

# Chapter 9

## Case Study – France

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**Abstract** Emerging health risks, weapons of mass destruction, and terrorism – including biological weapons and bioterrorism – are identified in the 2008 White Paper on defence and national security as threats for France and its citizens. Since the beginning of the century, the 2001 anthrax attacks in the USA and subsequent hoaxes as well as the global SARS outbreak and influenza pandemic threats have all contributed to raise public awareness about health emergencies, leading authorities to adapt and improve planning for such events. This chapter focuses on natural and intentional public health threats and on biopreparedness from a French perspective, describing legal and organizational frameworks, plans and guidelines.

### 9.1 Introduction

The scope of public health threats encompasses epidemics and pandemics, known and (re)-emerging pathogens, accidental releases or contamination, but also malevolence and bioterrorism [8]. As the European Security Strategy identifies threats facing the European Union, the French White Paper on defence and national security (2008) identifies a number of threats and vulnerabilities for France and its citizens. Among these are weapons of mass destruction, terrorism, and emerging health risks, and the issue of the rising number of French citizens living abroad. Other identified vulnerabilities are ballistic and missile threats, major attacks against information systems, new and robust espionage activities, major criminal networks, natural catastrophes, as well as industrial disasters and technological risks. The strategy also integrates four new security parameters: the growing interconnection between

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threats and risks resulting from globalization, continuity between domestic and foreign security, the possibility of sudden strategic disruptions, as well as developments impacting military operations.

From a French point of view, surveillance and assessment of public health threats require taking into account metropolitan France, as well as overseas departments and territories spanning three continents. Due to the increasing circulation of goods and people, monitoring of events at the international level is also a requirement, aimed at detecting and characterizing health threats which could affect the French population nationally or abroad. This case study mainly focuses on major threats linked to infectious diseases, be they natural or intentional.

## 9.2 Infectious Diseases: Trends and Threats

The 2010 annual report of the French National Institute for Public Health Surveillance (InVS) highlights that infectious diseases trends in France include a recurrence of measles, due to inadequate vaccine coverage, and increases in sexually transmitted diseases such as gonococcal infections, as well as a higher incidence of invasive pneumococcal infections. In addition, development of drug resistant strains is a public health challenge. Emerging carbapenem-resistant *Enterobacteriaceae* are for example considered worrisome, even if few cases have been detected in France until now. The 2010 *Bulletin Épidémiologique Hebdomadaire* (BEH) about surveillance assessments of infectious diseases, published by InVS, also underlines the risk of introduction of chikungunya and dengue viruses by travelers arriving or returning from endemic areas, as a potential vector (a mosquito, *Aedes albopictus*) is now present in Southeastern France. In 2008, according to Inserm – CépiDc data, mortality caused by infectious and parasitic diseases represented 2% of the deaths in France.

Regarding potential major health threats, epidemic and pandemic threats remains a great cause for concern, as the dedicated interdepartmental website and national plan show. In 2004, following the SARS outbreak, a new chapter about serious health threats was inserted in the Public Health Code. It is worth noting that the scope of this chapter encompasses all kind of threats, including intentional ones, as bioterrorism is also a concern.

Biopreparedness takes into account agents responsible for anthrax, botulism, plague, smallpox, tularemia, and viral hemorrhagic fevers, all listed in the CDC category A of high-priority agents including organisms that pose a risk for national security. They are among 30 diseases requiring mandatory written reporting, ruled by Article L.3113-1 of the Public Health Code, completed with articles D.3113.6 and D.3113.7 which establish the list. Also, authorities published guidelines and factsheets explaining how to react in the context of a bioterrorist event involving one of these agents or some others.

Except for smallpox, which has been eradicated, these diseases still also represent natural public health threats, even if there are no or few cases. Even if the annual

incidence is very low in France, mainly with foodborne cases, the occurrence of unusual and severe cases of botulism provides additional reasons for continuing surveillance [6]. According to 2010 InVS epidemiological data, there are also few cases of tularemia, the reporting of which became mandatory in 2002. Reporting of anthrax cases has been mandatory since 2003, but cases are extremely rare with only one imported case (2003) and three patients infected with cutaneous anthrax (2008) reported in the last decade [5]. Regarding plague, the last cases occurred in 1945. However, this disease is endemic in some areas in Africa and Asia that have close links to France. As for viral hemorrhagic fevers, most cases in metropolitan France are caused by Puumala virus (Hantavirus), responsible for a relatively mild form of hemorrhagic fever with renal symptoms, and yellow fever (Arbovirus) for which vaccination is mandatory to travel to French Guiana. No case of African hemorrhagic fever has been identified in France since the inclusion of these diseases on the mandatory reporting list, however, the risk of importation must not be ignored.

### 9.3 Serious Public Health Threats and Biopreparedness

#### 9.3.1 *Organization at National Level*

The General Secretariat for Defence and National Security (SGDSN), reporting to the Prime Minister and working closely with the President of the Republic's office, is responsible for risks and threats assessment, as well as planning and inter-ministerial coordination regarding prevention and response to major threats, including CBRNE terrorist threats and public health threats such as pandemics. According to article L.1141-1 of the Defence Code, each ministry is then responsible for preparation and implementation of incumbent defence measures.

Considering terrorism issues, the CBRNE Strategic Committee was created in 2008, as required in the White Paper. It coordinates the definition of joint orientations and monitors their implementation. Chaired by the Secretary General for Defence and National Security, it convenes representatives from relevant ministries (Ministries of Interior, Health, Defence, Industry, Agriculture, Transports and Budget), and thus aims at ensuring coherence and complementarities. Its role also includes considering how scientific and technological developments can meet operational requirements.

The CBRNE prevention and response plan relies on a number of texts. The 2009 French State Doctrine for the Prevention and Response to CBRNE Terrorism (“Circulaire n°747/SGDN/PSE/PPS, 30 October 2009”) defines the framework and identifies ten objectives (Fig. 9.1), each corresponding to a number of specific missions and activities. The interministerial system to address CBRN terrorist threats is specifically described in another document (“Circulaire interministérielle n°007/SGDN/PSE/PPS, 8 October 2009”).

<b>Organization, planning, training</b>	<ol style="list-style-type: none"> <li>1. Organization of the action of State administrations, specialized entities, territorial collectivities and operators</li> <li>2. Optimization of the use of units and resources</li> </ol>
<b>Prevention</b>	<ol style="list-style-type: none"> <li>3. Dissuade or prevent the occurrence of a CBRNE attack</li> </ol>
<b>Response (1)–Detection</b>	<ol style="list-style-type: none"> <li>4. Threat detection or detection of a CBRNE terrorist action</li> </ol>
<b>Response (2)–Protection of the population and potential targets</b>	<ol style="list-style-type: none"> <li>5. Protection of the population, sites and critical infrastructures</li> </ol>
<b>Response (3)–Intervention</b>	<ol style="list-style-type: none"> <li>6. Confronting a terrorist action, preventing the sequence of events</li> <li>7. Responding to a real terrorist attack and conducting efficient and secure response actions</li> <li>8. Assessment of the situation and mitigation of consequences</li> <li>9. Caring for (potential) victims</li> </ol>
<b>Rehabilitation</b>	<ol style="list-style-type: none"> <li>10. Management of consequences to return back to normal as soon as possible</li> </ol>

**Fig. 9.1** Objectives of the state doctrine for the prevention and response to CBRNE terrorism

In case of a serious crisis such as a pandemic or bioterrorist event, while the President of the Republic and the Prime Minister are responsible for political and strategic actions, the Ministry of Interior takes charge of operational conduct of the response, the Ministry of Health remaining responsible for health issues. The Ministry of Interior can activate a decision-making interministerial crisis committee (CIC), involving representatives of cabinets or directorate of a number of ministries, including the Ministry of Health, as well as representatives of the National Defence General Secretariat and the Government Information Service. The Ministry of Health also activates the public health crisis centre. In addition, the Ministry of Foreign and European Affairs relies on a crisis centre permanently activated, which intervenes when a crisis threatens the security of nationals abroad or involves a humanitarian situation.

### ***9.3.2 Defence and Security Areas, a Key Level***

Governmental plans are adapted at the level of ministries, defence and security areas, and departments (one of the main administrative divisions in France). Defence and security areas, seven for metropolitan France and five overseas, constitute a key territorial division in terms of crisis management. The prefects for the defence and security areas (PZDS), coming under the authority of the Prime Minister and of each of the ministries, are responsible for the preparation and implementation of national

security measures, notably those regarding civil security and crisis management, and supervising actions from regional and departmental prefects.

They have been granted broader competencies in 2010 to improve planning and crisis management capacities (“Décret n°2010-224, 4 March 2010”). Among other missions, they set direction and priorities, relying on an assessment of risks and potential effects of threats, and are tasked with the translation of governmental planning at the level of the area, ensuring the implementation at the departmental level is effective. They organize operational surveillance, are responsible for the coordination with military authorities regarding national and defence security measures, and coordinate civil security means and actions. Regarding this last mission, according to Article R.1311-3 of the Defence Code, they can involve public and private means, requisitioning them if necessary. Reference health institutions are designated in each defence and security area (“Décret n°2005-1764 du 30 décembre 2005 relatif à l’organisation du système de santé en cas de menace sanitaire grave et modifiant le Code de la santé publique”).

The prefect for the defence and security area relies on an interministerial general staff (EMIZDS) and, in case of a crisis, can activate an operational centre at the level of the defence and security area (COZ), which ensures coordination of aid and rescue operations. A representative of the armed forces takes part in the EMIZDS. He relies on an inter-armed forces general staff for the defence area (EMIAZD), with close links with the EMIZDS, and organizes involvement of armed forces in civil defence missions.

### ***9.3.3 Civil Security and the Involvement of the Armed Forces in the National Territory***

Protection of the population and of the national territory is a priority. The French White Paper on defence and national security identifies a strategy involving both civil and military means. Armed forces must be able to contribute to the response, should a non-military crisis situation arise, whatever its nature. Law enforcement and civil security forces are first-responders, but armed forces can provide support, especially if public means are limited, inadequate, unavailable, or non-existent. Furthermore, the Ministry of Defence contributes directly to civil security and assistance, including in the context of public health threats, through civil security military units placed at the Ministry of Interior’s disposal, as well as with the Paris Fire Brigade and Marseille Marine Fire Battalion, or the Army Health Service and its hospitals.

Armed forces can intervene within the national territory in several contexts:

- National security, including maintenance of law and order, armed forces participating in addition to law enforcement forces (police and gendarmerie);
- Civil security, which addresses “risk prevention whatever their nature, information, warning of populations, as well as protection of persons, possessions and environment against accidents, disasters and catastrophes by implementing

relevant measures and means under the responsibility of the State, “territorial collectivities” and other public or private persons” (“Loi n°2004-811 du 13 août 2004 de modernisation de la sécurité civile”);

- Non-specific mission, such as making equipment available, with or without staff on secondment.

As explained in joint service concept CIA-0.7 n°163/DEF/CICDE/NP of 11 May 2007, on the national territory, among other missions, armed forces can contribute to the fight against terrorism, in particular international terrorism, the fight against arms trafficking, arms components and proliferation, the protection of sectors of vital importance, the protection of major events on the national territory, and aid and emergency relief for populations in a crisis situation.

Armed forces can assist following the appropriate administrative or legal requisition and, in specific cases, if there is otherwise a request for support. Administrative requisitions can occur in the context of maintenance of law and order, violation of public security in emergency cases, and intervening against terrorism or in the case of a major crisis on the national territory. Actions are then carried out under the responsibility of civil authority and under military command, in coordination with law enforcement authorities.

## 9.4 Legal Framework, Plans and Guidelines

### 9.4.1 *Exceptional Situations and Serious Health Threats*

Several dispositions govern exceptional situations which can call for the extension of powers granted to authorities and restrictions on fundamental liberties.

A decree by the Council of Ministries may proclaim a state of emergency under the Act n°55-385 of 3 April 1955, in the event of imminent danger arising from serious disturbances of public order or from events which by virtue of their nature and severity are deemed to be public disasters. Prorogation beyond 12 days may be authorized only by law. Comparing with the state of siege, civil authorities and not military ones are granted extended powers.

Article 36 of the 1958 French Constitution governs the state of siege, codified in Articles L.2121-1 to L.2121-8 of the Defence Code. Enacted by the Council of Ministers, it can be proclaimed only in case of imminent peril resulting either from a foreign war or an armed insurrection. Prorogation beyond 12 days may also be authorized only by law.

Besides, Article 16 of the Constitution extends the powers of the President of the Republic. It authorizes him to take measures required by the circumstances, “[w]hen the institutions of the Republic, the independence of the Nation, the integrity of its territory or the fulfillment of its international commitments are under serious and immediate threat, and when the proper functioning of the constitutional public powers is interrupted”. The Constitution requires the President to consult the Prime Minister, Presidents of the Assemblies, and Constitutional Council (*Conseil constitutionnel*).

The latter then issues an advisory opinion that the President can disregard but which is made public. Constitution Act n°2008-724 of 23 July 2008 introduced democratic control on duration. After 30 days of exercising such powers, the president of one of the two assemblies, 60 Senators or 60 Members of the National Assembly can appeal to the Constitutional Council for it to consider whether the conditions laid in the first paragraph still apply. Its decision is publicly announced. After 60 days and at any moment thereafter, the Council carries out such an examination as matter of standard procedure.

Legislators went further regarding the specific issue of preparing the public health system for major health hazards. Law n°2004-806 of 9 August 2004 on public health policy created a new preliminary chapter regarding serious health threats in the Public Health Code. Law n°2007-294 of 5 March 2007 on the preparation of the health system to deal with large-scale health threats added other articles; this chapter became Chapter I of the new title dedicated to serious health threats.

Article L.3131-1 of this chapter states that “in the event of a major health hazard requiring emergency action, in particular a possible epidemic, the Minister for Health may, by order with justification and in the interests of public health, prescribe measures proportionate to the risk incurred and appropriate to circumstances of time and venue, in order to prevent and limit the consequences of the possible threats on the health of the population”, and “[t]he Minister may empower the territorially competent representative of the State to take all the measures required for the implementation of these provisions”, which implies the necessity to have an adequate articulation between the Ministry of Health and the Ministry of Interior. Article L.3110-2 rules that justifications of measures taken in implementation of the previous article must be periodically reviewed.

Considering these two articles, in a published opinion about ethical issues raised by a possible influenza pandemic, the National Consultative Ethics Committee for Health and Life Sciences (CCNE) draws attention to the risk of extending restrictions on fundamental liberties “beyond what is strictly required to contain the influenza pandemic, either because of a maximalist (and therefore inappropriate) conception of the precautionary principle or as a demagogic concession” [2].

The title about serious health threats also includes dispositions to protect health professionals from potential civil liability in carrying out their duties following decisions from the Ministry of Health accordingly, on the one hand, and makes provisions for compensation of potential victims, on the other hand. Some dispositions also relate to the constitution and organization of a health reserve corps.

## ***9.4.2 Preparation and Response Plans***

### **9.4.2.1 ORSEC Civil Emergency Plan**

In France, the pre-hospital strategy in case of mass casualties relies on regulation and advanced medical posts, with a controlled evacuation in order to protect hospitals

from massive influx. It thus differs from the “scoop and run” strategy where the patient is immediately taken to hospital.

Revised by law n°2004-811 of 13 August 2004, the ORSEC plan, adapted in each department and defence and security area, specifies the global organization of civil security response in the case of mass casualties and inventorying public and private resources which could be used. Some measures are generic, while others address specific risks and threats (e.g. white plans).

#### 9.4.2.2 White Plans

Complementary with the previous plan, each public or private health institution has to develop a White Plan (“Circulaire n°DHOS/CGR/2006/401, 14 September 2006”), a crisis response plan in the case of a mass influx of patients or victims or in the case of an exceptional health crisis situation. They are also obliged to have an operational crisis cell responsible for alert and crisis management (Articles L.3110-7 to L.3110-10 of the Public Health Code). White Plans include a CBRN component. CBRN risk management takes into account the geographical location of health institutions as well as emerging risks.

White Plans are integrated in a “widened” White Plan, coordinating the public health system at the department level. It defines the role of health actors according to three types of scenarios: mass influx of victims with no risk of contamination, contaminated and contaminating victims, and evacuation of health medical institutions.

#### 9.4.2.3 CBRN Threats and “Pirate” Plans

Vigipirate, a governmental plan of vigilance, prevention and protection, addresses terrorism and aims at protecting populations, institutions and infrastructures, as well as at preparing for response. It relies on a principle of shared responsibility and a permanent security posture, with the addition of graduated and flexible measures according to the national and international threat assessment. There are four colour-coded alert levels.

No indication of threat
Vague threat
Plausible threat
Highly plausible threat
Immediate threat of major attacks

This plan can be complemented by “Pirate” plans, focusing on specific threats. All these plans, elaborated under the responsibility of the SGDN (now SGDSN), result from an interministerial process.

The CBRN plan, which is classified, results from the merging of the Piratome (NR), Biotox (B) and Piratox (C) plans. The implementation of the whole plan or of part of it is not dependent on the Vigipirate alert level, but an alert level can involve the implementation of specific measures. The CBRN plan is regularly tested through exercises.

The plan specifies how to initiate the implementation of the plan, when necessary, and describes alert chains and responsibilities. Various situations are taken into account. It addresses for example issues such as contamination of the food chain, of a pharmaceutical chain or of the water network, as well as the receipt of a suspicious letter or parcel. It also considers events which could occur abroad, in order to be able to protect the national territory as well as to help French citizens which could be affected.

The CBRN plan is also complemented by other guidelines and plans such as:

- A document that details what procedure should be implemented in case of a suspicious letter, parcel, package or substances (“Circulaire n° 750/SGDSN/PSE/PPS, 18 February 2011”). To help avoid exceeding the analysis capacities, a specific cell (*Cellule nationale de Conseil – CNC*) has been created in the aftermath of the events in the United States in 2001. Its role is to contribute to a triage strategy and to help and counsel the department prefect.
- Specific guidelines regarding plague, anthrax and tularemia have been annexed. It deals in particular with: (1) Strategies of response, within three potential scenarios; (2) How to take charge of exposed individuals (on site, at home, at hospital), including evacuation and decontamination, as well as potential isolation; (3) How to transport specimens for the biological analysis, from the site of the bioterrorist attack to the laboratory; (4) How to plan for mass prophylaxis with antibiotics; (5) Environmental detection and decontamination; (6) How to take care of the deceased; and (7) Details and addresses for the Biotox-Piratox laboratories network. There is also a guide for toxins.
- A document addressing the consequences of a smallpox threat, specifying the strategy of response, including vaccination according to the number of exposed and geographic distribution, and the response organization. Mandatory vaccination was abrogated in 1984. However, Article L.3111-8 of the Public Health Code states that “in case of war, public disaster, epidemics or epidemic threat, anti-smallpox vaccination or re-vaccination can be made mandatory [...] for each person, whatever the age”. Articles D.3111-19 to D.3111-21 give the specific details.
- A plan dedicated to the distribution of medicines which would be transported from national sites of stockpiling and would be distributed under the responsibility of a pharmacist, with the Minister of Health in charge of the coordination (“Circulaire du 20 mars 2003 relative à l’organisation de la distribution de médicaments dans le cadre d’une agression bio terroriste de grande ampleur”).

Plans are periodically amended to take into account lessons learned from past crises and they are regularly tested through exercises at various levels.

#### **9.4.2.4 Threat of Infectious Diseases and Specific Health Plans**

Besides the smallpox governmental plan mentioned above, a number of other specific health plans address infectious diseases issues. They include the SARS and pandemic influenza national plans, as well as some plans, the implementation of which is required from prefects at the departmental level. They deal with the distribution of antibiotics (*Plan Fluoroquinolones*), drinking water, and air monitoring (*Plan Eau potable* and *Plan Air*).

### **9.5 Focus on Public Health Services**

Public health services are key components, deeply involved at each stage, from preparation and prevention to early warning and crisis management. The cabinet of the Ministry of Health assesses propositions from public health agencies and issues decisions. The Senior Defence and Security Officer (HFDS) coordinates actions related to CBRN. In the case of a crisis, the Ministry can activate the public health crisis centre, which is in liaison with the Ministry of Interior's CIC and with health structures at territorial, national, European and international level.

The Ministry of Health includes a service dedicated to crisis situations, the Department of Public Health Emergencies (DUS). It relies on a number of public health agencies and on a laboratory network. The most relevant agencies in the context of an infectious disease crisis are the French National Institute for Public Health Surveillance (InVS), the French Health Products Safety Agency (AFSSAPS), and the Health Emergency Preparedness and Response Agency (EPRUS). Food safety and environmental issues are addressed by the French Agency for Food, Environmental and Occupational Health and Safety (ANSES).

#### **9.5.1 Department of Public Health Emergencies (Département des Urgences Sanitaires – DUS)**

This structure within the General Health Directorate, Ministry of Health, takes part in the preparation of the response to health risks and threats linked to natural events, outbreaks, technological accidents or terrorism acts, including bioterrorist events. It relies on a global integrated approach.

A key component, the DUS, develops policy and doctrine for the health reserve corps and prepares the response to serious health threats, including terrorist actions. It is responsible for the operational coordination of the response, including the operational management of emergency or health crisis situations. A unique point of entry for information relative to alerts, it gathers, analyses and registers information when national or international events occur. There is an operational centre for the reception and regulation of health and social emergencies (CORRUSS).

The DUS receives information from departmental and interregional institutions and from InVS. The DUS is also linked with other services dealing with crises, for example the Interdepartmental Operations Centre for Crisis Management (COGIC) of the Ministry of Interior or the French Joint Operations Planning and Command and Control Centre (CPCO) of the Ministry of Defence.

### ***9.5.2 French National Institute for Public Health Surveillance (Institut de Veille Sanitaire – INVS)***

InVS, the motto of which is “watch, monitor, alert”, is responsible for continuous monitoring of the population’s health status, health surveillance, health alerts, and assistance in health crisis management.

Surveillance of infectious diseases is one of the missions given to the Institute, tasked with identifying public health threats at an early stage, giving early warning, and providing information to decision-makers. It also monitors on-going events and does post-crisis evaluation in order to integrate lessons learned. In fiscal year 2010, the budget for the infectious disease surveillance programme amounted to EUR 21.2 million, representing 33% of the overall operating budget. The A(H1N1) influenza programme received an additional 2% [4].

The Institute uses specific as well as non-specific (syndromic) surveillance systems. Syndromic surveillance can be defined as the collection of non-statistical data on health trends, followed by their analysis and interpretation. Its objective is the early detection of health threats and real-time (or near real-time) health impact assessment of events. It has for example proven effective in the monitoring of infectious disease outbreaks such as gastrointestinal diseases, influenza, and viral meningitides, as well as cold spells or heat waves. This tool must be effectively integrated into the public health system [7]. It is intended to enhance and not replace other traditional approaches for epidemic detection.

Adapted to take into account bioterrorism (or even chemical or radiological terrorism), it could contribute to the early detection of a bioterrorist event, focusing on symptoms instead of confirmed diagnoses (detection through syndromic surveillance instead of through clinician reporting), thus reducing the delay between exposure and administration of a prophylactic or curative treatment (when available). It could also give information about the size, spread, and other characteristics of an outbreak after detection.

In France, the Syndromic Surveillance Programme was launched in 2004 by the InVS, following the consequences of the 2003 heat waves. Prior to that, the health surveillance and early warning systems were nearly entirely based on sentinel networks and mandatory declarations for a list of diseases. The methodology is based on use of retrospective and prospective studies. It implies defining specific criteria, like alert indicators and thresholds. Bioterrorism is one of the potential situations taken into account.

The French syndromic surveillance system, SurSaUD<sup>®</sup>, relies on three kinds of sources to collect data: emergency departments (OSCOUR<sup>®</sup> network), emergency general practitioners service (*SOS Médecins*) and, for mortality data, city registry offices. These three systems are entirely computerized and automated. The data are automatically collected daily, and then transmitted after encryption. This transfer respects the national patient confidentiality rules. For the sake of analysis, the following data are collected from the emergency departments: age, gender, zip-code, reason for emergency admission, and main medical diagnosis (based on the CIM10). The collected data must then be analyzed which relies on algorithms.

Evaluations are crucial to be able to demonstrate the utility of syndromic surveillance. However, they are difficult to carry out and specific criteria of evaluation must be defined [1]. The French system has, for example, been assessed in the context of the 2006 heat wave [3]. Almost all the data required for daily analysis were acquired. But one important observation was that it was not possible to use other data transmission methods other than internet, highlighting the necessity to develop solutions to be able to proceed even in case of a network failure. The authors also noted the study presented some limitations, as several parameters were not taken into account and the time period was limited as was the representativeness (with less than 40% of all emergency departments regional activity analyzed). They underlined the need to research and determine criteria which should be evaluated in other situations, as well as the possible necessity to confirm the results through other studies under the same weather conditions.

At the European level, the InVS coordinates Triple S – Syndromic Surveillance Survey and assessment towards guidelines for Europe – a 3-year project launched in 2010. Co-financed by the European Commission, it involves 24 organizations from 14 countries. Its objective is to assess existing European syndromic surveillance systems and will provide scientific and technical guidelines for the development of such systems. It aims at enhancing European capabilities regarding (near) real-time surveillance and monitoring in the context of expected or unexpected health-related events.

### ***9.5.3 French Health Products Safety Agency (Agence Française de Sécurité Sanitaire des Produits de Santé – AFSSAPS)***

Created in 1998, AFSSAPS's missions encompass scientific and medico-economic evaluation, laboratory control and advertising control, as well as inspections of industrial sites. It takes safety decisions concerning health products, from manufacturing to marketing, and coordinates monitoring activities once they are authorized. This includes the management and evaluation of biomedical research, to ensure protection for the people involved by assessing the safety and quality of products.

AFSSAPS contributes to preparedness and response against bioterrorism and emerging health threats by assessing therapies and publishing therapeutic guidelines. Factsheets for drug treatment protocols address anthrax, plague, tularaemia,

brucellosis, viral hemorrhagic fevers, smallpox, botulinum toxin, Q fever, other bacterial infections, biological agents for which no specific or prophylactic treatment can be recommended, as well as the course of action in an emergency situation when the agent is not yet identified (available on the AFSSAPS website). It would be involved in crisis management regarding issues pertaining to medical countermeasures. It could for example need to issue temporary authorizations for use (ATU), which are exceptional procedures enabling the use of pharmaceutical products without a marketing authorization in France, outside the usual framework of a clinical trial (e.g. for smallpox vaccination). ATU can be granted for health products meant to treat, prevent, or diagnose serious or rare diseases, when no appropriate approved therapeutic alternative exists and when the efficiency and safety are presumed given current scientific knowledge of the product. Moreover, in this context, maintaining stockpiles means performing regular quality controls and has thus generated specific requirements in terms of laboratory activities.

At last, AFSSAPS contributes directly to biological safety and security. According to Article R.5139-1 of the Public Health Code, created by Decree n°2010-736 of 30 June 2010, it issues and manages authorizations regarding production, transport, importation, exportation, possession, supply, transfer, acquisition, and use of microorganisms and toxins. Article L.5139-1, modified by Ordinance n°2010-18 of 7 January 2010, specifies that these measures apply to microorganisms and toxins when their use could pose a risk for public health, as well as to products containing these agents.

#### ***9.5.4 Health Emergency Preparedness and Response Agency (Etablissement de Préparation et de Réponse Aux Urgences Sanitaires – EPRUS)***

This specific structure was created in 2007 to improve preparation and response to health crises and is dedicated to the management of acquisition, production, imports, stockpiling and distribution of pharmaceutical products: it manages the French national stockpile of medical countermeasures (“Loi n°2007-294 du 5 mars 2007 relative à la préparation du système de santé à des menaces sanitaires de grande ampleur”, “Décret n°2007-1273, 27 August 2007”). Its mission is to implement the crisis management strategies drafted by the General Health Directorate.

It also has to organize the health reserve corps, recruiting on a voluntary basis. It can be called when facing a situation of exception exceeding the usual capacities, in order to strengthen medical and social care structures. Reservists can be mobilized through a joint decree from the Ministries of Health and Interior. This corps is divided in two, with health professionals liable to be called up very quickly for intervention on national territory or abroad, and a pool including retired health professionals and medical and paramedical students for reinforcement in case of a long term serious health threat.

### ***9.5.5 Biotox-Piratox Laboratories' Network***

In 2003, in the aftermath of the anthrax letters event and the following hoaxes, a three-level laboratories network was created in order to deal with the consequences of a biological attack. The network includes civilian private and public laboratories, as well as military laboratories. A scientific council consisting of civilian and military experts meets monthly.

The network provides capacities in terms of biological or chemical toxicological analysis of environmental, veterinary or human samples. Laboratories can be involved in evaluating suspicious envelopes, parcels or substances; foul play against animals, plants, and especially the food chain, the water network, and the transport of biological agents; and victims in case of biological or chemical attacks. Achieving a better coordination and standardization of laboratory procedures implies a process of accreditation. Beyond detection and identification for crisis management, the objective is also to take into account forensics requirements and guarantee traceability with a procedure acceptable from a legal point of view (the sample constitutes evidence).

The first level of this network gathers many laboratories which have a role for screening and alert. They can collect and send samples, and ultimately proceed to a first analysis. The second level, which has a key role in the global system, is composed of reference laboratories and associated laboratories, designated in each defense area, and which have the capacities to identify some or all agents linked to bioterrorism. The last level is constituted by national reference laboratories; the BSL-4 laboratory is integrated in this level, as well as military laboratories such as the Centre d'Études du Bouchet (CEB) or the Centre de Recherche du Service de Santé des Armées (CRSSA).

## **9.6 Conclusions**

From prevention to recovery, actions and response of stakeholders have a direct impact on the development and management of the crisis and its consequences. Proceeding to post-crisis assessments and sharing experiences, in order to enhance existing plans and procedures, is a crucial aim. The French plan against bioterrorism pre-dated the 2001 anthrax attacks, but these events, followed by numerous hoaxes, contributed to raise awareness and prompted a reassessment of existing measures. SARS outbreaks and influenza pandemic threats have also led to improvements in terms of biopreparedness.

Regardless of the nature of the potential crisis involving an infectious disease (natural, accidental or intentional), effective planning, preparedness training and efficient crisis communication have a determining impact on individual and societal resilience. In this perspective, one objective of the strategy developed in the pandemic influenza plan is indeed to organize and ensure continuity of Government action as well as of social and economic life. It is of importance to continue to adopt

and adapt efficient institutional and business continuity plans to be able to face a public health crisis, and though there is a focus on critical infrastructure operators, all enterprises are encouraged to do so. But the key challenge remains to raise and maintain awareness not only of first-responders and operators but also of French citizens, as they are also key players, the reactions of whom may have a direct impact on the development and management of a crisis and its consequences.

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