EUROPEAN CENTRE FOR DISEASE PREVENTION AND CONTROL

Mr Giovanni Butarelli
Assistant European Data Protection Supervisor
EDPS
Rue Wiertz 60
B-1047 Brussels
Belgium

Stockholm, 13 October 2011
Our ref:SRS-11-2207-DECOkajo

Ref: Prior Checking opinion on the European Surveillance System (TESSy) notified by the European Centre for Disease Prevention and Control (ECDC) - 3 September 2010 (EDPS case no 2009-0474)

Dear Mr Butarelli

According to the Opinion in reference, ECDC should report to the EDPS on the measures taken to comply with the recommendations. ECDC should also provide EDPS on the measures taken thus far, and provide the EDPS with a clear roadmap (including action items and deadlines) for final adoption and implementation.

We take note that the EDPS in the Opinion 3 September 2010 finds no reason to believe that there is a breach of the provisions of the Regulation provided that the recommendations in Section 3 are implemented. Please find herewith the recommendations and the actions undertaken by ECDC or the roadmap to comply with the recommendations.[1]

1. **Allocation of responsibilities**

Recommendation

Controllers and processors must be clearly indicated in a way which corresponds to the effective role as well as the legal status of the organizations involved. It must be specified who is responsible for what, and how data subjects can exercise their rights. Adoption of a set of data protection guidelines for TESSy is recommended.

Actions

The controller of data for TESSy is the Head of the Surveillance and Response Support Unit, Denis Coulombier, who has the operative responsibility on TESSy data. The Director of ECDC, Marc Sprenger has the executive power to decide on the distribution of data.

[1] Note all quotes from the EDPS Opinion are in italics.

The flow of operational responsibility for data access has been approved by the ECDC Management Board and is described in the attached document "MB20-15 Policy on Access and Use of Data from TESSy" on data access for scientific purposes with the Member States in an advisory role. The procedures can be found in the mentioned attachment. As ECDC has no means of identifying an individual data subject with the data in its possession. Only the Member States may be in a position of informing a data subject on which data relating to the same data subject is captured within TESSy. In case of such request from a data subject ECDC will direct him/her to the National Authority of his/her place of residence.

2. Data quality and training

Recommendation

Data quality should be individually assessed by the users uploading personal data on TESSy. To facilitate this, data protection should be integrated into the training provided to users.

Actions

Data protection has been integrated into all ECDC TESSy training. Data quality is tested by the trained up-loader. Quality of data is further enhanced by the validation protocols built-in in the TESSy software and by the TESSy helpdesk. In addition, there is a validation process undertaken after each data call.

A module on data protection has been added in all TESSy trainings (online and residential).

A confidentiality declaration (found in the attached document "MB20-15 Policy on Access and Use of Data from TESSy") is signed by all people handling or receiving TESSy data and a confidentiality clause/declaration has been included in the online sign-in procedure in TESSy.

3. Retention of data

Recommendation

Record IDs should be automatically deleted when their use is no longer necessary.

Actions

The data collected by TESSy does not allow identification of individuals by ECDC and has long term epidemiological, statistical utility. Record ID will be retained for 10 years counted from the receipt of the record and then deleted. The records themselves will not be deleted.

4. Transfers to third parties

Recommendation

Additional safeguards should be implemented, as discussed in Section 3.8, with respect to transfers to third parties and the WHO.

Actions

Additional safeguards are part of the procedures for granting access of data to third parties and WHO and are defined in the documents approved by the Management Board. See attached document "MB20-15 Policy on Access and Use of Data from TESSy".

5. Access rights of data subjects

Recommendation

Despite the statistical nature of the data, the ECDC should re-assess whether there may be any situations in which a data subject may wish to have access to their data, rectify such data, or object to its use. Adequate measures should be put in place to address such situations, even if access requests may be rare. At a minimum, a contact person should be indicated at each organization using TESSy to deal with access requests.

Actions

ECDC has re-assessed the TESSy database. There are no instances in which an individual can be univocally identified solely with the information collected in TESSy. Any request for right of access and rectification will be referred back to the relevant Member State that may or may not be in the position to identify a record as pertaining to a specific individual. ECDC is not in a position to delete records upon request of a data subject given that that they cannot be referred to a specific individual. Member States may delete records re-uploading a data batch if they wish to do so.

6. Information to data subjects

Recommendation

To ensure consistency and transparency, the operator of TESSy should provide comprehensive and user-friendly information to data subjects on its website. This should be complemented by notice provided by Member State contact points in accordance with national data protection laws.

Actions

The information on TESSy is available on the web site including precise information on TESSy and the collected data.

The web site contains information on the contact points in each Member State and a link to each Competent Body in each Member State.

7. Security

Recommendation

A dedicated security policy should be adopted as soon as possible to help ensure the security of TESSy, and to verify and document good administration.

Actions

A comprehensive information systems security policy is in place in ECDC since 30 May 2011.

The Opinion of the EDPS in Section 3 also addresses some specific questions that we would like to respond to.

Questions

When allocating responsibilities in the TESSy data protection guidelines, in particular, the following issues need to be addressed:

- *Who are responsible for ensuring the quality (proportionality, accuracy, etc) of the data?*

  See first paragraph of this letter.

- *Who can determine retention periods?*

  The Senior Management Team of ECDC advised by the Advisory Forum.

- *Who determines who can have access to the database?*

  ECDC and the Competent Bodies with approval of the Management Board have determined who can have access to the TESSy database through a defined "nomination process". The process for other persons or institutions to get access is laid down in the procedure approved by the Management Board of ECDC in November 2010 as described in the attached document "MB20-15 Policy on Access and Use of Data from TESSy".

- *Who are authorized to make a transfer of the data to third parties?*

  The ECDC Director and the data controller Denis Coulombier may delegate experts in the Surveillance and Response Support Unit to transfer the data according to the procedure approved by the Management Board (attached document "MB20-15 Policy on Access and Use of Data from TESSy").

- *Who are providing notice to data subjects?*

  The Director of ECDC will refer the data subjects to the relevant public health authorities in the Member State as ECDC cannot link the data in TESSy to an individual data subject.

- *Who are responsible for acting when access, rectification, blocking, or erasure is requested by data subjects?*

  The relevant public health authorities in the Member States are responsible.

- *Who bears ultimate responsibility for the security of TESSy?*

  The Director of ECDC that may delegate the Head of the Surveillance and Response Support in ECDC.

- *Who makes decisions regarding the design of TESSy?*

  The Head of the ECDC Surveillance and Response Support Unit does.

  To facilitate compliance by the various users, the EDPS recommends that data protection elements should be integrated to any training given to the users of the system. This may include, among others, information on:

  - *how to ensure that only relevant and not excessive data are included in the database (e.g. appropriate "anonymization techniques" are used)*

    - The Competent Bodies and the Advisory Forum are assuring the scientific and Public Health relevance of the data.

- *how to ensure that any incorrect data are rectified and data included are kept up-to-date*

    - This is done through the data validation process. See also reply on "Data quality and training".

- *how to inform data subjects*

    - Only the relevant public health authorities in Member States are able to identify the records as belonging to a specific individual and thus are in a position to inform data subjects. From the data in TESSy, ECDC has not enough information to do so.

- *how to provide them access to their personal data, upon request*

    - See above.

I Hope to have been able to respond to all EDPS requests. ECDC will also keep EDPS informed on the progress of all actions still in the roadmap and on new TESSy developments that might have an interest in data protection. Finally, I would like to apologize for the long delay in responding.

Yours sincerely,

[redacted]

Denis Coulombier
Head of Unit
Surveillance and Response Support Unit
ECDC

Attachment

MB20-15 Policy on Access and Use of Data from TESSy

MB20-15 Policy on
Access and Use of Da

CC: [redacted] European Commission, DG SANCO, C3 Health threats
[redacted] European Commission, DG SANCO, C3 Health threats

EUROPEAN CENTRE FOR DISEASE PREVENTION AND CONTROL

Mr Giovanni Buttarelli
Assistant European Data Protection Supervisor (EDPS)
Rue Wiertz 60
B-1047 Brussels
Belgium

Stockholm, 5 June 2012

Our ref: SRS-12-1202-DECOkajo

Dear Mr Buttarelli,

Re: Follow-up on the recommendations of the Prior Checking Opinion on the European Surveillance System (TESSy) notified by the European Centre for Disease Prevention and Control (ECDC) issued on 3 September 2010 (EDPS case no 2009-0474)

According to the Opinion referred to above, ECDC should report to the EDPS on the measures taken to comply with the EDPS recommendations, as well as inform EDPS on new TESSy developments that might be of interest from a data protection perspective. I would like to remind you that a letter was sent by ECDC in this respect on 13 October 2011, by which the EDPS was informed of the measures taken thus far. By the present letter, I would hereby like to address two issues.

Firstly, I would like to inform you that after a request from the WHO Regional Office for Europe, ECDC has decided to allow authorized staff at WHO Regional Office for Europe to **access the full database** of the European Surveillance System (TESSy) data regarding Measles and Rubella. The amended procedure will allow for Measles and Rubella case-based data to retain the national unique identifier (RecordId) as provided by the Member State (MS) in TESSy, and to make it accessible to a **limited number of recipients** (staff maintaining the system, i.e. members of the SRS Unit at ECDC, selected trained staff at WHO/EURO and the MS that provided the data). All personally identifiable information is removed from the dataset by the submitting MS prior to case-based data being uploaded into TESSy. The access to the national unique identifier (RecordID) will not allow ECDC staff to trace any individual data subject.

At this point, I would like to highlight ECDC's will to **fully comply with the Regulation (EC) 45/2001**. The EDPS, in point 3.8 of the Opinion referred to above, recommended that ECDC *"explores the possibilities of compliance with Article 9 of the Regulation in the framework of the follow-up of the prior checking opinion"*. After broad consultations with the parties involved with regard to the transfer of data from ECDC to WHO Regional Office for Europe, ECDC has agreed to use the **derogation under article 9.6(d)** of the Regulation (EC) No 45/2001. According to this provision, personal data may be transferred, if the transfer is **necessary on important public interest** grounds. In the case at hand, the transfer is necessary in the interest of **public health**. To this respect, the WHO Regional Office for Europe sent a letter to ECDC, outlining the scientific and technical reasons why such transfer of data is necessary, and by which it clarified that the data access requested will allow it to keep on performing essential Public Health work, with the aim to contribute to the eradication of the above mentioned diseases. Moreover, WHO has assured ECDC of the **adequacy** of the

data protection offered. WHO has explained that the access to the data requested is not excessive for the aim pursued by the WHO Regional Office for Europe and supported by ECDC to eliminate Measles, Rubella and Congenital Rubella in the WHO-EURO Region. Furthermore, no technical solutions other than the access to the full set of variables included in the TESSy databases for Measles and Rubella may allow an effective intervention from WHO towards the monitoring and elimination of such diseases.

According to Article 9.8 of the Regulation, the EDPS shall be informed of any categories of cases where Articles 9.6 and 9.7 were applied. I would, therefore, like to hereby inform the EDPS of **our decision to apply paragraph 9.6.d** with regard to transfer of the said data to the WHO Regional Office for Europe from TESSy.

Secondly, I would like to inform you on an operation, which is actually a by-product of TESSy, since it concerns a repository in which we collect all the correspondence regarding the requests of access to TESSy data by institutions and researchers outside ECDC. The purpose of this operation is to track all data requests, in order to enhance performance and control of use. I would like to consult you on whether this operation should be separately notified, or whether it should be included as an update to the existing notification.

Yous sincerely,

[redacted]

Denis Coulombier
Head of Unit, Surveillance and Response Support

CC: Marc Sprenger, ECDC Director

Rebecca Trott, Data Protection Officer, Senior Legal Advisor, Head of Legal and Procurement Section

GIOVANNI BUTTARELLI
SUPERVISOR

Mr Denis COULOMBIER
Head of Unit Surveillance and Response Support
European Centre for Disease Control (ECDC)
Granits väg 8
171 65 Solna
SWEDEN

Brussels, 09 June 2015
GB[redacted]D(2015)0953 **C 2009-0474**
Please use edps@edps.europa.eu for all correspondence

Dear Mr Coulombier,

I am writing to you in the follow-up of ECDC's prior checking for the European Surveillance System (TESSy), following up on your letters of 13 October 2011 (your reference: SRS-11-2207-DECOkajo), 5 June 2012 (your reference: SRS-121-1202-DECOkajo) and further contacts on staff level in April 2015.

The EDPS Opinion issued on 3 September 2010 contained several recommendations, which will be addressed below, starting with the question of transfers to third parties, but otherwise following the order of the Opinion.

The question of **transfers to third parties** is a major issue for TESSy. ECDC has provided the templates for data requests, confidentiality declarations and the data agreement, which provide additional safeguard. In your letter of 5 June 2012, you informed us that ECDC planned to give the World Health Organization (WHO) Regional Office for Europe access to TESSy data for Measles and Rubella. You explained that ECDC wanted to base this access on Article 9(6)(d) of Regulation (EC) 45/2001 ("the Regulation")[1] and that additionally, the WHO has assured ECDC of the adequacy of its level of data protection.

The WHO is an international organisation and transfers to it thus fall within Article 9 of the Regulation, triggering specific rules.

Article 9(6)(d) is a derogation from the general rules contained in this Article and allows transfers that are necessary on important public interest grounds, also in the absence of adequate safeguards. However, being a derogation, it should be used sparingly and can in any case not be used for transfers that are repeated, massive or structural.[2] For this reason, **Article 9(6)(d) is not an appropriate basis** for the WHO's access.

[1] OJ L 8/1 12/01/2001.
[2] EDPS Position Paper transfer of personal data to third countries and international organisations by EU institutions and bodies; available here:

That being said, **Article 9(1) and (2) may allow for transfers** to the WHO, provided the level of protection it affords is indeed **adequate**.[3] **It is up to ECDC to assess the level of adequacy and to document this assessment**. Unilateral assertions of the WHO are not sufficient to prove this.

Concerning the **allocation of responsibilities**, ECDC has provided an overview of the different actors involved in TESSy and their roles and responsibilities, which is documented in an internal policy adopted by ECDC's management board. This recommendation is **closed**.

As regards **data quality and training**, ECDC explained how data protection aspects have been integrated into training for TESSy users. ECDC also explained that data quality is first assessed by the uploading user and that additionally, built-in validation protocols check the content. This recommendation is **closed**.

Regarding the **retention of data**, the EDPS had recommended to establish a fixed retention period for the record ID[4], keeping it for not longer than necessary. ECDC has established a period of 10 years.[5] This recommendation is **closed**.

For the **access rights** of data subjects, the EDPS had recommended to re-assess if there are any situations in which data subjects may wish to exercise their rights and to put adequate measures for dealing with them into place. At a minimum, a contact point should be appointed at each organisation using TESSy. ECDC explained that there were no instances in which persons could be uniquely identified from the data held in TESSy. The EDPS would like to point out that the possibility of indirect identification, e.g. by cross-checking with another dataset is enough to trigger the applicability of data protection rules.[6] That being said, ECDC will refer data subjects to the relevant national authority (the data source), who may be able to retrieve the information. This is an acceptable solution; this recommendation is **closed**.

On the issue of **information** to data subjects, the EDPS recommended making comprehensive and user-friendly information available to data subjects on ECDC's website. This should take the form of a short document ("data protection notice") providing the elements required under Article 12 of the Regulation. Some information about the processing of personal data is included in the "Policy on data submission, access, and use of data within TESSy – 2011 revision", which is published on ECDC's website. This document contains a chapter entitled "data protection", which does not contain all elements of information required under Article 12(1) of the Regulation. In the interest of transparency, this information **should be provided in easily accessible form** on the TESSy website, **for instance in the form of a separate privacy statement** quickly summarising these elements.[7]

Finally, as concerns **security**, we had recommended developing a dedicated security policy for TESSy based on a risk assessment. ECDC replied that a comprehensive information

---

https://secure.edps.europa.eu/EDPSWEB/webdav/site/mySite/shared/Documents/Supervision/Papers/14-07-14_transfer_third_countries_EN.pdf, especially pages 14 and following.

[3] See pages 10 to 14 of the EDPS Position Paper referred to above; the material principles to assess are summarised on pages 10 and 11.

[4] This ID allows linking back entries in TESSy to the data source in a national database and may thus possibly allow re-identification of data subjects when linked to the data source. The record ID is not given to third parties when they request access to data.

[5] In the first place, it is for ECDC as controller of TESSy to establish and justify a conservation period in light of the business needs for TESSy. It may be the case that different diseases may justify different conservation periods, as there may be a need to update entries for e.g. a case of HIV after many years, while for influenza, a need for updates would appear to be very unlikely after a few weeks.

[6] See Article 29 Working Party Opinion 04/2007 on the concept of personal data, interpreting the corresponding provisions in Directive 95/46/EC, especially pages 12-20. Available here: http://ec.europa.eu/justice/policies/privacy/docs/wpdocs/2007/wp136_en.pdf

[7] For the same reasons as for the right of access, individual notification of this privacy statement to data subjects in TESSy is not feasible.

systems security policy has been in place at ECDC since 30 May 2011. This recommendation is **closed**.

In your latest letter you also mentioned processing operations linked to TESSy for the purposes of managing and tracking all requests to TESSy data (e.g. by external researchers) and asked if these should be considered as part of TESSy, or be notified separately.

Based on the information provided, these processing operations only serve to manage and track the requests for TESSy data. They can be considered as an auxiliary part of TESSy, and be covered in the same internal Article 25 notification.[8] This part of the processing related to TESSY will only fall under the obligation for prior checking if it constitutes an evaluation in the meaning of Article 27(2)(b) of the Regulation[9] of the requesting researcher.

Thank you for your cooperation and please keep us informed about how ECDC will implement the remaining recommendations on information and transfers.

Yours sincerely,

Giovanni BUTTARELLI

Cc: [redacted] ECDC
[redacted], ECDC

[8] These researchers would then constitute a new category of data subjects, with obviously different data categories from the entries in TESSy; unlike for data subjects of entries in the TESSy database, the rights to access and rectification are easy to implement for this new category of data subjects.

[9] This depends on the process to vet such access requesst: if it is "intended to evaluate personal aspects relating to the data subject [here: the researcher requesting access], including his or her ability, efficiency and conduct", it would fall under Article 27(2)(b). If, on the other hand, the assessment is more formal or not related to personal aspects, it would not fall under Article 27 (e.g. if it only consists of questions such as "is the requester affiliated with a research institute/university?", "are the requested data relevant for answering the research question submitted?").

WOJCIECH RAFAŁ WIEWIÓROWSKI
ASSISTANT SUPERVISOR

Mr Denis COULOMBIER
Head of Unit Surveillance and
Response Support
European Centre for Disease Control
(ECDC)
Granits väg 8
171 65 Solna
SWEDEN

Brussels, 02 December 2015
WW[redacted]D(2015)1545 **C 2009-0474**
Please use edps@edps.europa.eu for all correspondence

Dear Mr Coulombier,

Thank you for your letter dated 21 July 2015 (your reference SRS-2015-OUT-1743-DCLiGr), in which you provide information on the way in which ECDC plans to implement the two remaining recommendations from the EDPS letter of 9 June 2015.

These two remaining recommendations concerned the information to data subjects and transfers to the WHO.

For information to the data subjects, we take note of ECDC's commitment to publish the relevant information on its website. For the transfers to the WHO, ECDC committed itself to performing the relevant assessments.[1]

Once these assessments will be concluded, please inform us about their outcome. We expect that the case can be closed upon receipt of this information.

Thank you for your cooperation.

Yours sincerely,

Wojciech Rafał WIEWIÓROWSKI

Cc: [redacted] ECDC
[redacted] ECDC

[1] See also EDPS Position Paper transfer of personal data to third countries and international organisations by EU institutions and bodies; available here: https://secure.edps.europa.eu/EDPSWEB/webdav/site/mySite/shared/Documents/Supervision/Papers/14-07-14_transfer_third_countries_EN.pdf.

ECDC Management Board
Twentieth Meeting
Stockholm, 9-10 November 2010

Agenda Item 12

MB20/15
26 October 2010

Policy on Access and Use of Data from TESSy

Summary:	The Founding Regulation of the ECDC (Regulation (EC) 851/2004) calls ECDC to "develop with the competent bodies of the Member States and the Commission appropriate procedures to facilitate consultation and data transmission and access" (article 11.2). During its 16th Meeting in Warsaw, the Management Board approved the document "Access to ECDC MS Data in TESSy by Third Parties" including the "Policy on data submission, access, and use of data within TESSy among the ECDC, the European Commission and the EU Member States" (Annex) that envisaged a revision of the procedures after one year. The purpose of this document is to provide the report of the test period and to present the revised procedures on access and use of data in TESSy. This revision is guided by the Opinion of the European Data Protection Supervisor on TESSy (03.09.2010 Case 209-0474) and also by the experience so far.
Action:	For approval.
Background:	Article 15(3) of the Treaty on the Functioning of the European Union, EC Regulations 45/2001, 1049/2001, 178/2002, 726/2004, 851/2004, 1907/2006, Commission Decision 2119/98/EC, 2008/721/EC, and other EU legislation on confidentiality European Commission - Directorate-General Health & Consumers Brussels, 10 November 2008 "Common guidelines on practical arrangements for the sharing of scientific data between the scientific committees and panels of European Agencies and the scientific committees of the Commission" Opinion of the European Data Protection Supervisor 03.09.2010 (Case 209-0474) on TESSy Opinion 01/2010 of Data Protection Working Party Policy on data submission, access, and use of data within TESSy among the ECDC, the European Commission and the EU Member States (as approved by the ECDC Management Board 25 June 2009). Opinions of the ECDC Data Protection Officer and experience acquired by the TESSy team in the last year with the requests for data.

Table of Contents

Background

1. Since 25 June 2009, an analytical overview of the requests for access to data has highlighted some difficulties in the policy approved at its 16th Meeting (Warsaw, 24-25 June 2009) by the Management Board in the document "Access to ECDC Member State Data in TESSy by Third Parties" (Annex: "Policy on data submission, access, and use of data within TESSy among the ECDC, the European Commission and the EU Member States"). The same document envisaged a revision after one year.

2. The overview shows that almost none of the requests for data access received in the last year fit the categories identified in the above noted document. Typical examples are the requests for data coming from an European Agency contracting the analysis of the requested data to an external consultant. There were some internal inconsistencies in the policy as spelled out by the document. For example, the documents referred to cells of not more than five records also describing case based data. The draft contract provided was not adapted to the parties/categories requesting data (as per example above). The "Peer Review Group" envisaged by the document was not yet set up, and therefore the requests requiring this (three requests) could not yet be processed.

3. The European Data Protection Supervisor expressed an Opinion on TESSy (Case 209-0474; 03.09.2010) and a further analysis of the relevant[1] regulations was undertaken.

4. This has led to the development of a proposal for Standard Operation Procedures to manage the requests of access to TESSy data according to the various different categories of identified TESSy data users.

5. The procedures have been defined in two documents "Procedure on managing requests for TESSy data or access I (received from the European Commission, EU Agencies, their contractors, ECDC contractors, ECDC grantees, WHO/Euro)" and "Procedure on managing requests for TESSy data II (received from academic institutions, universities, non-EU public health agencies, non-governmental organisations, commercial companies and individual scientists").

6. A standard "Declaration Concerning Confidentiality and Data Use" form has been developed for the recipients of TESSy data. The following activities are also part of the background work:

- Based on the examination of existing contracts and consultation with the ECDC Legal and Procurement Section, a "sample" agreement for Agencies and third parties has been drafted and is ready for use.
- A "Request for TESSy Data for Research Purposes" form has been finalised and is ready for use to collect the relevant information of the various requests for data.

[1] Article 15(3) of the Treaty on the Functioning of the European Union, EC Regulations 45/2001, 1049/2001, 178/2002, 726/2004, 851/2004, 1907/2006, Commission Decision 2119/98/EC, 2008/721/EC And Other EU legislation on confidentiality; European Commission - Directorate-General Health & Consumers Brussels, 10 November 2008 "Common guidelines on practical arrangements for the sharing of scientific data between the scientific committees and panels of European Agencies and the scientific committees of the Commission"; Opinion of the European Data Protection Supervisor 03.09.2010 (Case 209-0474) on TESSy; Opinion 01/2010 of Data Protection Working Party; Policy on data submission, access, and use of data within TESSy among the ECDC, the European Commission and the EU Member States (as approved by the ECDC Management Board 25 June 2009); Opinions of the ECDC DPO and experience acquired by the TESSy team in the last year with the requests for data.

- Personnel have been identified to receive and follow up on the application procedures and the requests for information.
- A timeline and procedures to deal with the data requests, to follow up on the data transfer, to assess the data usage and to request data destruction have been defined (a specific template "Declaration on Data Destruction" has been drafted).
- The "peer review" group to advise on the data requests from third parties will be nominated.
- Amendments to the Management Board document on data access (25 June 2009) have been collected in order to propose an updated Management Board "Policy on data submission, access, and use of data within TESSy – 2010 revision" (Annex I and appendixes).

7. The TESSy Helpdesk Manger should register all requests for access in SharePoint in a database of TESSy data requests. The Helpdesk Manager should also record all the subsequent steps described by the documents mentioned in paragraph 5.

Questions for the Management Board

1. Does the Management Board agree that the TESSy data is co-owned by the Member States and ECDC as the trustee custodian of the data?

2. Does the Management Board approve the document "Policy on data submission, access, and use of data within TESSy – 2010 revision" in Annex I and all its appendixes?

Annex I - Policy on data submission, access, and use of data within TESSy – 2010 revision

1. Purpose

In accordance with the founding regulation of the ECDC (Regulation (EC) 851/2004) the EU Member States have to provide ECDC "in a timely manner with the available scientific and technical data relevant to its mission". The European Surveillance System (TESSy) is provided by the ECDC to collect, analyse and disseminate surveillance data on infectious diseases in Europe.

The founding regulation also calls for ECDC to "develop with the competent bodies of the Member States and the Commission appropriate procedures to facilitate consultation and data transmission and access" (article 11.2). The purpose of this revision is to describe users' rights and responsibilities of competent bodies and of the ECDC regarding the submission, access, and use of data in TESSy. This procedure is confirmed and signed by the ECDC, all Member States and the Commission"

2. Data submission to TESSy

2.1. Authentication

All users of TESSy must authenticate themselves when accessing the system using a personal login. ECDC will provide each user with account/password information and assist in system access issues after having received a request for access from the 'nominator of TESSy users'.

2.2. User nomination/confirmation

The Director of each national Competent Body for surveillance will nominate a person and his/her alternate ("nominator of TESSy users") who will be responsible for approving new TESSy user nominations from the Member State, and notifying ECDC about changes in user privileges or inactivation of user access to TESSy and data access for others not nominated for access to national data. All access to data is nominal and is subject to the commitment on confidentiality. The different roles of TESSy users in TESSy are described hereafter. The user will submit a signed request for access to TESSy, co-signed by the "nominator of TESSy users" for the respective country or the nominator of TESSy users can send an e-mail with the nomination form (and the confidentiality declaration when applicable) copied to the new user. ECDC will then create user accounts for this individual.
For the Dedicated Surveillance Networks (DSN) whose coordination activities are being transferred to ECDC, the nominator of TESSy users will be asked to confirm the existing national representatives in the DSNs or nominate new contact points for the respective disease(s). For diseases, not covered by a pre-existing DSN, ECDC will also request nominations from the Competent Body. For all users of TESSY, the "nominator of TESSy users" will also indicate to ECDC what the scope of access of the new user should be (see below "user types and roles").
The Director of each Competent Body for surveillance will also nominate an individual and his/her alternate who will be responsible for approving requests for publication of national case-based data ("approver of data publication").

2.3. User types and roles

Each user nomination will specify the user's role or roles in TESSy and his/her scope of access to data.
Nominated users can be assigned one or more of the following roles by the nominating competent bodies:

Data Submitter:

Has access to the data upload wizard, data validation, and data reports.
Prepares the data in TESSy format, uploads it (either manually or via machine-to-machine communication), reviews the pending batches of data (any warnings or errors), and then either erases them from queue or commits the data into the database.
Can view raw data and case-based data for all countries for the disease(s) for which rights are authorised and can download it.

Data Downloader:

Has access only to data reports and downloads, but cannot upload or confirm data uploads.
Can view raw data and case-based data for all countries for the disease(s) for which rights are authorised and can download it.

Data Viewer (reports only):

Has access only to aggregate data reports, but cannot download or upload or confirm data uploads.
Can view a predefined (and agreed upon by all Member States) series of aggregate reports by country or disease.
Each nomination will also specify whether the individual will have access to data for a specific disease/disease group or to data of all notifiable diseases.

2.4. Changing user account roles and account termination

The user nominator will notify the ECDC when:

- a TESSy user no longer performs the defined surveillance roles and the user's account should be terminated.
- a user's role in TESSy should be modified and how.
- ECDC will make the requested changes in the user accounts.

3. Data storage and custody

3.1. Storage

The submitted data will be stored in the TESSy database and is maintained by the ECDC.

3.2. Ownership, trusteeship and data handling

Member States are the original data owners and provide all data in compliance with the EU regulations including EC decisions (notably Decision 2119/98 EC). ECDC is the co-owner and custodian of the data, which is in its trusteeship, and can assist Member States in data upload and reporting.

4. Use of TESSy data by nominated users

4.1. Access

Access to data refers throughout the procedure to validated data within TESSy.
The ECDC staff can access all case-based data and analyze it. ECDC staff is bound by confidentiality. The same rules apply to TESSy trained EC personnel and TESSy trained personnel of other European Agencies.
Access to aggregated and case-based data will be given to data submitters and data downloaders according to the scope (all diseases or only specific ones) authorised by the user nominator.
For some diseases ECDC and the WHO Regional Office for Europe have agreed and may agree in the future to jointly coordinate the surveillance of these diseases for the whole WHO European Region using TESSy as the joint database. Therefore, authorized staff at the WHO Regional Office for Europe and in the non-EU countries participating in the surveillance of these diseases will have direct access to aggregated and case-based data on these diseases. They will adhere to the same principles and procedures as outlined in this document and will complete the confidentiality declaration form.
Access, use and analysis do not imply right to publication (see 6.).

4.2. Training for TESSy users

All users who want/need to have direct access to TESSy data must undergo training in the concepts, principles and use of TESSy. For users in Member States this training will be provided either in training workshop at ECDC or in the format of online training. For diseases with joint surveillance with WHO, staff from WHO will be invited to the workshops and online trainings. Internal trainings will be organised for ECDC staff and for EC personnel and personnel of other European Agencies (see note 1).

5. Request of TESSy data from the European Commission, European Union Agencies, WHO-EURO and third parties

5.1. European Commission, other European Union Agencies[2], WHO-EURO

In agreement with the European Commission - Directorate-General Health & Consumers Brussels, 10 November 2008 "Common guidelines on practical arrangements for the sharing of scientific data between the scientific committees and panels of European Agencies and the scientific committees of the Commission" European Agencies may receive TESSy data upon requesting them filling in the data request form (published on the website) and providing a completed Confidentiality Declaration form for each person handling the data (including hired consultants that will be subject to all confidentiality clauses valid for the ECDC staff). The same applies to the European Commission. WHO-EURO may request data using the same procedure, the request will be reviewed internally by ECDC and data released if appropriate (if relevance and confidentiality are guaranteed).

5.2. Third parties

Third parties are defined as persons or institutions which are not part of the nominated TESSy user group and are not the ones described by paragraph 5.1.
Third parties must submit a request for data to the ECDC according to the data request form published on the website and following the procedures described therein.
The decision to make the data available will be guided by the following principles:
Data requests from academic institutions, universities, non-EU public health agencies, non-governmental organisations and commercial companies will be assessed and recorded by ECDC (see procedure II). The requests positively assessed will be forwarded to an Advisory Peer-Review Group for further opinion, the Advisory Peer Review Group consisting of 3 national surveillance coordinators (nominated by the Member States) and 2 ECDC experts (nominated by ECDC). Terms of reference of the group and criteria for the assessment will be published on the ECDC website together with the minutes of the meetings. The data will be made available to the applicants by providing the requested data set as an extraction from TESSy.
On acceptance of their proposal, third parties need to sign a contract which explains and defines rights and obligations of use of TESSy data (see draft contract).
All Member States whose data are part of the extraction will be informed.

6. Data use and publication

TESSy aggregated data can be made accessible on the ECDC web site to the general public in the form of agreed upon aggregated data summary reports. The reports will be agreed a priori with the nominated approvers of data publication.

[2] The European Agencies are the ones indicated in the official EU website at the URL http://europa.eu/agencies/index_en.htm.

A decision about which other data should be available for the public, and in which format, will be made in agreement with the Competent Bodies for surveillance.
Any publication of TESSY case-based data is subject to approval by ECDC and the Member States involved. Requests for such permission should be addressed to ECDC, who will forward them to the nominated "Approver of data publication". This procedure may result in requests to amendments to the proposed publication.

7. Data protection

With reference to the protection and free movement of personal data, Directive 95/46/EC and Regulation 45/2001/EC apply to Member States and the ECDC and the European Commission, respectively. These directives apply without prejudice of Decision 2119/98/EC and Decision 2000/57/EC and are guided by Article 15(3) of the Treaty on the Functioning of the European Union, EC Regulations 1049/2001, 178/2002, 726/2004, 851/2004, 1907/2006, Commission Decision 2119/98/EC, 2008/721/EC; European Commission - Directorate-General Health & Consumers Brussels, 10 November 2008 "Common guidelines on practical arrangements for the sharing of scientific data between the scientific committees and panels of European Agencies and the scientific committees of the Commission"; Opinion of the European Data Protection Supervisor 03.09.2010 (Case 209-0474) on TESSy; Opinion 01/2010 of Data Protection Working Party.

7.1. Anonymisation of data

All personally identifiable information will be removed from the dataset by the submitting Member State prior to upload of case-based data into TESSy. Where unique record identifiers are used to report case-based data, they must be anonymised and must not be traceable to individuals. ECDC should not be able to identify any person with the information in its possession.

7.2. Confidentiality of data

All data which is not presented publicly must be considered confidential by all users of TESSy or any data recipient.
Each individual in possession of TESSy data not already in the public domain should be bound to confidentiality.
Force majeure in the form of extreme cases of public health interest may allow divulgation by ECDC of aggregated data.
All nominators (primary and their alternates) of TESSy users in national competent bodies are responsible for explaining and enforcing the confidentiality principles upon the users they nominate if necessary requesting the filling in of the Confidentiality Declaration form.

8. Validity of this procedure

All procedures will be subject of annual reviews.

9. Appendixes

Appendix 1 Declaration Concerning Confidentiality and Data Use

Appendix 2 Sample Agreement for Agencies and third parties

Appendix 3 Request for TESSy Data for Research Purposes

Appendix 4 Declaration on Data Destruction

Appendix 1 - Declaration Concerning Confidentiality and Data Use

DECLARATION CONCERNING CONFIDENTIALITY AND DATA USE

Experts recipient of a TESSY Data

SURNAME:

FIRST NAME:

TITLE/FUNCTION:

AFFILIATION:

I hereby declare that I am aware of my obligation to respect confidentiality. I know that I am obliged not to divulge information acquired as a result of the work of the group I am member of, if this information is subject to a request for confidentiality.
I acknowledge that the data set is provided in good faith to the best of ECDC's knowledge and ability, free of error at the time of supply.
I understand that ECDC shall not be responsible for any errors, omissions or mistakes contained in the users' data nor for any consequences or liabilities arising from its use. Nor shall ECDC be responsible for any effects of the materials supplied on software or hardware of computer systems or of legal and natural persons to which I may communicate the data. In any event ECDC's liability shall be limited to re-supply of corrected materials and data.
I am aware that all publications referencing country's data (except for the publicly available aggregate data) produced by any party shall not be published without each country's explicit consent. Requests for such permission shall be addressed to ECDC, who shall forward them to the nominated "Approver of data publication".
I acknowledge that shall destroy any data or any copy of the documents provided after the analysis for which the data has been requested is concluded. This applies to the data set provided and to all data files which have been derived from this dataset or which are the result of the link of this database with data sets from other sources.
I shall provide ECDC with a copy of all reports that have been produced using the data. I shall remain bound by this obligation even after expiry or termination of the contract.
Done at _____ *on* _____

Signature _____

Appendix 2 - Sample Agreement for Agencies and third parties

Agreement between ECDC and Name of Applicant (or Institution) on the provision and use of *describe database* as requested for study purposes (may describe study)

The **European Centre for Disease Prevention and Control** (hereinafter referred to as "ECDC"), which is represented for the purposes of the signature of this agreement by Marc Sprenger, Director;

and

Name of Applicant (or Institution) (hereinafter referred to as "Acronym"), which is represented for the purposes of the signature of this agreement by Name Surname, Director;

Preamble

Whereas

the ECDC was established as an European Union Agency by Regulation (EC) no. 851/2004 of the European Parliament and of the Council of 21 April 2004 establishing a European Centre for Disease Prevention and Control;

recognising that Acronym requested access to a set of TESSy data for research purposes (detail of the request/study: scope and dates). See Annex XX;

Recognising that ECDC Management Board specified in the document (MB decision on data sharing) the conditions for data access;

acknowledging that ECDC is willing to provide the said data to Acronym;

have agreed as follows:

i. Subject and scope of the agreement

Article 1

In this agreement, unless the context otherwise indicates:

"Data set" is the set of data extracted from the TESSy (The European Surveillance System) data base according to the description provided in Annex XX that ECDC will make available to Acronym.

"Parties" are ECDC and Acronym taking part in this agreement.

Article 2

This agreement specifies the conditions of provision and use of confidential data for study purposes, the obligations of the parties and the measures for respecting the confidentiality of the data.

Article 3

The parties shall take all the necessary regulatory, administrative, technical and organisational measures to ensure that the dataset is used only for the study purposes specified in Article 7; that the data set is not distributed to parties not subject to confidentiality obligations, and that there will be no attempt to identify by any means whatsoever, any individuals, nor will Acronym claim to have done so. In particular, the data shall not be linked with other data sets from any source without ECDC's explicit prior written consent.

Article 4

The data may be used by Acronym solely for the study purposes specified in Article 7. Acronym shall not process, disseminate or otherwise allow any of the data to be made available or used for any other purpose whatsoever. Acronym shall remain bound by this obligation even after expiry or termination of the agreement. Failure to comply with these requirements shall be subject to legal action.
Access to the data set may be granted to the individual researchers employed by Acronym exclusively for the study purposes defined in this agreement (and subjecting them to the same conditions laid down in this agreement).

Before providing access to the data set to other researchers employed in any form by Acronym, the principal researcher shall personally ensure that any individual researcher working with the data has signed a Confidentiality Declaration as per template in Annex XX promising that he/she will abide by all the provisions stated in this agreement.

The data set may be used only in compliance with the national data protection legislation of the country where the data set will be stored, and strict data protection codes of good practice must be in place at all times. No copy of all or part of the data can be made and none of the data may leave Acronym premises.

After expiry or termination of the agreement Acronym will sign a declaration to the effect that it has ensured that any data provided under this agreement have been destroyed. This declaration applies to the data set sent by ECDC to Acronym and to all data files which have been derived from this dataset or which are the result of the link of this database with data sets from other sources.

ii. Data use

Article 5

The data set is provided in good faith to the best of ECDC's knowledge and ability, free of error at the time of supply. ECDC shall not be responsible for any errors, omissions or mistakes contained in the users' dataset nor for any consequences or liabilities arising thereof. Nor shall ECDC be responsible for any effects of the materials supplied on software or hardware of computer systems of Acronym or researchers. In any event ECDC's liability shall be limited to re-supply of corrected materials and data.

Article 6

Acronym will receive the Data set as requested and may share the Data set with a contractor for the study purposes mentioned in this agreement and under the conditions stated in this agreement.

Article 7

The title of the planned research project mentioned in the agreement is: Description of the project used in the data request form.

iii. Reports and publications based on the supplied data

Article 8

All publications referencing country's data (except for the publicly available aggregate data) produced by Acronym shall not be published without the country's explicit prior written consent obtained through ECDC.
Requests for such permission should be addressed to ECDC, who will forward them to the nominated "Approver of data publication".

Acronym is required to provide ECDC with a copy of all reports and/or articles that have been produced using the data. To allow for a central list of all data recipients and analyses to be continuously updated, these copies shall be given to ECDC as soon as possible with the necessary mention (e.g. 'not to be quoted'). In any case, these copies shall be given to the section responsible for data management at ECDC at latest immediately after the reports have been presented (papers) or published. Acronym shall remain bound by this obligation even after expiry or termination of the agreement.

Article 9

Acronym undertakes to acknowledge the source of the data by stating – ECDC, [description "TESSY, Date, Release X.Y.] – and to add a disclaimer that ECDC has no responsibility for the results and conclusions which are those of the researcher(s) when disseminating the results of the work to which this agreement relates.

iv. General administrative provisions

Article 10

Any communication relating to this agreement or to its implementation shall be made in writing. Ordinary mail shall be deemed to have been received by ECDC on the date on which it is registered by the section responsible indicated below. Communications shall be sent to the following addresses:

ECDC:
European Centre for Disease Prevention and Control
Surveillance Unit
Title Name Surname
Head of Unit
17183 Stockholm
Sweden

Acronym
Full denomination
Legal Representative
Full Name and title
Address

v. Duration and termination of the agreement

Article 11

The agreement is concluded for a period of a year running from the date of its signature any prolongation or amendment of this agreement is subject to an exchange of letters and the signature by the parties.

Article 12

The parties may amend or terminate this agreement by exchange of registered letters signed by the legal representatives of the parties. Termination may be also requested by one party for breach of any of the provisions of this agreement.

Article 13

Acronym will ensure that there will be no further use of the information made available by ECDC under this agreement after its expiry or termination.

vi. General provisions

Article 14

The agreement shall be governed by the European Union.

Article 15

Any dispute between the parties resulting from the interpretation or application of the agreement which cannot be settled amicably shall be brought before the General court of the European Union.

Article 16

The Director of ECDC and Legal Representative of Acronym may delegate the technical aspects of this agreement respectively to the Head of ECDC Surveillance Unit and The legal representative of Acronym.

Signed in Date

The Director ECDC The legal Representative of Acronym

Appendix 3 - Request for TESSy Data for Research Purposes

The European Surveillance System (TESSy)
Data request form

REQUEST FOR TESSY DATA FOR RESEARCH PURPOSES

In accordance with the founding regulation of the ECDC (Regulation (EC) 851/2004) the EU Member States have to provide ECDC "in a timely manner with the available scientific and technical data relevant to its mission". The European Surveillance System (TESSy) is provided by the ECDC to collect, analyse and disseminate surveillance data on infectious diseases in Europe.

To allow the ECDC to grant access to case-based /aggregate data from TESSy or extraction of TESSy data, for research purposes, the following information of the applicant is given:

1) **Applicant details:**

   Organisation:

   .....

   Address:

   .....

   Country:

   .....

   Contact person (Name of person to whom the access is to be granted):

   .....

   .....

   Contact details (Telephone, Email, Fax):

   .....

   .....

   .....

2) **Purpose of the analysis and use of TESSy data:**

   For what purpose are the TESSy data needed and how will the results of the analysis be used? Please include details of specific projects.

   Attach relevant research proposal(s), a CV and a list of recent relevant publications of the principal researcher.

.....

.....

.....

.....

.....

3) **Need for access to case-based data (not applicable for extracted aggregate data)**

Why do you need access to the case-based data?

.....

.....

.....

4) **What information do you need? Please describe exactly (e.g. age, gender, causing pathogen, molecular characteristics of the causing pathogen, etc.)**

.....

.....

.....

.....

I hereby declare that the above information is correct and complete.

Place, date _____

Signature

_____

Name of applicant (please print)

_____

_____

_____

Address (Organisation)

Appendix 4 - Declaration on Data Destruction

Declaration on Data Destruction

I, NAME SURNAME, hereby declare to have destroyed all TESSy data received as per the Declaration Concerning Confidentiality and Data Use signed the DAY – MONTH – YEAR upon receiving the TESSy dataset TESSY, DATE, RELEASE X.Y.

Signed, LOCATION, DATE SIGNATURE

Annex II - Overview of all external requests for TESSy data (status: 15.10.2010)

Annex 2

Overview of all external requests for TESSy data (status: 15.10.2010)

1. Freelance researchers, Universities and Commercial Organisations

[redacted] *Epidemiologist in infectious diseases works on project with Novartis Vaccines and Diagnostics, Switzerland*

- The request for **direct access** to TESSy sent to TESSy on 12.03.2010.
- Did not specify for which diseases she needs access.
- Application form to be filled in and signed by the applicant sent on 14.04.2010.
- No response received yet. To be archived.

[redacted] *independent researcher*

- The request for **direct access** to TESSy sent to TESSy on 30.03.2010.
- Interest in **HIV/AIDS and Sexually Transmitted Infections (STI)** data.
- Application form to be filled in and signed by the applicant sent on 14.04.2010.
- No response received yet. To be archived.

[redacted] *Duke University, North Carolina*

- The request for **direct access** to TESSy sent to TESSy on 07.04.2010.
- Interested in **Influenza** data.
- Application form to be filled in and signed by the applicant sent on 14.04.2010.
- No response received yet. To be archived.

[redacted] *Novartis Vaccines and Diagnostics*

- The request for **direct access** to TESSy sent to TESSy on 01.04.2010.
- Did not specify for which diseases he needs access.
- Application form to be filled in and signed by the applicant sent on 28.04.2010.
- No response received yet. To be archived.

[redacted] *WU (Vienna University of Economics and Business)*

- The request for **direct access** to TESSy sent to TESSy on 17.03.2010.
- Interested in HIV/AIDS data.
- Application form to be filled in and signed by the applicant sent on 14.04.2010.
- The application form received back on 06.07.2010.
- Acknowledgment sent back to the applicant.
- Pending PEER –review group screening.
- Ms. [redacted] contacted at the end of July again; there was no response from her so far.

- Contacted her via E-mail again on 11.10.2010. Pending response.

[redacted] *National Health Laboratory Service –South Africa*

- Copy of his application form (filled in and signed) received on 30.09.2010.
- Requires data, not direct access to TESSy.
- Interested in Legionnaires' disease.
- An acknowledgment letter was sent on 11.10.2010.

[redacted] *HPA – UK*

- Request for **Influenza data** from TESSy sent to TESSy on 28.09.2010.
- Application form to be filled in and signed by the applicant was sent on 11.10.2010.

2. EU Commission (DG SANCO, JRC, etc.), EU agencies, contractors of EU Commission and EU agencies, ECDC contractors and WHO-Europe

EU Commission JRC - Institute for Protection and Security of the Citizens (IPSC) - Ispra, IT

- First request in February 2009 for direct report and download access for all diseases in TESSy. This was one of the first requests for data and download access received (the exchange started before the MB decision of the 25th June 2009) when the internal procedures were not yet developed. The Opinion of the European Data Protection Supervisor was not yet finalised raising some excessive caution on ECDC part and delaying the process.
- The Institute was provided training on TESSy access using the "SMART Bridgit Software" (the software allows wide sharing of computer windows between trainers and trainees). The training was provided at ECDC 10 March 2010 to two JRC colleagues.
- In the same date access rights for all diseases (report and download) were granted to JRC – IPSC.

ECDC - [redacted] requested access for BCoDE consortium-Grant of ECDC

- The consortium includes researchers from Universities in The Netherlands, Italy, Germany and Estonia.
- Interested in data from TESSy related to the following diseases: **Influenza, Measles, Hepatitis B and Salmonella.**
- Application form sent on 07.06.2010. The form should be filled in by the leading researcher of the consortium.
- No response received yet. To check with Mr. [redacted]

Prof. [redacted] Centre for Men's Health, Leeds Metropolitan University, contractor of EC-DG SANCO

- Requested extract **of data** from TESSy on 02.03.2010.

- Interested in **HIV/AIDS, Sexually Transmitted Infections (STI), Hepatitis B and C** and **Tuberculosis** for his assignment by EC-DG SANCO.
- Already had discussion with the Disease Specific Experts involved.
- Confidentiality declaration signed. **Tuberculosis data** provided on 27.07.2010.
- **HIV/AIDS and STI** data has been provided according to the application form. Some additional HIV and STI are going to be provided after the finalisation of the discussion between the Disease Specific Experts and Prof. White.
- To check the status of the contract with the ECDC Legal office.

EFSA - Biological Hazards Unit, works on assignment by DG SANCO, data will be submitted to a contractor: American company VOSE Consulting

- Requested extract **of data** from TESSy on 10.05.2010.
- Requested Salmonella data for 2006, 2007, 2008, and 2009. The data will be used by contractor of EFSA based in USA.
- Already had discussion with the Disease Specific Experts involved.
- Confidentiality declaration signed. Salmonella data provided on 06.07.2010.
- To check the status of the contract with the ECDC Legal office.

EFSA - Unit on Zoonoses Data Collection, own assignment, data will be submitted to a contractor: Danish Technical University (DTU)

- Requested extract **of data** from TESSy on 02.09.2010.
- Requested Salmonella data for 2006, 2007, 2008, and 2009. The data will be used by contractor of EFSA based in DK.
- Already had discussion with the Disease Specific Experts involved.
- Since the identical Salmonella data has already been provided to EFSA (Biological Hazards Unit see above) our decision is that they can use the already provided data.
- Confidentiality declarations signed both by EFSA and DTU. No specific agreement needed according to the new protocols, recently drafted (data due to European Agency).
- Permission to use the already provided to EFSA data granted on 05.10.2010.

WHO European Centre for Environment and Health, Bonn Office contactor of DG Sanco

- Requested extract of Salmonella (for 2006-2009) and Cryptosporidiosis (for 2006-2008) data from TESSy for work on project CEHAPIS (climate change, environment and health action plan and information system) on 26.05.2010.
- Signed confidentiality declaration.
- Data provided on 28th of July after approval by Disease Specific Expert and the Head of Unit.
- October 28th we need to check the status.
- No request for publication yet.

[redacted]

Subject: FW: 2013-0089 Transfert de données des employés de la BEI à l'OCDE (Consulttaion 27.3)

Follow Up Flag: Follow up
Flag Status: Flagged

From: [redacted]@edps.europa.eu>
Sent: 10 October 2013 10:31
To: [redacted]@EIB.ORG)[redacted]@EIB.ORG>
Cc: European Data Protection Supervisor <EDPS@edps.europa.eu>; [redacted]@eib.org) [redacted]@eib.org>
Subject: 2013-0089 Transfert de données des employés de la BEI à l'OCDE (Consulttaion 27.3)

Cher [redacted]

Dans ce dossier, le CEPD a conclu qu'une notification préalable n'était pas nécessaire. Toutefois, sachant que le traitement concerné suppose un transfert international de données, nous vous avons demandé d'apporter des éclaircissements sur les mesures prises par la BEI pour se conformer aux articles 8 et 9 du règlement 45/2001.

Êtes-vous en mesure de nous apporter ces éclaircissements?

En tout état de cause, sachez que le CEPD est en train d'élaborer des lignes directrices sur les transferts, dont les orientations principales seront discutées lors de la prochaine réunion des DPD en novembre.

Bien à vous,

[redacted]

[redacted]
Legal Officer
Tel. [redacted] | Fax [redacted]
[redacted]@edps.europa.eu
European Data Protection Supervisor
Postal address: Rue Wiertz 60, B-1047 Brussels
Office address: Rue Montoyer 30, B-1040 Brussels
@EU_EDPS www.edps.europa.eu

[redacted]

Subject: FW: Case 2013-0089

Follow Up Flag: Follow up
Flag Status: Flagged

[redacted]

From: [redacted]@EIB.ORG>
Sent: 09 January 2015 09:59
To: [redacted]@edps.europa.eu>
Cc: [redacted]@eib.org>; European Data Protection Supervisor <EDPS@edps.europa.eu>; [redacted]@edps.europa.eu>; [redacted]@eib.org>
Subject: RE: Case 2013-0089

Chère [redacted],
Je vous confirme que j'ai donné suite à votre invitation de vérifier si les transferts en question respectent l'article 9 à la lumière du « Position Paper ».
Une demande d'ínformation complémentaire sur le cadre juridique dans lequel opère l'OCDE en matière de protection de données a été adressée au contrôleur et l'analyse sur l'existence d'une protection adéquate sera par la suite approfondie. Je vous communiquerai la conclusion dès que possible.

Je prends bonne note de la clôture du dossier 2013-0089
Bien à vous
[redacted]

From: [redacted]@edps.europa.eu]
Sent: Thursday 25 September 2014 16:58
To: [redacted]
Cc: [redacted]; European Data Protection Supervisor; [redacted]
Subject: RE: Case 2013-0089

Cher [redacted],

Je me réfère à nos derniers échanges dans ce dossier.

Comme vous le savez, le CEPD a récemment adopté un *Position paper* sur les transferts de données personnelles effectués en vertu de l'article 9 du règlement 45/2001 (https://secure.edps.europa.eu/EDPSWEB/webdav/site/mySite/shared/Documents/Supervision/Papers/14-07-14_transfer_third_countries_EN.pdf).

Nous vous invitons à examiner ce document afin de vérifier, à la lumière du *Position paper*, si les transferts de données par la BEI vers le Service international des rémunérations et des pensions de l'OCDE respectent l'article 9 du règlement 45/2001, en particulier concernant l'évaluation de l'adéquation ou la mise en place de mesures de protection adéquates pour le transfert. Au besoin, vous pouvez soumettre au CEPD une consultation (en vertu de l'article 46(d) du règlement 45/2001) en nous indiquant son objet précis et en nous fournissant toutes les données nécessaires à l'analyse.

Par ailleurs, nous **clôturons** le dossier sous rubrique qui avait trait à la nécessité ou non de soumettre le traitement à un contrôle préalable du CEPD (consultation sur pied de l'article 27(3) du règlement 45/2001).

Bien à vous,

[redacted]

[redacted]
Legal Officer
Tel. [redacted] | Fax [redacted]
[redacted]@edps.europa.eu
European Data Protection Supervisor
Postal address: Rue Wiertz 60, B-1047 Brussels
Office address: Rue Montoyer 30, B-1040 Brussels
@EU_EDPS www.edps.europa.eu

From: [redacted]
Sent: 25 October 2013 17:12
To: [redacted]
Cc: [redacted] European Data Protection Supervisor
Subject: RE: Case 2013-0089 D-550

Cher [redacted],

Merci pour votre message.

Comme déjà indiqué dans mon e-mail du 10 octobre, nous reviendrons vers vous avec une position formelle lorsque l'EDPS aura adopté ses guidelines sur les transferts.

Bien à vous,

[redacted]

From: [redacted]@EIB.ORG]
Sent: 15 October 2013 10:49
To: [redacted]; European Data Protection Supervisor
Cc: [redacted]
Subject: Case 2013-0089 D-550

Dear[redacted]
Just to confirm you that the EIB on the transfer at stake to the OCDE applies regulation 45/2001 relevant provisions.
The assessment on the necessity to transfer the data and on the absence of reasons to assume that the data subject's legitimate interests might be prejudiced (article 8, assuming that the OCDE is applying French law) or the assessment on the existence of an adequate protection (article 9, for the case where the OCDE is applying a national law not applying Directive 95/46/EC) has been timely done when the agreement with the OCDE has been signed.
Moreover, data at stake are being sent by the EIB to the OCDE within a encrypt base with password.
I hope this could sufficient to have the closing letter on this file.
Looking forward to see you
[redacted]

From: European Data Protection Supervisor [mailto:EDPS@edps.europa.eu]
Sent: Thursday 21 March 2013 15:49
To: [redacted]
Subject: Our ref. 2013-0089 D-550

Dear Sir,

Please find attached a scanned version of a letter sent to you by regular mail.

Best regards,

EDPS Secretariat
Tel. +32 2 283 19 00 | Fax +32 2 283 19 50
edps@edps.europa.eu
European Data Protection Supervisor
Postal address: Rue Wiertz 60, B-1047 Brussels
Office address: Rue Montoyer 30, B-1040 Brussels
@EU_EDPS www.edps.europa.eu