

Appendix 3 Response to the remarks formulated as a result of the public consultation of 15 July - 15 September 2021

Several organizations indicated they had no specific comments on the opinion. Specific comments were only received from FEVIA.

Organization	Remark	Response
FEVIA	<i>Practical and technological remarks</i>	
	The technological support at labs for a general application of WGS appears to be too limited at this time for Fevia. If the transition from the currently applied typing methods for pathogens to WGS is carried out, a sufficiently long transition period (years) should be provided. It seems to us that the frequent use of WGS as an environmental monitoring technique at food companies is not yet on the agenda. Fevia does acknowledge that WGS can already offer many opportunities for companies to carry out additional research in the presence of persistent strains.	
	The Scientific Committee confirms that a sufficiently long transition period is advisable. During this period the labs can invest in appropriate infrastructure, can acquire the technical expertise needed, set-up a standardized flow for implementation of the WGS method that can be validated.	
	Fevia fears that if WGS in time becomes "the standard technique" for the identification of isolates this will be restrictive for the practical implementation of controls. Since WGS, like other techniques, is defined by its technical advantages and disadvantages. By excluding other available techniques we would lose the advantages of these techniques.	
	As stated in the opinion it is likely that in the future WGS will become the preferred method for bacterial food safety investigation, due to its high discriminatory power and the fading out of various older typing methods at an international level. However non-WGS molecular typing methods can still prove to be valuable. For example to perform a first screening to determine a subset of strains of interest for WGS analyses. The Scientific Committee is of the opinion that depending on the purpose the most suitable technique should be chosen.	
	<i>Economic-Financial Remarks</i>	
	If the decision is now taken to switch (generally) to WGS and if it is desired to retain the number of samples taken using the traditional analysis techniques for environmental monitoring, the costs for food companies will increase significantly. Any additional cost is a threat to the competitive position of Belgian companies.	
	Fevia also fears that if the cost of WGS becomes too high, some operators would opt to reduce the number of samples taken in order to reduce costs. This would not be a favorable evolution for food safety.	
This opinion highlighted advantages and disadvantages of WGS. It is not within the assignment of the Scientific Committee to make any decision regarding the switch to WGS. The Scientific Committee is of the opinion that depending on the purpose the most suitable technique should be chosen.		

	<p><i>Legal remarks (addressed to the FASFC)</i></p> <p>Fevia considers it desirable that a clear legal framework is provided by the FASFC around the use of WGS, more specifically with regard to:</p> <ul style="list-style-type: none"> • The making available of obtained data on WGS in databases. Fevia requests that the obtained data are treated confidentially and that clear agreements are made about this. • Liability Companies are afraid that they will be held liable for facts that have long since expired. This is conceivable if their current data were to be compared with the data from outbreaks that have occurred long ago. This would mean that companies could be held liable for old facts of which they could not have been aware at the time because of the state of technology. Fevia asks that companies be protected against this. • Threshold values The WGS technique does not have threshold values for distinguishing the amount of genetic differences between non-pathogenic and pathogenic strains. This a major uncertainty in the use of WGS in investigating foodborne outbreaks. The text mentions several times that judgments will be made by a multidisciplinary team of experts. This seems to Fevia a very vague description and raises several questions. E.g. is this judgment final or can a counter-revision of the data be requested by another team? <p>How to handle the legal framework is something for the competent authority to reflect on. The Scientific Committee cannot answer these questions.</p> <p>Some clarification concerning the threshold values: These threshold values are not to distinguish between non-pathogenic and pathogenic strains, but rather to link closely related strains to an outbreak or not. As outbreak investigation combines different types of information (e.g. epidemiological data, genetic information) a multidisciplinary team is needed.</p> <p>When does the FASFC estimate to switch to WGS? When this happens, certain questions will need to be answered:</p> <ul style="list-style-type: none"> • Will there be changes in the number of controls carried out at companies and the content of the controls? • How will the FASFC carry out these controls? <p>Will this have an impact on the costs for companies?</p> <p>The Scientific Committee cannot answer this question. That will be decided at the FASFC level.</p>
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