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**From:** Mr Giovanni BUTTARELLI, European Data Protection Supervisor  
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**To:** Delegations

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**Subject:** Proposal for a Regulation of the European Parliament and of the Council on official controls and other official activities performed to ensure the application of food and feed law, rules on animal health and welfare, plant health, plant reproductive material, plant protection products and amending Regulations (EC) No 999/2001, 1829/2003, 1831/2003, 1/2005, 396/2005, 834/2007, 1099/2009, 1069/2009, 1107/2009, Regulations (EU) No 1151/2012, [...] /2013 [Office of Publications, please insert number of Regulation laying down provisions for the management of expenditure relating to the food chain, animal health and animal welfare, and relating to plant health and plant reproductive material], and Directives 98/58/EC, 1999/74/EC, 2007/43/EC, 2008/119/EC, 2008/120/EC and 2009/128/EC (Official controls Regulation)

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- Formal comments of the European Data Protection Supervisor

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Delegations will find in Annex the above-mentioned formal comments of the EDPS signed by Mr Giovanni Buttarelli, Assistant European Data Protection Supervisor, addressed to the President of the Council of the European Union.

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## **Comments of the EDPS on the Proposal for a Regulation on official controls and other official activities performed to ensure the application of food and feed law, rules on animal health and welfare, plant health, plant reproductive material and plant protection products**

### **I. Introduction**

1. On the 6th of May 2013, the European Commission published a proposal for a Regulation on official controls and other official activities performed to ensure the application of food and feed law, rules on animal health and welfare, plant health, plant reproductive material and plant protection products (hereinafter the 'proposed Regulation').
2. The EDPS had not been consulted prior to the adoption of the proposal. Nonetheless, on 7 January 2014 and in the light of the potential impact that the controls on the agri-food chain may have on personal data, DG SANCO decided to inform the EDPS of the initiative, and to ask for clarifications regarding the envisaged processing of personal data.
3. The proposal is currently undergoing the first reading in the Parliament and in Council. In this regard, the Joint Working Party of Veterinary Experts (Public Health) and Phytosanitary Experts of the Council assessed it in a meeting held in December 2013. A vote on it by the European Parliament's Committee on Environment, Public Health and Food Safety (ENVI) is scheduled for the 20th of February 2014. We welcome a consultation at this stage procedure. However, we would like to remind that pursuant to Article 28 (2) of Regulation No 45/2001 the Commission is under the obligation to consult the EDPS when it adopts a legislative proposal relating to the protection of individuals' rights and freedoms with regard to the processing of personal data, which means that we should have already been consulted at the stage of inter-service consultation. Therefore, we recommend the Commission to consult us earlier for the future.

### **II. General comments**

#### *a) Applicability of the data protection legal framework to the proposed Regulation*

4. The proposed Regulation lays down rules for the performance of official controls and other official activities by the competent authorities of the Member States and by the Commission, as well as for the establishment of a computerised information system to manage information and data in relation to official controls in the area of food safety. It has a broad reach on the entire chain of production and distribution of food and

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feed in the internal market, and a great array of data, not necessarily personal, may be collected and processed according to its provisions.

5. Hence, in order to infer the application of Directive No 95/46/EC and Regulation No 45/2001 on the control activities regulated by the proposal, it must be first clarified whether and to what extent the envisaged processing involves 'personal data' in the meaning of current legislation, and secondly ascertained whether data relate to individuals.

*b) Types of data processed and their definition as 'personal'*

6. The proposed Regulation reforms the legal framework of official controls and other official activities performed to ensure the application of food and feed law, as provided for in Article 1 (2). In order to pursue this aim, competent authorities of the Member States (see Title II, Chapters I-IV) as well as the Commission (see Title VI, Chapter I) shall perform official controls on operators and the activities and operations under their control. Controls may be performed through inspections in the premises of the operators, access to their computerised information management systems, their animals and goods, their documents and any other relevant information (Article 14 (1)). In case of infringement of food and feed rules, competent authorities may take decisions which may affect the interests and the rights of the operators (see, *inter alia*, Article 6). According to Article 10 (3) read in conjunction with recital 32 "*Competent authorities shall be entitled to publish or make otherwise available to the public information about the rating of individual operators based on the outcome of official controls*". Furthermore, according to Article 130, information and documents concerning official controls will be exchanged by means of a new established EU wide IT network, the 'IMSOC', which will update the TRACES system (Trade Control and Expert System) and coordinate it with existing systems managed by the Commission (such as the the Rapid Alert System for Food and Feed, RASFF).
7. In the light of the foregoing we understand that two general set of data may be processed under the Regulation: data related to the operators (e.g. individual or company's names, place of establishment, websites, ratings etc.) and data related to operators' assets (e.g. animals and goods).
8. Article 2 (1) (a) of Directive No 95/46/EC and Article 2 (1) (a) of Regulation No 45/2001 define 'personal data' as any information relating to an identified or identifiable natural person. In general terms, information can be considered to "relate" to an individual when it is about that individual. Data related to operators (e.g. individual or company's names, place of establishment, websites, ratings etc.) are very likely 'about' him and 'personal' in the meaning of Directive No 95/46/EC when the operator is a 'natural person', whereas the 'personal' linkage between the data regarding the assets of the operators and the operators themselves is less evident, nonetheless it can be inferred. In fact, as the Article 29 Working Party pointed out in its Opinion on the concept of personal data "*in some situations, the information conveyed by the data concerns objects in the first instance, and not individuals. (...) Data can be considered to "relate" to an individual because their use is likely to have an impact on a certain person's rights and interests, taking into account all the circumstances surrounding the precise case. It should be noted that it is not necessary*

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*that the potential result be a major impact. It is sufficient if the individual may be treated differently from other persons as a result of the processing of such data" (emphasis added).*<sup>1</sup> Indeed, as already mentioned above, the result of processing data related to animals and goods of the operators can lead to decisions (see Article 6) addressed to the latter, which are able to affect their legal sphere, thus fulfilling the condition that "*the individual may be treated differently from other persons as a result of the processing of such data*".

9. However, in order to trigger the full application of data protection rules for both categories of information singled out above, another condition must be met, that is the information must relate to an identified or identifiable "*natural person*". According to Article 2 (2) (26) of the Proposed Regulation 'operator' means **any natural and legal person** subject to one or more obligations provided for in the rules referred to in Article 1 (2), except the competent authorities and the other bodies in charge of official controls and other official activities. Hence, operators who run their business activities as natural persons are data subjects in the meaning of the data protection rules. Additionally, even operators which act as legal persons can be deemed data subjects, provided that "*the official title of the legal person identifies one or more natural persons*"<sup>2</sup> or other information about legal persons may be also considered as "relating to" natural persons<sup>3</sup>, or if the national laws including those implementing Directive No 95/46/EC at domestic level extend the protection of personal data to legal persons as well.
10. To sum up, the data protection legal framework (Directive No 95/46/EC and Regulation No 45/2001) is applicable to the processing of personal data envisaged by the proposed Regulation provided that the information qualifies as 'personal data' because it relates to an identified or identifiable individual.
11. In the light of the foregoing, we suggest adding a substantive provision referring to national rules implementing Directive No 95/46/EC and to Regulation No 45/2001, which is also applicable, by dint of article 3 (1) therein, as a consequence of the fact that the proposal entrusts the Commission with several tasks potentially entailing the processing of personal data (e.g. performing controls according to Title IV, Chapter I; setting up and managing Information management systems, according to Title VI, Chapter IV).

### *III. Specific comments*

#### *a) Confidentiality obligations of the staff of the competent authorities - Article 7*

12. We note that Article 7, read in combination with recital 26, instructs the competent authorities of the Member States to ensure that staff responsible for official controls does not disclose information acquired during the performance of such controls which are covered by professional secrecy. It subsequently lists some exceptions to the above mentioned duty of professional secrecy, by stipulating that it shall be respected unless there is an overriding public interest justifying disclosure and provided that the

<sup>1</sup> Article 29 Working Party, Opinion 4/2007 on the concept of personal data, WP 136, pp. 9-10.

<sup>2</sup> Joined Cases C-92/09 and C-93/09, *Schecke and Eifert*, [2010] ECR I-11063, paragraph 53.

<sup>3</sup> Article 29 Working Party, Opinion 4/2007 on the concept of personal data, WP 136, pp. 23-24.



operator concerned has been allowed to comment upon it prior to the disclosure and such comments have been taken into account, or released alongside the information being divulged by the competent authorities.

13. Furthermore, recital 26 stipulates that the duty to professional secrecy is without prejudice to the obligation to inform the general public where there are reasonable grounds to suspect that food or feed may present a risk for health in accordance with Article 10 of Regulation (EC) No 178/2002, adding that a publication of information made in response of the latter risk for public health 'should' not affect the rights of individuals with regard to the protection of their personal data as provided for in Directive No 95/46/EC.
14. We welcome that the proposal takes into account the need to ensure the confidentiality of the information gathered by the competent authorities of the Member States in the course of their activities, and that it circumstantiates the conditions upon which exceptions to the duty of secrecy may be needed.
15. However, we want to underline that the right to protection of personal data is a fundamental one under EU Law, and that Directive No 95/46/EC constitutes the main piece of EU secondary legislation implementing it. Therefore, compliance with Directive No 95/46/EC should be deemed mandatory, and treated as such in the text of the proposal. Moreover, national rules implementing Directive No 95/46/EC shall apply to any kind of processing of personal data entailed by the proposed Regulation, not only to the circumstances whereby information regarding the operators is disclosed in accordance with Article 10 of Regulation (EC) No 178/2002. As already said above, a substantive provision referring to both Directive No 95/46/EC and Regulation EC 45/2001 should be added in order to make explicit that data protection rules apply to the processing performed by the staff of competent authorities.

*b) Transparency of official controls - Article 10*

16. According to Article 10 '*Competent authorities shall perform official controls with a high level of transparency and make available to the public relevant information concerning the organisation and the performance of official controls*'.
17. More specifically, the proposal authorises competent authorities to publish information about the cases where measures were taken as the outcome of **established non - compliance** of the operators, the cases where the **penalties** referred to in Article 136 have been imposed (paragraph 1 c)-d)), as well as about the **rating of individual operator's** based on the results of official controls (paragraph 3).
18. We would like to raise your attention to the point that, according to the case law of the European Court of Justice '*no automatic priority can be conferred on the objective of transparency over the right to protection of personal data*'.<sup>4</sup>

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<sup>4</sup> Joined Cases C-92/09 and C-93/09, *Schecke and Eifert*, [2010] ECR I-11063 paragraph 85 and Case C-28/08 P, *Commission v Bavarian Lager*, [2010] ECR I-06055, paragraphs 75 to 79.

19. The publication of sanctions or ratings mentioning the identity of the individual operator responsible of a breach may affect his/her right to the protection of personal data. For this reason, we would like to recall that the **purpose, necessity and proportionality of the measure should be sufficiently established**, assessing each case in light of the specific circumstances, **on a case by case basis**, taking account of the relevant circumstances, such as the gravity of the breach, the degree of personal responsibility, recidivism, and the existence of a threat for the safety and health of either humans or animals. For instance, in the event of a threat to the safety and health of either humans or animals, publication of sanctions and controls' results would very likely be a proportionate and legitimate processing of personal data on the basis of Article 10 of Regulation (EC) No 178/2002, which stipulates that *'where there are reasonable grounds to suspect that a food or feed may present a risk for human or animal health, then, depending on the nature, seriousness and extent of that risk, public authorities shall take appropriate steps to inform the general public of the nature of the risk to health'*.
20. Besides the latter situation, we note that such publication should be avoided when less restrictive means may be used for the same purpose.
21. Moreover, as and when the publication takes place in the Internet, it is necessary that Member States ensure that personal data of the persons concerned are kept online only for a reasonable period of time, after which they are systematically deleted.
22. In the light of the foregoing, we advise to amend Article 10 of the proposed Regulation so as to ensure that the transparency of controls is guaranteed in compliance with the data protection legal regime and that the publication of information relating to 'data subjects' (individual operators) is assessed on a case by case basis.

*c) Information management system for official controls ('IMSOC')*

23. According to Article 130 of the proposal *"the Commission shall set up and manage a computerised information management system for integrated operation of the mechanisms and tools through which data, information and documents concerning official controls are managed and handled ('the IMSOC')"*.
24. Within this system a wide exchange of data will take place, including personal data in the meaning explained above. IMSOC shall fully integrate and provide the necessary updates to the TRACES system and to other computerised systems managed by the Commission and used for the rapid exchange of data, information and documents in relation to risks to human, animal health and welfare, and plant health. We understand that the IMSOC will also coordinate the exchange of information with the RASFF system, and will be used to facilitate the administrative assistance and cooperation between competent authorities in different Member States, including the assistance to and from third countries (Article 105).
25. Concretely, the system relies on information inserted by competent authorities at domestic level, and further processed by the Commission at European level. TRACES is a trans-European network for veterinary health which notifies, certifies and monitors imports, exports and trade in animals and animal products, and allow to

trace and retrace consignments in the internal market. RASFF collects and circulates information about a serious health risk deriving from food or feed. Notifications are entered into the system by competent authorities of the Member States and further circulated by the Commission.

26. However, it is unclear from the proposal what is the exact number of computerised systems that the IMSOC purports to coordinate and what are the features thereof. Furthermore, it is not specified whether future systems may also be incorporated in it. We recommend a clear mechanism that ensures that before each extension of functionalities, or expansions into new policy areas, data protection concerns are carefully evaluated, and, if necessary, additional safeguards or technical measures will be implemented in the architecture of IMSOC. This should require an impact assessment and the consultation of the EDPS and national data protection authorities beforehand.
27. The proposal does not set out the responsibilities of the Commission as "controller". Neither it tasks the Commission with the application of the principles of 'privacy by design' to the IMSOC. A substantive provision which clearly allocates responsibilities to the Commission as a controller pursuant to Article 2 (1) (d) of Regulation No 45/2001, including the necessity to include the principle of privacy by design in IMSOC should be added.
28. Furthermore, the IMSOC shall guarantee the security of personal data's processing pursuant to Article 22 of Regulation No 45/2001. A reference to this provision should be added in Article 130, paragraph 2 of the proposal, and a risk assessment required before the expansion of IMSOC to new policy areas or before adding new functionalities with an impact on personal data.
29. The system may process data related to administrative infringements that may have an effect on an operator's right to perform work/services in the internal market. These are sensitive data in the meaning of article 8 (5) of Directive No 95/46/EC. It should be clarified that sensitive data may only be processed on the basis of a specific ground mentioned in article 8 of Directive No 95/46/EC.
30. Furthermore, operators who can be considered data subjects in the light of the criteria set out above should be fully informed of the processing of their personal data in IMSOC. The information must be provided by the competent authorities, as soon as they undertake the processing of personal data at national level, and by the Commission for the part of processing on which it has the controllership. To this end, the Commission shall give a privacy notice pursuant to Articles 10 and 11 of Regulation No 45/2001 in a proactive manner. This would require the Commission to provide a first 'layer' of data protection notice and other relevant information to data subjects on its multilingual website, also 'on behalf of' competent authorities, that is, covering the information required under Articles 10 or 11 of Directive No 95/46/EC. It would then often be sufficient for notices provided by competent authorities in Member States to simply refer to the notice provided by the Commission, only complementing it as necessary to comply with any specific additional information specifically required under national law.



31. Data subject shall be granted the rights conferred on them by Directive No 95/46/EC and Regulation No 45/2001. The Regulation should specify to whom a request of access can be addressed, and it should also require competent authorities to cooperate with respect to access requests as necessary. Rectification and deletion should be carried out as soon as possible, and a time limit should be set out.
32. Finally, as regarding the exchange of information with third countries, which may take place in the realm of administrative assistance and cooperation envisaged by Article 105 of the proposal, it should be specified that competent authorities or operators in a third country that does not afford adequate protection should not be able to have direct access to IMSOC unless there are appropriate contractual clauses in place. These clauses should be negotiated at the EU level.
- c) Powers of competent authorities and Commission*
33. Article 14 (1) provides for operators to give the staff of national competent authorities access to '**their premises**', '**their computerised information management systems**' and '**their documents and any other relevant information**'.
34. In the same vein, Article 115 (3) stipulates that, in the course of the controls in Member States described by paragraph 1 therein, Commission experts may perform **on the spot verifications** and accompany the staff of the competent authorities performing official controls.
35. Neither of the two provisions specifies whether inspections may take place in private premises, although this possibility cannot be excluded, given that some of the '**operators' premises**' referred to in article 14 (1) may wholly or partially coincide with their '**private premises**'. Moreover, we want to highlight that the power to inspect business and private premises is very intrusive, and should be exercised with full respect of the relevant legal framework at national level including **prior judicial authorisation where requested**.
36. We acknowledge that the powers to inspect operators' '**computerised information management systems**' and '**their documents and any other relevant information**' are foreseen for the pursuit of legitimate aims, i.e. ensuring safety of agricultural products in the market and ensure compliance with food and feed law. However, we would like **requirements of necessity and proportionality**, i.e. they have to be limited to what is appropriate to achieve the objective pursued and not go beyond what is necessary to achieve it.
37. It is therefore essential in this perspective that the provisions are clearly drafted regarding their personal and material scope as well as the circumstances in which and the conditions on which they can be used. Furthermore, adequate safeguards should be provided for against the risk of abuse. **This should not be done with an implementing act**, as provided for by Article 14(4) of the proposal, yet by the European Parliament and Council during the legislative procedure.
38. A **prior judicial authorisation** should be required to access operators' '**computerised information management systems**' and '**their documents and any other relevant information**' too, where requested by national law.

39. Moreover, we recommend introducing the requirement for competent authorities to request access to these records by **formal decision**, specifying the legal basis and the purpose of the request and what information is required, the time-limit within which the information is to be provided as well as the right of the addressee to have the decision reviewed by the judiciary.

Brussels, 20 February 2014