In response to information provided by the competent authority, any factual error noted in the draft report has been corrected; any clarification appears in the form of a footnote.
Executive Summary

This study visit took place in Germany from 20 to 23 September 2016 and is the second one from DG Health and Food Safety in the context of the activities aimed at reinforcing the animal health emergency preparedness systems in the EU. Its main objective was to allow national experts from Austria, Belgium, Italy and Spain to observe and learn from the strategies adopted in Germany, to ensure that a satisfactory animal health emergency preparedness system is in place, and to identify good practices and consider how these might be incorporated into their country’s strategies in that respect. This study visit focused on the provisions and practical arrangements in place to deal with large-scale animal disease outbreaks, or “worst-case scenarios”.

The national experts had the opportunity to observe the German contingency plan arrangements for a worst-case scenario and consider the practical relevance of the activities seen and information discussed. There was a general consensus among them that the great level of detail in the German contingency plan for tasks, activities and responsibilities and the completeness in aspects such as identification of financial sources and communication, provide a very good tool to respond effectively to extensive animal health emergencies.

Following the study visit, the Chief Veterinary Officers of the four national experts were asked to report on the value of this study visit and on the possible incorporation of any of the actions mentioned above in their animal health emergency preparedness framework.

All of them agreed on the major relevance of this type of initiative to bring together officials with equivalent expertise from a few Member States who can openly and constructively share their experiences, not only during the study visit (during formal and informal times), but also afterwards by increasing their future cooperation. While the format was considered fit for purpose, suggestions to improve it included more focus on discussions, a reduced scope, and better coordination of presentations by the inviting country.

They highlighted the following elements that they were considering introducing or improving in their own countries:

- A Task-Force or a tool to better integrate national and regional levels, coordinate activities and identify synergies;
- Procedures and protocols, integrated in a quality management and information technology system, available down to field staff;
- Epidemiology expert teams identified and available at national level;
- A procedure to upscale workforce (through job description and resource allocation);
- The validation and approval of a vaccination strategy, involving all relevant stakeholders;
- The involvement of stakeholders in the development of a compensation scheme;
- Contracts with external service providers, including outsourcing certain activities (e.g. stamping out) and including inter-regional aspects related to such services;
- Elements to take into account to identify suitable spots for establishment of local crisis centres.
# Table of Contents

1. Introduction ....................................................................................................................................1
2. Objectives and scope ......................................................................................................................1
3. Background ....................................................................................................................................2
   3.1 Rationale behind the study visit .................................................................................................2
   3.2 Selection of the participating Member States ............................................................................2
   3.3 Format of the study visit ............................................................................................................3
4. Outcome of the study visit – Topics discussed and consensus reached .........................................3
   4.1 General organisation and value of the study visit ......................................................................3
   4.2 General organisation ..................................................................................................................4
   4.3 Organisation in a federal country ...............................................................................................5
   4.4 Worst case scenario ....................................................................................................................6
   4.5 Vaccination ................................................................................................................................8
5. Closing Meeting .............................................................................................................................9
6. Overall Conclusions .......................................................................................................................9
### Abbreviations and definitions used in this report

<table>
<thead>
<tr>
<th>Abbreviation/terms</th>
<th>Explanation</th>
</tr>
</thead>
<tbody>
<tr>
<td>CA</td>
<td>Competent Authority</td>
</tr>
<tr>
<td>DG</td>
<td>Directorate General</td>
</tr>
<tr>
<td>EU</td>
<td>European Union</td>
</tr>
<tr>
<td>Land / Länder</td>
<td>One or more of the 16 Federal States of Germany</td>
</tr>
</tbody>
</table>
# 1 Introduction

The study visit took place in Germany from 20 to 23 September 2016 and is the second one from Directorate General (DG) for Health and Food Safety in the context of the activities aimed at reinforcing the animal health emergency preparedness systems in the European Union (EU).

The study group comprised two members of the Commission services and a national expert from each of the following Member States: Austria, Belgium, Italy and Spain. The study group was accompanied throughout the visit by representatives of the Länder task force for animal disease controls and the national contact point for inspections at the BVL.

# 2 Objectives and Scope

The main objective of the study visit was to allow the national experts to observe and learn from the strategies adopted in Germany to ensure that a satisfactory animal health emergency preparedness system is in place, and to identify good practices and consider how these might be incorporated into their country’s strategies in that respect.

In terms of scope, this study visit focused on the provisions and practical arrangements in place to respond to large-scale animal disease outbreaks, or “worst-case scenarios”.

The study visit took place in agreement with the German Competent Authorities (CAs). Full legal references are given in Annex 1. Legal acts quoted in this report refer, where applicable, to the last amended version.

In pursuit of the objective the following meetings were held and sites visited:

<table>
<thead>
<tr>
<th>Meetings/Visits</th>
<th>No.</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Competent Authority</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Central</td>
<td>2</td>
<td>Initial and closing meetings.</td>
</tr>
<tr>
<td>Regional (Länder)</td>
<td>2</td>
<td>Lower Saxony and North-Rhine-Westphalia</td>
</tr>
<tr>
<td>Local (Kreis)</td>
<td>1</td>
<td>Borken</td>
</tr>
<tr>
<td>Laboratory</td>
<td>1</td>
<td>Official laboratory in North Rhine-Westphalia</td>
</tr>
<tr>
<td>Site visits</td>
<td>2</td>
<td>Mobile disease control centre, permanent logistical disease control centre</td>
</tr>
</tbody>
</table>

---

3 BACKGROUND

3.1 RATIONALE BEHIND THE STUDY VISIT

Between 2012 and 2015 DG Health and Food Safety carried out a series of audits in Member States that aimed to evaluate the fitness for purpose of surveillance systems for the early detection of exotic and re-emerging animal diseases, and the suitability of the animal health emergency preparedness systems to respond promptly and effectively to contain outbreaks of those diseases.

One of the main conclusions of those audits was that most Member States have taken important steps forward in recent years to prepare largely adequate contingency plans in accordance with EU guidelines and requirements, and to make arrangements to enable their effective implementation. Nevertheless, the Commission services identified during those audits a number of areas where additional efforts needed to be made by a number of Member States in order to reinforce some of the operational components of their animal health emergency preparedness systems.

The challenge associated with the close interplay between all measures necessary to implement in the event of a large disease outbreak, was an area where further improvements could be made. Therefore, the Commission services considered it necessary to increase the co-operation and communication between the CAs of Member States in order to improve their level of preparedness with respect to the area selected for this study.

3.2 SELECTION OF THE PARTICIPATING MEMBER STATES

The hosting Member State for this study visit was selected on the basis of the knowledge acquired during an audit carried out on this topic in Germany in 2013 (ref.: DG(SANCO) 2013-6778 – MR Final). The report of that audit, including the action plan provided by the German CAs to address its recommendations, is published on the Website of DG Health and Food Safety at:


The report, which was studied by the national experts in preparation for the study visit, provides, amongst other things, an extensive description of the topics listed here below, which are considered important to understand the setting out and implementation of provisions and practical arrangements in the event of a large-scale disease outbreak in Germany:

- Organisation of the CAs and general structures of the animal health emergency preparedness system.
- Relevant legal and administrative issues in relation to the topics covered by the scope of the study visit – functioning of the federal structure, the responsibilities of the national and Länder CAs, specific arrangements at Land level (e.g. cooperation with other CAs and with other stakeholders in the event of an animal health crisis).
• Expertise available and applied research applicable to the topics covered by the scope of the study visit.

The other participating Member States were selected on the basis of their political organisation, namely extended decentralisation system.

3.3 FORMAT OF THE STUDY VISIT

In addition to the pre-study familiarisation of the national experts with the animal health emergency preparedness system in place in Germany, the main organisational features of the study visit included:

• The national experts were invited to prepare a short presentation for the opening meeting where they identified those specific areas where they, and the systems in place in their countries, could benefit from participation in this initiative.
• The German CAs made available to the national experts comprehensive information on the organisation and operation of their animal health emergency preparedness system.
• The study was conducted in a very open and transparent manner which led to constructive discussions where knowledge and experience with the solution of specific problems related to the areas under consideration were extensively shared.
• Short daily de-briefings took place at the end of each day to review the main points discussed and further clarify each national expert’s impressions on the specific aspects considered more relevant for them.
• During the closing meeting of the study visit, each national expert provided a brief presentation summarising the issues they found more interesting or useful, in accordance with the programme of the study visit and with what they had highlighted as their main expectations.

4 OUTCOME OF THE STUDY VISIT – TOPICS DISCUSSED AND CONSENSUS REACHED

4.1 GENERAL ORGANISATION AND VALUE OF THE STUDY VISIT

1. Significant differences existed between the represented countries both on the level and tasks that are devolved to regional level and on the level integration between central and other regional governments.

2. The national experts valued the possibility of seeing how contingency planning varies between Member States. The different methods of organisation and approaches can serve as a benchmark for their own national approach.

3. The national experts highlighted the benefit to discuss with expert colleagues issues that they had difficulties solving at national level.

The following areas were highlighted by national experts either as examples of good practices from which they felt they and other CAs could learn and if suitable to their national
situation, build onto their national contingency planning, or as issues equally shared in their respective countries.

4.2 General Organisation

4. The system for contingency planning in Germany is developed under an overarching quality management system, is web-based and organized by topic, with horizontal information (valid for all types of crises) and detailed specific information for specific diseases. It includes not only guidance but all other necessary documentation that can be foreseen as needed during a crisis, integrated in a single list. The level of detail is such that all activities have been split into individual tasks, responsibilities are clearly defined, and there is a set of simple practical instructions available for each task, validated both at Land and federal levels. This approach has many benefits: easy to access, easy to update, clear links easy to follow for practical implementation. The German authorities were considering moving to paperless reporting, using smartphone applications.

5. The high level of connectivity of information management systems (veterinary management, laboratory information, animal identification, disease notification) and the clear display and links between contingency plan and afferent documents, provide for a robust support for decision making, implementation and communication of activities.

6. There is an updated catalogue of supplies (equipment and consumables) available at all Länder. This could be used by any local crisis centre in case it runs out of some items during an emergency.

7. At local level, the authorities have identified facilities that could host operational (logistic) local disease control centres. In these, it is possible to implement a lay-out and flow that would ensure good biosecurity. When these sites are in use by other services during "peace" time, plans to make them available rapidly are developed. In addition, there is a mobile disease control centre which can be transported and set up in few days in any pre-determined place of the country.

8. Many provisions for animal disease control have been outsourced to service providers. In the Länder visited, for activities such as culling and decontamination of farms the competent ministries and agricultural organisations have agreements with firms possessing the relevant expertise, in order to enable them to provide appropriate and adequate resources if required. The contracts and arrangements are subject to scrutiny by the authorities and detailed instructions (based on details included in the contingency plans), including on their capacity to deliver and operative maintenance. The competent authority supervises investment plans, storage and maintenance of equipment and training of contractor’s staff. The contracts are signed as “stand-by” contracts, with the aim of keeping costs under control when a crisis occurs.

9. Germany benefits from a network of 21 rendering plants within its territory, all able to process category 1 and/or 2 material whose capacity (in normal or maximal mode) has
been assessed and included in the contingency plans. Arrangements for processing in case of animal health crisis are dealt with at Land level (or lower).

10. Financial compensation in the event of an animal health crisis is governed by the Animal Health Act, through an animal disease fund. This is a solidarity fund, legally supervised by the Ministry, but not funded with public funds (although the Länder concerned would participate to 50% of compensations made in case of epizootic disease). All farmers have to notify their livestock to the fund contribute to it accordingly annually. The fund foresees compensation on the value of animals, culling and disposal costs, and decontamination; it covers epizootic diseases, but also other diseases subject to regional control. The operation manuals include current market prices and estimation tables which are used by experts to estimate the fair market value of animals. The compensation is linked to correct livestock notifications by the farmers and to compliance with legal provisions on animal health.

11. The German contingency plan includes great details on communication. There are functional email lists and it details the chain of communication from the suspicion stage.

12. The integration of local veterinary services within the local administrative structure makes it easier to receive administrative support. Strategy boards at local level gather other authorities and stakeholders, ensuring common understanding of decisions taken. Support from other services is institutionalised.

13. The plan contains checklists for delineation and publication of restricted zones. There are dedicated communication/press officers available at local and regional level to support veterinary services. The authorities also communicated information through social media in last small scale crisis, and the experts raised the relevance to be reactive on such communication channels in order to monitor public perception.

14. Authorities organise, at all administrative levels, drills and simulation exercises. As many staff as possible from across the entire administration are involved so that a sufficient number of people – including from other administrative areas – can be deployed in the event of a crisis. The exercises serve to enhance the technical skills of specialist staff. External animal disease experts are invited to attend and evaluate performance during simulation exercises. Communication experts, such as journalists, are also invited to attend and may organise interview coaching or mock press conferences with the participants.

4.3 ORGANISATION IN A FEDERAL COUNTRY

15. Despite the highly devolved level of administration, the German authorities showed a very integrated system of federalism with a willingness to collaborate resulting in a defined and well developed coordination methodology between federal, Länder and local level that can deliver the desired results.

16. This coordination element included a permanent contingency planning task force which was an inter-Länder structure, bringing the interests of the Länder into national decisions. This ensures participation of all Länder in technical matters via working
groups with the objective of reaching a harmonised approach and procedural guidance, and ensures effective consultation of the parties in case of crisis.

17. At political level, integration is ensured by a central crisis group, gathering Ministers of the Länder and of the federal level, in case of widespread outbreaks affecting several Länder, or when economic impact can be substantial (e.g. vaccination against foot-and-mouth disease). The decisions taken by the group are binding to all its members. Experts thought that the possible loss in rapidity of decision was largely counter-balanced by the benefit of reduction of the risk of inadequate decision.

18. Operational manuals contain, in addition to a nationwide part, specific parts adapted to each Land (with Länder-specific legislation, communication structures, instructions, contractual arrangements, adapted templates for official communications, etc).

19. The authorities underlined the availability of expertise for the whole territory through the existence of a 24/7 service at national level, being able to provide support from the beginning of a crisis (suspicion). A list of 80 available experts (epidemiology, crisis management, culling,...) nominated by all Länder is available for immediate deployment to any place of crisis. Financial and technical arrangements are in place.

20. In case of crisis affecting more than one Land, the decision to deploy the mobile crisis centre is taken by all Länder based on a set catalogue of criteria and a recommendation of Federal Research Institute for Animal Health.

21. Maximising the benefit and lessons from simulation exercises and drills represents a particular challenge in federal-type countries, issues of local and regional relevance needs to be clearly separated from issues of national relevance, while at the same time a feedback is of interest to other regions. The dedicated taskforce in Germany has an essential role in that respect.

4.4 WORST CASE SCENARIO

22. In case of major or developing crisis, all Länder can avail of the general disaster contingency planning, under the auspice of the Ministry of Interior and in accordance with the administrative provisions on staff work. Some Länder, recognising that their veterinary services do not have sufficient capacity, have decided they would respond systematically to all animal disease emergencies under this system. The Ministry of Defence is also involved in crises, as it is in charge of areas owned by the army and has its own official veterinarians. In addition, the army’s coordination centre provides mainly logistical support to the civilian side.

23. An agreement between all Länder governs the use rendering plants in neighbouring Länder in the event of large-scale outbreak. In some Länder, fixed fees are set for disposal in the event of epizootic disease by means of a framework agreement with the operators of rendering plants. This last piece of information was found particularly relevant by the experts, as many operators run sister-companies in other Member States.
On the longer term, the competent authority identified that the evolution of transmissible spongiform encephalopathies legislation could affect the overall capacity of rendering, by reducing the amount of material to be processed under specific conditions.

24. The contingency plans of the countries represented during this study visit do not cover specifically the deliberate release of strains of animal pathogens. There was a consensus among national experts that the technical control of the disease would not differ much, and that the planning of the criminal/terrorist aspects of such a scenario should be dealt by the relevant authorities.

25. The German authorities developed a calculation sheet of resources needed for each individual measure. This was possible as there is a high level of breakdown of tasks in the contingency plan. This, together with detailed contracts for killing and rendering activities, enables an analysis of the capacity of response to large events. Germany developed a mathematical model (stochastic modelling) to assess various scenarios. This enables the authorities to identify the need for financial reserve (in worst-case scenarios for foot-and-mouth, avian influenza). This also allows the identification and elimination of possible bottlenecks, such as the availability of sufficient staff and material for killing or cleaning and disinfection. Such bottlenecks may evolve in time. In the past, there was a tendency towards small slaughterhouses closing down, whose staff would be involved in killing measures. This development was taken into account in reserve agreements with farmers’ associations.

26. The result of such analyses allowed the competent authority of the availability of adequate milk processing capacity during a large foot-and-mouth disease outbreak. The authority emphasises that it might be necessary to provide the industry with an incentive to process (and market) milk from a restricted area.

27. The task force carries out regular surveys of the testing capacity of national and Länder testing facilities, in order to capture the maximum capacities for avian influenza, foot-and-mouth disease, classical and African swine fevers, and the testing procedures used to this end (serological, molecular biology and virological testing).

28. The national experts agreed that it was important to have laboratories prepared for upscaling (including validated protocols and minimum biosecurity standards such as the ones foreseen in Annex XV to the Directive 2003/85/EC2 on foot-and-mouth disease). This includes identify limiting factors at laboratory level when dealing with large outbreaks and preparing people (redeployment) and flows (both incoming, such as sourcing reagents (identify and get contract with providers, develop a shared reagent bank,...) and reception of large amount of samples, and outgoing such as diversion of other routine tests).

---

4.5 Vaccination

29. The national experts agreed on the importance to develop a vaccination strategy ahead of a crisis, and to have it discussed and validated by the stakeholders and the political level. They found simulation models very useful tools to assess benefits and drawbacks of various scenarios (target species, size of vaccination area, geographical dynamics of vaccination, fate of vaccinated animals…). They also found important developing a decision-tree for taking the decision to vaccinate (including at what level the decision is taken in a federal country).

30. In addition to epidemiological considerations, experts agreed that the analysis must include technical aspects (personnel and quantity of vaccine likely to be available), an impact assessment on the trade of affected commodities (which can be included in the simulation models), and the public and professional perception of alternatives. Many experts believe that mass killings will no longer be acceptable by the public in future outbreak managements.

31. In order to get good immunization coverage rates in a speedy fashion, experts reached agreement that strategy for vaccination must be tailored to each disease, and updated according to technical, scientific and regulatory environment (e.g. vaccines allowing differentiation between field virus and vaccine strains). It is difficult to get the industry on board when the implications (on trade) are not clear (e.g. avian influenza).

32. An essential factor of success of vaccination campaign is its fast roll-out, hence the interest of validated plans and detailed preparation. In case of vaccine not readily available, experts favour the option to order vaccine manufacture ahead of the final decision (as the cost of destruction, if vaccination is eventually not retained, would be lower than the cost of delayed vaccination).

33. Member States rely of the availability of antigens at the EU-vaccine bank (classical swine fever, foot-and-mouth disease). Attendees to the visit indicated the tendency to discontinue national vaccine bank (already done in Italy, under evaluation in Belgium, but not considered in Germany) and highlighted the critical importance of a careful assessment of needs and suitable detailed arrangements for supply to ensure adequate response in worst-case scenario.

34. Contingency plans considering the use of vaccine not registered in EU, availing of Article 8 of Directive 2001/82/EC, should carefully evaluate the options available, and define minimum quality validation and controls needed on such vaccines and each batch, as these aspects remain under the responsibility of each Member State. Such analysis would allow a better grounded decision and risk management for vaccines the efficacy and safety of which have not been sanctioned by a European registration.

35. Experts indicated that plans need to cater for practical aspects related to identifying and registering vaccinated animals (provision for individual identification when necessary, adaptation of the identification databases to register vaccinations).

---

5 CLOSING MEETING

On 23 September 2016 a closing meeting was held where both the German competent authorities and the four national experts presented their general impressions and preliminary conclusions on the study visit.

6 OVERALL CONCLUSIONS

Contingency planning needs continuous improvement, integrating best practices identified, and adapting to technical, socio-economic and regulatory evolutions. The difficulty to keep a focus on events that may never happen was raised during this visit.

The capacity of response of Germany in case of animal health crisis benefits from extended resources, thanks to the size of the country, and from provisions for collaboration and resource sharing. Although this cannot be replicated as such in other Member States, the visiting national experts have identified practical elements that they want to introduce in their own arrangements.

Following the study visit, the Chief Veterinary Officers of the four national experts were asked to report on the value of this study visit and on the possible incorporation of any of the actions mentioned above in their animal health emergency preparedness framework.

All of them agreed on the major relevance of this type of initiative to bring together officials with equivalent expertise from a few Member States who can openly and constructively share their experiences, not only during the study visit (during formal and informal times), but also afterwards by increasing their future cooperation. While the format was considered fit for purpose, suggestions to improve it included more focus on discussions, a reduced scope, and better coordination of presentations by the inviting country.

They highlighted the following elements that they were considering introducing or improving in their own countries:
- A Task-Force or a tool to better integrate national and regional levels, coordinate activities and identify synergies;
- Procedures and protocols, integrated in a quality management and information technology system, available down to field staff);
- Epidemiology expert teams identified and available at national level;
- A procedure to upscale workforce (with job description and resource allocation);
- The validation and approval of a vaccination strategy, involving all relevant stakeholders;
- The involvement of stakeholders in the development of a compensation scheme;
- Contracts with external service providers, including outsourcing certain activities (e.g. stamping out) and including inter-regional aspects related to such services;
- Elements to identify suitable spots for establishment of local crisis centres.
<table>
<thead>
<tr>
<th>Legal Reference</th>
<th>Official Journal</th>
<th>Title</th>
</tr>
</thead>
</table>