

Survey of EU warning systems

Revised version

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Abbreviations

ADNS	Animal Disease Notification System
CCA	Crisis Coordination Arrangements
CIWIN	Critical Infrastructure Warning Information Network
DG	European Commission Directorate-General
ECURIE	European Community Urgent Radiological Information Exchange system
EUROPHYT	European Network of Plant Health Information Systems
EWRS	Early Warning and Response System
JRC	Joint Research Centre
LEN	European Law Enforcement Network (deals with public order and security matters)
MAHB	Major Accident Hazards Bureau
MIC	Monitoring and Information Centre for civil protection coordination
RAPEX	Rapid Alert System for Non-Food Products
RAS BICHAT	Rapid Alert System for Biological and Chemical Attacks and Threats
RASFF	Rapid Alert System for Food and Feed
SEMA	The Swedish Emergency Management Agency

1 Summary

A number of early warning and information systems for serious events that may have consequences for more than one EU Member State exist within the EU today. The systems have evolved by sector and their origins can often be traced to specific events that have affected the Union's Member States. The EU's early warning system for radioactive and nuclear power accidents was created, for example, in the wake of the Chernobyl disaster in 1986.

As the systems have existed for various lengths of time, there is a prevalence of procedural differences between them. The different areas of application of the systems also mean that certain systems are used on a regular basis while others are used less frequently. This is also dependent on whether the system is used primarily for early warning or for information purposes.

An undertaking has been in place the past few years for integrating and connecting the various European Commission directorate-generals (DG) in a cross-sector network in order to enable speedy information dispersal to all concerned sectors if a serious event, regardless of character, were to arise. The network is called ARGUS and is managed by the Commission. According to officers at ARGUS, the following eight systems are part of ARGUS: the Monitoring and Information Centre for civil protection coordination (**MIC**), the European Community Urgent Radiological Information Exchange system (**ECURIE**), the Animal Disease Notification System (**ADNS**), the European Network of Plant Health Information Systems (**EUROPHYT**), the Early Warning and Response System (**EWRS**), the Rapid Alert System for Non-Food Products (**RAPEX**), the Rapid Alert System for Food and Feed (**RASFF**) and the Rapid Alert System for Biological and Chemical Attacks and Threats (**RAS BICHAT**).

Several systems function today as both information and warning systems. With regards to certain systems, it is unclear whether they are a warning system or an information system since the agents involved are not always of the same opinion. Aside from these ambiguous cases, this report does not exclusively address warning systems but also includes regular information systems (MARS and TRACES). The reason for this is that the latter are sometimes designated warning systems, which may be worth knowing. The report includes two systems (CIWIN, LEN) that are under discussion but not yet in operation as well as the RAS CHEM system, which will come into operation in 2007.

2 Introduction

The knowledge of how each system functions rarely reaches those outside the respective system's users. This is a problem both within the Commission and the Swedish emergency management system. The Commission's cross-sector warning system ARGUS was created on the EU level in 2006 to increase contact between the systems and to spread knowledge beyond the immediate user circle. ARGUS connects the various sector warning systems with the aim of creating better coordination of EU measures in the event of a major crisis.

Because knowledge of EU warning systems is relatively limited in the Swedish emergency management system in general, SEMA (The Swedish Emergency Management Agency) wants to create a comprehensive view of the systems that exist within the EU to date. The EU warning systems comprise an important component in Swedish emergency preparedness because they are connected to some of the authorities within the Swedish emergency management system. The information that is communicated through the warning system also applies to events that may affect the Swedish community to the utmost degree.

This report is purely descriptive and as such contains no evaluation or analysis of the existing design or procedures of the respective systems, nor have we made any prognosis with regard to the future development of the systems.

System information was gathered from the European Commission web site, EU documents and by means of telephone interviews with, and in some cases on-site visits to, persons in charge of the respective systems both at the Commission as well as at the responsible Swedish authority.

A number of other systems undoubtedly exist within the EU but these systems are not included in this account. The systems that have a Swedish contact point and that are connected to ARGUS were selected. In addition to these eight systems, a number of systems that are sometimes referred to as warning systems on the European Commission's web site, etc are included in this report.

The presentation begins with a description of ARGUS and then describes the warning and warning/information systems. These are listed according to which of the Commission's DGs they belong to. The regular information systems are presented next followed by the systems that are not yet in use (and may never be used). Fourteen systems of varying character will be presented in total. Finally, information related to the warning systems within the EU that do not categorically fall under earlier headings are presented under the Other warning systems heading.

The section dealing with the warning and warning/information systems is divided into the following subheadings: *Legal grounds, members and objective, The Commission's points of contact and Swedish points of contact and procedures*. In cases where the system in question entails a type of

cooperation with systems that are not included in the EU collaboration there is a subheading entitled *Connections with systems outside of the EU*. Other system descriptions do not follow this grouping since there is less information surrounding these systems, nor are they the most relevant since they either do not presently exist or only exist as information systems.

3 Survey

3.1 Warning systems

The Commission's cross-sectoral warning system ARGUS (Secure General Rapid Alert System)

In order to be able to coordinate multi-sectoral crises within the Commission, the Commission has created a general system that is safe from wiretapping – ARGUS.¹ The decision to establish ARGUS was partly a result of the management of the tsunami disaster in 2004, since it was determined that Commission coordination was deficient. ARGUS, established after Commission Decision (2006/25/EC, Euratom) to supplement their internal procedures, was phased in during 2006.

The aim of the system is to provide a cross-sectoral platform for rapid information exchange between the various sections of the Commission and to ensure high-level political coordination in the event of a major multi-sectoral crisis. ARGUS links the sector-based warning systems to a great number of Commission departments: The Secretariat-General, DG Communication, DG Environment, DG Health and Consumer Protection, DG Justice, Freedom and Security, DG External Relations, DG Humanitarian Aid, DG Personnel and Administration, DG Information Society and Media, DG Taxation and Customs Union as well as Legal Services and Joint Research Centre. In addition to the aforementioned, additional DGs can join if they so wish or be added in the event of a crisis.

The four people responsible in the Commission for ARGUS belong to the Programming and Resources Unit of the Secretariat-General. The Commission's safety department in Brussels, the Security Office, is the operative contact point of ARGUS with staff on call around the clock every day of the year. The Security Office lies under the Personnel and Administration DG's Security directorate, the Protection and Crisis Management Unit. Twenty persons work at the unit. The internal security of the Commission, such as personnel issues, lies within the scope of their work tasks.² Three persons are constantly available during daytime and two persons man the office at night.

Should an incident occur in a sector, the person in charge in the DG alerts the other DGs via the ARGUS electronic network, whereupon the information is disseminated to the other members of ARGUS. Because warnings are usually disseminated via the sector-specific warning systems, ARGUS is alerted via the Commission staff in charge of each warning system. The Member States' national points of contact for the various warning systems have, thus, no direct contact with ARGUS. Reporting obligation follows the regulations for each respective warning system and the reaction to the crisis

¹ Annex 1 shows a flow chart for the activation of ARGUS.

² The Security Office is also the primary alarm recipient of warning signals throughout the MIC system and ECURIE. Because it is manned around the clock, it can also in theory be used to alert those in charge of all other warning systems. However, many warning systems have developed their own alarm systems.

is to be dealt with within the framework of the sector-specific systems. According to officers at ARGUS, the following eight systems are part of ARGUS: the Monitoring and Information Centre for civil protection coordination (**MIC**), the European Community Urgent Radiological Information Exchange system (**ECURIE**), the Animal Disease Notification System (**ADNS**), the European Network of Plant Health Information Systems (**EUROPHYT**), the Early Warning and Response System (**EWRS**), the Rapid Alert System for Non-Food Products (**RAPEX**), the Rapid Alert System for Food and Feed (**RASFF**) and the Rapid Alert System for Biological and Chemical Attacks and Threats (**RAS BICHAT**).³ These are described later in the report. The persons in charge for some of the systems are of the opinion however that they are not a part of ARGUS. This may partly be due to the fact that ARGUS has not had to be activated since the system was established or because the respective systems are not technically connected to ARGUS, which can make the connection less obvious.

The definition of being connected to ARGUS is not that the systems are electronically connected to each other. Instead, the officer on duty at the respective DG informs the other members of ARGUS that an incident has occurred by manually entering a message into ARGUS. Thus the persons in charge of each respective system are not able to communicate with each other by means of automatic information transfer from the sector systems to ARGUS. The information communicated through ARGUS is thus dependent on what the ARGUS correspondent, or another person in charge of ARGUS, enters into the system.

Warnings are issued according to their crisis level. Two exist: level I and level II. A level I crisis is not considered to be multi-sectoral. Such crises should be dealt with within the DG that is most closely affected, preferably through the warning system concerned. Other DGs should be kept informed. Level II is of a more serious nature and requires more coordinated internal measures. This level is activated upon a decision from the President of the Commission, either on his own initiative or at the request of another member of the Commission. The President also decides which Commissioner will retain overall responsibility for a level II situation, if not the actual President him/herself. The President will then call in a Crisis Coordination Committee made up of top officers from the various sections of the Commission (primarily DG directors). The committee will supervise the situation and make decisions internally in accordance with the requirements of the situation.

Members of ARGUS are listed according to function, not by individual name. The DG that effects a warning via ARGUS is responsible for specifying which other DGs are affected. When the DG effecting the warning in the web

³ Even functions such as DG European Community Humanitarian Office, Crisis Response Mechanism, Rapid Reaction Mechanism and Customs Information System are included in ARGUS. The aforementioned functions are more internal to the Commission and have no points of contact with the agencies in the Member States. Because of this, these are not included in this survey.

system enters that the warning concerns a level I, he/she must inform other concerned DGs via an SMS text message. In this phase the Commission's communication service is connected through its emergency number. Should a DG wish to request an activation of level II, a text message must be sent to the officer on duty at the Security Office, who in turn will contact the President of the Commission. In light of the situation, the President may consequently decide whether level II ought to be activated. Should level II be activated, the Security Office disseminates the information as a message in the system, which generates a text message to all members of ARGUS. The Security Office is also responsible for continually informing ARGUS members of the President's decisions throughout the process.

ARGUS is also a part of the warning system used prior to the activation of CCA (Crisis Coordination Arrangements), which is a cross-sectoral crisis management function on a political level. CCA is activated⁴ when a Member State or an EU body with information concerning a transpired or potentially serious crisis informs SITCEN⁵ about the situation via a special alarm telephone number. SITCEN, which is always manned, sends the information to the presidency (experts on duty in their permanent representations), the President of the Commission (the officer in charge of the President's personal office), The Council Secretariat (Deputy Secretaries General) as well as the Commission (officers on duty at ARGUS). The Council can activate CCA by directly alerting the expert on duty at ARGUS. The Cabinet Office's Unit for Preparedness and Analysis (EBA) is the Swedish contact point for all types of situations that may potentially activate CCA.ⁱ

3.1 3.1.2 DG Environment

3.1.1 MIC (Monitoring and Information Centre)

Legal grounds, members and objective

MIC is one of several functions of the EU Community mechanism, which was created according to Council Decision (2001/792/EC, Euratom), regarding the establishment of a Community mechanism to facilitate reinforced cooperation in civil protection assistance interventions. The mechanism consists of the CECIS (Common Emergency and Information System) communication system, an educational system, a system for experience exchange, a list of the experts and resources of the Member States as well as the possibility to offer coordination groups and evaluation groups to the country requesting aid. The mechanism can be activated by EU countries as well as non-EU countries that are in need of aid because of a major accident

⁴ Annex 2 contains a flow chart of the course of action of Member States prior to activation of CCA. Annex 3 contains a flow chart of the course of action within the EU prior to activation of CCA.

⁵ SITCEN (Situation Centre) is EU's common situation centre that collects and processes notifications from EU Member States, etc. SITCEN is situated at the Council Secretariat and is manned around the clock to ensure constant monitoring of crises and conflicts in progress or flare ups.

or catastrophe. In addition to the EU Member States, Liechtenstein, Norway and Iceland are members of the Community mechanism.

By means of the Community mechanism, resources and expertise of contributing states can be channelled to countries that have been hit by a major accident or disaster and that have requested aid. The mechanism is primarily intended as support for the people affected, but likewise for environment and property that have been damaged in a major accident or catastrophe. An example of this may be chemical, biological, radiological and nuclear terrorism, technical and radiological accidents, oil leaks at sea and other environmental accidents.

The Council Decision concerning the Community mechanism not only enables inquiry for assistance but also contains an obligation to inform the EU in the event of a serious accident. Member States must, without delay, inform MIC and other Member States that are at risk of being affected by the accident. Member States are obligated to follow the Council Decision but no sanctions will be incurred if a Member State fails to notify of the event of a major accident. Moreover, because what constitutes a major accident is unclear, it can be difficult to enforce observation of the decision. The following definition of a major accident is given in the financial instrument for civil protection that was adopted by Council Decision (2007/162/EC, Euratom): "any situation that has or may have an adverse impact on people, the environment or property and that may result in a call for assistance under the mechanism." In light of this it is up to every Member State to decide whether an accident is of the magnitude that MIC ought to be informed. As a rule, Member States that wish to receive a lot of information themselves report accidents with more frequency than other Member States. For this reason, the nature of the accidents that are reported by the Member States to MIC often vary to a great degree.

The Commission's contact point

MIC is a part of the Civil Protection Unit at DG Environment, Directorate Communication, Legal Affairs and Civil Protection. There are 20 or so officers at the unit. Most of these officers work with MIC-related issues as well as other issues within the domain of civil protection.

Swedish contact point

The Swedish contact point for the Community mechanism is the Swedish Rescue Services Agency (SRSA). This means that the SRSA receives inquiries and information from MIC and furthers it to the Swedish agencies concerned. In the event of a Swedish disaster that is estimated to require assistance from the Community mechanism, the inquiry will proceed via the SRSA to MIC, which in turn will contact the other Member States.

Procedures

Two administrative officers at MIC stand in readiness around the clock on a rolling schedule. They also receive alerts during office hours. MIC is not manned around the clock but on-duty officers must report for duty within 20 minutes in the event of emergency.

On 2 July 2007 the CECIS system became operative. This is a secure system for the transfer and storage of information. Member States and MIC enter information into CECIS in the event of a serious incident, whereupon the system generates an e-mail to the members of the system. However, it will be difficult to abandon the earlier system of e-mail and fax, so the systems are planned to run in parallel up to 1 November 2007.

The Commission's Security Office is the recipient of CECIS as well as of the telephone calls, faxes and e-mail messages of the Member States in respect of serious events. In the event of an alarm from a Member State, the Security Office contacts the officer on duty at MIC per telephone. In the case of warnings that are not included in CECIS, Member States cannot send out an alarm to all Member States simultaneously. Instead, it is sent via MIC. Those on duty at MIC then forward the alarm to the other Member State's contact points, either via CECIS, e-mail or fax in accordance with the established forwarding list. MIC can require the Member States to give notification that they have observed the dispatch (this is normally not done however because it may generate an unnecessary amount of information). If the alarm is of a very serious nature, those on duty set up an information notice on ARGUS.

Alarms from MIC are sent via CECIS, fax and e-mail to all contact points of the Member States. In Sweden the fax arrives at SOS Alarm in Karlstad while ordinary e-mail and CECIS go to the expert on duty at the SRSA as well as to the International Department. SOS Alarm also call the expert on duty, who always has a pager on his/her person. The expert on duty is available around the clock and is required to answer a call within 10 minutes. Dissemination of information in the Swedish system occurs via a network consisting of, among others, the Swedish Rail Administration, the Swedish Coast Guard, the National Board of Health and Welfare, Affärsverket Svenska kraftnät [the National Grid Company], the Swedish Maritime Administration, the Swedish Civil Aviation Authority, SEMA, the Swedish Radiation Protection Authority (SSI), the Swedish Geotechnical Institute, the Swedish Nuclear Power Inspectorate and The Swedish Defence Research Agency. When the SRSA receive an alarm regarding an incident that may have consequences for Sweden from MIC, the information is furthered to all within the network without appraisal being made about who is involved. The International Department of the SRSA then evaluates whether Sweden is in a position to provide assistance, with the support of all concerned agencies, where appropriate. In the case where aid efforts are deemed legitimate and the country in question accepts the offer, the efforts are then carried out through the International Department of the SRSA. In cases of aid to a country that is not receiving development aid, the Swedish Government Offices provide funding. In other cases, funding is provided by the Swedish International Development Cooperation Agency.

The SRSA are on around-the-clock alert and, in the event of a serious emergency in Sweden, they phone to the Security Office in Brussels to inform MIC. The SRSA do not have the authorisation to decide whether Sweden is in a position to request emergency assistance from the EU, but because the SRSA is the authorised contact point for the Community

mechanism in Sweden, any Swedish request for assistance will be channelled through the SRSA.

3.1.3 DG Energy and Transport

ECURIE (European Community Urgent Radiological Information Exchange system)

Legal grounds, members and objective

In accordance with Council Decision (87/600/Euratom), it is required that immediate notice be given to members of ECURIE if an affiliated state takes steps for the protection of its own population. This is to ensure that all Member States are promptly informed in the event of an emergency situation that involves a risk of radiation. The Member State that measures exceptionally high levels of radiation in the environment, or that has been affected by an accident which results in, or may result in, leakage of radioactive substances, must consequently inform the Commission and Member States concerned about which protective measures and steps to notify the public have been planned or executed. The latter occurs in accordance with Council Directive (89/618/Euratom) pertaining to requirements of informing the general public. In addition to the EU Member States, Switzerland is also a member of the system. Member States have a reporting obligation. Should a Member State fail to report as required by the decision, the Commission could bring a Member State before the European Court of Justice, which is the highest instance for the interpretation of European Community law. However, according to those in charge of ECURIE, it is highly unlikely that this would happen.

The Commission's contact point

The Radiation Protection Unit in Luxembourg, under the Nuclear Energy Directorate at DG Transport and Energy, is in charge of the ECURIE at the Commission. Responsibility for technical elements and the development of the computer processing system rests with the Joint Research Centre (JRC). Two persons at the Radiation Protection Unit work fulltime with ECURIE and an additional 13 persons make up an Emergency Team that is called in on emergencies. They all have access to information in ECURIE.

Swedish contact point

In the event of a disaster on foreign soil, the Swedish Meteorological and Hydrological Institute (SMHI) (contact point) will receive the Swedish alarm. The Swedish Radiation Protection Authority (SSI) is the Swedish contact point (competent authority) for radiological emergency situations and houses Sweden's only ECURIE computer. SMHI and SSI both receive the ECURIE alarm. SSI decides whether an alarm should be sent internationally from Sweden, and SOS Alarm sends the alarm. SSI also alerts the EU via the ECURIE computer.

Procedures

SMHI (contact point) is always the recipient of alarms in the event of a disaster on foreign soil irrespective of whether the alarm is issued from the EU, the IAEA or states holding a bilateral agreement. SMHI is manned around the clock. In the case of an accident on foreign soil, SMHI receive a fax, whereby they then contact SOS Alarm in Stockholm for the further

dissemination of the information to the Swedish Nuclear Power Inspectorate (SKI), the SRSA and the SSI. Besides fax, an alarm is dispatched from the EU ECURIE computer, which goes directly to SSI because they house the only ECURIE computer in Sweden.

The SSI is Sweden's contact point for Nuclear Energy disasters and radiological emergency situations. The institute has an emergency preparedness organisation in the form of an on-duty radiation protection officer that is available around the clock. The on-duty officer responds within 15 minutes and must be available to the agency within one hour. The on-duty radiation protection officer initially has the same powers as the Director-General at SSI and activates the emergency preparedness organisation. The SSI's emergency preparedness group consists of approximately 20 persons who are representatives of the different functions in the emergency preparedness organisation. The group is made up of whoever may be currently available and is then made active. The on-duty officer can be contacted via mobile telephone as well as by pager. The same applies for the emergency preparedness group. The group is contacted via SOS Alarm and as a first step, the on-duty radiation protection officer must gather information and evaluate how serious the situation is.

In addition to being dispatched by fax to SMHI, the ECURIE alarm also goes directly to the mobile telephone of the on-duty radiation protection officer. The information is encrypted and the on-duty radiation protection officer must visit the ECURIE computer in order to receive clarification concerning what has occurred, and where. Encryption is useful in the sense that it rules out unauthorised access and allows each Member State to receive the information in their own language, after decoding. The fax received by SMHI is also encrypted. In the case of an incoming EU alarm the SSI is responsible for disseminating the information within Sweden. Should the alarm turn out to be serious, the SSI, through SOS Alarm in Stockholm, will alert the government, the county administrative boards and the agencies concerned.

Every Member State has been issued ECURIE computers, which are not used for any purpose other than ECURIE. The Swedish ECURIE computer is set up in the emergency preparedness room at the SSI where it is connected both via the Internet and ISDN in order to prevent interruption in the event of electrical or telephone failure. ECURIE is designed in the same way as an e-mail program, where warnings are managed as outgoing and incoming mail. Exact times are given in Coordinated Universal Time (UTC) in order to facilitate for the Member States to calculate how much time has passed since the event occurred. The ECURIE computer is set up on UTC time, as is a clock in the emergency preparedness room. A complement to this is the information network EURDEP, where Member States can report gamma-ray emission test readings every day from their gauging stations placed throughout the country (35 gauging stations in Sweden).

SMHI has a special fax that is only intended for atomic energy emergency warnings from the EU, IAEA and countries with a bilateral agreement. The

same fax receives all further information surrounding any incidents, but SMHI programs the fax to send all information to the SSI where there is a special fax apparatus for atomic energy disasters. As is the case with the ECURIE computer, this fax is housed in the SSI's emergency preparedness centre and is connected to a warning light on the door as well as on another floor. This is to ensure that any incoming fax is immediately noticed. The fax machine also sends out incoming information to the mobile telephones of the emergency preparedness group.

The system is tested several times a day, by means of persons in charge at the Commission dispatching automated test messages to the Member States. The tests are sectioned into different levels, which require various levels of working response from the Member States. At levels 1 and 2, Member States must send an acknowledgement and at level 3 there are planned exercises. When the test message has come in but has not been acknowledged, a red light flashes on the ECURIE box, which indicates the level of the test messages received. There are also warning lights to indicate whether the system in general is not functioning. Should a Member State not reply within a period of two days, the Commission will contact them in order to inquire why a response had not been received. Important information that is not⁶ classified as an ECURIE alarm but that the Member States ought to be aware of is also sent via the system. In this case, there is no obligation to acknowledge the message.

The unit in Luxembourg is not manned around the clock but has an on-duty administrative officer that works in rotational weekly shifts. The primary alarm recipient of the Commission is the Security Office in Brussels, which is manned around the clock. The Security Office houses two ECURIE computers and two ECURIE faxes that are solely designated to incoming alarms pertaining to radiological emergency situations. When the ECURIE computer receives an incoming alarm, a text message is generated to both the on-duty experts at the Radiation Protection Unit and at the Security Office. Member States can also contact the Security Office and the experts on duty at the Radiation Protection Unit via mobile telephone. An incoming alarm to the Security Office is immediately forwarded via mobile telephone to the Radiation Protection Unit experts on duty in order to ensure that the alarm has really reached its destination. The experts on duty, who have a reaction time of one hour, call in the Unit's Emergency Team and make sure that the contact points within the Member States have been informed via the computer and fax systems (affected Member States should also inform the Member States concerned, at the same time as they warn the Commission). The Radiation Protection Unit has two ECURIE computers for that purpose and can even receive assistance from the Security Office to speed up the process of furthering the information between the Member States and the Commission. The Security Office works as a back-up should the computer system within DG Transport and Energy fail. Should a Member State not respond to an alarm within a one-hour period, the Commission will dispatch a new message in the system, together with a new fax. Afterwards

⁶ One example of this might be that a Member State has discovered that a radioactive source has been stolen.

the Commission will phone in order to inform the country that a serious incident has taken place.

The Unit's emergency team makes a collective evaluation about whether ARGUS should be informed. After this, any group member can enter information into ARGUS. Incoming alarms via ARGUS go directly to the experts on duty at the Radiation Protection. The Security Office is not involved in the transfer of the information.

In the case of an accident in Sweden, the one who discovers the accident (affected nuclear station, SMHI, the SSI through their gauging stations, Customs and Excise by means of the instruments issued them by the SSI, the municipalities through their mobile measuring systems, etc.) informs the regional SOS Alarm centre. SOS Alarm then contacts the county administrative board concerned, the SKI, as well as the on-duty radiation protection officer at the SSI. The latter makes the decision about whether or not the emergency preparedness group needs to be called in. The on-duty radiation protection officer acts in the capacity of Emergency Superintendent until such is selected. The Emergency Superintendent ought to normally be a Chief Officer in the SSI's ordinary organisation. The Emergency Superintendent appraises whether the Swedish networks, the EU, the IAEA and states with bilateral agreements are to be informed. The SSI then informs SOS Alarm in Stockholm, who alert the government, other county administrative boards and agencies concerned, as well as the EU, the IAEA and other parties abroad. Countries abroad are contacted by means of urgent messages with pre-programmed fax destinations. The SSI also dispatches warnings via ECURIE. The authority to enter information into ECURIE lies with about 20 persons in the strategic information group, many of whom are included in the emergency preparedness group. In order to dispatch an alarm to the EU, the ECURIE Alert folder must be opened in the system, whereupon a comprehensive questionnaire begins.

The information is then sent to the Commission, which then forwards it via the ECURIE system and fax to all Member States. No alarm is dispatched directly from one Member State to another Member State unless these states have entered into a bilateral agreement for this purpose. The system has the capacity to send direct messages to all within ECURIE but the decision was made to have all information go through the Commission which checks that the alarm has come from an authorised source before it is disseminated.

Connection to systems outside the EU

According to IAEA's convention EMERCON, notice is only required in case of an accident in which another country could be affected by a discharge. On 14 November 2006, the EU and the IAEA signed an agreement on mutual early warning that came into force one month later. The information is exchanged between ECURIE and IAEA's warning system ENATOM via fax. The contract between EMERCON and ECURIE basically means that an ECURIE Member State only needs to alert one of the systems in the event of an incident, whereupon the system should guarantee that the other one is informed. Despite the difference that prevails in the criteria for what should

be set out, the Commission chooses to inform ENATOM about alarms which per definition do not actually reach IAEA's alarm threshold. ENATOM is on the same forwarding list for fax as the Member States in ECURIE and the recipients will receive exactly the same information. For Sweden, SKI and SSI decided in the end of May 2007 that SSI will disseminate the same information to both systems, in spite of the different thresholds for when the alarms should be executed. The intention is to harmonise the two data formats on the two warning systems in the future, in order to achieve automatic information exchange. These plans have not come a long way however since there are certain difficulties in synchronising the systems, which currently look very different.ⁱⁱ

3.1.4 DG Health and Consumer Protection

According to those in charge of ARGUS at the Secretariat-General all the information/alarm systems at DG Health and Consumer Protection listed below are connected to ARGUS. There are differences of opinion about this, but ARGUS would most likely be activated in the event of a serious disaster in one of the areas contained by the systems below, even if the warning would not be issued via the technical system *per se*, but through other channels.

When any of the systems' experts on duty receives a warning about an event of an extremely serious cross-sectoral nature, they make an appraisal about whether or not ARGUS should be informed. After that the person on duty calls to the ARGUS correspondent of DG Health and Consumer Protection, who coordinates ARGUS-related activities within the DG. The ARGUS correspondent is the only one who has the possibility to determine whether or not ARGUS should be activated. There are no clear criteria specifying when ARGUS is to be activated, other than common sense and consultation with the experts of the warning system who requested that ARGUS should be activated. A number of persons serve as ARGUS correspondents on a shift schedule. Should those on duty at the sector system not be able to contact the correspondent, he/she should refer to the list of other persons to be contacted. Most of the persons who serve as correspondents are unit managers in the various directorates within DG Health and Consumer Protection. If the correspondent decides that ARGUS should be informed, he/she is also responsible for entering the message into ARGUS.

ADNS (Animal Disease Notification System)

Legal grounds, members and objective

ADNS is a system for reporting animal diseases. The legal grounds of this system are the Council Directive (82/894/EEC) and the supplementary Commission Decision (2004/216/EC). Commission Decision (2005/176/EC) determined the procedures and codification for reporting within the system. In addition to the EU Member States, other associated countries are Andorra, Switzerland, the Faeroe Islands, Iceland and Norway. The Directive

instructs Member States to inform the Commission and other Member States, via ADNS, of outbreaks of epizootic disease pursuant to those diseases, 26 in number, that are listed by the EU (included among these are for example BSE, foot and mouth disease and avian flu).

The Commission's contact point

Those in charge of ADNS at the Commission belong to DG Health and Consumer Protection, Animal Health and Welfare Directorate, the Animal Health and Standing Committees Unit.

Swedish contact point

In the event of an outbreak of a serious contagious animal disease in Sweden, the Swedish Board of Agriculture has an overall responsibility, according to epizootic and zoonosis law. The Swedish Board of Agriculture is the decision-making authority in issues such as these. The Board is the contact point for the ADNS but the National Veterinary Institute (SVA) also has access to the system.

Procedures

In the event of an outbreak that is not connected to an earlier regional outbreak, or in the case of a new outbreak (otherwise known as a primary outbreak) a warning must be sent to the Commission and to the other Member States as soon as the outbreak is confirmed. Member States that do not follow the obligation to report within 24 hours will most likely become the object of some kind of reprimand, but the form of reprimand remains to be seen. Since it is nearly impossible to gather all the information within a period of 24 hours, a primary notification is often followed by supplementary notifications. When the final report is ready, it is also entered into the database and the Commission makes an annual inventory of the incidents that have occurred.

For a secondary outbreak, which is an outbreak subsequent to a primary outbreak in an already contaminated region, the information must be entered into the ADNS on every first working day of each week at least. Every Friday at 15.30 the Commission sends an e-mail summary to all the ADNS associated countries of the primary and secondary outbreaks of infectious animal diseases for the previous week. The veterinary authorities in the respective countries execute a risk appraisal. The subsequent risk management is the shared responsibility of the Commission and the Member States.

Notifications are registered by the Member States either directly into the system or via an e-mail to the Commission. As soon as the notification is registered into the system an e-mail message is sent to all the countries that are connected to the ADNS.

In Sweden, the Swedish Board of Agriculture often receive an alert via the National Veterinary Institute's epizootic on-call team who were alerted by suspecting animal owners or veterinarians. They may also contact the County Veterinary Officer, who then contacts the Swedish Board of Agriculture in turn. The Swedish Board of Agriculture can also be directly

contacted during the day through the officers in charge or via the on-duty officers of the Swedish Board of Agriculture. The National Veterinary Institute and the Swedish Board of Agriculture then decide whether testing is in order. According to epizootic law, anyone who suspects a case of epizootic disease is obligated to immediately report it to the National Veterinary Institute and the Swedish Board of Agriculture. Often, those who suspect disease contact the National Veterinary Institute first for consultation. The National Veterinary Institute can be reached around the clock via its epizootic on-call team. They are obligated to report all suspected cases of epizootic disease to the Swedish Board of Agriculture.

In addition to informing the ADNS in the event of a confirmed outbreak in Sweden, the following people and organisations must also be notified as soon as possible: the general public, affected neighbouring countries, industries, slaughter houses, county and district veterinarians, politicians and the EU working group of Chief Veterinary Officers of the Member States (CVO). Specific e-mail lists of agents who may be affected in the event of an outbreak have been drawn up for this purpose. These are also used in the event of an incoming warning from the EU that can have consequences in Sweden.

The key to the codification of information in ADNS is obtainable from the Swedish Board of Agriculture. Here, five persons, one of which is principally responsible for the system, are authorised to enter information about an outbreak. These five persons are in place in the Infection Combating Unit, Breeding and Keeping Unit and Species Protection and the Infectious Disease Control Unit. New notifications from other Member States and the Commission should be read at least once a day. The Swedish representative to the CVO, who belongs to and is situated at the Swedish Board of Agriculture, also has authorisation to the system. Occasionally, the Commission will check directly that Member States that are concerned by the outbreak in a neighbouring Member State have received the warning, but in a Swedish context, the Commission has never followed up on whether or not the Swedish Board of Agriculture have observed a notification. This may be due to the fact that Sweden is rarely exposed to the risks associated with serious outbreaks. Sweden is in a region of few outbreaks and imports relatively little livestock.

According to the officer in charge at ADNS at DG Health and Consumer Protection, ADNS is a monitoring system and not a warning system. Very urgent warnings are not conveyed via the system for this reason, nor is it connected to ARGUS. According to a person in charge of ARGUS, ADNS is, however, a source of information for ARGUS. It is likely that this person is referring to the procedure of Member States contacting the unit managers in DG Health and Consumer Protection's Animal Health and Standing Committees via their representatives in CVO in case of emergency. In the event of a crisis, the reporting party and representatives in the CVO have continuous contact with the concerned Directorate. The unit managers are available around the clock per mobile telephone and they and their colleagues can be called in on short notice to check the dissemination of information and the course of events. It is common practice for the Swedish

Board of Agriculture to inform the Commission as early as when suspicion arises in order to heighten the state of readiness of the Commission. This is done in spite of the fact that information does not go out to the other Member States until the outbreak is confirmed by those in Sweden. Suspicion is reported by e-mail or a telephone call from the Swedish CVO representative. There is no EU standard for alarm routines in cases of mere suspicion - these differ from Member State to Member State.

Connection to systems outside the EU

ADNS is not connected to the World Organisation for Animal Health (OIE) early warning system that is obligated to report within 24 hours. Virtually all worldwide veterinary agencies are connected to OIE's network. Afflicted countries must inform both the EU and the OIE.ⁱⁱⁱ

EUROPHYT (European Network of Plant Health Information Systems)

Legal grounds, members and objective

In Council Directive (2000/29/EC) it was decided that the Commission would "establish a network for the notification of new occurrences of harmful organisms", which became EUROPHYT.⁷ The obligations of the Member States were not stipulated in the Directive and there are no legal grounds for the procedures and routines within the web-based system. EUROPHYT is for reporting such diseases (bacterial diseases, fungal and viral diseases, for example) along with pests and harmful organisms within agriculture, horticulture and forestry, which is governed by plant protection law. In addition to the Member States, Croatia and Turkey and the European and Mediterranean Plant Protection Organisation (EPPO) participate. The third country, whose consignment contains the infection, is also informed via e-mail by the Member State who discovered the infection in question.

The Commission's contact point

Those responsible at the Commission belong to DG Health and Consumer Protection, Directorate Safety of the Food Chain, the Unit for Biotechnology and Plant Health as well as DG Health and Consumer Protection's Food and Veterinary Office Directorate, the Unit for Food and Plant Origin, Plant Health, Processing and Distribution.

Swedish contact point

The Swedish Board of Agriculture is the Swedish contact point for EUROPHYT, and the officer in charge belongs to the plant inspectorate, which is a part of the plant section of the Swedish Board of Agriculture.

Procedures

The system is primarily used for imports from a third country. In addition to cases of harmful organisms/disease, import consignments that do not comply with the requirements of the Community (in the case where

⁷ Europhyt is composed of two parts: EUROPHYT-CIRCA and EUROPHYT-PHY. The first is primarily an information database while the latter functions as a warning system.

documents are missing, where documents are not filled in properly or the goods are not correctly marked) are entered into the system. The system is also used to report harmful organisms/diseases in consignments within the EU, for which a Member State has established a protected zone. By establishing a protected zone, Member States that have not been afflicted by the harmful organism/disease try to stop the potential contaminator from entering the country. All discoveries of harmful organisms for quarantine within the EU as well as harmful organisms that must not be spread to any Member State's protected zone must be reported.

Notifications in EUROPHYT must be made within 24 hours of the discovery of the suspected case. However, this time limit may be difficult to achieve in certain cases since laboratory results are required to confirm the contamination. Unconfirmed cases may be reported but must later be supplemented. Once a Member State has made a notification in the system, the notification will be sent out via e-mail to all members of EUROPHYT. Though EUROPHYT is both a warning system and an information system, the notifications look the same in both cases. Member States then determine how serious the information is for their own country. Even non-emergency cases provide an indication of which countries and consignments should be observed extra carefully.

Incoming notifications go directly into the EUROPHYT system and are then sent to the Swedish Board of Agriculture's common e-mail account which they check several times daily. Each week the Swedish Board of Agriculture sends out a summary of the reports that may be of interest to Swedish inspectors. Should an emergency case arise, notification is sent in a separate e-mail message with pertaining information. Though not common practice, Member States that discover harmful organisms may choose to make oral reports to the Commission in urgent cases.

In Sweden, serious harmful botanical organisms are usually discovered by a regional inspector who has the authority to enter the information into EUROPHYT. However, before any notification is dispatched from Sweden, it must be inspected and approved by an authorised officer of the Swedish Board of Agriculture. After entering the information, inspectors usually also send an e-mail or make a phone call to an authorised person at the Swedish Board of Agriculture to alert them to the Swedish notification that must be sent to the other Member States. Those in charge at the Swedish Board of Agriculture also check daily that there are no Swedish notifications waiting in the system.^{iv}

EWRS (Early Warning and Response System)

Legal grounds, members and objective

In the beginning of the nineteen-nineties the United Kingdom was afflicted by a major outbreak of mad cow disease (BSE) and in 1996 the first case of *variant Creutzfeldt-Jakob disease* (vCJD) was discovered in people who had eaten BSE-contaminated beef. In the wake of the vCJD discovery,

discussions began within the EU regarding a system for disseminating information when contagious diseases in humans are discovered.

The early warning and response system for communicable diseases, EWRS, was established by the Decision No 2119/98/EC of the European Parliament and the Council as a part of the Community Network for Epidemiological Surveillance and Control of Communicable Diseases. *Other* parts consist of long-term and surveillance measures. Through Commission Directive (2000/57/EC) the operative procedures were determined for EWRS. The objective of the network is to immediately inform the affected EU agents of outbreaks that may have cross-border consequences. It was used, for instance, when avian influenza in people and SARS were discovered. Member States, the Commission and the European Centre for Disease Prevention and Control (ECDC) are linked together by means of EWRS. Member States that disseminate information in EWRS can choose whether they want to also distribute information to WHO. WHO has no authority to enter information into EWRS.

There is an obligation to report, but what constitutes an immediate notification has not been determined. Should a Member State fail to inform EWRS in the event of serious risk, the Commission could bring a Member State before the European Court of Justice. However, the need has never arisen since Member States satisfactorily fulfil their obligations in this respect.

The Commission's contact point

DG Health and Consumer Protection, Directorate Public Health & Risk Assessment, Health Threats Unit.

Swedish contact point

The National Board of Health and Welfare's on-duty Infectious Disease Control as well as the unit Officer for the National Board of Health and Welfare's Unit for Communicable Disease Prevention and Control have authorisation to enter information into EWRS.

Procedures

By means of the web-based warning system, the Member State's national health agencies can quickly inform other members of the network about outbreaks of infectious diseases that threaten to spread to other countries within the Union. EWRS defines three levels of warning: level 1 entails exchanging information regarding the risk of an outbreak occurring, level 2 to that of a potential threat and level 3 to that of a confirmed threat. The agency in charge in the respective country must immediately give notification in the event of an outbreak that corresponds with any of these descriptions. For level 2 and 3 threats, the nature and scope of the threat as well as a description of the measures that the reporting Member State intends to take must be indicated. Once annually, before 31 March, the Member States are obliged to compile a report of which incidents have occurred during the year.

EWRS consists of a web page for protected information where Member States can state the reason why they are informing other members within the system as well as the types of incidents concerned, their scope etc. After a Member State has entered a warning on the web page, the system generates an e-mail that is automatically sent out to all EWRS members. The e-mail only indicates that something has occurred. To receive information about the incident, the contact points must visit the web site. Within the system, a Member State may choose to limit the number of Member States to inform (selective messaging). These messages always reach the Commission as well.

When a message about a possible threat comes in to the Commission, the on-duty administrative officer at the Health Threats Unit attends to it. Such administrative officers are selected on a weekly basis according to a rolling schedule. The Commission has set up a text messaging function allowing all administrative officers at the Health Threats Unit to receive a text message immediately when a level 2 or 3 warning is entered into the system. In the primary stage, only the administrative officer on duty is obliged to act. In very urgent cases, the person on duty may be contacted by telephone, and visa versa. The Member States could also contact the Commission's Security Office which will then see to it that the person on duty at EWRS is made aware of the incident. Should the person who is on duty fail to answer, the person who will be on duty the following week is contacted and so on, until somebody has acted on the warning. If the person on duty estimates the situation to be serious they will contact the ECDC for their appraisal.

In the event of a serious crisis, the Health Emergency Operations Facility (HEOF) is used, which is a structure consisting of both a crisis and communication centre as well as staff that are called in. Since the crisis and communication centre houses computers and communication equipment, this section of HEOF is also used on a daily basis. The personnel organisation is only activated in the event of a very serious crisis. This organisation then draws on the resources from all the units in the Public Health and Risk Assessment directorate. The personnel section of HEOF is activated by the director of Health and Consumer Protection and consists of 150 persons who are pulled from their ordinary duties to work in shifts at HEOF.

In Sweden, the National Board of Health and Welfare has created a special e-mail box for incoming messages in EWRS, which is monitored by the Infectious Diseases Control standby unit. The National Board of Health and Welfare is now purchasing a service that will allow the Infectious Diseases Control standby unit to receive messages directly to their mobile telephones so that those on duty do not have to monitor the inbox. After receiving a warning by telephone, the standby unit visits the web site. After an incoming warning on EWRS, the Infectious Diseases Control standby unit, in consultation with the Head of the Infectious Disease Control Unit, makes an assessment about which Swedish agencies (most often doctors for infectious disease control and the Swedish Institute for Infectious Disease Control) are to be informed. This communication is conducted via e-mail. The Infectious Diseases Control standby unit also has the responsibility of disseminating

information about Swedish incidents to other members of EWRS. As the national contact point, the National Board of Health and Welfare may suggest granting reading rights to other parties which the Commission then grants. The Swedish Institute for Infectious Disease Control and an administrative officer of the Swedish Ministry of Health and Social Affairs have the possibility of reading information in EWRS.

Connection to systems outside the EU

The World Health Organisation, WHO, adopted a revision of the existing International Health Regulations in May 2005, which came into force on 15 June 2007. With this, new regulations were incorporated into Swedish legislation. Part of IHR is for increasing information exchange between WHO's 193 members about infectious diseases and the purpose of the revision is to prevent the spread of serious threat to people's health across borders. IHR entails that all operations having responsibility for people's health are obliged to report suspected international threats to people's health to the National Board of Health and Welfare, which in turn will forward the information to WHO. Every WHO country shall select a national contact point, who can be reached around the clock by fax, telephone and e-mail from the selected WHO contact points. The WHO members have, to date, only selected national contact points, but the intention is that WHO will establish an information system of some kind. Eighty percent of EWRS members have presently selected another contact point for IHR than for EWRS, which means that it is not possible to use EWRS to disseminate information to WHO in accordance with IHR. However, the possibility of coordinating the EWRS and WHO systems is currently being discussed.^v

RAPEX (Rapid Alert System for Non-Food Products)

Legal grounds, members and objective

RAPEX is a system that primarily aims to allow the possibility of information exchange in the event of a serious EU-wide risk to the health and safety of consumers, as in the case of electrical fault and toxins. Foodstuffs and pharmaceuticals are excluded from this warning system, and are regulated by special warning systems described later on in this survey. In addition to the EU Member States, Norway, Liechtenstein and Iceland are members of the system. According to Directive 2001/95/EC of the European Parliament and the Council, a Member State that takes measures to limit the release of a product onto the market or that requires that such products be recalled, shall notify the Commission of the measures taken via RAPEX. Commission Decision (2004/418/EC) concerning the determination of guidelines for the administration of RAPEX and for information pursuant to chapter 5 of Directive (2001/95/EC) serves as the basis for each Member State's risk appraisal.

Since the Directive states that Member States must report the risks associated with a product, the Commission could take active measures against a Member State that fails to inform of the potential risks associated with a product. In this case, the Commission would bring the Member State

before the European Court of Justice. The Commission generally prefers not to take these measures but rather by means of communication to reinforce the importance of Member States leaving notification at the earliest possible opportunity.

The Commission's contact point

Issues pertaining to RAPEX within the Commission are dealt with by DG Health and Consumer Protection, Consumer Affairs Directorate, Product and Service Safety Unit. The RAPEX group consists of twelve persons, four of whom work full-time with RAPEX issues. The remaining members are called in during periods of intense workload or when someone from the core group is absent.

Swedish contact point

The Swedish Consumer Agency is the Swedish RAPEX contact point and administrative officer in charge are situated in the Market Control and Trade Contacts Units.

Procedures

The time span runs from that of the point of discovery, to up to three days at the latest between that of the discovery of the emergency situation in the country, the information ought also to simultaneously be mediated to the Commission via its mobile telephone to the Health and Consumer Protection DG and the Consumer Affairs Directorate, Product and service safety unit. The RAPEX group of the Commission is on twenty-four hour standby and its two on-duty administrative officers can be reached by mobile telephone. An administrative officer is in charge of monitoring the e-mail inbox but all members of the RAPEX group have access to incoming notifications.

In the event of risks of a less immediate nature, the time span for Member States is between 10 and 45 days. The time span for feedback from the Commission to the Member States is between 5 and 45 days. In light of this, RAPEX acts as a combined information and warning system.

Once a Member State has entered a notification into RAPEX, it is presented directly on the computer screen of the person in charge at the Commission. The Commission subsequently checks and evaluates the incoming warning and checks whether another Member State has entered a warning about the same product in order to avoid redundancy. The system only sends out one warning regarding a product regardless of how many Member States have warned about its risks. After examination, the Commission forwards the information to other Member States (as long as the measures are in accordance with Community legislation) as soon as possible or within three days at the latest. Warnings from Member States always go via the Commission. Member States have no direct contact.

The Member States immediately see the degree of severity of the notification because the Commission indicates either "serious risk", "non serious risk" or "for information only" in the first field. (The Commission does not assess the quality of purely informational messages. These are merely forwarded since they require no follow-up on the part of the Member

States.) For very serious situations, a fourth category, "notification requiring emergency actions", is used. In such cases, measures must be taken within minutes. This category has never been used. If a risk were of such a serious nature, the Commission would also phone the Member States' contact points. In such events, the Swedish contact point is the Head of the Swedish Consumer Agency's unit Market Control and Trade Contacts. For this purpose, the Commission has access to the mobile phone numbers of this person and the other contact points within the Member States. There is no special on-duty organisation at the Swedish Consumer Agency over and beyond the accessibility of unit chief via mobile phone.

Every Member State is obligated to investigate whether goods that have been stopped by other Member States are found within their own country. If the product is discovered on its domestic market, the Member State is obligated to act on the warning and report the measures that have been taken in the country. RAPEX knows if a Member State's contact point has not received a dispatched message. RAPEX passes this information on to the Commission, who then follows up on the issue. Primary notifications and Member State reactions to them are gathered in a file. Thus, all information pertaining to the case is gathered in a single location within the system. Every Member State can object to an issued alarm, in which case, the Commission will consult with the Member State that issued the warning in RAPEX. In Sweden, this means that the Swedish Consumer Agency will turn to the agents who issued the alarm in the Swedish system in order to obtain more information. They then report back to the Commission. The information pertaining to the objection and the follow-up is then stored in the same file as the original warning and reactions.

All warnings are compiled in the weekly summary and published on the Commission's web site before being distributed in the weekly summary. The agencies within the Swedish network receive the weekly RAPEX notification summaries via e-mail; these are distributed in Sweden by the Commission via the Swedish Consumer Agency. They are then responsible for investigating and informing the Swedish Consumer Agency of whether the products are found on the market. It is always the Swedish Consumer Agency that forwards the information to and from the Commission, even if the product in question falls under the category of another agency within the Swedish system. The Swedish network consists of the following agencies: the Swedish Work Environment Authority, the Swedish Road Administration, the Swedish National Electrical Safety Board, the Swedish Board of Agriculture, the Swedish Chemicals Agency, the Medical Products Agency, the Swedish Rescue Services Agency, the Swedish Radiation Protection Authority and the Swedish Maritime Administration, the Swedish Municipal Consumer Administration as well as trade organisations and companies of various sizes.

Despite the fact that the Swedish Consumer Agency follows the Commission's guidelines, the authority is dependent on other parties in the Swedish system understanding the importance of and following the guidelines. This is because they have an obligation to report potential risk products to the Swedish Consumer Agency which in turn examines the

information before registering the notifications in RAPEX. Information is sent to the Swedish Consumer Agency via a form template that the parties concerned have access to. After filling it in the party sends it to the administrative officer in charge at the Market Control and Trade Contacts units of the Swedish Consumer Agency. The Swedish Consumer Agency's network in Sweden is utilised both for sending warnings to the EU and for disseminating information within Sweden should an alarm from the EU be received. In serious cases, the media will also be contacted in order to inform the public at large. It is impossible to make a direct and immediate report to the Commission because the information from all parties must be accurate before the Commission is informed. In the case of a discovery on the Swedish market, the Swedish Consumer Agency must examine the legitimacy of the warning, lawyers must examine the legal aspects of recalling the product from the market and the manufacturers and importer of the product must be identified.

Connection to systems outside the EU

Because almost 50% of the products that are reported in RAPEX are imported from China, the EU has, by means of a Memorandum of Understanding with China, created a RAPEX China. This system is not open to members of RAPEX. Instead, the Commission uses it to notify the Chinese authorities of dangerous Chinese products so that these agencies can quickly recall dangerous domestic products from the market, issue export prohibitions and take other measures. The system does not deal with products that are exported from the EU to China since the number of dangerous products is exceedingly small in such cases. By means of the Memorandum of Understanding the EU has also formalised an information exchange with the USA since the EU and the USA often import the same products. This information is exchanged via e-mail between designated contact points.

There are connections between RAPEX and the ICSMS surveillance and information system, even if ICSMS deals with several more types of products than RAPEX and does not have the same legal basis. Because ICSMS is not legally regulated, a greater amount and type of information can be entered. Eleven of the Member States participate in the network today at their own expense. Because many of the Member States' contact points are also contact points for ICSMS, it will be possible in the future to fill in a common form for both systems. The systems will not be connected to each other in other respects.^{vi}

RAS BICHAT (Rapid Alert System for Biological and Chemical Attacks and Threats)

Legal grounds, members and objective

EU cooperation with regards to preparedness in the event of biological and chemical threats and attacks was immediately intensified after the terrorist attacks of 11 September 2001 in the USA as well as the subsequent incidents of the intentional spreading of anthrax spores. At the Council meeting on 15 November 2001, the EU Ministers for Health Affairs

encouraged the Commission to prepare a programme of preparedness and intervention measures for use in times of biological and chemical threat. This then became the Council's and the Commission's BICHAT programme (programme of cooperation on preparedness and response to biological and chemical agents attacks) which was adopted by The Health Protection Committee⁸ on 17 December 2001. The RAS BICHAT warning system is a part of the programme and was came into operation in June of 2002.

By means of RAS BICHAT, members are warned of probable or real emissions of biological or chemical substances as a result of an antagonistic attack. The system connects the Health Protection Committee board members with predetermined contact points, which oversee the system around the clock so that members can quickly be called in and take charge of communications in the event of an emergency. The object is to create an information system that stores and modifies the information in order to be able to quickly discover, trace and evaluate threats as well as send out advance warnings before an event has been officially confirmed. Member States shall inform each other when they suspect danger, in events of a cross-border nature, in events that require cooperative effort within the EU and in events that may require assistance from other countries. In addition to the warning function, the system can be used for information exchange and the coordination of crisis management operations between Member States.

RAS BICHAT does not rest on any other formal foundation than the BICHAT programme and no reporting obligation as such exists. There are plans to formalise and update the content of the programme within two years, whereupon obligation to report may become a reality.

The Commission's contact point

The Commission's contact point is DG Health and Consumer Protection, directorate Public Health & Risk Assessment, Health Threats unit.

Swedish contact point

The National Board of Health and Welfare's on-duty Infectious Disease Control is the Swedish contact point.

Procedures

The Member States enter warnings into the web-based system for RAS BICHAT, whereupon this generates a text message to all employees of the Health Threats unit. The employees can then log on, regardless of location, to the web system via their laptop computers. Member States must additionally contact the Commission by means of phoning the Security Office in Brussels, which in turn phones the person on duty at DG Health and Consumer Protection DG, Health Threats unit. This person has an hour

⁸ The Health Protection Committee was created by decision of the Council in 2001 and is an informal cooperative body under the Member States' Health and Medical ministries and the EU Commissioner for Health. The committee consists of officials from the Member States, observers from ECDC, EMEA and WHO as well as candidate countries, Norway, Iceland, Liechtenstein and Switzerland.

to respond to the Crisis and Communication Centre. At this stage, this person is the only person who is obligated to respond to the warning. After one hour the Security Office phones the Crisis and Communication Centre in order to ensure that the person on duty is present. If the person on duty judges that reinforcements are necessary, he/she calls in more staff. Once on site, the person on duty must examine the content of the warning, verify that the sender is legitimate and phone the issuing Member State to ensure that the contents of the message are correct and there is no additional information to gather. After this a warning is sent through RAS BICHAT to the other Member States' contact points and to the Health Protection Committee board members. Thus, a warning from a Member State never reaches other Member States directly through the system. All Member States must respond to the warning within an hour, either through a Health Protection Committee board member or through their national contact point. If an answer has not been returned within the set time, the Commission will call to the Member State in question for a follow-up.

In the event of a serious crisis, the Health Emergency Operations Facility (HEOF) is used, which is a structure consisting of both a crisis and communication centre as well as staff that are called in. Since the crisis and communication centre houses computers and communication equipment, this section of HEOF is also used on a daily basis. The personnel organisation is only activated in the event of a very serious crisis. This organisation then draws on the resources from all the units in the Public Health and Risk Assessment directorate. The personnel section of HEOF is activated by the director of Health and Consumer Protection and consists of 150 persons who are pulled from their ordinary duties to work in shifts at HEOF.

When a warning is issued in RAS BICHAT, the National Board of Health and Welfare's on-duty Infectious Disease Control, which is on around-the-clock standby, is met by an e-mail message.⁹ The e-mail merely states that an incident has occurred. The on-duty Infectious Disease Control has to visit the protected web site of RAS BICHAT in order to obtain the incident details. The on-duty Infectious Disease Control also has the responsibility of alerting the other concerned agents in Sweden. Who these parties are varies depending on the type of incident. Staff in the on-duty Infectious Disease Control unit, the unit Officer for the National Board of Health and Welfare's Infectious Disease Unit and an administrative officer at the Swedish Ministry of Health and Social Affairs have access to RAS BICHAT. Warnings issued to the EU also go through the on-duty Infectious Diseases Control unit. This unit receives information about the Swedish incident from SOS Alarm and determines whether the warning is to be furthered to the EU.

⁹ SOS Alarm was previously tasked with receiving alarms through RAS BICHAT, but because these alarms are currently only web-based, the information proceeds directly to the on-duty Infectious Disease Control. If the Commission for some reason were not to receive a response from the National Board of Health and Welfare, they could possibly mediate the information via SOS Alarm, which then receives the task of reaching the on-duty Infectious Disease Control Unit. This is not wholly solved to date however.

Connection to systems outside the EU

In the event of a serious incident, the Commission will inform the members of the Global Health Security Initiative (GHSI), which is an informal structure for speedy information dissemination regarding CBRN terrorist attacks. Members of GHSI are WHO, the European Commission, France, Germany, Italy, Japan, Mexico, the United Kingdom and the USA. Information between the selected contact points for the respective country/organisation is exchanged via phone. The Health Threats unit is the contact point for the Commission.^{vii}

RASFF (Rapid Alert System for Food and Feed)

Legal grounds, members and objective

RASFF is an information and warning system between the Member States of the EU, Norway, Iceland, Liechtenstein, the Commission and the European Food Safety Authority (EFSA). The Regulation (EC) No 178/2002 of the European Parliament and the Council states that parties connected to RASFF are obliged to immediately report to the Commission if foodstuffs or fodder products that can cause serious health risks are discovered in the domestic market. Because RASFF is based on a regulation, the provisions are binding and the parties have reporting obligations. Should a Member State fail to report in accordance with the regulation, the Commission could bring a Member State before the European Court of Justice. However, the regulation does not specify what constitutes an "immediate notification". Notifications from Member States often take several days because all the information must be checked, examined and analysed. For this reason, it is improbable that the Commission would bring a Member State before the European Court of Justice.

The Commission's contact point

Commission responsibility for RASFF lies with DG Health and Consumer Protection, directorate Safety of the Food Chain, Hygiene and Control Measures unit. Six persons work with RASFF issues in the unit.

Swedish contact point

The official Swedish contact point for RASFF is the National Food Administration. However, the National Food Administration and the Swedish Board of Agriculture have divided the task. The National Food Administration is responsible for reporting on foodstuffs and the Swedish Board of Agriculture for reporting on fodder/feed. Information sent by the Commission includes both suspected fodder/feed and foodstuffs. This means that both the National Food Administration and the Swedish Board of Agriculture receive information that affects the other party. The greater part of RASFF messages deal exclusively with foodstuffs.

Procedures

Due to some unclear points in the regulation, Sweden and the Commission sometimes differ in their criteria assessments. The unclear points are due to be corrected in a new regulation, which is still in the draft stage. Therefore, it may take a few years for the new regulation to come into force.

Additionally, the procedures for RASFF (such as the time within which a Member State must warn other Member States and the requirement that all Member States have a standby unit to deal with events occurring after office hours) are to be regulated in more detail.

Member States send notifications to the Commission via e-mail. These do not reach other Member States directly. Instead, the Commission appraises the information and then decides to either dismiss the notification or to immediately forward it to the other Member States. Should a notification be dismissed, the Member State may supplement the information and resubmit it for appraisal. Approved notifications are usually also supplemented with further information as more details are made available to the Member State. The Commission also appraises the threat level of the notification and marks the message according before disseminating it to the other Member States. Notifications are marked on a three-level scale: "alert", "information" and "news". The "news" category is primarily intended for system changes, new on-duty numbers to call on weekends/holidays and other administrative errands. Information to the EU from non-participating countries that have had problems with certain devices or products is also listed under this category. A notification is normally classed as an alert if the product in question already exists on the EU market. If the information regards a product that was turned away at a customs control zone, it is classed as information. In negotiations for a new regulation, adjustments to the scale are currently being discussed since the current scale is viewed as too non-descript. For example, a current alert message does not contain an appraisal of the threat risk level, which is an aspect that could be included in the future.

The Commission is obliged to disseminate all messages that indicate problems and risks with foodstuffs and fodder/feed that do not comply with the requirements set out in the foodstuffs/fodder/feed safety regulations. If a consignment, a container or a shipment is turned away by an authority at an EU customs border control, the Commission is obliged to immediately inform all EU customs control stations and the country from which the consignment of goods originated.

The Commission sends out summaries of incoming notifications via e-mail several times daily. The type of threat, the country of origin and occasionally other countries that may be affected are indicated in the notification introduction. The Commission also publishes weekly notifications from Member States on their web site, but company details are deleted in order to protect confidential information.

In autumn 2007 the Commission will test the first version of a web-based system for notification with the aim of quicker dissemination of structured information to the network. Within this system, regulating authorities in the Member States will enter information to be approved by the Commission and those centrally in charge before further dissemination in the system.

Should a very severe situation occur outside of office hours, the Member States must immediately contact the RASFF group via their emergency

telephone number. The number connects to the on-duty administrative officer, who is on-call around the clock per mobile telephone. (On-duty administrative officers rotate on a weekly basis). Should the alarm prove to have implications for more than one Member State, the person on-duty rings the mobile phone numbers of the Member States' contact points. In Sweden, this has only occurred to test that the person on-call is in fact reachable around the clock.

the National Food Administration

Via RASFF, the National Food Administration has established a special e-mail address for foodstuff notifications that is open to the public. However, it is primarily intended for local supervisory bodies such as municipalities. This e-mail account also receives notifications from RASFF. Some 15 to 20 persons in the National Food Administration have access to RASFF. The e-mail account is monitored every day in accordance with an ongoing schedule. Sweden has presently set up an emergency telephone number for the Commission in the case of issues concerning foodstuffs. This number belongs to an administrative officer at the National Food Administration's municipality support unit. Local supervisory bodies can also call this number in the event of emergency events occurring after regular office hours. However, there is a list of several on-call mobile telephone numbers that is to be used in the future.

The Unit for Meat Inspection and the National Food Administration's Supervisory Department may discover risk products in their own inspections and inform via RASFF directly. The possibility of Sweden to be able to warn the EU via RASFF assumes however that even local authorities report suspicious cases to the National Food Administration. For this reason, the National Food Administration continually informs of the importance of reporting suspicious cases. Within the near future, the agency is planning a RASFF training opportunity for involved parties.

The Livsteck.net web site (a forum for supervisory agencies at local, regional and central level) offers a downloadable notification form that authorized parties can send to the National Food Administration per fax or e-mail. The National Food Administration then enters the message into RASFF. The regulations give a general indication of what is to be reported in RASFF but the National Food Administration also reports threats that are not listed in the regulations. For this reason, the Commission occasionally rejects notifications that it does not consider to meet the requirements of RASFF. With regards to outgoing warnings, in addition to the report to the RASFF, the National Food Administration sends an e-mail message to any affected municipality recommending that they log in to Livsteck.net and read the notification. At Livsteck.net the National Food Administration publishes all notifications regarding products in Sweden, regardless of whether the risk was discovered in Sweden or by means of a RASFF message.

For incoming warnings in RASFF, the National Food Administration often request a follow-up from the Commission in order to be able to identify which Swedish municipalities may be affected. The affected municipalities

are informed directly. If a great number of municipalities are involved, the National Food Administration contacts the central warehouse. Warnings from the Commission always imply that products be drawn in from the Swedish market, because the Member State that issued the warning is assumed to have made an adequate examination of the facts. Though Member States have no obligation to inform the Commission of the measures they have taken, they must inform the Commission of whether the product has been exported to other countries. Sometimes the Commission requests that the Member States that have the product in their markets retest the product. Currently products carrying questionable markings etc are reported, something that does not necessarily mean that the product in question poses a risk. Such products are usually inspected in order to ensure that this is the case.

After information concerning a risk has been published at Livsteck.net, the respective municipality must take appropriate action, which is to contact the supplier, who must inform the distributor and the public at large. Municipality registers contain all facilities, so it is relatively simple to trace companies that are distributors. These, in turn, know which retail stores have received the goods. According to article 19 of the Regulation, agencies have no obligation to inform the public. Instead, the obligation lies with the company. Agencies are only in the position to persuade the company to live up to their obligation.

The Unit for International Trade at the Supervisory Department is the final recipient of informational RASFF notifications (products that have been turned away at a customs control station), since the unit works with the TRACES system, which is designed specifically for customs control stations.¹⁰ Since information at the "alert" level is at risk of being overlooked in the veritable stream of notifications, the EU is discussing transferring the information function to TRACES so that the concerned administrative officers receive the information that is intended for them.

the Swedish Board of Agriculture

There is currently only one administrative officer at the Swedish Board of Agriculture, who deals with issues concerning RASFF. This administrative officer belongs to the Feed Quality Unit. However, two are meant to be available in the event of a crisis. Several Swedish Board of Agriculture employees have access to RASFF and can read the current warnings if the administrative officer in charge is not present. The Swedish Board of Agriculture reads incoming notifications once daily.

Via RASFF, the Swedish Board of Agriculture has established a special e-mail address for feed/fodder notifications that is open to everyone who has responsibility for fodder/feed in Sweden. The Swedish Board of Agriculture has also designed a special form in which a person who discovers suspicious fodder/feed can fill in the information that the Swedish Board of Agriculture needs in order to report it in RASFF. The practical implications of this are that most of these reports are sent by fax or post. The Swedish Board of

¹⁰ More information on TRACES may be found in the survey a little later on.

Agriculture makes an appraisal and a laboratory analysis from the information contained in the form before filling in the standard Word document that are required for RASFF notifications. The notification grade, i.e. "alert" or "information", does not appear in the form, but in cases of urgency, the subject line of the e-mail indicates that it is an emergency. Companies and others involved are urged to send in a report as soon as possible while the Swedish Board of Agriculture awaits the laboratory report so that all relevant information can be sent to the Commission. In very urgent cases the Swedish Board of Agriculture can phone in an advance warning to the Commission before sending the e-mail. This has not happened as of yet.

The regulations indicate what is to be reported in RASFF, but should a non-indicated risk occur in a suspect feed/fodder, the Swedish Board of Agriculture reports it. For example, the regulations do not govern feed/fodder for pets, but the Swedish Board of Agriculture usually reports abnormalities to be on the safe side. This varies from Member State to Member State however. What is reported in RASFF applies to domestic feed production as much as it does to imported feed.

Since Sweden imports very little feed, it is rare that warnings from the Commission affect Sweden. Should Sweden be affected, the Swedish Board of Agriculture would use its comprehensive e-mail recipient list of agents within the industry. Moreover, the Swedish Board of Agriculture can identify all who are involved by searching through the feed register. All companies within the industry are obliged to report themselves and the fodder/feed they keep to this register. As of 2007 all landowners who purchase fodder/feed must also register themselves to the feed register. Because the register contains information about all users of a certain feed, those who are at risk of being affected can be quickly identified. The National Veterinary Institute and the National Food Administration is also informed in serious cases. Each week the administrative officer of the Swedish Board of Agriculture compiles the reports from the Commission for internal circulation within the Board of Agriculture, to customs veterinarians, among others, who can then be on the watch for certain products. Companies are often quick to report and stop deliveries when it becomes known to them that their own product poses a risk.

Connection to systems outside the EU

The RASFF group in the Commission is the determined contact point for the entire EU with regards to information exchange and alarm activation in questions of foodstuff safety between the EU and WHO's international food safety network, INFOSAN. In the future, the Commission plans to establish national RASFFs for other interested countries, who could build a regional network and eventually a worldwide network. This work will begin with three seminars in 2007.^{viii}

3.2 Information systems

MARS (Major Accident Reporting System)

In accordance with the Seveso II Directive of 1992, the Member Countries of the EU must rapport serious chemical accidents to other Member States and the Commission via MARS. The aim of MARS is to exchange important experiences regarding serious incidents with the purpose of improving preventive work within the EU. The system is administrated by the Accident Hazards Bureau (MAHB), which is a part of the EU's Joint Research Centre (JRC). Communication, Legal Affairs and Civil Protection of the Environment DG, Civil Protection Unit as well as MAHB constitute the Commission's determined contact points for MARS, but it is primarily the MAHB and Member States that have contact.

According to Swedish national regulation (2003:789) on protection against accidents, the operations in Sweden must immediately inform the Swedish Rescue Services Agency (SRSA) in the event of an incident within their own operation. Reports are sometimes made by others however. Reports are phoned in to an expert on duty at the SRSA, after which the SRSA is responsible for informing the government and other involved authorities. As a Swedish contact point, the SRSA also has the responsibility of informing the Commission. The report can be submitted up to three months after the accident. It is not the expert on duty who reports to MARS but the administrative officer in charge at the SRSA. Initially, the administrative officer only registers a short report in MARS.

A more complete report is registered in MARS once the accident investigation is concluded, preferably within a year. The complete report contains a more detailed description of the substances involved, the consequences of the accident and the lessons learned for preventing a similar accident in the future. The longer report can often take more than a year to complete since many Member States choose to await legal action and court decisions pertaining to the accident before they submit a full report. The only excuse for postponing the report is to await the conclusion of such legal processes. The Commission reserves the right to send formal notifications to the Member States if they do not follow the directive, such as in the case of omitting to report on time.

The preliminary and complete reports are registered by the Member States in the form of a working draft in MARS. The Commission then edits them into a final report. These become viewable for the Member States when the database is updated, one to two times annually. For cases in which the Commission determines that the Member States would benefit by receiving information sooner, the report will be sent via e-mail to the administrative officers in charge in the Member States. These administrative officers also have regular contact with each other and the Commission by way of their participation in the Committee of Competent Authorities within the Seveso domain, where both the SRSA as well as the Working Environment Agency participate.^{ix}

TRACES (Trade Control and Expert System)

TRACES was created by Commission Decision (2003/623/EC) and is the EU's common computer system for veterinary inspections and traceability. Through Commission Decision (2004/292/EC) the Member States are required to use the system. Norway, Andorra and the Faeroe Islands also participate. DG Health and Consumer Protection, Directorate Animal Health and Welfare, Animal Health and Standing Committees Unit, is responsible for the development, operation and some support of the system while every Member State is responsible for domestic support, training and administration of the same.

The earlier ANIMO system (messaging system between the veterinary agency and official veterinaries, for animal trade, among other things) and SHIFT (rapid alert system for health controls on imports of veterinary concern) are integrated within the system with the aim of achieving an all-embracing control of animal transport within the EU. SHIFT was never brought into operation in a practical sense, and because of this, TRACES is primarily a registration and inspectoral system. The transportation of living animals and certain animal products between Member States, the importation of animal foodstuffs, and other animal products from countries outside of the EU are registered in the system. The object is to connect TRACES and RASFF in the future.

An awaited delivery of animalistic products or living animals must be reported to the border customs control at least one working day prior to the actual arrival time. This can be done in TRACES. For transportation within affiliated TRACES countries, the first part of the health certificate can be filled in by the exporter.¹¹ The official veterinarian then opens this and executes a certificate. If the system does not function within 24 hours, section one of the certificate must be faxed to the recipient country. Agents who import from a country outside of the EU can fill in the first part of the customs control document (Common Veterinary Entry Document (CVED)) in the system and contact the appropriate customs control station via fax or telephone. It is unclear whether sanctions are issued to Member States that fail to report a delivery or a suspected contamination. If a Member State discovers that information surrounding a certain delivery is missing, they must contact the central agency of the Member State from which the consignment originated. They will in turn report to the local agencies/veterinarian concerned.

The system makes it possible for authorities in the concerned Member States to continuously follow the consignment as well as to view the history of the exporter in question. By means of historical data, Member States can

¹¹ Part 1 contains information about the consignment, such as sender, recipient, contents of the consignment, etc. Part 2 contains a health assurance of the animals written up by a vet after he/she has examined the export shipment. Part 3 contains information about inspections of the consignment in the recipient country, if any, and only reaches the authorities concerned.

examine whether any of the exporter's prior consignments were contaminated or had a risk of contamination, and accordingly come to a decision concerning testing. When contamination is suspected, the subsequent 10 consignments from the same plant must be tested. Testing is otherwise done at the regular stipulated interval. Presently it is difficult for Member States to see how many subsequent consignments are inspected since Member States cannot know if another Member State has done a contamination inspection. The system shall be improved to this end.

TRACES can be viewed as a warning system since Member States that are at risk of receiving a suspected consignment are quickly informed of it. Furthermore TRACES can be connected with the Geographic Information System (GIS) for more specific monitoring, and blocking zones can be established in areas that are exposed to a high risk of contamination. This also allows for planning and reorganisation of shipments using the information in TRACES as a basis. For the transportation of living animals, CVED provides information regarding the exporter, importer and recipient of the consignment, the exact point in time that the consignment left the location of origin, the arrival time to a certain customs control station, and the vehicle in which the transportation was made etc. For some consignments of risk products, such as meat in feed/fodder, veterinary officers must confirm receipt of the consignment at the final destination. This is to counteract that risk products go astray.

The Swedish Board of Agriculture and the National Food Administration are the Swedish contact points for TRACES. This is due to the fact that a distinction is made between non-human and human consumption of animalistic products in the EU. County Administrative Boards have the authorisation to access the system, district veterinarians have the authorisation to check information pertaining to their own areas and customs control veterinarians have authorisation that is limited to their own stations. Private companies can only view their own certificates and search for the addresses of facilities of interest.

For transports within the EU the respective country of origin is responsible for examination and contamination testing of the animals and products. On transit through the EU, the central agencies in the concerned countries as well as the local authorities within the areas of passage are authorised to follow the consignment. The Member State that is the final destination of the consignment in question is also entitled to follow it but the information is not available to other Member States. However, all Member States receive messages concerning transports that are refused at the exterior borders of the EU in order to make Member States aware of the possibility that the shipment may try to enter by way of another Member State. Customs authorities will also be connected to the system in the future.

The system is used in real time. As a result, the Commission does not compile weekly or annual reports. Users can perform searches on specific profiles. In the future TRACES, will be developed into a database through which Member States can collect statistics. The Commission has no active

role in TRACES other than to manage the operation of the system. In TRACES communication is primarily between the various Member States.^x

3.3 Systems under development

CIWIN (Critical Infrastructure Warning Information Network)

The system is presently under discussion and will be part of the European Programme for Critical Infrastructure Protection (EPCIP). In the Commission's message concerning EPCIP of 12 December 2006 it came to the fore that CIWIN is aimed to be a voluntary network system to which Member States may wish to belong in order to quickly exchange information regarding threats to critical infrastructure. CIWIN could function additionally as an alternative system for early warnings that would be connected to ARGUS as is the case with other systems. The Commission has contracted the computer company, UNISYS, to study during the autumn of 2007 how the national systems of the Member States might be integrated with CIWIN. This included a visit to KBM, in the character of a national contact point, in June. Presuming that CIWIN is established, the responsibility for the system will lie with DG Justice, Freedom and Security, probably its Internal Security and Criminal Justice Directorate, Preparedness and Crisis Management Unit.^{xi}

LEN (European law enforcement network dealing with public order and security matters)

According to the web site of the Justice, Freedom and Security, an order and security warning system was to be established under the administration of Europol in 2005. It would be utilised by EU crime fighting agencies and Europol should establish a communication centre with an officer on duty around the clock for this purpose. Member States would be required to select a responsible national contact site that has the authorisation to receive warnings and take further actions when required.

In the Hague Programme adopted in 2004 this network was a measure which was to be implemented. However, it received a lot of resistance from the Member States since these were not of the opinion that LEN would add value in relation to existing networks and procedures. This was also the Swedish opinion because Sweden, in addition to several other Member States, was sceptical to sharing secret information since no report of how the system would deal with such information existed. The Commission has given UNISYS the task of performing a preliminary study that is to continue until the spring of 2008. To this purpose UNISYS visited Sweden in the middle of June. The result of the study is still unknown.^{xii}

RAS CHEM

This system is still under development and implementation is planned for the end of 2007. In this web-based system Member States will quickly be able to inform each other in the event of a serious chemical incident. When a Member State enters a warning into the system it will reach all. DG Health and Consumer Protection, Directorate, Public Health & Risk Assessment, Health Threats unit, will be the Commission's contact point for RAS CHEM. The Swedish participant in RAS CHEM will be the National Board of Health and Welfare's Supervisory Unit for Crisis Preparedness.^{xiii}

4 Other systems

Pharmaceutical risks

Within the domain of DG Enterprise and Industry, a warning system for dangerous pharmaceutical products has been established with the Medical Products Agency as the Swedish contact point. This system is sorted under this heading and not under any of the earlier headings because it is not named in relation to ARGUS or to EU's crisis preparedness. Another reason for this classification is that the Medical Products Agency is not required to participate in the Swedish emergency management system. It may be interesting however to present a short summary of the system.

In Directive 2001/83/EC of the European Parliament and the Council, it is stipulated that the European Medicines Agency (EMA) together with the Commission and the medicines agencies of the Member States shall establish a network for information exchange regarding safety supervision. Reports about serious side effects must immediately be communicated to other network members within 15 days at the latest. Such is the manner of the reporting obligation in accordance with the stipulations of the Directive. It also states in the Directive, that the Commission, in consultation with the Member States, EMA and concerned partners, shall develop guidelines for reporting that are to be published in volume 9 of *Medicine Regulations within the European Community*. In Regulation (EC) 726/2004 of the European Parliament and the Council, it is stipulated further that: "If it is of the utmost significance that swift measures be taken in order to protect the health of people and the environment, a Member State may, within its territory, at its own initiative or at the behest of the Commission, temporarily prohibit the use of a human medicine that has been approved in accordance with this ordinance. When a Member State acts on its own initiative it must, at the next weekday at the latest, inform the Commission and the agency regarding the reason for the measure. The agency shall inform the other Member States without delay."

When a Member State discovers a potential health risk it must report this to the Member States, the Commission and the EMA in order that medicine companies in the Member States can immediately collect data and consult with specialists in order to coordinate the subsequent measures of the Community. The discovery normally comes about through a large number of cases of serious side effects within the Member States or by a study initiated by the agency and the manufacturer itself informs the domestic medicine agency. The network exchanges information by means of the electronic Rapid Alert and Non-Urgent Information System. EMA can also execute a rapid alert or an NUI. NUIs cover information of a less urgent character than rapid alerts. In cases of domestic as well as incoming warnings, the Medical Products Agency must inform pharmacists, the Swedish Central News Agency and hospitals.

For an appraisal of the level of risk, the Member State shall use the Commission's recall severity level classification. Class I cases ("Potentially life threatening or can cause health risks") must be communicated to all

Member States when discovered, if possible, otherwise within 24 hours. The communication is to go out to the pre-determined recipient list of contact points in all affiliated countries found in the electronic network (which far surpasses the amount of EU Member States) as well as to EMEA. In such a case that the system does not function as it should, it is recommended that those affiliated to the network designate a fax apparatus solely for the purpose of receiving warnings via the system, in which numbers for all contact points within the community are to be programmed. In the event of a dire emergency, it is recommended that Member States call the emergency numbers specified for each contact point in addition to faxing and e-mailing.

Class II threats, which could cause illness or incorrect treatment, must also be communicated through RAS, but solely to the Member States to and in which the product has been sold or is believed to have been sold. The company that produces the medicine must also be informed as soon as possible, but not via the system because they are not connected. The same applies for WHO.^{xiv}

Standardisation

A project for developing a standard for procedures in the event of warnings within and/or between different bodies and agents ("inter/intra organisational warning procedures") is presently in progress in the International Standardisation Organisation (ISO).

The introductory standardisation work has been conducted within the ISO/TC/223 Societal Security working group and in a sub group to this, entitled WG3, Command & Control, Cooperation & Coordination. Swedish representatives in the work of inter/intra organisational warning procedures are presently the Swedish Emergency Management Agency (SEMA, Technical Unit).

Great Britain took on the responsibility of managing the project. In the spring of 2007 they made their proposal. A vote was taken in ISO/TC/223 Societal Security, which (according to customary ordinance) required that the majority voted for the suggestion and that five countries committed to participating in the project. Only after this procedure was finished, the standardisation work itself began. The working period began on 16 July 2007 and a standard must be forthcoming within 36 months. Germany, Sweden, Thailand, Finland, Canada, South Africa, Japan, the USA and Serbia are participating.

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- ⁱ Presentation of ARGUS at PROCIV 17/01/2006,
http://ec.europa.eu/staffdir/plsql/gsys_www.branch?plang=EN&pId=263&pDisplayAll=1, interview with ARGUS officer at the Secretariat-General of the Commission, 26/06/007 as well as an interview with an Officer at the Commission's Security Office, 09/07/2007.
- ⁱⁱ http://www.ssi.se/beredskap/PDFer/Beredskap_Broch_sv.pdf,
<http://rem.jrc.cec.eu.int/40.html>,
http://rem.jrc.cec.eu.int/uploads/media/contact26082005_01.pdf,
http://ec.europa.eu/energy/nuclear/radioprotection/emergency_en.htm,
 an interview with a Swedish Institute of Radiation Protection employee, 10/05/2007 as well as an interview with ECURIE Officers at the Transport and Energy DG, 10/05/2007.
- ⁱⁱⁱ http://ec.europa.eu/food/animal/diseases/adns/index_en.htm,
http://www.jordbruksverket.se/amnesomraden/krisberedskap/smittsam_madjursjukdomar_4.14586571043c6e11ac8000749.html, interview with an employee of the Swedish Board of Agriculture, 03/05/2007 as well as correspondence with an ADNS Officer at The Health and Consumer Protection DG, 29/06/2007 to 13/08/2007.
- ^{iv} <http://ec.europa.eu/idabc/en/document/2267/5637> as well as an interview with an employee of the Swedish Board of Agriculture, 11/05/2007.
- ^v http://ec.europa.eu/health/ph_threats/com/early_warning_en.htm,
http://ec.europa.eu/health/ph_threats/com/ewrs_sec_2005_394.pdf,
http://www.socialstyrelsen.se/Smittskydd/specnavigation/Regelverk/Lagar_forordningar/IHR.htm,
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- ^{vi} <http://www.konsumentverket.se/mallar/sv/artikel.asp?lngCategoryId=1694&lngArticleId=4760>,
http://ec.europa.eu/consumers/cons_safe/prod_safe/gpsd/notification_dang_sv.pdf,
http://www.eucm.leidenuniv.nl/content_docs/eucm_report_annex_april_2006_web_publication_version.pdf, interview with an employee of the Swedish Consumer Agency, 24/04/2007 as well as an interview with a RAPEX administrative officer at the Health and Consumer Protection DG 04/07/2007.
- ^{vii} <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:52003DC0320:SV:HTML>,
http://ec.europa.eu/health/ph_threats/com/preparedness/HEOF_en.htm,
http://www.upmc-biosecurity.org/website/events/2005_biosafety/speakers/thinus/thinus.html,
http://eur-lex.europa.eu/LexUriServ/site/sv/com/2006/com2006_0552sv01.pdf,
http://ec.europa.eu/health/ph_threats/Bioterrorisme/bioterrorism01_en.pdf, interview with an employee of the National Board of Health and

Welfare, 24/05/2007, as well as an interview with an Officer at the Health and Consumer Protection DG, the unit for Health Threats, 13/07/2007, as well as correspondence with, SOS Alarm Sverige AB, 17/08/2007.

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[lex.europa.eu/LexUriServ/site/en/com/2006/com2006_0786en01.pdf](http://eur-lex.europa.eu/LexUriServ/site/en/com/2006/com2006_0786en01.pdf)

xii

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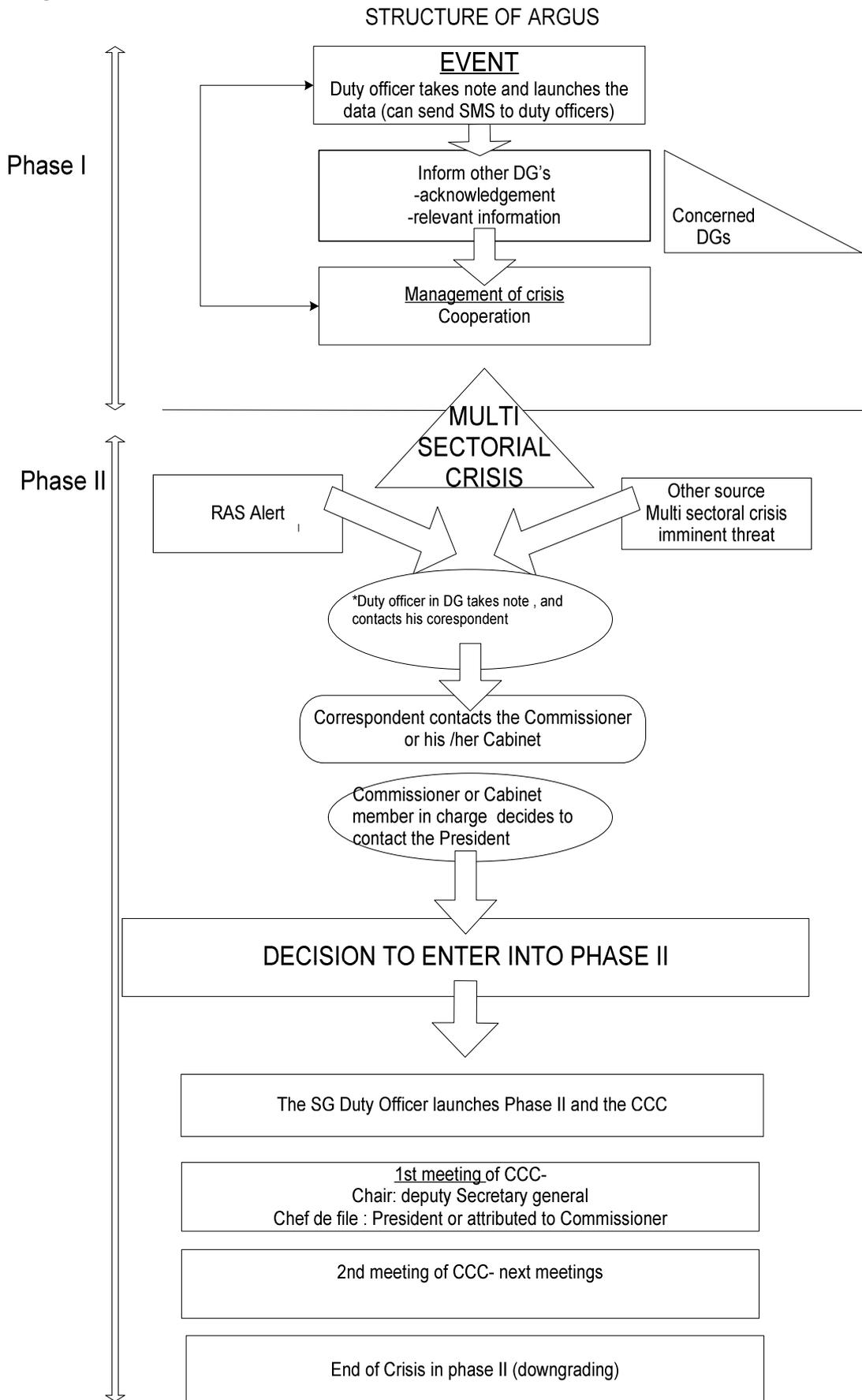
xiii

http://ec.europa.eu/health/ph_threats/com/preparedness/rapid_alert_en.htm Interview with an employee of the National Board of Health and Welfare 24/05/2007 as well as an interview with Officers at the Health and Consumer Protection DG, Health Threats Unit 13/07/2007.

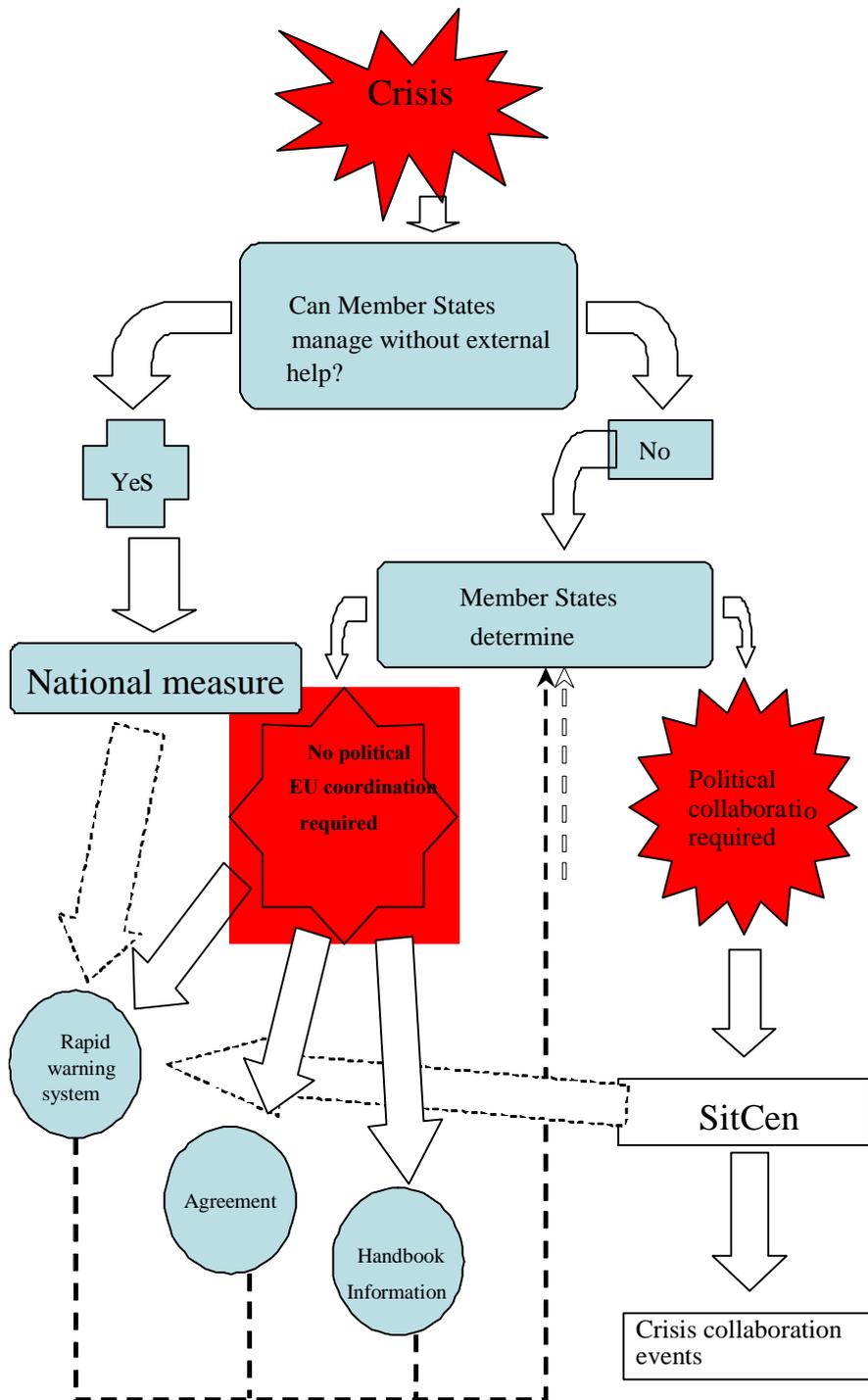
xiv http://www.lakemedelsverket.se/Tpl/NormalPage_2433.aspx,
http://eur-lex.europa.eu/LexUriServ/site/sv/oj/2001/l_311/l_31120011128sv00670128.pdf,

http://www.emea.europa.eu/Inspections/docs/CoCP/CoCP_RapidAlertProc.pdf,
<http://www.emea.europa.eu/Inspections/docs/2302007en.pdf>,
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Annex 1. Activation of ARGUS (Source: internal document at the Secretariat-General)

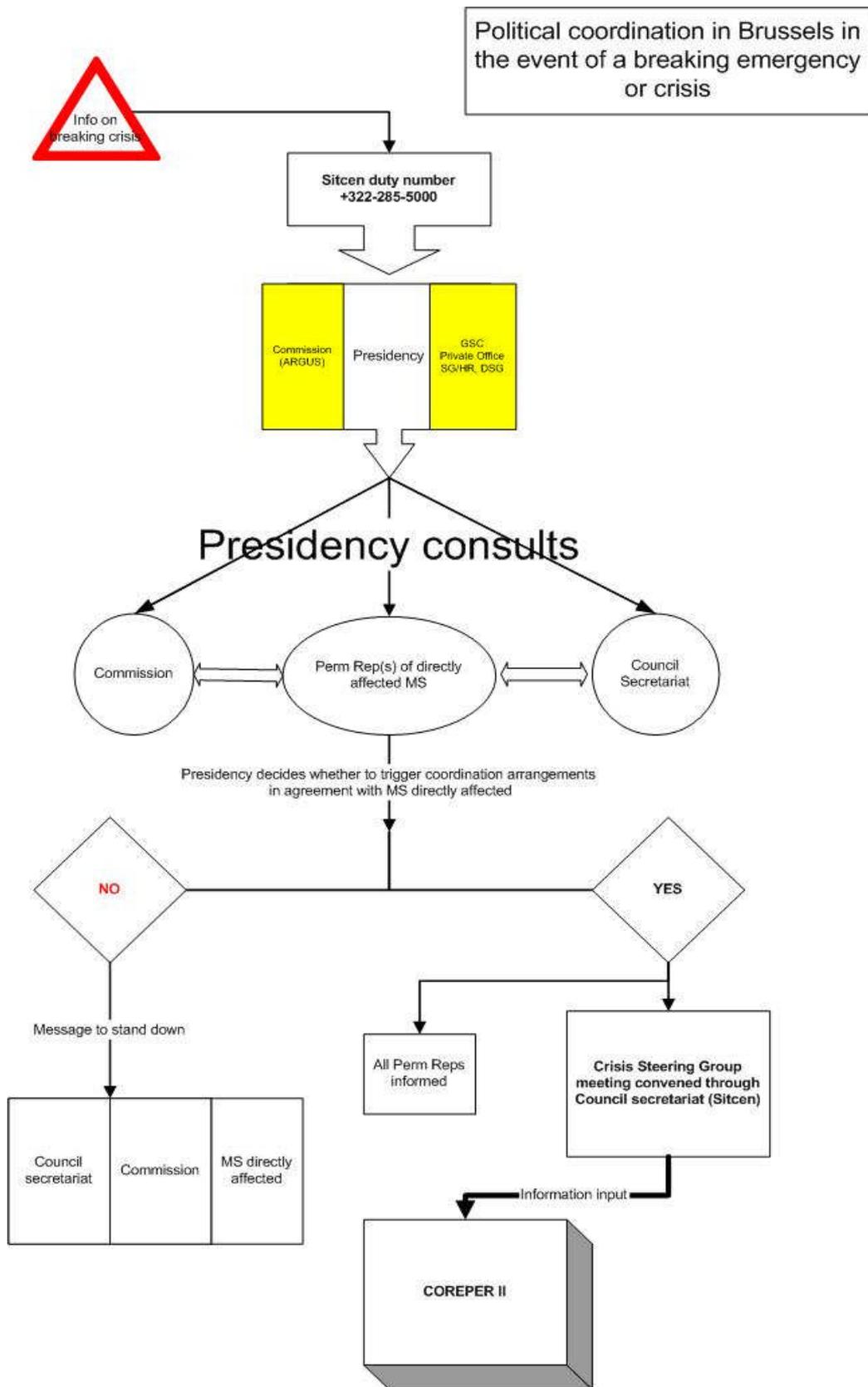


**Annex 2. Procedures in the EU Member States prior to a possible activation of CCA
(Source: Manual on EU emergency and crisis coordination, version of May 25, 2007)**



Annex 3. EU procedure for possible activation of CCA

(Source: Manual on EU emergency and crisis coordination, version of May 25, 2007)



Annex 4. Overview of contact points
Warning and information systems

System	Sweden^{xiv}	EU
ARGUS	Respective contact point for the sectoral warning systems	Secretariat-General, programming and resources unit Operative contact point is the Commission's Security Office at DG Personnel and administrations the directorate for Safety Protection and Crisis management unit.
ADNS	The Swedish Board of Agriculture The Swedish Board of Agriculture, The Infection Combating Unit, Breeding and Keeping Unit and Species Protection and the Infectious Disease Control Unit	DG Health and Consumer Protection's Animal Health and Welfare Directorate, the Animal Health and Standing Committees Unit.
ECURIE	The Swedish Meteorological and Hydrological Institute (SMHI) (Contact point). The Swedish Radiation Protection Authority (SSI) (Competent authority), On-duty radiation protection officer	Security Office of DG Personnel and administrations directorate Security, Protection and Crisis management unit. The Radiation Protection Unit in Luxembourg, under the Nuclear Energy Directorate at DG Transport and Energy

EUROPHYT	The Swedish Board of Agriculture, the plant inspectorate.	DG Health and Consumer Protection's Safety of the Food Chain Directorate, the Unit for Biotechnology and Plant Health as well as DG Health and Consumer Protection's Food and Veterinary Office Directorate, the Unit for Food and Plant Origin, Plant Health, Processing and Distribution
EWRS	The National Board of Health and Welfare's on-duty Infectious Disease Control as well as the unit Officer for the National Board of Health and Welfare's Unit for Communicable Disease Prevention and Control	DG Health and Consumer Protection's directorate, Public Health & Risk Assessment, Health Threats Unit.
MIC	The Swedish Rescue Services Agency (SRSA) Administrative officer on duty. The Swedish Rescue Services Agency (SRSA), International department	The Civil Protection Unit at DG Environment, Directorate Communication, Legal Affairs and Civil Protection
RAPEX	The Swedish Consumer Agency, the Market Control and Trade Contacts Units.	DG Health and Consumer Protection's Consumer Affairs Directorate, Product and Service Safety Unit
RAS BICHAT	SOS Alarm The National Board of Health and Welfare's on-duty Infectious Disease Control	DG Health and Consumer Protection's directorate, Public Health & Risk Assessment, Health Threats Unit
RASFF	The official Swedish contact point for RASFF is the National Food Administration. However, the National Food Administration and the Swedish Board of Agriculture have divided the task	DG Health and Consumer Protection's directorate, Safety of the Food Chain, Hygiene and Control Measures unit.

Information systems

System	Sweden	EU
MARS	The Swedish Rescue Services Agency (SRSA) Supervisory unit	DG Environment, Directorate Communication, Legal Affairs and Civil Protection, Civil Protection Unit as well as Major Accident Hazards Bureau (MAHB) constitute the Commission's determined contact points for MARS, but it is primarily the MAHB and Member States that have contact.
TRACES	The Swedish Board of Agriculture and the National Food Administration	DG Health and Consumer Protection, Directorate Animal Health and Welfare, Animal Health and Standing Committees Unit

Systems under development

System	Sweden	EU
CIWIN	The Swedish Emergency Management Agency (SEMA)	DG Justice, Freedom and Security
LEN	The Swedish National Police Board	DG Justice, Freedom and Security
RAS CHEM	National Board of Health and Welfare's Supervisory Unit for Crisis Preparedness	DG Health and Consumer Protection