



Opinion on a notification for Prior Checking received from the Data Protection Officer of the European Medicines Agency (EMA) regarding the processing operations "Listening Points/Informal procedures" (management of cases of psychological or sexual harassment).

Brussels, 7 February 2011 (Case 2010-598)

1. Proceedings

On 10 August 2010, the European Data Protection Supervisor (EDPS) received by regular mail from the Data Protection Officer (DPO) of the European Medicines Agency (EMA) a notification for prior checking data processing operations related to the "Listening Points/Informal procedures" (management of cases of psychological or sexual harassment).

On 9 August 2010, the EDPS requested further information from the controller on the basis of the notification received by electronic mail. He received part of the responses on the same day. A second, third and fourth set of questions was sent on 25 of August, on 7 of October and 14 of October, and answered on the 6 of September, the 8 of October, on 18 of November and on 7 of December. A final information request was sent on the 14 of January 2011 and answered on the 19 of January.

On 2 February 2011, the EDPS sent the draft opinion for comments to the controller. He received the comments on 4 February 2011.

2. The Facts

Articles 1(d), 12 and 12(a) of the Staff Regulations prohibit any discrimination based on sex and call officials to refrain from any form of harassment (see also Articles 11, 54 and 81 of the conditions of Employment of Other Servants of the European Communities).

The EMA drafted a policy (hereinafter: the draft Policy) on "*protecting the dignity of the person and preventing any form of psychological or sexual harassment*" within the context of the Staff Regulations of Officials and Conditions of Employment of Other Servants of the European Communities No 259/68, a policy which is to be implemented into two different procedures: informal and formal. The present prior check analyses the data processing operations carried out by EMA during the informal procedure to prevent psychological and sexual harassment.

Implementing modalities and role of each stakeholder in the informal procedure are addressed in the EMA draft Manual for "*informal procedures for cases of psychological and sexual*

harassment" (hereinafter: the draft Manual), which be reviewed in the light of experience according to the notification.

The **data processing operations** put in place by the Listening points in the framework of the informal procedure can be summarised as follow:

Any person who feel he/she is a victim of psychological or sexual harassment may ask for informal assistance by contacting (over the phone, in writing or in person) the Listening Point of his/her choice. After having informed the alleged victim of his/her rights (orally and via a Declaration of confidentiality), the Listening point, with his/her consent, may take personal notes and seek conciliation with the other party. If no solution can be found in a given period, the alleged victim may lodge a formal complaint. The Listening point fills in anonymous statistical reports annually with aggregated data.

In exceptional cases, Personnel (one of the Sections of the Human Resources Sector) can deal directly with an alleged victim, if, for example, he/she should not wish to be referred to a Listening Point. Likewise, Head of Units and Sectors, Section Heads and the Staff Committee may also be called upon to act within the informal procedure. In such cases, these exceptional actors shall act according to the same principles as the Listening Points.

The Human Resources Sector, together with Personnel, is responsible for drawing up and monitoring implementation of the policy relating to psychological and sexual harassment. The Head of Human Resources, Section Head Personnel and Personnel Officers constitutes the central service which staff can approach for information on policy and procedures. After one year of implementation, an ex-post evaluation and a survey of Listening points and staff will be carried out separately.

Potential data subjects are each and every person working in the Agency, regardless of grade or contract of employment (including trainees and all those working under national law i.e. interims as well). Everyone may point out a situation of harassment (as an alleged victim or a witness) to a Listening point, the Staff Committee, any Head of Unit/Sector or Section Head of their choice. Alleged harassers and other stakeholders are also considered as data subject if involved in cases of presumed harassment handled in the framework of an informal procedure.

Data likely to be collected, retained and processed are contained in the *opening and closing forms* (including the reference number, start date of the procedure, name/grade/sector of the alleged victim, and of the harasser if informed about the procedure, steps undertaken, results and solution, use of medical or other services), as well as in the *files or documents* collected to properly administer the case, and in the *anonymous statistical records*. In addition, with the consent of the victim, Listening points take *personal notes*.

Sensitive data are not kept in the file or in the opening or closing forms unless they are the reason for harassment or a key point within a case.

Pursuant to *point 5.1 Data categories* of the draft Manual, the Listening points must ensure that all data and documents are **adequate and not excessive** in relation to the purpose for which they are collected. Any document that does not fit with these principles cannot be forwarded in the event of a formal procedure.

In addition, personal data will be **handled exclusively for the purpose and under the conditions set in the draft Policy** pursuant to the Declaration of Confidentiality.

The basic principle of the informal procedure is to ask for the **consent of the victim** before taking any steps, except in urgent cases where the victim may be in danger or unable to act.

Personal data are **processed manually**; they are **stored both in paper and electronic form**, locked away or filed in a confidential part of the electronic archives (EDMS/DREAM).

Internal data transfers are allowed only to the parties involved. In addition, Listening points or Personnel may, in order to resolve a case, need to contact or inform other services on a need-to-know basis. Confidentiality while sharing is inherent to the informal procedure and based on the alleged victim's consent and information, except in exceptional cases as foreseen in Article 20(1)(c) of the Regulation according to the notification (for example, in very rare and problematic cases where his/her health is in danger and he/she is not capable of initiating the opening of the procedure).

After closure of the case, the file created, including documents provided by the victim, the opening and closing forms, as well as further relevant documents considered as necessary to explain and understand the initiatives taken, will be handed over to Personnel according to the rules for the handling of personal data as laid down in the Regulation 45/2001.

According to the notification, in the event of or multiple cases, Personnel must inform the Head of Administration and the Executive Director with the closing forms and files of the victims and the person complained of. The victims must, however, be informed and the information can only be passed on with their consent.

However, the **personal notes** are not be shared with others or further processed, even if a formal procedure is initiated. Delegation of cases to persons who are not Listening points is not allowed.

The opening of a formal procedure automatically closes informal procedures underway. Listening points shall by principle not be involved in the formal procedure, but may be called as witnesses to testify to facts relevant to the inquiry which they have been informed of during the informal procedure. All documents from the informal procedure made available for the formal procedure can only be provided with the express written consent of the victim.

No **transfer of data outside the institution** is envisaged, unless they relate to procedures pending in front of the European Ombudsman, the Court of Justice of the EU or the Court of Auditors. Furthermore, documents may be collected and held with the objective to reply to legal authorities on national level. Finally, if an occupational health or psychological review should be necessary, Personnel will contact the medical services.

According to **EMA's retention policy of personal data**, if no informal procedure is opened after contacts with the Listening points, no data will be recorded.

If an informal procedure has been opened, the Listening point must not retain any confidential information three months after closure of the case. All documents not forwarded to Personnel (such as the personal notes) are destroyed or returned to the victim.

Documents transferred to Personnel are stored for a maximum period of five years from the start of the procedure and may be held for further five years if an administrative or legal procedure requires their consultation. The starting date of the informal procedure is the day the victim agreed to open an informal procedure.

Furthermore, if the person complained of has not been informed about the informal procedure, all data regarding him/her must be deleted from the files and no elements permitting his/her identification can be kept anywhere.

Likewise, as individuals considered as witnesses might not be aware of their role in the procedure, undisclosed information concerning them can be retained for a maximum period of two months from the start of the procedure.

According to EMA, **statistical data** are processed without time limit as they are anonymised and out of the scope of the Regulation. They are derived from the Listening points and the annual Staff Engagement Survey (SES), and are published. Collected are information about the gender of the alleged victims and harassers, their contractual category, and their age range (20-40; > 40). Only anonymous data can be passed on for statistical purposes without the consent of the victim. Any contact with Listening points will lead to an anonymous note sent to Personnel for statistical purposes at the latest at the end of the calendar year, including in cases where no informal procedure has been opened.

A clear obligation **to inform the data subjects** of the extent to which personal data will be kept as confidential are made in both the draft Policy and the draft Manual. In addition, it is recalled that the alleged victim and harasser must be informed about the existing (in)formal procedures as such and of their rights, as well as of the existence and content of the draft Policy and Manual, and of the general Data Protection Declaration. A Declaration of Confidentiality, to be completed and signed by the Listening Point, also includes a short Privacy Statement "*Protection of personal data*": both documents recall information on the data retention period, the identity of the Listening point, the purpose of the processing and its legal basis, the rights of data subjects and the right to recourse to the EDPS. All these documents will be published on the Agency's intranet.

As regard the **information of the alleged harasser**, the Listening point informs him/her about the opening and modalities of the informal procedure only after the consent of the alleged victim.

As regard **the information of the persons considered as witnesses**, the Listening point approaches them only with the consent of the victim. Such restriction to information notice serves to prevent harassed individuals from feeling responsible to involve colleagues/third parties at a very early stage of the procedure.

As regard procedures to **grant rights**, data subjects command:

- *A right to access data.* The draft Manual details the right to access data by asking the party responsible for the processing, within fifteen working days after request:

- Each data subject may see the documents he/she has provided;
- The alleged victim is allowed to see the opening and closing forms of his/her case;
- The alleged harasser is allowed to see the opening form concerning him/her if he/she has been informed of the informal procedure after the consent of the victim;
- The limitations foreseen in Article 20(1)(c) of the Regulation apply for the rest of the documents: no access is allowed if they contain personal data on other persons or confidential declarations, if they should harm any implicated party, the good administration of cases or future relations between parties.

- *A right to rectify data.* The alleged victim has the right to review the file prepared by the Listening point by asking the Controller to rectify his/her personal data.

- *A right to block and erase data.* The right to block personal data in accordance with Article 15 of the Regulation is guaranteed in the Declaration of confidentiality. The notification states in addition that no specific time limit for blocking and erasure of data is foreseen.

If data subjects should feel that their data have not been properly handled, they have a right to recourse to the European Data Protection Supervisor.

As far as **security and confidentiality measures** are concerned, [...].

3. Legal Aspects

3.1. Prior Checking

Applicability of the Regulation. Regulation (EC) No 45/2001 (hereinafter: the Regulation) applies 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"* and to the processing by a body of the EU (former "community body") insofar as such processing is carried out in the exercise of activities all or part of which fall within the scope of former "Community law" (Article 3 of the Regulation, in the light of the Lisbon Treaty).

The processing operations put in place in the frame of the fight against harassment by EMA falls within the scope of the Regulation. Indeed, they entail, first the collection and further processing of personal data (for example by means of the personal notes) as defined under Article 2(a) of the Regulation; which, second, undergo "manual processing" operations where they form part of a filing system within the institutionalised informal procedure, as stated under Article 3(2) of the Regulation. Third, the processing is carried out by an EU body (former "Community body" - Article 3(1) of the Regulation).

Grounds for Prior Checking. Article 27(1) of the Regulation subjects to prior checking by the EDPS *"processing operations likely to present specific risks to the rights and freedoms of data subjects by virtue of their nature, their scope or their purposes"*, listed in Article 27(2). The data processing in presence, for example the notes of the Listening points, are subjected to prior checking by the EDPS pursuant to paragraph (b) as they contain information about the conduct of the data subjects (among others of the alleged harasser). In addition, data related to health being potentially included, paragraph (a) applies in a complementary way.

Prior Checking. Processing operations under prior check analysis include operations likely to be carried out within the informal procedure by the Listening points. Processing operations within the formal procedure falling into the scope of administrative inquiry and disciplinary procedures will therefore not be addressed in this Opinion. Such operations have however already been prior checked by the EDPS (case-file no 2010-0047).

The EDPS however notices that the modalities of selection of the "Listening points" -who play an essential role in the informal procedure-, have not been notified yet for prior checking. The selection of listening points implying an evaluation of data subjects and therefore qualifying for prior checking pursuant to Article 27(2)(b), the EDPS invites the EMA to notify him these processing operations pursuant to the *Guidelines on the selection of confidential counsellors and the informal procedures for cases of harassment*¹.

Notification and Due Date for the EDPS Opinion. The Notification was received on 10 August 2010. The two months period was suspended for 121 days to obtain further information from EMA. The Opinion must therefore be adopted no later than the 9 February 2011.

¹ Cf. the "Guidelines on the selection of confidential counsellors and the informal procedures for cases of harassment" (2010-945) under adoption.

3.2. Lawfulness of the Processing

Personal data may only be processed pursuant to one of the legal grounds of Article 5 of the Regulation, paragraph (a) *"if the processing is necessary for performance of a task carried out in the public interest on the basis of the Treaties establishing the European Communities or other legal instruments adopted on the basis thereof"*. As already mentioned, the legal basis for the fight against harassment, a task obviously carried out in the public interest, is Article 12(a) of the Staff Regulations. In addition, Articles 1 and 31 (1) of the Charter of Fundamental Rights of the EU state that every worker has the right to working conditions which respect his or her dignity. The establishment of informal procedures is one of the crucial elements put in place by EMA to combat psychological and sexual harassment in the Agency and can be regarded as necessary in order to create a good working environment. In addition, the EMA *"Policy on protecting the dignity of the person and preventing any form of psychological or sexual harassment"* and the EMA *"Manual for Informal Procedures for Cases of Psychological and Sexual Harassment"* will complete, once adopted, the legal basis of these operations.

3.3. Processing of Special Categories of Data

Article 10(1) of the Regulation establishes that *"the 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"*. The prohibition is lifted if grounds can be found in Articles 10(2) and 10(3) of the Regulation.

The purpose of an informal procedure within EMA does not seem to be the collection of special categories of data. Indeed, the notification specifies that Listening Points and Personnel will not keep data of this nature in the files they are dealing with, unless they are the reason for the harassment occurrence or a key point within a case. Data concerning health or sex life may, in particular, be processed. Article 10(2)(b) states that the prohibition may be lifted if the processing is 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 or other legal instruments adopted thereof. The legal basis described here above (Article 12(a) of the Staff Regulations) shows that the Agency has the obligation to fight against harassment and to guarantee a work environment free of any form of psychological or sexual harassment. Processing of sensitive data relevant for the case at stake and proportionate to the purposes may therefore be justified on this basis.

3.4. Data Quality

Adequacy, Relevance and Proportionality. According to Article 4(1)(c) of the Regulation *"personal data must be adequate, relevant and not excessive in relation to the purposes for which they are collected and/or further processed"*.

Concerning the informal procedure, the EDPS first distinguishes two types of data. Data qualified as "hard" or "objective", collected by means of the forms (administrative and identification data in opening and closing forms), and data qualified as "soft" or "subjective" collected in particular by means of the personal notes of the Listening points (allegation and declaration based upon the subjective perceptions of data subjects). This distinction will also play a role in the exercise of the right of rectification of the data subject (see Section 3.7 on Rights of access and rectification below).

As underlined in the notification, the collection of soft data does not follow systematic rules as it is not possible to determine *a priori* the type of standard soft data collected. This does not mean that their collection may be random. They must be adequate, relevant and not excessive in relation to the fight against psychological and sexual harassment. This analysis must be conducted on a case by case basis by the Listening points.

The purpose of the collection of hard data, possibly provided by the data subjects themselves, through the opening and closing forms, or/and through further documents, is, at first, to manage the historical records, and most importantly to prevent future new cases and to identify recurrent cases (to be brought to the attention of the Executive Director, Head of Unit or Sector, and Section Heads). The necessity and the relevance of such data collected by means of these forms should then be carefully re-evaluated in a few years time in relation to the purposes above mentioned. The EDPS welcomes this re-evaluation in order to ensure the respect of the data quality principle.

The EDPS welcomes the fact that the principles of adequacy and proportionality of Article 4(1)(c) are reminded in the draft Manual. The EDPS nevertheless recalls that entities involved in the informal procedure should be explicitly reminded that data collection must be relevant with the purpose of the collection as well, this for both hard and soft data.

The EDPS also recalls the need to ensure the anonymous nature of the statistical data. Indeed, the ability of identifying the alleged victim or harasser, and/or third persons involved in the procedure might arise in the present case. The necessity of collecting each single data for statistical purposes should be proved by principle, as well as the absence of risk of data subjects' identifiability. The EDPS welcomes EMA's commitment to these principles in its Anonymous Statistical Record.

Article 4(1)(d) provides that personal data must be **accurate and, where necessary, kept up to date**. As for the informal procedure, the requirement of accuracy cannot appertain to the facts brought by the alleged victim or harasser (so called "soft data") - part of the notes is based on the subjective perception of the data subject - but to the fact that these specific facts have been brought by the data subject. In this regard, the rights of access and rectification of the data subjects enable individuals to control whether the data held about them reflect the facts they wanted to transmit and, in that sense are accurate (see also Section 3.7 on the Rights of access and rectification below).

Fairness and Lawfulness. Article 4(1)(a) of the Regulation requires that data must be processed fairly and lawfully. The issue of lawfulness was analysed above (see Section 3.2 on Lawfulness of the processing above). The issue of fairness is closely related to what information is provided to data subjects, which is further addressed in Section 3.8 on Information to the data subjects below.

3.5. Conservation of Data

Pursuant to Article 4(1)(e) of the Regulation, 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"*.

As stated in the facts, documents related to the informal procedure are stored by Personnel for a period of five years (from the start of the procedure when the alleged victim gave his/her

consent to open an informal procedure) and may be held for further five years if there is an administrative or legal procedure requiring their consultation.²

Personal data on the other hand will not be retained by the Listening Points more than three months after the closure of the case. At the end of this period, data are destroyed or returned to data subject who provided them (alleged victim or harasser, witnesses and third parties).

The EDPS welcomes the data retention periods adopted by the EMA and considers them as compatible with Article 4(1)(e).

In addition, the EMA should ensure that the data stored for a longer period (statistical purpose) are kept in anonymous form only, following Article 4(1)(e) of the Regulation (see Section 3.4 on Data quality above).

3.6. Transfers of Data

Articles 7, 8 and 9 of the Regulation set forth certain obligations which should apply when data controllers transfer personal data to third parties. The rules applicable to transfers to Community (EU) institutions or bodies (based on Article 7 of the Regulation) and to recipient subject to Directive 95/46/EC (based on Article 8 of the Regulation) apply in this case.

Article 7(1) of the Regulation establishes that data shall only be transferred if the data are "*necessary for the legitimate performance of the tasks covered by the competence of the recipient*".

The EDPS notes in the first place that the EMA based the transfers of data on the consent of the data subject. The EDPS reminds the EMA that transfers of data should only be based on Articles 7 and 8, and that the exception of Article 20(1)(c) does not apply to data transfers. EMA should therefore evaluate the necessity of data transfers in the light of Articles 7 and 8. The EMA should amend its Manual and the policy accordingly.

In the second place, as far as **internal transfers** are concerned, *structural* (automatic), and *ad hoc* (case by case) transfers should be distinguished:

- In cases of *structural transfers* the EDPS considers that the HR Sector and Personnel may also be the recipient of the data processed. Indeed, due to the sensitive nature of the informal procedure, the network of Listening points is in charge of the core activity of the procedure whereas the HR Sector and Personnel is playing a role of administrative support. These transfers to HR Sector and Personnel should be limited to the data necessary for the legitimate performance of their tasks (administrative support) as foreseen in Article 7(1). In this respect, hard data should be transferred. The EDPS insists on the fact that any structural transfer of soft data should be prohibited (in particular to the personal notes of the Listening points).

The EDPS therefore questions the necessity of the transfer of "files" to Personnel (as well as to the Heads of Human Resources and of Administration) as described in the facts and invites the EMA to reconsider such transfers.

- In case of *ad hoc transfers* of harassment related data (should they be hard or soft) to any third person (to the Executive Director and Head of Administration in the event of recurrent

² If an alleged harasser was never informed of an informal procedure opened concerning him/her, no personal data on this person shall be retained by the Listening Points, Personnel or the HR Sector beyond an additional period of three months after the closure of an informal procedure.

cases e.g.), they may be considered as legitimate if the competence of the recipients has been verified and if the transfers have been evaluated, on a case by case basis, as necessary for the legitimate execution of the tasks of those recipients in accordance with Article 7(2) of the Regulation. The EDPS insists on the fact that, if the transfer follows a request from the recipient, both the controller and the recipient shall bear the responsibility of the legitimacy of this transfer. If doubts arise should as to the necessity, the controller shall seek further information from the recipient.

Moreover, the principle of accuracy of the data exposed in Section 3.4 on Data quality above should be all the more taken into account: additional information might be necessary to enable recipients to understand the personal notes of the Listening points. In addition, the EDPS recalls that statements of data subjects, especially of the alleged victim, are to be considered as such and not as verified facts as if it would be a formal procedure. When transferring the data, this difference must be made clear to the recipients.

EMA must also ensure that the recipients process personal data only for the purposes for which they were transmitted, in compliance with Article 7(3) of the Regulation.

In the third and last place, as far as **external transfers** are concerned, for example to medical advisors/psychologists or counselling service through Personnel and/or to judicial national authorities, the EDPS recalls that the necessity for transferring data to these recipients should be carefully analysed before hand, in compliance with Article 8(a) and (b) of the Regulation. Finally, in case of transfers to recipient not subject to Directive 95/46/EC, Article 9 must be complied with.

3.7. Rights of Access and Rectification

According to Article 13 of Regulation (EC) No 45/2001, the data subject shall have the right to obtain, without constraint from the controller, communication in an intelligible form of the data undergoing the processing and of any available information as to their source. Article 14 of the Regulation provides the data subject with the right to rectify inaccurate or incomplete data.

The EDPS welcomes the fact that a right of access and a right to review/rectify is partly guaranteed in the processing operations under analysis. However, neither the right of access nor the right of rectification are guaranteed by principle, both rights should not be limited to data only provided by data subjects.

The EDPS is aware that there is, a limitation to the right of access and rectification of the data subject, foreseen in Article 20 of the Regulation "*The Community institutions and bodies may restrict the application of (...) Articles 13 to 17*". However, as an exception to a general rule, this limitation must be interpreted restrictively and applied on a case by case basis, never automatically and if necessary, after the consultation of the DPO. Accordingly, the general rule regarding files and personal notes within the informal procedure should be the rights of access and rectification to all persons concerned.

As for the right of access, the general rule applicable is the access to any personal data concerning persons involved, provided by themselves or not. However, pursuant to the exception of Article 20(1)(c) of the Regulation, alleged harassers may have their right restricted if necessary to safeguard "*the protection of the data subject or of the rights and freedoms of others*". Their access is then subject to them having been informed by the

Listening point, with the agreement of the alleged victim, of the existence of an informal procedure against them. Furthermore, Article 20(1)(c) may in certain cases also be applied to protect the rights of other persons concerned, especially of witnesses. The EDPS however reminds the EMA that this limitation should only be applied when strictly necessary to protect the rights and freedoms of others, and in order to secure the good administration of cases or the future relations of the parties as suggested by EMA.

As for the right of rectification, if inaccurate hard data should be rectified following Article 14 of the Regulation, the notion of inaccurate soft data, as explained above, refers to the fact that specific statements have been made by the data subject. In the case of soft data, the data subject may also ask to add his/her opinion to the file to ensure the completeness of the file in accordance with Article 14. The EDPS therefore welcomes the fact that the EMA guarantees the right of rectification in the light of Article 14; a distinction between objective/hard data and subjective/soft data should nevertheless be done when granting this right.

The EMA must in any event take into account and comply with Article 20(3) of the Regulation: *"If a restriction provided for by paragraph 1 is imposed, the data subject shall be informed, in accordance with Community law, of the principal reasons on which the application of the restriction is based and of his or her right to have recourse to the European Data Protection Supervisor"*.

Article 20(4) of the Regulation must also be taken into account: *"If a restriction provided for by paragraph 1 is relied upon to deny access to the data subject, the European Data Protection Supervisor shall, when investigating the complaint, only inform him or her of whether the data have been processed correctly and, if not, whether any necessary corrections have been made"*. The right of indirect access will come into play when, for instance, the data subject has been informed of the existence of the processing operation, or is aware of it, but has a restricted right of access under Article 20.

Likewise, Article 20(5) provides that: *"Provision of the information referred to under paragraphs 3 and 4 may be deferred for as long as such information would deprive the restriction imposed by paragraph 1 of its effect"*. It may therefore be necessary for EMA to defer provision of information in order to protect the victim.

The EDPS also recommends that both the right of access and of rectification should be fully guaranteed for witnesses and other stakeholders involved in the informal procedure.

Finally, the EDPS recommends the EMA to specify the duration needed for the blocking or erasure of the personal data, duration which differs from the timeframe necessary to treat a case within the informal procedure.

3.8. Information to the Data Subject

Pursuant to Articles 11 and 12 of the Regulation, those who collect personal data are required to inform individuals that their data are being collected and processed. Individuals are further entitled to be informed of *inter alia* the purposes of the processing, the recipients of the data and the specific rights that individuals, as data subjects, are entitled to.

As stated in the facts, in order to comply with this obligation in the case under analysis, information is provided in two stages during the informal procedure at the EMA.

First, the draft Policy contains general provision on compliance with the data protection legislation of both the formal and informal procedures. In addition, the EMA drafted a Manual specific to the modalities of the informal procedure, including information on data protection necessary to comply with most articles of the Regulation. Both documents will be distributed to all staff and be published on the EMA Intranet. The EDPS considers this as a good practice.

Second, data subjects are individually provided with information on their rights by the Listening points after having requested their assistance. In particular, a *"Declaration of confidentiality for informal procedures for cases of psychological and sexual harassment"* includes a specific Privacy statement, where most information requested by Article 11 of the Regulation is quoted. While welcoming such written commitment to Article 11, the EDPS enjoins the EMA not only to include the specific Privacy statement in the Declaration of confidentiality, primarily addressed to the Listening points. A separate statement should allow the communication of information to all parties involved. In addition, the EMA should explicitly mention in the specific Privacy statement, as required by Article 11: paragraph (a) *the identity of the controller* (besides to the identity of the Listening point considered as co-controller), and paragraph (f) *the time-limits for storing the data*.

Article 20(c) of the Regulation, discussed above (see Section 3.7 on the Rights of access and rectification), provides for certain restrictions to the right of information of alleged harassers in the cases where alleged victims do not give their prior consent. At this occasion, the EDPS recommends, while stating in the informative documents the right of the alleged harasser to be informed, to explicitly mention the limitations to his/her right foreseen in paragraph (c).

Article 20(5) may also be applied in specific circumstances: *"Provision of the information referred to under paragraphs 3 and 4 may be deferred for as long as such information would deprive the restriction imposed by paragraph 1 of its effect"*.

Article 11 and 12 of the Regulation are therefore respected, provided that all informative documents mentioned above are adapted accordingly to reflect the provisions made in this Opinion. It applies in particular to the retention of data, to the right to information and to the right of access and rectification.

3.9. Security measures

[...]

4. Conclusion

There is no reason to believe that there is a breach of the provisions of Regulation (EC) 45/2001 provided that the considerations in this Opinion are fully taken into account. In particular, the EMA must:

- Formally remind all entities involved in the informal procedure that the collection of any data must be relevant in relation to the purposes for which they are collected;
- Ensure that data kept for longer than the regular retention periods are kept in anonymous form only;

- Evaluate the necessity of data transfers in the light of Articles 7 and amend the draft Manual accordingly;
- Reconsider the necessity to automatically transfer "files" to Personnel, as well as to the Heads of Human Resources and of Administration) in the framework of an informal procedure;
- Ensure compliance with Articles 8 and 9 in case of external data transfers;
- Grant the right of access and rectification as explained in point 3.7 of this Opinion;
- Specify the duration necessary for the blocking or erasure of the data;
- Inform all data subjects as explained in point 3.8 of this Opinion, establish a specific Privacy statement for all data subject in accordance with Article 11;
- Do not only include the specific privacy statement in the Declaration of confidentiality; Adapt it to reflect all provisions of Article 11;
- *[Recommendation on security]*
- *[Recommendation on security]*
- *[Recommendation on security]*
- Adapt all informative documents provided together with the notification so as to reflect the recommendations made in this Opinion.

Done at Brussels, 7 February 2011

(signed)

Giovanni BUTTARELLI
Assistant European Data Protection Supervisor