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**“MARKET SURVEILLANCE IN THE EU –
OVERVIEW OF THE FRENCH SYSTEM”**

This paper on the French market surveillance system has been circulated for information to delegates. It is a presentation made by Mrs. Poncin, French Ministry of the Economy, Finance and Industry in Asia on 23 and 24 September 2004, in the context of a seminar co-sponsored by the European Commission in the field of technical regulations, standards and conformity assessment.

The paper is reproduced in the form in which it was received by the secretariat.

This paper is structured in the following way: first review the place granted by the French authorities to market surveillance, next present an organisation of market controls in France and give a few concrete examples in areas covered by the "New Approach" Community policy and finally discuss emerging market surveillance issues in international trade relations.

What is market surveillance?

Market surveillance can be defined as one or more supervision procedures adopted and managed by the authorities to make sure that:

- the products placed on the market, consumer goods and equipment, meet public criteria for public health protection, security, consumer and worker protection, environmental protection as well as efficacy criteria;
- business transactions between economic operators take place in compliance with the principle of fair competition.

This is a broader definition than the one normally used these days by the European Union (in the European context, the expression "market surveillance" refers to an instrument to ensure application of the EC so called New Approach policy).

- **What are the key words of this definition?** Products placed on the market, a reference to the legal framework, to administrative organisation and supervision techniques, but also a concept of society. **Market surveillance not only implies a legal framework, an administrative organisation and supervision techniques. Making sure that newly marketed products are safe is not just a legal obligation for the authorities, it is also a moral and political responsibility.**
- In addition to an inspection - and therefore disciplinary - rationale, market surveillance serves an economic purpose. It is an economic regulation instrument whose aim is to make sure business transactions take place on a same level playing field. This is an important factor for the French authorities and for the other European countries.

SECTION I – WHICH PLACE IS GIVEN TO MARKET SURVEILLANCE IN FRANCE?

A. THE EXPERIENCE OF FRANCE:

As preliminary comments, it is worthwhile saying that the expression "market surveillance" is not a legal term found in traditional French law or in the laws adopted by France to transpose Community regulations on technical harmonisation and technical conformity of products and services. It can be considered as an administrative term which was introduced about twenty years ago during the great reform of Community policy on technical harmonisation (the so-called "New Approach" and "Global Approach").

The whole EC legislation, and not only the New Approach, is aimed at ensuring the criteria of innocuousness, safety and efficacy of the substances, processes and products are satisfied.

In French laws and regulations, the principle of market surveillance is expressed as follows: the term general product safety is used for consumer goods; drug-vigilance for medical drugs (pharmacovigilance in French); and medical devices vigilance for medical devices (materio-vigilance in French). The concept of sanitary vigilance is an important pillar of the sanitary safety policy. The objective is to detect incidents/accidents prejudicial to the safety and health of people and to environment, and to identify their origin by implementing a prevention policy.

1. *The experience of France- A long-established practice and law antedating the construction of a single Europe*

However, France can claim historic experience with practical application of the concept of market surveillance and laws from before the construction of a single Europe. The origins of French market surveillance rules can be found in contract law, general legislation and jurisprudence (case law). Two laws in particular need to be mentioned since they are the legal cornerstone of France's modern market surveillance system:

- the law of 1 August 1905 on fraud and forgery - punitive rules which complement Civil Code provisions on attempts to mislead buyers. This has become a de facto consumer protection chart. Its application is monitored by a special administrative department created in 1907 - the Fraud Control department, nowadays part of a larger administration belonging to the Ministry of the Economy, Finance and Industry and known as the General Directorate for Fair Trading, Consumer Affairs and Fraud Control¹;
- the law of 21 July 1983 on consumer safety, which confirmed and unified the safety obligations found in contract law. A considerable body of case law has arisen around this law, which stipulates inter alia that providers must ensure the safety of anyone who may be harmed by products or services put on the market. This law inspired the development of a Community law- the EC directive on general product safety.

Moreover, the law of 1 July 1998 on reinforcing health monitoring and control of all products for human use

2. *A prerogative of the authorities*

Regardless of the type of product placed on the market, the authorities may inspect its conformity according to predetermined procedures. Economic operators putting a product for the first time on the market (producers, importers) are obliged (by law) to verify beforehand that it is in compliance with the laws in force in France and to provide evidence of conformity when requested by the inspection authorities.

However, this inspection prerogative is subject to rules. When the French authorities decide to adopt particular market surveillance measures (other than those transposing Community directives), such measures may not generate unjustified barriers to trade (based upon the criteria of necessity and proportionality provided for by the EC law and the French law) .

3. *A new dimension with the setting up of the European Union*

With the setting up of the European Union, the adoption of harmonised safety rules within the framework of the single market and a new division of monitoring tasks for product safety between the authorities and economic operators, in certain sectors, have prompted the authorities to review their administrative organisation and rules of law.

¹ *Direction Générale de la Concurrence, de la Consommation et de la Répression des fraudes* - DGCCRF

The European Community has particularly introduced the concept of administrative cooperation between Member States. Moreover, market surveillance procedures are no longer managed exclusively by the authorities but also by other players, such as businesses, conformity assessment notified bodies, and European and national standardisation organisations.

B. THE LEGAL FRAMEWORK

In the European Union, Member states are competent to enforce EC legislation, this principle is called subsidiarity. This does not rule out Community actions in the field of market surveillance, but Member state remain competent to implement the EC legislation on market surveillance.

The European Treaties of Maastricht, Amsterdam and Nice have not affected the legal power of the EU Member States to adopt all measures required for surveillance of their home market, if such measures do not interfere with Community instruments or if Community instruments are deemed inadequate.

1. *Sector oriented EC obligations on market surveillance*

"e.g. the RTTE Community directive 99/05

The Member States must:

- make sure the equipment/products placed on the market comply with the substantive requirements (placing on the market provision);
- take all necessary measures to withdraw equipment which does not comply with substantive requirements from the market or to stop its operation, prohibit its marketing or use or restrict its free movement (safeguard provision);
- take adequate measures against anyone affixing non-conform CE markings.

2. *Cross-functional Community obligation: Two EC directives with different objectives:*

(a) *Ex-ante product safety and the prevention of damage: Community directive 2001/95, amended, on general product safety:*

- It imposes a general safety obligation for newly marketed products intended for or likely to be used by consumers;
- It sets out relevant obligations for producers and distributors and for the Member States;
- This Community directive can be considered complementary sector-oriented legislation since it specifies necessary administrative and inspection requirements not stipulated in the New Approach Community directives;
- It sets up a rapid information alert system- RAPEX

(b) Compensation measures: Community directive 1985/374 of 25 July 1985 concerning liability for defective products and French law

General remarks: In addition to preventive and punitive rules, compensation of victims is an important pillar of the legal system. In France, compensation may reflect civil liability (when damage occurs), insurance (producers generally take out liability insurance) and criminal liability (when the provider is at fault).

The Community directive on product liability is a keystone of the existing liability system, whose purpose is to provide compensation for damage caused by unsafe products. Its aim is therefore to protect the consumer. This harmonisation directive has prompted France to adjust its national laws on liability

The content of EC directive can be summarised as follows:

- damage caused by products;
- liability for the producer and burden of proof for the consumer: *the victim must prove the damage, the defect and the causal relationship; the producer must prove the existence of facts releasing it from liability;*
- "The producer is liable for damage caused by a defect in its product";
- grounds for release from liability, such as the development risk ("the producer is not liable if it proves that the state of scientific and technical knowledge at the moment when it placed the product on the market was insufficient to detect the existence of the relevant defect");
- compensation in principle entirely.
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The example of electrical equipment (low voltage directive)

What are the EC OBLIGATIONS ON MARKET SURVEILLANCE FOR THE ELECTRICAL EQUIPMENT?

(EC directives 73/23, 93/68, directive 2001/95 on general safety)

MEMBER STATE	PRODUCER:
<p>1. Actions on the market</p> <ul style="list-style-type: none"> ▪ Checks, to take samples ▪ Information on product with risks ▪ Dangerous product: temporary ban (supply, of marketing), withdrawal, recall from consumers and destruction. <p>2. Transparency and notification</p> <ul style="list-style-type: none"> ▪ safeguard clause (restrictions on the placing on market) ▪ RAPEX ▪ Access to information by on products with risks/ rules of confidentiality <p>3. Legal system: sanctions and remedies</p> <p>4. Administrative cooperation</p>	<p>1. Action on the market</p> <p>Monitoring of the safety of products; e.g. to organise a system to be informed of risks linked to products, to take actions such as withdrawal from the market, warning consumers and recall from consumers</p> <p>2. Transparency</p> <p>Information of the consumer on risks Information of the competent authority on dangerous products and on action taken</p> <p>3. Cooperation</p> <p>With the competent bodies on actions</p>
	<p>DISTRIBUTOR: not to supply dangerous products, to participate in the monitoring, to inform competent authority</p>

EC COMMISSION: EC decision for product with serious risk

2. The structure of French market surveillance law

French law on market surveillance is highly sophisticated. It is based upon general provisions (such as the product safety obligation stipulated in the Consumption Code) and on particular regulations. It factors in Community legislation.

The market surveillance rules for each sector or product are set out in one or more legal codes. e.g. the Consumption Code for consumer products (including toys), the Labour Code and the rural Code for machinery and personal protection equipment, the Public Health Code for medical drugs, medical devices and cosmetics, and the Post Office and Electronic Communications Code for telecommunications terminal equipment.

In transposing the "New Approach" Community legislation into French law, France may use a range of legal instruments of which laws or government ordinances, decrees, etc....

SECTION II- ORGANISATION AND INTERVENTION TOOLS

Organisation and intervention tools- Five administrations with leadership

A. An administrative organisation driven by several authorities

1. The system hinges on **five Administrations with central and decentralised directorates or offices**: the Ministry of the Economy, Finance and Industry², the Ministry for Agriculture, Food, Fisheries and Rural Affairs³, the Ministry for Health and Social protection, the Ministry for Employment, Labour and Social Cohesion⁴ and the Ministry for Ecology and Sustainable Development⁵.

Overview of market surveillance by sector:

- * **Consumer goods/ consumer protection objective:** Ministry of the Economy, Finance and Industry (Three directorates are concerned: General Directorate for Fair Trading, Consumer Affairs and Fraud Control, the General Customs and Excise Directorate⁶ and General Directorate of Industry⁷.)
- * **Food, veterinarian drugs and living animals/ health protection objective:** Ministry for Agriculture, Food, Fisheries and Rural Affairs.

(possible joint actions with MINEFI/DGCRF and the Ministry for Health)

- * **Health (medical drugs for humans, medical devices, cosmetics):** Ministry for Health and Social protection

² *Ministère de l'Economie, des Finances et de l'Industrie (MINEFI)*

³ *Ministère de l'agriculture, de l'Alimentation, de la Pêche et des Affaires Rurales*

⁴ *Ministère de l'Emploi, du Travail et de la Cohésion Sociale*

⁵ *Ministère de l'Ecologie et du Développement Durable*

⁶ *Direction Générale des Douanes et des Droits Indirects*

⁷ *Direction générale de l'Industrie*

- * **Machinery and personal protective equipment:** Ministry for Employment, Labour and Social Cohesion

(Possible joint actions with MINEFI/DGCCRF)

- * **Environment and chemicals:** Ministry for Ecology and Sustainable Development

(possible joint actions with the Ministry for labour, for Agriculture, MINEFI/DGCCRF, Ministry for Health)

2. Main features of French system

2-1. Customs applies market surveillance rules to products imported from countries outside the European Community. This occurs at the border. In all other cases, the remaining supervisory authorities take action on the French market.

2-2. The administrations owe their authority to the lawmaker, who decides to grant particular powers to inspection bodies answerable to the relevant ministries. The authority and powers of inspection officials are laid down in legal codes, as are penalties and compensation measures.

Their structure rely on a central Directorate and on decentralised units. In the field of telecommunication equipment, market surveillance is monitored by the ART (Agency) as well as by two competent authority (Customs and DGCCRF).

2-3. The competent authorities may have access to scientific and technical expertise (laboratories and access to bodies in charge of risks assessment).

2-4. Depending upon the product in question, a market surveillance action may involve more than one administration (non simultaneous inspections).

2-5. Cooperation between administrations at the national level, between national and Community authorities and between Member States.

2-6. An economic operator may take legal action to dispute regulatory measures adopted by a government service charged with market surveillance.

French competent authorities

B. MINISTRY OF THE ECONOMY, FINANCE AND INDUSTRY AND MARKET SURVEILLANCE

B-1. FRENCH CUSTOMS

- The French Customs administration is charged with market surveillance at the border. Its mission is to check, **before customs clearance**, that products or the French market comply with the substantive requirements and conformity assessment procedures laid down by EC or French current regulations (e. g. EC directives under the Old and the New Approach- noise limits for construction site machinery; electromagnetic compatibility; the low-voltage directive; toys; pleasure boats; machines; personal protection devices and telecommunications terminal equipment, and products covered by specific French technical regulations (such as bicycles, articles for babies, etc.).

- Such inspections are not conducted systematically and take the form of spot checks. Inspection of product documents, which may be complemented by physical product examination (including laboratory tests). This type of inspection is mainly conducted to check compliance with CE markings.

B 2. GENERAL DIRECTORATE FOR FAIR TRADING, CONSUMER AFFAIRS AND FRAUD CONTROL (DGCCRF)

1. General presentation

- It sees to fair and safe operation of the markets, which involves the development of rules, inspections and as applicable court-ordered penalties. Its task is primarily to guarantee the quality of products and services and to protect the consumer. **It has therefore been given preventive and disciplinary authority to enforce market surveillance of consumer goods.**
- It oversees products already placed on the French market, which it monitors independently or in collaboration with other administrations, and conducts administrative cooperation actions with European counterparts (cross-border operations).
- Its administrative organisation consists of a central administration, local services and specialised units to supply the necessary technical expertise.. Its expertise is as necessary complemented by **recommendations from scientific bodies** (such as the French Food Safety Agency⁸, and by information obtained from a network on collecting data on home and leisure accidents).

2. Three main tools:



- (a) Regulatory approach: 3 instruments
- * **Definition and/or contribution to the definition of EC or national safety rules**
 - * **Implementation of Community rules**
 - * **Adoption of prohibition and emergency measures**: see point C.



Specific inspections of sensitive sectors where anomalies or accidents remain too frequent.



Information for professionals and local elected officials.

C- WHICH INTERVENTION TOOLS AND PENALTIES ?

C-1 THE CUSTOMS

1. Economic operators have three solutions: to make their product conform under Customs control if technically feasible; to-export their product or destruction of their product if dangerous. **Products which do not comply with the regulations are always seized.**

⁸ *Agence Française de Sécurité Sanitaire des Aliments (AFSSA)*

2. Penalties

* “Gentlemen agreement”

Fine (legal action): the operator is fined once or twice the value of the seized goods and required to pay a sum of money for its goods and means of transportation to avoid confiscation

C-2 DGCCRF

It may adopt temporary or final measures depending upon the degree of danger presented by the product and upon its compliance or non-compliance with the regulations:

* If the product is acknowledged to be in compliance or is not regulated, the Minister of Consumer Affairs and the other ministers concerned may adopt:

- **Temporary:** Suspension of the product for a term of at most one year to suspend the manufacture, the importation or the marketing of the relevant products or services, or to direct their withdrawal or recall from the consumer. The operator is sent an injunction to review its manufacturing process and a dialogue is organised with representatives from industry, employee and consumer organisations.
- **Permanent measures (decree) to rule the conditions of manufacturing and marketing of the product.** Moreover the decree may order products to be withdrawn from the market, to be recalled for modification or to be destroyed if necessary (...) and stipulate consumer information obligations.

* When a product is dangerous and is not in compliance with the regulations it becomes the preserve of the criminal courts (which may order its confiscation).

* In the case of a non-conform product: the economic operator is ordered to make its product conform, destruction of product. The DGCCRF cannot seize a product (decision of the criminal courts).

III. MARKET SURVEILLANCE AND INTERNATIONAL TRADE RELATIONS

A. **WTO AGREEMENT ON TECHNICAL BARRIERS TO TRADE (TBT AGREEMENT)**

The disciplines of the WTO/TBT Agreement do not expressly address market surveillance. The administrative organisation and the tools of intervention in the field of market surveillance are not covered by the definition of TBT agreement related to a technical regulation (since this document does not set out the characteristics of products, processes and production methods). However, market surveillance is on the agenda of the TBT Committee for two reasons:

- Regulatory measures adopted for dangerous products, which rule the manufacturing conditions for a product may be covered by the TBT rules, and therefore should be notified;
- It is an important system to allow implementing a conformity assessment system based on the supplier's declaration.

The TBT triennial review concluded in November 2003, the WTO Committee acknowledged this aspect when stating in paragraph 35: "To be effective, the supply conformity declaration needs to be accompanied by the following: effective legislation on product liability, improved market surveillance mechanisms with adequate resources and appropriate enforcement powers, penalties (...) and redress channels for consumers".

This proposed list of measures related to market surveillance is obviously not limited to products covered by the supplier's declaration, but is relevant for any risk products.

B. MARKET SURVEILLANCE AND TRADE NEGOTIATIONS

1. MUTUAL RECOGNITION AGREEMENT

The mutual recognition agreements negotiated by the EU with third countries do not include a general provision on market surveillance. Why? whatever there is a MRA, the imported product has been certified or not by a conformity assessment body under an MRA, national law and market surveillance procedures have been implemented for marketed products. However; every MRA provides for a procedure of exchange of information between regulatory authorities, as it relies on the confidence principle and on a high level of security and protection. Moreover, for sensitive sectors covered by the MRA, e.g. the medical device and medicinal products sectors, MRA clearly refers to vigilance procedures, to alert system and to a procedure of exchanging information on the incidents detected.

With regard to the structure of the MRA agreement, the agreement signed on February 2004 with the United States in the field of marine equipment is innovative, not only because it aims at equivalency of technical regulations but also because it includes provisions on market surveillance and on an alert system, in the framework agreement .

2. OTHER TRADE NEGOTIATIONS/DISCUSSIONS

The issue of market surveillance is one element of the chapter of technical regulations and standards dealt with in the regional and bilateral negotiations conducted by the EC with Mercosur countries and under the framework of Euro-Mediterranean partnership. This is a good approach. It can be foreseen that market surveillance will be more and more present in the future when having starting negotiations or dialogues on technical regulations and standards.

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