EVENT REPORT

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SIGMA: a viable approach to optimise data collections on animal diseases and animal populations – Report of the 16th Animal Health and Welfare Network meeting

European Food Safety Authority

Abstract

The SIGMA project originates from an internal review, performed by the Animal Health and Welfare (AHAW) team (EFSA Animal and Plant Health unit), on the current data standards and data collection practices related to certain animal diseases (namely, Avian Influenza, Africa Swine Fever, Lumpy Skin Disease, *Echinococcus multilocularis*). This was triggered by requests from data providers to simplify the process which, at present, entails a considerable effort for the countries submitting data to EFSA for risk assessment purposes. In addition, EFSA identified the benefits to be gained from a higher degree of standardisation of the data which should be the most up to date and submitted within a timeframe that can be extremely short in case of an outbreak.

The pilot phase of the SIGMA project started officially in 2018 and was presented in May 2018 to the members of the AHAW Network. After one year of activities, EFSA wanted to provide an update by illustrating the achievements (the data model, the country cards) and the ongoing activities (the technical questionnaires on the data flows, the study on the legal implications). In addition, EFSA aimed at gathering feedback from the countries engaged in the pilot (Spain, Italy, Croatia, Romania, Austria, Estonia and Bulgaria) and at understanding all possible concerns and suggestions from the countries that did not engage. This report contains all the elements listed above and can be considered a up-to-date overview of the SIGMA project.

Key words: SIGMA, data collection, standardisation, automation, legal implications

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1. Introduction

One year on since the SIGMA project was presented for the first time to the Animal Health and Welfare Network (European Food Safety Authority, 2018.SIGMA -A comprehensive animal disease data collection approach. EFSA Supporting publication 2018:EN-1428. 7pp) [1] , it was important to provide the Member States and the relevant countries with an update and state of play. Additionally, EFSA identified the need to clarify operational aspects related to the SIGMA project such as the interaction with the data providers within a country, the available means to face lack of resources in the individual countries and the management of the data from a legal point of view (confidentiality, public access to data. Finally, it was important for EFSA to involve the European Commission in the optimisation process triggered by the SIGMA project.

For this reason, the agenda of the 16th Animal Health and Welfare Network was mainly focussed on the SIGMA project, with the aim of addressing these potential concerns.

2. Update from EFSA

The Network Meeting started with a broad introduction given by EFSA, with the aim of recalling the reasons behind the SIGMA initiative, the main ideas, principles and goals. The achievements up to this point and the intense networking activities were also illustrated.

2.1. SIGMA main principles

The main principles underpinning the SIGMA approach (see Figure 1), are briefly listed below:

- EFSA retrieves in an automated way the data from existing repositories (e.g. ADNS);
- The data to be submitted to EFSA on a legal basis (e.g. Avian Influenza surveillance) and the additional optional data (requested to improve the quality of the risk assessment), are **extracted and standardised** in an automated way (see Figure 2)
- Once extracted and standardised, **the data are submitted by the data provider** to EFSA (note: the submission is not automatic, unless explicitly requested by the country) and will be stored in the EFSA Scientific Data Warehouse (SDWH)
- The data in the SDWH will be made available to the data providers for their own purposes (e.g. national reports or reports to be submitted to other institutions).

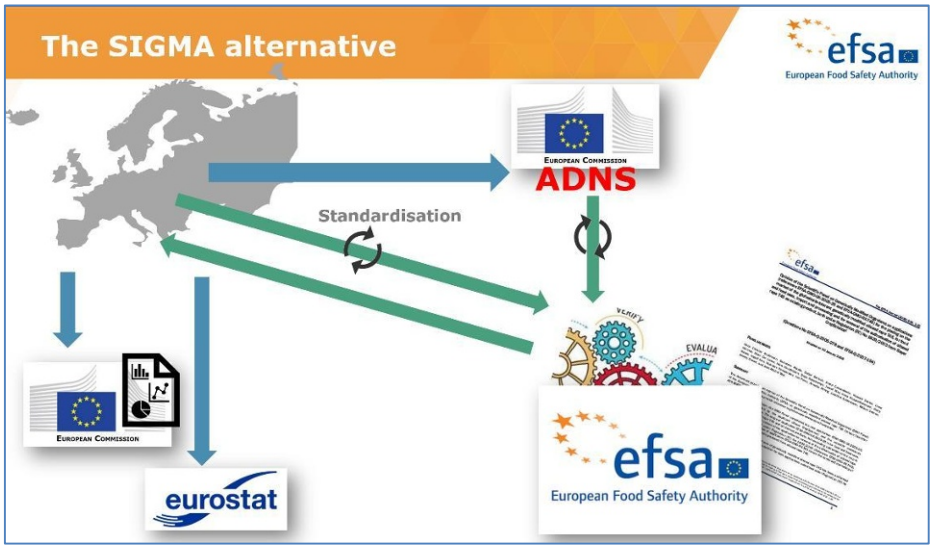

Figure 1: schematic representation of the SIGMA approach.

[1] https://www.efsa.europa.eu/it/supporting/pub/en-1428

The extraction and the standardisation of the data at country level is performed by the SIGMA EST (see Section **Error! Reference source not found.**), which is developed by the SIGMA Consortium from an existing computer programme called "*Do Ut Des*" (see Figure 2)

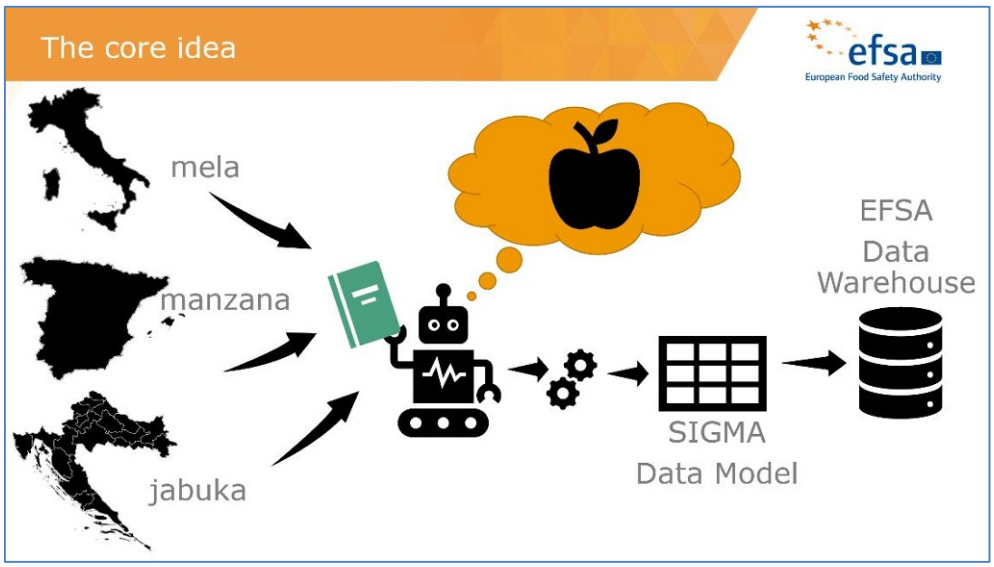

Figure 2: schematic representation of the role of the extraction and standardisation tool. Apple: concept / item to be retrieved. Value of a variable in the SIGMA data model; Robot: SIGMA EST. Book: dictionary for the data mapping and the matching between the country data model and the EFSA SIGMA Data Model

The principle is mainly as follows: once the data items to be retrieved are clearly identified and univocally defined by EFSA ("apple" in Figure 2) it is possible to create the "dictionaries" ("book" in Figure 2) to translate the items from the country language to the EFSA SIGMA data dictionary ("the standards").

By a proper set of instructions, the process of matching the data at country level with the information required by EFSA can be automated ("robot" in Figure 2). The next step is to translate those items into the EFSA SIGMA language ("gearwheels" in Figure 2). The country / data provider is then able to check for consistency the outcome of this automated process and, after validation, submit the data to EFSA.

The SIGMA Consortium highlighted an important feature of the SIGMA EST, i.e. the reversibility of the process. In other terms, each data provider will be able to use his own data, stored in the EFSA SDWH, in two different ways:

- As they are, i.e. using the EFSA SIGMA terminology, producing reports that are fully comparable with the ones from other countries
- Translating them back to the original language, producing report with a lower degree of comparability, but probably more adequate for internal communication

EFSA drew the attention of the audience to an important aspect of the SIGMA EST: once developed, tested and validated, **the SIGMA EST software will be owned by the country**, not by EFSA nor the SIGMA Consortium. In practice, the SIGMA Consortium, upon agreement of the country and relevant data providers, performs the work of alignment between the national data model and the SIGMA data model, on behalf of and without any charge for the country. This is possible as the EFSA management decided to invest in this important project, providing funding and expertise. In change, the engaging countries are requested to increase the quality and the level of resolution of the data and to maintain the tool provided by the Consortium (the SIGMA EST). Naturally, should there be problems not manageable by the national IT experts, EFSA will support the data providers in addressing the issues.

2.2. Achievements

An overview of the SIGMA output was provided:

One of the earliest outputs of SIGMA were the **Country Cards**: a set of synthetic documents where the national authorities or institutions involved in the management of the data of relevance (animal population and laboratory data) are listed. So far, 18 Country Cards have been published in the EFSA website and grouped in a dedicated Virtual Issue (Animal Health: Data sources on animal diseases in European Union Member States. Harmonised data collection for more effective risk assessment[2]). The MSs included so far in the Virtual Issue are Austria, Belgium, Bulgaria, Cyprus, Czech Republic, Denmark, Estonia, Finland, Greece, Ireland, Italy, Latvia, Lithuania, Poland, Portugal, Slovakia, Spain and Sweden. EFSA stressed the importance of having a complete overview across EU, not only within the scope of the SIGMA project, but also for mutual support and cooperation between countries. For this reason, to the missing countries was asked the effort of filling in the online survey.

With the publication in January 2019 of the **Scientific Report** on the SIGMA project[3], EFSA defined the **SIGMA Data Model** underpinning the data collection on animal population (establishments of poultry, pigs and bovines) and on laboratory data (analytical method and final official result of samples tested for avian influenza, African swine fever and lumpy-skin disease).

In 2018 the **SIGMA Consortium** was awarded by EFSA and appointed to support the implementation of the SIGMA project. The first deliverable was a report on a scoping exercise aiming at producing an inventory of the tools (e.g. software / applications) used for risk assessment purposes in the EU (in press). From this exercise it appeared that one of the most used applications by the MSs was the one developed by the Friedrich Loeffler Institute (FLI) to perform risk assessment on African Swine Fever (ASF) data. The second deliverable, as a follow up of the first task, is a report on the technical feasibility of linking the ASF tool of FLI to the EFSA SDWH. The two reports will be published in the EFSA website as external reports by summer 2019. The Consortium is also activity working with the seven engaged MSs to map the data flow within each country, from the point where the data are generated up to the data provider, i.e. the legal entity that validates and submit the data. This is an essential step for the development of the SIGMA EST. The external reports are foreseen by the end of 2019.

2.3. Communication and networking activities

EFSA promoted the SIGMA project in different ways:

- SVEPM congress, March 2018 in Tallin: presentation of a poster with the core idea and the outline of the SIGMA project
- 15th AHAW Network meeting. May 2018. Parma: first official in full presentation of the SIGMA project to the members of the Animal Health and Welfare Network.
- Chief Veterinary Officers (CVOs) meetings, Brussels: the Head of Unit of ALPHA was invited twice to attend these meetings to update the CVOs on the ongoing risk assessment activities, with insights on ASF. SIGMA was presented to the audience as an important step to improve the quality and the speed of the risk assessment process
- 38th Meeting of the Focal Point Network, 26-27 February 2019 (Parma)[4]. A dedicated session was organised to introduce the SIGMA project to the pre-accessing countries. Based on the positive feedback from the audience, EFSA organised a workshop dedicated to SIGMA and zoonoses data collection
- 71st meeting of the EFSA Advisory Forum, 3-4 April 2019 (Bucharest). The ALPHA head of unit presented the SIGMA project, particularly focussing on the benefits
- Workshop on the SIGMA Project and zoonoses data collection, 23-24 April 2019 (Skopje). The workshop was organised by EFSA and financed by the EC, under the EFSA Pre-Accession

[2] https://efsa.onlinelibrary.wiley.com/doi/toc/10.1002/(ISSN)1831-4732.AnimalHealth

[3] https://www.efsa.europa.eu/it/efsajournal/pub/5556

[4] https://www.efsa.europa.eu/sites/default/files/event/FP190226-a.pdf

programme 2017-2019. The SIGMA project was presented in full to the pre-accessing countries and the first collaboration started.

- GRAID Symposium, 15 May 2019, Amsterdam: presentation on the importance of harmonisation and standardisation of data across EU for risk assessment purposes. Case study: SIGMA project.

There are also many interactions with other European and international institutions and projects related to animal disease data collection with the aim of creating synergies and avoid overlaps, e.g. in the development of the data model or in the evaluation of a reporting tool:

- EuFMD (FAO). Workshop on possible interaction between the EFSA SIGMA project and the EuFMD spread model (the Australian AADIS). The model is in fact flexible enough to be adapted and used for animal disease other than Foot and Mouth Disease. Nonetheless, the model is rather sophisticated and capable of computing a considerable amount of data at a very high level of precision. Considering the final high quality of the data that EFSA expects to gather, assuming the willingness of the MSs and interested countries, the EuFMD model could be made available to EFSA and to the data providers as a risk assessment tool. EFSA and EuFMD are exploring the technical feasibility.
- OIE, in relation to the World Animal Health Information Database (WAHID) Interface
- ORION (One health surveillance initiative on harmonization of data collection and interpretation)
- ENETWILD: A European network of wildlife professionals capable of providing reliable data on species distribution and abundance of selected host species and their pathogens.
- G-RAID (Generic approaches for Risk Assessment of Infectious animal Disease introduction)
- INSPIRE KNOWLEDGE BASE (Infrastructure for Spatial Information in Europe)

3. Feedback from the countries involved in the pilot phase

The involved MSs were asked to provide EFSA with a feedback on four aspects related to this pilot phase:

- The time dedicated to the SIGMA project since their engagement
- How many persons are involved / dedicated to the SIGMA project
- If the work performed by the SIGMA Consortium was in line with the expectations
- Any other remark, issue, question or suggestion

3.1. Time dedicated to the SIGMA project

The period of engagement is not the same for all the seven countries that engaged in the pilot phase of SIGMA. The time dedicated, therefore, varied according to the date of engagement. Overall, based on the values provided by the countries that managed to make an estimation, the time spent was relatively limited (10 full working days, over the engagement period).

Considering the challenges of the project and the potential impact of the benefits, the time spent seemed to be more than adequate.

3.2. Personnel involved / dedicated to the SIGMA project

Each MS, based on its organisation, allocated the resources in a different way. The number of people involved varies between 2 and 8 persons. In general, when more experts are involved, these have different responsibilities and competencies. SIGMA is, indeed, a multi-disciplinary project that requires the interaction between many aspects: IT infrastructure, IT system, data science, epidemiology, veterinary medicine, knowledge on the field work.

3.3. Work of the SIGMA Consortium

This was the first official feedback since the SIGMA project entered in its pilot phase, with the interaction between the SIGMA Consortium and the data providers. It was important for EFSA and the Consortium to understand if there was something to improve in the approach.

The feedback was very good and the work of the Consortium is perceived as highly professional. The MSs reserved the possibility of providing more specific feedback during the entire process, which was of course granted by EFSA.

3.4. Remarks, issues, questions and suggestions

The open question was the opportunity for the countries to express their concerns or needs they might have. The contributions can be grouped in the following categories and related questions or remarks:

- Technical aspects
  - To what extent the process will be automated?
  - Will be the data provider able to check the data before official submission to EFSA?
  - Concerns regarding the feasibility due to the potentially heterogeneous situation in the country (data dictionary not necessarily consistent within the country; different/ many national data repositories)
  - Nature of data to be submitted and which of them are compulsory to be submitted?
  - Frequency of the data submission
- Legal aspects linked to the submitted data
  - Confidentiality
  - Public access and Data Protection
  - Consider electronic official certification for servers (security data exchanges)
- Communication
  - More frequent reports and/or updates
- General remarks
  - Full support to the project towards a more rational approach to the data collection
  - Ensure full interaction with European and international bodies running and/or promoting similar projects to avoid duplications (e.g. IMSOC legislation; ADIS)

4. Feedback from the countries not involved in the pilot phase

The countries not involved in the ongoing pilot phase were asked to fill in an online questionnaire with the goal of understanding the reasons for not engaging so far. EFSA is perfectly aware that the SIGMA project has many implications and affects different domains (technical, scientific, legal and even political, in certain circumstances). In fact, EFSA was uniquely interested in understanding if the reasons preventing the countries from engaging was related to the some aspects of the project itself. Nonetheless, in some cases, EFSA could help also to face some problems occurring at national level (e.g. lack of personnel)

EFSA received feedback from 15 countries and the results are reported and discussed below (see Figure 3).

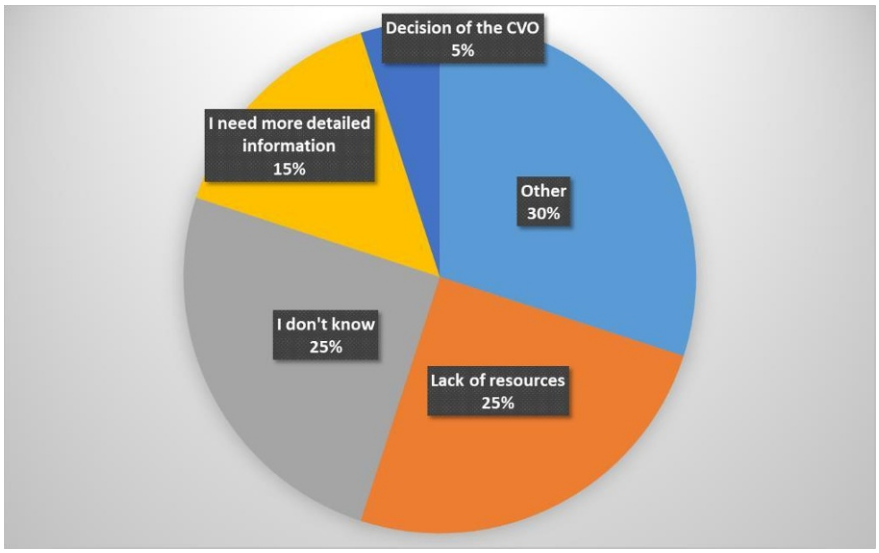

Figure 3: results of the online survey sent to the countries not involved, at this stage, in the SIGMA pilot phase. The question was "As far as you know, what prevented the engagement of your country in the SIGMA project?"

The most common problems identified are:

- The **lack of communication** from EFSA side (more detailed information needed)
  - More information regarding the frequency of data transmission expected and the type of data concerned with specification of future use
  - More info about required workload and financial resources if joining Sigma and what has to be allocated for joining Sigma
  - EFSA is working only with Member States on the SIGMA project. Possibility for pre-accessing countries to engage[5]
  - Better understanding of the file format needed
  - How to engage in the SIGMA project at this stage / resources needed
- The **lack of internal resources**
  - interest in the SIGMA project, but scarcity of personnel
  - Fully support SIGMA project, but time and staff shortage

A considerable part of respondents (30%) did not identify the main problem among the ones proposed by EFSA and reported more explanation. Here are the main categories identified through the analysis of the responses. Here below are listed the items as submitted *via* the online questionnaire by the participating countries.

- **Relevance** for the country
  - Feeling not to be able to contribute much, as little activity regarding ASF, LSD and AI
  - Services in data analysis and interpretation: it would be more useful to develop such skills at the vet services
- **Political issues**
  - Brexit
- **Technical / Scientific concerns**

[5] This item was inserted under the "lack of communication" as at the time of the network meeting the pre-accessing countries were already informed and some already expressed their interest in contributing and being part of the project

  - Disease surveillance and control programs are applied in continuum and population data at farm level reflect a transient status therefore this data do not have sufficient accuracy
  - IT limitations to allow online access to data

- **Legal issues**
  - Data at farm level is data made available to EFSA following mandates submitted under Regulation (EC) No 178/2002 and subject to the provisions of the latter Regulation in terms of confidentiality and transparency. Data providers and data owners (e.g. farmers / farmer associations) have concerns about the level of protection of the data.
  - Regulation (EC) No 1049/2001 on public access to documents is applicable to all documents and data hold by EFSA and therefore can concern the data under the SIGMA project. Data providers are concerned as, in case of a request of PAD, EFSA will disclose the data.
  - The new Regulation (EU) 1725/2018 on the protection of personal data applicable to EFSA needs to be taken into account when publishing or giving access to data, since data at farm level may contain personal data. The data providers are concerned as the privacy and integrity of individuals need to be protected by EFSA the moment it uses the data collected.

It turned out that the concerns reported by the countries were essentially the same, independently from the level of engagement in the project (compare section 3.4). This was an important point, as it made clear to EFSA that the communication is one of the most important activities that has to improve.

The points raised by the network were addressed during the second day of the meeting and EFSA proposed to gather all the questions and related answer in a document (SIGMA Q&A) to be published in the EFSA website. In this report, only the most relevant / most frequently reported concerns will be addressed (see Section 5).

5. EFSA addresses the main concerns of the Network

In this section, the main or most frequent questions raised by the network are addressed. More detailed explanations can be found in this document under the relevant sections. The full list of questions and answers will be published in the EFSA website.

- **Level of automation of the process and level of control of the data provider**

The only process that is automated is the extraction and the standardisation. The data provider, after this step, can check the outcome of the process. If the outcome is correct, the data provider validates and submit the data to EFSA. As the data are standardised at the source, the submission to the DCF will not generate any error, reducing considerably the effort to be dedicated to the submission of data to EFSA. In addition, note that a set of data may be relevant for more than one mandate, e.g. the consistency of the pig population might be relevant both for ASF risk assessment (AHAW team) and for the Trichinella annual report (BIOMO). This means that, finally, the data providers will not have to submit twice the same data.

- **What if there is no consistency in the data dictionary within the country? What if there are many data owners / data providers in a country**

Probably the best option is to create a Country Data Collection Point (CDCP) where the national data are gathered from many sources in a consistent way. The CDCP will represent the data provider for EFSA. As an alternative, certainly more demanding, the Consortium may set up a SIGMA EST tool for each data owner / provider in the country.

- **What type of data are requested by the SIGMA Data Model**

The data requested are population data, at farm level, including information relevant for risk assessment and epidemiological evaluations: e.g. number of animals, type of production, etc.

The SIGMA data model has also a section dedicated to the laboratory data, built on the EFSA SSD2 (Sample Standard Description v.2). The main information is related to the provenience of the sample (link to the farm where it has been collected or to the geo-location of the finding in case of wild animals) and to the final official result. Note: the pending results are not requested as they are useless for risk assessment purposes (unless sophisticated inferential / Bayesian approaches are used, entailing the inclusion of bias in the output)

More detailed information can be found in the SIGMA Scientific Report published earlier this year.

- **Which of the data requested by the SIGMA Data Model are compulsory**

The MSs and the pre-accessing countries have obligations only towards the European Commission: the data that are mandatory to submit are listed in the relevant legislation. All other type of information is submitted to EFSA on a voluntary basis.

Nonetheless, the CVOs frequently complain with the EC about the data collection processes in EFSA which entail a huge effort for the MSs. The submission of data as proposed in the SIGMA data model, will avoid all sort of double reporting to EFSA and will decrease dramatically the effort required by the data providers to collate the data that EFSA requires. In addition, the implementation of the SIGMA approach will guarantee the necessary quality of the data for a proper risk assessment.

- **What is the frequency of the data submission?**

For the population data: one submission a year is more than sufficient, particularly because at this point in time the information available does not fit the risk assessment needs at all. Extra requests of submission may occur upon urgent requests of the EC.

For the compulsory laboratory data: the number of submissions and the pace as specified in the relevant legislation

For the optional (epidemiological) data: one submission a year. Obviously, if a country decides to provide that information, these data can be sent together with the compulsory data

- **What about personal and confidential data?**

Personal and confidential data are covered by the relevant EU legislation, as for the ongoing data collections.

- **How can I check the progresses of the project?**

EFSA is developing a webpage in the EFSA website. In this page it will be possible to find: fact-sheets related to SIGMA, Questions & Answers, Presentations, Events, Progresses.

- **I have some concerns regarding the potential overlapping of the SIGMA project with similar initiatives, including EFSA initiatives (Avian Influenza, African Swine Fever)**

EFSA has a huge networking activity to ensure full synergy with European and international projects and initiatives with similar objectives.

Regarding the EFSA ongoing data collections on ASF and AI, it is important to recall that SIGMA is still in its pilot phase. It was not possible to make sure that the SIGMA data flow will have been in place at the right time to fulfil the timing indicated in the mandates received by the EC. For this reason, the ASF and AI data collections, at the moment, are still run as *ad hoc* data collections, in the classical way. As soon as the data provider is ready to submit the data with SIGMA, no other data submission will be required.

- **How can I engage with the SIGMA project?**

Your CVO has to send an e-mail to ALPHA@efsa.europa.eu expressing the interest in engaging in the SIGMA project

- **What is required to participate to the SIGMA project in term of workload and financial coverage?**

No financial effort is required as the work performed by the SIGMA Consortium is covered by EFSA. Nonetheless, the Consortium needs to work closely with the national experts to understand the relevant aspects of the data flow. However, the time estimated, based on the feedback received from the countries that are already collaborating, is very limited.

- **Is it possible for a pre-accessing country to engage in SIGMA?**

Yes, it is. Please refer to your Focal Point for more detailed information.

- **How to face internal issues preventing the engagement of my country, e.g. scarcity of personnel, time shortage**

EFSA still has some budget to be allocated to facilitate the implementation of the SIGMA project. One option is, as an example, to hire a local expert to be dedicated to the interaction between the country and the Consortium. Please contact EFSA (ALPHA@efsa.europa.eu) to request this type of support.

- **My country is not affected by the diseases listed in the SIGMA project (ASF, LSD, AI). Why should I engage?**

As a matter of facts, unfortunately, no country can be considered disease-proof: in this case, it is important to invest in preparedness. A proper data submission system can be crucial to react rapidly to an emergency.

In addition, the data on population are always relevant: (i) to estimate the degree of exposure and to estimate the impact of a potential introduction of a disease; (ii) for other reporting purposes, e.g. the zoonoses annual report

- **Beware that yearly "snapshots" of the animal population have a limited validity as the situation changes very rapidly.**

Considering that at this moment there is barely no consistent data across EU on data population, a yearly update will represent a considerable improvement.

- **I don't think the IT system in my country is at an adequate level to be part of the SIGMA project**

This is probably an additional reason to join the SIGMA project. In some of the seven countries involved in the pilot phase, EFSA and the SIGMA consortium are actively working to provide solutions to overcome IT issues.

6. Data submission to EFSA: legal aspects

The EFSA Legal and Assurance Services provided the audience with an overview of the legal framework of the data collection in the animal health sector. The SIGMA project, as its aim is essentially to optimise the ongoing data collection activities between EFSA and the MSs and pre-accessing countries, is to be run under the same legal framework than the rest of the data collection in the animal health sector and in EFSA.

Some of the relevant legislation applicable to such activities are listed below:

- Regulation (EC) No 178/2002 (GFL)
  - Art. 33: of Regulation (EC) No 178/2002 (GFL) collection of data
  - Art. 29 and 31 of Regulation (EC) No 178/2002 (GFL): mandates submitted to EFSA
  - Art. 38 & 39: confidentiality and transparency requirements and application of Regulation (EC) No 1049/2001 to EFSA
- Treaty on the Functioning of the EU
  - Art. 15: principle of transparency, public access to documents
- Regulation (EC) No 1049/2001: Public access to documents

- Regulation (EC) No 1367/2006: Access to environmental information

Particular attention was given to the Regulation on Public Access to Documents/Data (PAD) and its impact on the data submitted to EFSA. To better clarify, EFSA provided some examples of requests relating to data collected with a focus on the animal health sector where so far EFSA received two requests on two relevant cases. The cases resulted in a partial release of the data collected, following consultation with the data providers. EFSA not owning the data always clarifies with data providers/owners whether one or more exceptions of the PAD Regulation apply to the release of the data to a requestor.

EFSA presented to the data providers a way to anticipate such requests by means of an "*ex ante* clearance" prior submission of data, consisting in the identification of the information in the data which, in their view, should be considered falling in one exception of the PAD Regulation, such as the protection of personal data (Article 4(1)(b)) or confidential commercial information (Article 4(2), first indent of the PAD Regulation). This verification could be done in all the variables of the SIGMA Data Model providing detailed justification on the grounds for protecting certain entries of the data. This opportunity allows data providers to inform EFSA beforehand of any concern they may have if a citizen or a legal person is requesting access to their data and to avoid having a short deadline to reply to a consultation in a reactive way under the legal deadlines to reply of the PAD Regulation.. In other terms, in case EFSA receives a PAD, and only in this case, the data submitted to EFSA will be disclosed as specified in the "*ex-ante* clearance" document signed by the data provider and EFSA. However, in order to consider specific situations which can arise over time, EFSA will always notify to the data providers when a PAD request is received and the moment when the data is planned to be released. If a requestor is also interested in data fields masked a priori, the data provider will be consulted before EFSA decides on the reply to the requestor.

As a **summary** of the procedure related to the SIGMA framework, here follows a short description of a viable approach for the data submission:

- Each data provider stipulates an agreement with EFSA about which data are considered personal or confidential (*ex-ante* clearance), in view of appropriate legally based justifications **Note**: many participants reported the Concerns of their countries in relation to the submission of the geo location (i.e., x-y coordinates). it is important to recall some crucial considerations in relation to this aspect:
  - XY coordinates of establishments and related sub-units (e.g. farms) are normally covered by the new GDPR in case they lead to a specific person and can therefore considered personal information. in case of a PAD EFSA will be allowed not to disclose this information
  - there are many technical possibilities to protect even more the geo-location: XY coordinates of farms can be jittered or truncated, bringing bias to the exact values without depriving them of their usefulness in risk assessment
- The data are extracted and standardised automatically by the dedicated software SIGMA EST
- The standardised data are checked by the data provider for consistency
- The data are validated and submitted by the data provider to EFSA
- The submitted data are stored in the EFSA SDWH and will be made available to EFSA for the relevant risk assessment.
- In case, and only in this case, EFSA receives a PAD requesting for the data underpinning a given scientific output, EFSA will disclose the variables following the agreements in the *ex-ante* clearance, i.e. the protected variables will be masked with the appropriate information to the requestor on the exception of the PAD Regulations which EFSA considers should apply and the non-protected variables will be disclosed in the agreed format, as available.

7. Inputs from the European Commission

The representative for the European Commission welcomed the initiative as a promising project, highlighting the advantages that its implementation could bring to the stakeholders:

- The countries and the data providers will be able to reduce the workload dedicated to the data submission, by means of automated procedures and avoiding double reporting
- In addition, the data providers will benefit of the interesting feature of the extraction end standardisation tool of translating back the data submitted to EFSA into their original language
- EFSA will be able to elaborate scientific outputs in a shorter time and based on a more reliable set of standardised data
- The EC will receive higher quality outputs in a shorter time

The European Commission noted the importance of sustainability of the SIGMA project: the fact that EFSA is behind such a considerable change in the data collection process is certainly positive as far as the continuity is ensured.

Some recommendations were brought to the attention of EFSA:

- The SIGMA project must be anchored to scientific mandates. The data need to be collected with a specific purpose
- For this reason, the data collected need to be proportionate to the scope as described in the mandates
- It is essential to ensure consistency between the data collected by EFSA in the framework of the SIGMA project and other official data sources (e.g. ADNS)

The representative for the EC, considering that the SIGMA initiative is on a voluntary basis, also noted that the willingness of the MSs and the pre-accessing countries to participate to this pilot phase is crucial for the success of the project.

7.1. EFSA addresses the recommendations of the European Commission

Regarding the anchoring to the mandates, EFSA confirmed that this is fully ensured. The ongoing pilot phase, indeed, is focussing on animal diseases for which there are ongoing activities linked to active mandates. This principle will be maintained in the future and the data providers will be requested to submit the data only within the remit of specific mandates. Nonetheless, should the pilot phase be successful, as the elements available so far indicate, the SIGMA approach could be extended to other EFSA units (e.g. the BIOMO unit). Consequently, as described elsewhere in this document, the data on population will be very likely collected on a regular basis by EFSA (once a year), since these data are needed for the annual zoonoses report. Should the AHAW unit receive a mandate on a new disease, there will be no need to start a dedicated data collection as the data will be already available.

In relation to the proportionality of the data requested to the scope for which they are intended to be used, it is relevant to stress that the type of information is rather basic. The novelty of the approach is more about the standardisation of the data, rather than the quantity. What EFSA is demanding to the data providers is basically to increase the level of resolution of the data. Considering that the extraction and the standardisation process will be automated (not the submission), this is not a point of concern as there is no additional burden, but rather a reduction of the actual burden. What concerns the most to the data provider, when referring to this increase of resolution, is the level of protection of the data. This aspect was fully clarified during the Network meeting (see Section 6).

Last, concerning the consistency across the reports, as recalled in this document, the Data providers will be able to check the outcome of the extraction and standardisation made by the SIGMA EST. This will give the opportunity to check for consistency between the data submitted to EFSA and other data submissions to other systems. In addition, is common practice, EFSA submits the draft of the scientific output to the relevant data providers before publishing it. Therefore, the data providers, over the entire risk assessment process, will have twice the chance to make sure the correctness of the

submitted information. Should there be any inconsistency between the data submitted to EFSA end ones submitted to other systems (for example, the ADNS) it will be possible to align them.

8. Conclusions and action points

The conclusions from the meeting are summarised below:

- Population data are essential for a proper risk assessment. This gap should be definitely covered.
- EFSA and the data providers need to ensure consistency across the reports (e.g. EFSA scientific outputs and ADNS)
- Aggregated data cannot be submitted in SIGMA. Nonetheless, the data provider can still decide what is the level of resolution to use (e.g. 10 farms → 10 records/rows containing only the geo-information at NUTS 3 level). Considering the level of protection of the XY coordinates in relation to the establishments and related sub-units, however, the data provider will be requested to seriously consider the opportunity of providing EFSA with such information for risk assessment purposes
- The job at country level is mainly performed by the SIGMA Consortium with no cost for the national administration (as it is funded by EFSA). The development of the extraction and standardisation tool (SIGMA EST) is performed by the SIGMA Consortium and is delivered to the data provider.
- The applicable legislation is the same for SIGMA and applied to the ongoing EFSA data collection activities.
- The ex-ante clearance is proposed to allow the data providers and EFSA to agree beforehand and clarify which data should not be disclosed in case of a PAD request is submitted and on which grounds of exception of the PAD Regulation.

Following the suggestions and the comments from the participants, the following action points have been identified:

- Design of a space in the EFSA website dedicated to the SIGMA project. The webpage should include all relevant updates
- Create a communication platform (Office Teams) where to share communications and material (presentations, templates, etc)
- Investigate about electronic certification
- Contact the countries manifesting the need of personnel to support the SIGMA project
- Those countries that are starting with the design of a national data model could take inspiration or take it as it is the SIGMA standard / dictionary
- All countries that need support for the implementation of the SIGMA project can contact EFSA (alpha@efsa.europa.eu)
- Expand SIGMA to the Zoonoses data collection

References

European Food Safety Authority, 2018.SIGMA -A comprehensive animal disease data collection approach. EFSA Supporting publication 2018:EN-1428. 7pp (https://www.efsa.europa.eu/it/supporting/pub/en-1428)

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EFSA (European Food Safety Authority), Zancanaro G, Antoniou SE, Bedriova M,Boelaert F, Gonzales Rojas J, Monguidi M, Roberts H, Saxmose Nielsen S and Thulke H-H, 2019.Scientific report on the SIGMA Animal Disease Data Model: A comprehensive approach for thecollection of standardised data on animal diseases. EFSA Journal 2019;17(1):5556, 60 pp.https://doi.org/10.2903/j.efsa.2019.5556 (https://www.efsa.europa.eu/it/efsajournal/pub/5556)

Glossary and Abbreviations

ADNS	Animal Disease Notification System
AHAW	Animal Health And Welfare
AI	Avian Influenza
ASF	African Swine Fever
BFSA	Bulgarian Food Safety Agency
CDCP	Country Data Collection Point
CVO	Chief Veterinary Officer
EC	European Commission
EMU	Institute of Veterinary Medicine and Animal Sciences, Estonian University of Life Sciences
FLI	Friedrich-Loeffler-Institut
GDPR	General Data Protection Regulation
IPA	Instrument for Pre-Accessing (countries / programme)
IZSAM	Istituto Zooprofilattico Sperimentale dell'Abruzzo e del Molise "G. Caporale"
LSD	Lumpy Skin Disease
PAD	Public Access to Data
SDWH	Scientific Data Warehouse
SIGMA	Not an acronym. It's the Greek letter, used in statistics to denote the standard deviation. The 'motto' of the project is, in fact, "less deviation from the standard and more standard deviation"
SIGMA Consortium	Consortium composed by IZSAM, FLI, SVA, BFSA, EMU
SIGMA EST	EFSA Extraction and Standardisation software
SVA	Swedish National Veterinary Institute

Annex A – Quality feedback on the 16th AHAW Network meeting

After the meeting, EFSA launched an online questionnaire requesting feedback on the quality of the meeting.

Here below are reported the replies.

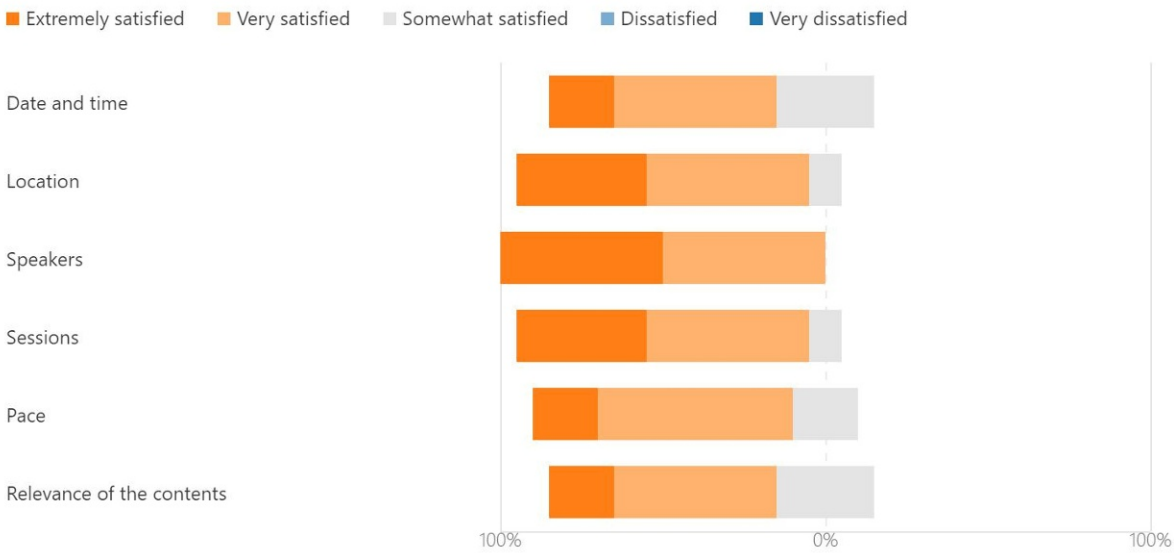
1. Overall, how satisfied were you with the event?

More Details

Extremely satisfied	0
Very satisfied	9
Somewhat satisfied	1
Not so satisfied	0
Not at all satisfied	0

2. Please rate your satisfaction level with the following aspects of our event.

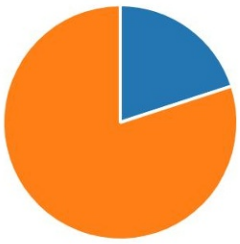
More Details



3. Was this your first time to attend one of our events?

More Details

Yes	2
No	8



4. What did you like most about the event?

More Details

9
Responses

Latest responses

"The topics and the way of the organisation and the possibilities to kn...

"the discussion and interaction between participating experts "

"The project discussed is interesting and useful. The project leaders ar...

5. What did you like least about the event? In particular, we would like to know more in case you answered "Dissatisfied" or "Very dissatisfied" in question 6.

More Details

9
Responses

Latest responses

"I liked everything "

"n/a"

"As this is a network, I find it important that the participants make an...

6. How much you welcome the proposal of using Microsoft Office Teams as sharing platform to enhance the interaction between you and EFSA?

More Details

10
Responses

★★★★☆
3.90 Average Rating

7. Do you have any suggestions for us to improve future events?

More Details

6
Responses

Latest responses

"No "

""

"Maybe in some ways try to encourage the representatives to particip...