

GERMANY'S STATEMENT  
ON THE REVIEW OF THE PANDEMIC INFLUENZA PREPAREDNESS FRAMEWORK  
SESSION OF THE 140<sup>TH</sup> WHO EXECUTIVE BOARD, 27 JANUARY 2017

Germany aligns itself with the proposal read out by Malta on behalf of the European Union and its Member States. Germany welcomes most recommendations of the PIP Review Group without reservations. Germany agrees that the PIP Framework is a bold and innovative tool which is generally well implemented. The development of additional process measures, to enable better monitoring of key areas of work, might further accelerate the Framework's implementation and would allow for greater clarity on progress. We would like to point out that the animal influenza virus as potential influenza viruses with human pandemic potential should be considered until further progress.

We share the view that expanding the Framework to seasonal influenza would bear a bundle of consequences. These consequences still need to be thoroughly considered in advance to avoid deleterious implications on the timely functioning of the GISRS system and the public health response to seasonal influenza viruses. Therefore we agree that the current scope of the PIP Framework should remain on pandemic influenza at this time.

While noting the Review Group's recommendation on amending the definition of PIP Biological Materials to include genetic sequence data, we recommend that any decision on this amendment should be done through a continued analytic and consultative process. Potential consequences of amending this definition must be well assessed including the risk of delaying GSD sharing. In addition, further clarity is needed on realistic approaches to monitor the use of GSD and on models to share benefits for the use of GSD.

In this regard we would like to refer to the already well-established and widely used sharing mechanism of influenza virus GSD from GISAID. This sharing mechanism is applied for GSDs uploaded in EpiFlu™ and allows traceability of GSD. We appreciate that the Review Group underlined the critical role of the WHO Collaborating Centres and other key laboratories in the GISRS network. In this regard Germany welcomes the Review Group's recommendation to the DG to ensure that activities of GISRS and the PIP Framework remain closely aligned and integrated in the Global Influenza Programme.

We welcome the recommendation to further align capacity building activities under the PIP Framework to IHR implementation activities. Germany will maintain its commitment to global influenza preparedness and to the PIP Framework. One important pillar of this commitment is our partnership with GISAID. We will continue to host the database EpiFlu™ as an important tool for sharing of genetic sequences data in the spirit of the PIP Framework, ensuring fair, timely and transparent access to GSD in a sustainable way.

Thank you!

GERMANY'S STATEMENT  
ON SUBSTANTIVE ISSUES AND CONCERNS REGARDING THE PIP FRAMEWORK AND ITS IMPLEMENTATION  
Special Session of the PIP Advisory Group, 13 October 2015

Germany would like to thank the Advisory Group and the PIP-Secretariat for the invitation to this important meeting and the opportunity to express its views on some aspects that should be considered during the review process, especially the importance of capacity building and the sharing of influenza genetic sequence data (GSD)

Germany considers the PIP framework as a very successful instrument for fostering pandemic preparedness and contributing to an equal access to efficient countermeasures. However, there is some room for improvement.

The first years of the PIP process focused on epidemiological preparedness and the establishment of national influenza centers. In the next years, the production capacity for vaccines will be a key priority. The Global Action Plan to increase vaccine supply, GAP, has at least in some regions resulted in an improved rate of vaccination and availability of vaccines. We are, however, far from having sufficient production resources. Germany would appreciate it if both activities, namely the PIP process and the GAP, would co-operate with a view to increasing regional vaccine production technology and the development of more efficient vaccines that need a smaller amount of antigens.

Another aspect that Germany would like to highlight is the handling of gene sequence data.

The Federal Republic of Germany entered, in 2010, into a public-private partnership with the GISAID Initiative and has since hosted the publicly-accessible EpiFlu™ database, employing a unique sharing mechanism which ensures that inherent rights (e.g. IPR) of contributors of GSD are not forfeit. Access to EpiFlu™ is free and open to anyone who positively identifies himself or herself and agrees to respect the rights of contributors. This ensures fair and transparent sharing of GSD, making certain that all users mutually respect the rights of contributors and other users. Importantly, this mechanism provides contributors with the necessary incentive to rapidly share GSD, in the interests of Global Public Health.

The WHO Collaborating Centers for Influenza (WHO CCs) provide scientific oversight and, as stressed in last year's AG October Report, most GISRS laboratories use GISAID.

In relation to monitoring the use of GSD under the PIP Framework, access to GSD in EpiFlu™ can be traced, permitting lawful audits and providing the basis for an enforceability mechanism, and recourse of MS should the need arise. Like other MS, Germany is concerned about access to GSD of highly pathogenic influenza viruses and believes systems like GISAID make a valuable contribution to Global Health Security. It is of the opinion that GSD have to be part of the sharing and benefit schemes under the PIP Framework. Systems like GISAID contribute in this sense to Global Health Security.

While the PIP-FW does not address a generic term for such a database, we would like to point out that GISAID satisfies all the conditions of the Definition of an Open Access Contribution stated the Berlin Declaration (2003), in particular "to provide a mechanism to enforce proper attribution":

Germany understands that some aspects of the handling of data might need clarification and streamlining with the PIP process. We would be happy to contribute to the further development of the PIP process, in particular by contributing our experience with the data-sharing system.

Thank you for your attention!

# Implementation of Decision WHA70(10)8(b)

## Germany's comments on the „Scoping Paper“

### Overarching aspects

#### GISRS

Germany would like to emphasize once again the importance of GISRS in facing seasonal and pandemic influenza for the past 65 years. Germany therefore welcomes the recommendation to the DG to ensure that activities of GISRS and the PIP Framework remain closely aligned and integrated in the Global Influenza Programme.

One very important tool supporting the activity of the GISRS community is the sharing of genetic sequence data (GSD). In particular, it is crucial to promote the timely sharing of GSD. In this context, while the submitters of GSD are encouraged to share their data rapidly, they must be permitted to continue choosing where to submit their data, whether to databases with identified user access (e.g. GISAID), or to databases with anonymous user access (e.g. GenBank). Both types of databases are publicly accessible and their use is free of charge. Actually, most GISRS laboratories share GSD through GISAID, because its Database Access Agreement ensures that submitters retain their intellectual property rights to the data they submit.

#### Nagoya Protocol

#### Seasonal Influenza in the context of the PIP Framework

*Germany reiterates its view expressed at the 2017 EB meeting that expanding the Framework to seasonal influenza would bear a bundle of consequences. These consequences still need to be thoroughly considered in advance to avoid deleterious implications on the timely functioning of the GISRS system and the public health response to seasonal influenza viruses. Therefore we agree that the current scope of the PIP Framework should remain on pandemic influenza at this time.*

#### GSD in the context of the PIP Framework

Germany recognises the already well-established and widely used GISAID sharing mechanism for influenza viruses. This sharing mechanism as applied to GSD allows:

1. rapid sharing of the data (e.g. within 48 hours of uploading GSD of H7N9 in China Apr'2013),
2. acknowledgement of the data providers, and active collaboration between data providers and data user, and
3. full traceability of GSD.
4. sharing of benefits

The sustainability of the GISAID database, operating since 2008, is ensured by an agreement Germany signed in 2010 with the GISAID Initiative on the hosting of the database. This agreement was renewed in January 2017.

Germany is therefore of the opinion that the four key principles expressed in Nr 39 of the scoping paper are largely fulfilled by GISAID, as its established sharing mechanism already ensures these principles. As regards benefit sharing, Germany recognizes that this remains a complex issue that

needs further discussion, but likes to **refer to the GISAID sharing mechanism, where access and benefit sharing are already** embedded.

Germany would like to point to the reference in Annex 4 Nr. 9 and in Annex 5 – Guiding principles Nr. 9 – which is ambiguous and ultimately misleading, as it implies there is a requirement for GISRS laboratories to submit GSD “to both GISAID **and** Genbank”, although the PIP FW provides a clear choice of either or (**see 5.2.2 of the PIP-FW**). It is therefore important to highlight the distinction in the two examples of databases accessible to the public recognized by the PIP FW, that one database is only accessible to identified users having agreed to its terms of use (i.e. GISAID), while the other provides access to anonymous users (i.e. Genbank) without any requirement for identification, or any terms on the use of GSD. The implied requirement “to both GISAID **and** Genbank” denies submitters **their right** of sharing their data in a publicly accessible database of their choice. This choice is clearly stated in the FW itself in 5.2.2 and is granted to the WHO Collaborating Centres for Influenza in the core terms of reference (Annex 5, B. Nr. 5). This ambiguity needs urgent clarification in order to avoid uncertainty among the influenza community, which could lead to a slowdown in the sharing of GSD as it existed before the GISAID sharing mechanism became operational.



Ref.: C.L.27.2016



The World Health Organization (WHO) presents its compliments to Member States, Associate Members and regional economic integration organizations and has the honour to refer to C.L. 21.2015, C.L.10.2016 and the update by Dr Kaseba-Sata, Chair of the Pandemic Influenza Preparedness (PIP) Framework Review Group, to the Sixty-ninth World Health Assembly on progress to complete the Pandemic Influenza Preparedness Framework Review.

Member States, Associate Members and regional economic integration organizations are invited to the sixth and final face to face meeting of the PIP Framework Review Group to provide an overview of its preliminary findings. The meeting will take place on 29 August 2016 in WHO headquarters, Executive Board Room.

The meeting will be held in two sessions: from 09:30 to 12:30 for Member States only; and from 14:00 to 17:00 for Member States and stakeholders. The meeting will be Webcast and interpretation in the six official languages will be provided. Following this meeting, the Review Group will continue its deliberations in closed sessions. Further details on the review of the PIP Framework are available at: <http://www.who.int/influenza/pip/2016-review>.

Notes Verbales providing the composition of delegations must be sent by email to [pipreview@who.int](mailto:pipreview@who.int) by 12 August 2016. The following information for each participant is required: name, institution, title, and email address.

The World Health Organization takes this opportunity to renew to Member States, Associate Members and regional economic integration organizations the assurance of its highest consideration.

GENEVA, 22 June 2016

German Comments

Thank you Chair for providing this very informative debriefing. We are already looking forward to your more detailed assessment at the end of the review period.

Germany welcomes the work of the PIP-Secretariat and the initiated review process.

We are grateful that MS were given the opportunity to contribute to the work of the Review Group of the PIP Framework by answering the very relevant questionnaire of the review group; and Germany was happy to provide detailed answers.

We also welcome the most recent report of the PIP Advisory Group.

Please allow me the following comments to this report:

With regard to the recommendations made, we see the potential of some uncertainties regarding the interpretation and intention of single recommendations.

Certainly, we agree that **sustainability** of access to data must be secured. However, it might be questioned if “redundancy” of information provided by databases and the postulation of having “multiple databases” - as stated in recommendation 53 on page 8 (last bullet) of the report - are an indispensable requisite to reach this aim. Parallel systems should be avoided, as multiple databases might imply a duplication of efforts. We already have reliable and considerable access to data in the current databases. One example is GISAID-We would like to underline that one of the reasons for the German Government to host GISAIDs EpiFlu is to ensure sustainability to this database. The agreement with GISAID to do so is concluded without any time limit.

In addition, please let me highlight that Germany greatly welcomes the fact that WHO offers a platform for experts of WHO's Global Influenza Surveillance and Response System (GISRS) and WHO Collaborating Centers to actively participate in the discussion on the development and improvement of the matters mentioned before and other related issues, such as the development of Standing Operating Procedures (SOPs) for data providers and databases, which requires the inclusion of the experience of established databases.

Please let me ensure, that the PIP -Secretariat , the Advisory Group and the Review Group have our full support and confidence.”





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Comments from the Federal Republic of Germany to the WHO-paper “Draft optimal characteristics of an influenza genetic sequence data sharing system under the PIP framework”

Dear Anne,

Thank you for giving us the opportunity to comment on the paper mentioned above. Please find Germany's comments in the annex.

Best regards,

On behalf of the ministry

Dr. Karin Schwabenbauer

## Germany's Comment to the document "Draft optimal characteristics of an influenza genetic sequence data sharing system under the PIP framework"

### General comments:

1. We welcome the paper and the work of the TWG to compile the draft paper under consideration. Especially the Annex 2 with the Database Questionnaire Results is very helpful.
2. We are grateful for the very valuable support of the PIP-Framework Secretariat steering and facilitating the overall process.
3. One crucial aim of the current review process must be to further develop the PIP-Framework to find solutions for "issues relating to the handling of genetic sequence data" (PIP-Framework 5.2.4.), including developing mechanisms, in analogy to the sharing of biological material, allowing for benefit sharing.
4. One important point is to ensure clarity when addressing the different types of databases. As there are fundamental differences between GISAID EpiFlu and GenBank with respect to the inherent rights on GSD, the wording in the Annex 5, Guiding principles ....., Nr. 9 of PIP-Framework should be corrected in order to avoid the current ambiguity of the language. If a contributor choose to preserve his/her inherent rights while sharing GSD, he or she cannot upload the GSD in GenBank, a public domain database. This doesn't prevent a contributor to upload the GSD in both types of databases, if he or she chooses to give up these inherent rights.
5. The overall objective of the timely sharing of IVPP and access to vaccines and sharing of other benefits (PIP-Framework 2.) does apply for GSD and its products as well. Given the technological development of the recent years, adequate handling of GSD is even more important for pandemic (influenza) preparedness and response, including issues of biosecurity.
6. While describing optimal characteristics of a sharing system it is equally important not to jeopardise the freedom of choice of contributors when sharing their IVPP GSDs in databases. This aspect is of utmost importance for public health authorities as it contributes to the motivation to share GSDs in a timely manner.
7. Reliable and sustainable Databases hosting GSD are crucial for the appropriate handling of GSD. GISAID EpiFlu has proven to be a well-functioning, widely accepted and sustainable funded database, enabling the private, public and scientific sectors, including GIRS, to share GSDs in a responsible way. It is unfortunate that the paper has not addressed this existing sharing mechanism and how it already contributes to the PIP Framework. From our experience, most of the optimal characteristics and best practices,

described in this document, are already implemented by GISAID. It would be helpful to acknowledge this when considering sharing systems.

8. The different options outlined in the paper need some further elaboration. Only the addition of some background information on the advantages and disadvantages of the respective options outlined, would allow taking a firm stand for a certain option.
9. In our view the identification of aspects that are important to facilitate the access to the database for data providers and users, to ensure the quality of data as well as the security and sustainability of the system are important parts of a mosaic to fulfill this purpose.
10. As stated before in this context it is important to follow a clear line in terminology when defining the data base requirements that is consistent with the terminology in the PIP Framework itself. This is particularly important concerning the mode of access for users and the assurance of inherent rights for data providers.

## Remarks to the text:

### **Section I Obligations and Expectations of Data Submission**

“Optimal characteristics I.2”, Page 7

First paragraph: the term “publicly accessible database” is not precise enough. We would like to maintain the clear language of the PIP Framework as already mentioned, speaking of “public domain or public access databases”, with reference to GenBank and GISAID respectively. Furthermore, it is unclear what is meant and which databases are subsumed under the term “complementary databases with **different conditions of access**”.

Best practices:

Number 1: With view to the right of contributors to choose if their inherent rights are preserved when they upload GSD's to databases, we would prefer Option 2.

The term “freely with all” needs to be defined; if it corresponds to the term “public domain database” (see above), this should be clearly stated.

Number 2: Options 1 and 2: We do not understand the usefulness or practicality of ‘sharing’ all GSD after 6 months, or any other stated period (a virus may be classified as IVPP at some later date) with INSDC. This would mean that contributors of IVPP GSD who have chosen to protect their inherent rights to their data by submission to GISAID are forced to forego this option and renounce their rights! Since it is not permissible to transfer data from GISAID's database to another database, the data provider would have to upload the data separately to INSDC, thus negating the initial choice. This is, however, unnecessary as the GISAID's EpiFlu database is publicly accessible and has a high quality annotation and curation system for collecting all IVPP GSD, providing a very complete and qualified collection of all relevant IVPP GSD, meeting most, if not all optimum criteria, listed in this document, for sharing data under the PIP FW.

### **Section II. Timeliness of Data Submission**

Optimal characteristic II.1, page 8

In view of the best practice, number 2 under Section I, the meaning of the term ‘publicly accessible database’ from a practical perspective becomes unclear, emphasizing the need for more precise explanation of the terms used.

Optimal characteristic II.4, page 9

Option 2 is desirable and essential, as it acknowledges all who have contributed to the availability of the data, and is practical as it is already a condition of access to and use of data in the GISAID database.

Optimal characteristic III.1, page 11

Option 2: From the perspective of animal influenza experts number 2 is essential.