



Food and Agriculture Organization
of the United Nations

Meeting Report

Side Event on Whole Genome Sequencing (WGS) and Food Safety

Joint FAO/WHO/OIE side event of the 39th Codex Alimentarius
Commission, FAO Headquarters, Rome, Italy

12 September 2016

Executive summary

FAO/WHO/OIE implemented a side event on Whole Genome Sequencing (WGS) and Food Safety during the 39th Codex Alimentarius Commission at FAO headquarters in Rome, Italy. Recent advances in Whole Genome Sequencing (WGS) technology have the potential to play a significant role in the area of food safety. In addition, it provides opportunities for enhanced integration of information from other sectors such as human and animal health which could contribute to greater consumer protection, trade facilitation, and food/nutrition security. The event focussed on the importance of FAO, WHO and OIE collaborating to jointly address food safety issues and there were discussions on how WGS for food safety can potentially impact the work of Codex. During the one and a half hour event attended by 114 people, the panelists explained to the audience about the relevant work carried out by their respective organizations and participants exchanged their views, concerns and expectations of WGS in food safety with the panelists. The opening remarks were given by Ms Renata Clarke (FAO) and Ms Awa Aidara-Okane (WHO) provided the closing remarks. Presenters and panellists were Ms Amy Cawthorne (WHO), Mr Antonino Caminiti (OIE), Ms Masami Takeuchi (FAO) and Ms Sarah Cahill (FAO).

Year of publication: 2016

Acknowledgement

FAO/WHO/OIE would like to express their appreciation to all the side event participants for their valuable inputs. The side event was co-organized by FAO/WHO/OIE and administered by Masami Takeuchi (FAO) under the overall guidance of Renata Clarke (FAO). The meeting report was prepared by Amrutha Anandaraman (FAO), reviewed by Cornelia Boesch (FAO) and finalized by Masami Takeuchi (FAO).

Acronyms

| | |
|---------|--|
| AMR | Antimicrobial resistance |
| CAC | Codex Alimentarius Commission |
| FAO | Food and Agriculture Organization of the United Nations |
| GMI | Global Microbial Identifier |
| IAEA | International Atomic Energy Agency |
| IDF | International Dairy Federation |
| INFOSAN | International Food Safety Authorities Network |
| ITPGRFA | International Treaty on Plant Genetic Resources for Food and Agriculture |
| OIE | World Organisation for Animal Health |
| OIRSA | Organismo Internacional Regional de Sanidad Agropecuaria |
| STEC | Shiga toxin producing <i>Escherichia coli</i> |
| VTEC | Verotoxin producing <i>Escherichia coli</i> |
| WAHIS | World Animal Health Information System |
| WGS | Whole Genome Sequencing |
| WHO | World Health Organization |

Distributed materials

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

- FAO Highlight (June 2016): Whole Genome Sequencing (WGS) for food safety
Available at: <http://www.fao.org/documents/card/en/c/a7855bac-6fca-4038-b302-9061a43fc69d/>
- OIE World Assembly Document adopted in May 2016: Chapter 1.1.7. Standards for high throughput sequencing, bioinformatics and computational genomics.
Available at:
http://www.oie.int/fileadmin/Home/eng/Health_standards/tahm/1.01.07 HTS BGC.pdf

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Joint FAO/WHO/OIE side event
during the 39th Codex Alimentarius Commission
28 June 2016, FAO Headquarters, Rome, Italy

Whole Genome Sequencing (WGS) and Food Safety



1. Introduction

On 28 June 2016, FAO/WHO/OIE organized a side event to the 39th Codex Alimentarius Commission at the FAO headquarters in Rome, Italy on Whole Genome Sequencing (WGS) and Food Safety. The side event was held to discuss the importance of FAO, WHO and OIE collaborating to jointly address food safety issues using WGS and how WGS for food safety can potentially impact the scientific advice of Codex. The final meeting agenda is attached as Annex 1. The list of the 114 participants is attached as Annex 2. All presentation materials are available from <http://www.fao.org/food/food-safety-quality/a-z-index/wgs/>. The recording of the event is available at <http://www.fao.org/webcast/home/en/item/4153/icode/>.

2. Opening Remarks (Ms Renata Clarke, FAO)



Ms Renata Clarke welcomed all the participants to the side event. In her opening remarks, she stated that there were multiple requests during CAC made to FAO to collaborate with other international organizations. She emphasized that FAO is collaborating with international organizations such as the WHO and OIE - 1) to make efficient use of the limited resources available, 2) for outreach on issues of common concern 3) to tackle the common issues of concern within a one health approach and 3) to share ideas and experiences and benefit from the wealth of knowledge that exists among the different organizations.

Food safety is a global concern and has a great impact on public health. Public health in turn is highly relevant for equitable economic development. Food safety also remains a challenge for market access for small businesses. In order to tackle these food safety challenges, many new tools are being developed and their full potential and benefits are being understood. Ms Clarke introduced

the topic of WGS to the participants and explained that it is a tool which gives us the entire genetic makeup of any organism with precise identification and high speed. It is applied by food safety regulatory bodies for outbreak management and also provides a clear advantage to conduct studies on antimicrobial resistance (AMR). While there are several countries using WGS for food safety management both in the public and private sector, there are other countries where its application is limited. The purpose of the event is to raise awareness of the power of WGS in the field of food safety and to provide an opportunity to exchange experiences and concerns of the countries as well as the international organizations such as FAO, WHO and OIE. It is essential to take immediate actions to address the needs of the countries, as no time can be wasted.

3. Opening presentation: WGS on food safety and potential relevance to the work of Codex (Ms Sarah Cahill, FAO)

Ms Sarah Cahill illustrated how WGS in the context of food safety can potentially have an impact on the scientific advice and ideas provided to Codex. WGS is a tool that allows us to better understand the variations within and between species with a precision that other technologies do not allow. It also is often presented as a tool that is revolutionizing the way food safety regulatory authorities around the world work.



The global problem of food borne diseases has made it critical to use and improve the available tools so that food safety management actions are taken in a timely manner. Ms Cahill illustrated the need for a rapid response by reminding the audience of the *Escherichia coli* (*E. coli*) O104:H4 outbreak of 2011, which caused a significant economic burden in Northern Europe due to the false identification of cucumbers from Spain as the source of the *pathogen*. WGS, with its strength in identifying the source of the outbreak, would significantly reduce the probability of such mistakes. Another example Ms Cahill provided was the number of recalls of food products that have doubled in the past 10 years. Half of these are related to microbiological contamination, and WGS has the potential to look at these issues in more depth. Ms Cahill further mentioned additional uses of WGS in food safety such as: source attribution by tracking microorganisms through the food chain; evaluation of the microbial ecology through environment monitoring; disease surveillance and identification of specific traits of the microorganisms for evaluate of their virulence.

On the topic of information sharing with member countries, Ms Cahill introduced the joint FAO/WHO technical paper on the Applications of WGS in food safety management (<http://tiny.cc/WGS-TP>) which explains the current applications, benefits and drawbacks of WGS, challenges of applying WGS in the regulatory framework and considerations for countries with limited capacity and resources. In this document four case studies from the United States of America (USA), Denmark, England and Kenya are developed to elucidate how WGS has changed food safety management. In USA, 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. 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 highlights 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 indicates the potential usefulness of WGS in developing countries, but 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

Ms Cahill went on to discuss the benefits and potential drawbacks of implementing WGS for food safety management. The cost of WGS has been identified as both a benefit and a drawback. When analyzing the cost of WGS in order to provide well equipped labs and the required infrastructure for its implementation, WGS is not expensive as its benefits definitely warrant the investment. After the initial investment, WGS is not expensive as the cost of sequencing and analysis is rapidly declining. WGS can, however, prove to be expensive and thus a drawback depending on where one stands at the food control program, prerequisites like political will, infrastructure, internet and power supply, and other programs like food recall, food monitoring and inspection.

Ms Cahill flagged the importance of data sharing at both national and global levels by introducing some of the global initiatives including the Global Microbial Identifier (GMI), an initiative started a decade ago to find sustainable and effective ways to share data at the national and the global level. There are clear benefits for everyone to have an access to globally shared WGS data and without a doubt, such as efficient use of resources, studying the trend analysis of pathogens, rapid response to disease outbreaks all of which lead to improved mitigation of health and positive social and economic impact. However, several concerns have been identified regarding data sharing. The research sector is concerned about the data ownership, transparency and metadata access. Data sharing also has the ability to influence trade, and the discussion of data sharing has already begun in order to have a global governance through the Nagoya protocol, signed by over 70 parties at present. There are ongoing discussions regarding sharing of information about pathogens of high public health concern at FAO, WHO and OIE.

Ms Cahill elucidated the importance of engaging countries in order to share views, concerns and experiences. FAO held a technical meeting on the impact of WGS on food safety management in May 2016 to provide countries with such a platform (<http://tiny.cc/WGS-TM>). Participants recognized the benefits of employing WGS for food safety management but were acutely aware of the challenges as well. The meeting confirmed the need for capacity development in bioinformatics in developing countries. During the meeting, global data sharing was also a big topic. The meeting was concluded with the message that WGS, being a cross cutting transboundary tool, can contribute to the one health approach, thus overcoming the challenges.

On Codex, Ms Cahill highlighted the relevance of WGS: In 2015, during the side event to the Codex Committee of Food Hygiene, there were discussions on the ongoing work of WGS in different countries along with some sensitization to potential applications of the technology. Within the Codex context, molecular techniques to control pathogens in food and that WGS can be included as one of the methods. FAO, based on the recent studies in 2016 on using WGS for public health surveillance of STEC and VTEC (Shiga toxin/Vero toxin producing *E. coli*), can provide scientific advice to Codex on the hazard identification and characterization of the same.

Ms Cahill concluded her presentation by stating that WGS is becoming embedded in the regulatory systems of several countries due to its potential benefits. There is a transition period to switch from the traditional sub typing methods to WGS. All countries may not be able to apply it in the foreseeable future but should be aware of its capability and potential implications to ensure that it does not contribute to inequities and trade barriers. Enabling effective and appropriate global data sharing is key to unlock true potential but there are barriers which can be overcome through collaboration and working together with international organizations.

Question by Mr Nicolaas Van Belzen, IDF: During your presentation, you spoke about the challenges related to data interpretation. Would this be a concern for detection of sequences-both for pathogens as well as for AMR, if errors are made which could lead to wrong decisions making?

Answer by Ms Cahill: Though data interpretation remains a challenge, there are activities to have a good quality control on data interpretation. The required skills are available and have to be used within the context. The meta data around the WGS needs to be considered. Transparency is critical while employing WGS. Since there is a learning curve associated with every new technology, WGS could be used alongside traditional methodologies to cross check the data and results obtained.

4. WHO Activities on WGS (Ms Amy Cawthorne, WHO)



Ms Amy Cawthorne opened her presentation by stating that WGS is a tool that has an enormous power to improve public health. She stressed that countries need support from international organizations to bring the benefits of the technology to the floor. Alongside, new skill sets need to be developed to use the technology and tools need to be simplified for data interpretation. Building partnerships at the regional level is key for developing countries. To address these issues, WHO is developing a technical guidance on WGS as part of systems strengthening for foodborne disease surveillance and outbreak response. A horizontal scanning paper is also being developed by WHO along with its partners. An expert meeting is planned to be held in October 2017 to provide a roadmap for developing countries to implement WGS. WHO is developing a foodborne disease surveillance manual that will also cover WGS.

Ms Cawthorne explained that WHO helps countries to take a step-wise approach towards a functional and sustainable system to detect, assess and respond to foodborne diseases. In the first step, countries are shown how to develop the ability to start detecting food borne disease events. At the second stage, during which the indicator based surveillance is strengthened, WGS is used as a tool for foodborne disease surveillance and outbreak response. At the third stage the surveillance data is integrated to better understand the risks along the food chain where WGS is routinely used surveillance.

WHO is implementing several national plans to help countries build a sustainable foodborne disease surveillance system. WGS training courses and mentoring programs are being conducted. Currently, approximately 20 countries are undergoing such training. WHO also facilitates discussions in order to create opportunities for developing countries to discuss global data sharing issues. An INFOSAN meeting is scheduled to be held in October 2016, to discuss the uptake, use and challenges of new or important technologies in the work of INFOSAN members in managing food safety events of an international nature.

5. OIE Activities on WGS (Mr Antonino Caminiti, OIE)

Mr Antonino Caminiti stated that since animals can be a source of pathogens in food products of animal origin, and also through fecal contamination of plant derived foods and water, it is important for OIE to continuously monitor the safety of animal derived food products. WGS is an effective tool for disease surveillance, however, there are challenges such as lack of standards, insufficient use of

epidemiological data, issues with data sharing due to lack of trust and because mutual benefit are not understood. OIE has a network of 300 reference centers that work together to interpret sequences obtained from WGS. Mr Caminiti described how the veterinary service and the laboratories of the OIE member countries work together to collect epidemiological data of animal health events and how these data are sent to the OIE through a well-established notification system. The OIE verifies and validates the data for subsequent release to the general public through WAHIS, the World Animal Health Information System.



The strategy of OIE is to i) create an information platform to collect sequence data and ii) promote a consensus building process to develop standards for sequence generation and interpretation. The OIE platform will be able to combine sequence data of animal health events with the corresponding epidemiological data stored into WAHIS. The OIE platform and WAHIS will be two separate systems that are structurally different but work together. The objective of the platform is to gather sequences from the OIE reference laboratories, national laboratories and scientific institutions, provide a service for data storage, share sequence data within and outside of the OIE network and provide assistance and expertise to the member countries.

Mr Caminiti, in a demonstration of the OIE platform, explained step by step how to access the platform from the WAHIS portal by giving an example of Brucellosis. Outbreak information can be found based on the year and the place of the outbreak and the status of the outbreak can be viewed including information about the susceptible cases, deaths, availability of sequences, quality assembly and pipeline.

6. FAO Activities on WGS (Ms Masami Takeuchi, FAO)



Ms Masami Takeuchi opened her presentation by reminding the public of FAO's mandate: "Food security exists when all people, at all times, have physical, social and economic access to sufficient, safe and nutritious food" (FAO World Food Summit, 1996). She further explained that the activities of the Food Safety and Quality Unit of FAO are part of the FAO strategic objective entitled "enable inclusive and efficient agricultural and food control systems". Ms Takeuchi explained that FAO's strategic objectives are achieved through different activities, which include putting information within reach, developing capacities, providing policy support, providing a meeting place for nations, and exchanging knowledge and expertise among countries.

For easy access of information by all, the technical paper on Applications of Whole Genome Sequencing (WGS) in food safety management, developed by FAO and WHO, is available online at <http://tiny.cc/faowgs>. A drafting workshop was held for the development of the technical paper and the presentations from the workshop are available at <http://www.fao.org/food/food-safety-quality/a-z-index/wgs/workshop-wgs-for-food-safety/>. The presentations from the Technical meeting are available at <http://www.fao.org/about/meetings/wgs-on-food-safety-management/>. She stated that other documents being developed by FAO on the topic of WGS will be published online at the same address.

Ms Takeuchi demonstrated or illustrated or how FAO's capacity development efforts on WGS are undertaken:

- Providing scientific advice to countries which will help countries assess the global trend of the pathogens, and having an understanding of the WGS technology development and use.
- Undertaking national projects to assist in conducting national capacity development needs/gaps assessment.
- Undertaking Regional projects to provide assistance in creating a network for effective collaboration towards common goals.
- Conducting workshops and training to address the gaps faced, especially in developing countries.
- Facilitation of a Global network (network of networks) to linking countries with technical networks and initiative.

Ms Takeuchi stated that FAO provides policy support, through standard setting and development of internationally harmonized texts and guidelines by the Codex Alimentarius, discussion of implication of internationally binding protocols, treaties and agreements on technical issues in food and agriculture. FAO is a meeting place for nations to share their experiences, concerns and discuss issues. The technical meeting on the impact of WGS on food safety management was one of such meetings.

FAO facilitates the exchange of knowledge and expertise by providing technical guidance (publications) on the applications of technology which include discussion on effective and fair global data sharing and case studies and pilot projects to document lessons-learned. Ms Takeuchi stated that along with colleagues from the animal and plant division, FAO is developing an in house paper on the use of WGS within a one health approach.

Various initiatives undertaken by the FAO include:

- Technical guidance for genome sequencing (plants and microorganisms)
- Support in pathogen sequencing
- Provision of Sequencing Service (through reference laboratories)
- Linking databases (ITPGRFA) / development of a database (genetic module)
- Training on bioinformatics for pathogens
- FAO Reference center for bioinformatics- in the animal sector of FAO
- Development of guidelines and protocols for nuclear techniques- joint collaboration by FAO and IAEA
- Technical trainings through South-South Cooperation
- Development of a guidance on Digital Unique Identifier (ITPGRFA)
- Provision of a portal (single gateway for genetic data)
- Guidelines on molecular characterization (Animal genetic resources)
- Commission on genetic resources for food and agriculture: An official forum on biodiversity for food security (include plants, animals, aquatic resources, forests, microorganisms and invertebrates)

Ms Takeuchi concluded her presentation by stating that FAO will listen to the needs of Members who may be in different situations with different capacity levels, and continue seeking the best ways to assist countries with effective scientific advice and capacity development efforts.

7. Panel Discussion

Mr Nicolaas Van Belzen, IDF: In the OIE platform, it is possible to conduct a search on any sequenced data, to check if a submitted sequence matches a known pathogen?

Mr Caminiti: The main purpose of the platform is to create a record of pathogens reported by member countries to the OIE. The epidemiological data that are sent to the OIE by the countries are very uniform and consistent. Thus any interpretation starts from the epidemiological data and the sequenced data comes to the picture later. Right now, we integrate epidemiological data with the sequence and not vice-versa.

Mr Charles Ochodo, Kenya: While WGS is a wonderful technology, I have a concern. There is a great deal of AMR experienced in my country. Can WGS be used to predict the direction of mutation such that early actions can be taken?

Ms Cahill: WGS can be used to study the pattern and the direction in which the resistance is developing. With WGS everything cannot be kept under control. Nevertheless, it would help in being better prepared for what could happen in particular scenarios in the future.

Ms Aidra-Kane: WGS is not a miracle technology that has the ability to solve all the food safety related problems. It is indeed a great marker, and a strong tool to trace the origin of the food borne illness or AMR, but as to be assisted by a robust epidemiological data. Prediction of the direction of mutation requires more than WGS.

Ms Linnette Pauletta Peters, Jamaica: Using WGS for detecting and sequencing microorganisms, say for example, *Salmonella*, is it possible to determine if the pathogen originated from a particular country?

Ms Aidra-Kane: If *Salmonella* has been identified in a sample from a patient, it is possible to trace the food product associated with the pathogen using WGS. It is not possible to predict the country of origin unless very specific information is available, especially if the strain is common.

Ms Cahill: Countries will not be able to apply WGS to every trace back investigation. Data sharing will be the major factor here. There have been cases where historic data sets of sequencing were used to find similar strains and trace back with more accuracy. WGS can be used to its full potential with better data sharing. It is the key here to obtain as much information as possible about the origin of the pathogen given the large movement of goods. Data needs to be recorded and shared to make a geographical linkage. Having large databases of information to see what other similar sequences are in there is beneficial. It is challenging, however, WGS alone will not be effective to tracing an outbreak.

Mr Claus Heggum, Denmark: Certain pathogens undergo mutation at a very high frequency, whereas, some strains of pathogens such as *Listeria* are genetically stable for over 18 years. Thus, won't tracing back using WGS and data sharing would be more efficient for certain pathogens than the other? Is tracing back the origin of a pathogen feasible, considering the frequency of mutation?

Ms Cawthorne: It is right that some strains are stable and some strains aren't. WGS still remains beneficial when we look at the rapid and diagnostic capacity of the technology. It is possible to identify the source of the contamination in the food chain and study the

contamination. There are powers as well as limitations to the technology. But the real time capacity of WGS makes it a very feasible technology.

Mr Lauriano Figuerra, Organismo Internacional Regional de Sanidad Agropecuaria (OIRSA): How much does it cost for the ground set up of WGS?

Ms Cawthorne: While there are no fixed and set costs for setting up WGS, the cost depends on the amount of samples there are to sequence and on the throughput of the sequence. The cost would also depend on the epidemiological and bioinformatics capacity available. Cost is an area that international organizations are working on in order to provide advice on the ramification issues of not implementing the technology. WHO will release a practical guide in 2017 for countries covering in detail about cost of WGS.

Ms Takeuchi: At the end of the technical paper on Applications of WGS on food safety management, there is an additional reading section where one can find materials on the cost issues related to WGS. There are ongoing researches on the cost benefit analysis and the consequences of not implementing the technology in the future.

Ms Linnette Poulletta Peters, Jamaica: Looking at the cost implications for developing countries, can organizations such as WHO consider setting up regional laboratories for uniform access of the facility?

Ms Cawthorne: Since many countries will take time to develop the skill set required for WGS, having a regional model is being considered. The need for technology for public health, disease surveillance and trade purposes may require countries to obtain access to WGS much sooner. Data sharing within the regions and among different regions needs to be considered too.

8. Conclusion and a Way forward (Ms Awa Aidra-Kane, WHO)



Ms Awa Aidra-Kane thanked all the participants for attending the side event on WGS for food safety. She is convinced that sharing relevant information by the different organizations about WGS for food safety would benefit countries. FAO, WHO and OIE can facilitate the formation of networks for countries to share their views and experiences and is always ready to address requests for assistance from the country members.

Annex 1. Meeting agenda

| Time | Item | Speaker |
|-------|-----------------------|------------------------|
| 12.45 | Welcome remarks | Renata Clarke (FAO) |
| | Opening presentation | Sarah Cahill (FAO) |
| | WHO activities on WGS | Amy Cawthorne (WHO) |
| | OIE activities on WGS | Antonio Caminiti (OIE) |
| | FAO activities on WGS | Masami Takeuchi (FAO) |
| | Panel discussion | All |
| 14.00 | Closing remarks | Awa Aidara-Kane (WHO) |

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