



**Food and Agriculture Organization
of the United Nations**

Final Meeting Report

Technical Meeting on the impact of Whole
Genome Sequencing (WGS) on food safety
management: within a One Health approach

The 9th meeting of the Global Microbial Identifier
(GMI9)

23- 25 May 2016
Rome, Italy

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Acronyms

AMR	Antimicrobial resistance
CBD	Convention on Biological Diversity
CDC	Centers for Disease Control and Prevention
CFSAN	Center for Food Safety and Applied Nutrition
DDBJ	DNA Data Bank of Japan
DNA	Deoxyribonucleic Acid
DOI	Digital Object Identifier
DTU	Technical University of Denmark
EMBL	European Molecular Biology Laboratory
EMPRES	Emergency Prevention System for Animal Health
EMPRES-i	EMPRES Global Animal Disease Information System
EPT	Emerging Pandemic Threats
EU	European Union
FDA	Food and Drug Administration
FAO	Food and Agriculture Organization of the United Nations
GMI	Global Microbial Identifier
IHR	International Health Regulations
IT	Information Technology
ITPGRFA	International Treaty on Plant Genetic Resources for Food and Agriculture
NCBI	National Center for Biotechnology Information
NGO	Non-governmental Organization
NGS	Next Generation Sequencing
OIE	World Organisation for Animal Health
WGS	Whole Genome Sequencing
WHO	World Health Organization

Executive summary

The 9th meeting of Global Microbial Identifier (GMI), which was preceded by a Technical Meeting on the impact of Whole Genome Sequencing (WGS) for food safety management: within a One Health framework, was held at the headquarters of the Food and Agriculture Organization of the United Nations (FAO), Rome, Italy on 23- 25 May 2016. The Meeting was attended by 175 participants from 50 countries including 26 developing countries, highlighting the significant level of interest in the topic by many experts and government officials. In its full 3-day programme, the meeting discussed benefits and potential drawbacks of WGS, considerations for developing countries, key needs for global actions and potential roles of international organizations, existing initiatives on WGS of pathogens, global capacity for identification and characterization of pathogens, issues relevant to epidemiology and surveillance, issues around global data-sharing and technical discussions on metagenomics.

WGS is a technology that crosscuts different sectors such as health, agriculture, food safety and medicine. This multi sector collaboration would aid in the efficient use of data to achieve the vital purpose which is to save lives. A key message that was elucidated at the meeting was that, with the continuous improvements in technology and infrastructure, more number of countries will consider and implement the technology, not only for food safety, but also for clinical and public health, for environmental investigations and for trade and economic reasons which will impact countries that overlook the technology. In most developing countries, awareness, as previously mentioned, remains low. Hence, participants from these countries recognized the strong need for to raise awareness and transfer the knowledge to their national counter parts in order to start discussions about considering and assessing the readiness to employ WGS for food safety management.

Year of Publication: 2016

Keywords

Food safety, microbiology, whole genome sequencing, WGS, microorganisms, pathogen, detection, analysis, foodborne outbreaks, antimicrobial resistance, AMR, data sharing, food security, food recall, public health, One Health, FAO, WHO

Technical Meeting on the Impact of Whole Genome Sequencing on Food Safety Management within a One Health Approach

The 9th meeting of the Global Microbial Identifier (GMI9)

23-25 May 2016, FAO Headquarters, Rome, Italy

Introduction

1.1 Background to the meeting

Genome sequencing, including DNA sequencing and Whole Genome Sequencing (WGS), refers to a family of novel analytical techniques which have recently emerged as new tools with the ability to completely revamp the current knowledge about microbiological diversity in relation to health, and microbial genetic information and its application for identification and tracking of microorganisms as used in food production, food control, clinical microbiology and epidemiology.

Genome sequencing has the power to revolutionize how we produce safe foods through making available an unparalleled depth of genetic information, with a level of precision not previously possible, that can help detect and identify pathogens, reducing risks to public and animal health from pathogenic organisms and improve agriculture through smarter food and better plant and animal breeding. While pathogen genomics has already been used widely in clinical and public health virology, with the rapid implementation of Next Generation Sequencing (NGS) in public health, research and food- and environmental- microbiology laboratories, the ability to generate pathogen genomic information has become within reach of bacteriologists as well. The possibility of quickly generating WGS for analysis of outbreaks for instance, with the rapidly declining cost of this technology, is leading to breakthroughs in the field.

WGS applications in food safety management, including the opportunities it provides for enhanced integration of information from other sectors, such as human and animal health, could contribute to enhanced consumer protection, trade facilitation, and food/nutrition security. However, outside high-income countries, the level of understanding regarding benefits and implications concerning the use of genome sequencing in the area of food safety significantly varies. Capacity implications, regulatory implications and resource implications need to be considered for those countries wishing to engage in this technology. It is a role of FAO's to keep all Members informed on the latest scientific developments in the food and agriculture sectors, and provide technical assistance to those who need it.

This meeting aimed to provide a unique opportunity for people in various countries to understand the current applications and the use of data generated from the genome sequencing and its implications on food safety management. The Technical Meeting was integrated with the 9th meeting of the initiative of Global Microbial Identifier (GMI), an informal global taskforce of scientists and experts who share the aim of making genomic technologies and informatics tools available for improved global diagnostics, surveillance, research and public health response (<http://www.globalmicrobialidentifier.org/>). FAO is one of the technical collaborators of GMI together with the World Health Organization (WHO) and World Organisation for Animal Health (OIE).

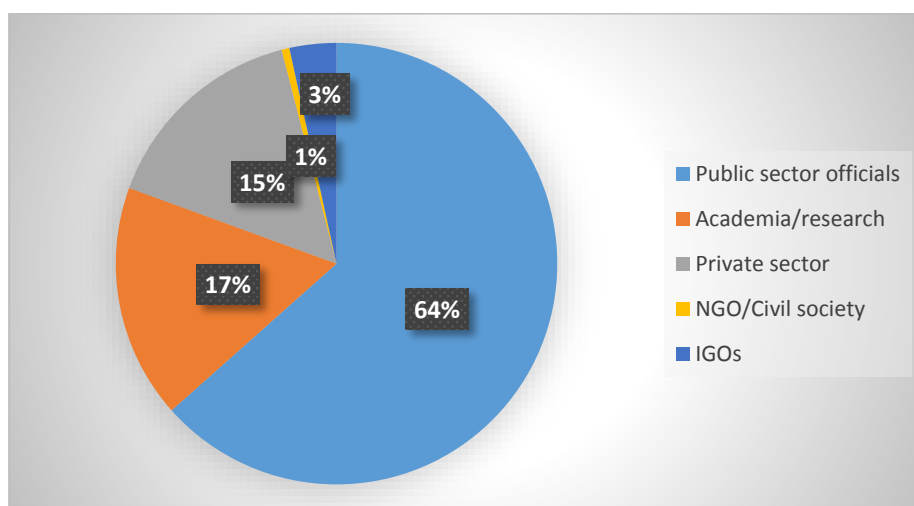
1.2 Objectives and scope of the report

While this meeting report is equally useful for any people both in developed and developing countries, including meeting participants, GMI members, experts from academia/research institutes, private sector, NGOs and the general public, the main aim for FAO to publish this report is to provide an overview of the meeting to the public sector officials in developing countries who were not able to participate in the meeting so that they are able to obtain key messages from the meeting in order for them to discuss, recognize and voice their needs with careful considerations for all stakeholders potentially impacted by the technology. It is also important to note that the emphasis of the meeting was put on applications of WGS for food safety within a One Health approach.

1.3 Overview of the meeting participants

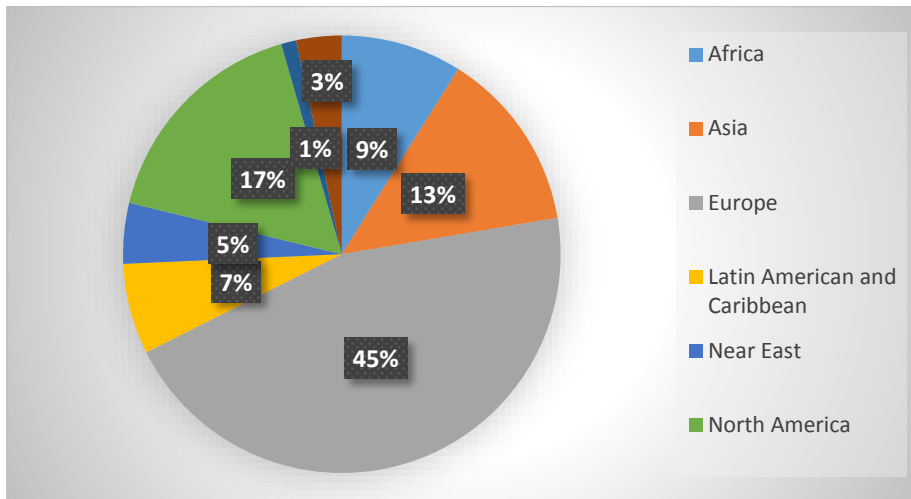
The Technical Meeting was attended by a total of 175 people (see Annex 1 for the list of participants). Among them, 64% were from the public sector, 17% were from Academia and research institutes, 15% were from the private sector, 3% were from the inter-governmental organizations and 1% was from NGOs/Civil Societies (Figure 1).

Figure 1. Sector distribution



As shown in Figure 2, almost half (45%) participants were from Europe, followed by North America (17%), Asia (13%), Africa (9%), Latin America and Caribbean (7%), Near East (5%) and the Pacific (1%). Inter-governmental Organizations (3%) were not counted for the consideration of the geographical balance.

Figure 2. Regional distribution



Participants are from a total of 50 countries and among them, 24 were developed countries and 26 were developing countries.

1.4 Structure and proceedings of the meeting

The meeting was held in three days, with the 9th meeting of GMI for 2 days, preceded by a one-day FAO session (see Annex 2 for the meeting agenda). The FAO session provided an overview of the Technical Paper entitled “Applications of Whole Genome Sequencing in food safety management” developed by FAO in collaboration with WHO (<http://tiny.cc/WGS-TP>) and discussed benefits and potential drawbacks of WGS, considerations for developing countries and key needs on global actions and potential roles of international organizations. On 24 and 25 May 2016, the meeting included the topic of currently available systems for WGS, global WGS capacity in identification and characterization of microorganisms, initiatives and activities related to epidemiology and surveillance, issues around international data-sharing and activities and global trend on metagenomics. There were two break-out sessions for 4 GMI Working Groups: Working Group 1 focuses on the issues around political challenges, outreach and building a global network; Working Group 2 works on projects on repository and storage of sequence and meta-data; Working Group 3 works on projects on analytical approaches and Working Group 4 conducts ring trials and quality assurance. For more details about GMI WGs, visit <http://www.globalmicrobialidentifier.org/Workgroups>.

2. Key messages from the meeting

2.1 WGS as a tool

The opening lecture first introduced the technical paper on the application of WGS in food safety management, developed by FAO in collaboration with WHO, to explain what WGS is and how some countries are using the technology in the area of food safety. It is important to highlight that throughout the 3-day meeting, the focus of the meeting was not on the technology itself. Participants recognized that WGS is just one of the newly emerged laboratory tools to sequence DNA. During the series of panel discussions, various experts described the simplicity, precision, speed and flexibility of WGS and how it is advantageous over the multiple traditional culture-based methodologies in routine clinical and food bacteriology combined. At the same time, they clearly pointed out that it does not replace

the need for basic epidemiology, health surveillance and food monitoring. WGS simply provides the sequence of any organisms and it is in use in various sectors not only in food safety and public/plant/animal health, but also in the pharmaceutical sector and even in criminal investigation. During various presentations and discussions, participants recognized how sequencing alone, which is the simplest part of the process, is not enough and the importance of taking an integrated approach with collaboration among clinicians, laboratory experts, epidemiologists, food/environment inspectors and so forth to fully benefit from the technology in order to achieve the goals of food safety management, which are to save lives and reduce economic losses.

2.2 Impact and implications of employing WGS for regulatory frameworks

Once the focus of the meeting became clear to all participants that it is important to discuss the impact and implications of the use of WGS for food safety rather than the technology itself, participants quickly recognized that there are various factors that affect, and are impacted by, introducing WGS for food safety management. In particular, participants from developing countries have expressed the strong need to discuss capacity implications, regulatory implications and resource implications prior to considering possible engagement with this new technology.

2.3 Overview of the benefits

The opening lecture introduced four case studies to highlight practical applications of WGS in food safety management in four countries and benefits which were underpinned by several prerequisites. In the United States, the real-time WGS-based health surveillance and food monitoring for *Listeria (L.) monocytogenes* led to the rapid identification of the source of illness, more precise and faster than traditional subtyping methods. The regulatory response to this was significantly accelerated and additional cases likely prevented. In Denmark, routine food and environment monitoring for *L. monocytogenes* together with health surveillance using WGS succeeded in linking apparently sporadic cases over a long time period and the underlying outbreak source was identified and eliminated. In England, a WGS-based investigation identified the root cause of a *Salmonella* outbreak and prevented future outbreaks. This case study also highlighted the importance of the availability of WGS data from multiple countries, demonstrating how global sharing of WGS data could enhance the response to international foodborne outbreaks, to further protect public health and identify a particular source of contamination. The experience shared by Kenya showed the potential usefulness of WGS in developing countries, however having WGS data in itself was not sufficient and there was a need identified for a significant amount of advocacy and understanding of both advantages and possible disadvantages of using the technology in countries with limited capacity and resources.

An expert from Denmark discussed that WGS techniques are relatively easy to learn and a single methodology can be applied for a large number of pathogens, thus minimizing training requirement. Performance of WGS, especially its precision provides better confidence in identifying clusters and linking sporadic cases. In Denmark, WGS has replaced multiple laboratory serotyping procedures as it comprises of one microbiology workflow for most of the similar conventional tests. An expert from Tanzania stated that from his own experience to sequence a pathogen, WGS results can be obtained quicker (within a few days from submission) than the traditional molecular typing methods. The universal nature of WGS

makes it efficient to sequence targeting any kind and multiple number of organisms as the method is not pathogen-specific. He said that this feature is crucial especially in developing countries to support enhancing effectiveness of the national food control systems.

During one of the panel discussions, participants recognized multiple benefits of using WGS not only as a regulatory tool but also for numerous offshoot applications including supply chain management, quality assurance, and process evaluation. WGS helps efficiency in the process of decision making for outbreak management. When there is an alert regarding an imminent food safety related emergency, it is important for risk assessors to screen the available data rapidly, to pinpoint what the likely/exact cause of the problem so that risk managers are able to make an appropriate decision on the actions to follow. Given the time constraints present during such emergencies, the universal nature and the ease of obtaining the sequence of the organism with WGS makes it a very efficient process for the risk assessors to rapidly provide precise and science-based scientific advice to risk managers. As one of the biggest benefits of WGS with its high specificity and sensitivity, it provides greater confidence in regulatory decisions made by competent authorities in food safety, public health and agricultural sectors, as well as those decisions made by food producers and providers. Using WGS is likely to help competent authorities ensure that they are in compliance with relevant international trade agreements and practices, and thus it results in trade partners having increased confidence in a nation's food control system. It was also noted by the participants as a benefit that WGS provides a basic common language that are suitable for exchanging electronically around the globe. Panelists discussed that this is an added value over current methods of global data sharing, because it provides the context for local investigations, using globally available data.

2.4 Cost – is it a benefit or a drawback?

The issues around cost of WGS were discussed at length with a variety of views from the different participants. Experts who are already applying WGS for food safety management stated that WGS is cost effective, because the routine use of the single sequencing step will eventually replace multiple traditional subtyping methods necessary to characterize pathogens, which vary according to the pathogens of interest. Participants recognized that the cost of sequencing and analyzing the sequence is rapidly declining over time, even though the cost of the reagents and initial investment are still too expensive for many countries. A developing country participant explained that scientists and researchers from low-income countries are very sensitive about the cost implication of the methods used in their researches because it directly affects the possibility of obtaining research funding. If there is a clear indication of the cost-effectiveness as well as the declining cost of WGS itself, policy makers will be highly interested in considering application of this technology in food safety management, especially in the countries with limited resources.

However, some developing country participants stated that the cost is still high even in their national contexts. Also many participants agreed that in countries where there is no suitable facility or equipment in place for WGS, and/or no sufficient capacities in using/interpreting WGS, implementing the technology requires a high cost of initial investment in setting up and maintaining of the working environment for the routine use of WGS for food safety management. Several participants explained that their countries have a single, centralized lab facility for different sectors (plant genetic resources, animal health, public health,

fisheries, forestry, etc.) to use WGS for different purposes and such arrangement could be a possible solution for developing countries to solve their monetary problems.

Thus the discussion was concluded with a common understanding that WGS cost can be both a benefit and a drawback at the same time. If a given country already has an effective food control system, WGS will likely reduce the cost of food safety management, and if the country still needs to strengthen the basic food control system, it can be expensive. However, participants also realized that such monetary calculations are not comparable to the number of deaths, illnesses, hospitalization that occur during serious foodborne disease outbreaks. It is difficult to obtain concrete figures to measure the overall food security cost since economic and trade implications associated with WGS need to be considered. In other words, the eventual cost of not employing WGS for food safety management is difficult to estimate. Importantly it was recognized that a full (economical) cost-benefit analysis of applying the technology routinely in food safety (and health) sectors is still missing.

2.5 Overview of the potential drawbacks and challenges

While participants recognized clear benefits of WGS learning through the case studies and panel discussions, certain drawbacks and challenges were highlighted by the many participants. An expert from Thailand flagged the issue around the pace of advancement of the technology. He is currently researching on the technology and he expressed his concern about the time required for researchers in developing countries to obtain the funding to purchase the necessary equipment and supplies while on the other hand, researchers in developed countries might move ahead and proceed with advanced versions of the equipment. Due to budget constraints and allocation of resources in developing countries, participants are concerned the possible discontinuation of the funding at any time from the government which would affect the sustainability of using WGS for food safety management. As WGS is relatively new, many people who have been recently introduced to the technology may consider that WGS is extremely novel, thus it must be expensive. This perception of cost can be a real barrier in considering adoption of the technology into day-to-day food safety management.

Participants from both developed and developing countries discussed the difficulties experienced with data storage. The WGS data, which are generally stored in the FASTQ format in the data repositories, are very big the accumulated file size can be in the range of tera- and peta-bytes. It requires both physical space for data servers and virtual space for server storage disks and chips thus can be costly to store the WGS data in local data repositories. A participant from Singapore explained how WGS data is sometimes handled and transferred in a large-capacity mobile hard drives to be shipped to another location even within the same country. This process is necessary for applications of WGS in food safety management, because WGS is only effective when matching the relevant data from clinical isolates and food/environmental isolates is done properly and in order to conduct such matching process, the relevant data must be shared among different sectors (i.e., health and food). In addition to the physical transfer, the large amounts of WGS data often need to be transferred through the internet. A participant from Ghana flagged that this creates another challenge for developing countries where there are frequent interruption of power supply and low internet bandwidth to upload, use or analyze the data.

Earlier, experienced experts spoke about the positive impacts on improved access to trade by using WGS in food safety management. However, some participants from developing countries expressed concerns over possible imbalance of trade opportunities. If some countries use WGS for food safety management, these countries are likely to apply the same system for imported food. However, many developing countries with limited capacity and resources may not be able to provide the same level of WGS-based data on food products they export. A commitment at the global level becomes essential for countries with established WGS capacity to assist developing countries to fully benefit from the technology without causing trade disputes. Panelists pointed out that some challenges will emerge around the issue of trust on the part of data producers, generators and collectors regarding the use of their data. Participants were apprehensive about data holders being over-protective about the data which leads to data sharing becoming problematic – even within the same country.

Among all potential drawbacks and challenges discussed, the biggest concern was on the need for basic epidemiology, surveillance and food monitoring/testing infrastructure for effective national food control systems. Many developing countries are still in the process to develop such basic functional surveillance and food monitoring systems. If there is no isolate to analyze, the implementation of WGS has no usefulness. The equally important element is to have certain functional authorities/agencies to act on the data produced through WGS. In countries where there is no such infrastructure, establishing effective food control system that include routine collection and analysis of clinical, food and environmental samples is a key pre-requisite to implementing WGS. While all identified potential drawbacks can be overwhelming, participants recognized that there are always ways to minimize the impact of such drawbacks, often through global actions. Participants discussed the need to discuss various approaches to address the problems at the global forums and to seek positive partnership and collaboration around the world.

2.6 Challenges for data interpretation (bioinformatics)

It is important to note that almost all participants understood that the sequencing process itself is quite simple and does not require over-extensive training or in-depth understanding of what it is if it is only for obtaining the WGS data. However, the common understanding was that interpretation of WGS data (bioinformatics) is not at all simple and requires specific expertise therefore can pose a challenge in any countries. Different views were expressed by different participants on the needs of developing capacity of bioinformatics. Several participants expressed their concerns about the lack of bioinformaticians in their countries for the analysis and interpretation of the WGS data obtained as some experts emphasized the need for a robust background in bioinformatics and capacity in order to fully benefit from WGS. These experts stated that conducting several workshops for training would not be sufficient as practical skills and detailed knowledge need to be developed. On the other hand, some participants said that having a globally accessible online repository-bioinformatics tool that can automatically analyze, match and interpret the obtained WGS data at the same time the data is put in the repository can make the in-depth training unnecessary. This argument was not favored by many others who stressed the importance of having a certain level of capacity with the basic principles of bioinformatics for the

purpose of the validation of methods, quality assurance of WGS data and the future development of the tools and analysis methods.

Regarding the issues around bioinformatics, participants further discussed several potential risks involved in handling and using the WGS data.

- Relying solely on the WGS data to make food safety management decisions is not yet recommended as sequencing results can contain errors, including sequence-specific errors. There are ways to reduce the frequency of such errors, and further optimization of the technology is expected to limit this occurrence. Also errors during the interpretation process, including human errors should be considered. False negative results due to poor analysis could lead to bad decisions which could damage the credibility of a country's food control system. Experts suggested that proficiency tests conducted by labs around the different regions and countries could be a potential solution to avoid such situations.
- Participants discussed the possibility that WGS as a new technology could give rise to misperceived ideas. Certain countries may think that WGS is the solution to all their food safety problems, whereas in reality, it is only a tool to facilitate interpretation and identification of sequences. On the other hand, certain countries could be hesitant to consider the new technology due to the false assumption of it being extremely expensive or difficult to implement.
- Sensitivity of WGS is surely advantageous as it can provide precise results which helps in identification of the exact strain during an outbreak investigation. However, the same sensitivity can lead to detecting a trace level of microorganisms, in every environment, and possibility to share such results in a public domain can make some people hesitant to use WGS and openly share relevant data.
- WGS provides the genotype of the organism, which is sufficient in order to detect pathogens. Participants discussed the possibility that the easiness of WGS may trigger the scientific community to underestimate the value of phenotyping which assists in understanding the behaviour, characteristics and interactions of the organism with other organisms. Significant scientific development may be gradually lost if phenotyping is not carried out alongside with genotyping and serotyping, which is conducted to establish a distinct variation within a species of bacteria or virus or among immune cells of different individuals.

2.7 Issues around global data sharing

It was no doubt for any participants that there are clear benefits of having access to globally shared WGS data for managing both local food safety issues and international outbreaks. Experts explained using various case studies, how effective and useful the real-time globally shared WGS data is when there is a food safety problem linked to internationally traded food products to identify the root cause of the problem. The analysis results from such WGS data are particularly useful for the risk managers who are tasked to take rapid and appropriate interventions to minimize negative health, social and economic impacts. In a long run, analytical studies of the pathogens based on accumulated WGS data will be able to pave way to wider possibilities in identifying the trend of pathogen movement, mutation and evolution.

While such benefits of having access to globally available WGS data are clear to all participants, there were diverse attitudes observed towards how the mechanism of such global data sharing should be constructed. Some supported making a rapid global agreement on the mechanism and start sharing relevant WGS data for global good as early as possible, and some were reluctant until eventual and various implications of sharing their data become clarified.

Several industry experts expressed a concern if WGS data sharing becomes mandatory for food industry due to its additional cost. Some experts explained that the latest types of sequencers have automated functions to upload the data onto the database of a choice thus there can be no additional cost required. However, such new sequencers can be expensive for small and medium enterprises thus this may not be true and uniform to all the food companies. Industry experts also raised a concern over real-time global data sharing, since there may be a liability issue once they are aware of any contamination in their facility. Some participants stated that it would create a challenge for many developing countries without standard procedures for the regulatory authorities to work with the industry to manage food safety issues, because they will not know the exact steps and approaches to take immediately after being notified on detected food safety contamination from food industry based on the WGS data. Thus once again the importance of having a functional and inclusive national food control system as a prerequisite to implementing WGS was confirmed. At the end of the discussion session, participants from the private sector expressed their willingness to adopt the technology, to address such data-sharing challenges, and to hold positive attitude to assure food safety as ultimately it is everyone's interest to protect public health and maintain safety and quality of food.

Panelists discussed the following possible ethical, social and legal challenges that regulators and public sector officials may face in terms of setting up a mechanism for global data sharing.

- 1) Ethical and social issues: Ethical and social challenges exist on sharing local data globally. In particular, within the context of inequities and different levels of capacity. The perception that data that is produced in low income countries is used by high income countries without due credit triggers ethical concerns. Another challenge is that scientists may choose to hold onto their data to avoid other scientists unethically using their data for publication. A functioning and effective global WGS data sharing mechanism will only be possible if there is a system that gives all data submitters the assurance that sharing their data will not work against them.
- 2) Legal issues: A few global legal frameworks, such as the International Health Regulations (IHR) and the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization to the Convention on Biological Diversity (hereinafter referred to as Nagoya Protocol) exist.
 - a. IHR: Since the data contains meta-data, privacy and confidentiality remains a key issue. IHR provides the structure for sharing meta data with information on individuals as it is critical information in managing serious outbreaks. Therefore it is not entirely impossible to handle such sensitive information at the global level, but many experts consider that IHR is extremely purpose-specific and not easily applicable for other purposes. Some participants felt that as the complexity of each country's legal structure and country context is

prominent in this area, developing a globally harmonized legal framework for all types of WGS data sharing for all countries is not a realistic solution.

- b. Nagoya Protocol: Some experts discussed that ever since the launch of the human genome project, there has been a rapid and drastic increase in genomic data sharing. Therefore it is no longer possible to share data with a few colleagues on a trusted basis. Various experts discussed the meaning, implications and impact of the Nagoya protocol and agreed that further analyses at the global level are necessary as it can be a major issue that might challenge effective global WGS data sharing. Experts suggested the GMI initiative to draft a position paper to stimulate international community to consider reviewing the protocol so that it successfully serves its original purpose of global benefit of data sharing. The panel discussion on the topic was concluded with a common understanding that having global guidance/actions from international organizations would be valuable to discuss the process, mechanisms and possible solutions for flagged concerns, balancing with widely acknowledged benefits of global data sharing.

2.8 How WGS crosscuts and is relevant to a One Health approach

Panelists discussed the importance for all stakeholders to recognize that WGS is a tool that can be used in multiple sectors, and it is possible that in a given country, even if the food safety sector has not yet employed the technology, WGS may be already in use in many other sectors, such as agriculture, health, environment, trade, economy, legal and research sectors. It is important to fully understand this cross-cutting nature of WGS, because using WGS in a single sector alone or multiple sectors in silo is not effective. It is particularly true for foodborne disease outbreak investigations where all health, food and environment sectors need to collaborate in order to have a match in data. In the area of application of WGS to food safety, a One Health approach is significantly relevant. A participant from Ghana stated that in his country, the medicine and health sector advance at a faster pace when compared to the agriculture and food sector. Another participant stated that it is opposite in his country, the agriculture sector is more advanced than the health sector due to the Government's resource allocation. Thus, the level of capacity is different among various sectors in different countries. Participants discussed that having separate protocols, guidance, rules and mechanisms for WGS in each sector is not effective and can be costly.

An expert shared his experience that multi-sectoral collaboration is not always as easy as it is hoped to be. However, by following pragmatic solutions, gradually establishing collaborative partnerships at regional and global levels across the sectors, countries and entities would create positive synergies. Sharing the expertise and knowledge across the sectors both within a country and across the countries is beneficial. When such multi-sectoral collaboration is a challenge, the individual willingness becomes one of the important elements to look beyond the challenge itself and work towards the results. The willingness to be patient and to collaborate with other persons, sectors, countries without the feeling of jurisdiction and personal ego at the individual level will help in succeeding in effectively identifying synergies among different sectors thus applying the One Health approach to food safety management will also be a success.

The panel discussion was concluded with a common understanding that it is essential for food safety sector officials to look into other sector(s) that might have been already advanced in use of WGS to consider a possibility in working together to set up the process and guidance. This is not only about national-level collaboration and seeking effective collaboration at regional and global levels is encouraged.

2.9 Future prospect of the technology

A large number of participants of the Technical Meeting indicated the high level of interest in the topic of WGS for food safety management and several experts confidently stated that WGS is the future to food safety management and is here to stay. Some developed country participants have already been benefitting from the technology and have been moving forward with it. Some other participants are still careful and prefer further analyses before jumping to the technology. Thus the pace at which the different countries are advancing is varied. A key message that was elucidated was that, with the continuous improvements in technology, infrastructure and capacity development, more number of countries will consider and implement the technology, not only for food safety, but also for many other reasons including trade and economic reasons which might impact countries that overlook the technology. In most developing countries, current level of political awareness of WGS remains low. Hence, these participants from developing countries recognized the strong need for raising awareness and transfer the knowledge to their national policy makers in order to start discussions about considering and assessing the readiness to employ WGS for food safety management. All realized that no matter what they decide on their vision around WGS implementation in their countries, certain countries will keep advancing with WGS for food safety management. Many developing country participants were positive about taking a step-by-step approach to first clearly understand the capacity development needs, and then to address the gaps will lead them to a better situation where they can realistically consider pros and cons of employing WGS for food safety management.

3. Considerations for developing countries

Two sessions of Round-Table meeting with 19 participants from 16 developing countries were held as a sub-session during the lunch breaks on the first two days of the Technical Meeting to understand the needs of developing countries. The participants were from China, India, Thailand, Vietnam, Philippines, Mongolia, Sudan, Egypt, Botswana, Ghana, Mozambique, Namibia, Iran, Mauritius, Bangladesh and Tanzania. This section provides a summary of these two sessions and the detailed proceedings of the meeting is attached as Annex 3.

3.1 Current situations and challenges

All 19 participants said that there is an established framework for national food control systems in their countries, but there are many challenges associated with its functionality. Food safety is surely one of the national priorities for many developing countries, but when it comes to resource allocation on the topic, it is often underestimated by policy makers unless there is an ongoing food safety emergency situation. Participants from Ghana and Iran stated that diseases caused by HIV AIDS, Malaria and Tuberculosis are often seen as higher priority than foodborne diseases. Participants from India, Mozambique, Namibia and Botswana said that in their countries, priority of food safety depends on the commodity's

trading status. Food safety of products that are exported in a large amount are generally considered as high priority, thus creating a double standard. While many participants recognize the importance of food safety in their countries, they are concerned that policy makers may not invest much on the topic unless there is a strong evidence-based study clearly explains why the Governments should be allocating resources. A participant suggested international organizations to assist in developing a set of indicators to assess the effectiveness of the national food control systems therefore the capacity development needs can be objectively measured and the impact and importance of food safety in developing countries can be effectively highlighted. This can be done with a vision of considering the use of WGS in the future and the results will be useful in making the policy makers aware of the reality and convincing them to invest in food safety. While the importance of a One Health approach is more and more recognized in the main programme of the Technical Meeting, participants are concerned that their systems are too fragmented thus inter-sectoral/inter-agency collaboration can be a significant challenge. Lack of coordination between the different sectors involved in the national food control systems affect the effectiveness of decision making.

When discussing the readiness of the countries, a participant from China explained that in her country, WGS is successfully employed with around 150 strains being sequenced on a daily basis with ongoing training for bioinformatics. Participants from India, Thailand, Iran, Vietnam, Tanzania and Mauritius stated that their countries are ready with sufficient infrastructure to employ WGS for food safety management. However, since WGS is used only in their research institutions at present, cost- benefit issues and feasibility in the long run need to be assessed before considering the use of the technology for regulatory purposes. Participants from Mongolia, Philippines, Bangladesh, Egypt, Sudan and Ghana explained that their countries' lab practices need to be strengthened and that they require various training of human resources in the relevant food safety departments before considering application of WGS in food safety management.

3.2 Identified needs from developing countries

Many developing country participants requested FAO to assist them in conducting initial workshops/meetings to raise awareness among the relevant national agencies, policy makers and stakeholders. Some participants think text-based materials such as guidelines and manuals for feasibility assessment would be useful to systematically understand the minimum requirements and necessary steps for the implementation of the technology. Participants also raised the need for globally harmonized guidelines and calibration of the WGS technique. Assistance to establish an informal international collaborative group for WGS was proposed for future partnerships and assistance from other countries, therefore, participants decided to already start an informal discussion group with the 19 members of the Round Table sessions. Regional and sub-regional grouping approach was also suggested as a beneficial way forward, especially to countries with similar situations. Chinese participant stated that through the mechanism of South-South Cooperation, it would be possible to organize a training workshop in China for this group on the basics of bioinformatics and all participants were positive about the offer.

All 19 participants agreed with the suggestions made in the Technical Paper on taking a step-by-step approach and conducting feasibility assessment to make an informed decision

whether or not employing WGS for food safety is beneficial, and if so, when to employ. There is also a need to sensitize both regulators and scientists in reference laboratories as well as in universities to the potential of WGS.

3.3 Practical tips for developing countries

During the main session of the Technical Meeting, several participants asked experienced experts to provide some practical recommendations and tips for developing countries when considering applying WGS for food safety management. Experts suggested the followings:

- First, read the Technical Paper developed by FAO in collaboration with WHO to understand the minimum requirements to implement WGS for food safety management.
- Strengthen multi-agency collaboration because food safety involves foods, clinical, veterinary and environmental/food/water agencies and for the successful implementation of WGS, it is essential to achieve a balance of clinical and food/environmental samples.
- Conduct pilot studies using WGS in combination with existing approaches to outbreak investigations to help everyone get comfortable with the approach.
- As a pilot, find a way to upload WGS data to the existing global databases such as NCBI, EMBL, or DDBJ. IT/computing costs will quickly consume resources, often to such an extent that it will inhibit sequencing throughput.
- Obtain bioinformatics help, either in-house or through a trusted partner. Request technical assistance from international organizations to have sustainable programme for training on bioinformatics.
- Set up partnerships with fully technologically developed laboratories to transfer knowledge between in a direct and collaborative way. This can be done online as well.
- Countries that are not ready to buy their own sequencers can submit isolates to partner country/laboratory for WGS analysis and work together to report and analyze data for joint moves forward in WGS capacity building for food safety using WGS.

4. Needs for global actions and potential roles of international organizations

Several participants expressed their appreciation to GMI to provide the series of informative discussion forums and they stated that the present meeting hosted by FAO was particularly useful in discussing the data governance issues and legal matters around harmonization and standardization at the global level. Experts stressed the importance of having access to a global platform to respond to food safety incidents effectively in time. Data sharing and building partnerships are essential as foodborne diseases can easily be internationalized, and do not stay one region/country. Participants asked international organizations to continue providing similar global forums to discuss further relevant issues. Building a network of networks would enhance sharing and learning from other countries' best practices with respect to WGS and data sharing.

Participants from developing countries recognized that for most of them, the first step would be to strengthen their national food control system and build capacity so that minimum requirements can be met to consider applying WGS. These participants requested FAO and other relevant international organizations to provide technical assistance in assessing capacity development needs in strengthening national food control systems (laboratory, epidemiology, food monitoring/testing, health surveillance, policy and regulation) and infrastructure, defining food safety priorities and the utility of WGS for priority pathogens.

Experts stated that for developing countries that are still in the process of creating a legal framework for a food control system, lessons can be learned from other experienced countries. Newer systems can be built to focus on identifying outbreak source and thus prevent diseases using integrated surveillance rather than using traditional approaches that do not address the problem directly. Experts stated that facilitation of a public-private collaboration by international organizations and collaboration with similar countries would make more economic sense and result in building a more effective framework. Many developing countries participants stressed the need for harmonized guidance in overcoming technical barriers to trade as they are cautious of how their countries will be affected by it given the increased pace of the advancement of the technology. Participants suggested that bringing up the issue at high-level meetings at the relevant international organizations' governing bodies might be an effective first step to discuss WGS as an opportunity for integrated surveillance and how it can be financed for application in developing countries.

The current uncertainties in the interpretation of the Nagoya protocol for access and benefit sharing of plant genetic resources was also highlighted as an issue that require global actions. Experts from the International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA) explained that data sharing and data linkage are important issues that require global actions and spoke about the initiatives taken by them. ITPGRFA works with CBD Secretariat to the Nagoya Protocol to assist countries to have neutral, support mechanisms for data sharing. ITPGRFA has also discussed the importance of setting up the system for Digital Object Identifier (DOI) which provides a universally identifiable set of descriptors for sequenced data. The experts from ITPGRFA explained that there are ongoing works in the creation of a global portal that will serve the DOI and provide search facilities for sequenced data for plant genetic materials. Currently ITPGRFA members are holding a series of global level discussions on the use of the materials, parameters on data sharing and availability of information on the public domain.

Experts working on sequenced data for animal diseases at FAO stated there have been ongoing works on integration of different databases for animal disease pathogens. They have facilitated linking of information of NCBI, OpenFlu database and Empres-i. Different types of non-sequencing related information are also available in the databases, for example, Empres-i contains epidemiological information while OpenFlu contains virus related information. FAO has a role to ensure that the information shared on the systems make sense when they are put together. Experts explained that this linking process required a careful preparation due to its difficulties in integrating the different format and contents of the linked databases. FAO also provides sequencing services for animal disease pathogens with an online ordering system with a confidential portal for each country to create their

own set of information on sequences. This is particularly useful for developing countries that lack the resources to carry out their own sequencing. Experts discussed various global activities conducted at FAO in the animal health sector can be expanded and/or replicated in the food safety sector and many countries, especially developing countries would benefit from such initiatives.

5. GMI Working Group Sessions

5.1 Political challenges, outreach and building a global network (Working Group 1)

General developments since GMI8:

The general interest in and recognition of GMI scope and activities has continued to increase over the last year. According to its Charter the GMI consists of 1) The Platform (organizing body, including the Steering Committee), 2) The Community Network (all individuals and organizations that subscribe to the GMI Website by filling in a profile), and 3) The Work Groups (Four WGs – originally five).

The following issues were specifically discussed at the WG1 break-out Sessions at GMI9:

1. Issues related to the free exchange of microbial genomic data incl. Nagoya protocol issues (see Haringhuizen paper Attachment 1)

One of the essentials in the 1993 Convention on Biological Diversity (CBD) is the principle stated in article 3, saying: *States have, in accordance with the Charter of the United Nations and the principles of international law, the sovereign right to exploit their own resources pursuant to their own environmental policies.* Microbial genomics are stated as part of these resources. This means that the answer to who owns bacteria and viruses and who may do what with them, is to be found in domestic laws and regulations and may differ between countries.

The Nagoya Protocol is a supplementary, legally binding agreement under the Convention on Biological Diversity (CBD 1993). The Nagoya Protocol (NP) is intended to create greater legal certainty and transparency and help ensure benefit-sharing regarding the utilization of genetic resources. The NP applies to all non-human genetic resources originating from the natural environment, including microbial genetic resources. Whether the utilization of genetic resources will include the digital genetic information of whole genomes is yet unclear. In practice, the NP suggests an obligation of a research institute, when receiving a genetic resource from another country, to investigate whether a Certificate with mutually agreed conditions is required. The NP also instructs to pay special legal attention to procedures for rapid diagnostics in health emergency situations. For GMI it is interesting to notice that the NP speaks in regard of emergencies of ‘present or imminent emergencies that threaten or damage *human, animal or plant health*’ ‘to consider the importance of genetic resources for food and agriculture and their special role for food security’.

Issues mentioned in the discussion included that while some scientists tend to worry about data sharing prior to publication and IP concerns a number of relevant issues are basically

out of control of scientists: sharing samples across borders; dual use regulations; trade/ag regulations, health regulations (including WHO International Health Regulations). The question was raised whether it would be possible to use the Nagoya protocol for multilateral sharing of materials? And whether the WHO/PIP protocol provides a way forward for a similar generic protocol for global sharing of isolates/sequencing data. Practical issues that are already confronted in real life are e.g.: a) purchase of source materials from a country, you isolate in one country, sequence in another; b) patient gets sick abroad, diagnosed after return and isolate is sequenced at home; c) isolate sequenced in a home country, sequence transmitted to international repository residing in another country, d) the existence of a public domain of microbiological genome data, etc. etc.

WG1 decided that there is a need to prepare a concise document to convey the message that in the future, DNA-sequencing will enable (and will necessitate) the sharing (and joint investigation) of sequences over borders in a way that does not correspond to the spirit of the NP. The document should explain the specific problems related to sharing of microbial WGS over borders with a view of improved characterization / identification; such sharing would for example be significant if a GMI system was up and running. The explanation could take outset in the EU separate Regulation 'on compliance measures for users from the Nagoya Protocol'. Responsible George Haringhuizen and friends (Dessai, USDA, Allard, USFDA, A. Cook, UK-FSA, K. Keddy, South Africa)

2. Issues from FAO/WHO Technical Background Paper: Applications of Whole Genome Sequencing in food safety management

In order to sensitize policy makers on global trends of applications of WGS it should be realized that communication issues constitute important elements in sensitizing the general public, but also political authorities, and stakeholders to the potential value of WGS technology in the regulatory process. Likewise the communication of potential significant improvement potential for food safety management will be important

Provision of forums to discuss relevant issues, including data governance and legal matters around harmonization and standardization at the global level should be linked to the provision of assistance to developing countries in assessing capacity development needs to strengthen national food control systems (laboratory, epidemiology, food control).

WG1 decided to develop a guidance WGS document for decision makers. The document could use the FAO/WHO document and the Aarestrup et al. paper (EID, 2012) as starting points but should ensure there is a broad focus including all relevant sectors: health, food, environmental, animal, etc. It needs to emphasize a likely future development where WGS will be shared across all regulatory agencies both domestically and globally, and the urgent need for communication between regulatory food and public health sectors in countries. The document should update success stories from the past 5 years, including national examples of use, preferably including examples from developing countries (e.g. Kenya) and should include links to videos from NCBI, EFSA, etc.

The document needs clear statements about what the new technology can do in all sectors as well as across sectors (One Health). It should emphasize the potential both in relation to pathogenic microorganisms, but also all other microorganisms, including relevant starter

cultures, probiotics, etc. The document should include relevant links to international agreements and regulations, including the IHR, and it should consider important stakeholders, including the industries of different sectors in the discussion. If possible, the guidance document should include recommendations for policy makers and stakeholders to 'support WGS implementation in your country' and to 'act in support of international initiatives in the area, including FAO, WHO and OIE initiatives.'

Responsible: Eric Brown and friends (Palmer Orlandi USFDA, Kris De Smet EU Commission, P. Gerner-Smidt, US CDC, Amy Cawthorne, WHO, S. Defibaugh-Chávez, USDA, J. Schlundt, NTU-Singapore)

In addition to the guidance document it was realized that more communicative, yet science-based material would be needed. Such material could be aimed at a) general public and political level as well as at b) more technical, scientific level. It was suggested that a **short** video (eg 5 min.) could be useful to cover a), while a slide deck (ppt.) could be useful for b)
Responsible: Marc Allard and friends (R. Sobia, UK-PHG, J. Schlundt, NTU-Singapore)

3. Issues related to potential Resolution text

Apart from minor editorial changes (e.g. change "bacterial and viral organisms" to "microorganisms") more specifically it was suggested to include under 'Urging member states' a statement relative to promote and enable conducive conditions for use of globally shared WGS data.

After a thorough and wide-ranging debate about the inclusion of the existing statement under 'Requests the Director-General' '..to explore with the United Nations Secretary-General options for a high-level initiative, including a high-level meeting, to increase political awareness, engagement and leadership on genomic sequencing for global diagnostic and surveillance purposes' it was decided to leave the statement in. This decision was based in the recognition that significant 'One Health' issues need to be considered in more than one UN Organization, thus generally need strategic guidance directly from the UN Secretariat.
Responsible: J. Schlundt

5.2 Repository and storage of sequence and meta-data (Working Group 2)

1. Discussion on the role of WG2 with respect to publicly available data

There was some discussion on whether WG2 should focus at all on the need for having protected data access. Although some may choose to build protected databases and not share their data publicly, it was mentioned that this is counter to the published goals of GMI and to this working group. To reiterate, the statement in the meeting report from GMI5 (<http://www.globalmicrobialidentifier.org/-/media/Sites/gmi/News-and-events/2013/5-meeting-2013-report.ashx?la=da>) is as follows and continues to be the guiding principle of this working group: General Goals 1) Minimum Data for Matching (MDM), consisting of reads and minimum metadata, should be deposited, and made globally and universally accessible as soon as available. 2) MDM may or may not be accompanied by assemblies and/or annotation and/or additional metadata. If not provided with initial submission, these may be added later by the submitter, or by some agreed upon 3rd party. 3) Ideally, any MDM

provided for purposes of searching the GMI databases should immediately also become a deposit available for searching by later submitters. 4) Any matches from the MDM search should be reported to searcher and to the relevant GMI Participants. 5) The data layer is provided by The International Nucleotide Sequence Database Collaboration INSDC and is therefore both international and public. 6) The search and analytical layers may be provided by INSDC members or by other parties. For research purposes it is fine to have a variety of tools and searches. But in order to provide a coordinated GMI there must be a more centrally controlled searching and reporting protocol that official sites adhere to and to whom the food safety agencies submit, which is much more limited.

2. The metadata standard

The fields for the metadata standard was first reported in the meeting report from GMI6 (<http://www.globalmicrobialidentifier.org/-/media/Sites/gmi/News-and-events/2013/6th-meeting-2013-report.ashx?la=da>). More than 117K submissions have already used this template and this template will be used as a model for metadata reporting in an ISO working group on standards for whole genome sequencing for food safety. As mentioned in the report for GMI8 information on how to submit is listed here:

Pathogen genome-scale sequence data submissions. If you wish to contact NCBI or ENA directly about submissions:

NCBI: <mailto:pd-help@ncbi.nlm.nih.gov>

ENA: <mailto:datasubs@ebi.ac.uk>

NCBI Submissions Information on how to submit

<http://www.ncbi.nlm.nih.gov/projects/pathogens/submit>

The submission page: <http://submit.ncbi.nlm.nih.gov>

The Pathogen system at NCBI requires three basic elements:

- At least one BioProject that describes the project or initiative (the BioProject only needs to be created once).
- For each pathogen sequenced, submission of a Biosample record that lists the isolate metadata – submission is via a downloadable template – (Pathogen affecting public health) that is used to describe the sample including differentiation of isolates from clinical vs. environmental/food/other sources as well as information on when and where the isolate was obtained. The template definitions can be viewed here: <https://submit.ncbi.nlm.nih.gov/biosample/template/?package=Pathogen.combined.1.0 &action=definition>
- For each pathogen, submission of the raw sequence data to SRA. For information on submitting assembled genomes or antimicrobial susceptibility information, please see the submission instructions linked above.

ENA Submissions <http://www.ebi.ac.uk/ena/submit/pathogen-surveillance>

This page provides instructions for submitters of genome-scale pathogen sequence data to the European Nucleotide Archive (ENA). It includes a minimal checklist of sample metadata information to be reported associated with sequence data generated in high-throughput genome-scale pathogen surveys or research studies in clinical, organismal and environmental samples. On this page submitters will find links to instructions for different categories of submission, as follows:

- Project registration - Submission of reads and samples - Genome assembly submissions of clinical, organismal and environmental samples

Both interactive and programmatic tools (Webin) are available to aid in the submission of data to ENA.

3. A need for a keyword to identify surveillance Bioprojects

EBI noted that there is a need to identify Bioprojects for which the underlying data is intended for pathogen surveillance. EBI has already proposed this at the INSDC meeting for 2016 and will continue to work with NCBI and DDBJ to incorporate this keyword.

4. Template to capture antibiotic susceptibility data.

With the increasing importance of antibiotic resistance it has become necessary to capture antibiotic susceptibility data along with the isolate metadata. As NCBI has already created a template as part of the US initiative to combat antibiotic resistance, and has accepted more than 2000 sample submissions using this template, it will serve as a prototype for INSDC and as part of the proposal for the ISO working group noted above. NB: this template does not yet serve the needs of the TB community, and that will be addressed at a later date.

NCBI antibiogram definition: <http://www.ncbi.nlm.nih.gov/biosample/docs/antibiogram/>.

The template definitions and validation rules are described on this page.

Mandatory fields:

- sample name/biosample_accession
- antibiotic
- resistance_phenotype
- measurement_sign
- measurement
- measurement_units
- laboratory_typing_method
- testing_standard

Optional fields:

- laboratory_typing_platform
- vendor
- laboratory_typing_method_version_or_reagent

5. Review of previous action items from GMI 5 through 8 including user survey

At GMI7 it was proposed that WG2 have a survey of members to see where the difficulties lie in submitting data. This survey was ready for GMI8 and the results were ready for GMI9. Unfortunately less than 12 people submitted replies to the survey, and the majority of those were not submitting data or did not intend to submit data. Although some specific issues were addressed for certain data submitters by both EBI and NCBI, it was felt that this survey did not work to identify the political, social, or technical issues with data submissions and WG1 has had discussions on this topic. Therefore, this action item was closed. Previous action items were reviewed and many appear to be out of data or not necessary at this time and were therefore removed from the list.

5.3 Analytical Approaches (Working Group 3)

1. Benchmark/ Validation datasets

Sub group 1 discussed bench mark and validation datasets. They decided to continue working on the pipeline comparison needs in order to have a central place to gather all the results and closely observe for updates and changes in data analysis

There was a joint decision to keep the website on GitHub under a new GMI header- which could then grant access to GMI members to submit new datasets. It was suggested that anyone that would want to collaborate and expand the datasets can submit the data to public databases and submit the tree to the open tree of life database. Subgroup one also decided to increase benchmark dataset diversity and identified a list of datasets along with people responsible for submitting them. The goal for subgroup 1 is to finish the framework and the workable dataset submission workflow by GMI10.

Goals: Finish framework and workable dataset submission workflow by GMI10

2. Software comparison

Sub group 2 spoke about the new platforms, ELIXIR, Debian Med and CWL have developed components necessary for automated benchmarking, which is more efficient than manually curating the website.

There has been progress with the cooperation with developers for automated benchmarking. The benchmark datasets from working group 3 and the Proficiency testing datasets from working group 2 will be utilized. The development in this field has just begun and the framework will be set up 3-8 months from now.

3. Metadata Ontology

This subgroup spoke about the goal for GMI. The goal is for GMI to provide develop a consortium in order to provide community standard set of meta data fields to use for the following, which will be country unique and mission unique:

- Food
- Anti-biotic resistance
- Virulence factors
- Submitter (Sample, Lab, Sequence)
- Bioinformatics workflows
- Sequencing workflows (extraction, library prep, sequencing, Quality Control)
- Geographic location
- Sample format (Food portion, Environmental swab, Fecal, Blood, etc.)

Their goal is to develop or adopt list of terms and hierarchal linkages, develop a community standard that could be adopted by NCBI or other databases. William and Gary will be responsible for this. They would take the OBO Foundry standards as a starting point.

4. Organism specific subgroup

The organism specific subgroup focused on data transfer and creation of an organism specific database.

They discussed Databases in general, internet connections and the pros and cons of massive databases like NCBI than smaller curated datasets for GMI. Some of the questions that were flagged were the sharing of new data with countries that have bad internet connections, unification of databases to have one big databases, to have an organism specific database. Transfer of data was another issue that was highlighted in the discussion- there were questions on if one should transfer the data as an assembled genome or as SNP markers. FDA's example on heavy bias on *Salmonella* was brought out during the discussion. It was said that FDA genomes would overrun curated genomes. They came to a common conclusion that it would be a better idea to have a curated database from the same species or taxon.

5. Software challenge/training

This subgroup discussed the challenges related to the software that are used for interpretation of datasets and potential training on bioinformatics. It was decided to plan a software challenge at GMI10. It was discussed to focus on the standard datasets and to try to compare and integrate as much as they can of the different software platforms before GMI10. These results will be presented at the next GMI. They discussed the need to coordinate with working group 4's proficiency testing results. A possibility of providing bioinformatics training was discussed. This would depend on facilities are resources are available. A suggestion was made to request software providers to provide training on their software. The subgroup stressed on the need to focus on outbreak analysis due to limitations of the datasets. It was decided to have metagenomics analysis training discussions at GMI11.

5.4 Ring trials and quality assurance (Working Group 4)

Working Group 4 discussed the completion and compilation of the analysis of the wet and dry lab results from the 2015 Proficiency Testing. They intend on rolling out the 2016 Proficiency testing which would include both the wet and dry lab components. The following taxa were decided to be included:

- *Klebsiella pneumonia* (Rolf Kas DTU)
- *Listeria monocytogenes* (FDA/CFSAN)
- *Campylobacter jejuni* and *Escherichia coli* (Eija Trees U.S CDC)

During the discussion, there were suggestions made to have Virus proficiency testing move forward along with the bacterial proficiency testing and it will follow the same format. The Viral strains, DNA and sequenced data to be analyzed will be sent out. The Bacterial Proficiency testing announcement will go out from GMI, however, members were encouraged to tap into other resources to expand the network to increase the number of participants. A schedule is created to create 100 participants for the proficiency testing in 2016. Part of the discussion also included the actions to be taken in case the number of participants exceeded 100.

The Time frame for the 2016 proficiency testing was discussed. It was planned to send out the invitations in June and to have the generation of sequenced data available by July.

Timeframe for 2016. Participants' invitations will be sent in June. In July the generation of sequenced data will be available and the samples will be sent out in October with a goal to have the wet lab sequencing in November.

It was agreed by the working group 4 members to make the protocol of the proficiency testing concise in order to avoid confusion as to naming/format/ uploads. The possibility of introducing new questions in the testing that could better assess how clusters are defined was explored. Participants discussed about including metagenomics to the testing due to the increased relevance and importance of the topic in WGS. It was also suggested to make more effective and efficient use of the forum that was created as a means to disseminate information regarding the proficiency testing and to answer any questions raised. Participants raised the possibility of providing accreditation to labs based on their performance in the proficiency testing.

Should WG4 provide some sort of accreditation based on a lab performance? Working group 4 also discussed on possible training, outreach and education as part of the existing mission or to have a separate working group for the same.

6 Final remarks by FAO

FAO is an organization driven by its Members and all activities FAO conducts are planned in response to the official requests made by FAO Members. While the system assures the appropriate prioritization of FAO's work, it has a possible limitation that the Members' request on issues around new technological development can be delayed thus necessary assistance from FAO may not be provided to Members in a timely manner. WGS is one of the topics that are rapidly developing thus the changes in its environment and requirement occur in a very short time. Proactive planning and actions would benefit Members therefore FAO will keep providing forums for Members to identify needs and issues that require international discussions.

Various sectors of FAO have been active in assisting Members to effectively generate and collect scientific data. FAO hosts several databases to provide neutral and global sharing data to benefit all. However, developing and hosting database have a long-term significant cost implications. If there is already a similar fit-for-purpose global database developed elsewhere, FAO's role is not to develop another one but to ensure the accessibility to the database by all in order not to create imbalanced opportunities. For WGS data for food safety, there are already three globally recognized databases for sequences and various regional level databases. Bearing in the mind the importance of harmonization of the content and the format of the databases, and upon Members' request, FAO can assist in ensuring a sustainable environment for such mechanisms that connect various global databases such that it is fair and accessible for all the countries. FAO can also assist in the formation of a network of networks by considering and selecting the relevant and experienced institutes and agencies from both developed and developing countries.

During the round-table sessions with developing countries, participants established an informal network for information exchange on the topic of WGS for food safety management. This will help the network members find persons in similar situations in different countries, who can then work together to tackle common challenges. Collaborating

through such networks would be a resource efficient approach and would stimulate people to find the most effective, fair and sustainable use of the technology for appropriate actions. The informal WGS network with the participants from the 19 developing countries is a starting point and FAO continues to assist in expanding the network and to provide information to discuss and share their experiences and challenges.

Assisting Members in developing its capacity is one of the key roles of FAO. In collaboration with other relevant international organizations, FAO will provide training, seminars, projects and programmes to address Members' capacity development need. Various tools and approaches can be utilized for this purpose, for example, regional/sub-regional approach for training of trainers, mentor-mentee match-ups, South-South Cooperation approach and so forth. Due to the nature of the novel technology, advances can be made at a fast pace. While this rapid advancement can provide multiple benefits, considerations need to be provided for developing countries to ensure that such benefits are received by all countries. FAO continues to contribute to the global effort in knowledge transfer and effective information sharing.

Meeting recordings

- During the morning session on 23 May 2016, participants discussed the benefits and potential drawbacks of employing WGS for food safety management. The recording of the session is available at: <http://www.fao.org/webcast/home/en/item/4089/icode/>.
- In the afternoon session on 23 May 2016, there were presentations about the step by step approach for developing countries to consider WGS for food safety assessment and a panel discussion on the global actions. The recording of the session is available at <http://www.fao.org/webcast/home/en/item/4111/icode/>.
- During the morning session on 24 May 2016, presentations introduced the GMI initiatives and the work carried out by the different groups. Experts explained the different WGS databases currently available, the GMI proficiency testing and the use of Bioinformatics in WGS data interpretation. The recording of the session is available at <http://www.fao.org/webcast/home/en/item/4112/icode/>.
- During the afternoon session on 24 May 2016, participants provided examples from their experiences in epidemiology and surveillance including speakers from PulseNet, FDA and the academic sector. The recording of the session is available at <http://www.fao.org/webcast/home/en/item/4113/icode/>. There were also individual working group discussions but the recording of these sessions are not available.
- The morning session on 25 May 2016 comprised of discussions about global data sharing and metagenomics. The recording of the session is available at <http://www.fao.org/webcast/home/en/item/4115/icode/>.
- During the afternoon session on 25 May 2016, participants broke out into different working groups. The working group discussion recordings are not available. The summary of the working group discussions were presented at the plenary and the recording of the final plenary session is available at <http://www.fao.org/webcast/home/en/item/4114/icode/>.

Meeting presentations

- Presentations from the Technical meeting on the Impact of Whole Genome Sequencing on food safety management (May 2016) Available at: <http://www.fao.org/food/food-safety-quality/a-z-index/wgs/wgs-food-safety/en/>
- Presentations from the Expert workshop on practical applications of Whole Genome Sequencing (WGS) for food safety management (2015) Available at: <http://www.fao.org/food/food-safety-quality/a-z-index/wgs/workshop-wgs-for-food-safety/en/>

Links

- FAO.2016. *Technical Background Paper on the Applications of WGS in food safety management*. (Available at: <http://www.fao.org/documents/card/en/c/61e44b34-b328-4239-b59c-a9e926e327b4/>)

- FAO.2016.Workshop proceedings: *Drafting the technical paper on Applications of Whole Genome Sequencing (WGS) for Food Safety Management* (Available at: <http://www.fao.org/3/a-bl207e.pdf>)
- FAO. 2016. Highlight :*Whole Genome Sequencing (WGS) for food safety* (Available at: <http://www.fao.org/documents/card/en/c/a7855bac-6fca-4038-b302-9061a43fc69d/>)
- FAO.2016. Website: The technical meeting website Technical Meeting on the impact of Whole Genome Sequencing (WGS) for food safety management. (Available at <http://www.fao.org/food/food-safety-quality/a-z-index/wgs/wgs-food-safety>)

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Annex 2. Meeting agenda

Day 1		
Introduction		
08:30 – 08:45	Opening remarks	Ren Wang, Assistant Director General, Agriculture and Consumer Protection Department, FAO
08:45 – 09:00	Objectives of the Technical Meeting	Masami Takeuchi, Food Safety Officer, FAO
09:00 – 09:45	Whole Genome Sequencing (WGS) – how significant is it to food safety?	Celine Nadon, PHA, Canada
09:45 – 10:00	Discussion	
10:00 – 10:30 Coffee break		
10:30 – 12:00	Panel discussion on benefits and potential drawback of WGS	
12:00 – 13:30 Lunch		
13:30 – 14:00	Step-by-step approach in considering WGS as a tool for food safety management – practical feasibility assessment	
14:00 – 15:00	Panel discussion on Considerations for developing countries	
15:00 – 15:30 Coffee break		
15:30 – 16:45	Panel discussion on global actions	
16:45 – 17:00	Closing remarks and a way forward	Markus Lipp, Senior Food Safety Officer, FAO

Day 2		
Introduction		
08:30 – 08:40	Overview of the GMI initiative and its working groups	Jorgen Schlundt, NTU, Singapore
08:40 – 09:00	FAO/WHO initiatives on WGS for food safety including the summary of Day 1	Masami Takeuchi, FAO
Active system		
09:00 – 09:15	NCBI pipeline	Bill Klimke, NCBI, USA
09:15 – 09:30	EBI – building the database with international isolates	Guy Cochrane, EMBL, Eur. Bioinformatics Institute, UK
09:30 – 09:45	Application of WGS in the industry	Alex van Belkum, Biomérieux
09:45 – 10:00	Genome Trakr	Eric Brown, FDA, USA
10:00 – 10:30 Coffee break		

Identification/characterization – global capacity		
10:30 – 10:45	Web applications for rapid microbial taxonomy identification	Ole Lund, DTU, DK
10:45 – 11:00	Middle East Respiratory Syndrome (MERS) / Ebola / Norovirus – WGS developments	Marion Koopmans, Erasmus, NL
11:00 – 11:15	The GMI Proficiency Test	Rene Hendriksen, DTU, DK
11:15 – 11:30	Building bioinformatics resources for the global community	James Pettengill, FDA, USA
11:30 – 12:00	Discussion	
12:00 – 13:30	Lunch	
Break-out session 1		
13:30 – 13:45	Introduction to the break-out sessions: working group approach	Jorgen Schlundt, NTU, Singapore
13:45 – 15:00	Working groups WG1: Philippines Room (C-277/281) WG3: Ethiopia Room (C-285/9) WG2: India Room (A-327/9) WG4: Nigeria Room (C-215)	
15.00 – 15:30	Coffee break	
Epidemiology and surveillance		
15:30 – 15:45	Real-Time Genome Sequencing of Resistant Bacteria Provides Precision Infection Control in an Institutional Setting	Dag Harmsen, University of Münster, Germany
15:45 – 16:00	The path to implementation of WGS in PulseNet	Peter Gerner-Smidt, CDC, USA
16:00 – 16:15	Tracking resistance genes using NGS	Patrick McDermott, FDA, USA
16:15 – 17:00	Discussion	
Day 3		
International data sharing		
08:30 – 08:45	Added Value of Open data sharing using examples from GenomeTrakr	Marc Allard FDA CFSAN, USA
08:45 – 09:00	Strengthening data sharing for public health – ethical, legal and political issues	Michael Edelstein, Chatham House
09:00 – 09:15	International challenges regarding the future sharing of sequence data	George Haringhuizen, RIVM, NL
09:15 – 09:30	WGS Sharing at OIE	Franck Berthe, OIE
09:30 – 09:45	WGS data sharing at FAO by the international Treaty on the plant genetic resources	Shakeel Bhatti, FAO, Jerome Reichman
09:45 – 10:00	Developing Global Norms for Data and Results Sharing During Public Health Emergencies	Cathy Roth, WHO

10:00 – 10:30	Coffee break	
Metagenomics		
10:30 – 10:50	Metagenomics – investigations of complex microbiomes	Stephan Schuster, NTU, Singapore
10:50 – 11:10	Real time surveillance of the healthy population in Copenhagen, Denmark based on sewage	Rene Hendriksen, DTU, Denmark
11:10 – 11:30	Developing a national strategy to bring pathogen genomics into practice	Sobia Raza, PHG Foundation, UK
11:30 – 11:40	GMI10 (Mexico) and GMI11	Lourdes Simental Ocegueda, Mexico
11:40 – 12:00	Discussion	
12:00 – 13:30	Lunch	
Break-out session 2		
13:30 – 15:00	Working groups WG1: Philippines Room (C-277/281) WG3: Ethiopia Room (C-285/9) WG2: India Room (A-327/9) WG4: Nigeria Room (C-215)	
15:00 – 15:30	Coffee break	
Closing session		
15:30 – 16:30	WG 1 Reporting back	
16:30 – 17:00	Conclusion and a way forward	Jorgen Schlundt, NTU, Singapore

Annex 3. Proceedings of the Round-Table sessions

Two sessions of the round table special meeting were on 24 and 25 May 2016 during the lunch breaks of the Technical Meeting. 19 people from 16 developing countries (Bangladesh, Botswana, China, Egypt, Ghana, Mauritius, Mongolia, Mozambique, Namibia, Philippines, India, Iran, Sudan, Tanzania, Thailand and Vietnam) participated in the sessions. The round table meeting provided a platform for exchanging country experiences, examining prerequisites for WGS implementation in their respective developing country and sharing of knowledge and concerns about the WGS.

Country situations

Amit Sharma (India)

Mr Sharma from India explained that the food safety is a priority in India, however, it is differentiated based on imports and exports. In India food safety is a priority when food is exported. There have been cases that India has faced problems due to lack of traceability during exports. A contaminant was found in U.S for a product originated from India. Later it was found that the source of contamination in France. The participant in India suggested the strong need for legal binding. WGS can be mandatory in countries like India where there is good infrastructure and pre requisites to implement it. There are already research institutes with WGS. However there needs to be a common platform as WGS becomes mandatory for exports, this will affect the economy of many countries that do not have the technology. He also expressed his concerns about WGS becoming a potential trade barrier. Though having the vision of employing WGS for food safety is good, it shouldn't become a mandatory requirement for trade, making the situation worse for developing countries.

Amornthep Archawakulathep (Thailand)

Mr Archawakulathep stated that in his country, WGS is being used in research institutes and university. Food safety is a priority in the country, however, implementing WGS for food safety is difficult due to cost issues and thus this will not be of top priority to the country. The true impact of WGS may not be realized. He believes that Regional or sub regional collaboration will be a good idea.

Asim Abu-Sarra and Nagmeldin Mohammed Osman (Sudan)

In Sudan, the participants stated that The SSMO which is the Sudanese Standards and Metrology Organization is the main organization to handle food safety issue. However, there are many agencies that handle the Food Control System. Consumer protection is of utmost importance in the country and food control is taken seriously due to the fact that there are a lot of imports than local food production.

Bashiru Boi Kikimoto and Ernest Bonah (Ghana)

Mr Kikimoto stated that they have a national policy on food safety and they have a lot of food borne disease outbreaks. These outbreaks are what that trigger the government to act on food safety. Another participant from Ghana, Ernest Bonah mentioned that in Ghana, the tourist authority after the national food control system, takes care of the food safety issues in restaurants. Thus there are issues between interactions with each other. The topic of food safety needs to be discussed with higher levels. His area of food safety deals with collection

of samples from different parts of the country. Thus collecting the data in Ghana is not a challenge. With the collaboration with Mr Kikimoto, he believes that WGS can effectively be implemented in his country as the other participant stated that with a little pursuing the government, it will be easy to make an impact. However, factors such as cost comparison, lab education and advocacy are important factors to be considered too.

Battsetseg Tsogtoo (Mongolia)

The participant from Mongolia stated that, similar to other countries, organization and cooperation between the different agencies is hard. They have inspection, food inspection, and labs. However trained human resources can be an issue. Political will power is confusing. More resources are needed for analysis.

Cecilia Vicanta Hinda (Namibia)

Ms Hinda from Namibia is from the fishery sector of her country and explained that since a lot of sea food is being exported from her country, the food safety in this sector is particularly strong. However, she feels that the food control system is fragmented. With regards to infrastructure, they have a huge public health lab with the required capacity. Applying WGS here would be relatively easy.

Dung Nguyen (Vietnam)

A participant from Vietnam mentioned that the country has good research institutions. However, the system is very complex since three ministries are involved in the area of food safety. When there is a food safety issue, the government pays attention. However, technology is not up to the mark except for in research institutes.

Fenquin Li (China)

The participant from China explained there are four different departments (FDA, NHFPC, AQSIQ and MOA) for food safety management. They have the resources of food borne microorganisms and are qualified to carry out WGS. About 10,000 strains are sequenced every year using WGS. They are nonprofit centers. In china there is ongoing training for bio informatics due to difficulties in data interpretation.

Gihan El Moghazy (Egypt)

In Egypt, Ms Gihan explained that the government is fragmented between health, agriculture, foreign trade and tourism. There is a lot of import and export and therefore the government is trying to establish food safety for import and export with local ministries. The participant also flagged the issue of custodian of the data if WGS is implemented. A concrete food safety authority needs to be established in her country.

Hedayat Hosseini (Iran)

Mr Hosseini from Iran said that the country is ready to implement the technology. They have an empowered food safety system. The Iran veterinary division and the Iran plant protection department are already in full swing carrying out their activities effectively. The food and drug authority in Iran controls food safety issues. Iran standards of food safety exist. However, non-communicable diseases are of more importance than communicable disease. Budget of non-communicable is higher. WGS will have a good impact though if implemented in Iran.

Helena Matusse (Mozambique)

In Mozambique, a unique agency for food safety was designed three years ago, said the participant. With WHO, the document was passed at the parliament. The priority of food safety depends on the commodity used. Mozambique exports sea products and hence the priority is high for these and they have the support of EU. Concerning agriculture they export groundnuts, and hence similarly they are trying to set up mechanisms, labs etc. for the food safety of groundnuts.

Hussein Tarimo and Rosinah Pitinyane-Modise (Botswana)

Mr Tarimo from Botswana stated food safety becomes a priority in their country only when there is a disease outbreak. Otherwise, food safety definitely takes a back seat in the country's priority and agenda. For policy makers, diseases that are not food borne, like HIV, Malaria have become the priority for the developing countries.

Ms Pitinyane-Modise from Botswana said that the WGS technology does look appealing. But while there is no effective and a fully functional food control system or a food safety policy, this technology is of no use for them. Ms Takeuchi explained that FAO can help in conducting feasibility assessment and studies for Botswana to identify areas of competencies and thus sort out the food safety policies for the country. Ms Takeuchi also explained about the FAO TCP project where every country can submit their applications to obtain support from the FAO.

Ms Pitinyane-Modise also stated that the fragmentation would be a difficult problem to overcome since the different departments have a fear of losing power/ posts. She flagged the issue about double standards. All the products that are consumed irrespective of imports or exports need to be safe. In Botswana, because beef export is high, food safety cannot be a priority only in the beef industry. Thus common harmonized standards need to be created. The Indian participant added to this comment by saying that the need for harmonized guidelines and calibration of techniques to establish uniformity everywhere is required.

Julius John Medardus (Tanzania)

Mr Medardus from Tanzania explained that in his country, WGS has been in use in the private sector since 2014. He suggested that this section could be strengthened with the support of international organizations like the FAO to help the community. Besides infrastructural requirements and technical challenges, as a nation, he stated that they are plagued by poor reinforcement of laws and regulations to ensure a fully functioning national food control system with effective food monitoring/testing surveillance and response. As a nation, Tanzania has the the national food safety system, but it is not fully functional. He gave an example of a food and drug regulatory organ called Tanzania Food and Drug Authority (TFDA) which was established through the act of the parliament in 2003. TFDA is a legal entity and has a central role in overseeing all activities regarding food and drugs in the country. Generally, it is not doing well because the poor reinforcement of the laws and regulations in place regarding food safety management issues in the country.

Miah Md Abdul Baten (Bangladesh)

In Bangladesh, the participant stated that the food safety authority is an autonomous body. It is part of the government, however it has the power to make independent decisions. The participants felt that the food safety is a great priority in his country and that the country situation with respect to food safety has been always monitored and worked on. Food security is a priority. There are three key elements in food safety in Bangladesh: enough food for everyone, safe water, food hygiene. He stated that the Bangladesh pure food ordinance was passed in 2005, however due to around 400 agencies involved within the country for food safety, there are legal issues and laws from the ordinance have not been implemented.

Sharmila Buldewo (Mauritius)

Ms Buldewo from Mauritius then spoke about the national food control system in her country and different countries gave their opinion on fragmentation of the food safety system. In Mauritius, There are different ministries though handling the food control system which creates the conflicts and finally affects the effectiveness of the national food control system. She believes that if is a control mechanism at the top, things can be more fluid and there is a strong need for more enforcement. Sharmila stated that there should be one independent body with some sort of rule coming from the prime minister's office (political will) as there is a real Lack of coordination. These are the gaps need to be filled rather than creating overlaps between the ministries.

In Mauritius, universities are using WGS. However, the question of whether the universities can carry out WGS for the regulatory framework has to be considered. In terms of research, the universities are playing their part, however, for routine testing, cost benefit issues and feasibility in the long run are involved.

Vernadette Sanidad (Philippines)

In Philippines, Ms Sanidad explained that, even though food safety is a great priority in the country the health sector is way ahead of the animal sector and. When it comes to the local government, implementation of food safety measures become a problem. They have a food safety act that was passed in 2013. There is a clear difference in the way food is dealt when it comes to primary food and processed food. Currently they are trying to establish traceability mechanisms. The research institute of tropical disease under department of health, have personnel with technical training and now there are requests to have the training done in animal and agriculture departments too.

Needs and concerns flagged during the meeting

- 1) Participants at the technical meeting requested FAO to define a technical indicator for countries to assess the importance/ priority of food safety in their country.
- 2) All the participants suggested that the topic of food safety to be discussed with higher levels Masami explained that status analysis of each country along with sensitization is essential.
- 3) Ms Moghazy, from Egypt requested hands on training from experts from developed countries where a pilot project is conducted, with sequencing one strain using WGS so

that developing countries get familiarized with the equipment and way of working. Countries could be divided according to similar capacity.

- 4) Ms Sanidad from Philippines was concerned about the continuity of the initiative of the possible collaboration with other countries, facilitated by the FAO. People suggested that the continuity should be secured by the collaboration.
- 5) Participants from Botswana requested assistance in conducting feasibility assessment and studies to identify areas of competencies and thus sort out the food safety policies for the country. Masami also explained about the FAO TCP project where every country can submit their applications to obtain support from the FAO.
- 6) During the meeting, it was suggested that WGS can make use of the idea of sub regional project – like the SADEC and SPS project. Capacities in other sectors like the plant and animal sectors can be used to train personnel for the food safety department. Participants from Thailand, Ghana and Iran were strongly in support of this idea Iran participant mentioned that every country is different and hence demand is different. Thus having a regional or a sub-regional focal point/ common lab is a great idea.
- 7) Mr Sharma from India stressed the need for harmonized guidelines and calibration of techniques to establish uniformity everywhere is required.
- 8) A participant from China proposed organizing a workshop for the developing countries for training in bioinformatics.
- 9) Ms Hinda from Namibia requested help for advocacy and feasibility assessment.
- 10) Ms Pitinyane Modise from Botswana stated that FAO can help them in resolving fragmentation issues.

Needs for global actions identified from the Post-Meeting Survey (in the order of priority)

- 1) Provision of assistance to developing countries in assessing capacity development needs in strengthening national food control systems (laboratory, epidemiology, food monitoring/testing, health surveillance, policy and regulation) and infrastructure, defining food safety priorities and the utility of WGS for priority pathogens
- 2) Provision of forums to discuss relevant issues, including data governance issues and legal matters around harmonization and standardization at the global level
- 3) Provision of technical guidance with good practices in application of WGS in food safety, as well as in global data sharing
- 4) Facilitation in linking developing countries with relevant networks, consortiums or entities where partnerships can be beneficial for such countries
- 5) Provision of harmonized guidance in overcoming technical barriers to trade that may result from WGS-triggered investigations.

Grouping of Countries according to similar country situations

