

Opinion on a notification for Prior Checking received from the Data Protection Officer of European Medicines Agency (EMA) on the processing of personal data in administrative enquiries and disciplinary procedures

Brussels, 21 April 2010 (Case 2010-0047)

1. Proceedings

On 22 January 2010, the European Data Protection Supervisor (EDPS) received from the Data Protection Officer (DPO) of the European Medicines Agency (EMA) a notification for prior checking relating to the processing of personal data in the frame of administrative enquiries and disciplinary procedures.

An extension of one month was set on 23 March 2010 for complexity of the issue in accordance with Article 27.4 of Regulation (EC) 45/2001.

A draft opinion was sent to EMA for comments on 16 April 2010. No comments were received.

2. The facts

Under Article 86 of the Staff Regulations of officials of the European Communities, "any failure by an official or former official to comply with his obligations under these Staff Regulations, whether intentionally or through negligence on his part, shall make him liable to disciplinary action". Disciplinary rules, procedures and measures and the rules and procedures covering administrative investigations are laid down in Annex IX to the Staff Regulations¹. The procedures described below apply to agents and former agents, servants and former servants, other persons working for the EMA such as persons employed under private law contracts, experts on secondment, trainees or other relevant persons.

EMA is currently adopting implementing rules on the conduct of administrative inquiries and disciplinary procedures.

Administrative Inquiries

An administrative inquiry shall be opened at the request of the Executive Director or any Head of Unit.

¹ Articles 49, 50, 50a and 119 of the Conditions of Employment of other servants of the European Communities lay down a similar mechanism for temporary and contract staff members.

Before opening the inquiry, the Head of Administration shall consult OLAF to ascertain that the office is not undertaking an investigation for its own purposes and does not intend to do so. As long as OLAF is conducting such an investigation, no administrative inquiry may take place at EMA.

The Executive Director shall appoint an investigator to carry out the inquiry. The Executive Director shall define the subject, purposes and scope of the inquiry.

Before the investigator starts the investigation, he/she must be given instructions with respect to the collecting evidence or data in order to comply with the general rules on the lawfulness of the processing of personal data in accordance with Regulation (EC) 45/2001.

The Head of Administration and the investigator shall exercise powers of administrative inquiry. They shall have the power to obtain documents, summon any person subject to the Staff Regulations to provide information and to carry out on-the-spot investigations.

As soon as an administrative inquiry suggests that a staff member may be personally involved in an investigation, that staff member shall be kept informed provided that information does not hinder the inquiry. In any case, conclusions referring to a staff member by name may not be drawn at the end of the inquiry unless that staff member has had the opportunity to express an opinion on all the facts, which relate to him or her. The conclusions shall record that opinion.

The staff member concerned shall have the right to access his/her complete disciplinary file and take copies of the documents which may be important to a proper defence during the disciplinary procedure. When information refers to other individuals, the right of access and to take copies of his/her disciplinary file may be limited to the information that relates uniquely to the staff member concerned.

Where absolute secrecy is required by the aims of the inquiry requiring investigative procedures, which are the responsibility of a national judicial authority, the obligation to invite the staff member to express an opinion may be deferred by decision of the Executive Director. In that case, no disciplinary procedure may be opened until the staff member has been able to express an opinion.

The Executive Director shall inform the staff member concerned of the conclusion of the inquiry together with the conclusions of the inquiry report and, on request, all documents directly linked to the allegations made, subject to the protection of the legitimate interests of third parties.

If, following an administrative inquiry, no charge is brought against the staff member, the inquiry shall be closed with no further action by decision of the Executive Director who shall inform the staff member in writing. The staff member concerned may request that the decision be placed in his/her personal file.

All relevant documents to the Administrative inquiry should be stored in a paper form and in an electronic version in a disciplinary file. Any subsequent amendments or corrections of these documents should be inserted in the disciplinary file. Disciplinary files are stored for a maximum period of 20 years if, following an administrative inquiry, a charge is brought against the staff member concerned, and for a minimum period of five years for administrative inquiries without disciplinary follow-up.

Disciplinary Proceedings and hearings

The Head of Administration shall be responsible for disciplinary procedures and shall undertake these procedures for EMA.

According to Article 3 of Annexe IX to the Staff Regulations, on the basis of the investigation report, after having notified the official concerned of all evidence in the files and after hearing the official concerned, the Executive Director may:

- (a) decide that no case can be made against the official, in which case the official shall be informed accordingly in writing; or
- (b) decide, even if there is or appears to have been a failure to comply with obligations, that no disciplinary measure shall be taken and, if appropriate, address a warning to the official; or
- (c) in the case of failure to comply with obligations within the meaning of Article 86 of the Staff Regulations:
 - (i) decide to initiate the disciplinary proceedings, or
 - (ii) decide to initiate disciplinary proceedings before the Disciplinary Board.

The staff member concerned shall sign the record of the meeting or make comments or remarks within 15 days from the receipt of the record.

If the investigator or the person authorised to that effect has to conduct interviews with certain persons following the hearing, the staff member may receive a copy of the signed records of these interviews provided the facts mentioned there have a direct bearing on the preliminary allegations made against him or her.

The Disciplinary Board's opinion is forwarded to the Executive Director and to the official concerned.

On receipt of the opinion of the Disciplinary Board and after hearing the official concerned, the Executive Director decides on the disciplinary penalty. The original of the decision is inserted in the personal file of the official concerned. The official receives a copy by registered letter with acknowledgement of receipt.

An official against whom a disciplinary penalty other than removal from post has been ordered may, after three years in the case of a written warning or reprimand or after six years in the case of any other penalty, submit a request for the deletion from his personal file of all reference to such measure. The Appointing Authority decides whether to grant this request (Article 27 of Annex IX to the Staff Regulations).

Other relevant information in the Notification:

Data subjects. As mentioned above, administrative inquiries and disciplinary procedures apply to agents and former agents, servants and former servants, other persons working for the EMA such as persons employed under private law contracts, experts on secondment, trainees or other relevant persons. The processing of personal data in the frame of these procedures therefore concern these persons, but may also concern

individuals who participate in an administrative inquiry and disciplinary procedures such as witnesses and whistleblowers.

Information to data subjects. The rules on the conduct of administrative inquiries and disciplinary procedures have not yet been formally adopted. When adopted, the final text will be made available to all EMA staff on the intranet.

Retention period. Disciplinary files are stored for a maximum of 20 years if, following an administrative inquiry, a charge is brought against the person concerned, and for a minimum of five years for administrative inquiries without disciplinary follow up. Further processing for historical, scientific or statistical purposes is not envisaged.

Recipients of data. Personal data processed in the frame of administrative inquiries and disciplinary procedures may be disclosed to the Head of Administration, the Executive Director, the Disciplinary Board and the investigator. If the staff member concerned contests the disciplinary decision, the disciplinary file may be referred to the Court of Justice of the European Union. Data may be sent to the European Ombudsman, if the staff member concerned addresses a complaint. Personal data are also transferred to OLAF as mentioned above to ensure that no parallel inquiry is pending at OLAF.

Security. [...]

3. Legal analysis

3.1. Prior checking

Regulation (EC) 45/2001² applies to the processing of personal data by European Union institutions and bodies.

The processing of personal data by the EMA in the frame of administrative enquires and disciplinary procedures is carried out by a European Union body in activities which fall within the scope of the Regulation.

Regulation (EC) 45/2001 shall apply to the processing of personal data wholly or partly by automatic means and to the processing otherwise than by automatic means of personal data which form part of a filing system or are intended to form part of a filing system. The processing in the procedure under examination is carried out both electronically and in a structured paper filing system. Regulation (EC) 45/2001 therefore applies.

Article 27(1) of Regulation (EC) 45/2001 subjects to prior checking by the EDPS "processing operations likely to present specific risks to the rights and freedoms of data subject by virtue of their nature, their scope or their purposes". Article 27(2) of the Regulation contains a list of processing operations that are likely to present such risks. This list includes, under paragraph (a) the processing of data relating to suspected offences, offences, criminal convictions or security measures and (b), the processing operations intended to evaluate personal aspects related to the data subject, including his or her ability, efficiency and conduct. Clearly the data processing operations in the frame of the probationary periods fall within Article 27(2) (a) and (b) and must therefore be prior checked by the EDPS.

² Regulation (EC) 45/2001 of the European Parliament and of the Council on the protection of individuals with regard to the processing of personal data by Community institutions and bodies and on the free movement of such data

The implementing rules on the conduct of administrative inquiries and disciplinary procedures have not yet been adopted. The EDPS therefore invites the EMA to take into account recommendations made in the present opinion accordingly.

The Notification was received on 22 January 2010. The deadlines to provide an opinion were suspended for XXX days. The period for rendering the EDPS opinion was extended for one month for complexity of the issue. The opinion must therefore be issued by 23 April 2010.

3.2. Lawfulness of the processing

Article 5(a) of the Regulation provides that personal data may be processed if “*processing is necessary for the performance of a task carried out in the public interest on the basis of the Treaties... other legal instrument adopted on the basis thereof*” or in the legitimate exercise of official authority vested in the Community institution or body...”

As mentioned above, the legal basis for the processing operations in question is provided by Article 86 and Annex IX to the Staff Regulations as well as by Articles 49, 50 and 119 of the Conditions of Employment of Other Servants. The processing of personal data in the frame of administrative inquiries and disciplinary proceedings is therefore based on a task to be performed in the public interest as provided for in the Staff Regulations and they can be considered as necessary for compliance purpose with the Staff Regulations.

As conducting disciplinary procedures is necessary for the legitimate exercise of official authority vested in the EU institutions, bodies and agencies, the processing of personal data carried out in the framework of conducting administrative inquiries and disciplinary proceedings can be considered as lawful.

The EDPS welcomes that the EMA is adopting implementing rules on the conduct of administrative inquiries and disciplinary procedures (hereinafter "draft implementing rules") in compliance with the Staff Regulations to complement the procedures and measures of administrative and disciplinary proceedings.

3.3. Processing of special categories of data

According to Article 10(1), processing of personal data revealing racial or ethnic origin, political opinions, religious or philosophical beliefs, trade-union membership, and of data concerning health or sex life, are prohibited unless an exception can be found in Article 10 (2) and (5) of Regulation 45/2001.

In the course of conducting administrative inquiries and disciplinary proceedings, it cannot be excluded that information which Article 10 of Regulation (EC) n° 45/2001 classifies as "*special categories of data*" be collected by EMA and further reflected in the report of an administrative inquiry or disciplinary proceeding.

In the event that this happens, the general rule of prohibition of the processing of such data applies or otherwise, it has to be evaluated in a restrictive manner whether the processing of such data would be considered as "*necessary for the purposes of complying with the specific rights and obligations of the controller in the field of employment law insofar as it is authorised by the Treaties establishing the European Communities or other legal instruments adopted on the basis thereof*".

In certain exceptional cases, the processing of such sensitive data could also be based on reasons of substantial public interest based on a decision of the EDPS in accordance with Article 10(4).

In any event EMA staff in charge of disciplinary files must be aware of the restrictive rules which apply to the processing of these special categories of data and avoid the inclusion of these data unless one of the circumstances foreseen in Article 10(2) is present in the particular case under investigation or Article 10(4) is to be applied. This should be made clear in the EMA implementing rules.

Administrative investigation files and disciplinary files are liable to contain data relating to offences, criminal convictions or security measures. Processing of such data is subject to authorisation in accordance with Article 10(5) of Regulation (EC) n° 45/2001. The decisions implementing Article 86 of the Staff Regulations and, by analogy, Articles 49 to 51 and 119 of the CEOS should be regarded as an authorisation to process these data.

3.4. Data Quality

According to Article 4(1)(c) of Regulation 45/2001 *"personal data must be adequate, relevant and non excessive in relation to the purposes for which collected and/or further processed"*.

Although certain standard administrative data, such as name, date of birth are always present in the investigation files, the EDPS acknowledges that there is no systematic rule regarding the nature of data which can be included in administrative or disciplinary investigation files; the precise content of a file will vary according to the purpose of the particular case. In this respect the notification form for prior checking includes a wide variety of types of data.

Guarantees should however be established in order to respect the principle of data quality. In this respect the EDPS welcomes that the draft implementing rules provide that, before the investigator starts the investigation, he/she must be given instructions with respect to the collecting evidence or data in order to comply with the general rules on the lawfulness of the processing of personal data in accordance with Regulation (EC) 45/2001 (see article 9 of the draft implementing rules).

Article 4(1) (a) of the Regulation provides that personal data must be processed fairly and lawfully. The lawfulness has already been examined in part 3.2 above and fairness will be addressed in relation to the information provided to data subjects (see below in part 3.9).

Data must be *"accurate and, where necessary, kept up to date; every reasonable step must be taken to ensure that data which are inaccurate or incomplete, having regard to the purposes for which they were collected or for which they are further processed, are erased or rectified"* (Article 4(1)(d) of the Regulation). The principle of accuracy of data is to be applied taking account of the nature and purpose of the processing concerned. In disciplinary proceedings, in particular, data are based on the subjective perception of the investigators or even suspicion and in some cases are totally unverifiable. Consequently, the requirement of accuracy cannot appertain to the accuracy of a statement, but merely to the fact that a specific statement has been made.

Nevertheless, a certain degree of accuracy and completeness should be ensured. In this respect the EDPS positively notes that the conclusions of an administrative inquiry referring to a staff member by name may not be drawn at the end of the inquiry unless that staff

member has had the opportunity to express an opinion on all the facts, which relate to him or her and that the conclusions shall record that opinion. Furthermore the EDPS considers that the fact that all relevant documents to the Administrative inquiry are stored in a disciplinary file and any subsequent amendments or corrections of these documents are to be inserted in the disciplinary file helps to contribute to the completeness of the information.

As will be examined below the rights of the data subject also help guarantee the accuracy of the data (see below 3.8. Right of access and rectification).

3.5. Confidentiality of communications

Under Article 36 of Regulation 45/2001, "*Community institutions and bodies shall ensure the confidentiality of communications by means of telecommunications networks and terminal equipment, in accordance with the general principles of Community law*". Any restriction of the confidentiality principle must therefore be "*in accordance with the general principles of Community law*".

It might be possible that the official or other servant responsible for conducting the investigation (in an administrative inquiry or disciplinary proceeding) may seek to check a staff member's e-mails while conducting forensic examinations of computers or may seek to have access to a list of telephone communications made. The collection of evidence concerning electronic communications must be qualified as interference in the privacy of communications and may hence imply the violation of the confidentiality of communications³.

The concept of "*general principles of Community law*" refers to the fundamental human rights enshrined in particular in the European Convention on Human Rights (ECHR) and the EU Charter of Fundamental Rights which is binding to EU institutions and bodies according to Article 6(1) TEU. In particular, Article 8 (2) of ECHR sets four criteria to be examined before the principle of confidentiality is restricted:

- Is the restriction authorised by a legal provision or equivalent measure?
- Is it necessary? Could the same result be obtained without breaching the principle of confidentiality? It would only be in exceptional circumstances that the monitoring of a staff member's personal use of the e-mail (apart from scanning viruses) or telephone would be considered as necessary.
- Is it proportionate to the concerns it tries to ally? The principle of proportionality implies that the application of the restrictions to the confidentiality of communications will be different if we are in the case of personal communications or business communications. It also implies that if it is necessary to check the e-mail accounts of workers in their absence, this should in principle be limited to e-mails that are not marked as private or personal or that are addressed to the address of the institution.
- Have all other intrusive means of investigation been exhausted?

³ A breach of confidentiality of communications is defined in article 5 of Directive 2008/977/JHA as any "listening, tapping, storage or other kinds of interception or surveillance of communications and the related traffic data by persons other than users without the consent of the persons concerned except when legally authorised to do so in accordance with Article 15(1)".

In practice, this means that any restriction on the principle of confidentiality of communications must be consistent with the fundamental human rights enshrined in the European Convention on Human Rights and the EU Charter of Fundamental Rights. Such restriction may take place only if it is *"in accordance with the law"* and *"is necessary in a democratic society"* in the interests of national security or public safety, for the prevention of disorder or crime, for the protection of health or morals, or for the protection of the rights and freedoms of others.

The EDPS consequently stresses that the confidentiality of communications can be infringed only in exceptional circumstances (in the course of inquiries within the framework of an administrative or disciplinary investigation where no other less invasive method could be used), that infringing the confidentiality principle should be an extraordinary procedure and that it must always be restricted to those data which are strictly necessary.

The EDPS recommends that a procedure be clearly established for the conduct of any interference on communications of staff members (access to online consultations, access to email accounts...). Any procedures established in this area should be carefully carried out taking also into account of the new EU legal framework concerning the new right to data protection and the reinforced protection of fundamental rights.

It has been made clear on the other hand, that the EMA does not envisage any interception or tapping of communications during the communication in the frame of administrative enquiries or disciplinary proceedings whether this be oral (audio/video) conversations or other automated communications.

3.6 Retention periods

Pursuant to Article 4(1)(e) of Regulation (EC) 45/2001 personal data may be kept in a form which permits identification of data subjects for no longer than necessary for the purposes for which the data are collected and/or further processed.

In this respect the EDPS welcomes that the EMA has established deadlines for the conservation of personal data in disciplinary files. Should the retention of data of administrative inquiries without disciplinary follow up be set for a minimum of five years, it must be established that any conservation of the data beyond this period must be duly justified (for e.g. new pending case against the person for which the disciplinary file may be relevant).

The EDPS also calls on EMA also to harmonise the conservation periods in the disciplinary files with conservation of data in the personal file of the data subject concerned. Indeed, the personal file of an official contains all documents concerning his administrative status and all reports relating to his ability, efficiency and conduct (Article 26 of the Staff Regulations). In principle, data are kept throughout the entire career of the official concerned and after the end of the career for an indefinite period.

The Staff Regulations do not contain any rule governing the time limit of the storage of disciplinary data in the personal file. However, according to Article 27 of Annex IX to the Staff Regulations certain information may be removed from the personal file. This is at the discretion of the AA. The data subject is therefore not granted with an automatic removal of the data after a certain lapse of time.

The EDPS considers that EMA should keep in the personal files only the copies of the final decisions taken in the disciplinary proceedings, taking into account the provisions of Article

27 of Annex IX of the Staff Regulations concerning the request of deletion of such data. In the case of denial of deletion, the Appointing Authority should motivate his decision. Should the disciplinary data be removed from the personal file in accordance with the provisions of Article 27 Staff Regulations, the data should also be removed from the disciplinary file so as not to void Article 27 of its effect. Furthermore, the EDPS considers that EMA should set a maximum data retention period for disciplinary related information contained in the personal file, i.e., the same length as the storage period for the disciplinary files or otherwise provide reason why a longer period is necessary.

3.7. Transfer of data

Article 7 of the Regulation, permits personal data transfers within or to other Community institutions or bodies *"if the data are necessary for the legitimate performance of the tasks covered by the competence of the recipient"* (paragraph 1). The recipient can process the data *"only for the purposes for which they were transmitted"* (paragraph 3).

This provision outlines a specific necessity requirement: internal transfers of data within the agency may only take place as long as they are necessary for the performance of the recipients' tasks and competences in the context of an administrative inquiry or disciplinary investigation. This would be the case for those recipients mentioned in the notification such as the Head of Administration, the Executive Director, the Disciplinary Board and the investigator.

If the staff member concerned contests the disciplinary decision, the disciplinary file may also be referred to the Court of Justice of the European Union. Data may be sent to the European Ombudsman, if the staff member concerned addresses a complaint. As mentioned in the draft implementing rules personal data are also transferred to OLAF to ensure that no parallel inquiry is pending at OLAF⁴.

The notification provides that should a request for data be made, the data will only be transferred following a request from the above mentioned recipients; the data controller has to verify the competence of the above mentioned recipients and make a provisional evaluation of the need for the transfer of the data and the above mentioned recipients will be informed of the obligations in respect of this transfer.

The EDPS notes that the requirements of Article 7 are met.

The notification does not mention transfers to recipients other than EU institutions or bodies. It may happen that data are transmitted to the competent national authorities such as a national Court where there is an infringement of national law. In such instances, Article 8 of the Regulation is applicable and provides that personal data may be transferred to recipients subject to the national law adopted for the implementation of Directive 95/46/EC only if "the recipient establishes that the data are necessary for the performance of a task carried out in the public interest or subject to the exercise of public authority". If data are transferred at the request of a national authority, it must therefore establish the "necessity" for the transfer. If, on the other

⁴ It must be noted that certain authorities such as the OLAF and the EDPS are not regarded as "recipients" within the meaning of Article 2 (g) of the Regulation as they are covered by the exemption provided for in that article, given that they are likely to receive data in the framework of a particular investigation or a disciplinary procedure. All transfers of data must be regarded as taking place *"in the framework of an inquiry" in the terms of Article 2g*. Article 2 (g) is to be understood as an exception to the right to information rather than as an exception to the application of Article 7.

hand, data are transferred on the sole initiative of the EU institution, agency or body, it will be for the latter to establish the "necessity" for the transfer in a reasoned decision.

With regard to those countries which have not extended the implementation of Directive 95/46/EC to judicial authorities, the application of Article 9 of Regulation 45/2001 should be considered. It is to be noted that in such cases, the Council of Europe Convention 108 is applicable to judicial authorities since it is considered to be a legal instrument which provides adequate level of protection.

EMA should ensure that these rules are respected should personal data be transferred outside the EU institutions and bodies in the frame of an administrative inquiry or disciplinary proceedings.

3.8. Right of access and rectification

Article 13 of the Regulation provides for a right of access to personal data being processed.

The EDPS welcomes that the EMA implementing rules provide the staff members concerned with the right of access to their complete disciplinary file (Article 5.6, 5.7 and 5.11). However, all other data subjects whose personal data may be processed in the frame of an administrative inquiry or disciplinary proceedings (witnesses, informants,...) should also be granted with a right of access and rectification as concerns any personal data relating to them. This should be explicitly provided. Any restrictions to the right of access of these persons should also be in line with Article 20 of the Regulation (see below).

As mentioned in the facts, the implementing rules also provide that if, following an administrative inquiry, no charge is brought against the staff member, the inquiry shall be closed with no further action by decision of the Executive Director who shall inform the staff member in writing. The staff member concerned may request that the decision be placed in his/her personal file (Article 5.8 of the EMA implementing rules). The EDPS underlines that the person concerned should also be granted access to the content of the administrative inquiry report even if no charge is filed.

Article 14 of the Regulation provides for a right to rectification without delay of inaccurate or incomplete data. According to the EMA implementing rules, the "conclusions referring to a staff member by name may not be drawn at the end of the inquiry unless that staff member has had the opportunity to express an opinion on all the facts, which relate to him or her. The conclusions shall record that opinion" (Article 5.5). Furthermore, "all relevant documents to the Administrative inquiry should be stored in a paper form and in an electronic version in a disciplinary file. Any subsequent amendments or corrections of these documents should be inserted in the disciplinary file" (Article 4.4. of the implementing rules). The EDPS is satisfied that these provisions contribute to the respect of the right of rectification taking into account the limitations to the rectification of subjective data as mentioned above (see 3.4. Data Quality).

The rights of access and rectification may be restricted in terms of Article 20(1) of the Regulation in particular *"where such a restriction constitutes a necessary measure to safeguard the prevention, investigation, detection and prosecution of criminal offences"*(point a) or (...) *"the protection of the rights and freedoms of others"* (point c)). The EDPS considers that Article 20 has to be interpreted in the light of the *ratio legis* of the provision so as to

provide for certain restrictions to the duty to inform the data subject in the course of an administrative inquiry or disciplinary investigation⁵.

The "*the protection of the rights and freedoms of others*" can apply, for example, as concerns the identity of whistleblowers. The Article 29 Working Party has made the following statement: "*[u]nder no circumstances can the person accused in a whistleblower's report obtain information about the identity of the whistleblower from the scheme on the basis of the accused person's right of access, except where the whistleblower maliciously makes a false statement. Otherwise, the whistleblower's confidentiality should always be guaranteed.*" The same approach has to be applied concerning the informants.⁶ Therefore, the EDPS recommends the respect of the confidentiality of the identity of whistleblowers in the frame of administrative inquiries and disciplinary proceedings in as much as this would not contravene national rules regulating judicial procedures.

Should a restriction to the right of access or rectification be imposed, the data subject should be informed of the principle reasons for the application of the restriction and the right to have recourse to the EDPS for indirect access according to Article 20 (4). This provision foresees that while the EDPS shall be investigating the complaint submitted by the data subject, the latter shall be informed by the EDPS whether the data have been processed correctly and, if not, whether any necessary corrections have been made. The information on the restriction to the rights of the data subject may be deferred for as long as such information would deprive the restriction of its effect.

3.9. Information to the data subject

Article 11 of Regulation 45/2001 provides for certain information to be supplied where the data have been obtained from the data subject. Article 12 of Regulation 45/2001 provides for certain information to be supplied where the data have not been obtained from the data subject. During the probationary reporting, personal data are obtained directly from the data subject and from other persons. Thus Articles 11 and 12 will apply.

The notification provides that the rules on the conduct of administrative inquiries and disciplinary procedures when adopted will be made available to all the EMA Staff on the intranet. The EDPS welcomes this, but reminds EMA that the persons concerned should also be informed about the processing of their personal data in compliance with Articles 11 and 12 of Regulation 45/2001.

This information should include the identity of the controller, the purposes of the processing operation for which the data are intended, the recipients or categories of recipients of the data and the existence of the right of access to, and the right to rectify, the data concerning him or her. Further information may also be supplied insofar as it is necessary to guarantee fair processing in respect of the data subject. Steps must also be taken to ensure that the officials and other data subjects concerned are given this information in clear terms.

Consequently, the EDPS recommends that EMA should provide all data subjects with an information privacy policy including general information on the procedure of an administrative or disciplinary inquiry in compliance with Articles 11 and 12 of Regulation 45/2001. Should an administrative or disciplinary inquiry be opened, all persons whose

⁵ See EDPS opinion 2004-198

⁶ Witnesses, on the contrary, do not in principle require the confidentiality of their identity. See EDPS Opinion of 23 June 2006 on "internal investigations" carried out by the European Anti-Fraud Office (OLAF) - Case 2005-418.

personal data may be processed in the frame of such an inquiry should furthermore be specifically informed of the processing of his/her data unless the restrictions provided in Article 20 (1) as explained above applies.

As mentioned above, the EDPS draws the attention to the fact that the restriction to the right to inform cannot be absolute. The controller should take into consideration Article 20 (3) of the Regulation and inform the data subject of the principal reasons on which the application of the restriction is based as well as of his/her right to have recourse to the EDPS. In some specific circumstances, however, it might be necessary to defer from Article 20 (3) so that the process of the investigation will not be harmed, as Article 20 (5) provides. The EDPS underlines that any decision for such deferral should be taken strictly on a case by case basis.

3.10. Security measures

According to Articles 22 and 23 of Regulation (EC) No 45/2001, the controller and the processor must implement the appropriate technical and organisational measures to ensure a level of security appropriate to the risks represented by the processing and the nature of the personal data to be protected. These security measures must in particular prevent any unauthorised disclosure or access, accidental or unlawful destruction or accidental loss, or alteration and prevent all other forms of unlawful processing.

On the basis of the available information, the EDPS does not see any indication to believe that EMA has not applied the security measures required in Article 22 of the Regulation.

3. Conclusion:

There is no reason to believe that there is a breach of the provisions of Regulation 45/2001 provided that EMA respect the following recommendations:

- that EMA staff in charge of the files are made aware of the restrictive rules which apply to the processing of special categories of data of the specific rules which apply to the processing of such data;
- that a procedure be clearly established for the conduct of any interference on communications of staff members (access to online consultations, access to email accounts...) taking into account of the new EU legal framework concerning the new right to data protection and the reinforced protection of fundamental rights;
- that EMA should establish that should the retention of data of administrative inquiries without disciplinary follow up be set for a minimum of five years, any conservation of the data beyond this period must be duly justified;
- that EMA establish as a rules that, should the disciplinary data be removed from the personal file in accordance with the provisions of Article 27 Staff Regulations, the data should also be removed from the disciplinary file;
- that EMA set a maximum data retention period for disciplinary related information contained in the personal file;

- that all persons other than the person subjected to an inquiry whose personal data may be processed in the frame of an administrative inquiry or disciplinary proceedings (witnesses, informants,...) also be granted with a right of access and rectification as concerns any personal data relating to them with possible restrictions in line with Article 20 of the Regulation;
- that the person concerned should also be granted access to the content of the administrative inquiry report even if no charge is filed;
- that EMA guarantee the confidentiality of the identity of whistleblowers in the frame of administrative inquiries and disciplinary proceedings in as much as this would not contravene national rules regulating judicial procedures;
- that an information privacy policy including general information on the procedure of an administrative or disciplinary inquiry in compliance with Articles 11 and 12 of Regulation 45/2001 be adopted;
- that any person subject to an administrative inquiry or disciplinary proceeding be informed of the processing of his personal data in accordance with Articles 11 and 12 of Regulation 45/2001 save restrictions in accordance with Article 20 of the Regulation.

Done at Brussels, 21 April 2010

(signed)

Giovanni BUTTARELLI
Assistant European Data Protection Supervisor