



Country Profile

The organisation of Food Safety,
Animal Health, Animal Welfare and
Plant Health Control Systems

Italy

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INTRODUCTION

This overview has been drawn up by the Food and Veterinary Office (FVO), a Directorate of the Directorate-General for Health and Consumers of the European Commission based on information supplied by Italy.

The aim is to present, in summary form, the latest information on how control systems for food and feed safety, animal health, animal welfare and plant health are organised in Italy.

Chapter 1 describes the overall organisation of the Italian authorities and the respective responsibilities of the ministries and government agencies in relation to the different components of the control system. A chart is used to help the reader better understand the inter-relationships between the responsibilities of the different bodies.

Chapter 2 gives a more detailed description of the main responsibilities for each of the eleven separate systems that form the complete range of control systems in Italy, covering the whole chain of plant, animal and food production. As in Chapter 1, organisation charts are used to help the reader.

Annex I provides details on the number of control staff in Italy. The statistics on staff resources have been provided by the Member States on a non-standardised basis.

The overview was updated following the most recent general follow-up audit in October 2011 and will be updated at regular intervals based on relevant information received by the Commission from the Italian authorities.

Acronyms are used extensively throughout this overview for the sake of brevity. A list of acronyms, abbreviations and special terms is given in Annex II as a guide for the reader

SUMMARY

In Italy most of the competencies for food and feed safety, animal health and animal welfare are assigned at national level to the Department of Veterinary Public Health, Food Safety and Collegial Bodies for Health Protection (DVPHFSCBHP) of the Ministry of Health.

The Ministry of Agriculture, Foodstuff and Forestry Policies (MIPAAF) is responsible for plant health and for controls on quality, labelling and traceability of food, feed and some aspects in the field of plant protection products and fertilisers.

Except for those matters explicitly reserved to the central government, such as matters of general State interest, import controls, international disease prevention, risk assessment in the food chain and consultation of producers and consumers, responsibility for controls has been devolved to regional level. The 19 Regions and 2 autonomous Provinces have responsibility, within their territories, for planning, co-ordination, guidance, authorisation, and verification, while the operational implementation of controls is handled at local level by 146 Local Health Units (AUSL) with a high degree of managerial autonomy.

There are 21 592 full-time equivalent staff involved in food safety controls in Italy. Of these 2,413 work at national level, 894 at Regional level, 12 035 at local level and 6 250 in laboratory services.

The updated MANCP for the period 2011-2014 is published on the Ministry website:

<http://www.salute.gov.it/pianoNazionaleIntegrato/paginaMenuPianoNazionaleIntegrato.jsp?lingua=italiano&menu=struttura>

The annual report for 2010 was provided to the Commission in June 2011 and is available at the following link:

<http://www.salute.gov.it/relazioneAnnuale2010/homeRelazioneAnnuale2010.jsp>

1. ARRANGEMENTS FOR THE IMPLEMENTATION OF CERTAIN REQUIREMENTS OF REGULATION (EC) N° 882/2004

Designation of competent authorities

Constitutional framework

The Italian Constitution allocates certain exclusive competences to the State (including international relations, matters of general state interest, import controls and international disease protection) and defines the areas where competence is shared between the State and the Regions. In the latter case, the State does not have exclusive legislative competence (but transposes EU Directives for the whole territory until overtaken by laws adopted in individual Regions). All administrative tasks in these areas and in the areas of health and food safety have been devolved to the Regions – unless otherwise provided.

The Ministry of Health (MH) was established most recently by Law n. 172 of 13 November 2009.

The 19 Regions and two autonomous Provinces have responsibility, within their territories, for planning, co-ordination, guidance, authorisation and verification of controls. (For the purpose of the country profile, references to "Regions" should be read as including the two autonomous Provinces).

Legislative Decree 193/2007 nominates MH, Regions/Autonomous Provinces of Trento and Bolzano, and Local Health Units as competent authorities for food safety, in order to implement Regulation (EC) No 852/2004, 853/2004, 854/2004 and 882/2004 and following modifications.

In Italy most of the competencies for animal health, food and feed safety, animal welfare, risk assessment in the food chain and consultation of producers and consumers are assigned at national level to the Department of Veterinary Public Health, Food Safety and Collegial Bodies for Health Protection, which is one (of 3) Departments in the Ministry of Health - MH. The operational implementation of controls is handled at local level by 146 Local Health Units (AUSL).

The Ministry of Agriculture Foodstuff and Forestry Policies (MIPAAF) is responsible for plant health and for the controls on quality of food, feed and some aspects in the field of plant protection products and fertilisers.

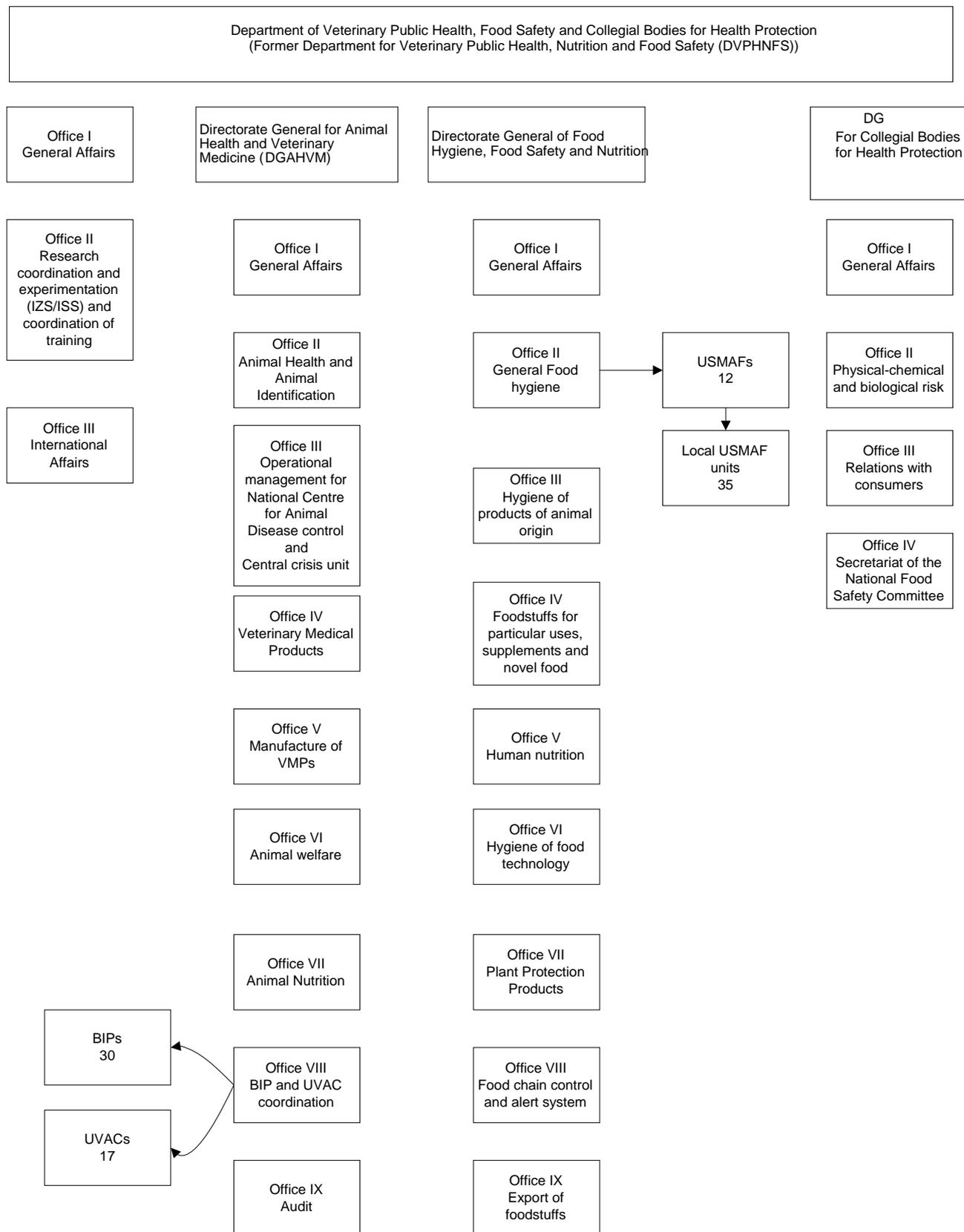
The central authority retains responsibility for national co-ordination, guidance, monitoring, supervision and inspection. The sectoral offices of the DVPHFSCBHP may carry out inspections directly (mainly in relation to specific problems and the approval of establishments for export to third countries), or through a dedicated body of the Carabinieri (the NAS). In parallel to these inspections, the DVPHFSCBHP (Audit Office DGAHVM) began to carry out audits of regional control systems in 2003 (see section on audit).

Ministry of Health – Department of Veterinary Public Health, Food Safety and Collegial Bodies for Health Protection (former Department for Veterinary Public Health, Nutrition and Food Safety)

Decree of the President of the Republic of 11 March 2011, n. 108, established the Department of Veterinary Public Health, Food Safety and Collegial Bodies for Health Protection. This comprises three Directorates-General (Directorate General of Animal

Health and Veterinary Medicine, Directorate General of Food Hygiene, Food Safety and Nutrition, Directorate General of Collegial Bodies for Health Protection).

The following organisation chart provides an overview of the DVPHFSCBHP:



NB. The re-organisation of offices within the Directorates-General was still ongoing and the table above needs to be updated as soon as the new chart is available.

Regional and local level MH

The following local offices of MH are responsible for import controls and intra-Union trade:

- 30 Border Inspection Posts (BIPs), responsible for controls on imported animals, food of animal origin and feedingstuffs;
- 12 Port, Airport and Border Health Offices (USMAF), comprising 37 local units at the main ports and airports, responsible for controls on imported food of non animal origin;
- 17 Veterinary Offices for Compliance with EU Requirements (UVAC), responsible for intra community trade of animals, food of animal origin and feed.

The BIPs and UVACs report to Office VIII of DGAHVM while the USMAF report to Office II of DGFHFSN and to the Directorate-General for Sanitary Prevention (DGPS) of MH.

A total of 263 staff are employed in the BIPs, 90 in the UVAC and 456 in the USMAF.

Carabinieri Health Protection Unit (NAS)

The NAS is a special branch of the Carabinieri which operates under the supervision and direction of MH. They are organised into a central command, with 3 field offices and 38 territorial inspection units and are responsible for investigations and controls on illegal adulteration of foodstuffs, fraud, and illegal trafficking of medicines. They may perform controls and investigations on their own initiative or on request from the offices of MH, including hygiene inspections of businesses, verification of own control systems, sampling and analysis of products, and examination of documents of authorisations. NAS officials have the title of health inspector and the authority of judicial police. Most of the 1,000 staff are warrant officers with specific technical training. The unit estimated that around 50% of their time is dedicated to food safety inspections.

Ministry of Agriculture Foodstuffs and Forestry Policies

Within the Ministry of Agriculture Foodstuffs and Forestry Policies (MIPAAF), the Department of competitive policies of rural and quality is responsible for the co-ordination of activities related to the quality of agricultural products and food.

Within the Directorate General of competitiveness for rural development (COSVIR), Office XI is responsible for plant health, seeds, propagation material, fertilisers and some aspects of the field of plant protection products. Office X is responsible for husbandry and products of animal origin.

Central Inspectorate for Quality Controls and Antifraud of Foodstuff and Agricultural Products (ICQRF)

ICQRF is an inspection body of the MIPAAF responsible for fraud prevention. It carries out controls on labelling and quality of foodstuffs, agricultural products feed, fertilisers and plant protection products.

At central level the ICQRF consists of a Directorate General for Planning and Inspection and Laboratory Co-ordination and a Directorate General for Quality Controls and Quality Systems. It has 12 regional inspection offices and 15 local units. The ICQRF has its own

laboratory network, comprising five chemical routine laboratories and a central reference laboratory responsible for research activity and confirmatory analysis. Most of the controls performed by the ICQRF are related to wine, alcoholic beverages, milk, dairy products and olive oil. Specific control campaigns are carried out in relation to feedingstuffs, ABP, traceability of meat, GMOs in soya and corn seeds, fertilizers and organic agricultural products.

All laboratories are accredited according to ISO 17025:2005.

The ICQRF carries out controls on feedingstuffs for the presence of prohibited animal proteins (PAP) and on organic products for the presence of residues of prohibited Plant Protection Products (PPPs). The ICQRF also conducts controls on wine production, fertilizers, fruit and vegetables to detect the presence of unauthorised additives. Feedingstuffs, fertilisers and wine are checked for the presence of heavy metals.

The inspection activity to check for the presence of PAP in animal feedstuffs accounts for about 15% of all controls. During inspections samples are taken and sent to ICQRF laboratories of Modena, Perugia and Salerno which have the expertises to perform optical microscopy for the individuation of animal flour residues in feed. In addition, the ICQRF laboratory of Catania is specialised in the analysis of organic products to test the presence of prohibited PPPs. The same laboratory also checks for the presence of unauthorised compounds used for surface treatments of fruit and vegetables.

ICQRF may undertake specific control activities in the food safety field on request of the judicial authorities.

Regional veterinary services and public health services

In the 19 Regions and 2 autonomous Provinces, responsibility for animal health, food of animal origin and feed safety and animal welfare is assigned to the Regional Veterinary Services (RVS) which are normally part of the Regional Public Health Services (RPHS) (with the exception of one of the two autonomous Provinces where the veterinary service is part of the Provincial Agriculture Authority). Responsibility for foods of non animal origin is assigned to a separate office of the same RPHS.

The internal organisation of the RPHS differs between Regions (e.g. in Tuscany the veterinary services and Food hygiene services form two high level independent organisational units responsible for public health whilst in Emilia Romagna these competencies fall within one high level organisational unit).

The RPHS have a co-ordination function while the implementation of controls is carried out at local level by inspectors employed in the AUSL.

A total of 103 veterinarians are employed in the RPHS.

Regional Plant Health Services

Plant health responsibilities are assigned to the Regional Plant Health Services (RPS) which are normally attached to the agriculture departments of the Regions and directly responsible for the implementation of controls.

Local Health Units

The Local Health Units (AUSL) are public bodies responsible at local level for the organisation and management of all public health services. They have a high degree of

managerial, administrative, financial and technical autonomy and are organised in sanitary districts, departments of prevention and hospital services.

Public health responsibilities are shared between two separate services within the Department of Prevention: the Food Hygiene and Nutrition Service (SIAN), and the Local Veterinary Services (LVS).

The LVS are responsible for: animal health; animal welfare; food of animal origin; and feedingstuffs, and are usually organised into three different areas:

- area A - responsible for animal health;
- area B – responsible for food of animal origin;
- area C – responsible for animal breeding and animal production and by-products.

The distinction between areas of activity does not apply in all the AUSL and the allocation of resources may vary according to the AUSL. The majority of inspectors in the LVS are veterinarians. A total of 5 517 veterinarians are employed in the AUSL.

SIAN is responsible for food of non animal origin. Some staff are medical doctors, but the majority are technicians with a second level diploma. The staff in charge of control activities are specifically designated for that purpose, whereas other staff are also involved in other public health activities.

Resources for performance of controls

See Annex 1

Staff qualifications and training

The Department of Veterinary Public Health, Food Safety and Collegial Bodies for Health Protection is responsible for the coordination and planning of the training programme funded by the Department. It undertakes an annual assessment of the training needs and their programming. There is also a website specifically dedicated to training activities:

<http://www.salute.gov.it/formazioneVeterinaria/formazioneVeterinaria>

Training is organized at all levels.

The Department assigns the development of training courses mainly to the IZSs, selected on the basis of specific competencies and coordinates the scientific programme jointly with the relevant offices at central level. The IZSs, also, inform the Department about their specific training projects for Third Countries or about their projects as National Reference Centres (NRC).

The Department is also the National Contact Point for DG SANCO's training programme "Better training for safer food". It provides an overview of the international training trends applicable at national level.

During systemic and sectoral audits conducted by the CCA, a specific verification of training courses provided to CA's regional and local staff is carried out. This assessment

may include the control of related documents (i.e.: programmes and lists of attendance and evaluation documents, etc.).

Laws DLgs 502/1992 and the subsequent DLgs 229/99 established the obligation of ongoing training for health professionals. Based on these regulations, since 2002, the Continuous Educational System for health professionals (Continuous Education in Medical Sciences – MCE) has been carried out. At the beginning the competences regarding the administration of this system and related organism (National Commission for ongoing training -NCCE) were in the Ministry of Health. On 1st January 2008 these competencies were devolved to Age.Na.S (National Agency for the Regional Health Services).

The bodies involved in the MCE are: Ministry of Health; Age.Na.S; Regions and Autonomous Provinces; National Commission for ongoing training; Professional bodies and associations; Scientific associations and Trade-Unions. The MCE programme provides for a system of specific credits for all the health professionals. On 5th August 2007, a State-Region Agreement established that all health professionals have to obtain 50 credits per year, with a minimum of 30 credits and a maximum of 70. In the period 2007-2010 this quota also included 60 credits obtained in the previous years.

One of the bodies of the NCCE is the Consortium for the Management of the National Register of Training Credits (CoGeAPS). This Consortium brings together all the national bodies of health professionals. Providers transmit credits obtained by each participant to CoGeAPS. The competent authorities or individuals can obtain information on the credits obtained by health staff from the relevant professional association.

Organisation and implementation of official controls

Co-ordination between Competent Authorities

Relations between the State and Regions are managed through the State-Regions Conference (established by Decree of the President of the Council of Ministers of 12 October 1983). The conference operates under the aegis of the Prime Minister's Office and comprises high level representation (Presidents of the Regions). The State-Region Conference has a permanent Inter-Regional Committee on Food Safety (currently chaired by Tuscany). This committee is assisted by technical working groups. The MH participates in these fora.

In relation to areas of exclusive competence, the State-Region Conference may be invited to give “conditional opinions”: The State may accept or reject these opinions, giving reasons (Legislative Decree 281 of 1997). In the case of shared competences, the State-Region Conference adopts co-decisions (Article 8 of Law 131 of 5 June 2003). This includes implementation arrangements for EU Regulations. For example, “Guidelines for official control in accordance with Regulations (EC) No. 882/2004 and No 854/2004” (DGAHVM/3/6238/P) were adopted on 31 May 2007.

In July 2007 a new Conference of heads of services in MH and the Regions was created (based on political agreement) to improve co-ordination, responsiveness to FVO recommendations and information exchange at technical level in the fields of food safety and animal health. The Conference has priorities to:

- ensure closer co-operation to provide effective support to the work of the National Committee for Food Safety;

- establish operational standards for the functioning of the three levels (State, Region, Local) and for internal and external audit;
- develop information systems at all levels to facilitate the management of the MANCP;
- develop an integrated food safety laboratory network.

This Conference led to the adoption of a Legislative Decree providing for the reorganisation of the institutional profile of Istituti Zooprofilattici Sperimentali, in compliance with Article 2 of Law n. 183 of 4 November 2010.

In relation to the Plant Health sector, Article 52 of Legislative Decree 19 August 2005, No. 214, establishes the National Plant Health Committee (NPHC) that is composed of the head of the central Plant Protection Service and the heads of regional Plant Protection Services. This Committee, through the monthly meetings, is the forum for coordination of the activities of the service. The NPHC has a role in relation to the development of strategies and procedures/guidelines for the operations of the national plant protection service. It is also a forum for exchanging good practice.

The funds for agriculture are managed at regional level. Law D.Lgs.214/05 gives the Regional Plant Protection Services all powers regarding to the eradication of outbreaks in their territories. If there are phytosanitary risks that affect several regions, national standards are established which override Regional provisions.

Co-operation within Competent Authorities

Arrangements are described for each sector in later chapters of the country profile

Regarding the sector of animal health and animal identification co-operation among Ministry of Health and other Competent Authorities take places in the context of cross-compliance in particular with MIPAAF (AGEA). At the present there is a flow of data concerning controls among Sanitary Authorities and AGEA. A proposal concerning a specific protocol of co-operation between Ministry of Health, Regional Authorities and AGEA was under consideration. A draft of protocol of cooperation was to be sent by MIPAAF to State/Regions Conference for examination and approval.

A technical meeting was scheduled on 24th April 2012 in the framework of State/Regions Conference.

In emergency situations the following Competent Authorities are officially involved: Ministry of Interior, Ministry of Defence, Ministry of Agriculture (MIPAAF), Ministry of Environment, and Ministry of Economy and Finance.

Official controls regarding the protection of animals travelling on Italian roadways are carried out with the collaboration of the Italian National Police force, which is under the Authority of the Ministry of Interior, responsible for road safety. Such collaboration is needed in order to halt vehicles transporting live animals travelling throughout the Italian roadway network and may be included in the routine activity of both road police and procedures programmed by State Health Officials or by the Veterinary Offices for EU Compliance (UVAC).

Some aspects of animal welfare are verified by a special investigation unit under the authority of the State Forestry Department called NIRDA (investigation unit on crimes against animals) that is also involved with the official control authority. This

investigation unit was established by a Decree of March 23 2007 by the Ministry of Interior, following the adoption of Law 189/2004 on "Measures regarding the prohibition of cruelty to animals, as well as their use in unauthorized competitions and in illegal fighting."

Regarding official controls on feed legislation, MIPAAF is involved in controls of the commercial quality of feedingstuffs through its inspection service, the ICQRF.

The representatives of ICQRF cooperate with the Ministry of Health in devising the PNAA (the national control plan on animal nutrition).

With regard to imports of live animals and animal products, the collaborative activities with other Competent Authorities, particularly with the Customs Agency, arises in two sectors:

- checks on animal products carried out on luggage of passengers or sent for personal use (Regulation EC No 206/2009- Decree of the Ministry of Health in cooperation with the Ministry of Economy and Finance 10 March 2004) and
- controls of live animals entering the EU for non-commercial purposes (Regulation EC No 998/2003 - Decree of the Ministry of Health in cooperation with the Ministry of Economics and Finance dated 20/04/2005).

On 22 May 2007 a Memorandum of Understanding was signed between the Customs Agency and the Ministry of Health, with the aim of strengthening cooperation between the two administrations and to develop joint actions in order to improve the system of import controls and prevent the introduction of illegal goods. This provided the basis for the inclusion of CN codes within the customs system AIDA of goods subject to veterinary supervision, according to the Decision 2007/275/EC.

The USMAF and BIPs perform their controls in close cooperation with the Customs Agency. A Presidential Decree No. 242 dated 4 November 2010 on the creation of a "*Sportello Unico Doganale*" or "single customs window" was published in January 2011. This will facilitate strengthened cooperation.

Contingency planning (CP)

A crisis unit was established in MH to handle all outbreaks, including co-ordination at national level (Legislative Decree 202 of 1 October 2005). In addition to contingency plans in the animal health sector, there are plans in place for Food and Feed safety (Intesa 24.1.2008) and Trichinella. CPs are framework plans and Regions/Local units produce own plans and nominate reference points.

The Central crisis unit established to handle all outbreaks was officially established by Ministry of Health Decree of 7 March 2008 concerning the chain of command, the working procedures, the responsibilities at different level and the organisation of the National Animal Disease Control Centre.

Having regard to Article 55 of Regulation (EC) no.178/2002, the Ministry of Health, by the means of Intesa between State-Regions, issued the "Contingency plan for feed and food safety". The plan defines 3 "Crisis Units", one for each competent authority (National, Regional and Local level) that are in contact with the EU Crisis Unit through

the National Unit. For each crisis unit, the plan defines the composition (staff) and the specific tasks.

In case of emergency, the contingency plan requires the immediate activation of the Crisis units; the first Unit has to activate the others as soon as possible, and not later than 24 hours. The operating procedures describe training which staff must receive and deals also with laboratory services and communication with citizens and between bodies.

In line with Article 13 of Regulation No. 882/2004 and Decision n. 478 of the 29th of April 2009, Italy laid down the “Emergency Plan for Food and Feed Safety” through the State-Regions Agreement of 24 January 2008. This provides for the establishment of crisis units at three levels. Office VIII DGAHVM coordinates these issues.

Conflict of interest

A Decree dated 28 November 2000 establishes a code of conduct for civil servants and prescribes the obligations of public officials as regards independence and involvement in other activities. In addition, there are a number of related provisions in the Penal code: Articles 314, 317, 318 and 319, 323, and 326.

As regards, the independence of official controls, this is also covered by the Professional Code (*Codice Deontologico*), with which every veterinarian must comply in the execution of his/her functions. The oversight of compliance with the professional code is carried out by an organisation (*Ordine dei Medici Veterinari*) that has the power to impose disciplinary measures on officials who violate such code, including possible exclusion from profession.

Enforcement measures

Public officials have powers of entry and inspection by virtue of Law 689/1981 (Article 13). Staff performing official controls at all levels have the status of civil servants and judicial police under Article 357 of the penal code and Law 441/1963, Articles 17 and 22. In addition, inspectors may request assistance from the police (Article 3 of Law 283/1962).

In addition to the powers of control and verification conferred on the regional competent authorities, MH, as Sanitary Competent Authority, has the power to carry out inspections, to access offices and documentation (D.L. n. 112/1998 regarding delegation of function and tasks from the State to the Regions, Law 283/1962, DPR 327/1980).

The legal bases for staff performing checks in the animal transport sector are Legislative Decree no. 151/07, laying down the penalties to be applied pursuant to (EC) Regulation n. 1/2005.

The basic law for administrative sanctions is Law 689/1981. A number of Legislative Decrees lay down sanctions for specific sectors: 190/2006 (Articles 18, 19 and 20 of Regulation 178/2002), 193/2007 (Regulations no. 852, 853 and 854 of 2004), 151/2007 (Regulation no. 1/2005) 142/2009 (Regulation 183/2005) and Law 198/2004 laying down sanctions for cruelty to animals.

Most infringements are covered by administrative sanctions except for those covered by Law 283/1962 (Articles 5, 6 and 12), Law 281/63 and the criminal code (Articles 515 and 516) which lay down criminal sanctions. Even in cases where administrative sanctions are imposed, in cases of suspicion of criminal relevance, there is an obligation to refer to the prosecutor for investigation.

The level of sanction applied takes account of the seriousness of the offence and of the financial circumstances of the offender among other things. There are also provisions for the imposition of other measures such as impoundment (art. 24 of Law 689/1981), the confiscation (Art. 19 of Law 689/1981) and, as regards food hygiene rules, the closing of the establishment (Article of 8 Legislative Decree 30/12/1999, n 507 and art. 517 *bis* Penal Code). Furthermore, the Law in question also provides for the concept of “recurrence” of the offence (committing a subsequent offence of the same type), in which case some benefits are lost.

Law 462 of 7 August 1986 provides that the MH publish a list of FBOs convicted of food adulteration and fraud:

<http://www.ministerosalute.it/sicurezzaAlimentare/paginaInternaMenuSicurezzaAlimentare.jsp?id=1186&lingua=italiano&menu=strumentieservizi>

In relation to plant health, Article 54 of Legislative Decree No. 214 dated 19 August 2005 provides for a comprehensive regime of sanctions. Regions have to impose penalties and collect the revenues.

For additional information, see Chapter 6 of the 2011-2014 MANCP:

<http://www.salute.gov.it/pianoNazionaleIntegrato/paginaInternaMenuPianoNazionaleIntegrato.jsp?id=2279&lingua=italiano&menu=capitolo6>

Registration / approval of food business establishments

Registration takes place at local level and approval at regional level according to guidelines implementing Regulation (EC) 852/2004 approved by the State-Region Conference adopted by Act of 9 February 2006. This Act was being reviewed by the conference.

The procedures for the approval and registration of feed business operators were described in the document named: “enforcement of (EC) regulation 183/2005 of the parliament and the council concerning feed hygiene – guidelines” of 28 December 2005.

See also Part 2 of the Country Profile.

Prioritisation of official controls

Organisation of food risk assessment

Presidential Decree n. 108/2011 established the new Directorate General of Collegial Bodies for Health Protection in MH. The National Secretariat for Risk Assessment in the Food Chain is part of this new Directorate General which is the national reference authority for the European Food Safety Authority. Furthermore, as laid down in DPR n.108/2011, it is responsible for performing risk assessment for physical, chemical and biological hazards for food safety purposes.

In addition to this, the Directorate General of Collegial Bodies for Health Protection has responsibility for consultation with consumers’ and producers’ associations and for undertaking preliminary investigation and coordination of risk assessment processes. It reports to the CNSA (National Committee for Food Safety) and the Strategic Steering Committee.

The CNSA collaborates with EFSA and gives scientific advice, requested by the Strategic Steering Committee, the central Competent Authorities, and the competent authorities of the Regions or Autonomous Provinces.

Guidelines for controls on establishments carried out by AUSLs were adopted in May 2007 following agreement between the State and Regions (“Criteria for risk categorization of establishments to set inspection frequency”, with Letter DGAHVM/3/6238/P).

Sampling and Laboratory analysis

National accreditation bodies

Under the Inter-ministerial Decree of 22 December 2009 (O.J. n. 20 del. 26/01/2010) ACCREDIA is designated as the Single National Body authorised to perform accreditation activities.

ACCREDIA is divided into 4 Departments. The “Department of testing laboratories for food safety” is in charge of accrediting official control laboratories as well as private laboratories performing own-checks analysis.

Accreditation is granted as a fixed or flexible scope accreditation. In 2011 ACCREDIA issued document RT 26 laying down “Conditions for flexible accreditation” which will enable official laboratories to meet the testing requirements of control authorities, including in case of alerts and emergency situations. ACCREDIA developed a database of official control laboratories, broken down by Region and Province, showing laboratories with tests accredited by material/product/matrix. This database can be consulted at the following address:

http://www.accredia.it/accredia_labsearch.jsp?ID_LINK=293&area=7

Laboratory services

At national level, the National Health Institute (ISS) is the main technical and scientific public body of the Italian National Health Service. The ISS (which is under the remit of MH) supervises the laboratories of the Italian National Health Service engaged in food and feed control and performs confirmatory analysis. Its activities include research, control, training and consultation in the interest of public health protection. An important activity of the Institute, carried out on behalf of the Minister of Health or the Regions, is inspection and quality control of food products and packaging. The ISS includes the Community Reference Laboratories for *Escherichia coli* (including *verotoxigenic E. coli*) parasites (in particular *Trichinella*), and the residues listed in annex I, group B 3 (c) of Directive 96/23/EC.

National Reference Centres are present in several IZS laboratories and in the ISS. All 10 IZS laboratories for the official control of feed and foodstuffs are accredited.

Laboratory services for animal health, food and feed are provided by a network of public laboratories at regional level. Analyses of food of animal origin and animal health are carried out by the Experimental Zooprophyllaxis Institutes (IZS). There are 10 IZS, with 90 field diagnostic units at provincial level. The IZS are subject to control and supervision by the Regions and co-ordination by the DVPHFSCBHP.

Tests on contaminants, pesticides and food of plant origin are performed by 27 Environment Protection Agencies (ARPA) with 54 local laboratories at the provincial level. ARPA comprises laboratories responsible for both environmental monitoring and

for food controls. ARPA laboratories report to the local AUSL and they may perform analyses for more than one AUSL in a particular a region.

Official testing is also carried out by the Public Health Laboratories (LSP) operating within the LHU's Prevention Departments. The tested matrixes include food of animal and non-animal origin, water and food contact materials. 16 LSP Laboratories had been accredited in the following Regions: Lombardia, Toscana, Marche, Sicilia and the Trento Autonomous Province.

Verification and review of official controls and procedures

Legislative Decree No 112 of 31 March 1998 (Article 115) reserves to the State, the competence for adopting guidelines and standards to be followed by the Regions. Guidelines are adopted through the State-Region Conference. For example, "Guidelines for official control in accordance with Regulations (EC) No. 882/2004 and No 854/2004" (DGAHVM/3/6238/P) were adopted on 31 May 2007.

However many other detailed operational procedures are also being implemented in order to carry out and to report the results of official controls.

Verification

Legislative Decree No. 112 of 31 March 1998 gives responsibility to the State for the steering and coordination of competences conferred on the Regions (Article 4). The same Decree (Article 5) allows the State to take measures in the event of serious failings by a Region to meet its obligations.

Legislative Decree No. 112 of 31 March 1998 (Article 115) empowers the State to conduct inspections and verifications in the Regions in order to verify that National and EU requirements are fulfilled. Decree (DPR) No 129 of 28 March 2003 (Article 5) attributes specific powers of verification within the scope of the MH. More detailed rules for verification were laid down in a note dated 5 March 2004 of the Director General of veterinary services.

Legislative Decree No 502 of 30 December 1992 (Articles 2 and 8) requires the Region to supervise the AUSLs and requires that both levels have control and monitoring arrangements.

The "Guidelines for official control in accordance with Regulations No. 882/2004/EC and No 854/2004/EC" (Prot. DGSAN/3/6238/P, 31 May 2007) sets out procedures for supervision across the three levels. At Regional level, data flows from the AUSLs are evaluated. Internal monitoring systems are operated within the AUSLs.

The Constitution guarantees the uniform application of shared competences by the Regions. The State has a range of instruments to monitor this, including the setting of indicators "Livelli Essenziali Assistenza" (LEA-minimum service level) under Decree of the President of the Council of Ministers of 29 November 2001. Performance by the Regions, as measured by LEA impacts on the level of State funding provided to the Region (3% of budget). The LEA Committee, established by an agreement of the State-Regions Conference in March 2005, carries out an annual assessment of the Regions on the implementation of a range of programmes. Since 2007, the LEA indicators had been applied to animal health, animal welfare and feed safety, and also for food safety since 2008. In 2011, the LEA indicators include all of these sectors (18 information flows and 5 activity indicators).

Supervision is also carried out through evaluation of information flows from the Regions, through the work of the Conference of heads of services in MH and by the Regions through the programme of inspections and audits.

In certain situations where a Region is considered to be failing in the execution of its responsibilities, there is a mechanism for enhanced supervision by MH. This is known as a "*Piano Di Rientro*". Currently, there are three Regions subject to such enhanced supervision in the veterinary/food safety area (Campania, Calabria and Molise).

Further measures are in the pipeline concerning uniform operational standards and better IT solutions for information exchange with the Regions in order to make verification systems more effective (expected by 2013).

Operational standards for competent authorities and related audit systems (*criteria for the operation and the improvement of official control activities carried out by Ministry of health, the Regions and Autonomous Provinces and AUSLs on Food Safety and Veterinary Public Health*) is being transmitted to the State-Regions Conference for the final approval by the Ministers and Presidents of the Regions. This document outlines the necessary "evidences" in order to ensure the implementation of each requirement or standard.

Audit

An audit system was introduced by MH in 2003. Office IX of DGAHVM is the designated Audit Office.

DVPHFSCBHP adopted an internal decree to establish the rules and operating procedure of the audit system. The main operating elements are described on the web site:

<http://www.salute.gov.it/sanitaAnimale/paginaInternaMenuSanitaAnimale.jsp?id=1555&lingua=italiano&menu=audit>

The audits comprise systemic audits of the overall management structure of the regional services, and sectoral audits looking vertically at the implementation of controls. A full regional audit is considered to be completed when the systemic audit and at least four sectoral audits have been carried out. The Regions and the sectors to be audited are selected following an assessment of epidemiological data, production data, feed-food business data, zoo-technical data, flow of information, information that might indicate non-compliance, and the outcome of previous FVO or CCA missions. The assessment also includes all information available from internal documents, which could reveal non-conformities in the procedures followed by regions.

At central level, the audits are carried out by the staff of Audit Office and by staff from the other sectoral offices of the Department.

Office IX DGAHVM produces a coordinated programme of audits and inspections, including its own audit activities and vertical audits and inspections undertaken by the other offices.

In 2009 and 2010, training was provided for about 90 internal staff in collaboration with ISS. These members of staff were selected to carry out audits based on their extensive knowledge of their respective sectors.

In 2011, the Department funded and coordinated training for about 80 staff of the Department concerning a managerial approach to veterinary public health. In particular, the main issues were: Veterinary Services and international cooperation; risk assessment

and control system in food safety; Essential Assistance Levels (LEA) in animal health and veterinary public health; the governance of animal health and veterinary public health systems (in particular, the use of project management tools, analysis of health issues for the planning of policies and interventions, development of cooperation networks among institutional actors).

MH planned 46 sector audits and 4 Systems Audits for 2010, of which 20 respectively were carried out. It was expected that audit rounds would be completed in up to 13 Regions by end 2011 and for all Regions by end 2014.

A summary of the audits undertaken can be found on MH website, at the “activities” section:

<http://www.salute.gov.it/sanitaAnimale/paginaInternaMenuSanitaAnimale.jsp?id=1556&lingua=italiano&menu=audit>

The audit system reports are published on the MH website

(<http://www.salute.gov.it/sanitaAnimale/paginaMenuSanitaAnimale.jsp?lingua=italiano&menu=audit>).

The Audit Office in MH annually performs a survey of the regional audit systems. In recent years, an increased level of regional audits was recorded. At Regional level, 15 Regions now operate audit systems and the remaining 6 are well advanced to introduce systems. For 2010, 79 Sectoral and 26 Systems Audits were undertaken by Regional audit services.

For MIPAAF, the ICQRF at central level has a specific office responsible for planning and monitoring inspection activities and laboratories analysis (PREF I and PREF II). This office conducts independent and objective audits and critical analyses of ICQRF regional inspection offices and laboratories control procedures in order to assess management control systems in order to ensure that regional inspection offices and laboratories are managed in compliance with the annual general control activity guidelines. The monitoring data is provided by the Inspection Office and Laboratory Information Management System, which is a database, giving details of control and laboratory activities. Subsequently, these information and records are extracted and run by PREF-II's staff in order to make statistical analyses.

Multi-annual National Control Plan (MANCP)

The DGFHFSN has general responsibility for drawing up and updating the Plan and the relevant Annual Report. This is done in collaboration with the National Health Institute (ISS). In order to facilitate the exchange of document, a specific IT platform was created (Community web for the MANCP).

An MANCP Evaluation unit (advisory body) was established by a Decree of the Head of Department on 26 June 2008 under the aegis of the DVPHFSCBHP. This unit consists of qualified representative from the MIPAAF, the Ministry of Environment, the Regions, the ISS and the Customs Agency. It is in charge of setting the Plan's strategic and operational goals and provides opinions to the Technical Secretariat with a view to implementing the Plan, also based on the findings of the Annual Reports.

The 2011-2014 plan was adopted by State-Region Conference on 16 December 2010 and was published on the Ministry website:

<http://www.salute.gov.it/pianoNazionaleIntegrato/paginaMenuPianoNazionaleIntegrato.jsp?lingua=italiano&menu=struttura>

The 2010 annual report was provided to the Commission in June 2011 and is available at the following link:

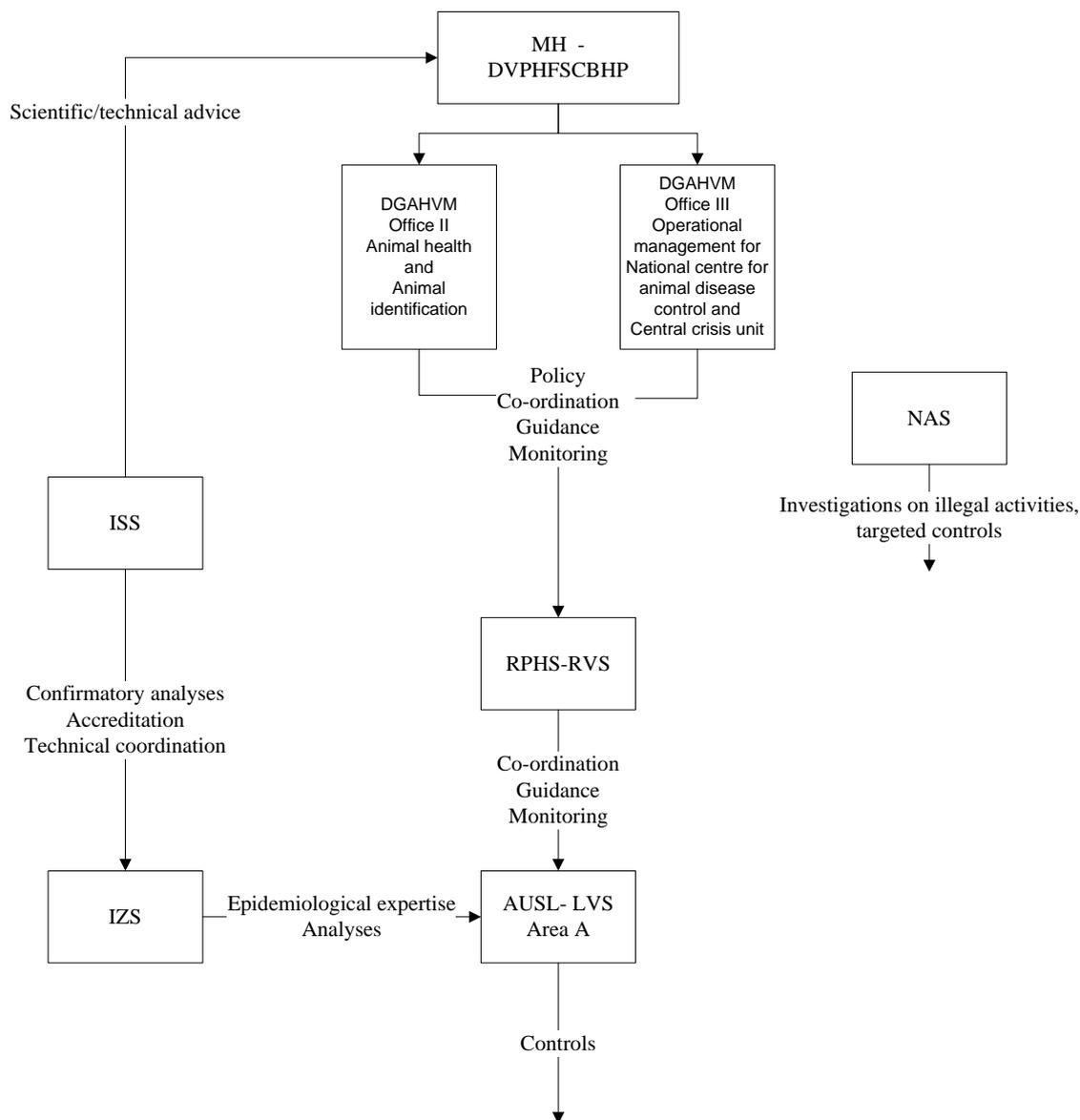
<http://www.salute.gov.it/relazioneAnnuale2010/homeRelazioneAnnuale2010.jsp>

The following chart gives an overview of the distribution of responsibilities in relation to control systems and operational levels. More detailed descriptions of the allocation of responsibilities between authorities in relation to each control system are given in the following chapters.

Sector	Policy co-ordination	Co-ordination of controls	Implementation of controls	Laboratories	Risk assessment, scientific advice
1. Animal Health	MH DGAHVM- II and III	RPHS-RVS	AUSL LVS (A)	IZS	SNVR
2. Food of Animal Origin	MH (III – DGFHFSN) MH (IV_DGFHFSN)	RPHS-RVS	AUSL LVS (B)	IZS	CNSA CUDN
3. Imports of animal and food of animal origin	MH DGAHVM (VIII)		UVAC, BIP	IZS	
4. Feedingstuffs - imports	MH DGAHVM (VII) MH DGAHVM VII - VIII	RPHS-RVS	AUSL LVS (C) UVAC, BIP	IZS IZS	
Feedingstuffs - production	MIPAAF DGRDIS		ICQRF	ICQRF	
5. TSEs/ABP	MH DGAHVM (III) / DGFHFSN (III)	RPHS-RVS	AUSL LVS (A)	IZS	
6. Veterinary medicines - authorisation, marketing & distribution	MH DVPHFSCBHP DGAHVM (IV - V)	RPHS-RVS	AUSL LVS (C)	IZS	
Veterinary medicines - residues	MH DGFHFSN (III)	RPHS-RVS	AUSL LVS (C)	IZS	
7. Foodstuffs and Food hygiene	MH DGFHFSN (II) MH (IV_DGFHFSN)	RPHS	AUSL SIAN	ARPA	CUDN
8. Imports of food of plant origin	MH DGFHFSN (II)		USMAF	ARPA	
9. Plant protection products - residues	MH DGFHFSN (VII)	RPHS	AUSL SIAN	ARPA	
Plant protection products - authorisation, marketing and use		RPHS	AUSL SIAN	ARPA	
10. Animal Welfare - slaughter/farms		RPHS	AUSL LVS (C)		
- transport	MH DGAHVM (VI)	RPHS	AUSL SLVS (C) Police		
- animal reproduction	MH DGAHVM (VI)	RPHS	AUSL LVS A or C		
11. Plant Health	MIPAAF COSVIR (XI)	RPS	RPS	RPS	

2. COMPETENT AUTHORITIES AND DISTRIBUTION OF RESPONSIBILITIES IN RELATION TO INDIVIDUAL CONTROL SYSTEMS

2.1. Control system for animal health



MH	Ministry of Health
DVPHFSCBHP	Department of Veterinary Public Health, Food Safety and Collegial Bodies for Health Protection
DGAHVM	Directorate General for Animal Health and Veterinary Medicine
NAS	Carabinieri Health Protection Unit
ISS	National Health Institute
RPHS	Regional Public Health Services
RVS	Regional Veterinary Services
IZS	Experimental Zoo-prophylaxis Institutes
AUSL	Local Health Units
LVS	Local Veterinary Services

Competent Authorities

The DVPHFSCBHP is the Central Competent Authority (CCA) for animal health. Within the DVPHFSCBHP, Office II and III DGAHVM are responsible for animal health, animal identification and Transmissible Spongiform Encephalopathies (TSEs). Their responsibilities cover general policy, co-ordination, monitoring and supervision.

Controls are carried out at local level by veterinarians working in area A of the Local Veterinary Services.

The CCA co-ordinates the regional authorities through regular bi-annual meetings. Information on epidemiological data and technical reports are forwarded by the AUSL to the Regions and by the Regions to the CCA twice a year.

Holding registration, animal identification and movement controls

National databases are in place for bovines, sheep and goats, pigs and poultry holdings. These databases are maintained by the Teramo IZS, which is also the National Reference Centre for epidemiology. AUSL have access to the national databases.

- The central bovine database has been recognised as fully operational by Commission Decision 2006/132/EC
- The bovine database includes health status

MH has put into place a monthly monitoring system for anomalies, including births, movement and slaughter. Each year, the MH sends a listing to each Region specifying the minimum number of controls to be carried out.

All small ruminant holdings, including holdings with three or fewer animals, must be registered in the central database. A unified model of the holding register is in use. Animals are identified at the age of 6 months or, in any case, before leaving the holding, with two ear tags or if destined for the national market, with a tattoo and an ear-tag. The system of on-the-spot inspections for sheep and goats and holdings comprises 3% of the holdings and 5% of the animals. Guidance notes have been sent to the RVS and LVS, and a standard checklist is required to be used.

All pig holdings are required to be registered. Pigs are identified by an ear tattoo containing the herd number. Holdings keeping not more than one animal for home consumption do not have to be registered in the central database.

A movement document (“form 4”) and passports for cattle are required for all movements which must be authorised by regional Competent Authorities (CAs). Seasonal transhumance of animals is subject to the approval of the mayor of the municipality. The registration of pig movements began in 2006.

Controls on 10% of registered cattle holdings are carried out by officers of the LVS each year using risk-based criteria defined by the CCA. A system of on-the-spot inspections for sheep and goats and holdings has been set up by the CCA and guidance notes and a standard checklist have been provided to the RVS and LVS. The target annual frequency for controls of small ruminants is 3%.

Animal health controls

Office II and III DGAHVM are responsible for drawing up national eradication programmes, which must then be implemented by the regional authorities. While the Regions are administratively controlled by the CCA, it does not have the authority to modify regional policies. Systematic verification and monitoring by the CCA is carried out in relation to the financial aspects of the eradication programmes.

Eradication, control and monitoring programmes cover bovine brucellosis, enzootic bovine leucosis, bovine tuberculosis, ovine and caprine brucellosis, bluetongue, salmonella in breeding poultry, African swine fever (in Sardinia), avian influenza, BSE, TSEs and Scrapie and Swine Vesicular Disease (SVD).

The Regions may adopt their own programmes on issues in areas not regulated at national level. These programmes are sent to the CCA for information only.

Special measures for the control of tuberculosis, bovine and buffalo brucellosis, sheep and goat brucellosis, enzootic bovine leucosis

The Minister for Health signed an Order on 14 November 2006 introducing special measures to be applied in Calabria, Campania, Puglia and Sicily for the control of tuberculosis, bovine and buffalo brucellosis, sheep and goat brucellosis, enzootic bovine leucosis.

A draft of the renewed Ordinance was discussed in 2011 with the Regions involved in this problem.

In view of the complexity of the problems in Campania, a "state of socio-economic emergency" was declared (by Decree of the President of the Council of Ministers) on 3 August 2007, as a civil defence measure, in the province of Caserta to address buffalo brucellosis.

In February 2009, MH had made a second proposal (under Article 19) to the Region of Calabria for the appointment of an "*ad acta*" Commissioner to be appointed.

The activity of the special Commissioner had been extended until 31 December 2009 and then, only in order to conclude reimbursement procedure to breeders by 30 June 2011 (OPCM no. 3932/2011).

Contingency plans

A chain of command from the CCA, through Office III DGAHVM of the former DVPHFSCBHP, to the RVS and the AUSL, applies to contingency plans.

A crisis unit was established in MH to handle all outbreaks, including co-ordination at national level (Legislative Decree 202 of 1 October 2005).

The tasks of the Crisis Unit are: (i) Planning of actions and of co-ordination of disease control and eradication measures on the whole national territory; (ii) Co-ordination, connection and overview tasks on disease prevention, information and control measures; (iii) Proper enforcement of the procedures and criteria for action management; (iv) Ensuring an effective connection between MH's central and local offices, the Regions and Autonomous Provinces and the local bodies.

The Central Crisis Unit issued guidelines on epidemiological surveillance and action strategy for AI control and eradication in Italy; recommendations on the conduct of people handling or coming into contact with birds and guidelines for operators exposed to AI outbreaks.

In the event of a notification of an infectious disease these bodies can act as crisis units at central, regional and local level. The central crisis unit is the decision-making body, but their decisions are co-ordinated at regional level, and implemented at local level.

Although the AUSL are the operational units, in the event of an emergency, the IZS plays the main role in co-ordinating control actions and provides, *inter alia*, any necessary epidemiological expertise.

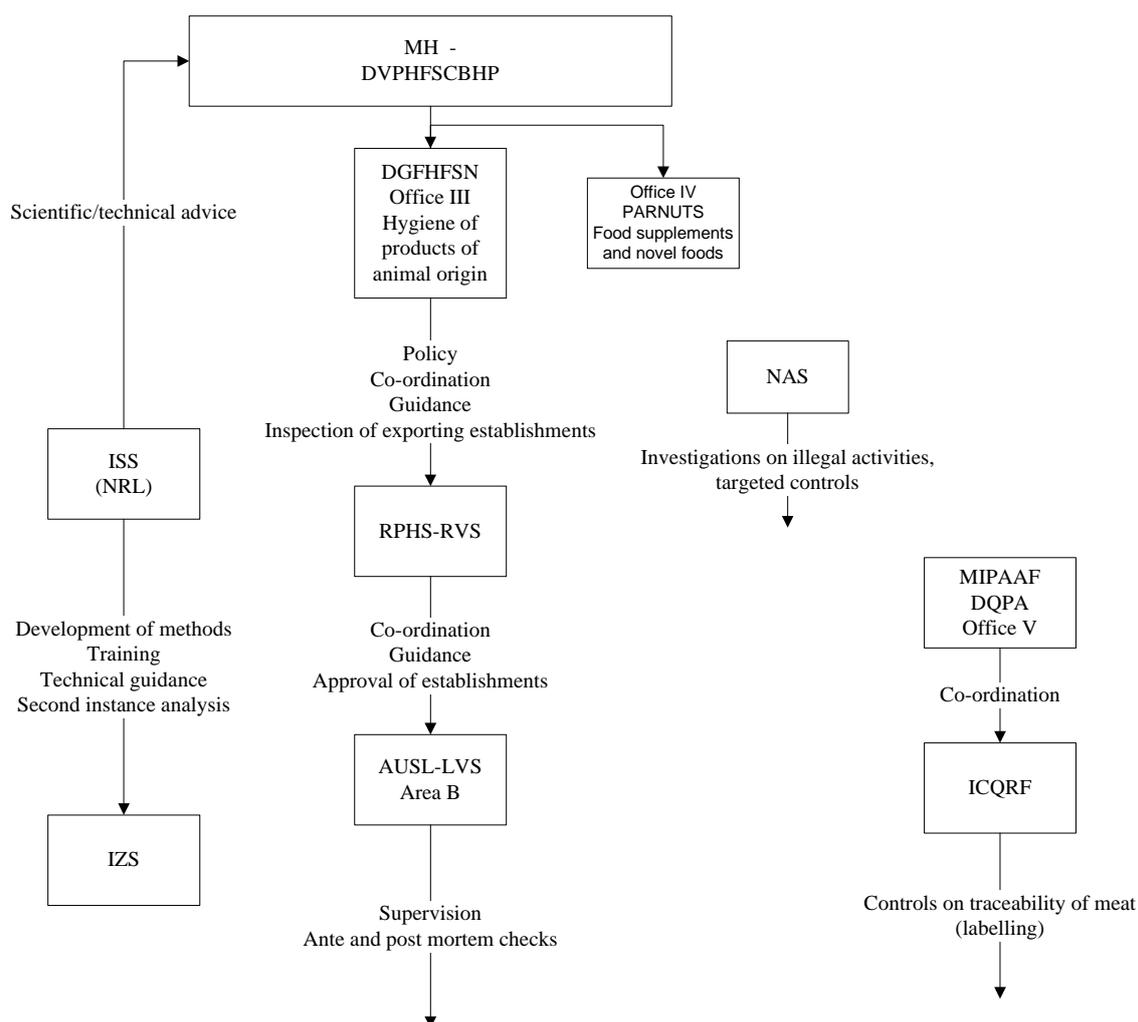
Laboratories

Official analyses in the area of animal health are performed by the IZS network. The ISS functions as: a central laboratory for the development of methods and training; gives technical guidance; acts as the National Reference Laboratory; and carries out second instance analysis. The ISS also acts as the technical scientific body of MH.

The laboratory network for sheep and goat brucellosis comprises approximately 78 official laboratories throughout the country. The national reference laboratory (NRL) for brucellosis in Teramo organises inter-laboratory proficiency tests every year in relation to the two official methods (RBAT and the CFT) at national level.

In 2010 and 2011 the NRL visited the following laboratories: IZS of Sicily, IZS of Puglia and Basilicata, IZS of Lazio and Tuscany, and IZS of Mezzogiorno.

2.2. Control system for food of animal origin



MH	Ministry of Health
DVPHFSCBHP	Department of Veterinary Public Health, Food Safety and Collegial Bodies for Health Protection
DGFHFSN	Directorate General for Food Hygiene, Food Safety and Nutrition
PARNUTS	Food for particular nutritional uses
NAS	Carabinieri Health Protection Unit
RPHS	Regional Public Health Services
RVS	Regional Veterinary Services
AUSL	Local Health Units
LVS	Local Veterinary Services
MIPAAF	Ministry of Agricultural and Forestry Policies
DQPA	Directorate-General for Quality of Agricultural Products and Consumer Protection
ICQRF	Central Inspectorate for Quality Control of Foodstuff and Agricultural Products
IZS	Experimental Zoo-prophylaxis Institutes
ISS	National Health Institute
NRL	National Reference Laboratory

Competent Authorities

The DVPHFSCBHP is the CCA for controls on food of animal origin. Within the DVPHFSCBHP, Office III DGFHFSN has responsibilities for general policies and has co-ordination, guidance and verification functions (managed through the State-Region Conference) on all food of animal origin, including milk, fishery products, bivalve molluscs, eggs and honey.

Office III DGFHFSN undertakes sectoral audits. In 2010 and 2011 inspections in establishments concerned by specific problems were performed in regions Lombardy and Tuscany (e.g. blue mozzarella cheese) and 8 sectoral audits, 2 in 2010 (Sardinia and Umbria) and 6 in 2011 (Marche, Molise, Trento, Friuli Venezia Giulia, Sardinia and Veneto).

The criteria for selection includes establishments showing anomalies in the SINTESI system, temporary approval, issues arising from test results prior to export and cases highlighted by inspections.

Office IV DGFHFSN has the responsibilities for general policies, coordination and guidance in the field of PARNUTS, i.e. infant/follow-on formula, and babyfood, food supplements, food added with vitamins and minerals and novel food. Office IV receives and evaluates the labels of infant formulae and food supplement, that have been marketed in Italy according to Dir. 2006/141/EC, transposed by DM 82/2009 and Dir. 2002/46/EC, respectively.

Office IV receives and evaluates the novel food dossier, with the scientific advice of the Commission for nutrition and dietetic (CUDN- commissione unica dietetica e nutrizione). Moreover the office IV releases the authorization to establishment to produce food for particular nutritional uses.

Office IV trained 36 Regional official control officers in the field of babyfood and novel food.

Office IV undertakes sectoral audits too, in 2010 one audit has been carried in Lombardia on Food for particular nutritional uses.

Registration and approval of establishments

Establishments are approved by the RVS following a visit by the AUSL. The list of approved establishments is maintained at central level by the DVPHFSCBHP and published on the Internet site of MH through the information system "SINTESI".

Official controls and inspections at establishments

The CCA provides guidance and co-ordination throughout the country including guidelines on ABP, Hazard Analysis and Critical Control Points (HACCP) in meat establishments, and on public health aspects of traceability of food and feed.

The CCA provides guidance and coordination on official controls to be performed in the PARNUTS, food supplements, food added with vitamins and minerals and novel food.

Legislative Decree 193 of 6 November 2007 transposes Directive 2004/41/EC and introduces sanctions in relation to Regulations (EC) Nos. 852/2004 and 853/2004. National guidelines on the implementation of Regulations (EC) Nos. 882/2004 and 854/2004 were issued by means of Ministerial Circular letter dated 31 May 2007,

following agreement at technical level at the State-Region Conference. These guidelines include standard reporting forms for the Regions to provide results to MH.

The RVS are responsible for the co-ordination and supervision of the work of the AUSL. Supervision of establishments and ante-and post-mortem checks are carried out at local level by the veterinarians working in Area B of the AUSL.

The CCA may call upon the investigation and inspection capabilities of the NAS to perform national surveys or targeted and unplanned inspections. These inspections are usually linked to emergencies, court proceedings or cases of illegal activity.

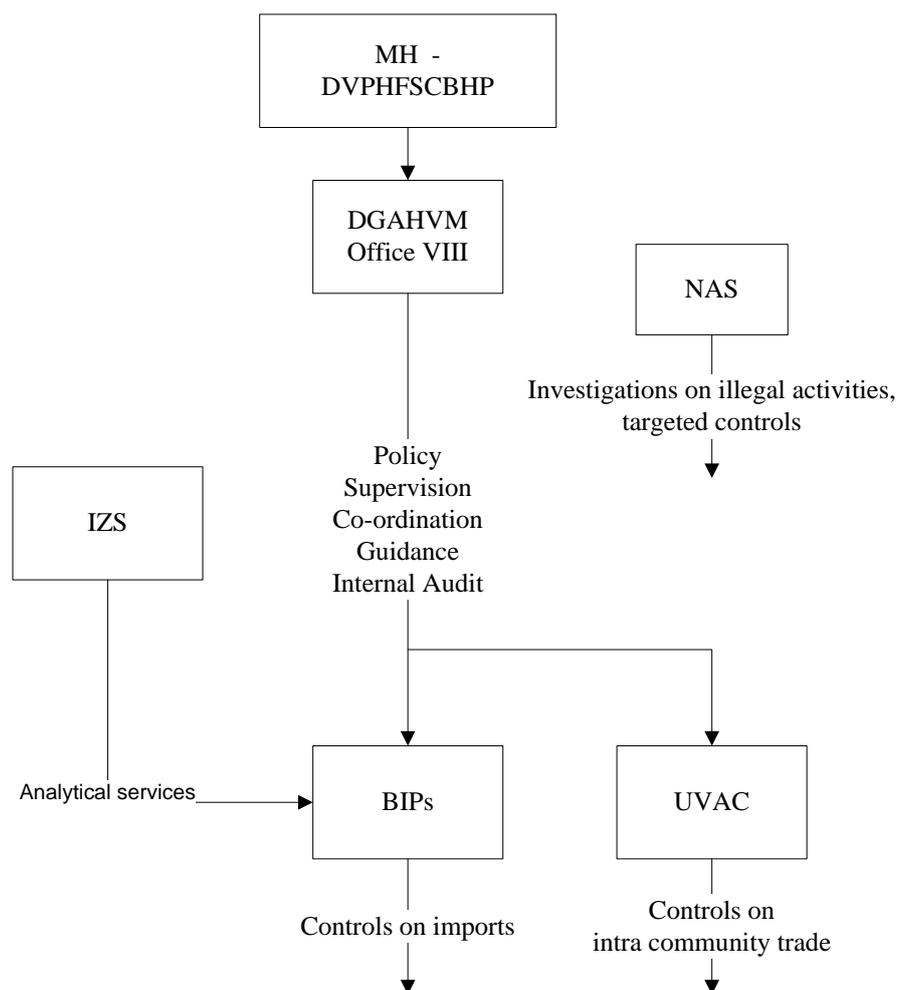
Official controls on identification mark and traceability

A system of controls on compulsory labelling requirements for beef has been in place since May 2005. Office V of the MIPAAF co-ordinates and monitors the implementation of control programmes prepared by the Regions and implemented by the AUSL. In parallel to the regional control programmes, the ICQRF carries out a priority programme of checks focusing on the more critical parts of the meat chain, especially traceability and labelling (cutting plants, large-scale distribution and traditional butchers' shops). Controls on the 87 approved voluntary labelling specifications are carried out by 14 independent bodies recognised by the MIPAAF.

Laboratories

Official analyses are performed by the IZS network. The ISS functions as a central laboratory for the development of methods and training, gives technical guidance, acts as the National Reference Laboratory and carries out second instance analysis. The ISS also acts as the technical scientific body of MH.

2.3. Control system for imports of animals and food of animal origin



MH	Ministry of Health
DVPHFSCBHP	Department of Veterinary Public Health, Food Safety and Collegial Bodies for Health Protection
DGAHVM	Directorate-General for Animal Health and Veterinary Medicine
NAS	Carabinieri Health Protection Unit
BIP	Border Inspection Posts
UVAC	Veterinary Offices for Compliance with Community Requirements
IZS	Experimental Zoo-prophylaxis Institutes

Competent Authorities

The DVPHFSCBHP is the CCA for import controls on animals and food of animal origin. Within the DVPHFSCBHP, Office VIII-DGAHVM is responsible for import of animals and products of animal origin and co-ordination of local offices.

Import controls

Controls on imported animals, food of animal origin and feedingstuffs are carried out at 30 Border Inspection Posts (BIPs) which report directly to MH. The veterinary staff of the BIPs are directly employed by MH as official veterinarians or as veterinarians under contract. The latter are also responsible for veterinary checks and are authorised to sign the Common Veterinary Entry Document.

A memorandum of understanding between Customs and MH on improving co-ordination was signed on 22 March 2007. The Customs information system (AIDA) flags consignments subject to veterinary control. The system prevents the release of those consignments without the necessary BIP clearance. A Presidential Decree on the implementation of the "Single window" was adopted on 4 November 2010 (DPCM no. 242). On the basis of this Decree, Service Conferences "Conferenze dei Servizi" are organised at local level and all Competent Authorities in the import sector are involved. All BIPs attend at local level the Conferences with Customs Authorities and provide detailed reports about the development of the "Single Window". At Central level a committee "Comitato di Monitoraggio" was instituted in order to carry out the monitoring of activities on the "Single Window". In addition, two specific sub-committees have been instituted for the interoperability of the information systems of the two Administrations (technical-architectural interoperability) and procedural interoperability (functional-procedural interoperability) in order to implement the Custom's "Single Window". The organisational structure and the activities at Central Level on implementation of the "Single Window" are available on the Custom Agency website:

<http://www.agenziadogane.it/wps/wcm/connect/internet/ed/servizi/sportello+unico+doganale>.

Comprehensive guidelines on import controls and the annual report on activities of the BIPs are available on the website:

<http://www.salute.gov.it/ministero/sezMinistero.jsp?id=80&label=uffici>.

Audit of BIPs

MH introduced a programme for the audit of BIPs in 2005. This programme involves a detailed examination of all aspects, both operational and procedural, as well as facilities, equipment and hygiene. The procedures for documentary, identity, physical and laboratory checks are assessed during the audit of BIPs by Office VIII. A new round based on a three-year cycle commenced in 2009. The annual activity on auditing of BIPs is described in the above mentioned annual report.

Listed BIPs

The listing of approved BIPs in Italy may be found at:

http://ec.europa.eu/food/animal/bips/approved_bips_en.htm

Laboratories

The laboratories of IZS provide analytical services to the BIPs. The results of analyses are entered by the BIP in TRACES and for specific checks are also sent to the CCA. The evaluation of all this data by the CCA enables a review of the implementation of the plan (follow up) each year.

The Technical Commission for Feedingstuffs (CTM) provides scientific and technical advice to Office VII-DGAHVM and gives official opinions on matters established by law.

The MIPAAF controls the commercial quality of feedingstuffs through its inspection service, the ICQRF.

Registration and approval of establishments and intermediaries

Approval for establishments manufacturing additives is given at CCA level by Office VII. Approval and registration of other FBOs (including the primary sector) are given by the RVS.

Detailed guidelines on the implementation of Regulation (EC) No 183/2005 were outlined in a letter dated 28 December 2005 (including templates for Food Business Operators (FBO) notifications to continue their activities in line with Art. 18 of Regulation (EC) No 183/2005). The main elements were published on the MH website.

These guidelines, which include standard models to be used for registration and approval, have been sent to all RVS and key FBO associations. The CA informs FBOs about new legal requirements through their respective association.

A list of approved and registered establishments is published on the MH website at: <http://www.salute.gov.it/sanitaAnimale/paginaInternaMenuSanitaAnimale.jsp?id=1572&lingua=italiano&menu=strumenti>

Official controls

The CCA prepares a 3-year multi-annual national control plan which provides the basis for regional plans. The national plan includes guidelines on: the development of regional plans based on risk; the selection of establishments to control; and the frequency and objective of control. The national plan also contains: detailed checklists as guidance for official controls at regional and local level; outlines of sampling priorities; and compulsory sampling targets for each RVS, which together with their LVS are responsible for the implementation of the plan.

The plan is amended when necessary by the CCA (e.g. law update, urgent situations, new problems, FVO recommendations).

The RVS develop regional plans based on the national plan and guidance, taking into account regional and local information on risk. The RVS may increase inspection and sampling targets, as appropriate. Since 2007, the CCA is responsible for approving regional plans.

The national plan includes controls on the presence of GMOs, additives, veterinary medicinal products, contaminants and the feedban. It provides for an inspection frequency of at least once a year for all registered and approved establishments and holdings using additives, premixtures of additives or medicated premixtures. In other cases inspection frequencies are established at regional level on the risk category attributed to the FBOs.

The AUSL are responsible for carrying out official inspections, sampling and on-the-spot verification to ensure that a feed business meets the requirements for obtaining and retaining an authorisation or registration. Within the AUSL, responsibility for

feedingstuffs is normally assigned to Area C of the veterinary services. Each AUSL has a contact person for feedingstuffs.

Responsibility for the control of imported feedingstuffs is assigned to the BIPs. Controls on feedingstuffs of animal origin coming from other Member States are carried out by the UVAC. In August 2006 a guidance document to support import controls was issued.

In specific cases the CCA can avail of the investigation and inspection capabilities of the NAS to perform national surveys or targeted and unplanned inspections. These inspections are usually linked to emergencies, court proceedings or cases of illegal actions.

Reports on the implementation of the plan are sent by the AUSL to the Regions which send them to the CCA annually, using standard reporting models.

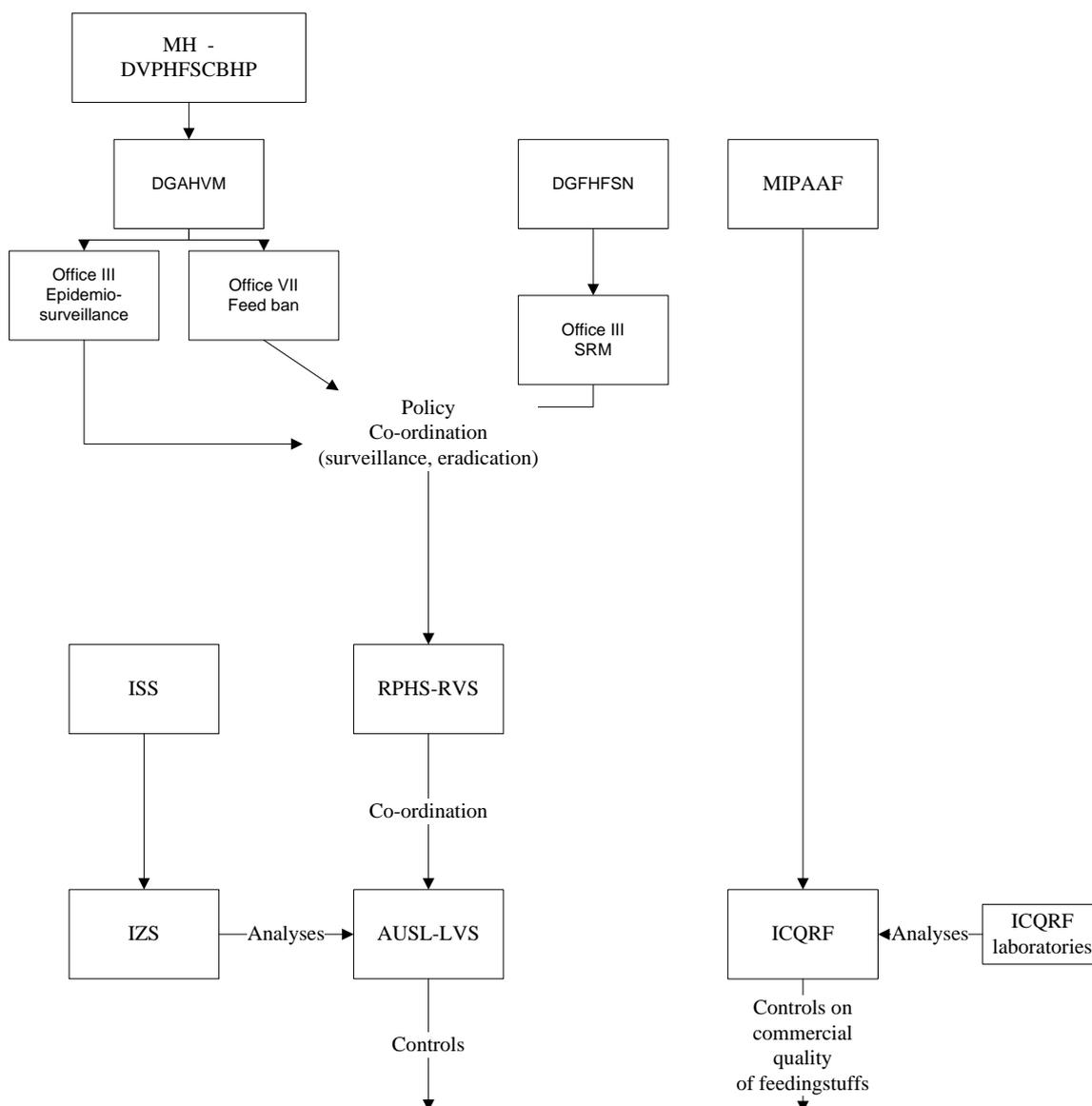
Laboratories

The National Reference Centre for feedingstuffs, including for the total feed ban, is CREAA, which is part of the IZS of Torino. The IZS Teramo is the National Reference Laboratory for dioxins and PCBs in feedingstuffs. The IZS of Padova is the National Reference Centre for Salmonellosis. The ISS is the National Reference Centre for Mycotoxins. The CREAA and the ISS were each designated by MH as NRL for additives in feedingstuffs in April 2009, in respect of specific categories of feed additives.

Official analyses of feedingstuffs are performed by 10 IZS laboratories.

2.5 Control system for TSE and Animal by-products (ABP)

TSE



MH	Ministry of Health
DVPHFSCBHP	Department of Veterinary Public Health, Food Safety and Collegial Bodies for Health Protection
DGAHVM	Directorate-General for Animal Health and Veterinary Medicine
DGFHFSN	Directorate General for Food Hygiene, Food Safety and Nutrition
MIPAAF	Ministry of Agricultural and Forestry Policies
SRM	Specified Risk Materials
ISS	National Health Institute
RPHS	Regional Public Health Services
RVS	Regional Veterinary Services
IZS	Experimental Zoo-prophylaxis Institutes
AUSL	Local Health Units
LVS	Local Veterinary Services
ICQRF	Central Inspectorate for Quality Control of Foodstuff and Agricultural Products

Competent Authorities

The CCA for TSEs is the DVPHFSCBHP. Within the DVPHFSCBHP, Office III DGAHVM is responsible for the overall planning, co-ordination, monitoring, supervision and verification of the implementation of measures on epidemio-surveillance and eradication.

Office III DGFHFSN is in charge of controls on SRMs and Office VII DGAHVM is responsible for controls on the feedban.

Epidemio surveillance

Controls are performed by the veterinary services of the AUSL and co-ordinated by the RVS. Official veterinarians working for the AUSL carry out controls at slaughterhouses and on the feed ban. In addition, they visit animal holdings and are responsible for taking samples for TSEs in sheep and goats, and monitoring BSE.

The MH has put in place a verification system for BSE. The National Reference Centre for TSE (IZS Torino) prepares a monthly summary of tested animals by risk category (routine, emergency and deferred slaughter and fallen animals) for each Region to facilitate reconciliation between animal and tested numbers. MH co-ordinates the process with regular information flows to/from the Regions.

Specified Risk Materials (SRM)

Controls on the removal and handling of SRM are covered in the Ministerial Decree of 16 October 2003 and guidelines of 1 July 2004 on the ABP Regulation. MH also issued a circular letter to the Regions on 9 March 2007 on the management of SRM and on verification procedures.

Total Feed ban

The annual control plan for feed covers the total feed ban. A memorandum of understanding between MH and MIPAAF on the control of animal feed for the prevention of BSE was adopted on 9 May 2006. This was subsequently revised and a new version adopted on 21 June 2007. A common sampling report is included in the memorandum of understanding and in the national feed control plan (PNAA). The memorandum of understanding also lays down how information is reported and exchanged. Results are transmitted from the reference laboratory to the MH and to the Regions every three months.

Since 2007, Office VII (responsible for the feed sector) assesses the quality of regional plans and whether those plans comply with the requirements of the PNAA. One of the aspects assessed is the criteria adopted by the RVS as a basis for their risk analysis.

As MIPAAF is responsible for feed quality, any feed safety issues are notified to MH for follow-up.

The national reference centre (Torino) receives all the results of controls and based on these, adjusts the risk based strategy for the following year's control plan. The annual control plan prescribes the number of samples to be taken in each Region.

The Central Inspectorate for Quality Control of Foodstuff and Agricultural Products (ICQRF) participates in the controls of the feed ban. Analyses are carried out by its laboratories. Co-ordination of all the authorities involved in controls of the feed ban is

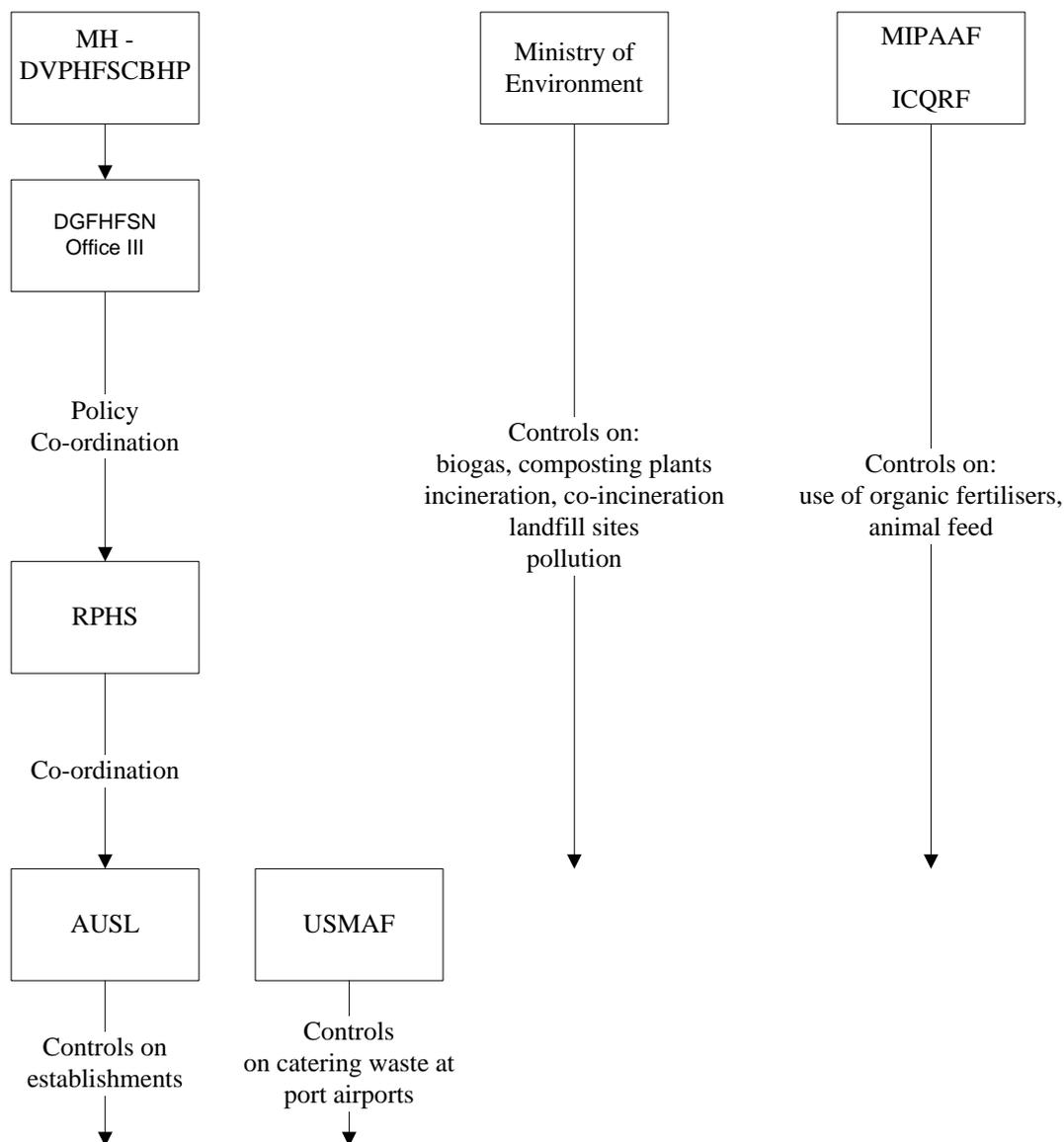
the subject of a protocol of understanding covering: the respective responsibilities; standard forms for inspection and sampling; and exchange of information.

Laboratories

The IZS in Turin is the National Reference Laboratory for BSE and the National Reference Centre for feedingstuffs. It carries out confirmatory tests for epidemic surveillance. The 11 ISS regional laboratories undertake the rapid tests.

The ISS, Rome, is the National Reference Centre for genotyping and molecular characterisation. These NRLs also organise ring tests and provide training.

Animal by-products



MH	Ministry of Health
DVPHFSCBHP	Department of Veterinary Public Health, Food Safety and Collegial Bodies for Health Protection
DGFHFSN	Directorate General for Food Hygiene, Food Safety and Nutrition
MIPAAF	Ministry of Agricultural and Forestry Policies
RPHS	Regional Public Health Services
AUSL	Local Health Units
USMAF	Port, Airport and Border Health Offices
ICQRF	Central Inspectorate for Quality Control of Foodstuff and Agricultural Products

Competent Authorities

The CCA for ABP is the DVPHFSCBHP. Within the DVPHFSCBHP, Office III DGFHFSN is responsible for the transposition of EU legislation and the harmonisation and co-ordination of ABP controls, in co-operation with the regional authorities.

Competencies for implementing the ABP Regulation are delegated to the regional authorities. Within the Regions, the RPHS are responsible for co-ordination while the AUSL are responsible for practical implementation of controls.

Responsibility for controls on international catering waste at ports and airports lies with the local port or airport health offices (USMAF) which report directly to MH.

Two other authorities are responsible for specific aspects of the Regulation:

- the Ministry of Environment is responsible for biogas and composting plants (controls only, approvals by MH), incineration and co-incineration, landfill sites, environmental pollution and incineration and burial sites;
- the MIPAAF is responsible for use of organic fertilisers and soil improvers and the animal feed sector.

Approval of ABP plants and other premises

The national guidelines adopted by the conference of the State and Regions on 1 July 2004 describe in general terms the approval of establishments and the authorisation of users under Article 23 of the ABP Regulation. A more detailed description of the minimum requirements for granting approvals is given in the technical guidelines developed by the ABP working group on which the national guidelines were based. These stipulate the minimum level of technical documentation needed to support an application, including the need for a validation of processing parameters, and a requirement that the local AUSL had inspected the establishment and given a positive opinion. In addition to these national guidelines, the Regions may develop further guidelines and checklists for the inspections, including those connected with the approval of premises.

Premises approved under the ABP Regulation are issued with a unique approval number comprising a set of digits followed by a specific acronym indicating the activity of the plant. If more than one activity falling under the scope of the ABP Regulation is undertaken at the same site, a separate approval number is issued for each, by means of different suffix codes to identify the activities. A list of the ABP premises approved in each Region is available on the Internet site of MH.

Collection of fallen animals

Vehicles collecting ABP have to be authorised by the AUSL. For commercial reasons, Category 1 and 2 materials are generally transported and processed as Category 1. Since 2001, it is been forbidden by law to import into Italy Category 1 materials from other countries. Movements of fallen stock classified as Category 1 materials have to be accompanied by a health certificate completed by officials from AUSLs. Fallen bovines of all ages are considered as Category 1 material. Farmers are generally responsible for arranging and paying for the collection and disposal of fallen stock, but in some Regions, 40-60% of these costs are paid by the Government. In the food processing premises all categories of ABP are dispatched with standardised commercial documents.

Category 3 materials are collected either for their destruction or permitted use. Former foodstuffs containing fresh meat are separated and sent for processing. Hides are generally sent directly from slaughterhouses to tanneries in Italy or other MS, or via intermediates before final processing.

A number of intermediate centres assemble small loads of ABP locally and consolidate them into larger ones to facilitate a more efficient transport system to processing or disposal sites.

Catering waste from restaurants is collected as domestic municipal waste.

The bulk of Category 1 and 2 materials are transformed in processing plants using methods 1 to 5 and the resulting meat and bone meal (MBM) and fats are disposed of by incineration or, in the case of fats, used as fuel.

The disposal of fallen stock by burial is permitted in certain remote areas. It is also permitted to bury dead pet animals.

Raw Category 3 materials are used in pet food or technical plants including, in particular, tanneries concentrated in two Regions, or transformed in a number of processing plants. The resulting processed products are further processed at other establishments or used directly in pet food or as fertilisers.

Category 3 materials for the feeding of animals under Article 23 of the ABP Regulation are generally supplied directly to authorised users.

Municipal waste is incinerated or land-filled.

Official controls

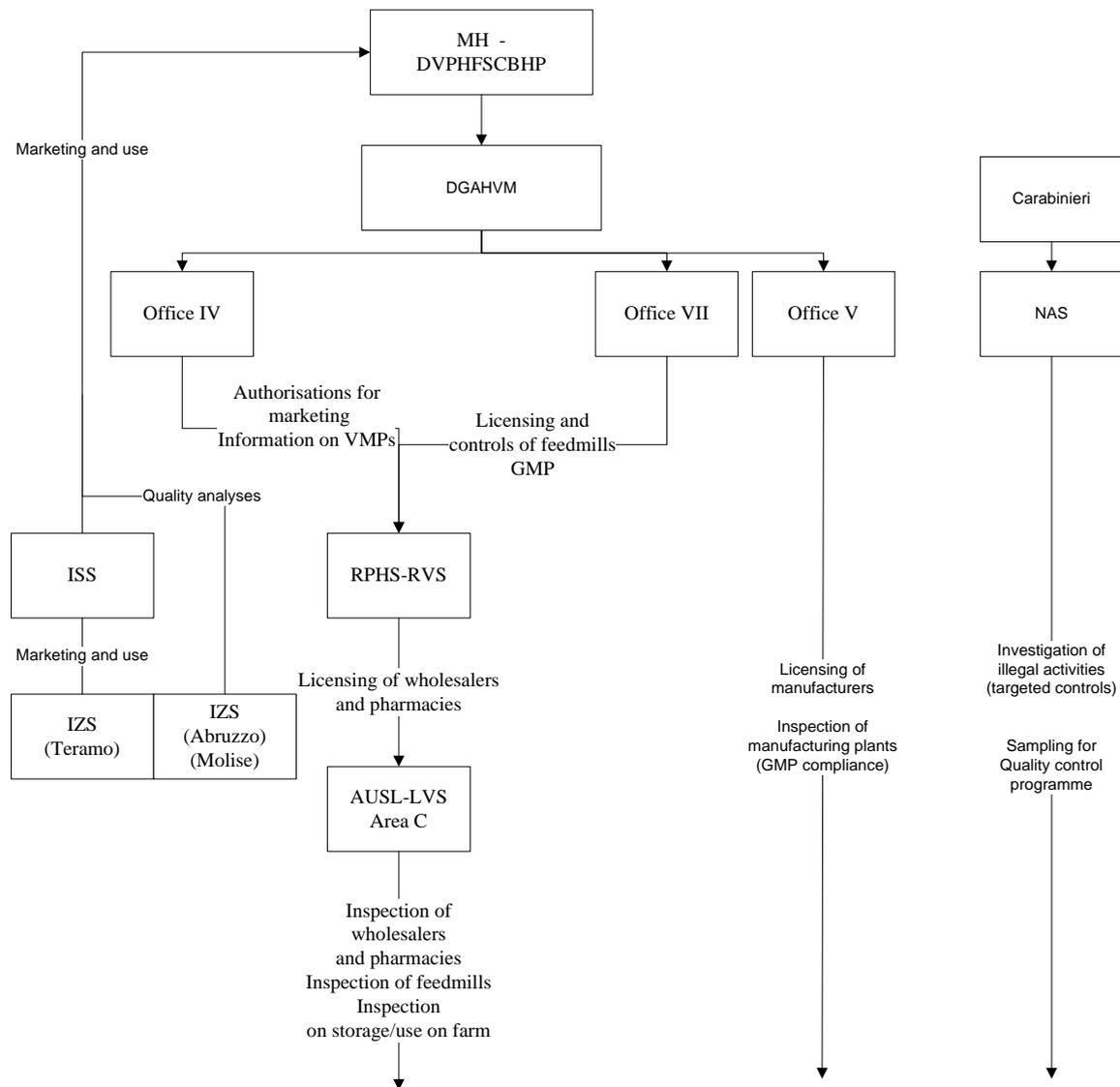
CCA guidelines for the implementation of controls on ABP, include minimum frequencies of inspection and standard checklists for controls.

Controls on production establishments are conducted as part of the supervision of food of animal origin establishments. For other categories of establishments, dealing with transport, collection, storage, handling processing, use and disposal of ABP, the recommended frequency for routine controls range from once a week to every three months. For controls on hygiene and own control systems the frequency is once or twice a year.

The systematic collection of data on the quantities of ABP produced, and their destination, began in 2006. The CCA has requested the Regions to report annually on the implementation of controls and follow-up activities in cases of non-conformities.

2.6 Control system for veterinary medicinal products (VMP) and residues

VMP



MH	Ministry of Health
DVPHFSCBHP	Department of Veterinary Public Health, Food Safety and Collegial Bodies for Health Protection
DGAHVM	Directorate-General for Animal Health and Veterinary Medicine
RPHS	Regional Public Health Services
RVS	Regional Veterinary Services
NAS	Carabinieri Health Protection Unit
AUSL	Local Health Units
LVS	Local Veterinary Services
GMP	Good Manufacturing Practice
ISS	National Health Institute
IZS	Experimental Zoo-prophylaxis Institutes

Competent Authorities

The CCA for veterinary medicines is DGAHVM, Offices IV and V. Office IV is responsible for issuing marketing authorisations for veterinary medicinal products and Office V is responsible for the licensing of MIA (manufacturing, importation, authorisation) and for compliance with GMP (Good manufacturing practices). Both offices are responsible for general policy, co-ordination, monitoring and supervision.

Controls are implemented by the AUSL under the co-ordination of the RVS, and by the NAS.

Authorisation of VMPs

Authorisations are issued by MH after an evaluation by Office IV DGAHVM with the support of a consultative committee.

Decree of 17 December 2007 (pursuant to Article 89 of Legislative Decree 193/2006) requires that VMP packaging include a bar code containing the identification of the medicine, its expiry date and the batch number.

Official controls on marketing/use

The RVS are responsible for the licensing of wholesalers and pharmacies. In Sardinia the DVPHFSCBHP (DGAHVM office IV) is responsible for licensing.

Wholesalers and pharmacies are inspected annually by the AUSL. The responsibility for checks on the storage/use of veterinary medicinal products on farms and by veterinary practitioners also lies with the AUSL. In this case there are no recommended frequencies for controls at national level.

Decree 193/2006 requires the Regions to report annually on the results of controls undertaken at wholesalers and pharmacies.

Feedmills are authorised to manufacture medicated feedingstuffs by the Office VII DGAHVM following an inspection and recommendation by the Regions. These feedmills are inspected annually by the AUSL.

The National Group for survey of veterinary medicines was established under Article 88 (4) of Decree 193/2006 with the objective of improving controls on the marketing of VMPs.

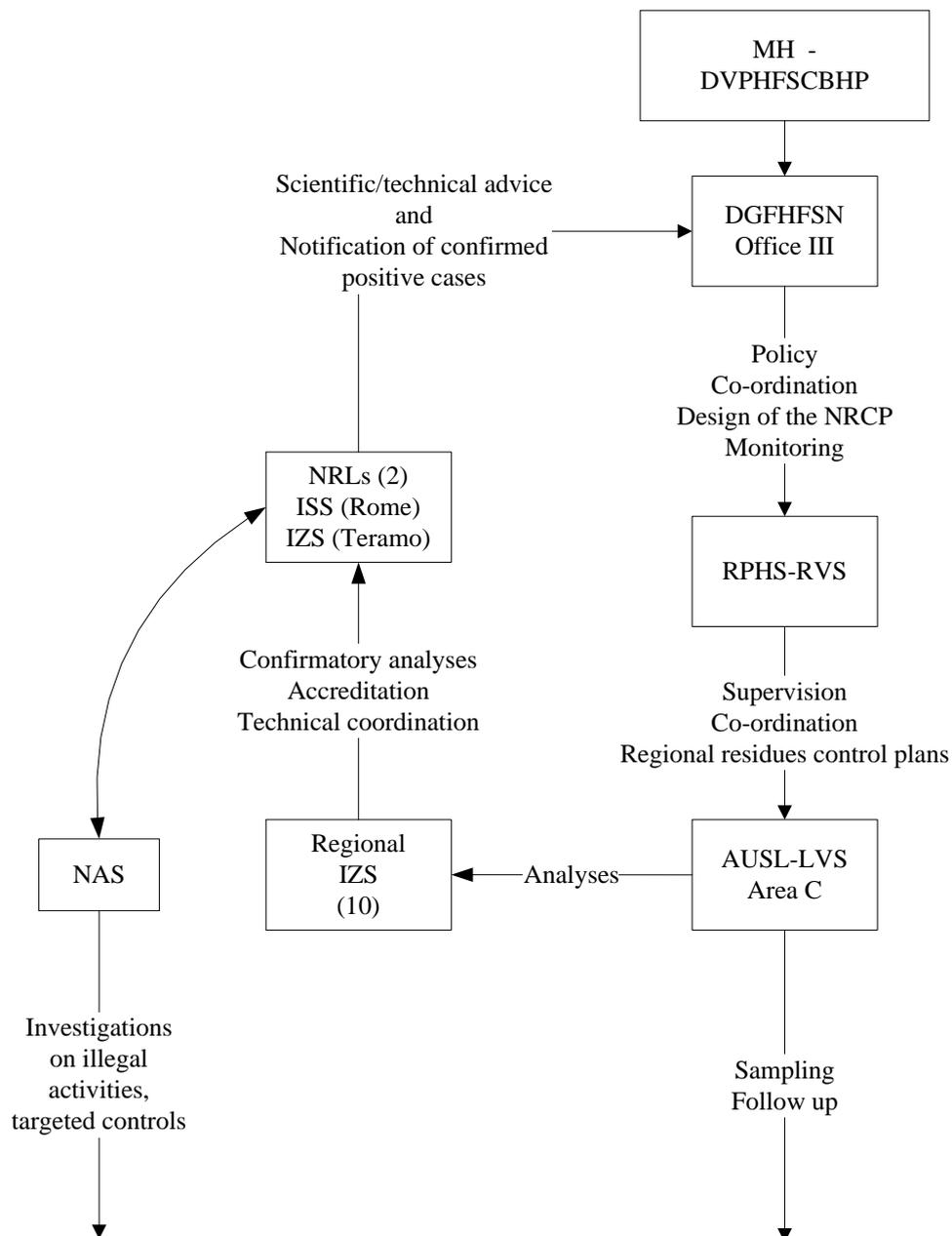
Decree 14/05/2009 published in the Italian Official Journal General Series no 198 of 27/08/2009 establishes the composition and operating modes of the National Group for survey of veterinary medicines, defines the tasks of the Regions, and sets down a format for data transfer from the Regions.

There is a national control programme for the quality of VMPs. Samples are taken by the NAS.

Laboratories

Two laboratories are used for controls on marketing and use: ISS and IZS at Teramo. As regards quality controls, the IZS at Abruzzo and Molise carry out the analyses.

Residues



MH	Ministry of Health
DVPHFSCBHP	Department of Veterinary Public Health, Food Safety and Collegial Bodies for Health Protection
DGFHFSN	Directorate General for Food Hygiene, Food Safety and Nutrition
NRL	National Reference Laboratory
RPHS	Regional Public Health Services
RVS	Regional Veterinary Services
ISS	National Health Institute
IZS	Experimental Zoo-prophylaxis Institutes
AUSL	Local Health Units
LVS	Local Veterinary Services
NAS	Carabinieri Health Protection Unit
NRCP	National Residues Control Plan

Competent authorities

Office III-DGFHFSN is responsible for developing the National Residue Control Plan (NRCP). Controls are implemented by the AUSL under the co-ordination of the RVS.

Official controls on residues

The NRCP is drafted by Office III DGFHFSN of the DVPHFSCBHP (CCA) with the involvement of representatives from all the Regions and the National Reference Laboratories (NRLs). The NRLs co-ordinate the technical requirements for the plan with the IZS's residue control laboratories which carry out the analyses.

The NRCP is distributed to the RVS, which develop their own regional residue control plans, decide on the distribution of sampling between the AUSL within their Region, and supervise the implementation of the plan. The Regions may establish dedicated task forces for this purpose.

RVS and AUSL may draw up their own more intensive residue sampling plans over and above the requisites of the NRCP. Results from this sampling are included in the annual report of the outcome of the NRCP.

The AUSL are responsible for sampling and for follow-up activities where infringements have been identified. Each AUSL has a contact person for veterinary residues. In case of non-conformities, the IZS immediately inform the CCA and, in parallel, the AUSL inform the Regions and provide details about the follow-up activities undertaken.

The CCA monitors the implementation of the plan and collates the data for transmission to the Commission. Data on analysis is entered by the IZS in a national information system. This provides web-based access for: the Official Veterinary Laboratories to upload data; the regional departments to validate them; and for CCA to monitor the action taken under the NRCP and compile national figures. The CCA transmits the results of the NRCP to the Commission database.

The NAS carry out national surveys on residues and may co-operate with the DVPHFSCBHP and/or AUSL on special campaigns involving simultaneous, unplanned sampling at national, regional or local level. The NAS are responsible for follow-up actions including legal measures following any non-compliant findings.

The NRCP is financed according to Decree no. 194 of 19 November 2008: "Official controls financing Act implementing Regulation EC 882/2004".

All the official controls, included those related to the NRCP, are financed through the fees charged to the FBO. 3.5% of the revenue is assigned to the Experimental Zoo-prophylaxis Institutes (IZS), the laboratories that perform analysis for the NRCP, to cover the expenses of these analyses. 1% of the revenue is assigned to the National Reference Laboratories. Moreover, the expenses deriving from additional controls are completely charged to the FBO, who pay directly to the laboratory for the analysis.

Laboratories

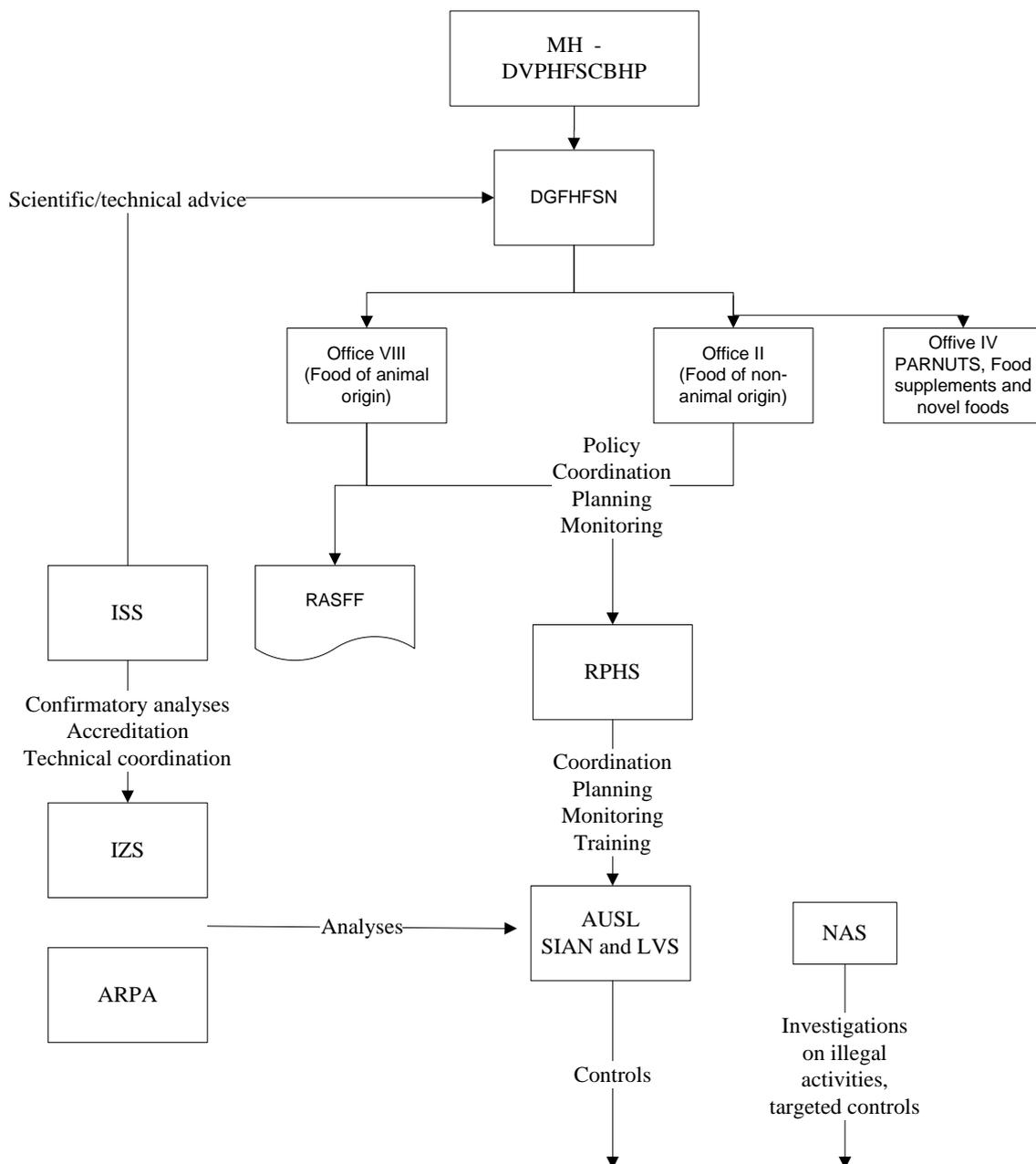
Analyses under the NRCP are performed by 10 IZS laboratories. Each sample is entered into a database by IZSs. Confirmatory analyses are undertaken by ISS. MH has access to the database at:

<http://62.123.162.33/izs/modules/sections/index.php?op=viewarticle&artid=25>

Italy has two NRLs: The ISS is NRL for residues referred to in Annex 1 to Directive 96/23/EC, with the exception of dioxin and PCBs. IZS Teramo is NRL for dioxins and PCBs.

The ISS does not perform any routine testing under the NRCP but carries out the confirmatory analyses. The NRLs are responsible for the NRL tasks under Article 14 of Council Directive 96/23/EC. The ISS assists the NAS in identifying the active substances in seized illegal drugs. Both NRLs and the 10 regional IZS laboratories are accredited by ACCREDIA.

2.7 Control system for foodstuffs and food hygiene



MH	Ministry of Health
DVPHFSCBHP	Department of Veterinary Public Health, Food Safety and Collegial Bodies for Health Protection
DGFHFSN	Directorate General for Food Hygiene, Food Safety and Nutrition
PARNUTS	Food for particular nutritional uses
ISS	National Health Institute
RASFF	Rapid Alert System for Food
RPHS	Regional Public Health Services
IZS	Experimental Zoo-prophylaxis Institutes
AUSL	Local Health Units
SIAN	Food Hygiene and Nutrition Service
LVS	Local Veterinary Services
NAS	Carabinieri Health Protection Unit
ARPA	Regional Agencies for Environment Protection

Competent Authorities

The DVPHFSCBHP is the CCA for official controls of foodstuffs and food hygiene. Within the DVPHFSCBHP, Office VIII DGFHFSN is responsible for policy issues, planning, co-ordination, monitoring, supervision and collating information from the Regions relating to the national programmes for the official control of foodstuffs (and for pesticides residues). Office VIII also co-ordinates the accreditation process for laboratories involved in official controls.

Office II DGFHFSN is responsible for official controls at the borders on foodstuffs of non-animal origin and contact materials arriving from third countries.

Office II DGFHFSN has trained, through 2 training courses, 46 auditors (ISO 19011) (28 in MH, 16 USMAF and 2 in BIPs) to conduct vertical inspections in the food hygiene sector, including imports of non-animal origin: 12 of whom have also been trained on Regional Systems of Prevention in order to conduct audits in this sector within the framework of the DVPHFSCBHP audit programme.

Office IV is responsible for policy issues, planning, co-ordination, monitoring, supervision relating to the official control on PARNUTS, food supplements, foodstuffs added with vitamins and minerals and novel food. Moreover, the Office IV is responsible for the notification procedures for all the product above cited, and for the receiving and evaluation of novel food dossier. In 2011 the CCA evaluates 13255 labels of the 17167 notified labels.

Office IV has trained 36 regional control officers in the babyfood and novel food sector, there other 3 training courses planned for the 2012-2013.

AUSLs are responsible for the control of FCM manufacturers. Presidential Decree of 14 July 1995 (Article 2, paragraph 1) and Notes by the General Directorate of food safety and nutrition (e.g. note n. 2964 of January, 24, 2006) give instructions on controls on this kind of operator.

Licensing and Registration of food businesses

In February 2006, the State–Region conference adopted guidelines for the application of Regulations (EC) Nos. 852/2004 and 853/2004.

Registration in accordance with guidelines on Regulation (EC) No. 852/2004 does not require a prior inspection by the AUSL. The existing administrative acts and authorisations for the notification of “start of activity” are used for the purpose of registration. The intention is to maintain a register/database of food businesses at local level by AUSL in line with requirements defined at regional level.

On 29 April 2010, an agreement was signed between the Government, autonomous regions and provinces on the "Guidelines for the application of Regulation No. 852/2004/EC of the European Parliament and Council on the hygiene of foodstuffs".

Official controls of food premises

By note dated 31 May 2007, MH issued guidelines to the Regions for official controls under Regulations (EC) Nos. 882/2004 and 854/2004. This includes standard reporting forms for the Regions to provide results to MH. Annexes 1-3 of these guidelines provide guidance on risk categorisation and inspection frequency and include a standard form for annual reporting on control activities to MH.

At regional level, the departments of health have responsibility for the official control of foodstuffs. The main role of the regional authorities is to provide guidance and staff training for official control activities at local level.

Official controls are carried out at local level by the SIAN and LVS of the AUSL.

The NAS take part in the control activities as part of their competence for monitoring hygiene measures and carrying out health inspections in a wide range of areas, including water, beverages, meat, processed food, dairy products and catering. They may be requested to perform control activities in support of MH or in cases of multi-regional or national significance requiring co-ordinated action.

DGFHFSN (Office VIII) produces an Annual Report on the results of monitoring and controls on foodstuffs in Italy which is published on the MH website.

Good Hygiene Practice Guides

In 2008, the DGFHFSN with the DGSA issued an Executive Decision to set rules for the Good Hygiene Practise Guides sector (GHP Manuals). Office II established a specific standard procedure (SOP). On 21 January 2011 the Working Group involved in the process of assessing and then validating guides to good practice, approved a “Guideline for the drafting and improvement of guides to good practice” in accordance with Reg. EC 852/2004. Office II oversees on the MH website a page dedicated to the GHP Manuals validation process:

<http://www.ministerosalute.it/sicurezzaAlimentare/paginaInternaMenuSicurezzaAlimentare.jsp?id=1187&lingua>

Rapid Alert System for Food and Feed (RASFF)

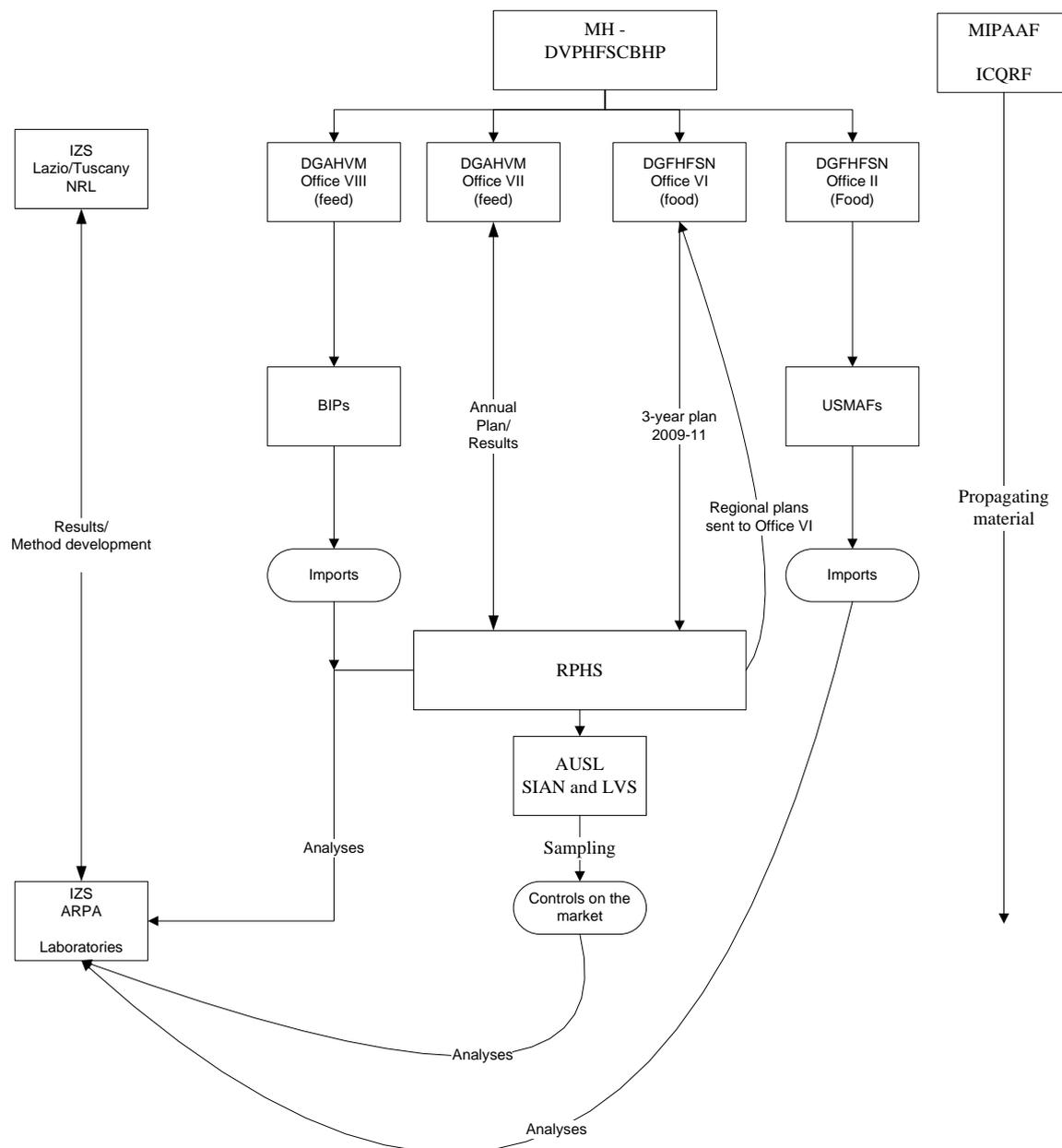
Office VIII is responsible for the operation of RASFF. It issues instructions and recommendations to the BIPs and to the Regions in order to improve the efficiency of the RASFF and monitors its operation. Risk assessment is carried out on a case-by-case basis in consultation with the sectoral offices of the DVPHFSCBHP and/or the ISS.

Laboratories

Analyses of foodstuffs of non-animal origin are carried out by the Regional Agencies for Environment Protection (ARPA). Decree of 27 February 2008 enables the IZS laboratories to undertake official analysis on food of non-animal origin. The number of accredited laboratories is as follows: 10 IZSS, 27 ARPA and 16 Public Health Laboratories (LSP) of AUSLs. Also branch offices of IZS and ARPA laboratories are accredited. Official laboratories are accredited by ACCREDIA.

The ISS provides a central laboratory capability for second instance analyses, the development of methods and the training of regional laboratory staff. In addition, the ISS acts as NRL for: monitoring viral contamination of bivalve molluscs; milk and milk products; E.coli (including verotoxigenic E.coli); parasites (in particular Trichinella); materials intended to come into contact with food; and Polycyclic Aromatic Hydrocarbons (PAH). It is also the National Reference Centre for botulism.

GMO



- MH** Ministry of Health
- DVPHFSCBHP** Department of Veterinary Public Health, Food Safety and Collegial Bodies for Health Protection
- IZS** Experimental Zoo-prophylaxis Institutes
- DGAHVM** Directorate-General for Animal Health and Veterinary Medicine
- DGFHFSN** Directorate General for Food Hygiene, Food Safety and Nutrition
- BIP** Border Inspection Posts
- RPHS** Regional Public Health Services
- USMAF** Port, Airport and Border Health Offices
- AUSL** Local Health Units
- SIAN** Food Hygiene and Nutrition Service
- LVS** Local Veterinary Services
- ARPA** Regional Agencies for Environment Protection
- MIPAAF** Ministry of Agricultural and Forestry Policies
- ICQRF** Central Inspectorate for Quality Control of Foodstuff and Agricultural Products

Competent authorities

MH is the CCA with responsibility for both GMO food and feed. Different offices within the MH are responsible for food and feed safety both on the market and at point of import.

Some 5-7% of the sampling activities of the NAS include samples for GM analysis.

GM food

Office VI in the DGFHFSN is responsible for GM food (with 0.7 FTE). This includes applications for authorisation of GM food. Office II of DGFHFSN is responsible for the organisation and co-ordination of procedures for the control of food of non-animal origin (both raw materials and processed food) by the USMAFs.

GM feed

Office VII DGAHVM is responsible for GM feed (with 0.3 FTE). This includes applications for authorisation of GM feed. Office VIII of DGAHVM is responsible for the co-ordination of border airports and ports (BIPs) for the compliance of imports of feed with the relevant legislation, including GMOs.

MIPAAF is responsible for controls on propagating material.

Official controls of GMO, including at import

Food

The regional and local authorities are responsible for undertaking inspection and sampling activities and the Regions must produce reports for MH (annually). The results of the analysis are directly uploaded by the laboratories to the information system of the IZS (CROGM).

The three-year control plan for 2012-2014 was sent to the regional authorities in December 2011. This plan is published at:

http://www.salute.gov.it/imgs/C_17_pubblicazioni_1666_allegato.pdf

Food imports

Control activities concerning GMO in foodstuffs are undertaken by the USMAF. Typical controls involve documentary, identity and physical checks, and sampling. Samples are taken from approximately 5-10% of consignments focusing largely on those declared free of GMO. Procedures are in place to notify all other USMAF and MH of any non-conformances detected. The AUSL of destination for a consignment is notified when the consignment contains GMO.

Feed

Controls are planned by the central authorities in Office VII DGAHVM on an annual basis. Each Region adapts the national plan to meet regional or local concerns.

Feed imports

GMO feed controls at the point of entry are performed by the veterinary services of the BIP. In August 2006 the CCA issued a guideline regarding criteria to be followed for

import control of feed, including GM feed. Documentary, identity and physical checks are undertaken. Samples are taken according to criteria established in the guidelines. The national feedingstuff control plan (PNAA) includes instructions on official controls on imported feed. The plans further develop the guidelines issued in August 2006 regarding the criteria, frequency and types of control required.

Official controls of GMO in propagating material

The ICQRF and the national agency for seeds (INRAN) together with Customs took 1.638 corn and 590 soya bean seed samples in 2010.

Laboratories

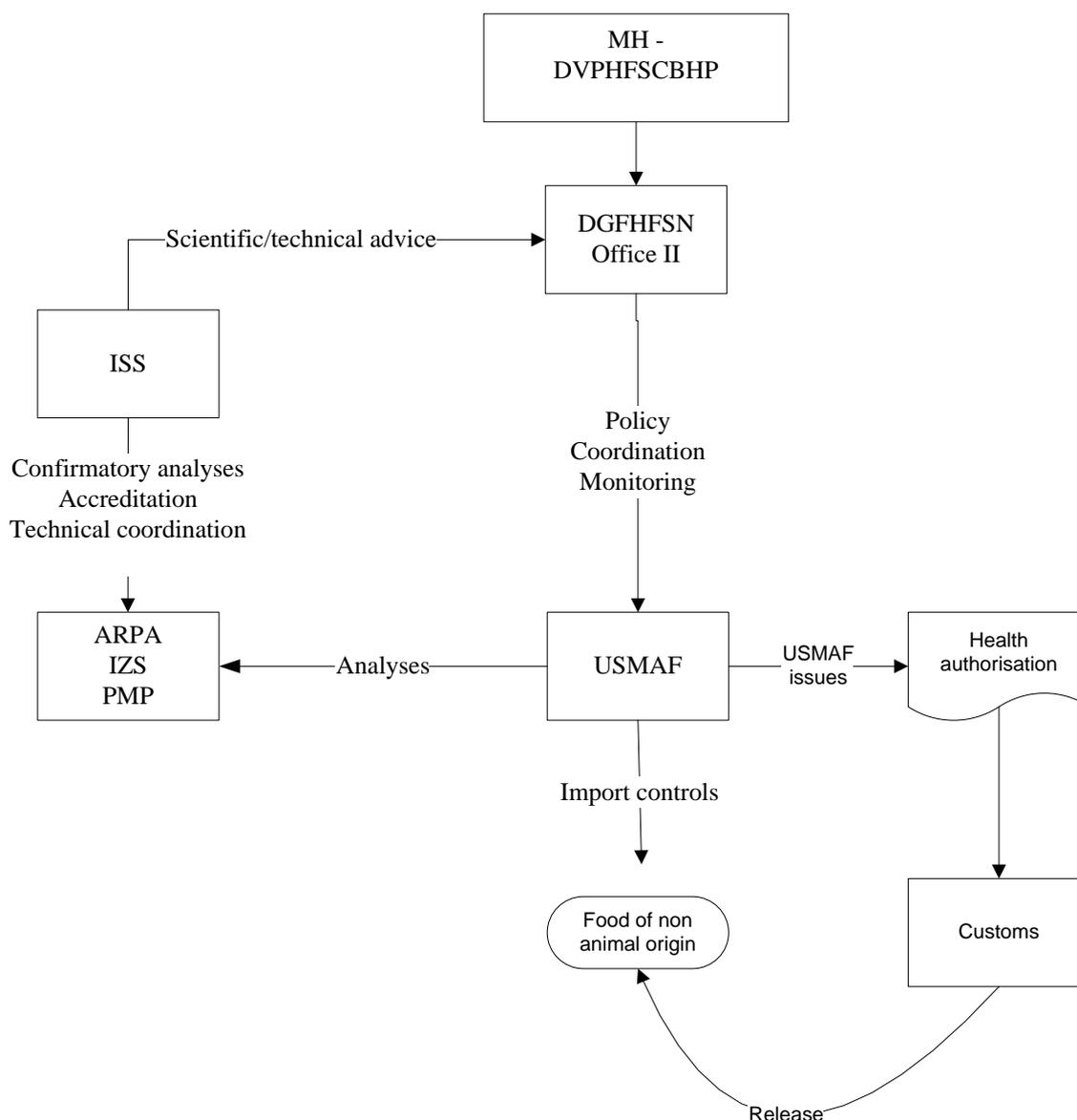
The IZS of Lazio and Tuscany is the national reference laboratory for GMO analysis and is a member of the European Network of GMO Laboratories. The NRL is accredited under ISO 17025 for GMO analysis since 2001. The scope of accreditation covers 26 qualitative PCR methods and 2 quantitative real-time PCR methods. It regularly participates in GeMMA proficiency test schemes.

In its function as national reference laboratory, IZS Lazio-Tuscany is also responsible for assisting other control laboratories in confirming or interpreting results and the set-up of a national network of GMO laboratories. It develops and harmonises methods and assists the MH in collecting and correlating data from the GM laboratories' official control activities. For this purpose, it has created a database, which is used to collect data from the GMO laboratories.

The NRL has created a scientific-technical group to strengthen the network of GM laboratories and to address issues such as validation of methods.

In addition to the NRL, 10 IZS laboratories, 8 laboratories of ARPA and 6 laboratories of AUSL undertake analyses for GM. Second instance analytical services are available to FBOs at the ISS.

2.8 Control system for imports of food of plant origin



MH	Ministry of Health
DVPHFSCBHP	Department of Veterinary Public Health, Food Safety and Collegial Bodies for Health Protection
DGFHFSN	Directorate General for Food Hygiene, Food Safety and Nutrition
ISS	National Health Institute
ARPA	Regional Agencies for Environment Protection
IZS	Experimental Zoo-prophylaxis Institutes
PMP	Multi-Territorial Prevention Offices
USMAF	Port, Airport and Border Health Offices

Competent Authorities

The DVPHFSCBHP is the CCA for official controls of food of plant origin and food hygiene. Within the DVPHFSCBHP, Office II DGFHFSN is responsible for policy development and deals with all issues related to the safety of products of plant origin.

Customs are responsible for ensuring that products submitted for import are accompanied by a health approval certificate issued by the USMAF.

The control of products on the market is undertaken by the AUSL and co-ordinated at regional level. While the AUSLs have no direct control over imports, they are informed of consignments of perishable products which are allowed to move to their point of destination pending analytical results, and also products placed under health restrictions.

Import controls

The USMAF carry out controls of imported goods. They have 37 local units at the main ports and airports, staffed mainly with health technicians supervised by medical doctors. Their responsibilities include a range of activities for international disease prevention. Checks on food of plant origin and food contact materials account for more than 60% of the overall CEDs issued by the USMAF.

Eighteen USMAF territorial units have been designated as points of import by Italy for food products coming under the relevant Commission Regulations on increased levels of controls.

The importer or his legal representative applies to the local USMAF to obtain a health authorisation which is necessary to allow the consignment to clear customs. The importer can also request the health authorisation via the Internet, using a specific software application. (NSIS system).

USMAF staff carry out health and hygiene inspections, comprising of one or all of the following elements:

- a systematic document check;
- a sample identity check based on the type of goods, especially in the case of packaged or perishable products;
- a physical check, including sampling and analysis.

As a rule, the analytical check is carried out at random on 5% of consignments where there is no reason of suspicion or where no other specific measures apply. (Presidential Decree of 23 November 1995 sets a minimum sampling frequency of 5%).

The USMAF offices issue the health authorisation (CED) if, on the basis of the accompanying documents, a decision not to carry out an inspection and/or analysis has been taken. When samples are taken, the USMAF offices produce the health authorisation to be issued once the results of the analysis carried out on the goods have arrived from the laboratory and are compliant.

Goods are released by Customs on the basis of the necessary documentation duly filled in and provided the health certificate has been presented. In the case of transfer of the goods to the final destination in Italy, information on the arrival of the goods is forwarded from the USMAF offices to the local AUSL, which carries out the sampling. Analytical results are reported back by the AUSL office to the USMAF office for issuing the health certificate for the release of the goods into free circulation. For goods in T1 transfer to another MS, the responsible USMAF office performs documentary and identity checks as needed.

Quality systems and supervision

A quality and audit system has been fully operational since 1 January 2008. This comprises 7 standard operating procedures and 1 operational instruction (on import of food of plant origin).

Laboratories

The ISS was designated on 7 March 2007 as NRL for the analysis of Mycotoxins in food and feed, in application of Article 33.1 of Regulation (EC) No 882/2004.

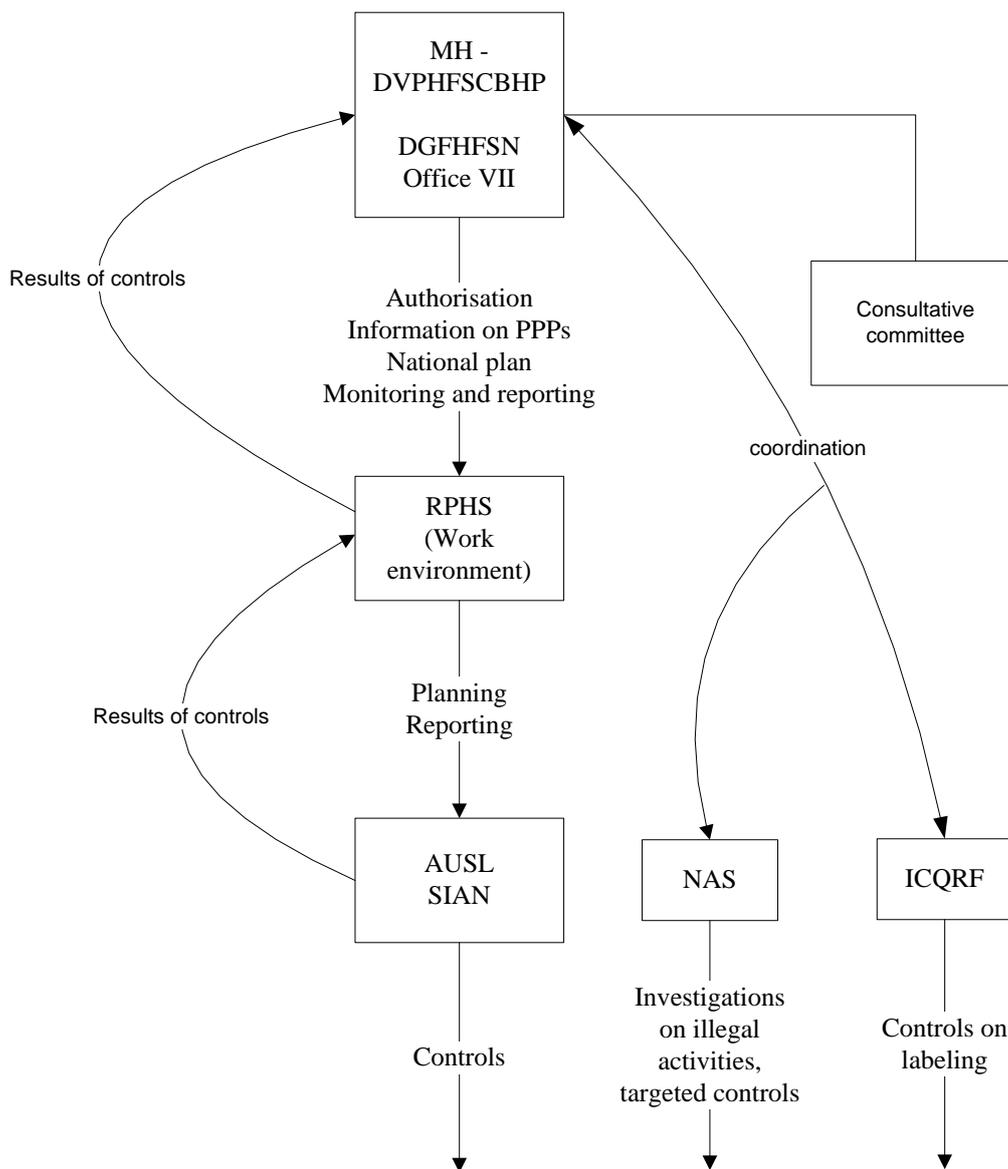
Routine analysis is undertaken mainly by the ARPA laboratories at regional level, the *Presidi multizonali di Prevenzione (PMP – Multi-area prevention centres)* and in some cases by IZS. The ISS provides a central laboratory capability for second instance analyses, the development of methods and the training of regional laboratory staff.

The ISS laboratory in Rome approves laboratories working in accordance with ISO 17025 and co-ordinates collaborative trials.

Decree of 27 February 2008 enables the IZS laboratories (all of which are accredited) to undertake official analysis on food of plant origin.

2.9 Control system for plant protection products (PPP) and residues

PPP



MH	Ministry of Health
DVPHFSCBHP	Department of Veterinary Public Health, Food Safety and Collegial Bodies for Health Protection
DGFHFSN	Directorate General for Food Hygiene, Food Safety and Nutrition
RPHS	Regional Public Health Services
AUSL	Local Health Units
SIAN	Food, hygiene and Nutrition Services
NAS	Carabinieri Health Protection Unit
ICQRF	Central Inspectorate for Quality Control of Foodstuff and Agricultural Products

Competent authorities

Within the DVPHFSCBHP, Office VII DGFHFSN is responsible for the authorisation and control of the marketing and use of plant protection products (PPP).

The NAS undertake investigations for the control of illegal pesticides and illegal uses of pesticides.

Authorisation of PPP

PPPs are authorised by MH following an evaluation carried out by Office VII DGFHFSN with the support of a consultative committee.

Some 6,000 PPP, containing around 350 active substances, are authorised in Italy. Details of authorised PPP together with relevant legislation are available on MH website at: <http://www.salute.gov.it/fitosanitari/fitosanitari.jsp?lingua=italiano>

Official controls on marketing/use

The Regions are responsible for the licensing of wholesalers and retailers following checks on the premises and the professional qualifications of the operators.

The regional services issue licences for use of pesticides. To obtain a licence, farmers must attend a specific course organised in collaboration with the AUSL. The regional services also provide advice to farmers on the use of pesticides.

A national plan (five year) for the official control of the placing on the market and use of PPP is established under a Decree dated 9 August 2002, updated by an agreement of the State-Region conference of 8 April 2009. It includes checklists and outlines general provisions and procedures for the transmission of results to the central level by the Regions.

The Regions report to MH annually on the results of controls. Office VII DGFHFSN is responsible for collating the results of inspections undertaken at a local level. The annual reports produced by MH also include data related to the activities of the NAS and the ICQRF.

At regional level, the Food Hygiene Service under the Regional Public Health Service (RPHS) is responsible for the marketing and use of PPP. Controls are carried out at local level by SIAN of the AUSL.

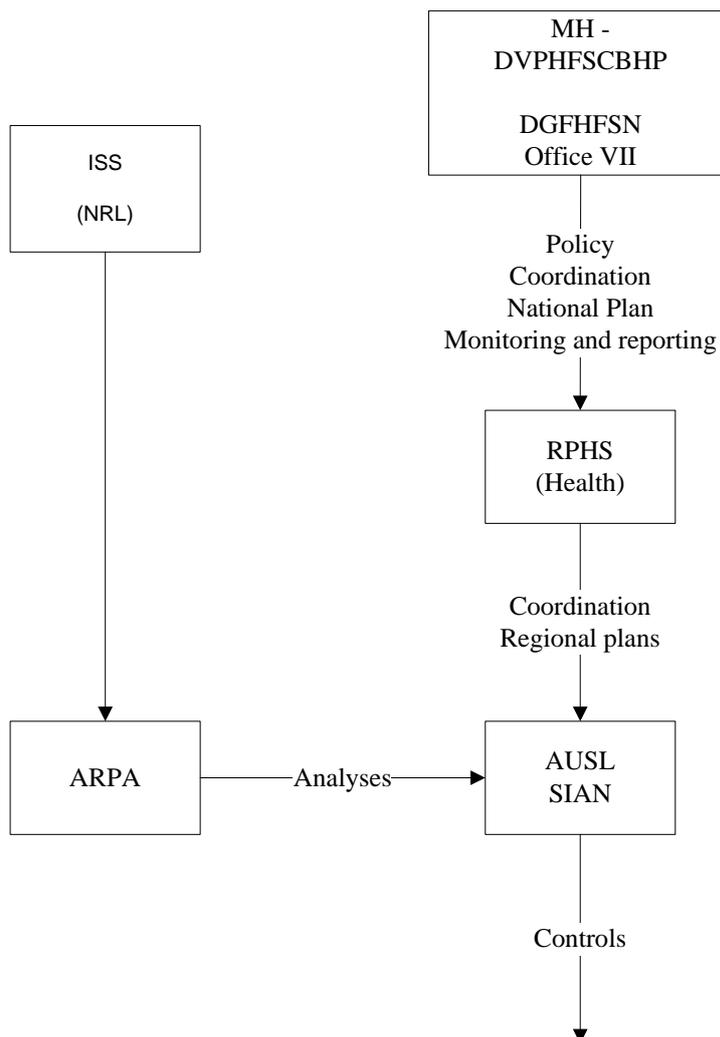
The ICQRF of the Ministry of Agriculture carries out inspections on the marketing of PPP. The labelling, packaging and formulation of PPP are checked to prevent and combat commercial fraud.

The occupational medicine service is responsible for safety at work and assists and informs farmers on handling of machinery and PPP.

Laboratories

Formulation analyses are carried out by some ARPA laboratories for the regional health services and, in the case of controls of the ICQRF, by its own laboratories.

PPP residues



- ISS** National Health Institute
- NRL** National Reference Laboratory
- MH** Ministry of Health
- DVPHFSCBHP** Department of Veterinary Public Health, Food Safety and Collegial Bodies for Health Protection
- DGFHFSN** Directorate General for Food Hygiene, Food Safety and Nutrition
- RPHS** Regional Public Health Services
- ARPA** Regional Agencies for Environment Protection
- AUSL** Local Health Units
- SIAN** Food, hygiene and Nutrition Services

Competent authorities

The DVPHFSCBHP is the CCA for controls on pesticides. Within the DVPHFSCBHP, Office VII DGFHFSN is responsible for controls on residues.

The ICQRF within MIPAAF has no responsibilities for pesticide residue controls, but carries out a monitoring programme for pesticide residues in organic food under Regulation (EC) No. 834/2007 and 889/2008, together with its 12 peripheral offices and 5 laboratories. The ICQRF also carries out marketing controls at retailers of PPPs.

Official controls on residues

A Decree of 23 December 1992 of MH specifies general criteria for the preparation of control plans at regional level. The number of samples to be taken in each Region is specified at central level. Office VII summarises the results of controls and prepares the annual report for the Commission.

At regional level, the health departments under the RPHS are responsible for controls on pesticide residues. They draw up detailed sampling plans and compile the results of controls.

Controls on pesticide residues are carried out at local level by SIAN of the AUSL. Sampling procedures are set out in a Decree of 23 July 2003 of MH.

The central or regional health authority may enlist the assistance of NAS, particularly where enforcement action is necessary.

Information on samples and results of analysis are directly uploaded by the regional laboratories to the national information system which allows web access to all laboratories. The laboratories send the annual results by 31 March of the following year. After an AUSL receives an analytical report showing a non-compliance, the case is usually forwarded to the Public Prosecutor.

Sampling of products at import is not covered by the national pesticide monitoring programme, but Ministerial Decree of 30 July 1993 lays down that 3% of imported consignments of food of plant origin be sampled for pesticide residue analysis. The results are reported within the USMAF Intranet, which is accessible to DGFHFSN.

Laboratories

The ISS was appointed as NRL for pesticide residue analysis in fruits and vegetables, animal products and for single-residue methods in March 2007. The ISS is not involved in pesticide residue monitoring, but carries out second instance analysis. Staff of the NRL are also involved in physical and chemical analysis of PPPs and the evaluation of active substances and EU MRLs.

The NRLs for pesticide residue analysis in fruits and vegetables, animal products and for single residue methods were accredited by the Italian accreditation body (ACCREDIA) in June 2010 in compliance with the ISO/IEC 17025. The Pesticide Section (*Reparto Antiparassitari*) of the National Institute of Health (*Istituto Superiore di Sanità*) is the located at the aforementioned NRLs.

The validation of the methods was carried out taking in accordance with the criteria of Commission document SANCO/10684/2009.

The laboratory has established a management system appropriate to the scope of the NRL activities. The quality manual and procedures take into consideration the following factors:

- education, training and skills of the laboratory personnel;
- accommodation and environmental conditions;
- test and calibration methods;
- equipment and measurement traceability;
- handling of test and calibration items.

The laboratory has also a procedure for the estimation of uncertainty.

Equipment of the laboratory:

GC/MS

GC/MS/MS

HPLC/MS/MS

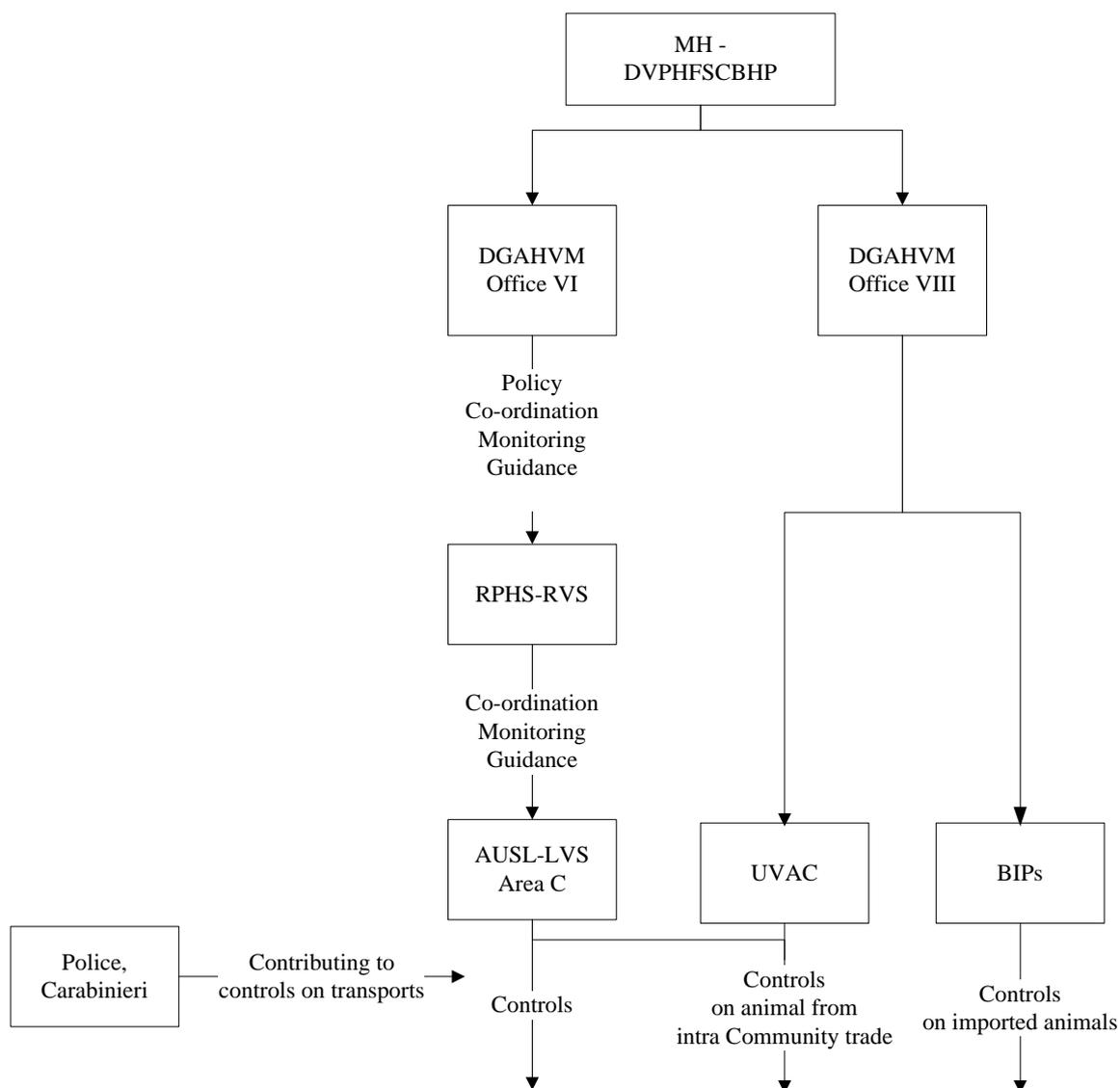
GC/FPD

GC/ECD

Analyses for national monitoring of pesticide residues in food of plant origin are carried out by the 32 ARPA/PMP/IZS laboratories. All laboratories have ACCREDIA accreditation.

Of the 32 laboratories, 18 have LC-MS/MS equipment.

2.10 Control system for animal welfare



MH	Ministry of Health
DVPHFSCBHP	Department of Veterinary Public Health, Food Safety and Collegial Bodies for Health Protection
DGAHVM	Directorate-General for Animal Health and Veterinary Medicine
RPHS	Regional Public Health Services
RVS	Regional Veterinary Services
AUSL	Local Health Units
LVS	Local Veterinary Services
UVAC	Veterinary Offices for Compliance with Community Requirements
BIP	Border Inspection Posts

Competent authorities

The DVPHFSCBHP is the CCA for animal welfare and animal reproduction. Within the DVPHFSCBHP, Office VI DGAHVM is responsible for policy issues, co-ordination,

monitoring, supervision and collating information supplied by the Regions and by the BIPs and UVAC.

BIPs and UVAC notify infringements to other Member States, third countries and international bodies. Both Office VIII DGAHVM and Office VI DGAHVM collect data on animal welfare from BIPs and UVAC.

Office VI undertakes vertical inspections in the Regions. The Office VI animal welfare inspection programme is included in the Office IX DGAHVM coordinated programme of audits and inspections.

A National control plan for risk-based on-farm controls was introduced in 2008.

Official controls on farm

Controls are co-ordinated by the RVS and performed by the veterinary services of the AUSL, in particular Area A and C. The RVS also collect and aggregate the data supplied by the AUSL veterinary services for subsequent forwarding to MH.

If necessary, the RVS may carry out inspections to verify the correct implementation of the legislation. Currently, all farms are visited at least once every three years.

The AUSL are responsible for taking action in the event of non-compliance which may include punitive measures and, when animals are severely maltreated, referral to the judicial authorities.

The CCA has issued guidelines for the control of animal welfare on farm for calves and pigs, including instructions on: specific requirements to be controlled; criteria for the planning of controls; checklists for controls; and a reporting system from the Regions to the CCA.

In the case of calves, a minimum annual frequency of 15% of farms to be inspected has been set at national level. Based on this general requirement the Regions are responsible for establishing annual control programmes which are sent to the CCA.

MH circulated procedures on 31 October 2007 on the correct implementation of Legislative Decree 267/2003 on the protection of laying hens (implementing Directive 1999/74/CE and 2002/4/CE). Checklists have been provided by MH to the Regions.

Official controls during transport

Roadside checks to monitor animal welfare during transport are carried out by the AUSL in conjunction with the police and Carabinieri. Inspections of animals coming from other Member States are normally conducted in conjunction with the UVAC.

Although the primary responsibility for the implementation of Regulation (EC) No 1/2005 rests with the AUSLs, UVAC, a local office of the CCA responsible for intra-EU trade, is involved in checks of animals in intra-EU trade. In addition police, Carabinieri and Forest Guards are also involved in implementation and enforcement of animal welfare during transport, and may perform checks, including roadside checks, on their own as jointly with official veterinarians (OV). They have the legal power to stop and inspect vehicles, check documents, assess the welfare of animals and issue sanctions. In case of doubt they may consult an OV.

The role of contact point as defined in Article 24(2) of Regulation (EC) No 1/2005 has been assigned to the OV responsible for animal welfare at central level.

The CCA has established a system of training on the requirements of Regulation (EC) No 1/2005 including specific requirements, such as those relating to partitions, individual stalls and access to water for equidae during transport.

A State-Regions agreement was published on 21 May 2008 giving practical guidance on the implementation of Regulation (EC) No 1/2005.

UVAC prepare an annual general programme of checks to be performed on the basis of the checks in previous years, which requires that approximately 2% of consignments of live animals coming from intra-EU trade are inspected at the place of destination. The actual checks are delegated to the AUSLs. An OV in UVAC decides on the consignments to be checked, on the basis of a risk assessment.

On 14 December 2006, the CCA sent an explanatory note to the CAs involved in the control of animal welfare during transport, which included a basic explanation of the requirements of Regulation (EC) No 1/2005 and details on: authorisation of transporters; training of drivers and attendants; and the role of the CCA contact point.

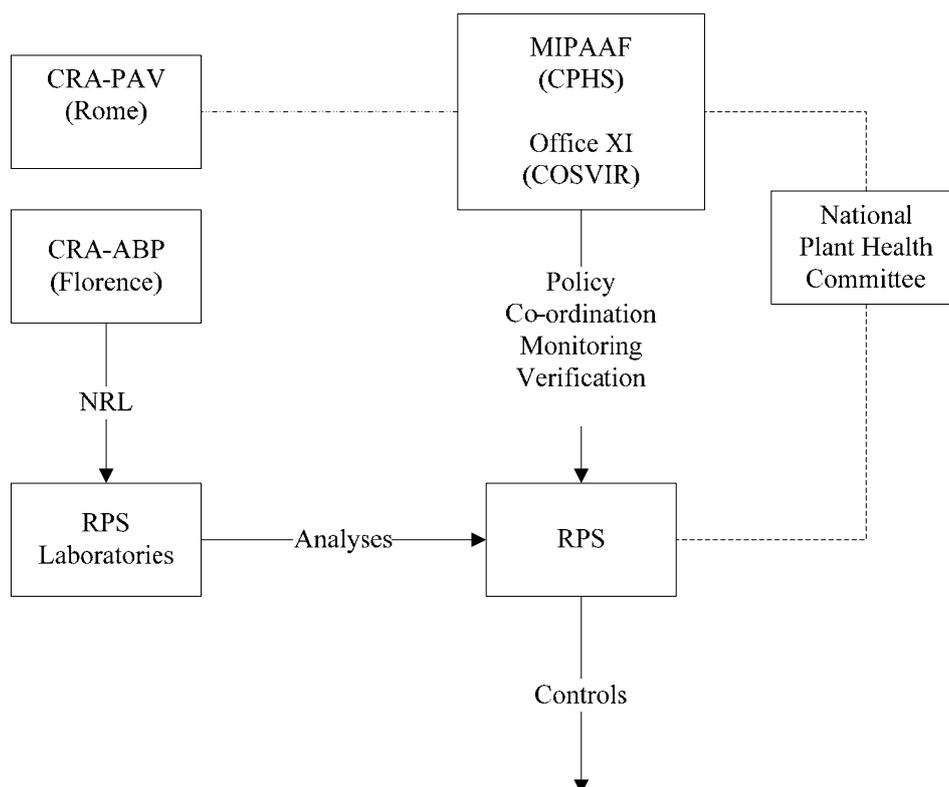
On 17 January 2007, the CCA sent a note on the application of Regulation (EC) No 1/2005, stating that, while awaiting clarification from the Commission on certain issues, such as navigation systems and monitoring of temperature of vehicles, the AUSLs should focus their inspections on the other requirements that are clear, such as fitness of animals for transport; checks of journey times and rest times; stocking density; and intervals for feeding and watering of animals.

Checklists have been prepared for controls during transport.

Official controls at slaughter

Three checklists for animal welfare at slaughter are in use.

2.11 Control system for plant health



MIPAAF	Ministry of Agricultural and Forestry Policies
COSVIR	Directorate-General of competitiveness for rural development
CPHS	Central Plant Health Service
CRA-PAV	Centre for Research in Agricultural Plant Pathology
CRA-ABP	Laboratory
NRL	National Reference Laboratory
RPS	Regional Plant Protection Services

Competent authorities

The Single Authority, within the meaning of Article 1(4) of Council Directive 2000/29/EC (CPHS), is the MIPAAF. Within the MIPAAF, the role of CCA is assigned to Office XI (Plant health, fertilisers and seeds) of the Directorate-General of competitiveness for rural development (COSVIR) which is responsible for: relations with the Commission and other Member States, third countries and international institutions; transposing EU legislation; issuing Decrees for the compulsory control of specific pests and parasites; collecting data on plant diseases at national level; and co-ordinating the activities of the Regions.

Legislative Decree No. 214 of 19 August 2005 establishes the National Plant Protection Service, which is composed of the Central Plant Protection Service, in MIPAAF, and the regional plant protection services and Autonomous Provinces, in each region. Each region organises its own service and may also use other public facilities. There are no other bodies to which powers are delegated in the plant health sector.

CPHS maintains the national register of plant health inspectors and organises training courses for inspectors at national level.

There are 2 FTE and Unit Head working on plant health, with a further 2 contract staff members recruited in September 2009.

The organisation of plant health services at national and regional level is set out in Decree No 214 of 19 August 2005. This Decree reinforces the co-ordination role of the CPHS by establishing a National Plant Health Committee, comprising representatives of each RPS as well as the CPHS. The Committee meets at least once a month to advise the CCA. Ministerial Decrees must obtained prior agreement of the NPHC and the State-Region Conference. In urgent cases, the Minister may make Decrees following consultation with NPHC.

National Plant Health Committee

The National Plant Health Committee, under Article 52 of D.lgs.214/05, is composed of:

- a) the Central Plant Health Service head or his delegate, to act as Chairman;
- b) the Regional Plant Health Service heads, or their delegates;
- c) an official of the Central Plant Health Service, to act as secretary.

The Committee makes technical proposals and have consultative tasks concerning the application of the above Decree, including the development of the necessary procedures for the National Plant Health Service and the development of the guidelines for the plant health inspectors' programmes.

The Central Plant Health Service has management and administrative responsibilities. It organises and prepares documents for meetings.

The National Plant Health Service activities are organised into working groups.

Each regional capital has a regional headquarters. Within a Region, there is generally one local office for each of the provinces, except for Sicily, where there are only two local offices for the whole Region consisting of nine provinces.

There is no national database or harmonised data recording system to facilitate the exchange of data between the CPHS and the RPS. Work has commenced to facilitate information exchange.

“Contingency Plans” have not been established yet. Eradication measures are borne by the owners or users of the land, any other necessary resources are provided by regional budgets. There is no national expenditure budget to eradicate outbreaks.

Plant passport system and internal market checks

The implementation of plant health legislation is handled at regional level by the RPS. Each Region generally has a local office in each of its Provinces. In some Regions, the RPS' are also responsible for quality control of propagating material.

National legislation (Legislative Decree 214/2005) defines the duties of inspectors, including: inspection of nurseries for plant passport purposes, conducting specific surveys (based on Ministerial Decrees), pre-export inspections and import controls.

The RPS are responsible for inspection of nurseries for plant passport purposes.

The plant passport system is laid down at national level by Legislative Decree 214/2005. Growers, traders and distributors of regulated plants and plant material have to be registered at regional level with the exception of local market production (see point 6, Article 20). Retailers selling to final consumers do not have to be registered. Professional

producers and packing centres for potato tubers (*Solanum tuberosum*) used for human consumption, *Citrus*, *Fortunella* and *Poncirus* fruit and their hybrids are also registered (Article 19 (point-2 letter-d) of Legislative Decree 214/2005). So-called 'secondary' *Citrus* fruit producers, only producing for the local market, are not registered.

The registrations are based on an application document, completed by the responsible person within the company and a visit by an inspector. Applications are detailed and include information about species and quantity of the regulated material and a plan of the premises and have to be introduced on standardised forms. VAT-numbers are used as individual identification numbers of the registered premises.

If appropriate, registered companies may obtain an authorisation from the regional headquarters to produce and issue plant passports. Such an authorisation stipulates in detail the species of plant for which passports may be issued.

Import controls

The RPS are responsible for import controls for plant health. Each RPS registers importers. All the import controls in Italy are executed at the point of entry.

There is no general agreement between the CPHS and the central authorities of Customs on harmonising co-operation at points of entry throughout Italy

The general Customs procedure provides for importers to issue a Customs declaration in paper form, which customs agents use for manual registration using the AIDA software. Customs agents are responsible for analysing the characteristics of the goods in order to determine which kind of document and controls are necessary. As regards regulated articles, AIDA does not automatically alert Customs agents to the need for a plant health certificate and control by RPS. This situation was being reviewed.

A "Single Window" Service was established by National Decree no 242 of 4 November 2010 in order to harmonise control procedures at the points of entry. The involved competent authorities include: Customs, Plant Health Services, Ministry of Health, Agecontrol (public agency for controls and EU activities), the veterinary services, Police Force, Coast Guard, Finance Guard and the CITES Management Authority.

It is the responsibility of the importer to give notice to the RPS that a plant health control is required and to provide all necessary information to the Service.

Laboratories

Each RPS has its own diagnostic laboratory. In addition, two laboratories act as reference laboratories: the CRA-PAV in Rome, and the CRA-ABP in Florence. University laboratories can provide additional capacity or expertise if required. A network of plant health laboratories was established by Decree No 214 of 19 August 2005. A Decree was being prepared to harmonise arrangements for accreditation.

The CRA-PAV research project "ARNADIA" aims to harmonise arrangements for accreditation through the preparation of diagnostic protocols for some harmful organisms. In this regard, the CRA was planning to organise training courses in order to transfer manual skills to the RPS laboratories. Furthermore, within the ARNADIA project, the RPS laboratories were involved in the ring test identifications carried out by the CRA-PAV. The process of accreditation of the CRA-PAV was in progress.

ANNEX I – STAFF RESOURCES¹

Authority	Staff with university degree	Technical staff	Administrative staff	Total	Note
National level					
DVPHFSCBHP	22		16	38	
DGAHVM	63	17	16	96	
DGFHFSN	56	25	30	111	The box "Staff with University degree" includes only healthcare professionals. The "technical and administrative staff" includes graduates in other subjects.
SNVR				13	
UVAC	48	22	20	90	Staff with university degree are the total number of veterinarians
BIP	110	110	43	263	Staff with university degree are the total number of veterinarians
USMAF	84	234	138	456	Medical directors of Level I and II
MIPAAF COSVIR XI				5	2011 data
ICQRF		565 (1)	276	841	(1) 25 directors, 369 inspectors, 164 analysts (<i>data updated until 26/09/2011</i>)
NAS				500	Inspectors
Regional level					
RPHS	139 (*)	15	133	287	
RPS		434 (2)	173	607	(2) 374 inspectors, 60 analysts, 173

¹ Statistics on control staff have been provided by Italy on a non-standardised basis.

					administrative staff; 2005 data
Local level					
AUSL LVS	5821(*)	1796	1398	9015	
AUSL SIAN	1058	1530	432	3020	
Laboratories					
ISS	109	77	17	203	
IZS	961	2681	969	4611	
ARPA/PMP/LSP	416	775	245	1436	
Total				21,592	

Note: Not all staff numbers are recorded as *full-time equivalents*

(*) Total number of veterinarians and other graduates.

ANNEX II – ACRONYMS, ABBREVIATIONS AND SPECIAL TERMS

ACRONYM	DESCRIPTION
ABP	Animal By-Products
APPA	Agency for Environmental Protection in the two autonomous provinces
ARPA	Regional Agencies for Environment Protection (<i>Aziende Regionali per la Protezione Ambientale</i>)
ASF	African Swine Fever
AUSL	Local Health Units (<i>Aziende Unità Sanitarie Locali</i>)
BIPs	Border Inspection Posts (<i>Posti di Ispezione Frontaliera</i>)
BSE	Bovine Spongiform Encephalopathy
CA	Competent Authority
CCA	Central Competent Authority
CEA	National Reference Laboratory for BSE
CED	Common Entry Document
CNSA	National Committee for Food Safety (<i>Comitato Nazionale per la Sicurezza Alimentare</i>)
CPHS	The central plant health service (in MIPAFF) <i>Servizio Fitosanitario Centrale</i>
CREAA	National Reference Centre for feedingstuffs <i>Centro di Referenza per la sorveglianza e il controllo degli Alimenti per gli Animali</i>
CSF	Classical Swine Fever
CTM	Technical Commission for Feedingstuffs
CUDN	Commission for dietetic and nutrition <i>Commissione Unica Dietetica e Nutrizione</i>
DGAHVM	Directorate General for Animal Health and Veterinary Medicine <i>Direzione Generale della sanità animale e del farmaco veterinario</i>
DGFHFSN	Directorate General for Food Hygiene, Food Safety and Nutrition <i>Direzione Generale per l'Igiene e la Sicurezza degli Alimenti e della Nutrizione</i>
DGPS	Directorate-General for Sanitary Prevention (<i>Direzione Generale della Prevenzione Sanitaria</i>)
COSVIR	Directorate-General of competitiveness for Rural Development, (<i>Direzione Generale della competitività per lo sviluppo rurale</i>)
DVPHFSCB HP	Department of Veterinary Public Health, Food Safety and Collegial Bodies for Health Protection
DVPHNFS	Former Department for Veterinary Public Health, Nutrition and Food Safety (<i>Dipartimento per la Sanità Pubblica Veterinaria, la Nutrizione e la Sicurezza degli Alimenti</i>)
EFSA	European Food Safety Authority
EURL	EU Reference Laboratory
FCM	Food contact material
FA	Food additives
FMD	Foot and Mouth Disease
FVO	Food and Veterinary Office
GMOs	Genetically Modified Organisms
HACCP	Hazard Analysis and Critical Control Points
ICQRF	Central Inspectorate for Quality Controls and Antifraud of Foodstuff and

ACRONYM	DESCRIPTION
	Agricultural Products (ICQRF) (<i>Dipartimento dell'Ispettorato centrale della tutela della qualità e della repressione frodi dei prodotti agro-alimentari</i>)
ISS	National Health Institute (<i>Istituto Superiore di Sanità</i>)
ISS ORL/ORL	<i>Evaluation and Accreditation Body (Organismo Riconoscimento Laboratori)</i>
IZS	Experimental Zooprophyllaxis Institutes (<i>Istituti Zooprofilattici Sperimentali</i>)
LVS	Local Veterinary Services (<i>Servizi Veterinari Locali</i>)
MANCP	Multi Annual National Control Plan
MH	Ministry of Health (<i>Ministero della Salute</i>)
MIPAAF	Ministry of Agricultural and Forestry Policies (<i>Ministero per le Politiche Agricole e Forestali</i>)
MRL	Maximum Residue Level
NAS	Carabinieri Health Protection Unit (<i>Comando Carabinieri per la Tutela della Salute - Nuclei Antisofisticazione e Sanità dei Carabinieri</i>)
NRCP	National Residues Control Plan
NRL	National Reference Laboratory
OF/SI	Organic fertilizers and soil improvers
PAP	Processed animal proteins
PARNUTS	Foodstuffs for particular nutritional uses
PMP	Multi-Territorial Prevention Offices (<i>Presidi Multizonali di Prevenzione</i>)
PPP	Plant Protection Products
RASFF	Rapid Alert System for Food and Feed
RPHS	Regional Public Health Services (<i>Servizi di Sanità Pubblica delle Regioni</i>)
RPS	Regional Phytosanitary Services (<i>Servizi Fitosanitari Regionali</i>)
RVS	Regional Veterinary Services (<i>Servizi Veterinari Regionali</i>)
SIAN	Food Hygiene and Nutrition Service (<i>Servizio Igiene degli Alimenti e della Nutrizione</i>)
SINAL	National System for Laboratory Accreditation (<i>Sistema Nazionale per l'Accreditamento dei Laboratori di Prova</i>)
SIS	Sanitary Information System
SNVR	Segretariato Nazionale della valutazione del rischio della catena alimentare
SRM	Specified Risk Materials
TSEs	Transmissible Spongiform Encephalopathies
USMAF	Port, Airport and Border Health Offices (<i>Uffici di Sanità Marittima, Aerea e di Frontiera</i>)
UVAC	Veterinary Offices for Compliance with Community Requirements (<i>Uffici Veterinari per gli Adempimenti degli Obblighi Comunitari</i>)
VMPs	Veterinary Medical Products



Country Profile

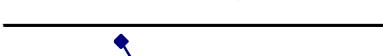
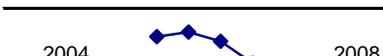
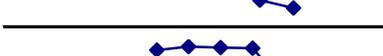
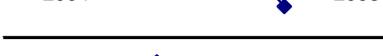
Summary data on Italy's
production, consumption and
trade of food, animals and plants

DG (SANCO)/2011/6088 Final
Valid as of May 2012

PRODUCTION, CONSUMPTION AND TRADE OVERVIEW

This part of the country profile presents summary data on Italy's production, consumption and trade of food, animals and plants. It gives the economic context for the control systems described in "The organisation of Food Safety, Animal Health, Animal Welfare and Plant Health Control Systems" overview. The data is based on Eurostat's publication on "Food: From Farm to Fork Statistics" which can be found on the following web site: [Food Chain Statistics](#).

ACTORS IN THE FOOD CHAIN

Holding rearing animals (Number)	2007	% EU-27	Trend (Absolute figures)
All holdings rearing equidae	34150	2.31%	1997  2007
All holdings rearing cattle	146990	4.30%	1997  2007
All holdings rearing sheep	75380	6.41%	1997  2007
All holdings rearing goats	33420	5.07%	1997  2007
All holdings rearing pigs	100950	3.55%	1997  2007
All holdings rearing poultry	75450	3.44%	1997  2007
All holdings rearing other livestock	3950	3.13%	1997  2007
Food production enterprises (Number)	2008 *	% EU-27	Trend (Absolute figures)
Production, processing, preserving of meat, meat products	4296	8.96%	2004  2008
Processing and preserving of fish and fish products	451	11.38%	2000  2003
Processing and preserving of fruit and vegetables	1975	19.91%	2004  2008
Manufacture of vegetable and animal oils and fats	3712	43.65%	2004  2008
Manufacture of dairy products	3996	32.99%	2004  2008
Manufacture of grain mill products, starches and starch products	1350	18.93%	2004  2008
Manufacture of other food products	50275	26.73%	2004  2008
Manufacture of beverages	2867	12.71%	2004  2008

* or most recent available data

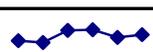
Food retail enterprises (Number)	2008 *	% EU-27	Trend (Absolute figures)
Retail sale in non-specialized stores with food beverages or tobacco predominating	50870	11.92%	
Retail sale of food, beverages, tobacco in specialized stores	112437	22.74%	
Retail sale of fruit and vegetables	18053	25.75%	
Retail sale of meat and meat products	30625	25.49%	
Retail sale of fish, crustaceans and molluscs	5919	17.53%	
Retail sale of bread, cakes, flour confectionery and sugar confectionery	8154	12.93%	
Retail sale of alcoholic and other beverages	4360	11.32%	
Restaurants; bars; canteens and catering	229889	15.91%	

* or most recent available data

Fishing vessels (Number)	2010	% EU-27	Trend (Absolute figures)
Number of fishing vessels	13515	15.78%	

Feedingstuffs and pesticides enterprises (Number)	2008	% EU-27	Trend (Absolute figures)
Manufacture of prepared feeds for farm animals	529	12.03%	
Manufacture of pesticides and other agro-chemical products	34	6.54%	

PRODUCTION

Livestock (1000 heads) - rounded	2010 *	% EU-27	Trend (Absolute figures)
Total of cattle population	5833	7.18%	2004  2010
Total of the pig population	9321	5.88%	2004  2010
Sheep total	7009	8.55%	2004  2010
Total of the goat population	983	7.35%	2004  2010
Total of equidae	157	4.20%	1995  2007
Poultry total	157240	10.10%	1995  2007

* or most recent available data

Slaughtering (1000 heads) - rounded	2010 *	% EU-27	Trend (Absolute figures)
Bovines	3862	13.86%	2004  2010
Pigs	12908	5.32%	2004  2010
Sheep	3744	9.17%	2004  2010
Goats	149	3.82%	2004  2010
Poultry	548068	8.21%	2004  2010
Equidae	99	55.49%	2004  2008

* or most recent available data

Milk and eggs production (1000 t) - rounded	2010 *	% EU-27	Trend (Absolute figures)
Milk collected by dairies	11135	8.79%	2004  2010
Eggs	743	11.80%	2002  2006

* or most recent available data

Fishery production (tons)	2009	% EU-27	Trend (Absolute figures)
Catches	253001	5.15%	2004  2009
Landings	242581	7.19%	2004  2009
Aquaculture	162325	12.63%	2004  2009

Crop production (1000 t) - rounded	2010 *	% EU-27	Trend (Absolute figures)
Cereals, incl. rice	20960	6.93%	2004  2010
Root crops	5108	5.01%	2004  2010
Industrial crops (total)	603	3.11%	2004  2010
Fresh vegetables, melons, strawberries	13973	23.11%	2004  2010
Fruit (excl. citrus fruit, grapes, olives)	5854	25.57%	2004  2009
Citrus fruit	4295	33.71%	2004  2010
Grapes	7788	22.25%	2004  2010

* or most recent available data

Food production turnover (Mio Euro) - rounded	2008 *	% EU-27	Trend (Absolute figures)
Production, processing, preserving of meat, meat products	20253	10.41%	2004  2008
Processing and preserving of fish and fish products	1998	9.63%	2000  2002
Processing and preserving of fruit and vegetables	9770	14.27%	2004  2008
Manufacture of vegetable and animal oils and fats	6039	15.16%	2004  2008
Manufacture of dairy products	17726	13.54%	2004  2008
Manufacture of grain mill products, starches and starch products	7409	15.50%	2004  2008
Manufacture of other food products	37494	13.28%	2004  2008
Manufacture of beverages	16014	10.72%	2004  2008

* or most recent available data

Feedingstuff production (1000 t) - rounded	2010	% EU-27	Trend (Absolute figures)
Premixtures for farm animal feeds	1463	9.55%	2004  2010
Preparations used for farm animal feeds (excl. premixtures)	12101	8.73%	2005  2010

CONSUMPTION

Gross apparent human consumption of main food items - 2009 (1)

	<u>Total</u>	<u>kg/head</u>
Cereals (excluding rice) (1000 t)	9604.00	160.03
Wheat - Total (1000 t)	9410.00	156.80
Barley (1000 t)	18.00	0.30
Maize (1000 t)	148.00	2.47
Dried pulses (1000 t)	108.00	1.83
Rice - total (1000 t)	602.00	10.40
Meat - Total (1000 t)	5457.00	90.00
Meat : Cattle (1000 t)	1404.00	23.00
Meat : Pigs (1000 t)	2297.00	38.00
Meat : Sheep and goats (1000 t)	83.00	1.00
Meat : Poultry (1000 t)	1159.00	19.00
Meat : Equidae (1000 t)	47.00	1.00
Drinking milk (1000 t)	3533.42	60.12
Whole milk (raw mat)	:	:
Cheese (1000 t)	1329.77	22.63
Eggs (1000 t)	655.00	:
Butter (1000 t)	169.43	2.88
Vegetable fats and oils (1000 t)	1650.00	27.89
Oil seeds and oleaginous fruit - Total	:	:
Apples (1000 t)	1194.00	19.90
Pears (1000 t)	685.00	11.41
Fresh peaches (1000 t)	1018.00	16.96
Grapes (1000 t)	216.00	3.60
Citrus fruit (1000 t)	2357.00	39.28
Oranges (1000 t)	1116.00	18.60
Nuts (1000 t)	292.00	4.87
Dried fruit (1000 t)	218.00	3.63
Cauliflowers (1000 t)	352.00	5.87
Fresh tomatoes (1000 t)	1013.00	16.88
Potatoes (1000 t)	2663.00	44.14
Vegetables (excluding potatoes)	:	:
Sugar (equivalent white sugar) (1000 t)	2560.00	43.56
Honey (1000 t)	25.00	0.43
	<u>Total</u>	<u>lt/head</u>
Wine (1000 hl)	21611.00	35.82

Degree of self-sufficiency of main food items (%) -2009 (2)

	<u>%</u>
Cereals (excluding rice)	79.66
Wheat - Total	76.64
Barley	65.48
Maize	84.80
Dried pulses	30.61
Rice - Total (equivalent milled rice)	163.21
Meat - Total	78.00
Meat : Cattle	61.00
Meat : Pigs	70.00
Meat : Sheep and goats	49.00
Meat : Poultry	108.00
Meat : Equidae	23.00
Drinking milk	:
Whole milk (raw mat)	:
Cheese	:
Eggs	:
Butter	:
Vegetable fats and oils	:
Oil seeds and oleaginous fruit - Total	36.73
Apples (1000 t)	:
Pears (1000 t)	:
Fresh peaches (1000 t)	:
Grapes (1000 t)	:
Citrus fruit	99.27
Oranges (1000 t)	:
Nuts	83.07
Dried fruit	8.51
Cauliflowers (1000 t)	:
Fresh tomatoes (1000 t)	:
Potatoes	55.79
Vegetables (excluding potatoes)	:
Sugar (equiv white sugar)	86.29
Honey	:
Wine - Total	159.25

(1) Rice 2004; Drinking milk, Cheese, Eggs, Butter, Sugar, Honey 2006; Dried pulses, Vegetable fats and oils 2007; Potatoes, Wine 2010

(2) Rice 2004; Sugar 2006; Dried pulses, Oil seeds and oleaginous fruit, Citrus fruit, Nuts, Dried fruit 2007; Potatoes, Wine 2010

TRADE

EXTRA-EU TRADE (2010)

TARIC CODE	COMMODITY	Imports (Mio €)	% EU-27	Imports (1000t)	% EU-27	Exports (Mio €)	% EU-27	Exports (1000t)	% EU-27
01	Live animals	12.25	4.51%	1.16	15.65%	5.19	0.38%	0.68	0.19%
02	Meat and edible meat offal	328.04	9.39%	62.09	7.02%	281.61	4.83%	146.60	3.70%
03	Fish and crustaceans, molluscs and other aquatic invertebrates	1206.88	8.62%	333.69	8.08%	55.48	2.17%	14.76	0.96%
04	Dairy produce; birds' eggs; natural honey; edible products of animal origin (not elsewhere included)	100.09	10.45%	25.14	6.58%	518.64	6.93%	87.07	3.00%
05	Products of animal origin (not elsewhere included)	96.48	9.25%	26.31	4.68%	36.01	5.52%	26.18	6.19%
06	Live trees and other plants; bulbs, roots and the like, cut flowers and ornamental foliage	48.38	3.20%	12.30	2.89%	115.13	6.64%	76.98	11.43%
07	Edible vegetables and certain roots and tubers	440.38	12.23%	513.45	13.12%	111.78	4.62%	72.41	1.76%
08	Edible fruit and nuts; peel of citrus fruit or melons	1155.10	8.97%	1120.41	8.98%	498.04	17.40%	502.69	14.63%
09	Coffee, tea, mate and spices	967.35	12.19%	470.20	14.13%	256.51	19.72%	44.55	14.70%
10	Cereals	648.46	24.61%	2886.64	28.66%	166.34	3.27%	440.16	1.55%
11	Products of the milling industry; malt; starches; inulin; wheat gluten	3.51	3.19%	3.16	2.24%	51.96	2.72%	134.44	2.82%
12	Oil seeds and oleaginous fruits; miscellaneous grains, seeds and fruit; industrial or medicinal plants, straw and fodder	560.80	7.68%	1408.03	8.12%	74.76	4.06%	126.96	5.76%
13	Lac; gums; resins and other vegetable saps and extracts	48.38	6.95%	18.80	9.64%	57.72	8.07%	7.16	7.12%
14	Vegetable plaiting materials; vegetable products (not elsewhere included)	29.46	18.26%	154.23	23.55%	0.78	7.11%	0.54	4.91%
15	Animal or vegetable fats and oils and their cleavage products; prepared edible fats; animal or vegetable waxes	1207.06	17.30%	1743.57	17.22%	807.32	25.46%	315.78	14.44%
16	Preparations of meat, of fish or of crustaceans, molluscs or other aquatic invertebrates	482.13	10.37%	124.07	8.82%	139.90	12.06%	32.27	8.51%
17	Sugars and sugar confectionary	151.79	8.19%	382.85	8.23%	61.98	3.03%	75.19	2.56%
18	Cocoa and cocoa preparations	253.06	4.75%	89.65	4.70%	345.41	9.48%	64.11	7.03%
19	Preparations of cereals, flour, starch or milk; pastrycooks' products	65.67	6.23%	31.79	5.79%	1046.38	18.50%	768.65	31.50%
20	Preparations of vegetables, fruit, nuts or other parts of plants	219.25	5.28%	242.81	5.79%	717.06	21.44%	821.68	26.77%
21	Miscellaneous edible preparations	73.81	3.45%	17.41	2.60%	312.57	5.69%	120.58	7.85%
22	Beverages, spirits and vinegar	199.85	4.19%	201.38	5.19%	2440.30	13.22%	1455.70	15.27%
23	Residues and waste from the food industries; prepared animal fodder	751.59	8.79%	2617.60	8.52%	149.98	5.10%	329.15	7.86%

INTRA-EU TRADE (2010)

TARIC CODE	COMMODITY	Imports (Mio €)	% EU-27	Imports (1000t)	% EU-27	Exports (Mio €)	% EU-27	Exports (1000t)	% EU-27
01	Live animals	1505.87	21.96%	575.38	18.78%	40.86	0.59%	10.94	0.32%
02	Meat and edible meat offal	4058.69	14.34%	1542.97	13.06%	1339.99	4.56%	421.30	3.31%
03	Fish and crustaceans, molluscs and other aquatic invertebrates	1966.86	15.99%	395.10	11.31%	313.76	2.43%	96.92	2.71%
04	Dairy product; birds' eggs; natural honey; edible products of animal origin (not elsewhere included)	3429.84	12.62%	3502.16	17.63%	1494.52	5.48%	607.28	2.98%
05	Products of animal origin (not elsewhere included)	113.71	7.12%	133.82	5.24%	68.77	4.58%	56.24	2.82%
06	Live trees and other plants; bulbs, roots and the like, cut flowers and ornamental foliage	477.28	5.99%	155.27	5.32%	526.97	5.67%	331.88	10.66%
07	Edible vegetables and certain roots and tubers	898.86	5.46%	1369.87	6.37%	1200.10	7.50%	1068.09	4.99%
08	Edible fruit and nuts; peel of citrus fruits or melons	919.99	5.39%	798.23	4.65%	2327.06	13.38%	2575.18	14.59%
09	Coffee, tea, mate and spices	137.20	3.17%	31.49	2.59%	502.11	10.46%	90.51	6.96%
10	Cereals	1400.30	13.16%	7932.52	14.16%	486.22	4.66%	945.41	1.67%
11	Products of the milling industry; malt; starches; inulin; wheat gluten	183.26	6.09%	412.41	5.43%	141.97	5.07%	302.95	4.30%
12	Oil seeds and oleaginous fruits; miscellaneous grains, seeds and fruit; industrial or medicinal plants, straw and fodder	443.00	6.39%	917.77	6.03%	203.85	3.01%	229.07	1.67%
13	Lac; gums; resins and other vegetable saps and extracts	81.29	9.20%	14.07	7.38%	67.07	8.09%	21.75	16.38%
14	Vegetable plaiting materials; vegetable product (not elsewhere included)	8.85	12.15%	20.04	9.03%	2.33	3.17%	2.25	0.85%
15	Animal or vegetable fats and oils and their cleavage products; prepared edible fats; animal or vegetable waxes	1636.07	13.79%	1251.23	9.75%	756.49	6.32%	496.87	3.78%
16	Preparations of meat, or fish or of crustaceans, molluscs or other aquatic invertebrates	645.97	7.49%	162.11	6.79%	526.53	5.56%	98.33	3.79%
17	Sugars and sugar confectionary	695.49	9.71%	1215.11	10.82%	181.48	2.59%	270.87	2.53%
18	Cocoa and cocoa preparations	569.06	5.34%	169.46	5.23%	666.30	6.02%	147.97	4.65%
19	Preparations of cereals, flour, starch or milk; pastrycooks' products	1021.97	6.58%	442.00	5.34%	2171.47	13.64%	1565.81	19.07%
20	Preparations of vegetables, fruit, nuts or other parts of plants	748.13	5.45%	713.99	5.17%	1827.00	12.83%	2189.97	14.90%
21	Miscellaneous edible preparations	719.17	5.09%	238.70	4.48%	990.24	7.40%	387.46	7.70%
22	Beverages, spirits and vinegar	1199.70	4.89%	1231.65	2.61%	3063.47	12.09%	8339.39	19.70%
23	Residues and waste from the food industries; prepared animal fodder	844.82	7.17%	1684.01	5.41%	335.39	2.63%	547.80	1.59%