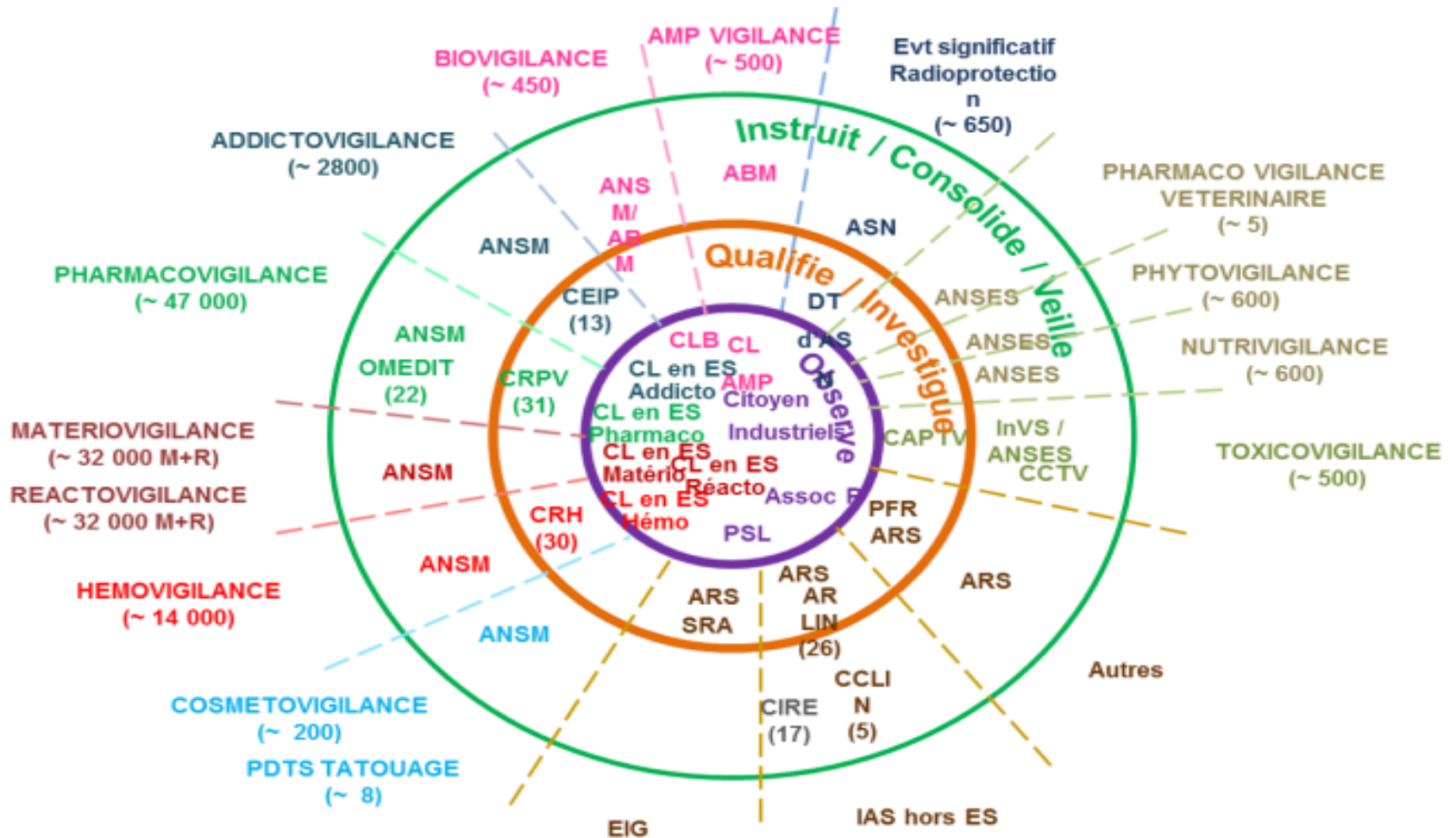
# Players of the health monitoring system

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17 **ARS** (regional health agencies, in mainland and overseas France):

- Health monitoring, emergency responses, crisis management in respect of Prefect attributions;
- Organisation of the description, notification and alert collection;
- Coordination of a regional network gathering entities involved in safety and quality of patient care;
- Coordination of a regional network gathering entities involved in health monitoring and vigilance;
- Coordination of investigations and local responses in the case of sanitary alert;

# An historical stratification





# Since 2013, reports to prepare a reform

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## Assessment:

- A fragmented functioning;
- A dense territorial network, but regionally varied and unclear (heterogeneity of the local organisations);
- Multiple and not communicating tools;
- A weak notification culture (fear of sanction);

# The 2016 reform objectives

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- Facilitate and promote the AE notification : web portal (see second presentation); whistle blower protection; non sanction hospital charters; recognition of the health providers contribution to the public health service
- Improve the regional organisation: promotion of the regional agencies leading role over all the local and regional entities involved in surveillance and vigilance;
- Improve overall steering and management: clarify roles and responsibilities; urbanize the information systems related to surveillance, alert and crisis management

**THANK YOU FOR YOUR ATTENTION**