

# TECHNICAL REVIEW REPORT

Grant Agreement number: **213178**

Project Acronym: **VITAL**

Project title: **Integrated Monitoring and Control of Foodborne Viruses in European Food Supply Chains**

Funding Scheme: **Small Collaborative Project**

Project starting date: **1/04/2008**

Project duration: **36 Months**

Name of the scientific representative of the project's coordinator and organisation:

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Period covered by the report: **from 1st April 2008 to 31st October 2009.**

Date of review meeting (if applicable): **11-12/01/2010**

Name(s) of expert(s):

- **Professor Christopher Griffith**

- **Dr. Sabah Bidawid**

Name of expert drafting the report:

Individual report

Consolidated report            **X**

## 1. OVERALL ASSESSMENT

### a. Executive summary

Comments, in particular highlighting the scientific/technical achievements of the project, its contribution to the State of the Art and its impact:

This is a very interesting project to review and the project team is an impressive group of experts from across Europe although, it is stronger numerically in molecular virology rather than risk management. Nevertheless, we believe that the project will still be able to deliver its outcomes, notwithstanding the greater pressure placed on a small number of individuals.

This is a very ambitious and timely project. Foodborne viruses have become increasingly significant pathogens, and as stated in objective one of the project, they are relatively understudied and more information is needed on contamination levels throughout the food chain. As such, this project is well thought of and spans viral contamination at various stages of production, processing and retail.

The data will be used to perform quantitative risk assessment which would; identify critical points of potential contamination, deliver appropriate intervention strategies, and support the development of guidelines (standards) for use by the food industry and regulatory authorities.

During the past 18 months, constituting this review period, a number of essential steps and challenges were met by the 7 Workpackage (WP) teams of experts.

Primary among these challenges was the unexpected unavailability of virus detection methods from other sources (CEN). This situation caused a few-month delay in the progress of the project as VITAL teams had to develop their own methods. These needed virus detection methods from various food matrices were successfully developed, validated, and the SOPs distributed to all beneficiaries. It is strongly recommended that these methods, which are currently used by the various WP teams, be published and probably validated at an international level for them to be more widely used and potentially to become internationally accepted standards. These methods have been used to assess the prevalence of target/indicator/control viruses (Adenovirus, Norovirus, Hepatitis E Virus, Murine Norovirus) in various food types such as soft fruits, vegetables, and pork products at nine identified modules along food production, processing and retail. To this effect, VITAL has met its stated objective of "Gathering Data", for this review period.

Progress towards developing an infectivity assay (3D-2D cell culture) for Hepatitis E Virus is still in its infancy, but would be an important achievement to realize during this project, and therefore should be pursued.

We did have a number of concerns prior to the review, and these are discussed as follows:

- Results of IAC presented in tables (pages 16-18) were confusing and would be difficult for other people to interpret. The team did provide an acceptable clarification and they are recommended to reformat these in the final report.
- Concerns with respect to the performance of one laboratory in the in trial were acknowledged, and an explanation provided, corrective actions have been devised. The project team are recommended to continue to monitor the problem to ensure its successful resolution.

- We did have concerns on the number of samples taken, especially given the number of sub-variables, and whether this would deliver sufficiently robust data. However, we believe the decision to divert more resources into the “fact finding mission” at the expense of sampling was the correct one. This will enable the project to provide a clearer explanation of the results they obtain and will be of particular benefit in the communication and “impact” part of the project. Nevertheless, the project team should take as many samples as possible.
- No mention of person-to-person spread (especially for norovirus) was made (see for example Dreyfuss, M.S., 2009, Foodborne Pathogens and Diseases, 6; 1219-1228). The project team are aware of this issue, and are recommended to consider using some of these models in the risk assessment phase.
- There is some confusion in the report over the use of the terms "questionnaires, audit, and fact finding mission". The team were able to provide adequate explanation but for a range of reasons are recommended to clarify the use of these terms throughout the document and in the workings of the project.
- This similarly applies to sampling and the use of terms such as random, opportunistic, convenience etc.

We both believe that the scientific data from the project will be very valuable and that the greatest challenges will be in the communication, utilization and impact of the data. The team are, therefore, recommended to produce a communication strategy for target groups of end users, including the scientific community, enforcement agencies and organizations, as well as a broad spectrum of industry. Such a strategy may include linking with the IAFP and the CIES. The team are further recommended, when devising their code of practice, to make use of “easy to follow” food safety management models developed elsewhere, e.g., SafeCatering. This will help to ensure “behavioural change” and thus the project would achieve its desired impact.

The project team need to ensure comprehensive editing of the final report. The project coordinating team need to also ensure a better audit trail over actions taken at various committees.

Due to the developments at Codex, beyond the control of the team, we support the modifications to T 6.3 and 7.1.

We recommend that the project team apply for a 6-month extension to support the communication and impact elements of the project.

- Excellent progress (the project has fully achieved its objectives and technical goals for the period and has even exceeded expectations).
- X Good progress (the project has achieved most of its objectives and technical goals for the period with relatively minor deviations).
- Unsatisfactory progress (the project has failed to achieve critical objectives and/or is not at all on schedule).

- b. Overall recommendations (e.g. on overall modifications, corrective actions at WP level, or re-tuning the objectives to optimise the impact or keep up with the State of the Art, or for other reasons, like best use of resources, re-focusing...).

See executive summary:

- recommend project extension
- use of terminology
- monitoring of laboratory performance
- clearer explanation of the data in tables
- development of the communication strategy
- person-to-person spread within the risk modelling
- linking with the IAFP and the CIES
- use of simplified approaches to developed for HACCP as the basis for industry guides.
- ensure clearer audit trail in the minutes of meetings

## 2. OBJECTIVES and WORKPLAN

- a. Have the objectives for the period been achieved? In particular, has the project as a whole been making satisfactory progress in relation to the Description of Work (Annex I to the grant agreement)?

Yes

Partially

No

### *Comments*

The project as a whole has made very good progress and has achieved most of its stated goals and timelines, despite unexpected delays and challenges. A "Guidance document on data collection and analysis" was completed and distributed to beneficiaries for data gathering. The main milestone for this review period was to 1) have "all labs fully prepared with necessary material and SOPs done in VITAL, 2) draft a guidance document on data collection and analysis, and 3) data gathering at various modules in Production, Processing, and Point of Sale. The set milestone and objectives were completed and met. The project was very well managed and various WP groups were well coordinated in their work flow.

b. Has each work package (WP) been making satisfactory progress in relation to the Description of Work (Annex I of the grant agreement)?

Yes

Partially

No

*Comments*

Despite some initial hurdles, overall, most WP teams have progressed well in this project. One of the labs (NVRI) seems to have some problems with method performance (results in Tables 8-14; pages 16-24), where prominent failures in detecting the IAC, and the occasional misdetection of the target virus, were evident.

WP6 seems to have encountered some cooperation problems and delays in the fact finding mission component of the project.

WP2- Ring Trials and Data gathering: Since WP2 constitutes a key foundation in this project, it is suggested that any discrepancy in experimental results be confirmed by sequence analysis. Such data will shed light on samples with failed IAC. The very low percentage of correctly identified non-contaminated samples should also be examined, possibly through sequence analysis, to understand and resolve the underlying issues that might have contributed to this matter. It is important to address this issue since the results obtained and data gathered can impact the outcome of planned risk assessment.

c. Have planned milestones and deliverables been achieved for the reporting period?

Yes

Partially

No

*Comments*

Completed milestones were documented and reported. Please see list on page 68 and Annex 2 of the report.

Main milestones and deliverables for this review period consisted of

- 1) all labs are fully prepared with necessary material- Achieved,
- 2) methods developed, validated by ring trials, SOPs written and distributed to beneficiaries- Achieved,
- 3) Data gathering from various critical point modules from Farm-to-Fork (production-processing-point of sale)- Achieved,
- 4) addressing ethical issues and women in science aspects, and
- 5) website creation. Therefore, main milestones and deliverables were met.

There were some delays in certain areas such as requests for “consumption data” for MPRN development and HACCP questionnaires were only received from some, but not all partners.

d. Are the objectives for the coming period(s) i) still relevant and ii) still achievable within the time and resources available to the project?

i	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
	Yes	Partially	No
ii	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	Yes	Partially	No

*Comments*

See earlier recommendations with respect to changes to T6.3 and T7.1, and the recommendation for project extension.

e. For Networks of Excellence (NoEs) only: N/A

Has the Joint Programme of Activities been realised for the period, with all activities foreseen satisfactorily completed?

<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Yes	Partially	No

*Comments*

N/A

**3. RESOURCES**

a. To the best of your estimate, have resources used, i.e. personnel resources and other major cost items, been (i) utilised for achieving the progress, (ii) in a manner consistent with the principle of economy, efficiency and effectiveness. Note that both aspects (i) and (ii) have to be covered in the answer.

i	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	Yes	Partially	No
ii	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	Yes	Partially	No

*Comments*

As indicated in pages 90-93: the current resources available to VITAL are utilised toward achieving the progress as outlined in the project. The consortium coordinators and leaders of the various WP teams have demonstrated careful budget management, thus meeting planned allocations for different objectives. Statistical review of the impact of reducing the number of samples taken to release 27,500 Euros, although unfortunate, illustrated a sound and responsible decision-making process in utilizing the funds in the most effective and efficient manner. As such, an estimated error increase of 1.7 seems acceptable in order to achieve the objective of an integrated monitoring and control of foodborne viruses in the food supply. Furthermore, the decision not to replace the two departing members of the PAB, and thus maintaining the membership at the at only three members, signifies a conscious effort and wise decision in better utilization of resulting extra funds without compromising the efficiency of the PAB activity.

- b. If applicable, please comment on large deviations with respect to the planned resources.

*Comments*

See comments on project extension.

**4. IMPLEMENTATION OF THE PROJECT**

a. Has the project management been performed as required?

Yes

Partially

No

*Comments*

WP 1 has done a truly impressive work in bringing together so many diverse and multidisciplinary teams from across Europe, to join forces and expertise to work on such an important and comprehensive project. The management team has acted in a very responsible manner, demonstrating clear capability in efficient and effective management and decision-making process, combined with good communication, flexibility and accommodation. Even though there were the occasional impediments and challenges, such as consortium consensus on signing MTAs, the management team was able to manage and overcome these difficulties, thus minimizing the negative impact that could have occurred on the progress of the project due to such delays. overall attendance at meetings seems good although one CAT meeting only had 50% participation . See also earlier recommendation about audit trail in committee minutes.

b. Has the collaboration between the beneficiaries been effective?

Yes

Partially

No

*Comments*

Overall, most participating beneficiaries worked well collaboratively. There were some situations that have resulted in delaying the progress of this project in relation to its stated timelines. Examples of this relate to the legal matters delaying consortium consensus signatures on MTAs between UB and two other partners, as well as the MTA with Washington University. There were some delays in receiving consumption data for MPRM and recruitment of participants by some partners. Overall, however, collaboration seems to be fluid among the beneficiaries.

- c. Do you identify evidence of underperforming beneficiaries, lack of commitment or change of interest of any beneficiaries?

Yes

Partially

No

*Comments*

Some methodology performance problems seem to have occurred in one of the labs (NVRI), as seen in the results obtained (Tables 8-14; pages 16-23). However, it is evident that corrective measures are being implemented to resolve this issue, and to ensure sufficient training to achieve equivalency of performance with other labs.

**5. USE AND DISSEMINATION OF FOREGROUND**

- a. Is there evidence that the project has/will produce significant scientific, technical, commercial, social, or environmental impacts (where applicable)?

Yes

Partially

No

*Comments*

Activities in this project have so far produced important methodologies of important and significant scientific impact, whereby these methods may become relevant Standards for a wider use globally. Whether these methods may be of commercial value remains to be seen as the project nears its completion and details of these methods become available. This project will shed light on the whole farm to fork continuum in regards to virus contamination. It will be extremely useful not only for the European Nations, but also for the global community. This project should produce significant data that will have a considerable environmental, public health, economic and social impact.

- b. Is the plan for the use of foreground, including any update, appropriate? Namely, please comment on the plan for the exploitation and use of foreground for the consortium as a whole, or for individual beneficiary or groups of beneficiaries and its progress to date.

Yes

Partially

No

*Comments*

Since the preliminary draft of the VITAL Code of Good Practice has already started, consideration is being given to initiate potential collaborative activities with Codex Alimentarius' Working Group on Viruses, which has drafted the "Code of Hygiene Practice for Control of Viruses in Food". Furthermore, with the Standard Operating Procedures (SOPs) having been prepared, collaboration with the CEN/ TC275/ WG6 /TAG4's standards for foodborne virus detection, is also being considered.

- c. Have the beneficiaries disseminated project results and information adequately (publications, conferences...)?

Yes

Partially

No

*Comments*

Despite the short period (18 months) of activity, the VITAL team has held a series of meetings and conferences to help the dissemination of information, preparing SOPs and gathering data for analysis. The VITAL website has been populated with relevant information, mostly to beneficiaries and limited to public at this point in time. Information was disseminated through oral/poster presentations at the FoodMicro2008 meeting and at COST 929 (2008) meeting. Two review papers are in preparation for publication and overall the project has the potential to lead to approx 15 publications.

- d. Are potential users and other stakeholders (outside the consortium) suitably involved (if applicable)?

Yes

Partially

No

*Comments*

- e. Is the consortium interacting in a satisfactory manner with other related Framework Programme projects or other R&D national/international programmes, standardisation bodies (if relevant)?

Yes

Partially

No

*Comments*

The consortium is aware of related project recently initiated by the WHO's Working Group on developing a code of good practices similar to the one planned in this study. VITAL is planning to collaborate with WHO in order to avoid duplication of the work. The suggested attempt to have the WHO invite the coordinator of VITAL to participate in the upcoming meeting on the development of code of good practice is a right step in the right direction. It was indicated in the minutes of D1.16 of 9<sup>th</sup> CAT meeting on September 24<sup>th</sup>, 2009, that Dr. N. Cook has been invited to attend the next meeting of the WHO Code of Good Practice.

## 6. OTHER ISSUES

- a. Have policy-related and/or regulatory issues been properly handled (if applicable)?

Yes

Partially

No

*Comments*

- b. Have ethical issues been appropriately handled (if applicable)?

Yes

Partially

No

*Comments*

Ethical issues related to the use of samples from humans (hands and fingers) were being examined, and an action plan to be posted on the website was being formulated by Marta Hernandez Perez. No further action in this regard at this point in the project.

c. Have safety issues been properly handled (if applicable)?

Yes

Partially

No

*Comments*

With so many highly recognized experts involved in this project, the issue of safety must have been an integral part of any work done. Sufficient training was provided to graduate students who were to be involved in testing samples or other experimental work.

d. Has progress on Gender Equality Actions been satisfactory (if applicable for this reporting period)?

Yes

Partially

No

*Comments*

A program for gender equality has been created in VITAL. The issue of the percentage of women involved in this project has been a topic of discussion and steps to increase the number of women participants in this projects have been explored.

Name (s) of the expert(s): Dr. Sabah Bidawid and Prof . Chris Griffith

Date: January 12<sup>th</sup>, 2010

Signature(s):

