

SEVENTH FRAMEWORK PROGRAMME

THEME 2

Food, Agriculture and Fisheries, and Biotechnology

Grant agreement for: **Small Collaborative Project**

Annex I - "Description of Work"

Project acronym: **VITAL**

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

Grant agreement no.: **213178**

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PART A. BUDGET BREAKDOWN AND PROJECT SUMMARY

A1. OVERALL BUDGET BREAKDOWN FOR THE PROJECT

Beneficiary Number in this project	Beneficiary short name	Estimated eligible costs (whole duration of the project)					Total Receipts	Requested EC Contribution
		RTD/Innovation (A)	Demonstration (B)	Management (C)	Other (D)	Total A+B+C+D		
1	Defra	464,880	0	73,409	0	538,289	0	422,069
2	KULeuven	270,000	0	0	0	270,000	0.00	202,500
3	VRI	144,053	0	0	0	144,053	0	108,040
4	UH	321,276	0	0	0	321,276	0	240,957
5	UPA	201,440	0	0	0	201,440	0	151,080
6	ISS	335,042	0	0	0	335,042	0	251,281
7	RIVM	498,783	0	2,000	0	500,783	0	376,087
8	WUR	418,221	0	2,000	0	420,221	0	315,665
9	NVRI	249,784	0	0	0	249,784	0	187,338
10	NIV-NS	149,200	0	0	0	149,200	0	111,900
11	UL-BF	230,966	0	0	0	230,966	0	173,224
12	ITACyL	242,997	0	0	0	242,997	0	182,248
13	UB	266,086	0	0	0	266,086	0	199,565
TOTAL		3,792,728	0	77,409	0	3,870,137		2,921,954

A2. PROJECT SUMMARY

Project full title:	Integrated monitoring and control of foodborne viruses in European food supply chains
Project short title:	Monitoring and control of foodborne viruses
Project acronym:	VITAL
Project objectives	<p>The concept of VITAL is the integrated risk assessment and management of contamination of the European farm to market food supply chain by pathogenic viruses.</p> <ol style="list-style-type: none"> 1. To acquire data on virus contamination of food and environmental sources suitable for quantitative viral risk assessment 2. To assess foodborne viral risks for determining high risk situations and efficacy of interventions 3. To develop new measures to prevent virus contamination of foods and the environment 4. To develop and assess measures for virus reduction and control in case of virus contamination

ABSTRACT

The concept of VITAL is the integrated monitoring and control of contamination of the European food supply chain by pathogenic viruses. VITAL will use advanced methods for virus detection throughout selected food supply chains from farm to market, to gather data on virus contamination of food and environmental sources suitable for quantitative viral risk assessment. Supply chains will be monitored for the presence of indicator viruses commonly found in faecal contamination events. These viruses can be distinguished into strains of human and animal origin, which will indicate contamination from a specific source. Modelling tools will be developed to define the quantitative viral risk for each scenario, and to assess foodborne viral risks for determining high-risk situations and efficacy of interventions. Modular process risk models will be developed to build up specific HACCP recommendations. Recent developments in risk management will be evaluated for their use in reducing foodborne viral infections. Survival of viruses in foods will be modelled, and disinfection procedures used in the food industry will be evaluated, to elucidate the critical points where virus contamination may be controlled. VITAL will disseminate its findings by producing handbooks and guidelines on appropriate control practices, and communicate requirements necessary for establishing reliable monitoring of food chains for viruses on a regular or as-needed basis. Therefore VITAL will provide to Europe a framework for monitoring, risk modelling, and procedures for control of foodborne virus contamination, which will be applicable to any virus, whether existing, emerging or re-emerging, that poses the danger of being transmitted by food. Implementation of such a framework of preventive or proactive virus contamination management will form a first line of defence against transmission of foodborne viral diseases in Europe.

A3. LIST OF BENEFICIARIES

Beneficiary Number	Beneficiary name	Beneficiary short name	Country	Date enter project	Date exit project
1 (coordinator)	Defra	Defra	United Kingdom	Month 1	Month 36
2	Catholic University of Leuven	KULeuven	Belgium	Month 1	Month 36
3	Veterinary Research Institute	VRI	Czech Republic	Month 1	Month 36
4	University of Helsinki	UH	Finland	Month 1	Month 36
5	University of Patras	UPA	Greece	Month 1	Month 36
6	Istituto Superiore di Sanita	ISS	Italy	Month 1	Month 36
7	National Institute for Public Health and the Environment	RIVM	Netherlands	Month 1	Month 36
8	Wageningen University Research	WUR	Netherlands	Month 1	Month 36
9	National Veterinary Research Institute	NVRI	Poland	Month 1	Month 36
10	Scientific Veterinary Institute "Novi Sad"	NIV-NS	Serbia	Month 1	Month 36
11	University of Ljubljana	UL-BF	Slovenia	Month 1	Month 36
12	Instituto Tecnológico Agrario de Castilla y León	ITACyL	Spain	Month 1	Month 36
13	University of Barcelona	UB	Spain	Month 1	Month 36

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PART B

B1. SCIENTIFIC AND/OR TECHNICAL QUALITY, RELEVANT TO THE TOPICS ADDRESSED BY THE CALL

B1.1 Concept and objectives

The concept of VITAL is *the integrated risk assessment and management of contamination of the European farm to market food chain by pathogenic viruses*. The VITAL consortium is composed of expert practitioners in food analysis, quantitative viral risk assessment (QVRA), risk management, and consumer safety. Together, their vision is an integrated approach to the management of foodborne viruses in Europe.

Members of the VITAL consortium are participating in two European Networks: **COST Action 929 “European Network for Food and Environmental Virology”** (www.cost929-environet.org), and the **Network of Excellence MedVetNet** (www.medvetnet.org), specifically Work Package 31 **“ZOOVIR-NET”**. The proposed project will draw together common aims of each network and add value to both. These Networks agree that a major issue regarding foodborne viruses is the lack of effective risk management strategies and prevention and intervention measures against food and environmental contamination. The current epidemiological surveillance systems can only react to and provide information on disease outbreaks that occur through contamination of food. Such reactive surveillance alone cannot lead to any reduction in disease incidence. Decreasing the incidence and spread of foodborne viral diseases should involve prevention of food contamination in the production phase, throughout processing, during trade and distribution, and in the preparation phase, both in professional settings and in the home. In our project, we will focus on the production and processing phase, moving away from the concept of endpoint monitoring towards input monitoring.

These systems will be founded through the achievement of the following core **scientific and technological objectives** of VITAL:

VO1: *To acquire data on virus contamination of food and environmental sources*

VITAL will use standardised detection methods for index (representative pathogenic) virus detection¹ throughout food supply chains from farm to market. Each data-gathering laboratory will use identical methodology to harmonise the data-gathering process within each food supply chain so that data can be fully comparable among and between the various food supply chains. The data acquired will be suitable for quantitative viral risk assessment (QVRA), by using advanced quantitative molecular-based methods coupled with infectivity measurements, for monitoring each supply chain. In the different product groups, we will look for the presence of indicator viruses commonly found in case of faecal contamination events. In so doing, we will distinguish between virus strains of human and animal origin, which will indicate whether the inputs or sources from which analysed samples were obtained would be open to general virus contamination from a specific source. Virus recovery and infectivity will be determined as data requirements for QVRA. Milestones towards this Objective will be M2.1, M2.2, M3.1 and M4.1 (see [B.1.3.7 List of milestones and planning of reviews](#)).

VO2: *To assess foodborne viral risks for determining high risk situations and efficacy of interventions*

New modelling tools will be developed to analyse monitoring data collected at each stage (i.e. production and processing) of each food supply chain to define the quantitative viral risk for each scenario studied. Moreover, sensitivity analyses will reveal the parameters most strongly influencing the risk. Rolling revision of QVRA will be performed to assess efficacy of intervention measures. Milestones towards this Objective will be M2.2, M3.1 and M4.1 M5.1, 6.1 and 6.3 (see [B.1.3.7 List of milestones and planning of reviews](#)).

VO3: *To develop new measures to prevent virus contamination of foods and the environment*

The data from monitoring of raw materials and food processing will be used with Modular Process Risk Models (MPRM) to build up specific HACCP recommendations. Recent developments in risk management such as safety plans and sanitary surveys should be evaluated for their use in reducing foodborne viral infections. Milestones towards this Objective will be M5.1, M6.2 and M6.3, 6.4 and 7.1 (see [B.1.3.7 List of milestones and planning of reviews](#)).

¹ VITAL will use previously developed and currently practiced methods for virus detection, emphasizing those that are being recommended as international standard methods. The methods and systems VITAL will use for virus detection will have the potential for generic application for detection of any other foodborne viruses.

VO4: To develop and assess measures for virus reduction and control in case of virus contamination

The survival of viruses in foods will be modelled, and disinfection procedures used in the food industry will be evaluated, to elucidate the critical points where viruses may be controlled within the food chain by hygiene, contamination, and quality management measures currently practiced by producers and processors to address bacterial and fungal food-safety concerns. The effectiveness of the strategy of control of zoonotic viruses through vaccination will also be examined. Milestones towards this Objective will be M6.3, 6.4 and 7.1 (see [B.1.3.7 List of milestones and planning of reviews](#)).

The outcomes of VITAL must be valued by Europe. To ensure this, we have a full and targeted dissemination plan (detailed in Section 3). VITAL will consolidate and deliver its findings by publishing industry- and practitioner-directed handbooks and guidelines on appropriate control practices for virus contamination, and by presenting to government policy-makers and regulatory agencies the requirements necessary for establishing reliable monitoring of food chains for viruses on a regular or as-needed basis.

Therefore VITAL will provide to Europe a framework for monitoring, risk modelling, and procedures for control of foodborne virus contamination, which will be applicable to any virus that poses the danger of being transmitted by food. Implementation of such a framework of preventive or proactive virus contamination management will form a first line of defence against transmission of foodborne viral diseases in Europe.

B1.2 Progress beyond the state-of-the-art

In the food industry, product safety depends very much on the controls that can be exercised during production. Principle elements of current food safety management initiatives are Good Practices (i.e. GAP, GHP, GMP), Hazard Analysis Critical Control Point (HACCP), Modular Process Risk Models (MPRM) and Microbiological Risk Assessment (MRA). To date, however, with respect to microbiological hazards, these concepts were directed at bacterial and fungal pathogens only since these organisms lead to obvious food decay. Analysing the impact of virus contamination of food is only based on gathering epidemiological information, which occurs only in response or as a reaction to disease outbreaks. A coordinated and validated system or network does not yet exist to routinely and proactively monitor actual food samples.

Risk analysis can be considered as the common framework for identifying and adopting regulatory requirements at national level. The World Trade Organisation (WTO) has advocated the adoption of a risk-based approach to food safety (WTO, 1995). Microbial risk assessment (MRA) is used to collect and analyse relevant information on emerging or uncharacterised foodborne pathogens to determine and quantify risks and guide risk management and communication. Industry does not necessarily need to conduct risk assessments, because it is a task for public health agencies; industry should be involved in assessment of risks and only actively needs to ensure it has proper food safety management systems in place. However, MRA studies may contain valuable information that can help strengthen industry's food safety management systems.

Although the HACCP concept includes monitoring of microorganisms, in-process data is seldom gathered and used. In reality, in-process data is typically too anecdotal to describe the process dynamics of a critical point. Importantly, microbiological monitoring methods are *still* being used mainly at the end of the production chain. **VITAL will demonstrate how to monitor food supply chains during other key stages.** Furthermore, more-objective statistical tools are rarely used to better describe and control the dynamics of critical points based on microbiological parameters. Therefore, to develop reasonable and effective HACCP plans, it will be necessary to first establish Modular Process Risk Models (MPRM) for each food supply chain (Nauta, 2002). A full description of an MPRM can be found in Nauta (2005). MPRM is recognized as a promising approach to risk management, although the uncertainty in the final risk estimate can still be great. This is due to the scarcity of data at several stages of the chain. Among others, the scarcity of quantitative data at several stages of the supply chain, and the absence of growth and inactivation models that include variability, and useful quantitative models. Therefore, one of the major challenges to MPRM and other microbiological risk management strategies applied to foodborne pathogen contamination management has been filling the gaps in microbiological knowledge that are crucial for risk assessment. **VITAL will supply quantitative data on virus contamination of key stages of several food supply chains.** Then, by integrating the MPRM functions with the development of HACCP models for each link of each food supply chain selected for study, VITAL will fill information gaps and improve confidence in MPRM. Hence, **VITAL will provide the first true integration of modular process risk modelling with hazard analysis and critical control points plan development and evaluation using *real-world* circumstances.**

Adopting risk-based (regulatory) measures as part of food safety management systems - especially HACCP and QVRA - requires sufficient scientific evidence to support regulatory rationale. Meeting this challenge has been quite successful in the case of several foodborne bacteria. However, for foodborne viruses, which are considered an emerging problem, the overall challenge is a much more daunting one. This is because sufficient scientific evidence and published information is lacking for the effective implementation of food safety systems involving foodborne viruses. Several studies have been performed which provide information on the hazard of foodborne viruses, as reviewed by Cook and Rzeżutka (2006), Koopmans and Duizer (2004), and Vasickova *et al.* (2005). Although much information is available that could be useful when formulating HACCP plans and specifically quantitative risk assessments, it is clear that there are several general areas where there are knowledge gaps, and there is an urgent need for information about those factors which would facilitate a realistic hazard identification, exposure assessment, and hazard / risk characterisation. The existing approach in Europe to analysing the impact of virus contamination of food is based solely on the gathering of epidemiological information, and, as such, operates only in response, or as a reaction, to disease outbreaks. There is no coordinated system in place for organised and validated monitoring of actual food samples. Therefore, as well as acquiring more detailed information from outbreak investigations, practical research is necessary to acquire more information on the presence of foodborne viruses throughout the food supply chain (Cook and Rzeżutka, 2006). **By gathering real in-process data for the first time, VITAL will provide necessary information to effectively substantiate hazard analysis and risk assessment before regulations are drafted to address virus contamination issues in food supply chains.** By sampling throughout various food supply chains, **VITAL will generate information on how foodborne viruses**

are introduced and how their presence is affected by elements of the production and processing of the foods.

Corrective actions are performed whenever a critical limit is not met. A hurdle to drafting recommendations for corrective actions against foodborne viruses is that information on virus survival characteristics is incomplete. However, available information indicates that foodborne viruses can survive, or persist in an infectious state, in foods and in the environment for extended periods, long enough to be a greater risk than some bacterial pathogens. (Rzeżutka and Cook, 2004). It would be advantageous to have complete knowledge of enteric virus survival in foods and in food production environments, and the factors which influence it, as a fuller extent of the risks these pathogens pose may thus be comprehended, and means to break or curtail the chain of transmission may be ascertained. Although some information on virus survival has been acquired (Rzeżutka and Cook, 2004), no study has comprehensively included all enteric virus types, even those which can be readily propagated in cell culture, and there is no hard information on important viral agents such as noroviruses and hepatitis E virus. Although limited *in vitro* replication of norovirus (Straub *et al.*, 2007) and hepatitis E virus (HEV) (Tanaka *et al.*, 2007) in cell culture has been reported, some further investigation is required to assure efficient propagation, to allow the effect of various factors on persistence of infectious virus to be studied. Based on these developments, **VITAL will produce data on the survival of norovirus, HEV, and adenovirus in pork products, salad vegetables, and soft fruit, and in model food production environments.**

The persistence of infectious viruses on foods may be challenged by various decontamination techniques, and the survival times of each virus type on different foodstuffs will provide baseline information to assess the efficacy of these techniques. Some studies have been performed to evaluate disinfection systems (Dawson *et al.*, 2005), but these need to be expanded to be more directly relevant to current industrial practice, and to determine the latter's effectiveness against a wider range of viruses, including those outside the currently most significant foodborne types. Decontamination procedures for viruses include physical inactivation, e.g. heat treatment, and chemical disinfection, e.g. chlorination, of the product and / or environment. At present, however, the procedures used in the food industry have not been fully evaluated for their effectiveness against viruses, and what information exists indicates that with fresh produce at least, current methods may be inadequate (Cook and Rzeżutka, 2006). **VITAL will provide novel information on the efficacy of elimination procedures against foodborne viruses.** Physical and chemical strategies for controlling contamination of the food supply chain will be evaluated in comprehensive studies utilizing the latest techniques for examining *actual*, not model, foodborne virus types.

Vaccination has an impact on transmission of infectious agents such as HEV between animals within a group and between groups of animals. By combining the transmission of infection dynamic modelling with a surveillance simulation system, the effect of vaccination can be evaluated as to whether the infection will die out or propagate itself in a population of animals including the prediction about the probability of detecting an infection based on a given sampling strategy. After developing the transmission model and linking it to the surveillance simulation system, interventions such as vaccination strategies can be evaluated using existing data during a desk-top effort. **VITAL will provide the first evaluation of strategies for vaccination of farm animals against hepatitis E virus, providing a basis for managing the risk of transmission of a zoonotic disease.**

A summary of the progress which VITAL will make beyond the state of the art is:

- Baseline -** Microbiological monitoring methods are used mainly at the end of the production chain.
Progress - VITAL will demonstrate how to monitor food supply chains during other key stages.
- Baseline -** There is no quantitative data on virus contamination within major food supply chains.
Progress - VITAL will supply quantitative data on virus contamination of key stages of several food supply chains.
- Baseline -** The effectiveness of procedural controls such as HACCP and MPRMs has not yet been evaluated for foodborne virus contamination.
Progress - By integrating MPRM functions with the development of HACCP models for major food supply chains, VITAL will fill information gaps and improve confidence in procedural controls.
- Baseline -** There is insufficient scientific evidence and published information for the effective implementation of food safety systems involving foodborne viruses.
Progress - VITAL will gather real in-process data, and provide information to substantiate hazard analysis and risk assessment.
- Baseline -** The existing approach to analysing the impact of virus contamination of food is based solely on the gathering of epidemiological information, and operates only in response, or as a reaction, to disease outbreaks.
Progress - By sampling throughout various food supply chains, VITAL will generate information on how viruses contaminate foods, and how their presence is affected by elements of the production and processing of the foods.
- Baseline -** There is no hard information on the survival of important viral agents such as noroviruses and hepatitis E virus in foods and food processing environments.
Progress - VITAL will produce data on the survival of norovirus, HEV, and adenovirus in pork products, salad vegetables, and soft fruit, and in model food production environments.
- Baseline -** The procedures used in the food industry have not been fully evaluated for their effectiveness against viruses.
Progress - VITAL will provide novel information on the efficacy of elimination procedures against foodborne viruses.
- Baseline -** There has been no evaluation of strategies for vaccination of farm animals against hepatitis E virus.
Progress - VITAL will provide the first evaluation of strategies for vaccination of farm animals against hepatitis E virus, providing a basis for managing the risk of transmission of a zoonotic disease.

B1.3 S/T methodology and associated work plan

VITAL’s research strategy is to gather data from food supply chains, and then this data will be collected and utilised in risk interpretation and to underpin recommendations for control measures.

B1.3.1 Overall strategy and general description

B1.3.1.1 Data gathering (WP2, WP3, and WP4)

The methodology described in this Section will be deployed to fulfil VITAL core objective VO1: acquisition of data on virus contamination of food and environmental sources.

The food supply chains

Four food supply chains considered to be susceptible to virus contamination will be selected for study: 1) soft fruit; 2) salad vegetables; 3) pork products, and; 4) shellfish. Data will be gathered by monitoring three intrinsic phases of each chain: food production, food processing, and point of sale. Each phase will have a specific Workpackage. The soft fruit, salad vegetable, and pork supply chains will be monitored at all three phases. With shellfish, because extensive data exists for raw materials and processing, only the point of sale will be monitored.

WP 2 will focus on farms and slaughterhouses. Viruses present at these points can contaminate raw food materials before processing and sale.

WP 3 will focus on food processing procedures. Viruses present during food processing have the potential to contaminate food at point of sale. The data acquired in WPs 2 and 3 will be included in the hazard analyses and risk assessments VITAL will perform.

WP 4 will survey locally produced and imported foods at point of sale. Viruses present on foods at point of sale have the potential to lead to infection of the consumer. The data from WP4 will be used to build up exposure assessment profiles.

Some beneficiaries will focus on one food supply chain, while others will monitor more than one (Table B1.1). Each beneficiary will use identical and standardised methodology (see below) to gather the data, so that the results of the data gathering can be fully comparable between and among the various food supply chains.

Table B1.1 Food supply chains analysed by each data-gathering laboratory

Data-gathering lab	WP2 Production	WP3 Processing	WP4 Point of Sale
Defra (VLA)	Pork	Pork	Pork
VRI	Pork, Soft fruit	Pork, Soft fruit	Pork, Soft fruit
UH	Soft fruit	Soft fruit	Soft fruit, shellfish
UPA	Salad veg	Salad veg	Salad veg, shellfish
ISS	Pork	Pork	Pork
NVRI	Soft fruit, Salad veg	Soft fruit, Salad veg	Soft fruit, Salad veg
NIV-NS	Soft fruit, Salad veg	Soft fruit, Salad veg	Soft fruit, Salad veg
ITACyL	Pork	Pork	Pork, shellfish

Table B1.2 shows the matrices which will be analysed in each phase of each production chain.

Table B1.2 Matrices to be analysed

			Production Chain			
			Soft fruit	Salad vegetables	Pork products	Shellfish
Phase	Raw materials	1	Irrigation water	Irrigation water	Pig faeces on farm	None
		2	harvesters' latrines	harvesters' latrines	Liver from slaughterhouse	None
		3	harvesters' hands	harvesters' hands	blood from slaughterhouse	None
		4	Animal-based fertilizers	Animal-based fertilizers	effluent in slaughterhouse	None
Phase	Processing	1	Equipment (e.g. freezing) / water	Equipment (e.g. chopping etc.) / water	Butchers' equipment	None
		2	Working surfaces	Working surfaces	Working surfaces	None
		3	workers hands	workers hands	workers hands	None
Phase	Point of sale	1	Locally produced fresh and frozen fruit	Locally produced fresh salad	Raw sausages	Locally grown shellfish
		2	Imported fresh and frozen fruit	Imported fresh salad	Liver	Imported shellfish

The reasons for the choice of these matrices are given below.

Irrigation water Water used for irrigation of crops may be drawn from sources (e.g. rivers) which may be contaminated with sewage, and thus contain viruses of human origin (Lodder and de Roda Husman 2005). Water sources may also be in contact with run-off from agricultural (e.g. pasture) land, or farm effluent, and thus contain viruses of animal origin (Schijven and de Roda Husman 2005). Therefore irrigation water is a potential vehicle for contamination of salad vegetable or soft fruit crops.

Harvesters' and workers' hands Infected persons in direct contact with foodstuff during harvesting or processing are a likely source of contamination with viruses. It has been estimated that a 10 second touch with virus-contaminated fingertips can transfer around 10 % of the viruses onto a food or a surface (Bidawid *et al.*, 2000).

Harvesters' latrines The faecal contents of harvesters' latrines can give a snapshot of any enteric viral infections the harvesters may be suffering from, and therefore what the crops may potentially be exposed to through contact with the harvesters. Also, on many farms there can be only rudimentary toilet facilities for the harvesters, and field latrines may be a point of potential contamination of crops.

Animal-based fertilizers These can be applied to growing crops, often by spraying. Manure, even if stored for several months before application, may potentially harbour infectious viruses from farm animals (Cook *et al.*, 2004).

Pig faeces on farm When pigs are infected with HEV, they excrete it large quantities of virus in their faeces. This is a source of contamination of water sources through run-off, and of manure fertilizer.

Liver from slaughterhouse Analysing liver for HEV will directly indicate the contamination of this raw food material.

Blood from slaughterhouse Analysing blood for HEV will directly indicate the contamination of this material. Also, blood may be used as a fertilizer.

Effluent from slaughterhouse The effluent from a slaughterhouse may run-off into watercourses, and thus have the potential to contaminate with animal viruses.

Equipment (e.g. freezing, chopping etc.) The equipment used in a food processing plant, or in a butchers, may if not thoroughly cleaned have the potential to act as a vehicle of virus cross-contamination between batches of food.

Surfaces The surfaces as the equipment used in a food processing plant, or in a butcher's, may if not thoroughly cleaned have the potential to act as a vehicle of virus cross-contamination between batches of food.

Local produce This will indicate the consumer's exposure to foodborne viruses from foods sourced within their community.

Imported produce This will indicate the consumer's exposure to foodborne viruses from foods from other countries.

The viruses

Pathogenic viruses originate from two sources to contaminate the food chain: humans and animals. To facilitate identification of whether contamination is of human or zoonotic origin, VITAL will monitor the presence of human and animal viruses at various points in the food supply chains. Adenoviruses infect both humans and a wide variety of animal species, are shed in large numbers in the faeces of infected individuals (Granoff and Webster, 1999), and are capable of robust survival (Cook and Rzeżutka, 2006). They have been proposed as an index of viral contamination, and the specific detection of adenoviruses from human or animal origin should be a useful tool for tracing the source of faecal viral contamination (Maluquer de Motes et al., 2004). Recent findings (unpublished) from the Framework 6 project "Methods for the detection of adenoviruses and noroviruses in European bathing waters with reference to the revision of the Bathing Water Directive 76/160/EEC (VIROBATHE)" (Project No. 513648), have supported the view that adenoviruses are quite commonly found when faecal contamination is evident. VITAL will view the detection of adenoviruses as evidence of a risk of wider human or animal virus contamination of the food supply chain under analysis. Hundesa et al. (2006) stated that due to their higher prevalence in faecal and environmental samples than bovine adenoviruses, bovine polyomaviruses are better candidates for tracing a bovine source of viral contamination. Human and porcine adenoviruses, and bovine polyomavirus, will thus be defined as "index" viruses in VITAL.

As well as the index viruses, the presence of HEV in pork production will be examined. HEV is regarded as a model zoonotic virus: if porcine adenoviruses are detected in samples of soft fruit, salad vegetables or shellfish, the sample will also be analysed for HEV. Furthermore, if it is considered during the monitoring that the foodstuff or material has a chance of being contaminated by norovirus and hepatitis A virus (HAV) (e.g. if an outbreak has occurred or is occurring locally), then the samples will be analysed for these agents. Additionally, should it so happen that an outbreak of a new virus type occurs, then this agent will be included in the monitoring program if possible (i.e. if suitable primer sets exist). The viral loads in all samples will be detected and quantified by RTPCR, QPCR and in vitro culture, this last approach to confirm the infectivity of detected virus. Table B1.3 shows the target viruses in each food supply chain.

Table B1.3 Viruses to be monitored in each food supply chain

		Samples analysed for					
		HAdV	BPyV	PAdV	HAV	NV	HEV
Production chain	Soft fruit	√	√*	√*	√	√	√
	Salad vegetables	√	√*	√*	√	√	√
	Pork products	-	-	√	-	-	√
	Shellfish	√	√	√	√	√	√

HAdV: human adenovirus; **BPyV:** bovine polyomavirus; **PAdV:** porcine adenovirus; **HAV:** hepatitis A virus; **NV:** norovirus; **HEV:** hepatitis E virus

√: in each sample (* but not latrine samples or harvesters' hand washings).

√: only if presence indicated (see above).

-: not taken

For extraction of virus particles from soft fruit, salad vegetables, and shellfish, we will base the methods developed for each type of food on those which the standardisation group CEN/WG6/TC275/TAG4 "Detection

of viruses in foods” have selected as the bases of their recommended methods. The protocols which are in the public domain will be provided to the data-gathering beneficiaries by the TAG4 members in the VITAL consortium. These methods facilitate the extraction of viruses from food samples, to a concentrate of 10 ml or less. For extraction of virus particles from irrigation water, we will use the freshwater standard operating procedure (SOP) which has been developed and applied by the VIROBATHE project. This method produces a 10 ml final concentrate. This concentrate can then be used for nucleic acid extraction. This will be performed by a proprietary method, - NucliSens® miniMAG™ (Biomérieux) - which is recommended by CEN/WG6/TC275/TAG4, and which can deliver nucleic acids in a 100 µl final extract. This extract (10 µl each reaction) will be used for PCR (for adenoviruses which have a DNA genome) and for reverse-transcription PCR (for HAV, HEV and noroviruses, which have an RNA genome) detection of the target viruses.

For extraction of virus particles **from animal products**, we will use the method of Feagins et al. (2007).

For extraction of viral nucleic acids **from human and pig faeces**, proprietary methods will be used, such as the QIAamp® Viral RNA Mini kit (QIAGEN)

For detection of viruses **on harvesters’ hands**, sampling will be performed by washing in buffer to elute any viruses, with subsequent concentration followed by nucleic acid extraction and (RT)PCR.

For detection of viruses **on environmental surfaces**, the swabbing procedure based on that to be published by CEN/WG6/TC275/TAG4 will be used.

At the project kick-off meeting in Month 1, a workshop will be held to discuss all SOPs in detail, and each data-gathering beneficiary will spend Months 1 to 9 establishing the methods in their laboratory. Representatives from all VITAL beneficiaries will attend this workshop, to facilitate the dissemination of knowledge, and integration of all VITAL beneficiaries within the project.

Each sample will be assayed for human adenoviruses using the primer sets of Allard et al. (2001) following the VIROBATHE SOP. For porcine adenoviruses, the primer sets of Maluquer de Motes et al. (2004) will be used, and the assays will be modified to include internal amplification controls (IACs). For bovine polyomaviruses, the primer sets of Hundesa et al. (2006) will be used. For HAV and norovirus, the primer sets which will be recommended by CEN/TC275/WG6/TAG4 will be used. For HEV, the assay of Rutjes *et al.* (2007) will be used.

The number of virus genomes (PCR-detectable units, or PDUs) in samples will be determined either by qPCR, or as most probable number (MPN) by the use of presence / absence in ten-fold dilutions of sample extracts. For the purposes of data analysis, it will be assumed that samples which test do not contain the target viruses.

Figure B1.1 overviews the basic monitoring methodology, and the viruses which will be sought in each food supply chain.

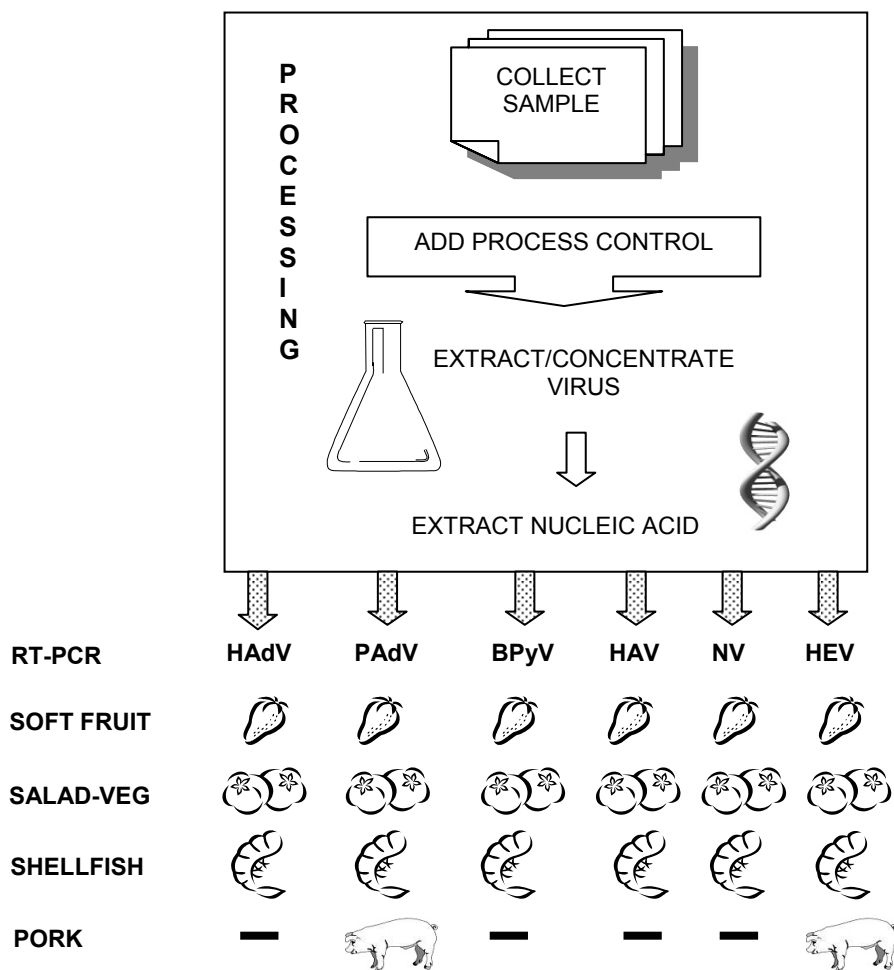


Figure B1.1 The VITAL monitoring methodology, and target viruses

If **adenoviruses** are detected, it will be informative to see if they are infectious. For this, infectivity cell culture – PCR (ICC-PCR) will be employed (Reynolds *et al.*, 1996). ICC-PCR has been used successfully within the VIROBATHE project, on environmental samples, and VITAL will use the previous project’s standard operating procedure for ICC-PCR, with the additional modification of detection of adenovirus mRNA as unambiguous confirmation of virus infectivity (Ko *et al.*, 2003). With foods or irrigation water samples, the remaining 1 ml aliquot of the concentrate can be used for ICC-PCR; if adenoviruses are detected in faecal samples, 1 ml of the sample can be clarified by centrifugation and filtration and then used.

Sampling All data-gathering laboratories will be required to analyse all matrices in each food supply chain, in the WPs in which they are involved (see Table B1.1).

Three samples will require one person-week for analysis from collection to result. In **WP2**, 120 samples can be analysed by one person. In WP2 each food supply chain has 4 matrices (see Table B1.2). Therefore 30 samples of each matrix can be analysed by one person in WP2.¹

In **WP3**, 90 samples can be analysed by one person. In WP3 each food supply chain has 3 matrices (see Table B1.2). Therefore 30 samples of each matrix can be analysed by one person in WP2¹.

In **WP4**, 60 samples can be analysed by one person. In WP4 each food supply chain (except pork, see WP4 description Table) has 2 matrices (see Table B1.2). Therefore 30 samples of each matrix can be analysed by one person in WP4.

By adding together each data-gathering laboratory’s contribution, Table B1.4 shows the total number of samples which will be taken within each food supply chain, in each WP.

¹ For organisation reasons, Defra will analyse a total of 90 samples in WP2. Approximately 22 samples of each matrix from the pork supply chain will be analysed by Defra in WP2. Defra will analyse a total of 45 samples in WP3, and 90 in WP4.

Table B 1.4 The total number of samples which can be taken within each food supply chain

Food supply chain	Number of samples taken		
	WP2	WP3	WP4
Pork	450	315	240
Salad vegetables	360	360	180
Shellfish	-	-	180
Soft fruit	480	360	240

Quality control The virus extraction methods will be quality controlled through the incorporation of process controls including artificially added non-foodborne viruses (Croci et al., in press). The process control virus will be one which can easily be cultivated on cell culture so that the number of particles added to each sample can be estimated. There are several good candidates for an appropriate process control (for example murine norovirus, or a genetically modified mengovirus with reduced pathogenicity) and one will be selected following discussion at the first VITAL project meeting in month 1. The (RT)PCR assays will conform to the CEN/ISO standard (Anonymous, 2005) by inclusion of IACs and assay controls.

Prior to the commencement of the monitoring, and periodically throughout, each data gathering laboratory will determine the efficiency of their extraction procedure(s), by counting the number of process control virus detected, and comparing with the number added. This will act as a **quality control**, as the individual laboratories can check their continued performance of the methodology, and each data gathering WP leader can ensure that all laboratories are operating effectively.

Reporting of data A spreadsheet will be prepared for each data-gathering laboratory to enter results from their analyses. Copies of the spreadsheets will be held on the consortium-only section of the project website, and updated regularly during the data-gathering WPs.

B1.3.1.2 Data analysis

The methodology described in this Section will be deployed, within Workpackage 5, to fulfil VITAL core objective VO2: To assess foodborne viral risks for determining high risk situations and efficacy of interventions.

The collection of data and analysis of the data is crucial to the produced outcome and its presumed implications. VITAL will focus on the collection of data in terms of the quality of the data, type of data (detection of infectious virus units or viral genomes, typing) and number of data (number of sites, number of samples). Data will be collected on intrinsic (e.g. HEV) as well as surface contamination of viruses in foods (e.g. HAV). And data collection will be performed for human pathogenic viruses which have high (e.g. hepatitis viruses) and low (e.g. norovirus) disease burdens and high (e.g. adenoviruses) and low (e.g. HAV) environmental burdens.

Risk assessment models have been developed for bacteria in food or viruses in water (Nauta, 2002, 2005); these will be implemented and adapted for the risks from viruses in food both by zoonotic and faecal-oral transmission to humans. Adenoviruses will be used to assess inactivation by natural processes and by treatment processes of foods. Moreover, adenoviruses can be used to trace faecal contamination to human and animal sources by means of molecular epidemiology to provide possible intervention strategies. The adapted models for foodborne viruses will be validated and subsequently improved with part of the collected data sets.

The infection risk, and the disease risk, for public health from exposure to viruses in foods will be assessed. For this purpose, exposure assessment will be performed encompassing data collection on viruses in foods and consumption patterns, combined with the hazard characterisation for the specific viruses included in the study. Risks for different human pathogenic viruses and different food products studied will be compared. Sensitivity and uncertainty analysis in the foodborne virus risk assessment will be conducted to identify significant data gaps, to prioritise the need for data, and to define the most effective intervention strategies.

The MPRM is a QMRA tool that provides a clear structure for transmission models of (complex) food pathways, which may involve the 'farm to table' trajectory. In general, the aim of the process model is to describe the transmission of the hazard, here the pathogenic virus, along the food pathway, taking into account the variability and uncertainty attending this transmission. For this purpose, the food pathway is split up into smaller steps, the modules. For each module, we are interested in the input-output relation for the number of viruses per unit of product, N , and the fraction of contaminated units, the prevalence P . By treating both N and P as uncertain and

variable throughout the model, we will be able to assess the uncertainty and variability in the final exposure, and thus the uncertainty in the final risk estimate. In VITAL, the input-output relationship in the modules (Figure B1.2) will be obtained by use of mathematical modelling. Seven steps can be discerned in the MPRM: 1) Definition of the statement of purpose, the (microbial) hazard and the food product, 2) Description of the food pathway, 3) Building the MPRM model structure by splitting up the food pathway into the modules, 4) Collection of the available data and expert opinions according to the model structure developed, 5) Selection of the model to be used for each module, 6) Plug the available data into the model, 7) Exposure assessment. Figure B1.2. displays the conceptual MPRM which VITAL will develop.

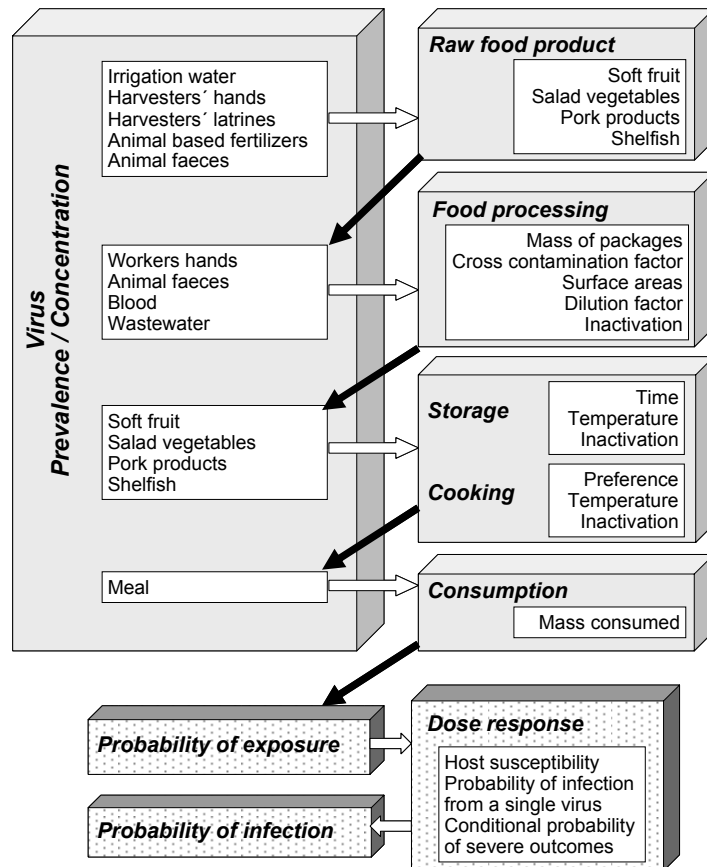


Figure B1.2. The VITAL Modular Process Risk Model for foodborne viruses

Furthermore, the quantitative data on viruses in sources for food production and virus inactivation in the food production and supply chains will provide information on health effects, by use of the MPRM producing infection and disease risks for exposure to viruses in foods.

At the second annual project meeting in Month 13, a workshop will be given by the WP5 leader for the data-gathering laboratories, to train them in the procedures of data analysis. Representatives from all VITAL beneficiaries will attend this workshop, to facilitate the dissemination of knowledge, and integration of all VITAL beneficiaries within the project.

B1.3.1.3 Control measures

The methodology described in this Section will be deployed to fulfil VITAL core objectives VO3: To develop new measures to prevent virus contamination of foods and the environment, and VO4: To develop and assess measures for virus reduction and control in case of virus contamination. The achievement of these Objectives will be the purpose of Workpackage 6.

VITAL will develop and propose HACCP models for managing or eliminating foodborne virus contamination at each stage of three different food supply chains (i.e. salad vegetables, soft fruit, and pork). This will be done by evaluating information about the procedural and physical methods current in the food industry, to determine whether they are fully suitable for control of foodborne viruses, then integrating the MPRMs developed in WP5 using the data gathered in WPs 2 and 3. The HACCP models will be generally applicable within each food supply chain. The models will be suitable as the basis of tailored HACCP plans for specific application as required by an end-user in the food industry.

The most current information from scientific, government and industry resources about approaches to monitoring and managing infectious agent risks in food supply chains is essential for successful guidance through and completion of Work Package 6 “Control Measures”. Knowledge of current regulations and practices aimed at managing other foodborne pathogens must be considered for sensible design and critical evaluation of HACCP systems for each food supply chain involved in this project. Therefore, government and scholarly publications and input from consultations with scientific, regulatory and industry contacts will be compiled and used to compose and maintain a comprehensive review of foodborne pathogen monitoring and management practices used in the food industry. Similarly, information specific to current and promising experimental approaches to safe and effective management of viruses in agricultural, clinical, and industrial environments and on or in plant and animal tissues will also be gathered and used to generate a current review of the agents and treatments effective against viruses associated with foods. All of this information will be disseminated to the beneficiaries through the project’s knowledge base and to the scientific community, regulatory and public health agencies, industry, and the public through published reviews and general web-based resources.

The efficacy of physical and chemical strategies for preventing, treating against (i.e. sanitizing, disinfecting, deactivating, etc.), and restricting or eliminating transfer or spread of the model foodborne viruses in this project will be evaluated in the laboratory and at selected representative production, processing and point-of-sale sites in WP6. Results from the evaluation of these approaches will then be used to rate the approaches according to their effectiveness, compatibility with existing food safety management practices, effect on final product quality, and possible use in prevention, protection, and intervention functions of HACCP systems that could be deployed at various stages of each food supply chain studied in this project.

Experimental programs to determine virus survival and evaluate decontamination techniques are eminently suitable for post-graduate studies. VITAL will support three post-graduate studies, each focussing on an individual virus: norovirus, HEV, and adenovirus. The first two studies will provide essential information about these foodborne viruses. It is also important to study survival and elimination of adenoviruses, as this will help us to better understand the significance of findings from our data gathering. All three viruses will be studied on soft fruit and salad vegetables (after Kurdziel *et al.*, 2001), and on surfaces such as aluminium, steel and wood, under various temperature conditions. The survival of HEV in pig faeces under various storage conditions, including application of manure to land, will also be evaluated. The studies will also use available information about current industry practice (e.g. Seymour, 1999) to build an experimental programme which will realistically model actual decontamination practices.

Within each of the three survival and elimination studies, one month each year will be spent at KULeuven or ITACyL, to evaluate decontamination techniques in pilot experiments simulating field scenarios, and to liaise with the HACCP evaluation. VITAL will evaluate not only the efficacy of interventions for virus reduction in experiments but also after application in the field. The experiments will provide data on the natural inactivation expected to occur in the production chain and the application in the field will show the actual reduction by measures taken already for the reduction of bacteria and fungi with respect to the reduction of viruses. These data will feed directly into HACCP and QVRA to subsequently deliver plans of action.

Rzeżutka and Cook (2004) recommended that virus survival studies are conducted using an identical approach, i.e. by the use of common features such as numbers of infectious virus used to artificially contaminate each sample, similar sampling times, and a standard procedure for statistical analysis of the results. The three VITAL studies will

adopt this recommendation. This will facilitate the acquisition of comparative data for all virus types studied, and the results obtained will underpin VITAL's recommendations on the operation of control measures.

Finally, bringing together the outcomes of the above work, and based on careful coordination and communication with other work packages of the project, HACCP models will be developed for each food supply chain studied in this project, relative to their general and unique features and major components. In each HACCP model, the *seven HACCP principles* will be directed towards the control of virus contamination. *Hazard analyses* will be performed for each known foodborne virus type. *CCPs* will be identified, where control methods can be applied and virus contamination can be prevented, eliminated, or reduced to the acceptable levels indicated by the hazard analyses. *Critical limits* for virus reduction will be established for each CCP. To ensure that the process is under control, *monitoring requirements* for the CCPs will be established, with guidance from the expert analysts in the VITAL data-gathering WPs. *Corrective actions* will be recommended to deal with any deviation from the critical limits; the recommendations will be underpinned by the information derived from the survival and elimination studies. *Record keeping*, and appropriate *verification procedures* will be set down.

Finally, the interaction between the data-gathering laboratories and the Expert Stakeholders, which this WP will facilitate, will allow the former to check current practices with the latter, to ensure that local and general food production practices are taken into consideration during the data-gathering WPs.

Strategies for vaccination of farm animals

Additionally, VITAL will examine the approach of vaccination against HEV in pigs. An existing surveillance simulation system to determine the herd sensitivity and herd specificity¹ of the diagnostic tests applied to fecal samples of pigs entering the slaughter line can be used to assess the efficacy in detecting HEV compared to the detection of HEV using waste water and blood. Decision making based on the history of freedom-of-infection of farms can be used as criteria to declare farms as infected and advising management and intervention measures ultimately aimed at decreasing the risk of human infections. The existing surveillance system, that has originally been developed for trichinellosis, has to be adapted to HEV and extended by a within and between pen transmission module based on experimental HEV infection data and the field prevalence data generated by VITAL. The resulting surveillance simulation system generates herd sensitivity and herd specificity for detecting infected farms at slaughtering and the number of infected batches of pigs at slaughter for the region simulated given the diagnostic test parameters of the individual tests. This information can be used to assess intervention strategies such as vaccination on the herd level by means of a desk-top effort. In the future, the system could be further extended using economic optimization techniques in terms of resources applied to minimize human risk of infection. The impact of HEV-associated disease in pigs has been regarded low compared to potentially serious zoonotic infections in humans. However, recently an association of HEV infections with clinical disease in pigs was reported. To date it is unclear if data on HEV induced clinical disease in pigs can become available. The study of the vaccination approach in VITAL will firstly focus on its effects on food contamination and public health protection. However, for veterinary reasons, VITAL will also try to look for trends in the improvement of swine health. The results of these studies will firstly be used by VITAL's beneficiaries to develop an effective HEV control strategy. If applicable, the results will also be used to improve animal health in Europe as well.

B1.3.1.4 Significant risks and contingency plans

The most significant risk to VITAL is that we do not detect viruses in the food supply chains. However, the expert environmental virologists in the consortium consider that adenoviruses will certainly be detected where there is significant contamination, and HEV (ubiquitous globally in pig farms) has been detected in point of sale pork products in Japan the Netherlands and the USA. During data gathering, we will select points at which contamination is likely to be present. For instance, in Poland, a currently running study has indicated that where there is a high density of livestock, *Cryptosporidium* oocysts can be detected in samples of salad vegetables sold at market (Rzezutka and Smith, personal communication). If *Cryptosporidium* can contaminate produce, then it is very likely that viruses will follow the same route. The high number of replicate samples we will acquire through studying the same production chains in different countries will also increase the likelihood of detecting virus contamination. Lastly, in the quantitative risk assessment we will also use data which has been gathered before by our own or other laboratories, and though these may make up only partial compartments in different states we will assume they are one production chain.

¹ herd sensitivity and herd specificity: the probability of a herd to be detected as positive or negative given that it is infected or not infected with HEV.

If optimisation of the recent cell culture methods for propagation of norovirus and HEV do not result (by Month 15) in developments that contribute to the study of survival and elimination of these agents themselves, we will fall back on currently used methods for surrogate viruses, e.g. murine noroviruses (Wobus et al. 2006), or HAV for HEV.

B1.3.1.5 References

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B.1.3.2 Timing of work packages and their components

Table B1.5 shows the timing of the different VITAL WPs and their components.

Activity	Month											
	1 - 3	4 - 6	7 - 9	10 - 12	13 - 15	16 - 18	19 - 21	22 - 24	25 - 27	28 - 30	31 - 33	34 - 36
WP1 Project management	[Shaded]											
WP2 Data-Gathering: Production	[Shaded]											
Preparation (Task 2.1)	[Shaded]	[Shaded]	[Shaded]	[Shaded]	[Shaded]	[Shaded]	[Shaded]	[Shaded]	[Shaded]	[Shaded]	[Shaded]	[Shaded]
Data gathering (Tasks 2.2 – 2.5)	[Shaded]	[Shaded]	[Shaded]	[Shaded]	[Shaded]	[Shaded]	[Shaded]	[Shaded]	[Shaded]	[Shaded]	[Shaded]	[Shaded]
WP3 Data-Gathering: Processing (Tasks 3.1 – 3.3)	[Shaded]	[Shaded]	[Shaded]	[Shaded]	[Shaded]	[Shaded]	[Shaded]	[Shaded]	[Shaded]	[Shaded]	[Shaded]	[Shaded]
WP4 Data-Gathering: Point-of-sale (Tasks 4.1 – 4.5)	[Shaded]	[Shaded]	[Shaded]	[Shaded]	[Shaded]	[Shaded]	[Shaded]	[Shaded]	[Shaded]	[Shaded]	[Shaded]	[Shaded]
WP5 Data analysis	[Shaded]											
Workshop and analysis of gathered data (T5.1 and T5.2)	[Shaded]	[Shaded]	[Shaded]	[Shaded]	[Shaded]	[Shaded]	[Shaded]	[Shaded]	[Shaded]	[Shaded]	[Shaded]	[Shaded]
MPRM development (T5.3)	[Shaded]	[Shaded]	[Shaded]	[Shaded]	[Shaded]	[Shaded]	[Shaded]	[Shaded]	[Shaded]	[Shaded]	[Shaded]	[Shaded]
Prioritization of risk assessment criteria (T5.4)	[Shaded]	[Shaded]	[Shaded]	[Shaded]	[Shaded]	[Shaded]	[Shaded]	[Shaded]	[Shaded]	[Shaded]	[Shaded]	[Shaded]
Assessment of foodborne virus risks along the developed MPRM (T5.5)	[Shaded]	[Shaded]	[Shaded]	[Shaded]	[Shaded]	[Shaded]	[Shaded]	[Shaded]	[Shaded]	[Shaded]	[Shaded]	[Shaded]
QVRA on intervention measures (T5.6)	[Shaded]	[Shaded]	[Shaded]	[Shaded]	[Shaded]	[Shaded]	[Shaded]	[Shaded]	[Shaded]	[Shaded]	[Shaded]	[Shaded]
WP6 Control Measures	[Shaded]											
Evaluation of HACCP (T6.1)	[Shaded]	[Shaded]	[Shaded]	[Shaded]	[Shaded]	[Shaded]	[Shaded]	[Shaded]	[Shaded]	[Shaded]	[Shaded]	[Shaded]
Survival and elimination experimental work (T6.2 and T6.3)	[Shaded]	[Shaded]	[Shaded]	[Shaded]	[Shaded]	[Shaded]	[Shaded]	[Shaded]	[Shaded]	[Shaded]	[Shaded]	[Shaded]
Design of HACCP models (T6.4)	[Shaded]	[Shaded]	[Shaded]	[Shaded]	[Shaded]	[Shaded]	[Shaded]	[Shaded]	[Shaded]	[Shaded]	[Shaded]	[Shaded]
Evaluation of pig vaccination (T6.5)	[Shaded]	[Shaded]	[Shaded]	[Shaded]	[Shaded]	[Shaded]	[Shaded]	[Shaded]	[Shaded]	[Shaded]	[Shaded]	[Shaded]
WP7 Delivering Impact	[Shaded]											
Preparation of Code of Good Practice (T7.1)	[Shaded]	[Shaded]	[Shaded]	[Shaded]	[Shaded]	[Shaded]	[Shaded]	[Shaded]	[Shaded]	[Shaded]	[Shaded]	[Shaded]
Preparation of Symposium, Workshop, etc. (T7.2 – T7.4)	[Shaded]	[Shaded]	[Shaded]	[Shaded]	[Shaded]	[Shaded]	[Shaded]	[Shaded]	[Shaded]	[Shaded]	[Shaded]	[Shaded]
Website construction and maintenance (T7.5)	[Shaded]	[Shaded]	[Shaded]	[Shaded]	[Shaded]	[Shaded]	[Shaded]	[Shaded]	[Shaded]	[Shaded]	[Shaded]	[Shaded]
Consortium Meeting organisation (T7.6)	[Shaded]	[Shaded]	[Shaded]	[Shaded]	[Shaded]	[Shaded]	[Shaded]	[Shaded]	[Shaded]	[Shaded]	[Shaded]	[Shaded]

Table B1.5 Workpackages GANTT diagram

B.1.3.3 Work package list /overview

Work package list						
Work package No ¹	Work package title	Type of activity ²	Lead beneficiary No ³	Person-months ⁴	Start month ⁵	End month ⁶
WP1	Project management	MGT	1	7.5	1	36
WP 2	Data-Gathering: Production	RTD	8	184.6	1	30
WP 3	Data-Gathering: Processing	RTD	4	109.25	4	30
WP 4	Data-Gathering: Point of sale	RTD	9	98.65	4	30
WP 5	Data Analysis	RTD	7	47.05	1	33
WP 6	Control Measures	RTD	2	192.4	1	33
WP 7	Delivering Impact	OTHER	5	68.45	13	36
	TOTAL					

¹ Workpackage number: WP 1 – WP n.

² Insert one of the following 'types of activities' per WP (only if applicable for the chosen funding scheme – must correspond to the GPF Forms):

RTD = Research and technological development including scientific coordination applicable for collaborative projects and NoEs

DEM = Demonstration - applicable for collaborative projects

OTHER = Other activities (including management) applicable for collaborative projects, NoEs, and CSA

MGT = Management of the consortium - applicable for all funding schemes

COORD = Coordination activities – applicable only for CAs

SUPP = Support activities – applicable only for SAs

³ Number of the beneficiary leading the work in this work package.

⁴ The total number of person-months allocated to each work package.

⁵ Relative start date for the work in the specific work packages, month 1 marking the start date of the project, and all other start dates being relative to this start date.

⁶ Relative end date, month 1 marking the start date of the project, and all end dates being relative to this start date.

B.1.3.4 Deliverables list

List of Deliverables – to be submitted for review to EC¹

Del. no.²	Deliverable name	WP no.	Lead beneficiary	<i>Estimated indicative person-months</i>	Nature³	Dissemination level⁴	Delivery date⁵ (project month)
D7.1	Project web-site (with public and project-only accessible pages)	WP7	UP	0.5	O	PU	1
D1.1	Minutes of 1 st PAB meeting	WP1	Defra	0.28	R	RE	1
D1.2	Minutes of 1 st CAT meeting	WP1	Defra	0.22	R	RE	2
D1.3	Minutes of 1 st RDMB meeting	WP1	Defra	0.24	R	RE	3
D1.4	Minutes of 2 nd CAT meeting	WP1	Defra	0.22	R	RE	4
D1.5	Minutes of 2 nd RDMB meeting	WP1	Defra	0.24	R	RE	6

¹ In a project which uses ‘Classified information¹’ as background or which produces this as foreground the template for the deliverables list in Annex 7 has to be used

² Deliverable numbers in order of delivery dates: D1 – Dn

³ Please indicate the nature of the deliverable using one of the following codes:

R = Report, **P** = Prototype, **D** = Demonstrator, **O** = Other

⁴ Please indicate the dissemination level using one of the following codes:

PU = Public

PP = Restricted to other programme participants (including the Commission Services)

RE = Restricted to a group specified by the consortium (including the Commission Services)

CO = Confidential, only for members of the consortium (including the Commission Services)

⁵ Month in which the deliverables will be available. Month 1 marking the start date of the project, and all delivery dates being relative to this start date.

D1.6	Minutes of 3 rd CAT meeting	WP1	Defra	0.22	R	RE	6
D5.2	A tool for data analysis	WP5	RIVM	4	R	RE	8
D1.7	Minutes of 4 th CAT meeting	WP1	Defra	0.22	R	RE	8
D1.8	Minutes of 3 rd RDMB meeting	WP1	Defra	0.24	R	RE	10
D1.9	Minutes of 5 th CAT meeting	WP1	Defra	0.22	R	RE	10
D5.1	A guidance document on data collection and analysis	WP5	RIVM	4	R	RE	12
D5.3	Document on available models	WP5	RIVM	4	R	RE	12
D1.10	Minutes of 6 th CAT meeting	WP1	Defra	0.22	R	RE	12
D1.11	Minutes of 4 th RDMB meeting	WP1	Defra	0.24	R	RE	13
D1.12	Minutes of 2 nd PAB meeting	WP1	Defra	0.28	R	RE	13
D1.13	Minutes of 7 th CAT meeting	WP1	Defra	0.22	R	RE	14

D6.1	Optimised cell culture-based propagation methods for HEV and norovirus	WP6	KULeuven	48	R	RE	15
D1.14	Minutes of 5 th RDMB meeting	WP1	Defra	0.24	R	RE	16
D1.15	Minutes of 8 th CAT meeting	WP1	Defra	0.22	R	RE	16
D1.16	Minutes of 9 th CAT meeting	WP1	Defra	0.22	R	RE	18
D1.17	Minutes of 6 th RDMB meeting	WP1	Defra	0.24	R	RE	19
D1.18	Minutes of 10 th CAT meeting	WP1	Defra	0.22	R	RE	20
D1.19	Minutes of 7 th RDMB meeting	WP1	Defra	0.24	R	RE	21
D1.20	Minutes of 11 th CAT meeting	WP1	Defra	0.22	R	RE	22
D5.4	A model for assessing risks from foodborne viruses.	WP5	RIVM	13	R	RE	24
D1.21	Minutes of 12 th CAT meeting	WP1	Defra	0.22	R	RE	24
D1.22	Minutes of 3 rd PAB meeting	WP1	Defra	0.28	R	RE	25
D1.23	Minutes of 8 th RDMB meeting	WP1	Defra	0.24	R	RE	25
D1.24	Minutes of 13 th CAT meeting	WP1	Defra	0.22	R	RE	26

D5.5	A Modular Process Risk Model for risk assessment for viruses in foods	WP5	RIVM	4	R	RE	28
D1.25	Minutes of 9 th RDMB meeting	WP1	Defra	0.24	R	RE	28
D1.26	Minutes of 14 th CAT meeting	WP1	Defra	0.22	R	RE	28
D2.1	Data from avenues of virus contamination of salad vegetable crops	WP2	WUR	53	R	RE	30
D2.2	Data from avenues of virus contamination of soft fruit crops	WP2	WUR	53	R	RE	30
D2.3	Data on virus contamination of pig faeces and unprocessed pig products	WP2	WUR	69	R	RE	30
D3.1	Data from avenues of virus contamination during processing of pork products	WP3	UH	34	R	RE	30
D3.2	Data from avenues of virus contamination during processing of salad vegetables	WP3	UH	40	R	RE	30
D3.3	Data from avenues of virus contamination during processing of soft fruit	WP3	UH	40	R	RE	30
D4.1	Data on virus contamination of locally produced raw pork products at point of sale	WP4	NVRI	18	R	RE	30
D4.2	Data on virus contamination of locally produced salad vegetables at point of sale	WP4	NVRI	18	R	RE	30
D4.3	Data on virus contamination of locally produced shellfish at point of sale	WP4	NVRI	18	R	RE	30
D4.4	Data on virus contamination of locally produced soft fruit at point of sale	WP4	NVRI	24	R	RE	30

D4.5	Data on virus contamination of imported produce at point of sale	WP4	NVRI	26	R	RE	30
D6.2	Data on the survival of HEV, adenovirus and norovirus under conditions encountered in food supply chains	WP6	KULeuven	28	R	RE	30
D6.3	Data on the effect of current food industry elimination procedures on HEV, adenovirus and norovirus	WP6	KULeuven	28	R	RE	30
D1.27	Minutes of 15 th CAT meeting	WP1	Defra	0.22	R	RE	30
D1.28	Minutes of 10 th RDMB meeting	WP1	Defra	0.24	R	RE	31
D1.29	Minutes of 16 th CAT meeting	WP1	Defra	0.22	R	RE	32
D5.6	A comparison of the assessed risks associated with different foodborne viruses in different food stuffs	WP5	RIVM	3	R	RE	33
D5.7	Data gap analysis for foodborne virus risk assessment	WP5	RIVM	3	R	RE	33
D5.8	Document on intervention strategies and their efficiency with regard to reduction of the burden of viruses in foods	WP5	RIVM	3	R	RE	33

D1.30	Minutes of 11 th RDMB meeting	WP1	Defra	0.24	R	RE	34
D1.31	Minutes of 17 th CAT meeting	WP1	Defra	0.22	R	RE	34
D6.3	HACCP models for managing foodborne virus contamination in food supply chains	WP6	KULeuven	62	R	PU	35
D6.4	Assessment of the efficacy of the intervention strategy of pig vaccination	WP6	KULeuven	27	R	PU	35
D7.2	Validated Code of Good Practice for Producers	WP7	UPA	48	O	PU	35
D7.3	Symposium: “New Developments in Monitoring and Control of Viruses in Food Supply Chains”	WP7	UPA	6	O	PU	36
D7.4	Workshop: “Taking Forward New Developments in Monitoring and Control of Viruses in Food Supply Chains”	WP7	UPA	6	O	PU	36
D7.5	Training course: “Monitoring of Viruses in Food Supply Chains”	WP7	UPA	6	O	PU	36
D7.6	Training course: “Control of Viruses in Food Supply Chains”	WP7	UPA	6	O	PU	36
D1.32	Minutes of 4 th PAB meeting	WP1	UPA	0.28	R	RE	36
TOTAL				704			

B1.3.5 Work package descriptions

Work package number	WP1	Start date or starting event:						Month 1
Work package title	Project management							
Activity Type	MGT							
Beneficiary short name	Defra							
Person-months per beneficiary:	7.5							

Objectives

- To perform the legal, financial and administrative management of the project
- To provide a project coordination and management structure matched to the complexity and requirements of the project

Description of work

The management of the project will be performed in a cascade from the Coordinator, through a Core Administration Team (CAT) and a Research and Dissemination Management Board (RDMB), to the Workpackage Leaders and Task leaders, as detailed in Section 2.1. VITAL will also have a Project Advisory Board (PAB) comprised of external experts. VITAL will use net-based conferencing to facilitate meetings between its beneficiaries. Meetings will comprise: Bi-monthly CAT meetings; Quarterly RDMB meetings; Annual PAB meetings; Ad hoc WP meetings; Ad hoc Task meetings.

Tasks

T1.1 Project administration The CAT will perform the maintenance of the consortium agreement, and the overall legal and administrative management of the project. The CAT will collate and process financial data and monitor expenditure within individual workpackages and the project as a whole. The CAT will coordinate all periodic reporting and communication with and as required by the Commission.

T1.2 Overseeing project progress. The CAT will liaise with the RDMB, assisting this body to monitor the milestone progress towards the achievement of VITAL's objectives, identifying any causes of non-delivery and taking appropriate corrective action if necessary. CAT members will liaise with the PAB, ensuring that advice from this body is implemented within the project. A CAT member will prepare the minutes of every RDMB and every PAB meeting. Minutes of all meetings will be disseminated to beneficiaries by placing them on the secure pages of the website.

Deliverables (brief description)

D1.1	Minutes of 1 st PAB meeting (Month 1)
D1.2	Minutes of 1 st CAT meeting (Month 2)
D1.3	Minutes of 1 st RDMB meeting (Month 3)
D1.4	Minutes of 2 nd CAT meeting (Month 4)
D1.5	Minutes of 2 nd RDMB meeting (Month 6)
D1.6	Minutes of 3 rd CAT meeting (Month 6)
D1.7	Minutes of 4 th CAT meeting (Month 8)
D1.8	Minutes of 3 rd RDMB meeting (Month 10)
D1.9	Minutes of 5 th CAT meeting (Month 10)
D1.10	Minutes of 6 th CAT meeting (Month 12)
D1.11	Minutes of 4 th RDMB meeting (Month 13)
D1.12	Minutes of 2 nd PAB meeting (Month 13)
D1.13	Minutes of 7 th CAT meeting (Month 14)
D1.14	Minutes of 5 th RDMB meeting (Month 16)
D1.15	Minutes of 8 th CAT meeting (Month 16)
D1.16	Minutes of 9 th CAT meeting (Month 18)

D1.17	Minutes of 6 th RDMB meeting (Month 19)
D1.18	Minutes of 10 th CAT meeting (Month 20)
D1.19	Minutes of 7 th RDMB meeting (Month 21)
D1.20	Minutes of 11 th CAT meeting (Month 22)
D1.21	Minutes of 12 th CAT meeting (Month 24)
D1.22	Minutes of 3 rd PAB meeting (Month 25)
D1.23	Minutes of 8 th RDMB meeting (Month 25)
D1.24	Minutes of 13 th CAT meeting (Month 26)
D1.25	Minutes of 9 th RDMB meeting (Month 28)
D1.26	Minutes of 14 th CAT meeting (Month 28)
D1.27	Minutes of 15 th CAT meeting (Month 30)
D1.28	Minutes of 10 th RDMB meeting (Month 31)
D1.29	Minutes of 16 th CAT meeting (Month 32)
D1.30	Minutes of 11 th RDMB meeting (Month 34)
D1.31	Minutes of 17 th CAT meeting (Month 34)
D1.32	Minutes of 4 th PAB meeting (Month 36)

Work package number	2		Start date or starting event:										Month 1	
Work package title	Data-Gathering: Production													
Activity Type	RTD													
Beneficiary short name	Defra	KULeuven	VRI	UH	UPA	ISS	RIVM	WUR	NVRI	NIV-NS	UL-BF	ITACyL	UB	
Person-months per beneficiary:	10.4	0.1	32.5	16.8	17.2	17.2	0.9	3	31.8	33	0.3	18.4	3	

Objectives

- To gather data on the presence of viruses of human and animal origin on soft fruit- and salad vegetable-producing farms.
- To gather data on the presence of viruses of animal origin in pig farms and slaughter houses.

Description of work

The human transmission pathway will be monitored on salad vegetable- and soft fruit- producing farms by analysing field latrines and harvesters' hands, and from irrigation waters. The animal transmission pathway will be monitored on these farms by analysing irrigation waters, at pig production farms by analysing faecal samples, and at slaughterhouses by analysing pig blood samples, liver samples and effluent of the selected facilities.

Pig farms and pig slaughterhouses will be monitored in the Czech Republic, Italy and Spain. Salad vegetable farms will be monitored in Greece, Poland and Serbia. Soft fruit farms will be monitored in Finland, the Czech Republic, Poland, and Serbia.

Since this WP will commence the VITAL monitoring programme, a first task will be the setting-up of the methodology in each data-gathering laboratory. A workshop will be held at the 1st meeting in which the TAG4 members will present each SOP in detail to the data gathering laboratories. The laboratories will then have 3 months to establish and fully familiarise themselves with the methods. The monitoring program will then be conducted over the following 12 months, to allow for the different seasonalities of food production.

T2.1 Preparatory activities. This task constitutes preparation for WPs 2, 3 and 4. Provision of SOPs, IAC incorporation in animal adenovirus PCRs, provision of process controls, acquisition of necessary materials, and testing of methods.

T2.2 Data-gathering: salad vegetable farms. Samples will be taken from irrigation waters, and animal-based fertiliser applied pre-harvest. During harvesting, samples will be taken from field latrines, and harvesters' hands.

T2.3 Data-gathering: soft fruit farms. Samples will be taken from irrigation waters and animal-based fertiliser applied pre-harvest. During harvesting, samples will be taken from field latrines, and harvesters' hands.

T2.4 Data-gathering: pig farms. Pig faeces will be sampled.

T2.5 Data-gathering: slaughterhouses. Liver, blood and slaughter effluent will be sampled.

WP2: Data-Gathering: Production.

Deliverables

D2.1 Data from avenues of virus contamination of salad vegetable crops. (Month 30)

D2.2 Data from avenues of virus contamination of soft fruit crops. (Month 30)

D2.3 Data on virus contamination of pig faeces and unprocessed pig products. (Month 30)

Work package number	3	Start date or starting event:											Month 4	
Work package title	Data-Gathering: Processing													
Activity Type	RTD													
Beneficiary short name	Defra	KULeuven	VRI	UH	UPA	ISS	RIVM	WUR	NVRI	NIV-NS	UL-BF	ITACyL	UB	
Person-months per beneficiary:	5.25	0.2	20	11.7	10	10.2	0.6	0.2	19	20	0.2	10.5	1.4	

Objectives

- To gather data on virus presence in pork-processing plants.
- To gather data on virus presence in soft fruit-processing plants.
- To gather data on virus presence in salad vegetables-processing plants.

Description of work

This WP will focus on gathering data on virus contamination in food processing environments (e.g. machinery, surfaces). In each of the three food processing environments, the potential of workers to contaminate the foodstuffs will be investigated through monitoring of hand washings. Preparatory activities for this WP will be performed in Task 1 of WP2 (T2.1).

Processing of pork will be monitored in the Czech Republic, Italy and Spain. Soft fruit processing will be monitored in the Czech Republic, Finland, Poland, and Serbia. Salad vegetable processing will be monitored in Greece, Poland and Serbia.

T3.1 Data-gathering: Soft fruit processing. This will be performed in processing factories in European countries which are major soft fruit producers, both those which have been implicated as the origin of foodborne outbreaks, and others. Critical points such as handling, freezing (including freeze-drying of berries for breakfast cereals) and packaging, will be monitored for the presence of viruses.

T3.2 Data-gathering: Salad vegetable processing. Processing of vegetables, especially lettuce, cabbage and onion, will be studied. Critical points such as washing, peeling, cutting, dicing, grating, packaging will be monitored for the presence of viruses.

T3.3 Data gathering: Pork processing. Critical points in the processing of pork products, e.g. pork sausages, pork liver, and pork blood sausage, will be examined. These will be for example preparation surfaces and cutting utensils or similar equipment (which have potential for mediating cross contamination).

Deliverables

D3.1 Data from avenues of virus contamination during processing of pork products. (Month 30)

D3.2 Data from avenues of virus contamination during processing of salad vegetables. (Month 30)

D3.3 Data from avenues of virus contamination during processing of soft fruit. (Month 30)

Work package number	4	Start date or starting event:											Month 4	
Work package title	Data-Gathering: Point of Sale													
Activity Type	RTD													
Beneficiary short name	Defra	KULeuven	VRI	UH	UPA	ISS	RIVM	WUR	NVRI	NIV-NS	UL-BF	ITACyL	UB	
Person-months per beneficiary:	7.15	0.2	13.8	13.8	13.1	6.9	1	0.2	15.5	13.3	0.2	13	0.5	

Objectives

- To gather data on the presence of viruses of human and animal origin on soft fruit- and salad vegetables at point of sale.
- To gather data on the presence of viruses of animal origin on pork products at point of sale.
- To gather data on the presence of viruses of human and animal origin in shellfish at point of sale.

Description of work

Food samples from each supply chain will be purchased directly from farmers' markets, grocery stores or supermarkets. Fruit and vegetables will be collected as fresh or frozen produce. . Samples of raw sausages, pork meat and liver will be collected from butchers or other points of sale. Each WP4 laboratory will sample the produce which is available at the time. Preparatory activities for this WP will be performed in Task 1 of WP2 (T2.1).

T4.1 Data-gathering: raw pork products at point-of-sale Locally produced raw pork products on sale at farmers' markets and other outlets, in the Czech Republic, Italy, and Spain, will be analysed.

T4.2 Data-gathering: salad vegetables at point-of-sale Locally produced salad vegetables on sale at farmers' markets and other outlets, in Greece, Poland and Serbia, will be analysed.

T4.3 Data-gathering: shellfish at point-of-sale Locally produced shellfish on sale in retail outlets in Finland, Greece, and Spain, will be analysed.

T4.4 Data-gathering: soft fruit at point-of-sale Locally produced soft fruit on sale at farmers' markets and other outlets, in the Czech Republic, Finland, Poland and Serbia, will be analysed.

T4.5 Data-gathering: imported produce at point-of-sale Imported raw pork products, salad vegetable, shellfish, and soft fruit, on sale at retail outlets will be analysed. Approximately 25 % of all samples analysed in WP4 will be imported produce.

Deliverables

D4.1 Data on virus contamination of locally produced raw pork products at point of sale. (Month 30)

D4.2 Data on virus contamination of locally produced salad vegetables at point of sale. (Month 30)

D4.3 Data on virus contamination of locally produced shellfish at point of sale. (Month 30)

D4.4 Data on virus contamination of locally produced soft fruit at point of sale. (Month 30)

D4.5 Data on virus contamination of imported produce at point of sale. (Month 30)

Work package number	5	Start date or starting event:											Month 1	
Work package title	Data Analysis													
Activity Type	RTD													
Beneficiary short name	Defra	KULeuven	VRI	UH	UPA	ISS	RIVM	WUR	NVRI	NIV-NS	UL-BF	ITACyL	UB	
Person-months per beneficiary:	3.45	3	5.4	3	3	3	11.5	0.5	5.4	5.4	0.1	3.2	0.1	

Objectives

- To guide data collection in terms of quality, type and number of data
- To develop MPRMs for the food supply chains (QMRA models)
- To analyse data collected in primary and secondary production for different viruses and different production chains, deriving prevalence and concentration data as well as process parameter values (inactivation, dilution, partitioning etc.) for the MPRMs.
- To evaluate and verify MPRMs (rolling revision)
- To assess foodborne virus risk
- To identify data gaps in the risk assessment (rolling revision)
- To evaluate intervention measures

Description of work

- T5.1** A workshop will be held at the 2nd project meeting to train the data gathering partners in the methodology required for the data analysis. This will include how to collect the gathered data into a form (e.g. a bespoke spreadsheet) suitable for analysis by the systems produced in this WP. The workshop will be based on the guidance document on data collection and analysis (Deliverable 5.1), which will be circulated to all beneficiaries prior to the workshop.
- T5.2** Collect and analyse data for hazard characterization and exposure assessment from WPs 2-4.
- T5.3** Develop a MPRM for each of the food supply chains for foodborne quantitative virus risk assessment (QVRA).
- T5.4** To recognize and prioritise the main criteria for risk assessment.
- T5.5** To assess the foodborne virus risks along the developed MPRM in T.5.3 by QVRA for specific viruses in food products such as HEV in pork products, HAV in shellfish and norovirus in fruit/vegetables using AdV as model viruses for contamination and inactivation.
- T5.6** To list and if appropriate evaluate effective intervention measures by exerting specific effective interventions and estimating the efficacy using the MPRM format in practice followed by quantitative evaluation by QVRA to show the estimated reduction in infection risk.

Deliverables

- D5.1** A guidance document on data collection and analysis. (Month 12)
- D5.2** A calculation software tool for data analysis. (Month 8)
- D5.3** Document on available risk assessment models to be able to meet the required criteria for QVRA (Month 12).
- D5.4** A model for assessing risks from foodborne viruses. (Month 24)
- D5.5** A Modular Process Risk Model for risk assessment for viruses in foods. (Month 28)
- D5.6** A comparison of the assessed risks associated with different viruses in different foodstuffs. (Month 34)
- D5.7** Data gap analysis for food borne virus risk assessment. (Month 33)
- D5.8** Document on intervention strategies and their efficiency with regard to reduction of the burden of viruses in foods. (Month 33)

Work package number	6	Start date or starting event:											Month 1	
Work package title	Control Measures													
Activity Type	RTD													
Beneficiary short name	Defra	KULeuven	VRI	UH	UPA	ISS	RIVM	WUR	NVRI	NIV-NS	UL-BF	ITACyL	UB	
Person-months per beneficiary:	27	20.5	2.9	2.7	2.7	2.7	39	24.1	2.7	2.7	23.5	2.9	39	

Objectives

- To review information on current monitoring and control practices used in the food industry against infectious agents.
- To evaluate the efficacy of elimination procedures, currently used in the food industry, against foodborne viruses.
- To use modular process risk models to develop effective HACCP models for the major stages of each food supply chain.
- To evaluate the efficacy of swine vaccination intervention strategies against HEV contamination and distribution

Description of work

T6.1 Critical evaluation of current HACCP systems. Fact-finding missions will be made to food processing companies and farms, to gather information on their current HACCP and other food safety management systems. This will be performed in liaison with the Expert Stakeholders (see section B2.3). This will identify any apparent deficiencies in current HACCP systems with regard to effective control of virus contamination.

T6.2 Survival and elimination of viruses. Existing cell culture systems for propagation of norovirus and HEV will be refined to produce tools for assessing virus infectivity. Then, persistence of infectivity of viruses will be evaluated under selected environmental and storage conditions relevant to food supply chains. Elimination procedures used in the food industry will be evaluated. This information will feed back into the QVRA and HACCP. The efficacy of suggested interventions will be evaluated in the laboratory, and in pilot and field experiments.

T6.3 Development of HACCP models. HACCP models, directed towards the control of virus contamination, will be developed for each food supply chain, by evaluating the information acquired from T6.1 and T6.2, then integrating the MPRMs developed in T.5.2 using the data gathered in WPs 2 and 3.

T6.4 Evaluation of the effect of vaccination. The existing Classical Swine Fever surveillance simulation model will be adapted to model the risk of viral contamination of the slaughter line by HEV.

Deliverables

D6.1 Optimised cell culture-based propagation methods for HEV and norovirus (Month 15)

D6.2 Data on the survival of HEV, adenovirus and norovirus under conditions encountered in food supply chains. (Month 30)

D6.3 Data on the effect of current food industry elimination procedures on HEV, adenovirus and norovirus. (Month 30)

D6.4 HACCP models for managing foodborne virus contamination in food supply chains. (Month 35)

D6.5 Assessment of the efficacy of the intervention strategy of pig vaccination. (Month 35)

Work package number	7	Start date or starting event:											Month 13	
Work package title	Delivering Impact													
Activity Type	OTHER													
Beneficiary short name	Defra	KULeuven	VRI	UPA	DUT	ISS	RIVM	WUR	NVRI	NIV-NS	UL-BF	ITACyL	UB	
Person-months per beneficiary:	5.15	3	6.4	3	5	5	1	2	6.6	6.6	20.7	3	1	

Objectives
<ul style="list-style-type: none"> To disseminate the outcomes of VITAL in such a way as to have the maximum impact on European food safety.

Description of work
<p>T7.1 Development and validation of a Code of Good Practice The COGP will be designed to assist food producers to control foodborne viral contamination. The COGP will be developed and tested between months 9 to 35, in consultation with the Expert Stakeholders, and in cooperation with Task 6.2. The COGP will be regularly updated by integrating information from the HACCP review and survival / elimination studies of WP6. The Expert Stakeholders will initiate the validation of the COGP document, by completing a questionnaire on the feasibility of the COGP, regarding various aspects such as concordance with regulations and quality assurance systems, cost, etc. For the salad vegetable or pork food supply chains, the validation of the COGP will be completed by testing it in practical application in simulated field scenarios at KULeuven or ITACyL. This validation will provide a platform for its practical applicability in implementation.</p> <p>T7.2 Symposium organisation A Symposium will be held in the last month of the project, in which VITAL's results will be presented and discussed. The Code of Good Practice will be distributed to interested parties from the food industry at the symposium and workshop.</p> <p>T7.3 Workshop organisation Interested parties from national and international bodies (FAO, WHO, EFSA, ECDC) will be invited to discuss the outcomes of VITAL with the project consortium members and the PAB members.</p> <p>T7.4 Organisation of a 1 day training course on foodborne viruses for risk managers in the food industry A slide presentation and a handbook will be prepared, containing information about virus hazards, critical control points, and details of appropriate elimination procedures. The course will be held concurrently with the Symposium. The Symposium, Workshop and Training courses will all be held in Month 35 under the auspices of the University of Ljubljana (UL-BF).</p> <p>T7.5 Website construction and maintenance The project website will contain public and project-only accessible pages.</p> <p>T7.6 Consortium Meeting Organisation. Three VITAL Consortium Meetings will be held, at the start of each project year. The first meeting, in Month 1, will take place at the Veterinary Research Institute, Brno, Czech Republic (VRI). The Second VITAL Consortium Meeting will take place at the Scientific Veterinary Institute "Novi Sad", Serbia (NIV-NS). The Third VITAL Consortium Meeting will take place at the National Veterinary Research Institute, Pulawy, Poland (NVRI). The Expert Stakeholders will attend the first and the third meetings. Representatives from national regulatory bodies, and from other relevant European projects, will be invited to attend as observers (at their own expense). Eleven RDMB meetings will be held throughout the project, and WP and Task Leaders will be able to organise their own <i>ad hoc</i> meetings. The RDMB, and the ad hoc WP and Task meetings, will be conducted using net-conferencing facilities.</p>

Deliverables

D7.1 Project website (with public and project-only accessible pages). (Month 1)

D7.2 Code of Good Practice for Producers to control foodborne viral contamination. (Month 35)

D7.3 Symposium “New Developments in Monitoring and Control of Viruses in Food Supply Chains” (Month 36)

D7.4 Workshop. “Taking Forward New Developments in Monitoring and Control of Viruses in Food Supply Chains” (Month 36)

D7.5 Training course “Monitoring of Viruses in Food Supply Chains” To be organised for analysts (Month 36)

D7.6 Training course “Control of Viruses in Food Supply Chains” to be organised for risk managers in the food industry (Month 36)

B1.3.6 Efforts for the full duration of the project

Project Effort Form 1 - Indicative efforts per beneficiary per WP

Project number (acronym): VITAL

<i>Workpackage</i> ¹	WP1	WP2	WP3	WP4	WP5	WP6	WP7	Total per Beneficiary
Defra	7.5	10.4	5.25	7.15	3.45	27	5.15	65.9
KULeuven	0	0.1	0.2	0.2	3	20.5	3	27
VRI	0	32.5	20	13.8	5.4	2.9	6.4	81
UH	0	16.8	11.7	13.8	3	2.7	3	51
UPA	0	17.2	10	13.1	3	2.7	5	51
ISS	0	17.2	10.2	6.9	3	2.7	5	45
RIVM	0	0.9	0.6	1	11.5	39	1	54
WUR	0	3	0.2	0.2	0.5	24.1	2	30
NVRI	0	31.8	19	15.5	5.4	2.7	6.6	81
NIV-NS	0	33	20	13.3	5.4	2.7	6.6	81
UL-BF	0	0.3	0.2	0.2	0.1	23.5	20.7	45
ITACyL	0	18.4	10.5	13	3.2	2.9	3	51
UB	0	3	1.4	0.5	0.1	39	1	45
TOTAL	7.5	184.6	109.25	98.65	47.05	192.4	68.45	707.9

¹ Please indicate in the table the number of person months over the whole duration for the planned work, for each work package by each beneficiary

Project Effort Form 2 - indicative efforts per activity type per beneficiary¹

Project number (acronym) :VITAL

<i>Activity Type</i>	Defra	KULeuven	VRI	UH	UPA	ISS	RIVM	WUR	NVRI	NIV-NS	UL-BF	ITACyL	UB	TOTAL ACTIVITIES
RTD/Innovation activities														
Data Gathering: Production	10.4	0.1	32.5	16.8	17.2	17.2	0.9	3	31.8	33	0.3	18.4	3	184.6
Data Gathering: Processing	5.25	0.2	20	11.7	10	10.2	0.6	0.2	19	20	0.2	10.5	1.4	109.25
Data Gathering: Point of Sale	7.15	0.2	13.8	13.8	13.1	6.9	1	0.2	15.5	13.3	0.2	13	0.5	98.65
Data Analysis	3.45	3	5.4	3	3	3	11.5	0.5	5.4	5.4	0.1	3.2	0.1	47.05
Control Measures	27	20.5	2.9	2.7	2.7	2.7	39	24.1	2.7	2.7	23.5	2.9	39	192.4
Total 'research'	53.25	24	74.6	48	46	40	53	28	74.4	74.4	24.3	48	44	631.95
Demonstration activities														
WP name														
WP name														
Etc														
Total 'demonstration'														
Consortium management activities														
Project Management	7.5													7.5
Total 'management'	7.5													7.5
Other activities														
Delivering Impact	5.15	3	6.4	3	5	5	1	2	6.6	6.6	20.7	3	1	68.45
Total 'other'	5.15	3	6.4	3	5	5	1	2	6.6	6.6	20.7	3	1	68.45
TOTAL BENEFICIARIES	65.9	27	81	51	51	45	54	30	81	81	45	51	45	707.9

¹ Please indicate in the table the number of person months over the whole duration for the planned work , for each work package, for each activity type by each beneficiary

B.1.3.7 List of milestones and planning of reviews

Milestone no.	Milestone name	WPs no's.	Lead beneficiary	Delivery date from Annex I	Comments
M2.1	All data-gathering laboratories fully prepared with necessary materials and SOPs	WP2	WUR	Month 9	Each data-gathering laboratory sends a completed checklist to WP2 leader
M6.1	Cell culture systems for norovirus and HEV optimised	WP6	KULeuven	Month 15	Report from the 3 doctoral studies sent to the WP6 leader
M6.2	Current HACCP systems evaluated	WP6	KULeuven	Month 24	Report sent to WP6 leader
M5.1	Modular process risk models developed	WP5	RIVM	Month 28	WP6 leader is able to integrate MPRMs into draft HACCP models
M2.2	All data gathered from the production phase of three food supply chains	WP2	WUR	Month 30	Completed spreadsheets sent by each data-gathering laboratory to WP2 leader
M3.1	All data gathered from the processing phase of three food supply chains	WP3	UH	Month 30	Completed spreadsheets sent by each data-gathering laboratory to WP3 leader
M4.1	All data gathered from four food supply chains at point of sale	WP4	NVRI	Month 30	Completed spreadsheets sent by each data-gathering laboratory to WP4 leader
M6.3	Survival and elimination data produced for three virus types	WP6	KULeuven	Month 30	Report sent to WP6 leader
M7.1	Draft Code of Good Practice sent to Expert Stakeholders for review	WP7	UP	Month 14	Expert Stakeholders confirm receipt to WP7 leader
M6.4	Draft HACCP models sent to Expert Stakeholders for review	WP6	KULeuven	Month 32	Expert Stakeholders confirm receipt to WP6 leader

Tentative schedule of project reviews			
Review no.	Tentative timing, i.e. after month X = end of a reporting period ¹	planned venue of review	Comments, if any
1	After project month: 12	NIV-NS	
2	After project month: 18	CSL	Mid-Term Review
3	After project month: 24	NVRI	
4	After project month: 35	UL-BF	

¹ Month after which the review will take place. Month 1 marking the start date of the project, and all dates being relative to this start date.

B1.4 Interdependencies of the activities and workpackages: The structure of VITAL

The overall structure of VITAL is shown schematically in Figure B1.3. The project will have an **overarching management structure**, which will oversee each level through cascading from the Coordinator to Workpackage leaders through to task leader. The **research elements** have interdependencies as will be detailed in each Workpackage. The outcomes of the research will be **actively disseminated** so that they deliver the intended impact.

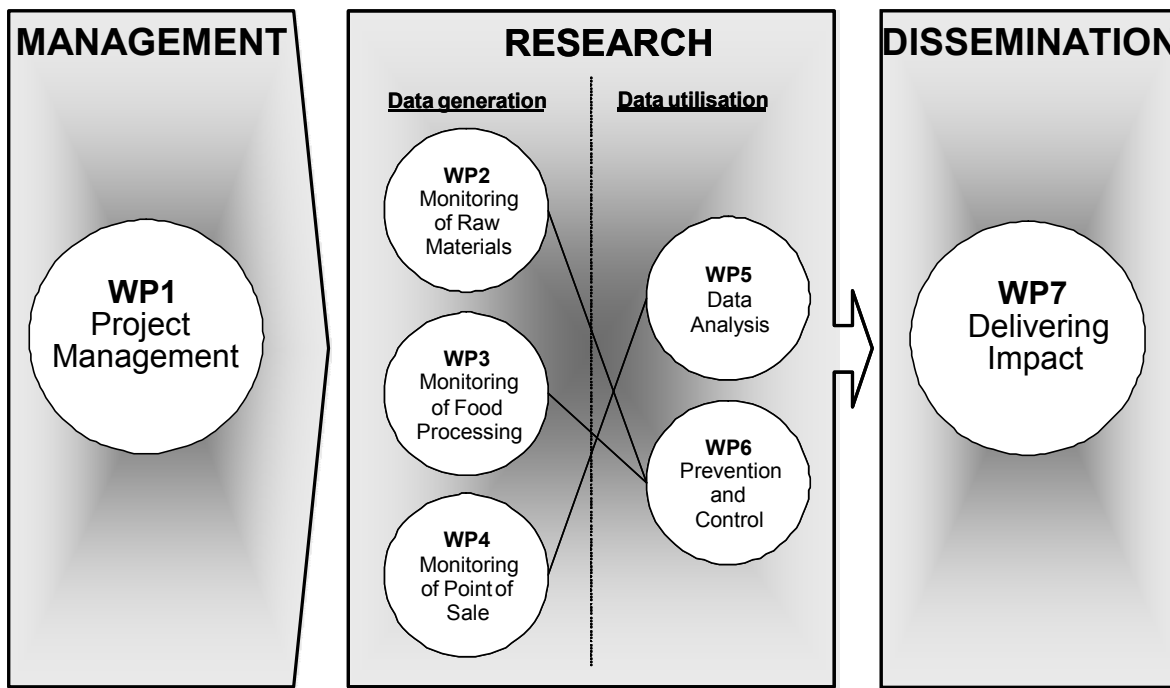


Figure B1.3. The PERT diagram of the structure of VITAL

B2. IMPLEMENTATION

B2.1 Management structure and procedures

The **Coordinator** will have the ultimate responsibility for the administration and delivery of the project. The Coordinator will chair the Research and Dissemination Management Board, and communicate information from the Project Advisory Board to RDMB and the Consortium. The Coordinator will be responsible for wider liaison with COST 929 ENVIRONET.

The **Vice-Coordinator** will co-chair the Research and Dissemination Management Board, and attend the PAB meetings. The Vice-Coordinator will review all draft reports before final submission. The Vice-Coordinator will be responsible for wider liaison with MedVetNet.

The **Financial Manager** will collate and process financial data and monitor expenditure within individual workpackages and the project as a whole.

The **Assistant Coordinator** will support the Coordinator with the day-to-day activities of project administration, and chair meetings in any absence of both the Coordinator and Vice-Coordinator. The Assistant Coordinator will also be responsible for the construction and upkeep of the VITAL website, and establishing the internet-based conferencing facilities (see below).

The management of VITAL will be organized around the Coordinator and the Workpackage leaders, with external experts providing guidance and advice.

Individual groups overseeing the core administration of the project, and the scientific and technical direction, will underpin the structure of VITAL, and communication of management information will regularly transmitted from these groups to the consortium. Figure B2.1 displays the key elements of the communication flow; fuller details of each element follow.

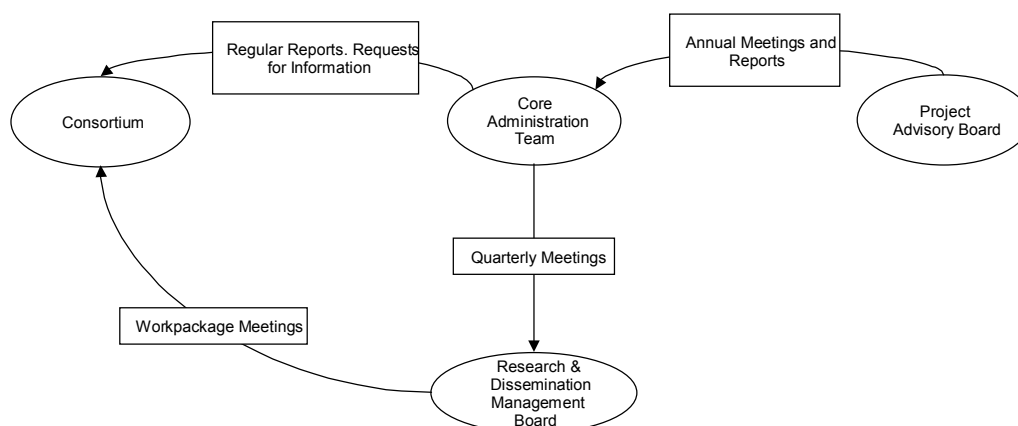


Figure B2.1. Flow Of Management Information In Vital

B2.1.1 Core Administration Team (CAT)

The CAT will have overall responsibility for the running and delivery of VITAL, including overseeing the administrative requirements, and coordination of the management and dissemination of knowledge within the project. The CAT will comprise the Coordinator, Assistant Coordinator, and the Financial Manager. They will be from the same institute (the Central Science Laboratory), which will facilitate the steady discharge of the CAT's responsibilities. The specific duties of the CAT are detailed in Figure B2.2.

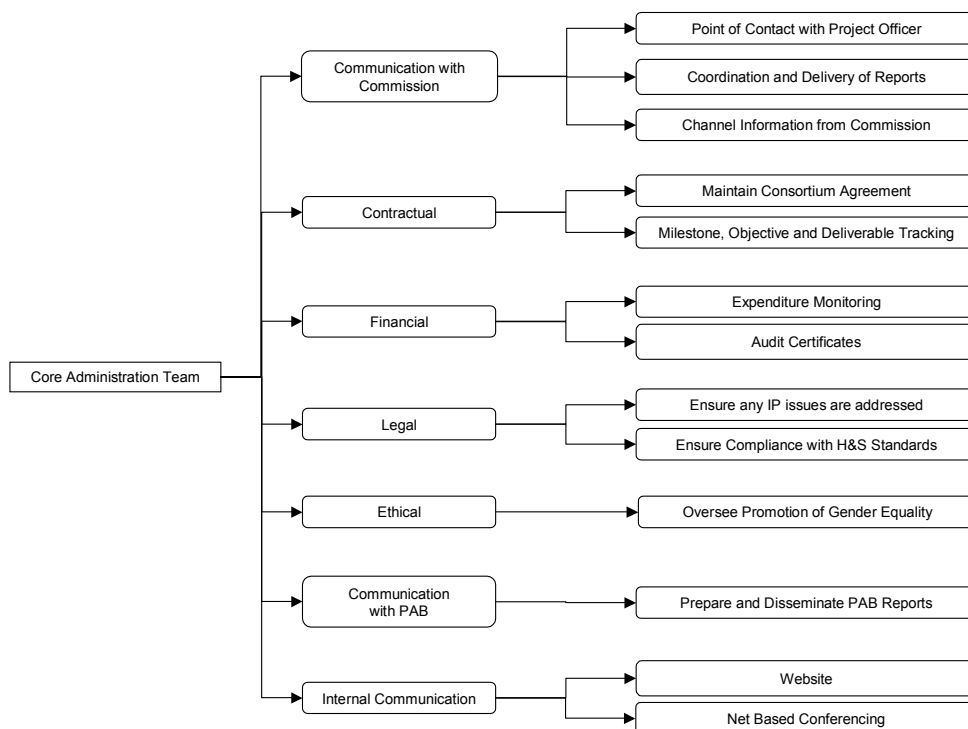


Figure B2.2. Duties of the VITAL Core Administration Team

The CAT will meet every 2 months throughout the project. At each meeting, the individual points of duty as outlined above and tasked in WP1 will be reviewed, and actioned as necessary. The latest RDMB report will be reviewed, and progress towards each milestone, objective, and deliverable recorded for reporting to the Commission. The CAT will review the report of the PAB, and prioritise any recommendations which need to be considered. Prior to each meeting, any administrative issues within the consortium will be identified. The CAT will ask each beneficiary's lead scientist whether there are any matters which could impact upon the running of the project, such as incorrect budget expenditure or staffing shortages. The CAT will oversee any necessary corrective action.

B2.1.2 Research and Dissemination Management Board (RDMB)

This will comprise the Coordinator, the Vice-Coordinator, and leaders of each Workpackage, and a representative from each VITAL beneficiary. It will meet every 3 months throughout the duration of the project. It will review the progress of the ongoing workpackages, especially with regard to the totality of the project. The specific functions of the RDMB are listed in Figure B2.3.

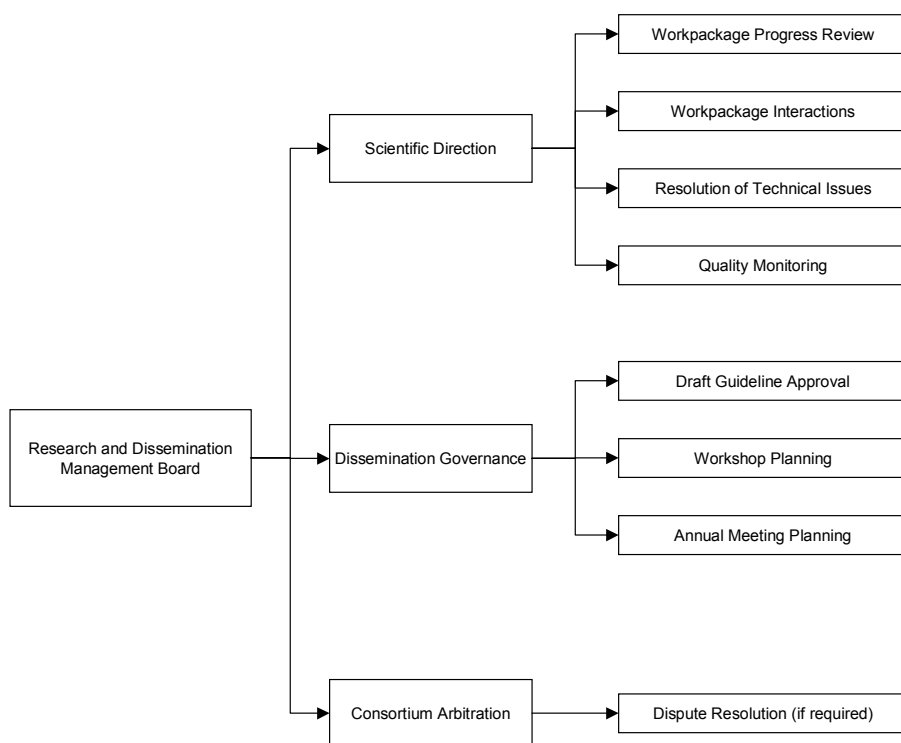


Figure B2.3. Functions of the VITAL Research and Dissemination Management Board

The RDMB will meet every 3 months throughout the project. At each meeting, the progress of the ongoing workpackages will be reviewed. Each WP leader will provide a brief report to the Coordinator, prior to each RDMB meeting, and these will be collated into a document for circulation to the RDMB members. The RDMB will discuss progress towards the upcoming milestones, and towards achievement of objectives. The RDMB will discuss any technical issues, e.g. modifications to protocols which may be considered following new information, and decide upon the response / actions. The RDMB will help to organise the scientific elements of the annual project meetings (the Consortium Meetings).

B2.1.3 Workpackage management

Each WP leader will hold WP internet-based meetings to discuss and review progress of the WP. Ad hoc internet-based meetings can be held at any time at the discretion of the WP leader.

B2.1.4 Task management

Each Task Leader within a WP can hold ad hoc internet-based meetings at their discretion.

B2.1.5 Project Advisory Board (PAB)

This is a group of expert scientists in fields which are relevant to the overall aims of the project. They will meet four times during the course of the project, to review progress and provide advice and recommendations. The Coordinator and Vice-Coordinator will attend the PAB meetings. The individual members of the PAB will be:

Dr. Serve Notermans, former food microbiologist at the Dutch National Institute of Public Health, TNO Food Research and vice-chair of the EFSA- panel on Bio-hazards is currently visiting professor at the Lancashire University and director of the Dutch ‘Food Doctors’ organization. He is an international expert in microbiological food safety systems. Spearheads of his current activities are among others new food safety systems including introduction of risk assessment in the HACCP food management and food safety control systems. In addition he is a specialist in the

epidemiology of food borne diseases. As expert he has been invited to participate in numerous FAO and WHO meetings on food safety. Dr. Notermans is author of over 300 scientific papers dealing with a broad area of food safety aspects.

Professor Clive Thompson, Chief Scientist of Alcontrol Laboratories, one of the largest environmental and food contract analysis organisations in Europe. He is an expert on environmental analysis and has many publications in this area. He was awarded the 2003 Society of Chemical Industry (SCI) Environmental medal for distinguished and sustained achievement in the areas of preservation, improvement or understanding the environment. He was recently made a Fellow of the Royal Society of Medicine. He has been involved with the FP6 Horizontal-HYGIENE project which is developing fit for purpose international standards for a range of potential bacterial pathogens that will be suitable for sludges, soils and treated biowastes. He also serves on various committees of ISO/TC 147 Water Quality; CEN TC 308 Sludge Characterisation; ISO TC190 Soil Quality and CEN TC 223 Soil improvers and growing media. Professor Thompson will give advice and guidance to VITAL, from a regular analyst's perspective.

Dr. Jan Vinjé, Head of the National Calicivirus Laboratory at the Center for Disease Control and Prevention (CDC) is an international expert in the area of enteric viruses with a special emphasis on noroviruses in both clinical as well as environmental samples. He has served on several Program Advisory Committees of the American Water Works Research Foundation as well as on the FP6 project "VIROBATHE". Dr. Vinjé is also the organism expert for caliciviruses for one of the US National Institutes of Health's Pathosystems Resource Integration Centers (PATRIC). Dr. Vinjé's expert opinion on the transmission and epidemiology of foodborne viruses will impart information from a transcontinental perspective.

Dr. Peter Wyn-Jones, University of Wales. Dr. Wyn-Jones is an international authority on viruses in the environment, and is a member of several international expert groups. He has recently coordinated the FP6 project "*Methods for the detection of adenoviruses and noroviruses in European bathing waters with reference to the revision of the Bathing Water Directive 76/160/EEC*" (VIROBATHE), which has provided considerable information on the application of detection methods for viruses, and the health-related implications of the presence of viruses in the environment. Dr. Wyn-Jones will chair the PAB; his experience in project guidance will be invaluable to focus the advice and recommendations of the Board to the VITAL consortium.

Dr. Marta Hugas, Head of Unit - Scientific Coordinator, Scientific Panel on Biological Hazards, European Food Safety Authority – EFSA, has agreed to attend the board as an observer.

B2.1.6 Internet-based conferencing facilities

To address concerns regarding climate change, VITAL will take seriously the need to reduce as much as possible the carbon footprint of the project. In order to reduce the number of project meetings which would normally be held several times each year, Internet-based conferencing facilities will be used to host these meetings. This facility will allow a virtual conference room to be used by up to 15 participants. Each member of the RDMB will have moderator status meaning each meeting can be hosted by a different member of the RDMB. This facility will allow complete flexibility during the meetings, in that documents can be viewed and edited on screen securely, files transferred securely, and the ability to record the sessions with audio, video and screen to enable accurate recording of minutes. This system will also allow members of the RDMB to participate in *ad hoc* meetings with any other RDMB member or other beneficiary representative at any time. WP leaders will also be able to host meetings with the members of their WPs, thereby reducing the time for problem solving etc. Employing internet-based conferencing facilities will not only eliminate the time spent organising and travelling to different European locations for a one day meeting, but it will also cut the carbon footprint of these meetings to a minimum.

To ensure that only the invited representatives can communicate with one another, and complete confidentiality of all communications is maintained, every session will be encrypted using the equivalent to the SSL standard as used for online banking.

B2.1.7 Consortium Meetings

VITAL will hold three Consortium Meetings, which will be actual not internet-based, which representatives of all beneficiaries must attend. The Consortium Meetings will provide the opportunity for all VITAL's scientists to meet each other and the members of the PAB, and thus aid the integration between the beneficiaries. The Consortium Meetings will contain discussions of progress in each WP, and other general information sharing. Each meeting will

fulfill a specific role: Consortium Meeting 1 will contain the workshop on the methodology to be used in the data-gathering WPs. Consortium Meeting 2 will contain the workshop on data analysis. Consortium Meeting 3 will contain a meeting with the Expert Stakeholders on the draft Code of Good Practice

Consortium Meeting 1 will take place in month 1 at the Veterinary Research Institute, Brno, Czech Republic. Consortium Meeting 2 will take place in month 13 at the Scientific Veterinary Institute “Novi Sad”, Novi Sad, Serbia. Consortium Meeting 3 will take place in month 25 at the National Veterinary Research Institute, Pulawy, Poland.

B2.1.8 Consortium Agreement.

A draft consortium agreement is under preparation. The draft has been circulated to all beneficiaries for comment, and the second draft, incorporating comments, will be sent out for final agreement.

B2.2 Individual beneficiaries

Beneficiary 1. Department for the Environment, Food and Rural Affairs (Defra)

This Beneficiary comprises two Executive Agencies of the United Kingdom's Department for the Environment, Food and Rural Affairs: the Central Science Laboratory (CSL) at York, and the Veterinary Laboratories Agency (VLA) at Weybridge, Surrey.

Central Science Laboratory (CSL)

CSL is an Executive Agency of the UK Government, part of the Department for Environment Food and Rural Affairs (Defra). Key work areas include food and environmental microbiology, the impact of food production and agricultural systems on the environment, animal health, and conservation & wildlife management. The MIC4 team (Virology and Molecular Methods) at CSL has over 12 years experience in the field of food and environmental virology, funded by both UK national bodies (e.g. Defra, Food Standards Agency) and the European Commission. The team has worked on development of detection methods for food and water-borne viruses, and studied the survival of viruses in foods, and the potential impact of zoonotic transmission of enteric viruses. The team has over 40 publications in the fields of food virology and detection methodology.

The Central Science Laboratory will perform all the project management of VITAL.

Key Personnel:

Dr. Nigel Cook, Senior Scientific Officer (VITAL Coordinator). Dr. Cook is the chair of COST Action 929 "A European Network for Environmental and Food Virology", and the UK Environmental and Food Virology Network. He has led workpackages in the FP5 RTD project: QLRT-1999-00226 "Validation and Standardization of Diagnostic Polymerase Chain Reaction for Detection of Foodborne Pathogens (FOOD-PCR)", and the FP6 project VIROBATHE. Participates in the British Standards Institute AW/9 committee for the microbiology of food and feed, as a co-opted member for his specialist expertise in viruses. Member of the International Life Sciences Institute Expert Group on Foodborne Viruses.

Mr. Martin D'Agostino, Higher Scientific Officer. VITAL Assistant Coordinator and Webmaster. Task Leader in FOOD-PCR, and Webmaster of COST 929 and VIROBATHE. Is a member of the UK Standing Committee of Analysts, and advisor to the UK National Milk Reference Laboratory.

Dr. Christina Steveni, CSL Accounts Coordinator. VITAL Financial Officer

Beneficiary 1. Department for the Environment, Food and Rural Affairs (Defra) (cont.)

Veterinary Laboratories Agency (VLA)

The Veterinary Laboratories Agency is a UK Government Agency conducting veterinary research and diagnosis. With one central laboratory (Weybridge) and 15 regional laboratories situated in farming regions, the VLA has expertise and EU/OIE/FAO/WHO reference laboratory responsibilities for many of the major farm animal diseases and zoonotics. As a government agency the VLA is non-profit making.

VLA has experience and skills in HEV RT-PCR and qPCR, serological assays, in environmental survival (including in food products) and in-vitro cultivation of HEV, and a particular interest in the transmission routes of zoonotically acquired hepatitis E.

Role in VITAL: Data gathering laboratory, Survival and elimination of HEV

Key Staff:

Dr. Malcolm Banks is deputy head of Mammalian Virology at the VLA and has over 30 years of experience of viral infections of farmed livestock and with relevance to this project, 13 publications related to hepatitis E in pigs and humans.

Recent and continuing hepatitis E collaborations include hospitals, environmental health organisations, universities and research institutes in the UK, Europe and the USA.

PhD student: A PhD student will be registered with a UK university and will spend 1 year of this studentship at WUR in The Netherlands and the remaining two years at the VLA Weybridge. This student will perform the majority of the analyses required for the VLA with supervision from Dr Banks and will be selected from candidates within the VITAL consortium.

Beneficiary 2. Katholieke Universiteit Leuven (KULeuven)

KULeuven carries out fundamental and applied research in all academic disciplines. The quality and quantity of its research output positions the K.U.Leuven at the forefront of European universities (www.kuleuven.be). Within the Department of Microbial and Molecular Systems, the Laboratory of Food Microbiology conducts basic research into the effects of (bio)chemical, physical and biological parameters on microbial growth, microbial growth inhibition or microbial inactivation to develop more efficient and safe food production and preservation technologies. The Microbial Process Ecology and Management (MPEM) research group at De Nayer Institute (Expert Stakeholder of K.U.Leuven; third party) specialises, amongst other research interests, in the use of microbial characterisation and diagnostics for development of rapid, at-line monitoring of the quality and safety of food production and processing systems.

Role in VITAL: Leading WP “Control Measures”.

Key staff:

Professor Kris A. Willems, Affiliated senior researcher at K.U.Leuven, Department of Microbial and Molecular Systems, Laboratory of Food Microbiology and head of MPEM and Vice President Industrial Microbiology and Food Safety (STRI). Experience in management of research and industrial projects; routine testing, production and QA/QC of diagnostics; viral antigen production; implementation of quality and food safety systems, e.g. EN 17 025, HACCP, BRC.

Professor Chris W. Michiels, Head of the Laboratory of Food Microbiology. Has published more than 100 peer-reviewed papers in the field.

Beneficiary 3. Veterinary Research Institute (VRI)

VRI, established by the Government in 1955, is a non-profit research organization budgeted from the Ministry of Agriculture of the Czech Republic. Activities include protection of animal health, zoonotic diseases, food and feed safety and consumer protection. VRI comprises accredited laboratories representing basic disciplines including bacteriology, virology, food and feed safety, and protection of the environment and the food chain.

Role in VITAL: Data gathering laboratory.

Key staff:

Professor Ivo Pavlik, Head of the Department of Food and Feed Safety, has 20 years experience in mycobacteriology research at VRI. He has obtained valuable information on the epidemiology and status of different zoonoses including bovine tuberculosis, avian tuberculosis and mycobacterioses in cattle and pig herds and in the wild and domestic birds' flocks. Current areas of interests include development of intravital diagnostic tests of different infectious diseases and molecular techniques for the study of molecular epidemiology.

Dr. Ivan Psikal, Researcher in vertebrate (higher/lower) virology for 20 years. He has expertise in emerging viral infections of cattle and pigs (gastrointestinal viruses, arteriviruses, circoviruses and hepatitis E virus) and rabbits (caliciviruses, leporipoxviruses). His work includes expert activities concerning the development and innovation of molecular diagnostic methods and for further exploitation of these methods to study viral diseases through the analysis of clinical and veterinary samples.

Dr. Petra Vasickova, Researcher. Study focused on identification of environmental and foodborne viruses and the implications for public health.

Beneficiary 4. University of Helsinki (UH)

The Department of Food and Environmental Hygiene belongs to the faculty of veterinary medicine. The research groups belong to “the group of excellence” category in Finland. Main interests are in bacteriology and toxicology. Our group started at the department in autumn 2004 and is active in the field of food and environmental virology. Our background is in clinical virology, especially molecular genetics and -epidemiology of noro-, rota- and other enteric viruses. We have used gene amplification methods for the detection of noro- and astroviruses in clinical stool samples and determined nucleotide sequences of Finnish norovirus strains already for a decade. We were among the first to demonstrate norovirus in water samples connected to a large community outbreak. The methods have proved to be sensitive and we have found noroviruses both in contaminated water and patient samples in a number of outbreaks. We have detected noroviruses in frozen berries linked to norovirus outbreaks. We have experience in analyses of viruses in many different environmental and food matrices such as sewage and oysters. We have participated in several EU-projects (Foodborne Viruses in Europe, EVENT-DIVINE, SAFER and SEAFOODplus) and also Nordic projects.

Role in VITAL: Data gathering laboratory; leading WP3 “Food Processing”.

Key Staff:

Dr. Leena Maunula. Microbiologist, university lecturer and a group leader at the Dpt of Food and Environmental Hygiene, University of Helsinki. Background in clinical virology, e.g. has established methods for detection of rota- and noroviruses for human diagnostics. Present research focus in food and environmental virology, special expertise in detection of viruses in drinking water. Participating in EU-projects EVENT/DIVINE and SEAFOODplus. Participating in COST Action 929 (ENVIRONET).

Professor Emeritus Carl-Henrik von Bonsdorff MD, joins as an important senior scientific adviser. A long and successful career in cell biology and virology. Participating in many expert groups e.g. in CEN/TC275/WG6/TAG4, in FAO/WHO expert group on foodborne viruses, and in COST Action 929 (ENVIRONET).

Beneficiary 5. University of Patras (UPA)

University of Patras is an institute located in Southwestern Greece, in Patras the third city in Greece. It is the third biggest University in Greece. It has more than 10000 undergraduate students. It has all major Schools such as Medicine, Polytechnic, Philosophy, Literature and Physical Sciences. The Laboratory of Hygiene belongs in the Medical School. The Laboratory has 5 Professors and 5 postgraduate students and 5 diploma students. The laboratory is fully equipped and its specialties are: Environmental Microbiology, Molecular Epidemiology, Epidemiology of Infectious Diseases, Water Microbiology, Water Virology.

Role in VITAL: Data gathering laboratory. Leading WP7 “Delivering Impact”.

Key staff:

Dr Apostolos Vantarakis Assistant Professor. Specialty in Epidemiology awarded by European Education

Programme in Epidemiology (EEPE). Has published 20 research articles in foreign language journals (with referees), 7 articles in Greek journals. He has been chief researcher in 21 national and international research projects. He has participated as an expert of Ministry of Agriculture in EU workshops on the microbiological quality of shellfish. He is representative of the Greek Standardization Body (ELOT) in CEN/TC275/WG6/TAG4. He is representative of Ministry of Development in EU in COST 929 ENVIRONET.

Beneficiary 6. Istituto Superiore di Sanita (ISS)

ISS is the National Institute of Public Health in Italy, with a mission that also includes prevention and control of infectious, foodborne and zoonotic diseases. As part of its institutional activity, ISS interacts with the network of 10 regional Veterinary Laboratories (IZS). ISS is composed of 7 Departments and 2 National Centres, enrolling over 700 scientists, for a total of over 1800 staff. ISS hosts five WHO Reference Centers (polio, arbovirus, Streptococcus, tropical diseases, alcoholism). The Department of Food Safety and Veterinary Public Health (SAAN) and the National Centre for Food Quality and Risk Assessment (CNQARA) are engaged in numerous institutional and research activities including foodborne viruses. In addition, ISS will be offered collaboration, at no extra cost to the consortium, with the Department of Veterinary Health and Animal Pathology, University of Bologna (www.unibo.it). This will provide access to pig farms in the major production area of Italy (contact person; Dr. Fabio Ostanello).

Role in VITAL: Data gathering laboratory.

Key Staff:

Dr. Franco Maria Ruggeri, Research Director, Dept SAAN. Active primarily on rotavirus, calicivirus and HEV. He is expert on antibody and molecular technologies. Pioneer in anti-viral sIgA MAbs and mucosal immunity to rotavirus. He studies enteric caliciviruses, particularly their molecular diagnosis and epidemiology, and is also involved on HEV research in pig. He is the is coordinator of MEDVETNET WG31 "ZOOVIR-NET". Dr. Ruggeri is the Vice-Coordinator of VITAL .

Dr. Dario De Medici, Senior Scientist at CNQRA. Expert in food microbiology and virology, molecular diagnostics and risk assessment. Member of Codex Alimentarius and other expert panels on food safety and detection methods. He has worked for several years on the detection of viruses in foods, and is a member of CEN/TC275/WG6/TAG4 and COST929.

Dr. Emiliana Falcone, Scientist at SAAN. Expertise in rotavirus, avian influenza and other viruses of domestic and wild animals. Works on molecular methods for detection and typing of viral isolates.

Dr. Simona Di Pasquale, CNQRA. Research activities in microbiology and hygiene of food products. Expert in methods for virus detection in food.

Subcontractor to Beneficiary 6 (ISS):

The Department of Veterinary Public Health and Animal Pathology, Faculty of Veterinary Medicine, Bologna University (Key person: **Prof. Fabio Ostanello**, Via Tolara di Sopra 50, 40064 Ozzano E., Bologna, Italy).

Prof. Ostanello's Group has consolidated experience in the field of swine viral diseases, including the specific aspect of hepatitis E virus. This group is currently active in collaborating with ISS in the framework of other projects (i.e. ZOOVIR-NET).

Beneficiary 7. National Institute for Public Health and the Environment (RIVM)

RIVM's knowledge and expertise in health, nutrition and environmental protection are used to advise the Dutch government, and shared with bodies such as WHO, FAO and EFSA. With our research, monitoring, modelling and risk assessment, we act to underpin policy. We investigate the extent of food-related infection in the Netherlands, along with the risk of people becoming infected after eating contaminated food and the effect of this on health. Moreover, intervention measures are designed and their efficacy evaluated. The group is actively involved in standardization of methods for microbial detection in animals, food and water.

Role in VITAL: Data analysis; Leading WP "Data Analysis". Survival and elimination of norovirus.

Key Staff:

Dr Ana Maria de Roda Husman, Head of Food and Water Microbiology of the Laboratory for Zoonoses and Environmental Microbiology at the Dutch Centre for Infectious Disease Control. Expertise (LZO) in quantitative assessment of the health risks posed by exposure to pathogens in food and water with specific knowledge of viruses. Vice chair of the COST action Environet. She is also chair of the microbial aspects group for the revision of the WHO Guidelines for Drinking Water Quality and active participant in the RIVM/WHO Collaborating Centre For "Risk Assessment of Pathogens in Food and Water".

Prof. Dr. Ir. Arie Havelaar, associate head of LZO and professor of microbiological risk assessment at the Institute for Risk Assessment Sciences (Veterinary Faculty, Utrecht University, the Netherlands). A world-renowned expert in microbiological risk assessment, he is Director of the WHO Collaborating Centre for Risk Assessment of Pathogens in Food and Water at RIVM and a member of EFSA's Panel on Biological Hazards.

Dr Jack Schijven is an expert in quantitative risk modelling and data analysis especially with respect to viruses.

Dr Saskia Rutjes is a virologist with outstanding knowledge of virus detection methods. She is involved in standardization of methods for virus detection in animals, food and water. She advises the Dutch National Standardization Committee and CEN/TC275/WG6/TAG4, ISO and the European Microbiological Advisory Group.

Beneficiary 8. Wageningen University Research (WUR)

The Animal Sciences Group is the leading contract research organisation in the field of infectious animal diseases in the Netherlands. In the Infectious Diseases Division, fundamental and applied research is linked to and translated into the practical situation. The Infectious Diseases Division's areas of research include Food Safety and Zoonoses, and Animal Disease Control. Research is carried out at its own modern facilities and the internationally recognised laboratory at the Lelystad headquarters. Research on Food Safety and Zoonoses focuses on control of infections from bacteria, viruses and parasites in all animal production chains, and the consequences of contamination on the quality of the end product. The Division has wide experience in collecting and testing all kinds of samples along the whole animal production chain. A large number of tests for the detection of important animal diseases is developed and optimized within the division. Detection and monitoring systems for zoonotic pathogens are developed and implemented to enable preventive measurements and to ensure the safety of products of animal origin.

Role in VITAL: Leading WP2; vaccination studies; survival and elimination of HEV.

Key Staff:

Dr. Wim H. M. Van der Poel, Research Leader. Theme leader of Scientific Integration of the EU network of excellence EPIZONE. Key scientist and partner in MEDVETNET WG31 ZOOVIR-NET and COST Action 929. He is a Netherlands representative expert in the CEN taskgroup 4 on standardization of methods for virus detection in foods.

Dr. Dörte Döpfer, veterinary epidemiologist within the Quantitative Veterinary Epidemiology Group of the Division of Infectious Diseases of ASG-WUR. Currently working on mathematical models for infectious disease specialising in complex host-pathogen interactions and transmission models for infectious disease, disease surveillance and risk analysis.

Dr. Bas Engel, Senior statistician of the Quantitative Veterinary Epidemiology Group of the Division of Infectious Diseases of ASG-WUR.

Beneficiary 9. National Veterinary Research Institute (NVRI)

NVRI is a scientific institution of the Polish Ministry of Agriculture and Rural Development. The major mission of the Institute is applied research in veterinary medicine, particularly concentrating on prophylaxis, diagnosis and control of infectious diseases, including zoonoses as well as food safety and toxicology. NVRI is the State Reference Centre for monitoring of infectious diseases in animals and monitoring of xenobiotic residues in food of animal origin and feedingstuffs. The Institute comprises departments representing basic scientific disciplines such as bacteriology, virology, environmental virology, biochemistry, parasitology, pathology, toxicology, pharmacology, physiopathology of reproduction, food and feeding stuffs hygiene.

Role in VITAL: Data gathering laboratory; leading WP4 “Point of Sale”.

Key Staff:

Professor Beata Mizak is head of Department of Food and Environmental Virology. She has extensive experience in work with viruses of carnivores and rabbits, with special interest in molecular biology. Her research activity includes methods for diagnosis of rabbit myxomatosis, viral haemorrhagic diseases of rabbits, and parvoviral infections in carnivores. Recently, because of the increasing importance of foodborne viral infections in Europe, she has reoriented her research activity to human viral pathogens, especially the epidemiology of foodborne virus transmission in Poland and molecular characterization of foodborne viruses. She Prof. Mizak is head of the National Reference Laboratory for viral contaminations of bivalve molluscs, rabbit myxomatosis, and viral haemorrhagic disease of rabbits.

Dr. Artur Rzeżutka is a senior microbiologist in the Department of Food and Environmental Virology. He is a virologist with experience in detection methods of human enteric viruses in soft fruit, and in molecular diagnosis of viral diseases of carnivores. His research is focused on environmental studies dealing with source recognition of foodborne viruses and routes of their transmission. As well as viruses, his work encompasses the epidemiology of cryptosporidiosis in livestock and humans, and the potential of the environment as a source of infective *Cryptosporidium* for food contamination.

Beneficiary 10. Scientific Veterinary Institute “Novi Sad” (NIV-NS)

NIV-NS performs research work in the field of veterinary medicine and multidisciplinary research in medicine, agriculture and protection of the environment. In the field of scientific and research work and laboratory (laboratory for molecular biology, bacteriology, serology, virology, microbiology and physical-chemical analysis in food, feed and drug examination approved for ISO 9001 and certain techniques accredited under ISO/IEC 17025) and clinic examination, the Institute develops strategic and operative developmental programs for protection of animal health, food and of feed safety and quality (HACCP system), welfare of animals and protection of the environment that are in accordance to international legislation and standards.

More than 20 per-review publications and 10 research projects in the Network topics during the last 5 years. NIV-NS possesses more than 40 years of experience in R&D of the needs of enterprises and in supporting agrarian regional policies. Moreover, NIV-NS is the leading representative in the field of veterinary medicine in Serbia.

Role in VITAL: Data-gathering laboratory.

Key Staff:

Dr. Tamas Petrovic, Chief deputy of the virology department in NIV-NS. Detection of biotic contaminants from environmental sources, various types of food, and water.

Dr. Sava Lazic, chief of the virology department in NIV-NS.. Expert in the field of contagious animal diseases, focused on the detection of the viral disease in animals.

Ms. Jasna Prodanov, Chief deputy of the department of epizootiology and health protection of pig in NIV-NS..Specialised in the field of health protection and production technology of pig, focused on the detection of clinical and pathological problems in pig production and their influence on the environment and public health.

Beneficiary 11. University of Ljubljana (UL-BF)

The Biotechnical Faculty of Ljubljana is constituted of the following departments: Agronomy, Biology, Forestry, Landscape Architecture, Wood Science and Technology, Zootechnics, Food Science and Technology and the Centre for Biotechnology. The Food Microbiology Group studies pathogenic and spoilage microorganisms in food. We have introduced a holistic approach to food safety, and included in this concept a consumers dimension.

Role in VITAL: HACCP studies; formulation of Code of Practice, development of response database and training course.

Key staff:

Professor Peter Raspor, doctor of biotechnological sciences, professor of industrial microbiology and microbiology at University of Ljubljana, Slovenia. Since 1992 head of the Chair of Biotechnology, Biotechnical Faculty, Food Science and Technology Department, Since 2003 Head of Undergraduate study of biotechnology. Since 1995 he is active with COST, having different functions up to president of Technical Committee, and currently vice-chairing COST Domain committee for food and agriculture. From 2000 to 2006 he was a FEMS Secretary General of the Federation of European Microbiological Societies. He is also involved with other international and national governmental and nongovernmental organizations. He is a member of many scientific and professional societies and a member of editorial boards or editor in highly respected journals in the field. He has published more than 100 scientific publications in food and microbiology and biotechnology fields. He has been awarded for his contribution to science and education, e.g. Doctorem Honoris Causa Universitatis de Sancto Stephano, Gödöllő, Hungary in 2002, Doctorem Honoris Causa University of Pecs, Hungary in 2003, “100 years of Virology” medal from All-Russian Scientific Council of Virology and the highest state Award for academics in Slovenia for achievements in the high education in 2003. In 2006 he got an award for long lasting cooperation from the University of Zagreb, Croatia.

Dr. Mojca Jevšnik, Lecturer, University of Ljubljana, College of Health Studies, Ljubljana. Researcher in the field of food safety related to consumer issues.

Beneficiary 12. Agrarian Research Institute of Castilla y Leon (ITACyL)

ITACyL is a public research institution of the Government of the Castilla and Leon autonomous region. The organisation supports the needs of agro-food companies and regional agrarian policies. ITACyL is the regional representative of the National Institute of Agrarian and Food Research (INIA). Its main goal is to strengthen the regional economy through the improvement and development of products, techniques and services for the agricultural and husbandry sectors, and for the food industry.

The Molecular Biology Laboratory is focused on Agricultural and Animal Research and Food Safety and Quality, in particular: (1) molecular diagnostic tools for diagnosis of foodborne pathogens; (2) molecular systems for detection, identification and quantification of animal pathogens. The Laboratory has implemented an Integrated Management System for Quality and Environment, and is in the process of accreditation of several molecular-based methods by ISO 17025.

Role in VITAL: Data-gathering laboratory.

Key Staff:

Dr. Marta Hernández, Head of the Laboratory of Molecular Biology. Possesses extensive experience in the field of analysis of foodborne pathogens by molecular approaches. She is currently the in ITACyL. Her current area of interest is assessment of food safety by molecular methodologies, particularly PCR diagnosis.

Dr. David Rodríguez-Lázaro, Researcher. Member of the governor council of the Food and Beverages group of the Spanish Society for Microbiology, and the Spanish Committee for the Normalisation of Food Microbiological Methods. Member of the Normalisation of Food Microbiological Methods Task Group of the International Standardisation Organisation. He is editor-in-chief of the journal “Food Analytical Methods”, and member of six Editorial Boards of international research journals in the area of Food Quality and Safety.

Beneficiary 13. University of Barcelona (UB)

The laboratory is in the Department of Microbiology and has been involved in the study of viruses transmitted through water or food for more than 18 years, developing molecular methods for the detection of human and animal adenoviruses, enteroviruses, hepatitis A and E viruses, and human and animal polyomaviruses and the evaluation of potential indicators of viral contamination. Prof. Girones coordinated the project FAIR CT-98-4039, on the study of the viral contamination in shellfish, has led the work package on QPCR and typification of viruses in the VIROBATHE project, is the principal investigator of the project of the Spanish ministry of Education and Science (AGL2005-07776-C03-02) on detection and epidemiological typing of pathogenic human emergent viruses of interests in food safety, and represents AENOR, on the working group of CEN for the standardization of techniques for the detection of viruses in food (CEN/TC 275/WG6/TAG4).

Role in VITAL: Studies on survival and elimination of adenoviruses

Key Staff:

Professor Rosina Girones, Tenure Professor of Microbiology, directs the laboratory and has more than 20 years experience in the study of viruses in water or food.

Dr. Silvia Bofill, Lecturing/research Associate, has eight years of experience in analysis of viruses in environmental samples and food.

B2.3 Consortium as a whole

To devise effective systems for surveillance and management of foodborne viruses requires the coordinated expertise in several areas, primarily food and environmental virology, zoonotic disease, risk analysis and management, and food safety. Real expertise in analysing actual food samples for viruses is also essential. Table B2.1 shows that the VITAL consortium, through its various individual beneficiaries, possesses all the necessary expertise to achieve the project's objectives.

Table B2.1 The expertise of the VITAL consortium

Expertise						
	Food and Environmental Virology	Zoonotic diseases	Risk Analysis	Risk Management	Food and Consumer Safety	Foodborne Virus Analysis
Beneficiary	Defra	Defra				Defra
	VRI	VRI				UH
	UH	ISS				UPA
	UPA	RIVM	Defra			ISS
	ISS	WUR	ISS	KULeuven	UL-BF	RIVM
	RIVM	NVRI	RIVM	UL-BF	UB	NVRI
	WUR	NIV-NS	WUR			WUR
	NVRI	ITACyL				UB
	NIV-NS	UB				
	UB					

The majority of the VITAL beneficiaries have previously collaborated, and are currently cooperating, in various research projects connected with the areas of expertise listed above. For instance, UPA and UB collaborated in the FP4 project FAIR-CT98-4039, “Development of techniques for monitoring and control of human viral contamination of shellfish”. Defra, RIVM, NVRI and UB have recently participated in the FP6 VIROBATHE project. ISS, RIVM, and UH are partners in the FP6 project “Providing tools to prevent the emergence of enteric viruses (EVENT)”. ISS and UL-BF participate in the FP6 Integrated Research Project “Improved bio-traceability of unintended microorganisms and their substances in food and feed chains (BIOTRACER)”.

Moreover, as related in Section 1.1, several beneficiaries are participating in two European networks, ENVIRONET and MedVetNet, and the VITAL project has been brought together through their vision. VITAL beneficiaries in ENVIRONET and MedVetNet are shown in Figure B2.4. Some beneficiaries are participating in both networks.

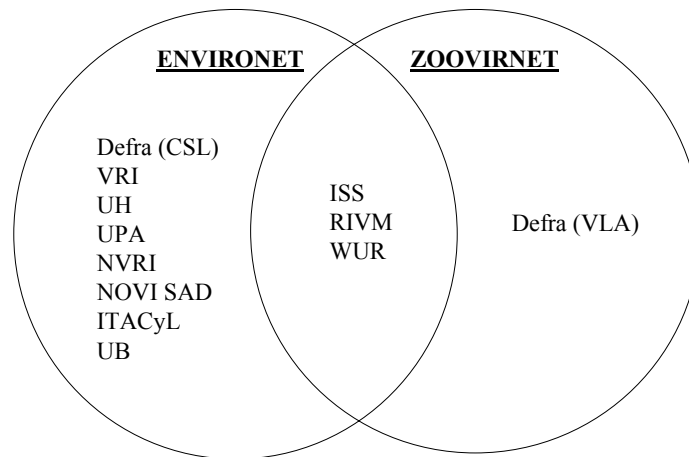


Figure B2.4. VITAL beneficiaries in COST Action 929 “ENVIRONET and WP31 of NoE MedVetNet “ZOOVIR-NET”

The VITAL Coordinator and Vice-Coordinator are leading ENVIRONET and ZOOVIR-NET, respectively. The Coordinator has worked in the area of food virology since 1995, developing new methods for food analysis and using them in actual food analysis for various customers, including the retail sector. The Vice-Coordinator is an expert on zoonotic viruses, especially in food-producing animals. COST Action 929 “ENVIRONET” has Working Groups on the topics of Current and Emerging Issues, Analytical Methods, Data Analysis, and Virus Stability. ZOOVIR-NET is working towards implementing knowledge and development of methods in detection, typing and epidemiology of possibly emerging zoonotic viruses within the European scientist community. Each of these areas is highly relevant to VITAL, and VITAL will benefit from the added interaction mediated through beneficiaries involvement with these Networks. ENVIRONET and ZOOVIR-NET are not themselves conducting experimental research, but are focussed on dissemination of information and cooperation amongst scientists from various areas. Therefore actual duplication of effort will not occur between VITAL and ENVIRONET, and each project will add value to the other. The VITAL Coordinator and Vice-Coordinator will ensure that synergies with ENVIRONET and ZOOVIR-NET are fully exploited, for example systems of data analysis which VITAL will test can be further evaluated by members of ENVIRONET, and exchange of isolated HEV samples can occur with other participants in ZOOVIR-NET.

The partners in ENVIRONET and ZOOVIR-NET have between them wide experience in many areas of their discipline, and in many individual instances are recognised as the leading experts in their fields. To ensure the full integrated portfolio of skills necessary for fulfilling VITAL’s aims, their capability will be augmented by the risk management know-how of Professor Willems and his team at the Catholic University of Leuven and the Food and Consumer Safety expertise of Professor Raspor and his colleagues at the University of Ljubljana.

Subcontracting

The group of Professor Ostanello at Bologna University, Italy, will contribute to the project as a subcontractor to Beneficiary 6, ISS. Within VITAL, Prof. Ostanello’s group will specifically perform the planning of the epidemiological study within swine farms in the Emilia-Romagna Region and the acquisition of samples. The University has been selected as a subcontractor since Bologna is close to the pig farms and slaughterhouse targeted for the study in Italy. This will be of significant benefit in mediating continuous contact with the source of samples, and allow saving of travel time and costs to the project). Prof. Ostanello’s group will contribute to the project activity of Partner ISS in Italy with respect to D2.3 “Data on virus contamination of pig faeces and unprocessed pig products” and D3.1 “Data on virus contamination during processing of pig faeces -pork products”. They will provide, in agreement with and according to the requests of ISS, qualified veterinary assistance in the collection of clinical and environmental samples in pig farms. The subcontractor will also provide collection of samples during critical points in the processing of pork products, e.g. pork sausages, pork liver, and pork blood sausage, including preparation surfaces and cutting utensils or similar equipment (which have potential for mediating cross contamination).

WP Leaders

The data-gathering WPs (2-4) are led by expert scientists who are among the very few in Europe who have been performing analysis of food or environmental (including on-farm) samples for viruses for several years. The data-gathering laboratories all have experience in analysis of fruit, vegetables or meat for human or animal viruses. Outside

of VITAL, there are very few laboratories with the necessary expertise or facilities to perform such analysis. Furthermore, the VITAL consortium includes the laboratories with most experience in Europe on the study of the molecular epidemiology of emergent viruses transmitted through water and food, and on the use of human and animal adenoviruses as potential markers of the presence of specific viral pathogens of human or animal origin.

The leader of WP5 “Data Analysis” has developed model risk analysis programs at RIVM, and leads the Data Analysis Working Group in COST Action 929). The laboratories in this WP all have extensive expertise in microbiological risk assessment, applied in European projects such as “Seafoodplus” and “Biotracer”, and COST Actions 97 “Development of monitoring procedures, rapid detection methods and techniques”, and 929.

The leader of WP6 “Control Measures” is a leading expert in the field of microbial ecology of industrial processes. The WP6 scientists possess knowledge of on-farm practices and food processing, and have links with local farms and processors. Several of the scientists have extensive experience of HACCP in food-producing environments. The studies of disinfection and survival will benefit from the advice of several VITAL scientists including the Coordinator, who have expert knowledge of virus behaviour in foods and food production systems.

The leader of WP7 “Delivering Impact” is a key participant in ENVIRONET, overseeing the dissemination of expertise throughout this European network through its program of scientific missions and exchanges. His institute is a cooperating laboratory for the Ministry of Agriculture in Greece. The whole VITAL consortium will participate in WP7, and every VITAL scientist has experience of scientific dissemination, at international level. Many of the VITAL scientists are members of international expert bodies such as FAO, WHO, EFSA, Codex Alimentarius Commission, etc., and several have experience of producing formal guidelines and recommendations to industry, on various aspects of food safety. The WP7 leader cooperates with the Greek Standardization body (ELOT) and represents Greece in CEN/TC275/WG6/TAG4.

VITAL will also have a group of Expert Stakeholders, representing various sectors of the food industry. They will not receive funding from the project, but have agreed to participate out of interest. They will provide information on their existing HACCP. They will also review the draft Code of Good Practice, and initiate its validation it by providing feedback on its practical applicability. Their association with VITAL will enhance the active dissemination of the project’s outcomes. The Expert Stakeholders are:

CoopItalia (www.e-coop.it) is the largest Italian retail company with 11,300 Euro sales, 1,300 stores and 55,700 employees. The laboratory personnel is composed of biologists and chemists, and their analyses range from classical methodology to molecular biological (PCR and Real Time PCR).

Danish Meat Research Institute was founded on 1st April 2006 and carries out a number of tasks for three major meat organisations in Denmark: the Danish Bacon & Meat Council (Danske Slagterier), the Danish Livestock and Meat Board (Kødbranchens Fællesråd) and the Danish Poultry Council (Det Danske Fjerkræraad). The DMA was formed to provide a strong meat and processing sector, politically and technically, as well as better total capacity. The DMA performs research and development, food safety, veterinary alert system, marketing promotion and market access, administration and financial management, and communication.

iMIK tv or the ‘Institute for Microbiological Food Safety’ (www.imik.org) is a consortium (legal entity) of 3 Flemish Research Institutes, i.e. Scientia Terrae vzw. (www.scientiaterrae.org), De Nayer Institute vzw (www.denayer.be) and Proefstation voor de Groenteteelt vzw (www.proefstation.be), created and funded by the Flemish Government and industry, i.e. LAVA cv and Univeg/Legumex nv. and Univeg/Fresway nv. As a consortium iMIK reaches out to a broad network of companies throughout the whole production chain of fresh produce (market gardeners, auctions, processing companies and point-of-sale), mostly including SME’s but also some of the major players, i.e. Univeg Group of companies and Quick Restaurants nv., in the market. Specific tasks of the institute are: Survey of current food safety practices throughout the whole food chain; Evaluation, implementation and training of innovative concepts and techniques in the production of fresh produce: Data gathering and management to support hazard analysis and risk assessment as well as the implementation of food safety systems, e.g. GAP, GHP, HACCP and risk analysis.

Mechelse Veilingen cv. (www.mechelseveilingen.be) is a co-operative society of over 2,500 market gardeners in Belgium. In 2006, the turnover of the Auction of Mechelen amounted to 238 million EUR, making it the largest European co-operative society as an auction. Almost 40% of all Belgian horticultural products, traded via the system of auctions, are sold at the Auction of Mechelen.

Pakkasmarja Oy (www.pakkasmarja.fi) is a cooperative of berry-growing farmers in Central Finland, the main berry-producing area in the country. They freeze mainly strawberries, but also other berries like currants. In addition, they import mainly (frozen) raspberries which they mix with other (domestic) berries. Information (in English) available at: <http://www.pakkasmarja.fi/index.php?kieli=3>

Laurilan Vihannespakkaamo processes fresh produce to be delivered to institutional central kitchens and restaurants in Finland. Most of the raw materials are imported and the company cuts them up and prepares fresh salad mixtures. Root fruits, like carrots and swedes are domestic and are grated for delivery.

The Spanish Food and Drink Industry Federation (FIAB) (www.fiab.es). Spanish representative of the Food European Technology Platform "Food for Life". The FIAB is an employers' federation which brings together most of the food manufacturing companies in Spain. It keeps the food manufacturing sector informed about events and processes -present, future or potential- which may affect its operations, and represents its interests in discussions with administrative and decision-making bodies, whether at national or EU level.

A representative from each Expert Stakeholder will attend the first and third VITAL annual meetings (months 1 and 25). At the first meeting, the Expert Stakeholders can interact directly with the VITAL scientists, and have an initial meeting with the representative from UL-BF who will perform the fact-finding missions and prepare the COGP. At the third meeting, they will be presented with the draft COGP, before they test its applicability.

Thus, the consortium has the necessary qualities to realise VITAL's vision of improving food safety in Europe.

B2.4 Resources to be committed

The most important resources in VITAL are its personnel. The deployment of the scientists will ensure that the highest quality competence and experience underpin the project throughout its duration. Other than personnel costs, the principal resources requested are consumables (chemicals, plastic and glassware, cell culture and microbiological media, molecular biology reagents) travel, and internet-based conference facilities. We do not request any major items of equipment be provided for this Project. All laboratories possess the equipment necessary to do the work.

Personnel

Project management: The Coordinator, Assistant Coordinator and Financial Manager will each require 0.5 months each year to attend the CAT. The Coordinator will require a further 0.5 months for other administrative duties, and the Financial Manager a further 0.5 months for financial management.

Research and Dissemination activities: The Coordinator requests 1 month to interact with each WP, which will include attending the Annual meetings (including the PAB) and the RDMB, for other coordination duties, and provision of scientific advice to beneficiaries, through all the WPs current in each year. The Assistant Coordinator requests a further 0.5 each year months to assist the Coordinator with coordination duties and advice provision (this time has been allocated in WP7). Each WP leader, and a representative from each beneficiary, is required to attend the RDMB.

The data-gathering activities will take 30 months per person, and we request experienced scientists to ensure that these activities are performed to the highest quality. Scientists from each VITAL institute will put at least 0.1 month into each data-gathering WP; this is necessary so that the coordination of the flow of work within WPs 2 –4 is interlaced among the beneficiaries.

For the VITAL risk analysis, we request 11.5 months scientist time for the WP leader's laboratory, including 2.5 months for the WP leader. We further request at least 3 months for each data-gathering laboratory in WP5, to ensure that data is transmitted and collected regularly and efficiently. Scientists in WUR, UL-BF, and UB request at least 0.1 month each for this WP, to assist and advise in the development of the MPRMs, and to gain information for the development of HACCP models and the Code of Good Practice.

We request 20.5 months for the leading institute in WP6 "Control measures", to guide the work of the beneficiaries, and also to assist in supervision of the 3 VITAL post-graduate studentships. The studentships will be hosted in UB (36 months), in RIVM (36 months) and in Defra / WUR (24 months in the former, with a 12 month stay in the latter), and we request senior scientist time at each host institute for supervision. For the vaccination studies at WUR, we request 11.1 months, scientist time. For the fact-finding missions to the farms and production premises from where data will be gathered, evaluation of HACCP, and liaison with the Expert Stakeholders, we request 23.5 months for UL-BF. The data-gathering laboratories request at least 2.5 months scientist time in this WP, to assist with the collection of information, to provide additional expert advice from local situations to the WP leader and the fact-finding missions, and to check current practices with the Expert Stakeholders. The Assistant Coordinator will require 1 month each year for webmastering, in WP7 "Delivering Impact". UL-BF requests 20.7 months staff time, to lead the development of the Code of Good Practice, and organise the Symposium, Workshop, and Training Courses. All VITAL institutes will participate in this WP; we have requested extra time for VRI, NVRI and NIV-NS to assist with the organisation of project annual meetings and the Symposium.

The subcontract to the University of Bologna, Italy, will require 25,000€ to cover expenses for: i. preparation of a detailed animal/tissues, /products sampling scheme; ii. traveling to the sampling sites (both farms and slaughterhouse); iii. materials, containers, and labels for sample collection, storage and classification; iv. shipment costs to ISS; v. person cost for the indicated activity, throughout the project lifespan; vi. expenses for telephone calls and meetings with ISS.

Equipment

All equipment necessary for conducting the experimental work performed by VITAL currently exists within the beneficiaries' institutes. Such equipment includes PCR thermocyclers and associated instrumentation, cell culture facilities, pilot facilities for simulated field scenarios etc. Thus, availability and maintenance of equipment is a commitment of each institute, and is not being requested in the budget.

Consumables

Consumables are the main tangible resource. Virus concentration procedures and (particularly) detection methods are demanding in the use of consumable reagents. This is particularly so in the case of molecular biology. The consumables budget for the data-gathering workpackages has been based on the number and type of samples which will be analysed. It has been estimated that for each sample, the treatment (i.e. extraction / concentration from the matrix, nucleic acid purification) will cost approximately 10 euros. Each (RT)PCR will cost approximately 5 euros. Five euros has been estimated as necessary for each process control, and approximately 20 euros for each ICC-PCR. Where samples (salad vegetables, shellfish and soft fruit chains) may require analysis for all the virus types (BAdV, HAdV, PAdV, NV, HAV and HEV), the total cost of one analysis is therefore approximately 65 euros. For samples from pork production, (RT)PCR need only be performed for PAdV and HEV, and therefore the total cost of one analysis is approximately 45 euros.

For the studies of survival and elimination, we request a provision of 1,250 euros per month, as these studies require intensive cell culture and PCR-based work.

We also request provision for stationery, necessary in report preparation, correspondence, courier costs, etc. The data-gathering institutes each request 2000 € for fuel costs during the data-gathering activities. The Coordinator furthermore requests a dedicated laptop PC for working off-site (e.g. during visits to beneficiary laboratories). The Coordinator's institute request 6,300 € to set up the Internet conferencing facilities between all 14 laboratories in VITAL.

Travel

While VITAL will use internet-based conferencing wherever possible, it is no substitute for actually meeting and interacting face-to-face with ones' colleagues. Therefore VITAL will have 3 Annual Meetings to which beneficiary representatives will travel. One thousand eight hundred euros is requested for beneficiary representatives to attend each meeting. A further one thousand eight hundred euros is requested for each beneficiary to send representatives to the final symposium and workshop.

The Coordinator requests 16,000 euros to allow the 5 PAB members to attend the Annual Meetings and the Symposium, where the Board will meet. The Coordinator requests a further 11,200 euros to allow 1 member from each of the Expert Stakeholders to attend the kick-off meeting and the third Annual Project Meeting.

12,000 euros is requested to allow the travel necessary for the fact-finding and HACCP audit missions.

For all of the above requested resources, each beneficiary has requested 75 % support from the Commission. Each beneficiary, either through their own internal resources, or from national funding bodies, will commit the remaining 25 %.

B3. IMPACT

The unique use of QVRA will yield the major impact of VITAL which is to show if a specific food production chain can produce virus safe food and if not at which stage which intervention would lead to reduced public health risks with respect to foodborne viruses.

B3.1 Strategic impact

Outbreaks of viral disease caused by contaminated foodstuffs have been a persistent problem, to which epidemiological surveillance systems are only capable of reaction. The search for solutions remains therefore, despite support at a European and national level, a major issue. By demonstrating the feasibility of pro-active integrated monitoring and risk management strategies for control of contamination of food supply chains by viruses, VITAL will achieve major and lasting advances in the field of food safety. Fundamentally, a new order will be established in the three key areas of VITAL's activities: food surveillance, risk analysis and control methods.

The outcomes of VITAL will deliver an impact cascade, which will drive forward European progress towards increased public health. This cascade is summarised in Figure 3.1

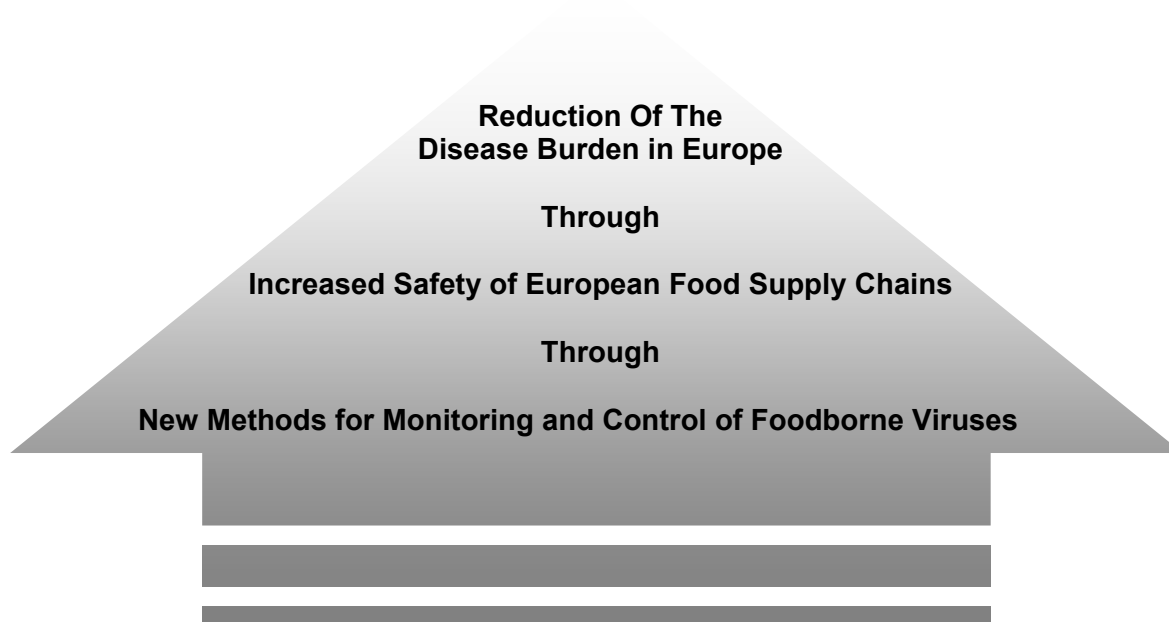


Figure 3.1 The VITAL Impact Cascade

Vital will provide:

New European systems for food surveillance

Gathering specific data on the contamination of the food supply chain with viruses as input for risk assessment has never been attempted on such a scale as proposed by VITAL. These data include knowledge on the detected viruses such as quantity, infectivity, type as well as on the methodology such as recovery and specificity. VITAL will validate the applicability of standard methods for detection of viruses in foodstuffs and associated materials. By conducting controlled surveys of produce in production, during processing and at market, VITAL will demonstrate the feasibility of effective monitoring of food supply chains for virus contamination and will integrate this achievement by delivering practical guidelines to the food and agricultural industry and to analysts, on how to implement monitoring with the purpose of risk assessment and management if and when it is necessary as determined by the competent authority. Thus, VITAL will build the groundwork upon which a European Food Surveillance Network for Viruses can be constructed. **The infrastructure of methodology and procedures which VITAL will exemplify, will be capable of generic application to analysis of foods for any virus, whether of current significance or emergent in future.** The detection methods for viruses in food supply chains will be rapidly and efficiently applied in countries like Greece,

Poland and Serbia which are important producer countries, and where information about the virological quality of this type of produce is very scarce. It must be emphasized that it is the first time that a project involving extensive monitoring of fresh produce for viruses will be performed in Europe. Also contamination of foodstuffs such as frozen berries can be greatly reduced when survey data from these countries has been gathered. At the same time the collaboration among European countries will strengthen the unity and level of food hygiene in Europe. This will in the long run increase the competitiveness of the European food industry compared to other food industries such as the USA.

New systems for data acquisition, analysis and transfer into risk assessment structures

VITAL will set up procedures for transmitting the data obtained from uniform monitoring activities directly into risk assessment modelling operations, to readily **quantify the immediate public health consequences of the level of virus contamination in various modules of food supply chains and to direct interventions.**

By using the tools for data analysis and risk assessment which VITAL will produce, any producer or legislator to be able to determine a quantitative risk based on the data collected on a specific virus in a specific food product. With the assessment of the actual health risk the risk managers (most often inspectors and legislators) will have access to a decision tool to determine if the food is produced safe up to the level that is acceptable to them, and if not a range of interventions from which they can choose with respect to efficacy. They can then decide based on scientific knowledge upon further action which they may base on cost and urgency for instance if the public is alarmed.

The information that VITAL will acquire using adenoviruses will show whether human or animal (and if so which animals) contaminate our foods with viruses. This will provide crucial information regarding which points interventions should be aimed at. To commodity boards and producers VITAL will provide both food safety plans and formats for sanitary surveys. These useful and transparent ready-to-use practical tools will help food identify and control sources of virus contamination of food supplies.

VITAL's panorama of data-gathering laboratories in various countries will ensure that different aspects of food production are taken into account, with the result that more accurate risk assessment models will be applied which take into consideration the variability in food production throughout Europe.

Sound establishment of foodborne virus risks and tolerances in food supply chains

VITAL will provide validated *scientific evidence* and *information* to improve the understanding of multiple factors that determine food product safety to industry as well as to regulatory officials. Central to VITAL's role in foodborne virus management research activities is the concept of proactively determining foodborne viral contamination, transmission, exposure, and disease risks for use with HACCP and other management systems based on empirical, real-world data as opposed to doing so reactively using only theoretical or speculative means. VITAL will promote and facilitate the adoption of the risk assessment approach as a basis for the implementation of food safety management systems by industry and regulators throughout Europe. In this way, VITAL will help to accomplish widely supported risk-based international regulations.

VITAL will offer new information to countries where the surveillance of food throughout the food chain is not applied so far. Also, the new monitoring data collected should encourage industries to adopt VITAL's HACCP models. In some countries, where HACCP has even today attracted criticism, especially regarding to viruses, the impact of VITAL should be profound.

New procedures for control of virus contamination of foods

VITAL will integrate awareness of viruses to the common rules of hygiene. The HACCP systems that VITAL will promote will help to prevent viral foodborne outbreaks and thus protect consumers. Besides the benefits to *public health* this will also have an *economical* benefit by reducing hospitalisations, and absenteeism from work due to illness; furthermore it will decrease economic losses to companies due to viral contamination of food products and the consequences by retraction of product from the market after illness but also the *political* consequences such as the loss of the good reputation of the product and/or the producer and the originating nation and the loss of the consumers trust and the trust of the importing nation.

VITAL will help regulatory officials to identify the potential for materials either produced or imported into a country to carry foodborne viruses, and to adopt appropriate measures to control exposure of the population. VITAL will provide

information for producers, processors, retailers, etc. on the challenge foodborne viruses pose to their existing supply chains, product designs, process conditions and consumer markets. VITAL will contribute to a *common approach* to assure that measures adopted / implemented are non-discriminatory between different European countries, not more trade restrictive than necessary and not maintained without sufficient scientific evidence.

Also, the information collected in VITAL should act as a baseline for including specific viruses in official guidelines for food quality (e.g. HAV in shellfish). The protocols, as well as the intervention strategies that VITAL will recommend, will be widely applicable to other viruses whether new or emergent, providing a consistent sound scientific baseline for any future issues concerning potential contamination of the European food supply chain with foodborne viruses.

In toto, the impact of VITAL will result in improved European preparedness for dealing with any virus that may enter the food supply chain, before it reaches the consumer.

B3.2 Plan for the use and dissemination of foreground

It needs to be recognised that knowledge of foodborne pathogens within the food industry mainly concerns bacteria and fungi, which behave very differently from viruses. Viruses contaminate at very high numbers and subsequently become inactivated over time; however, at the low temperatures at which many food products are kept and shielded from sunlight and oxygen and other inactivating factors the virus inactivation rates should be disregarded. Such knowledge on viruses from the VITAL expert virologist groups will be disseminated together with the outcomes of VITAL.

The dissemination of VITAL's outcomes, and the impact they have, are fundamentally linked. To ensure this, VITAL has a dedicated workpackage: WP7 "Delivering Impact".

VITAL will disseminate its results and outcomes via five avenues: Code of Good Practice, Symposium, Workshop, Training Courses, website, and existing Networks.

Code of Good Practice for Controlling Virus Contamination This will be produced following the fact-finding missions in WP6, and through continuing liaison with the Expert Stakeholders throughout WP7. The Code will be built up using expert advice and information and will be validated by each Expert Stakeholder to ensure that it is fit for purpose. The Code will contain the details of the VITAL HACCP models. The Code will be distributed to interested parties from the food industry at the project symposium and workshop. It will also be made available on the project website.

Symposium "New Developments in Monitoring and Control of Foodborne Viruses" In the final month of the project, a 2 day scientific Symposium will be held. This will comprise presentations from each WP leader on the outcomes of their WP, and an overview by the Coordinator and Vice-Coordinator. Keynote speakers will be invited from the PAB. A representative of the Expert Stakeholders will be invited to give a presentation on the predicted impact of VITAL's outcomes on the European Food Sector. There will also be poster presentations from individual scientists. The Symposium will be open to any interested party. Scientists from USA and Japan, scientific societies and industries will also be invited to participate.

Workshop "Taking Forward New Developments in Monitoring and Control of Viruses in Food Supply Chains" This workshop will be an excellent opportunity for interested parties, especially regulators, representatives of national and international bodies (e.g. EFSA, WHO, WTO), and members of the food industry, to discuss how the outcomes of VITAL will be integrated into food safety practices and regulations. Also invitations will be sent to scientific officers in Ministries of Food and Agriculture of all European countries. The aim of the workshop is to bring closer the scientists (virologists) with officials as well as industries in order to discuss the outcomes of the project and the role of viruses in food quality and public health. A specific section within the workshop will be devoted to regulatory issues. The possibility of sponsorship of additional workshops entirely focussed on regulatory issues will be explored with EFSA and / or other international and national regulatory agencies.

The workshop will be held after the Symposium, in the same venue. Concurrently with the Symposium, two training courses will be held in the venue. The participants in these courses would subsequently be able to attend the Workshop.

Training course "Monitoring of Viruses in Food Supply Chains" This one-day course will be organised for training analysts who were not part of VITAL, in the principles of integrated monitoring and risk analysis which VITAL will

formulate. Participants will be trained how to implement monitoring if and when it is necessary, and also in the way they can transfer this knowledge to colleagues in their countries. This course can therefore be seen as a “training the trainers” course, and will play an important role in disseminating VITAL’s outcomes.

Training course “Control of Viruses in Food Supply Chains” This one-day course will focus on the integrated management systems which VITAL will recommend to the food industry. The course will be targeted towards risk managers, and provide information about virus hazards, and appropriate HACCP.

(Additionally, a special **round-table** and an open discussion for the project’s results will be organised in Greece, during the HRWM Symposium (31st May to 5th June 2009). This workshop will be included in the official programme of the symposium and it will be a very good opportunity to discuss the project results (so far) with scientists from USA and Japan.)

Website In the first month of the project a website will be created. The website will be updated monthly. The website will have two types of access:

Public access: This will contain non-confidential project information, such as a summary, aims, and copies of work presented at concurrent symposia. Contact details of the VITAL scientists, and links to other relevant websites, will also be available.

Beneficiary-only access: This would contain all the project’s SOPs, which would be downloadable. Ongoing results of the workpackages would also be available. Copies of project reports would be held on these pages.

Networks VITAL will utilise the opportunities for dissemination of information which are available within COST 929 and MedVetNet.

COST Action 929 “*A European Network for Food and Environmental Virology*” currently contains colleagues from 24 participant countries. More are expected to join during the lifetime of the Action (it will run until October 2010, and a follow-up Action will be applied for). The Working Groups within COST 929 (“Current and Emerging Issues”. “Analytical Methods”. “Data Analysis”, and “Stability of viruses”) are platforms for exchange of information and discussion of mutual topics of interest among the members, and they will be ongoing fora for dissemination of VITAL’s results to colleagues outwith the project.

The results of VITAL will add value to various COST 929 deliverables, such as “An algorithm for acquisition, evaluation and interpretation of environmental data” and a “A documented structure for an environmental surveillance network”, and will thus achieve another level of dissemination.

Opportunities for colleagues who are outside VITAL to work in a VITAL laboratory and learn about the methods of integrated food monitoring and risk analysis will be found within the series of short-term scientific missions which the Action will fund each year. The 2nd COST 929 Symposium, “Future Challenges in Food and Environmental Virology”, will be held in September / October 2010, and each VITAL Workpackage leader will plan to present findings of their work at this meeting.

The *MedVetNet Network of Excellence* will be active until August 2009. The VITAL Vice-Coordinator will channel appropriate information (e.g. concerning risk assessment on foodborne zoonoses) from the project through MedVetNet’s Communications Unit, so that it will be disseminated to the range of scientists within the Network, and to interested parties who receive information from the Network. MedVetNet partners within VITAL will plan to present ongoing work during the Network’s Annual and Workshop meetings.

B4. ETHICAL ISSUES

The project does not raise any ethical issues.

B5. CONSIDERATION OF GENDER ASPECTS

The Small Collaborative project VITAL supports the European Commission policy on Gender Equality regarding the equality between women and men in accordance with Articles 2 and 3 of the Treaty on European Union (gender mainstreaming) as well as Article 141 (equality between women and men in matters of employment and occupation) and Article 13 (sex discrimination within and outside the work place).

It is widely recognised that there is a need to balance the gender ratio in research, where the total participation rate of women is particularly low, especially in managerial positions (including senior management posts). In order to promote gender equality within the project, VITAL has elaborated a GENDER ACTION PLAN (GAP) which involves evaluating the current situation and formulating the actions to be taken during the project's lifetime.

VITAL current situation regarding gender:

All beneficiaries comply with the principles of gender equality in work and daily living, giving equal opportunity for all staff whether male or female. The women participation rate in VITAL is 37.14 % of the total personnel committed to the project, which go beyond the average proportion of women in academic careers in most of the member States (National Policies on Women and Science in Europe. The Helsinki group on Women and Science. 2002.). The women are directly involved in the management of the project and in the scientific partnership as scientific team leader in the project.

Participation of women in VITAL is as follows:

- 1 (33%) (1 out of 3) women involved in the CAT.
- 5 (36%) (5 out of 14) women involved in the scientific partnership as scientific team leaders of the project.
- 1 (50%) (1 out of 2) women early researchers.
- 12 (37%) (12 out of 33) women experienced researchers.
- 3 (43%) (3 out of 7) women leaders of work packages.
- 1 (25%) (1 out of 4) women member of the Project Advisory Board.

Table B5.1 Gender distribution In the VITAL project

Beneficiary	Defra	KULeuven	VRI	UH	UPA	ISS	RIVM
Female	1	0	1	1	0	2	2
Male	3	3	2	1	1	2	2
Ratio %	25	0	33	50	0	50	50
Partner	WUR	NVRI	NIV-NS	UL-BF	ITACyL	UB	
Female	0	1	1	1	1	2	
Male	3	1	2	1	1	0	
Ratio %	0	50	33	50	50	100	

These female members have successful professional careers in research and in science policy and dissemination activities. Thus, from the outset, VITAL shows its commitment to the promotion of gender equality within the project. However, the intention is to promote and encourage the participation of more women, and so we have elaborated a series of actions.

Practical proposed actions

VITAL proposes the following action plan to endeavour to employ more women among the research staff, especially for the top decision-making positions. This plan does not just demonstrate that the acknowledgement that women are equal to men; it also manifests the project's desire that participation of women is promoted and encouraged. The Plan involves:

- the creation of a Gender Awareness Group (GAG), led by Dr. Marta Hernández and formed by all women involved in VITAL, which will monitor all the following tasks.
- The collection of statistical data on participation of women in the different events and tasks of VITAL.
- Guaranteeing the contribution of women in meetings and workshops through equal participation as invited persons and as attendants. During appointment at the 1st project meeting, strive to achieve a 50:50 gender balance amongst the Tasks leaders.
- The inclusion of a webpage section in the VITAL Internet site named “women and science”, which will contain all data concerning gender aspects.
- To continue to commit the Consortium to promote gender equality in the recruitment policy of the beneficiaries by requesting them to have (if not already possessed) a statement declaring and encouraging the applications of women. VITAL will endeavour to employ equal number of women and men among the research staff.

Thus, from the outset, VITAL displays commitment to the promotion of gender equality within the project consortium.

Annexes

Annex 1: Logical Framework

Table 1 – Specific Objectives for VITAL

Specific Objective	Key deliverable	Intervention logic	Objectively verifiable indicators	Source of verification	Assumptions
<p>Specific Objective 1: <i>To acquire data on virus contamination of food and environmental sources</i></p>	Data on virus contamination in four European food supply chains	Data-gathering laboratories in seven European countries, applying standardised analytical methodology to quantifiably detect viruses in samples taken from food supply chains	Data acquired from 3,165 samples	<p>Project Indicators: Results generated in WP2, WP3 and WP4. Uptake Indicators: Data on virus contamination of food and environmental sources used to inform quantitative viral risk assessments. Transfer Indicators: Data and risk assessments published in appropriate targeted literature.</p>	Each data-gathering laboratory has access to sampling points in the food supply chains, and each has the requisite equipment and expertise to perform the analyses.
<p>Specific Objective 2: <i>To assess foodborne viral risks for determining high risk situations and efficacy of interventions</i></p>	New modelling tools for quantitative viral risk assessment	Viral risks in food supply chains will be quantified by MPRM in presence and absence of different interventions	Quantitative foodborne viral risks that can be compared and will target interventions	<p>Project Indicators: Results generated in WP5 and WP6 Uptake Indicators: Risk assessments regarding impact on public health of virus contamination of food supply chains. Transfer Indicators: Risk assessments published in scientific literature. appropriate targeted literature.</p>	Data-gathering laboratories need to be able to analyse and deliver the appropriate data for QVRA and to identify intervention measures; models require adaptation for viruses in food
<p>Specific Objective 3: <i>To develop new measures to prevent virus contamination of foods and the environment</i></p>	HACCP models for managing virus contamination in food supply chains	VITAL liaises with Expert Stakeholders from food industry to ensure HACCP models are fit for purpose to be included in Code of	Code of Good Practice validated by Expert Stakeholders, and feedback report compiled.	<p>Project Indicators: HACCP models and COGP devised in WP6 and 7. Uptake Indicators: Code of Good Practice implemented by Expert Stakeholders, resulting in reduction in virus contamination of food supply chain.</p>	VITAL has a group of Expert Stakeholders representative of various sectors of the food industry, who will provide information on their existing HACCP.

		Good Practice		<u>Transfer Indicators:</u> Code of Good Practice distributed to interested parties from the food industry at the symposium and workshop.	They will also review the draft Code of Good Practice, and validate it by testing its practical applicability.
Specific Objective 4: <i>To develop and assess measures for virus reduction and control in case of virus contamination</i>	Information on survival and elimination of viruses in food supply chains and industrial processes	Comprehensive studies undertaken to model survival and elimination scenarios	Information gained from results of survival and elimination studies incorporated in HACCP models and COGP.	<u>Project Indicators:</u> Results generated in WP6 and disseminated in WP7 <u>Uptake Indicators:</u> <u>Transfer Indicators:</u>	VITAL can accurately model the conditions appropriate to the food supply chains. Pertinent information acquired from Expert Stakeholders.

Table 2 - Logical Framework WP by WP

Logical Framework for WP1 Project Management

Specific objective	Tasks	Indicative Effort*	Indicative Expenses**	Specific results produced	Sources of verification	Assumptions/Risks
All	1.1 Project Administration	3	Salaries: 16,050 Consumables: 0	Overall legal and administrative management of the project.	Reports and communication as required by the Commission.	None
	1.2 Overseeing Project Progress	4.5	Salaries: 25,125 Consumables: 1000	Milestoned progress towards the objectives. Implementation of from the Project Advisory Board.	Minutes of Management Meetings.	None
	Total	7.5	Salaries: 41,175 Consumables: 1000			

Logical Framework for WP2 Data-Gathering: Production

Specific objective	Tasks	Indicative Effort*	Indicative Expenses**	Specific results produced	Sources of verification	Assumptions/Risks
1: <i>To acquire data on virus contamination of food and environmental sources</i>	2.1 Preparatory activities.	40	Salaries: 87,878.87 Consumables: 14,625	Provision of SOPs, IAC incorporation in animal adenovirus PCRs, provision of process controls, acquisition of necessary materials, and testing of methods by partners.	Minutes of 1 st and 2 nd RDMB meetings in Months 3 and 6.	CEN TAG 4 methods and SOPs will be readily available. Process controls will be readily available to all partners. All partners are fully proficient in data-gathering methodology.
	2.2 Data-gathering: salad vegetable farms.	40.45	Salaries: 56,016.71 Consumables: 23,400	Virus contamination data from irrigation waters, and animal-based fertiliser applied pre-harvest. Virus contamination data from field latrines, and harvesters' hands.	Spreadsheet of data in secure pages of project website. Data summarised in Minutes of 5 th RDMB meeting in Month 16.	Data-gathering partners have access to farms.
	2.3 Data-gathering: soft fruit farms.	52.65	Salaries: 79,705.90 Consumables: 31,200	Virus contamination data from irrigation waters and animal-based fertiliser applied pre-harvest. Virus contamination data from field latrines, and harvesters' hands.	Spreadsheet of data in secure pages of project website. Data summarised in Minutes of 5 th RDMB meeting in Month 16.	Data-gathering partners have access to farms.
	2.4 Data-gathering: pig farms.	14.85	Salaries: 63741.91 Consumables: 5,130	Virus contamination data from pig faeces.	Spreadsheet of data in secure pages of project website. Data summarised in Minutes of 5 th RDMB meeting in Month 16.	Data-gathering partners have access to farms.
	2.5 Data-gathering: slaughterhouses.	36.65	Salaries: 138,204.04 Consumables: 15,120	Virus contamination data from pig liver, blood and slaughter effluent.	Spreadsheet of data in secure pages of project website. Data summarised in Minutes of 5 th RDMB meeting in Month 16.	Data-gathering partners have access to slaughterhouses.
	Total	184.6	Salaries: 425,547.43 Consumables: 89,475			

*Total Person Months (PM) allocated to task. ** Salaries and consumables. Amounts in kEuro, 1 million Euro ~ 1000 kEuro

Logical Framework for WP3 Data-Gathering: Processing

Specific objective	Tasks	Indicative Effort*	Indicative Expenses**	Specific results produced	Sources of verification	Assumptions/Risks
1: To acquire data on virus contamination of food and environmental sources	3.1 Data-gathering: Soft fruit processing.	40.85	Salaries: 63,034.22 Consumables: 23,400	Virus contamination data from critical points such as handling, freezing (including freeze-drying of berries for breakfast cereals) and packaging.	Spreadsheet of data in secure pages of project website. Data summarised in Minutes of 8 th RDMB meeting in Month 25	Data-gathering partners have access to processing factories.
	3.2 Data-gathering: Salad vegetable processing.	31.25	Salaries: 43,521.96 Consumables: 17,550	Virus contamination data from critical points such as washing, peeling, cutting, dicing, grating, packaging.	Spreadsheet of data in secure pages of project website. Data summarised in Minutes of 8 th RDMB meeting in Month 25	Data-gathering partners have access to processing factories.
	3.3 Data gathering: Pork processing.	37.15	Salaries: 130,659.84 Consumables: 14,175	Virus contamination data from critical points in the processing of pork products, e.g. pork sausages, pork liver, and pork blood sausage.	Spreadsheet of data in secure pages of project website. Data summarised in Minutes of 8 th RDMB meeting in Month 25	Data-gathering partners have access to processing factories.
	Total	109.25	Salaries: 237,216.02 Consumables: 55,125			

Logical Framework for WP4 Data-Gathering: Point of Sale

Specific objective	Tasks	Indicative Effort*	Indicative Expenses**	Specific results produced	Sources of verification	Assumptions/Risks
1: To acquire data on virus contamination of food and environmental sources	4.1 Data-gathering: raw pork products at point-of-sale	21.55	Salaries: 90,470.14 Consumables: 8,100	Virus contamination data from locally produced raw pork products on sale at farmers' markets and other outlets.	Spreadsheet of data in secure pages of project website. Data summarised in Minutes of 10 th RDMB in Month 31	Data-gathering partners have access to farmers' markets and retail outlets.
	4.2 Data-gathering: salad vegetables at point-of-sale	15.85	Salaries: 22,638.09 Consumables: 8,775	Virus contamination data from locally produced salad vegetables on sale at farmers' markets and other outlets.	Spreadsheet of data in secure pages of project website. Data summarised in Minutes of 10 th RDMB in Month 31	Data-gathering partners have access to farmers' markets and retail outlets.
	4.3 Data-gathering: shellfish at point-of-sale	16.25	Salaries: 47,549.47 Consumables: 8,775	Virus contamination data from locally produced shellfish on sale in retail outlets.	Spreadsheet of data in secure pages of project website. Data summarised in Minutes of 10 th RDMB in Month 31	Data-gathering partners have access to farmers' markets and retail outlets.
	4.4 Data-gathering: soft fruit at point-of-sale	21.15	Salaries: 33,259.35 Consumables: 11,700	Virus contamination data from locally produced soft fruit on sale at farmers' markets and other outlets	Spreadsheet of data in secure pages of project website. Data summarised in Minutes of 10 th RDMB in Month 31	Data-gathering partners have access to farmers' markets and retail outlets.
	4.5 Data-gathering: imported produce at point-of-sale	23.85	Salaries: 61,226.65 Consumables: 12,450	Virus contamination data from imported raw pork products, salad vegetable, shellfish, and soft fruit, on sale at retail outlets.	Spreadsheet of data in secure pages of project website. Data summarised in Minutes of 10 th RDMB in Month 31	Data-gathering partners have access to retail outlets.
	Total	98.65	Salaries: 255,143.70 Consumables: 49,800			

Logical Framework for WP5 Data Analysis

Specific objective	Tasks	Indicative Effort*	Indicative Expenses**	Specific results produced	Sources of verification	Assumptions/Risks
1: Specific Objective 2: <i>To assess foodborne viral risks for determining high risk situations and efficacy of interventions</i>	5.1 A data analysis workshop for data-gathering partners	3.6	Salaries: 19,106.33 Consumables: 0	All data-gathering partners trained in the methodology required for data analysis.	Workshop attendance list in Minutes of 8 th RDMB meetings in Months 25.	All data gathering partners will attend the workshop.
	5.2 Collect and analyse data for hazard characterization and exposure assessment	34.95	Salaries: 103,899.21 Consumables: 0	Hazard characterization of viruses found in supply chains and assessment of exposure of human population.	Spreadsheet of analyses in secure pages of project website. Analyses summarised in Minutes of 10 th RDMB in Month 31.	Sufficient data will be gathered from WPs 2, 3 and 4.
	5.3 Develop a MPRM for each of the food supply chains for foodborne virus risk assessment	3.65	Salaries: 26,750.9 Consumables: 0	Food supply chains modular risks for each virus type displayed and developed	MPRMs on website	Website can host MPRMs
	5.4 To recognize and prioritize criteria for risk assessment.	1.65	Salaries: 12,470.90 Consumables: 0	Virus food types identified and classed into various criteria	Criteria on website	Websites can host criteria
	5.5 To assess the foodborne virus risks.	1.65	Salaries: 12,470.90 Consumables: 0	Viruses assessed alongside risks of food	Risks on website	Website can host risks
	5.6 To list and if appropriate evaluate effective intervention measures	1.65	Salaries: 12,470.90 Consumables: 0	Document on intervention strategies and their efficiency with regard to reduction of the burden of viruses in foods.	Document delivered. Document posted on secure website pages.	Sufficient information will be acquired through liaison with WP6.
Total		47.15	Salaries: 187,169.14 Consumables: 0			

Logical Framework for WP6 Control Measures

Specific objective	Tasks	Indicative Effort*	Indicative Expenses**	Specific results produced	Sources of verification	Assumptions/Risks
Specific Objective 2: <i>To assess foodborne viral risks for determining high risk situations and efficacy of interventions</i>	6.1 Critical evaluation of current HACCP systems.	40.05	Salaries: 114,291.07 Consumables: 0	Identification of any apparent deficiencies in current HACCP systems.	Draft evaluation document reported in 8 th RDMB Meeting minutes at Month 25.	Effective and productive liaison with local farms, processors, and Expert Stakeholders.
Specific Objective 3: <i>To develop new measures to prevent virus contamination of foods and the environment</i>	6.2 Survival and elimination of viruses.	120.25	Salaries: 430,583.63 Consumables: 150,000	Information on effect of food production practices on viruses incorporated into QVRA and HACCP.	Draft Code of Good Practise, available to Expert Stakeholders on Month 34.	Food production practises can be modelled effectively.
Specific Objective 4: <i>To develop and assess measures for virus reduction and control in case of virus contamination</i>	6.3 Development of HACCP models	19.25	Salaries: 74,841.50 Consumables: 0	HACCP models developed for each food supply chain	HACCP models integrated into website	Information acquired from Tasks 6.1 and 6.2, integrated with the MPRMs developed in Task.5.2 using the data gathered in WPs 2 and 3.
	6.4 Evaluation of the effect of vaccination	12.85	Salaries: 884,74.50 Consumables: 2,250	Swine HEV surveillance simulation model. Assessment of HEV intervention by a swine vaccination strategy	Draft HEV surveillance simulation model reported to RDMB at month 25. Draft assessment of efficacy of HEV intervention by swine vaccination reported at Month 35	Successful Adaptation of existing CSFV surveillance model using generated HEV test data
	Total	192.4	Salaries: 708,190.70 Consumables: 152,250			

Logical Framework for WP7 Delivering Impact

Specific objective	Tasks	Indicative Effort*	Indicative Expenses**	Specific results produced	Sources of verification	Assumptions/Risks
Specific Objective 3: <i>To develop new measures to prevent virus contamination of foods and the environment</i>	7.1 Development and validation of a Code of Good Practice	28.25	Salaries: 88,427.94 Consumables: 0	A Code of Good Practice which has been implemented and evaluated for practicability of use by the Expert Stakeholders	COGP published on website	Expert Stakeholders are willing to implement COGP.
	7.2 Symposium organisation	15.15	Salaries: 49,557.17 Consumables: 1,500	A 2-day Symposium on “New Developments in Monitoring and Control of Foodborne Viruses”, in which the outcomes of VITAL are disseminated to a broader audience	Publication of Symposium Abstracts on project website	There will be sufficient interested parties to justify holding the Symposium
Specific Objective 4: <i>To develop and assess measures for virus reduction and control in case of virus contamination</i>	7.3 Workshop organisation	10.05	Salaries: 37,089.70 Consumables: 1,000	The workshop “Taking Forward New Developments in Monitoring and Control of Viruses in Food Supply Chains” for regulators, representatives of national and international bodies (e.g. EFSA, WHO, WTO), and members of the food industry, should encourage the outcomes of VITAL to be integrated into food safety practices and regulations.	List of Workshop participants on project website.	VITAL will attract interest from the relevant interested parties.
	7.4 Organisation of two 1-day training courses on foodborne viruses for risk managers in the food industry	7.35	Salaries: 17,943.90 Consumables: 1,500	The principles of integrated monitoring and risk analysis and control measures will be transferred to a wide group of stakeholders.	List of course participants on project website.	There will be sufficient interested parties to justify holding the training courses.
	7.5 Web-site construction and maintenance	3.2	Salaries: 14,740 Consumables: 150	A high quality and user friendly dissemination tool which will be a rapid communication vehicle for the project partners and a portal of knowledge to interested public parties	Website active.	N/A
	7.6 Consortium meeting organisation	4.45	Salaries: 62,53.07 Consumables: 12,300	An extensive integration of all VITAL participants resulting in common knowledge bond to producing a critical mass of expertise to drive out cutting edge information to the wider stakeholder community.	Minutes and Reports of meetings	N/A.
	Total	68.45	Salaries: 214,011.78 Consumables: 16,450			