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STAFF PAPER

**ON THE RESULTS OF A SERIES OF MISSIONS TO
REVIEW THE OPERATION OF CONTROLS OVER
VEROCYTOTOXIGENIC ESCHERICHIA COLI IN THE
FOOD PRODUCTION SECTOR WITH PARTICULAR
REFERENCE TO RED MEAT, MEAT PRODUCTS AND
MILK/MILK PRODUCTS**

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List of abbreviations and special terms

AEEC	Attaching Effacing <i>Escherichia coli</i>
CRL	Community Reference Laboratory
DG SANCO	Health and Consumer Protection Directorate-General
EHEC	Enterohaemorrhagic <i>Escherichia coli</i>
HACCP	Hazard Analysis Critical Control Point
HUS	Haemolytic Uraemic Syndrome
NRL	National Reference Laboratory
PFGE	Pulse Field Gel Electrophoresis
RAS	Rapid Alert System
USDA	United States Department of Agriculture
VTEC	Verocytotoxigenic <i>Escherichia coli</i>
WHO	World Health Organisation

1. INTRODUCTION

Infections caused by verocytotoxigenic *Escherichia coli* (VTEC), in particular those caused by the most common serotype *E. coli* O157:H7, have, in the past two decades, been recognised as a major cause of gastrointestinal disease in humans. There have been numerous high profile outbreaks of food poisoning, and many sporadic cases of VTEC infection in recent years, with a number of fatalities being identified. Children are particularly susceptible to its effects. It is, therefore, an issue of direct concern to consumers.

As indicated in the opinion (12 April 2000) of the Scientific Committee on food-borne zoonoses, there are, in principle, four routes of infection: person to person, food-borne (especially raw meat, unpasteurised milk, contaminated fresh produce, drinking water), environmental and direct contact with farm animals.

Because of the low infectious dose level of *E. coli* O157:H7, any survival or potential growth of *E. coli* O157:H7 can have serious food safety consequences. Although non-O157 VTEC serotypes have recently been implicated in food-borne illness, there is still very limited information on the vectors of these serotypes and on their persistence in the food chain.

As part of its planned inspection programme for the period January - June 2001, the Food and Veterinary Office carried out visits to six Member States (see Annex I) to review the epidemiology of VTEC infection and the monitoring and control systems for this pathogen in relation to bovine meat, meat products, minced preparations, minced meat and milk production. These were selected with a view to giving a broad view of the situation across the European Union, taking account of different control systems and food production practices. The original mission planning also included a visit to the United Kingdom, but this had to be cancelled due to the Foot and Mouth Disease epidemic. Nonetheless, the authorities provided considerable information on the situation in the UK.

The objective of these missions is two-fold; firstly to provide a review of the current situation regarding VTEC at a European level, and secondly to identify "best practices" in the Member States visited, with a view to their wider dissemination. The intention is both to inform consumers, and to contribute to decisions on future action in respect of this problem.

Each visit lasted one week and involved meetings with the animal health and public health services at all levels involved in monitoring and control of the pathogen (including any procedures to respond to outbreaks in the human population) in the above production sectors. In addition, the inspection team visited laboratories involved in VTEC research. Visits to farms and processing operations in the above sectors to review the situation "on-the-spot" were also undertaken. Where possible, contacts with bodies operating quality schemes, which include controls over the pathogen, were included.

The national authorities in the countries visited were extremely supportive of the objectives of these missions, and proved themselves both open and constructive in their responses to the evaluation teams.

The planning for this series of missions took account of the Opinion of the Scientific Committee on Veterinary Measures relating to Public Health on Food-Borne Zoonoses (12 April 2000), which is available on:

http://europa.eu.int/comm/food/fs/sc/scv/outcome_en.html

In addition, the findings of the Progress Report on the Network for the Epidemiological Surveillance and Control of Communicable Diseases in the Community (COM(2000) 471, dated 7 September 2000) were considered.

2. MAIN FINDINGS

2.1. Competent authority organisation and control activities

2.1.1. *Distribution of control responsibilities*

Distribution of responsibilities concerning VTEC controls is not subject to special arrangements in any of the visited Member States. The services responsible for animal health and food safety controls are mostly under the responsibility of one Ministry, although in some countries they are assigned to two different Ministries. Human health services were generally covered by one Ministry. In most of the Member States visited, control services are represented at central, regional and local level.

Some countries have created specific bodies for monitoring of zoonoses or for investigations at national level in case of food borne outbreaks (see 2.1.2 and 2.1.7). In most of the visited Member States, National Reference Laboratories (NRL) with responsibility for *E. coli* including VTEC have been designated. These NRLs were set up for animal health and food controls, as well as for human health protection (see 2.1.7).

2.1.2. *Co-operation/Co-ordination between official services*

2.1.2.1. Routine *E. coli* monitoring

Studies have been carried out in all Member States visited, to determine prevalence of certain VTEC in animal and human populations, as well as in food commodities. Most of these studies were performed on a temporary basis or were regarded as research projects (see 2.1.4 and 2.1.11).

Only a few Member States, particularly **Germany**, **Belgium** and **Sweden**, have introduced routine enterohaemorrhagic *E. coli* (EHEC) and VTEC monitoring.

Sweden has introduced an official programme for the monitoring of VTEC at farm level. The NRL for *E. coli* O157 has analysed 2000 faecal samples from cattle annually since 1997. The samples are collected at slaughterhouses from live animals.

As regards routine monitoring in the food-processing sector, official laboratories for the control of foodstuffs in **Germany** have been provided with a standardised laboratory method by the NRL. Although a nation-wide statutory official programme does not exist, risk products (e.g. minced meat, raw milk) are analysed

for VTEC on a routine basis. Competent authorities have worked out a proposal for the assessment of an isolation of VTEC from foodstuffs.

In **Belgium** harmonised methods for the control of VTEC in food have been developed, including a standard inquiry form. A representative number of cattle carcasses are examined for VTEC on a routine basis in the slaughterhouse.

Routine monitoring for EHEC/VTEC on suspect human cases was not performed in any of the visited Member States. NRLs in **Denmark** and **Germany** offered an analytical method to private laboratories, which are mainly responsible for routine analyses of suspect human cases.

2.1.2.2. Planning for *E. coli* outbreaks

Germany, Sweden and **Denmark** in particular have laid down official procedures, including guidelines, for action to be taken in case of food-borne outbreaks, including specific references to *E. coli*. They indicate responsibilities, information channels and details of follow-up investigations.

In **France** a joint protocol for investigations of haemolytic uraemic syndrome (HUS) outbreaks has been established, involving veterinary services and human health services.

2.1.2.3. Dealing with *E. coli* outbreaks

In general, local authorities are responsible for investigation and control of outbreaks. Some countries, eg. **Denmark** and **France**, have created national bodies for investigations of food-borne outbreaks at the national level.

2.1.3. *Legal powers for E. coli* controls

2.1.3.1. Obligation to notify isolations

Denmark, Germany, Sweden and **France** have all introduced some form of legal obligation to notify isolations of VTEC. The first country to introduce notification of enterohaemorrhagic *E. coli* (EHEC) in humans was **Sweden** in 1996. Obligations to notify cases of illness or isolations of VTEC in different sectors are described below.

On farm

In **Sweden** any case of *E. coli* O157 in animals linked to a human case of enterohaemorrhagic disease is notifiable, although this does not apply to findings of other VTEC strains in animals.

Other Member States visited have not introduced the obligation to notify VTEC findings in animals.

Food processing establishments

Under Community legislation, persons in charge of the operation of Hazard Analysis Critical Control Points (HACCP) systems or own-checks programmes in food

processing establishments are required to inform the competent authorities immediately if any findings constitute a risk to public health.

France is presently introducing an obligation on private laboratories carrying out analyses for food-processing establishments in the framework of own-checks programmes to notify the competent authorities without delay if any findings may constitute a risk to public health.

Human sector

The most comprehensive systems of notification of human diseases included all cases of death and illness from EHEC and HUS, as well as asymptomatic EHEC excretors. This system has been set up in **Germany** since 1998. Furthermore, **Denmark** has made VTEC and HUS notifiable, and all culture-confirmed cases are reported to the NRL for human *E. coli* infections.

In **Sweden** *E. coli* O157 in humans is notifiable. The other Member States have not introduced a similar obligation for notification of human cases, although **France** has a system for monitoring the prevalence of HUS in children under 15 years of age.

2.1.3.2. Powers available to official services

Powers available to official services for the control of animal health and food safety are in general extensive and sufficient to control situations that might pose a risk to human health.

The presence of *E. coli* O157 in foodstuffs is considered as a threat to human health and action is taken in the visited Member States, although findings of VTEC other than *E. coli* O157 does not necessarily lead to official action.

2.1.4. *Monitoring and control programmes*

Various studies have been carried out in all the Member States visited to determine the prevalence of certain VTEC in the animal population, as well as in food commodities. Most were run on a temporary basis, and were not designed as routine monitoring programmes. Most of these activities have been undertaken within the framework of Council Directive 92/117/EEC¹, and the data collected has been included in the report on "Trends and sources of zoonotic agents in animals, feedingstuffs, food and man in the European Union and Norway 1999".

Results of the studies are difficult to compare, as working methods, and the recording of data, were not standardised.

Farm level

With the exemption of **Sweden**, none of the visited Member States have introduced official monitoring and control programmes at farm level. However, in every

¹ *Official Journal L 062 , 15/03/1993 P. 0038 - 0048*

country visited, surveys on the prevalence of *E. coli* O157 or EHEC/VTEC in farm animals had been carried out. Associations representing the agribusiness had financed some of the surveys, whilst others were launched by official services or research institutes.

Analyses mostly concentrated on cattle faeces, although faeces from other farm animals, raw milk, environmental samples, sewage, manure and animal feed were also sampled.

The majority of the surveys concentrated on the presence of *E. coli* O157. However in **Germany** and **Belgium**, surveys are carried out which include serotypes other than *E. coli* O157.

Food processing establishments

Official services in all of the visited Member States have carried out surveys on the prevalence of VTEC in food commodities. A large number of surveys were carried out on bovine carcasses, meat, minced meat and meat preparations. Meat of other species, raw milk and raw milk cheese, as well as smaller numbers of other food commodities, were subject to analyses.

In **Belgium**, positive findings of *E. coli* O157 in bovine carcasses at the slaughterhouse result in checks for *E. coli* O157 on the farm of origin (animals, animal feed and environmental samples are analysed), and the prevalence of *E. coli* O157 in cattle on this farm is evaluated.

Minced meat and hamburgers at production and retail levels were subject to surveys in most of the visited countries.

Early surveys on food contamination concentrated on the detection of *E. coli* O157. Some countries, e.g. **France**, **Germany** and **Belgium**, have subsequently included other VTEC, which are known to be the cause of human disease.

In particular, **France** carried out major surveys on the prevalence of VTEC in raw milk cheeses, whilst in **Germany** raw milk for retail sale is regularly monitored.

2.1.5. Quality assurance schemes

No official schemes with regard to VTEC were present in the visited Member States.

Some of the visited companies had introduced private quality assurance schemes, which covered suppliers and the food-processing establishment. These included third party audits to ensure that specifications were met, and to verify the implementation of HACCP. One of the meat processing establishments required their supplying slaughterhouse to implement a HACCP programme. The quality assurance scheme had been developed with a particular view to control the risk of *E. coli* O157:H7 in meat used for the manufacture of minced meat.

Commission Decision 2001/471/EC² concerning HACCP and microbiological testing in slaughterhouse makes the operation of a HACCP system compulsory in slaughterhouses from June 2002.

2.1.6. Own-check programmes

The Member States considered the development of own-check programmes based on HACCP principles as being the full responsibility of food-processing establishments.

In **Denmark** and **Sweden** the competent authority approves the establishments' own-check programmes and supervises their operation, whereas competent authorities in other Member States limit themselves to supervisory activities only.

In general it is the decision of the food-processing establishments to include VTEC as a specific risk in their own check programmes.

2.1.7. Official laboratory networks

For the diagnosis of VTEC in animals and foodstuffs, Member States make use of the existing laboratory network, which is based on official laboratories in the veterinary sector. For laboratories carrying out official analyses of foodstuffs, Community legislation requires accreditation of laboratories.

As regards the human health sector, initial laboratory diagnosis is carried out in independent laboratories and, to a lesser extent, in official laboratories.

Denmark, Germany, Belgium and **Sweden** have officially designated NRLs for the control of VTEC. As the laboratory network is divided between human health and veterinary services, Reference Laboratories are set up in parallel. In the human health sector generally, existing Reference Laboratories for gastrointestinal diseases included VTEC in the scope of their activities.

The main objectives of the NRLs are research, with a particular interest in the development of suitable diagnostic methods, confirmation of suspect VTEC strains and further diagnostic activity on these strains.

The NRLs in **Denmark, Sweden, Belgium** and **France** are involved in the performance or co-ordination of investigations in the event of outbreaks, and may perform epidemiological studies.

All designated NRLs provide services for routine laboratories as regards confirmation of suspect isolates. However the spectrum of activities in the NRLs ranges from confirmation of *E. coli* O157, to confirmation and subtyping of all VTEC strains by various methods.

² *Official Journal L 165 , 21/06/2001 P. 0048 - 0053*

Methods used in the Member States for isolation of VTEC are largely un-harmonised, and are often limited to the detection of *E. coli* O157. The NRL in **Germany** has put considerable effort into the development of routine methods for the detection of all VTEC strains in animals, food and humans. Some NRLs, including **Germany, Belgium** and **France**, provide reference methods for routine diagnosis of VTEC to the laboratory network, and offer training so that the method can be applied for routine diagnosis in official laboratories as well as in private laboratories in the human health sector.

However, the extent to which VTEC and *E. coli* O157 analyses are performed by regional or local laboratories varies widely between Member States.

In the human health sector, methods can only be recommended to independent laboratories, as there is no legally binding obligation to use specific methods nor to carry out specific analyses.

Only in **Germany** and **Denmark** is communication and co-ordination on VTEC between NRLs for human isolates, and NRLs responsible for animal health and food safety, very advanced. For example, in **Germany**, a project is in hand to build up a common database for isolations of VTEC strains from humans, animals and food commodities with a view to carrying out epidemiological studies. In **Denmark**, the Danish Zoonosis Centre plays a key role in the co-ordination of the activities of the sectorial Reference Laboratories, and in the rapid exchange of information between the relevant bodies.

In respect of EU-funded research projects, VTEC laboratories co-operate throughout the EU (see section 2.1.11).

The Community Reference Laboratory (CRL) for milk and milk products in Paris co-ordinates activities to evaluate the ISO 16654 method for the detection of *E. coli* O157 in dairy products. The CRL also offers training sessions to NRLs for milk and milk products on this standard. The CRL on the Epidemiology of Zoonoses in Berlin collects information on VTEC in animals, animal products and humans on the basis of voluntary participation by the Member States.

2.1.8. Response to E. coli isolation or outbreak

In **Denmark, Germany, Sweden, France** and **Belgium** official procedures are laid down for the actions to be taken following the presence of a suspect or confirmed food poisoning case, including *E. coli*. When food poisoning is notified via the Rapid Alert System (RAS), the official services are responsible for notification of all concerned services.

In **Belgium**, when an *E. coli* O157 positive result is found through a survey programme, the official veterinarian of the abattoir concerned must review the general hygiene of the establishment and take action to prevent similar problems in the future.

In **Sweden**, if animals are found to be positive for *E. coli* O157 and the bacteriological findings in the animals are connected with a human case of EHEC or HUS, the following recommendations are issued by the county veterinarian:

- Unpasteurised milk is not to be used for human consumption,
- Minimise the number of person (in particular children) visiting the animals,
- Manure not to be spread on pasture,
- No slaughter for own consumption,
- Ruminants are isolated, and tested twice with negative results, before they can be sent to other herds,
- Ruminants are slaughtered at the end of the day and the carcasses sampled,
- Slaughterhouses to undertake special hygienic measures

These recommendations are lifted if the herd gives two consecutive negative test results, with an interval of at least one month between them.

2.1.9. Training programmes

In none of the Member States visited are specific training programmes organised in regard to the control over VTEC in the food production sector.

However, in **Denmark, Germany, Belgium, France** and **Sweden**, instructions were issued to elements of the official services and/or operators in the food processing sectors. These instructions were often general in nature, and related to routine hygiene practices in respect of all food-borne pathogens.

More specific instructions or guidelines were, however, also issued:

In **Belgium** and **Denmark**, a special instruction regarding VTEC was sent to regional veterinary services, slaughterhouses and butchers. Apart from these instructions, seminars and workshops are organised where the participation is on voluntary basis.

In **Belgium** a special circular was issued for the milk sector regarding the correct implementation of Council Directive 92/46/EEC with special attention to the labelling of raw milk (“raw milk, cook before use”).

In **France**, specific guidelines regarding milking hygiene are drafted by a professional milk organisation and the agriculture chambers. A special leaflet regarding HUS and VTEC, prepared for a study of HUS linked to farms, is now distributed to farmers during visits by the veterinary service.

In **Sweden**, since 1998, general prophylactic recommendations, aimed at reducing the risk of direct transmission to humans, have been issued and are updated annually by competent authorities in cooperation with the industry. These recommendations are published in specialized farmer publications and distributed to the public. To this end, the competent authority has guidelines available for herds of ruminants, which include information for visitors during the summer on how to behave when visiting a cattle farm. Specific recommendations were also addressed to home-made food production by farmers. In addition, all infected herds will receive a “guideline for handling of infected herds” (as in 2.1.8) including hygiene recommendations, sampling at slaughter and sampling of live animals before sale. The use of farm manure has also been the subject of recommendations from the CA, e.g. to avoid the spread of manure on lands where food is to be consumed without being heat-treated (berries, or raw vegetables).

In **Germany**, a national laboratory linked to the Ministry of Public Health issued a specific leaflet for medical doctors regarding diagnosis and treatment of EHEC infections. This information is also available on the laboratory website.

2.1.10. Education of consumers

Press releases and brochures are used in **Denmark, Germany, Belgium** and **Sweden**. They deal in most cases with a wide range of food poisonings and are not specifically related to VTEC risks.

In **Belgium**, two brochures were issued with very practical guidelines for the consumer in relation to preparing meals.

In **Sweden** press releases have been used to inform the public on how good hygiene practices reduce the risk of being affected by EHEC when visiting farms. This information focused in particular on the risk for young children in relation to farm visits. **Denmark** has also issued guidance for visitors to farms.

2.1.11. Research programmes

In all the Member States visited numerous research projects were or had been carried out in relation to VTEC. These projects covered the animal, food and human sectors as well as research into laboratory techniques. A high degree of commitment and competence was found in the sectors involved.

In **Denmark**, there is an agreed partition of tasks between the three National Reference Laboratories covering the animal, food and human sectors, and publicly funded research projects have been carried out in co-operation between the different laboratories in the past.

Two of the official research laboratories in **Germany** are directly involved in the EU funded IV framework project "AEEC (Attaching Effacing Escherichia Coli) infections", where studies of pathogenicity host response, epidemiology and attaching/effacing property are being performed. (Project number QLK2-2000-00600).

In **Belgium**, research is in hand on the genetic sub-typing of VTEC strains, in relation to their probable virulence for man.

The European Commission (DG RTD) has financed several research projects with regard to VTEC.

Laboratories in the Member States have been involved in a Commission supported Concerted Action FAIR CT 98-3935 "A European Study on animal, food and biomedical aspects of verocytotoxigenetic E. Coli including serotype O157: H7 an emerging pathogen". This Concerted Action has achieved at the European level considerable advances in standardisation of methodology, especially for strain typing. The aim is in fact to establish an inter-laboratory standardisation of a pulsed field gel electrophoretic (PFGE) protocol with the view to setting up a database of E. coli O157 PFGE profiles to which new profiles could be submitted electronically.

By using a computer network between official VTEC laboratories in the Member States this will make it possible in the future to link VTEC strains found in the food,

animal or human sector as part of epidemiological investigations. This valuable information has been channelled into the international surveillance network for the enteric infections –Salmonella and VTEC O157, supported by DG SANCO.

A recent Thematic Network (European Network for Hygienic Manufacturing of Food (QLK1 –1999-31359), involving experts from many EU and associate countries is actively working for the dissemination of knowledge concerning the design of buildings and open / closed food plants and food equipment. In addition widely approved guidelines and recommendations for hygienic requirements and tests in food manufacturing plants and equipment should be produced.

Moreover the efforts made by the Commission in making available through various European research projects quality and validation assurance tools for food control purposes have to be mentioned.

2.2. Provision of guidance to operators

In **France**, professional organisations had prepared several manuals, some of which are validated by the official veterinary services. These manuals are distributed to the members of the organisation but can also be purchased. The main items covered in the manuals for the milking industry are general hygiene practices, and the implementation of HACCP systems.

In **Denmark**, specific operational guidance was given to slaughterhouses in regard to the health risk of *E. coli* O157, and to prevent cross contamination and achieve a reduction in the prevalence of VTEC.

In **Belgium**, written procedures have been issued by official authorities highlighting the risks of contamination of *E. coli* O157 and the means to avoid such contamination. These procedures were addressed to managers of establishments, butchers and retailers and included basic guidance.

In **Sweden**, detailed guidelines are provided in respect of visits to ruminant farms by children under 5 years old.

2.3. Processed food controls

2.3.1. Pre-processing standards (on-farm, transport)

In **Sweden**, official recommendations are given to farms linked to an outbreak of human EHEC. Animals from these farms are tested for *E. coli* O157 every three months and recommendations remain in place until two consecutive negative results are achieved. Restrictions include controls over the sale of live animals, as well as restrictions on animals for slaughter (slaughter hygiene and swab tests at slaughter).

In **Belgium**, the farm of origin of bovine animals, which tested positive for *E. coli* O157 at slaughter, is subject to a testing programme. In this context, 10% of the animals may be tested, including animal feed and environmental samples. Animals sent to abattoirs from these farms will be systematically sampled, and restrictions on the use of raw milk for human consumption will be imposed.

Due to time pressures, information on the situation in respect of milk production could only be gathered in **Denmark, Portugal, Belgium and France**.

In both **France** and **Portugal**, farm-level, private, Quality Assurance Schemes were seen:

- In **Portugal**, these identified certain zoonoses and the hygiene of operations, as potential risk factors, and included health checks on workers, and the provision of technical advice to farmers on milk hygiene and handling practices.
- In **France**, one of the visited milk-processing establishments has built up an advisory system for farms supplying raw milk for the production of raw milk cheese. The system includes visits by company-based advisory staff. After a general inspection visit, and assessment of practices (milking, storage of the milk, cleaning and disinfection, environment, udder health, feeding), a risk evaluation of each farm is carried out. Risks that receive particular attention include inhibitory substances, total bacteria count, coliforms, psychrotrophes, *Staphylococcus* and *Listeria*. Although the system does not target VTEC in particular, risk elements associated with excessive bacterial contamination were identified and measures for their control were proposed to the farmer.

Based on the risk analysis, a HACCP for each farm was developed, and the farmer is required to monitor and record certain data such as temperature of the milk in the storage tank.

2.3.2. *Red meat production standards*

The controls in place to reduce the risk of transferring VTEC and other enteric organisms from contaminated hides, gastro-intestinal tract contents and faeces during the slaughter and dressing process vary between the visited Member States.

Avoidance of contamination during dehiding

A “clean cattle policy” has been developed in some Member States to control the risk of faecal contamination from the hides during the slaughter process.

Thus, in **Sweden**, the animals are evaluated for faecal contamination at ante mortem inspection (divided into categories 0 - 3), and a penalty is imposed on farmers for delivering dirty animals.

The **United Kingdom** reported that a Clean Livestock Policy is in place. The guidelines issued by the Meat Hygiene Service in 1997 for clean sheep and beef cattle for slaughter recognise 5 levels of fleece or hide contamination, and give advice on action to be taken in each category. Only animals in category 1 and 2 may normally be slaughtered. The Fresh Meat (Hygiene and Inspection) Regulations 1995 empowers the official veterinarian to prohibit the slaughter of any animal which is so dirty as to be likely to prevent hygienic dressing operations if it was taken into the slaughterhall.

The risk of contaminating the carcasses during removal of hides and feet is otherwise dependent upon the use of well trained staff and correct dressing techniques, as well as the use of equipment that is designed to prevent cross

contamination and which can easily be cleaned and sterilised (82°C hot water) between each carcass.

Avoidance of contamination during evisceration

During evisceration VTEC may be transferred to the carcass from the gastrointestinal tract and oral cavity. The importance of reducing the risk of contamination of the carcass at this stage of slaughter by rodding and clipping of oesophagus and bagging and tying of the rectum was generally recognised.

In **Sweden** and **Denmark**, carcasses identified with faecal contamination at post mortem inspection are recorded in a computerised system. If the level exceeds the “normal” level, corrective action is immediately taken to identify and resolve the problem. However, in the establishments visited, the “normal” level was found to be quite high (up to 19% of carcasses contaminated).

In the framework of own-checks programmes (often due to specific US requirements), random testing of carcasses for *E. coli* contamination was noted in establishments visited in **Denmark, Portugal, Germany** and **Sweden**. If the *E. coli* testing results are too high, remedial actions may be taken in order to improve the general hygiene in the establishment. Random *E. coli* testing programmes do not include further identification of positive samples to check for the presence of VTEC.

2.3.3. *Processing establishment standards*

Minced meat and meat preparations have been associated with a considerable number of outbreaks of VTEC. Minced beef is considered to be a particularly high-risk product because pathogens on the surface of the meat can become mixed into the product during the mincing process.

In **France** one meat processing establishment, in addition to the microbiological checks required under Community legislation, carried out additional checks for *E. coli* O157:H7 antigen with a rapid test. The test can be performed within a maximum of 24 hours. Five batches are pooled for one test, comprising an enrichment step and the antibody-antigen reaction. Until now no sample has been positive for *E. coli* O157:H7 antigen. Suspicious samples have been sent for confirmation to the laboratory of the *Ecole Nationale Vétérinaire de Lyon* but have all tested negative. As a negative test for *E. coli* O157:H7 is part of the release system, batches with a suspicious result are detained.

The beef burger producer visited in **France** was aware of the cooking procedures applied by its main customer in the framework of the customer's HACCP. To ensure that every batch of beef burgers reaches a temperature that guarantees destruction of *E. coli* O157:H7 when cooked in the restaurant, cooking equipment identical to the customer's is used to verify this standard.

One of the establishments visited in **Belgium** carried out microbiological analyses on the final product; minced meat and filet américain (a type of meat product composed of raw lean minced bovine or equine meat to which other foodstuffs and spices may be added), in the framework of its own-control programme. On these two products, the establishment performs VIDAS-ECO testing for the presence of *E. coli* O157 in the company's own laboratory several times per day. Since 1996, 8

cases have been positive. In the case of a positive sample, corrective actions are taken all along the line to improve the hygiene. After this corrective action is completed, a second VIDAS-ECO testing is performed. If this is also positive, the sample will be sent to one of the Belgian National Reference Laboratories for VTEC in food products. The result of this test will be received in the establishment 3-4 days later. However, there is no procedure for withholding products from the market until the establishment knows the results.

Systematic checks for the presence of VTEC are included in routine official zoonoses control programmes in **Belgium**.

In **Germany**, the important contribution of HACCP on the controls over VTEC in meat preparations at restaurant level was noted in a burger restaurant visited. There, a process is applied specifically to destroy *E. coli* O157:H7, using an automated method in accordance with USDA legal requirements, which require cooking of meat products at 68.3°C for at least 15 seconds.

In **Portugal**, microbiological testing for *E. coli* on the hands of operators was carried out once per month in the framework of a Quality Assurance Scheme in one establishment visited.

In **Denmark**, due to the known risk of pathogens in bean sprouts, sprout factories must check for Salmonella, *E. coli* O157, and *Listeria* (in case of alfalfa and peas) in each batch of seeds before use.

3. GENERAL CONCLUSIONS

3.1. Existing Community legislation, if properly applied, provides for a range of specific actions that would contribute significantly to the removal of *E. coli* from the meat and milk-processing sector. There is, however, relatively little specific legislation addressing this issue, although new proposals on zoonoses controls at Community level will strengthen the existing situation. All the Member States visited, and a number of private food-processing establishments, have given consideration to the control of *E. coli* O157 and other VTEC in the food production sector.

3.2. Research studies to evaluate the prevalence of certain VTEC in the animal and human population are carried out in all visited Member States, and the commitment to VTEC research was a welcome feature. In some Member States, the awareness of different VTEC strains and diagnostic methods is well advanced. Co-ordination of research has been achieved to a certain extent at the European level through the EU concerted action project 'A European study on animal, food and biomedical aspects of VTEC in particular serotype O157:H7, an emerging pathogen'.

Most of the studies, however, are on a temporary basis, and with a limited number of samples. Furthermore, these research studies are not always systematically co-ordinated at the national level, and consequently their results are not used for risk assessment nor transferred to routine applications. In none of the Member States visited have research results yet been finally assessed, whilst further research is still needed to obtain a

comprehensive picture of the risks of human infection linked to VTEC in foodstuffs.

- 3.3. Few of the visited Member States have introduced routine VTEC monitoring programmes. However, in one, routine VTEC monitoring is performed at farm level, whilst in another, a routine analysis for VTEC was performed on high risk food products. National authorities offered various reasons for their reluctance to introduce routine monitoring in the animal population and foodstuffs, including the unavailability of validated routine methods, and uncertainty over the pathogenic significance of some VTEC strains.
- 3.4. One of the key issues concerning *E. coli* controls is the system in place for notification of VTEC isolation in humans. The information obtained from human cases concerning the *E. coli* serotypes involved, and relevant pathogenic factors, as well as the source of infection, would enable the authorities to initiate targeted control activities and preventive measures in food commodities.
- 3.5. A broad approach to the notification of human cases results in the recognition of a number of *E. coli* serotypes as being potentially hazardous to humans, and subsequently to an approach to monitor and control all VTEC in food.
- 3.6. Suitable routine methods for the different diagnostic operations are still under development. National and international working groups and National Reference Laboratories are also working on harmonising protocols and methods. However at present, due to the differences in the diagnostic methods used in the Member States, the real prevalence of VTEC in humans is frequently under-estimated.
- 3.7. The elaboration of an ISO standard for the detection of *E. coli* O157 in food products is a step towards harmonised laboratory methods. At a national level, the development of routine protocols for the isolation of VTEC, and their implementation in official laboratories for the analyses of foodstuffs are an essential basis for routine monitoring of food. As not all methods are equally suitable for isolation and identification of all VTEC serotypes, the method chosen determines to some extent the outcome of the analysis. The methods used, and the number of samples taken in the existing surveys carried out in the Member States, do not allow an evaluation of the risk of *E. coli* in food on a proper statistical basis.
- 3.8. The action taken by national authorities in case of a VTEC finding depends very much on the serotype and the food commodity. In respect of *E. coli* O157 in ready-to-eat food, appropriate control actions are normally taken. For any other type of VTEC, and for other food commodities, there was no harmonisation of how to assess the significance of the VTEC finding, nor of the subsequent action to be taken.
- 3.9. Where an outbreak caused by VTEC in food is found, general procedures for the control of outbreaks are in place in the Member States. One Member State has issued a specific procedure for the investigation of HUS cases. In

one of the Member States visited, a network is in place to identify outbreaks of VTEC infections, and to link “sporadic cases” with one another.

- 3.10. In some Member States visited, official controls over VTEC were formalised by general instructions related to hygiene practices. More specific instructions regarding HUS and VTEC were issued by way of circulars. No official quality assurance schemes with regard to VTEC were present in the visited Member States. In some Member States, information on general food poisoning risks, albeit not specifically VTEC, is provided to the consumers by way of leaflets and press releases.
- 3.11. Non-official controls over verocytotoxigenic *E. coli* were seen at the different stages of the production chain in some Member States. These initiatives concentrated on controls over *E. coli* O157:H7 in meat and meat preparations. Very few initiatives were seen for other food commodities, and no other serotype than *E. coli* O157:H7 is included in these private controls.

4. RECOMMENDATIONS

- 4.1. The Opinion of the Scientific Committee on Veterinary Measures relating to Public Health on Food-Borne Zoonoses (12 April 2000), section 6.4 contains a number of valuable recommendations on actions that would help to control the presence of verocytotoxigenic *E. coli*. These should be used, in conjunction with the findings of this series of missions, to contribute to the development of specific control programmes at national and European level supported, where necessary, by legislative action. These programmes should aim to minimise consumer exposure to this pathogen, to ensure its effective control during food production and improve awareness amongst food producers and consumers of the risks posed.
- 4.2. It is important that research studies in the Member States are co-ordinated and results communicated in order to assist in the evaluation of the prevalence of VTEC at the different stages of the food production chain. The possible future role of the European Food Authority in this respect should be considered. The studies must be designed to ensure that the results are statistically valid. In achieving these goals, the number of samples, the serotypes examined and the methods used should be evaluated. The information should be used to assess the risks of human infection linked to VTEC in foodstuffs³.
- 4.3. Routine diagnostic methods for VTEC analysis in humans, animals and food should be developed, validated and implemented. A network of laboratories collaborating on this matter should be established at national and European level.

³ It should be noted that the Scientific Committee on Veterinary Measures relating to Public Health is currently carrying out an analysis of the risk of contamination with VTEC for all foodstuffs.

- 4.4. The existing Community Network (established under Decision 2119/98/EC⁴), and its supporting national networks, which collect information on human cases and the prevalence of VTEC in all food commodities, should be further developed to enhance their effectiveness in this sector.
- 4.5. The European Commission and the Member States should co-operate in creating guidelines on the action required to detect (including laboratory analytical techniques), prevent, control and investigate VTEC outbreaks in the animal and human populations.
- 4.6. The development of effective working links between human health and veterinary services should be given a high priority. Consideration should be given to establishing a single national service to carry out epidemiological studies and initiate the proper actions in case of any zoonoses outbreak, including VTEC.
- 4.7. Communication between all parts of the food production chain at national level should be improved, so that controls over food-borne pathogens are rendered more effective.
- 4.8. Operational guidelines should be prepared for all operators in the food chain, from farm through to processor, so that the risks to consumers by VTEC can be controlled. Critical Control Points for the control of VTEC in the food production chain should be specifically defined and their control supervised by the Competent Authorities.
- 4.9. National authorities should give a high priority to warning consumers of the risks posed by VTEC, and the action required to avoid and control the infection.
- 4.10. Accurate, reliable, "line-side" tests (simple, rapid, tests, that can be used within processing establishments to give an initial indication of contamination) should be developed, to facilitate the screening for, and initial identification of, VTEC in the food production chain.

ADDENDUM

The Member States visited during this series of missions were invited to comment upon the draft report. Detailed responses were received from Belgium, France and Sweden in particular, and some changes have been made to the final report to reflect these remarks. The Member State reactions (where comments were made) are attached as Annex II, III and IV to this paper, for information.

⁴ Decision No 2119/98/EC of the European Parliament and of the Council of 24 September 1998 setting up a network for the epidemiological surveillance and control of communicable diseases in the Community *Official Journal L 268 , 03/10/1998 P. 0001 - 0007*

ANNEX I

Country	Date	Mission No.
Denmark	26 February – 2 March 2001	DG(SANCO)/3172/2001
Portugal	19-23 March 2001	DG(SANCO)/3174/2001
Germany	2-6 April 2001	DG(SANCO)/3192/2001
Belgium	23-27 April 2001	DG(SANCO)/3173/2001
France	23-27 April 2001	DG(SANCO)/3170/2001
Sweden	14-18 May 2001	DG(SANCO)/3322/2001

ANNEX II

Commentaires sur le projet de rapport général relatif à la mission E.coli vérocytotoxique.

Modifications à apporter à :

2.1.2 Co-operation/Co-ordination between official services

➤ *Planning for E.coli outbreaks*

Il existe en Belgique un planning indiquant la conduite à suivre lors de cas d'intoxication alimentaire dans un contexte général (y compris E. coli). La procédure à suivre est reprise dans un formulaire d'enquête : Intoxication alimentaire. Une procédure écrite décrivant l'utilisation de ce formulaire est disponible pour tous les fonctionnaires en charge de cette enquête.

2.1.8 Response to E. coli isolation or outbreak

Dans le cadre de l'exportation des viandes de la Belgique vers les états membres, une procédure RAS est prévue lors de l'isolement d'un VTEC.

Des mesures additionnelles sont prises par les différents services responsables pour les denrées concernées en fonction de leur législation.

La circulaire du 17 août 1995 " Conduite à tenir en présence de cas suspects ou avérés d'intoxications, d'infections ou de toxi-infections d'origine alimentaire" donne une description claire de la procédure à suivre.

A la suite d'une notification dans le cadre du système d'alerte rapide, c'est l'IGDA qui rediffuse l'information auprès des différents services concernés. Un questionnaire en cas de TIAC a été établi. par l'IGDA

2.3.3 Processing establishment standarts

Définition **filet américain** : viande hachée (de bœuf ou de cheval) maigre pouvant être additionnée de sel et d'épices.

filet américain préparé : viande hachée (de bœuf ou de cheval) maigre à laquelle peuvent être ajoutés du sel, des épices, des œufs, de la mayonnaise, des herbes, fruits et légumes.

Définitions extraites de : *A.R. du 8 mars 1985 relatif à la fabrication et au commerce de la viande fraîche hachée ou moulue*

En Belgique, l'étude de la prévalence des *E.coli* enterohémorragiques dans les viandes hachées de bœuf est systématiquement introduite dans les plans officiels de recherche des zoonoses

Remarks from Ministry of Agriculture

(Veterinary Services and Veterinary and Agrochemical Research Centre)

In general, the text is well constructed and the part that refers to the visit to Belgium is broadly in line with the actual activities on the subject in our country.

Specific remarks:

- ✓ 2.1.3. On farm: In Belgium. A royal decree on zoonoses in farm animals imposes declaration of a number of zoonotic agents to the veterinary services, and although not explicitly listed, VTEC are included.
- ✓ 2.1.8. In Belgium. In case of the identification of a E. coli O157 contaminated carcass is found, the farm of origin is unequivocally identified, and specific sanitary measures are taken on that farm :
 - testing programme is carried out (see 2.3.1.)
 - systematic sampling of cattle for slaughterhouse purpose is compulsory
 - prohibition to sell untreated (heated) milk for consumption
- ✓ 2.1.11. In Belgium. Research is going on on the genetic subtyping of VTEC strains with respect to their probable virulence for man.

ANNEX III

NOTE A LA COMMISSION

Direction Générale Santé et Protection des Consommateurs

Objet : Projet de rapport général relatif à une série de missions effectuées dans les Etats membres afin de réexaminer les contrôles visant à détecter la présence d'*Escherichia coli* vérocytotoxiques dans la chaîne de production de denrées alimentaires.

Références : Lettre de la Commission 13.08.2001/D52625/SPG D(2001)3033
Projet de rapport général.



Les autorités françaises ont l'honneur de faire part à la Commission européenne, de leurs commentaires sur le projet de rapport général de la Commission cité en référence, relatif à une série de missions effectuées dans les Etats membres afin de réexaminer les contrôles visant à détecter la présence d'*Escherichia coli* vérocytotoxiques (VTEC) dans la chaîne de production de denrées alimentaires.

4/ RECOMMANDATIONS

4.6. En France, les autorités compétentes en matière de santé publique et les autorités compétentes en matière de santé animale et d'hygiène alimentaire dépendent de deux Ministres différents, le Ministre de la Santé, avec la Direction Générale de la Santé, l'Institut de Veille Sanitaire et les Centres Nationaux de Référence d'une part, et le Ministre de l'Agriculture et de la Pêche, avec la Direction Générale de l'Alimentation, d'autre part. Les missions attribuées à chacune de ces structures pour la mise en œuvre des enquêtes épidémiologiques et des mesures de gestion appropriées en cas de maladies zoonotiques sont définies de façon précise. Des protocoles d'actions conjointes des services de ces deux ministères ont été élaborés pour coordonner les investigations lors de la survenue d'épisodes de cas groupés de maladies d'origine alimentaire ; toutefois, l'attribution de ces différentes missions à une autorité unique n'est pas envisageable actuellement dans notre pays.

4.8. L'un des principes de base de la mise en place du système HACCP dans une entreprise du secteur alimentaire est l'analyse de l'ensemble des dangers potentiels d'une opération menée dans le cadre des activités de cette entreprise, que ces dangers soient chimiques, physiques ou microbiologiques (contamination des aliments, survie ou multiplication des germes, toxinogénèse). Le danger « VTEC » doit donc être pris en compte dans l'analyse des risques, au même titre que les autres pathogènes.

4.9. Le système de surveillance du syndrome hémolytique et urémique (SHU) chez les enfants de moins de 15 ans mis en place en France depuis 1993 montre que l'incidence moyenne annuelle de cette pathologie est faible (7,8 cas pour 10⁶ enfants de moins de 15 ans), et globalement stable. Aucun épisode épidémique n'a été signalé à ce jour dans notre pays. Tout en restant considérées comme un réel problème de santé publique par les autorités sanitaires françaises, les infections à VTEC ne font pas partie actuellement des

priorités de Santé Publique. A l'heure actuelle, il n'apparaît pas utile d'alerter le consommateur français sur le risque spécifique « VTEC » au regard de l'incidence de cette pathologie en France ; seule une information des consommateurs sur les règles générales d'hygiène, dont l'hygiène alimentaire, semble pertinente. Si cette situation venait à évoluer, une information spécifique des consommateurs relativement au risque d'infection à VTEC et aux mesures de prévention adaptées, pourrait devenir une priorité des autorités de santé publique.

ANNEX IV



Swedish Board of Agriculture
Animal Product Department

COMMUNICATION Dnr 33-5130/01

2001-10-17

European Commission
Food and Veterinary Office

Opinion from Sweden on the draft general report on the results of a series of missions to review the operation of controls over verocytotoxigenic *Escherichia coli* in the food production sector with particular reference to red meat, meat products and milk/milk products

The Swedish Board of Agriculture has taken part of the draft report and wishes to comment the draft.

2.1.8

“In Sweden, if animals are found to be positive for E. coli O 157, the following recommendations are issued to the farmer through collaboration between the official and private sector”

The Swedish Board of Agriculture would like to clarify that these recommendations are only issued if the bacteriological findings in the animals are connected with a human case of EHEC or HUS. The county veterinarian issues the recommendations.

2.1.9

*“In Sweden..... In addition, all **infected** herds will receive a **guideline** for handling infected herds...”*

The Swedish Board of Agriculture would like to clarify, that only herds where the bacteriological findings in the animals are connected with a human case of EHEC or HUS receive recommendations. The guideline is the same thing as the recommendations mentioned above.

Apart from these recommendations for specific herds, there are general guidelines directed towards all holdings with ruminants issued by the Swedish Board of Agriculture (Statens jordbruksverks allmänna råd (2001:1) i anslutning till lagen (1992:1683) om provtagning på djur, m.m.), which are mentioned elsewhere in the text.

2.3.1

*“In Sweden official **restrictions** are imposed on farms linked to an outbreak of human EHEC. Animals from these farms are tested for E. coli O 157 every three months and **restrictions** are lifted only after two consecutive negative results.”*

The word restrictions should be replaced by the word recommendations.