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Assessment of risk to public health from exposure to BSE infectivity from the Rendac Bergum rendering plant

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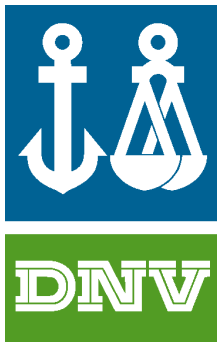

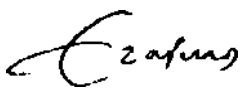

This investigation has been performed by order and for the account of Provinsje Fryslân, within the framework of project V/244920/05/BS, Assessment of Risk to Public Health from exposure to BSE infectivity from the Rendac Bergum Rendering Plant.

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Abstract

To identify and quantify the risks to the public health from the BSE infective agent arising from the activities at the Rendac Bergum rendering plant, a risk assessment study was performed. The flow of infectivity entering the rendering plant was modelled using an event tree approach. The model was evaluated using a probabilistic risk assessment approach to reflect the uncertainties in the input parameters. For input of fixed parameters, conservative values were used in order to present a worst case scenario. Selected variables were defined as a distribution of values and the result calculated many times using a Monte Carlo simulation tool. In 2001, in the Netherlands, a total of 20 animals were tested positive for BSE. It was assumed that all of these animals would have been processed at the Rendac Bergum plant as part of the SRM processing, and that they had the infectivity of a fully infected animal. The median value of the infectivity entering the process was estimated to be 3110 human oral ID_{50} units per year, with a range from 53 to 114,000. Ninety-nine per cent of the infectivity entering the plant was estimated to be inactivated by the rendering process. Of the remaining infectivity, most was found to end up in the Meat and Bone Meal (MBM) product: 8 human oral ID_{50} units per year. At the current production level this would result in about 7×10^{-8} human oral ID_{50} units per kg MBM. Currently all of this MBM is sent offsite for disposal by incineration. Infectivity from the plant could enter the environment through one of three routes, via sludge used in landfill or spread on the land as fertiliser, waste water discharged to the canal, or as particles released to the air. In all three cases the amounts of infectivity were found to be very small and could not pose any significant risk to the public health.

Preface

The risk assessment study described in this report was co-ordinated by RIVM and performed in a close collaboration between ID-Lelystad, Det Norske Veritas United Kingdom, and Erasmus University Rotterdam.
The study was dedicated to RIVM by Provinsje Fryslân in June 2001, after inhabitants in the vicinity of the Rendac Bergum rendering plant had expressed their concern about the possible health risk from exposure to the Bovine Spongioform Encephalopathy (BSE) infective agent that may be present in waste products or accidental releases from the facility.
The study was commissioned by Provinsje Fryslân and supported by the Ministry of Agriculture, Nature Management and Fisheries, the Ministry of Public Health, Welfare and Sports, and the Ministry of Housing, Spatial Planning and the Environment.
To ensure that all research questions were adequately addressed, a steering group was installed composed of the following people:

R. Afman	Province Fryslân
I. Arendzen	Ministry of Public Health, Welfare and Sports
B. Bruins	Inspectorate for Veterinary Public Health and Commodities
F. Duijm	Municipal Health Service, Groningen
P. Jellema	Rendac Bergum BV
E. Kuipers	Province Fryslân
SJ Koornstra	Province Fryslân
A.M. Lamberts-Takens	Inspectorate for Veterinary Public Health and Commodities
A. Pothaar	Wetterskip Fryslân
J.A.J. Lobstein	Wetterskip Fryslân
G. van der Meij	Ministry of Housing, Spatial Planning and the Environment, Environmental Health Inspectorate North
W. Paauw	Municipality Tytsjerksteradiel
W.H.M. van der Poel	National Institute of Public Health and the Enviroment
P.A.A. van Velzen	Ministry of Agriculture, Nature Management and Fisheries

During the research period the group gathered three times to discuss the objectives, the progress and the results of the project.
Apart from the members of the steering group, the authors would like to gratefully acknowledge J. Kliest, A.M. Henken, M. Nauta and A. Havelaar for their contribution to the research, and for critically reviewing the report.

Contents

Samenvatting

Het destructiebedrijf Rendac BV (Rendac) verwerkt dierlijke bijproducten in Nederland op de locaties Son (Br) en Sumar (Fr). Al het in Nederland geproduceerde 'Specified Risk Material' (SRM) alsmede alle kadavers van gestorven of in nood gedode dieren worden verwerkt door Rendac. (SRM omvat de weefsels van runderen die BSE infectiviteit kunnen bevatten). Tot voor kort werd al het in Nederland geproduceerde SRM verwerkt in Sumar, maar op dit moment gebeurt dat in Son. Voor het onderzoek is er vanuit gegaan dat al het SRM wordt verwerkt in Sumar.

Het doel van het onderzoek was het identificeren en, zo goed als mogelijk, kwantificeren van het risico voor de volksgezondheid van BSE agens dat vrijkomt door de activiteiten van het destructiebedrijf Rendac Bergum BV. Het risico is uitgedrukt als de te verwachten uitstoot van infectiviteit naar de omgeving met als eenheid de humane orale ID_{50} (de dosis waarbij de kans op infectie 50% is).

In 2001, is Nederland net als andere EU landen gestart met het testen van geslachte runderen op de aanwezigheid van het BSE agens. Alle dieren die bij de slacht ouder zijn dan 30 maanden worden getest. Runderen die klinische verschijnselen van BSE vertonen, alsmede gestorven en in nood gedode dieren, vanaf een leeftijd van 24 maanden, worden eveneens getest op BSE. In 2001 werden in totaal 20 dieren positief bevonden voor BSE. Al deze dieren werden verwerkt door het destructiebedrijf Rendac BV. Voor het onderzoek is er van uit gegaan dat al deze dieren evenveel infectiviteit bevatten als dieren met klinische verschijnselen. De mediane waarde van de infectiviteit aan het begin van het proces wordt geschat op 3110 orale humane ID_{50} per jaar (betrouwbaarheids interval 53 – 114000). Het vrij grote betrouwbaarheidsinterval wordt veroorzaakt door de onzekerheid van de rund-mens species barrière.

Er is een model gemaakt voor de wijze waarop BSE infectiviteit het destructieproces doorloopt, door gebruik te maken van stroomdiagrammen. Hiermee kan de stroom van BSE infectiviteit gevolgd worden, aannemende dat de infectiviteit geassocieerd is met de stroom van vaste stof. In het model wordt rekening gehouden met het effect van het sterilisatie proces op de reductie van infectiviteit en alle gegevens zijn gehanteerd met het oogmerk een 'worst case scenario' te presenteren. Verdamping en microbiële afbraak in de waterzuiveringsinstallatie dragen waarschijnlijk bij aan de reductie van infectiviteit, maar alleen inactivatie door sterilisatie en verbranding van materialen in de boiler zijn in de berekeningen meegenomen.

Op basis van eerder wetenschappelijk onderzoek wordt aangenomen dat de BSE infectiviteit door het destructieproces voor 99% geïnactiveerd wordt. Van de resterende infectiviteit zal het grootste deel (8 humane orale ID_{50} eenheden per jaar) terechtkomen in het vlees- en beendermeel. Dit eindproduct gaat op transport voor verbranding elders. Het slib van de waterzuiveringsinstallatie bevat naar schatting 1 humane orale ID_{50} eenheid per jaar, in 1000 ton. Dit slib wordt naar elders getransporteerd voor inactivatie door middel van 'deep well oxidation', storting op land of gebruik als meststof.

BSE infectiviteit afkomstig van het destructiebedrijf kan via 3 routes in het milieu terechtkomen. Via het effluent van de waterzuiveringsinstallatie dat wordt geloosd in het

Prinses Margriet kanaal, via het slib dat op land wordt gestort of wordt gebruikt als meststof, of via deeltjes in de gassen die in de omgevingslucht terechtkomen. De infectiviteit die in het kanaal terechtkomt werd berekend op 2×10^{-5} ID_{50} per jaar. In de totale hoeveelheid van 600000 m^3 die per jaar die geloosd wordt, resulteert dit in een concentratie van 3×10^{-11} humane orale ID_{50} eenheden per m^3. Deze hoeveelheid is extreem laag en zou zelfs geen significant risico opleveren wanneer het onverdunde water gebruikt zou worden voor drinkwater (wat niet het geval is).

De belangrijkste uitstoot naar het milieu blijkt het gebruik van het slib van de waterzuiveringsinstallatie. Wanneer dit wordt gebruikt als meststof op het land, resulteert dit in een uitstoot van 1 humane orale ID_{50} eenheid per jaar in 1000 ton slib. Hoewel dit materiaal waarschijnlijk over een groot oppervlak verspreid zal worden en het risico voor de volksgezondheid erg klein is, mag dit risico niet zonder meer genegeerd worden. Het risico voor runderen die op dergelijk land grazen zal een factor 10 hoger zijn omdat er in dat geval geen sprake is van de species barrière.

Ondanks de luchtbehandelingsprocessen zullen naar schatting 1×10^{-6} humane orale ID_{50} eenheden per jaar in de omgevingslucht terechtkomen. Een hoeveelheid van 1×10^{-5} ID_{50} is geassocieerd met het materiaal van het biofilter, en een hoeveelheid van 9×10^{-10} humane orale ID_{50} eenheden per jaar zullen met de verbrandingsgassen uit de boiler (die een deel van de geproduceerde vetten verbrandt) vrijkomen. Dit zijn extreem lage hoeveelheden die ook nog eens sterk verdund worden in de lucht, en geen significant risico opleveren voor mensen die in de omgeving van het destructiebedrijf wonen, werken of verblijven.

In het algemeen kunnen incidenten waarbij abnormale procescondities ontstaan leiden tot het vrijkomen van gevaarlijke substanties in het milieu. Er zijn daarom een aantal mogelijke scenario's van dit soort incidenten onderzocht. Hoe ze kunnen optreden en wat ze kunnen betekenen voor het aantal infectieuze eenheden dat in het milieu terecht komt. Beschreven zijn het verlies van inperking van infectieusiteit tijdens het transport, vermorsen van materiaal buiten het ontvangstgebouw, een stijging in het aantal BSE besmette runderen, verminderde inperking van afvalwater, en verbranding van al het vet in de boiler. Hoewel deze gebeurtenissen leiden tot een verhoogd risico op het vrijkomen van infectieus materiaal is in geen enkel geval sprake van een verhoging die leidt tot een belangrijk risico voor de volksgezondheid.

Dit onderzoek laat zien dat de hoeveelheid infectieus BSE agens, die kan vrijkomen in het milieu bij een normale bedrijfsvoering van het destructiebedrijf Rendac te Sumar, extreem laag is en geen significant risico opleveren voor de volksgezondheid.

Summary

Rendac BV (Rendac) is the major processor of animal by-products in the Netherlands and processes all of the Specified Risk Material (SRM) produced in the Netherlands as well as any fallen stock. (SRM represents the tissues that have the highest levels of infectivity in a bovine infected with BSE.) Rendac has two processing facilities in the Netherlands, one at Son and the other at Sumar. Until recently all SRM produced in the Netherlands was processed at the Sumar plant although currently the SRM is being processed at Son. For the purposes of this study it has been assumed that all SRM is processed at Sumar.

The objective of the study was to identify and, so far as possible, quantify the risks to public health from the BSE infective agent arising from the activities at the Rendac Bergum rendering plant. The risk has been presented in terms of the expected discharge of infectivity into the environment expressed as human oral ID_{50} units.

In 2001, the Netherlands, in line with other EU countries, started a programme of testing for the BSE infective agent. All cattle older than 30 months sent for slaughter are tested at the time of slaughter, as well as all cattle diagnosed as having BSE. All fallen stock aged over 24 months, received by Rendac are also tested for BSE. In 2001, a total of 20 animals were tested positive for BSE. It has been assumed that all of these animals would have been processed at Sumar as part of the SRM processing, and that they would have the infectivity of a fully infected animal. The median value of the infectivity entering the process was estimated to be 3,110 human oral ID_{50} units per year, with a range from 53 to 114,000. The wide range was primarily due to the uncertainty in the cattle to human species barrier.

The flow of infectivity entering the rendering plant has been modelled using an event tree approach. This tracks the infectivity flow assuming that the infectivity would be associated with the solid stream and takes account of the effect of the sterilisation process in reducing infectivity. The report has used conservative values in order to present a worst case scenario. For example, vaporisation and microbial degradation processes within the sewage treatment plant will very probably result in some additional reduction in infectivity, but only sterilization and burning of materials in the boiler have been assumed to reduce levels.

It was estimated that some 99% of the infectivity entering the plant would be inactivated by the rendering process. Of the remaining infectivity most was found in the Meat and Bone Meal (MBM) product (8 human oral ID_{50} units per year), which was sent offsite for disposal by incineration. Sludge from the waste water treatment process was estimated to contain 1 human oral ID_{50} unit per year, in 1000 tonnes, and this is normally sent offsite to a deep well oxidation facility, but may be put in landfill or spread on land as fertilizer.

Infectivity from the plant can enter the environment through one of three routes, via sludge put in landfill or spread on the land as fertilizer (see above), waste water discharged to the Prinses Margriet canal, or as particles released to the air. The infectivity discharged to the canal is estimated to be 2×10^{-5} human oral ID_{50} units per year. This is released in the 600,000 m^3/year of water discharged, giving a concentration of only 3×10^{-11} human oral ID_{50} units/m^3. This amount of infectivity is extremely small and could not pose any significant risk to the users of the canal, even if this was used as a source of drinking water (which it is not).

The most significant release to the environment was found to be the use of sludge from the waste water treatment plant when it was used in landfill or as a fertilizer and spread on the land, resulting in the release of 1 human oral ID_{50} unit to the environment in 1000 tonnes of sludge, per year. Although this material would be likely to be distributed over a large area, and the risk impact to human health would be very small, the risks associated with this practice cannot be ignored. The risk exposure to any cattle grazing the land would be a factor of 10 or more higher as there is no species barrier.

It is estimated that 1×10^{-6} human oral ID_{50} units per year could be released from the air treatment process, with 1×10^{-5} associated with the biobed material. An additional 9×10^{-10} human oral ID_{50} units per year with the combustion gases from the boiler (which burns some of the fat produced in the process). Both of these would be subject to significant dilution in the air. These are again extremely low levels of infectivity that would not pose any significant risk to people living in the vicinity of the Rendac Bergum plant.

It was recognized that hazardous substances may be released when normal operating conditions are disrupted in some way, or the loading entering the system changes. A number of scenarios have therefore been described representing the types of event that could occur and how these would alter the levels of infectivity potentially released to the environment. These were a loss of containment during transportation, spillage outside the reception building, an increase in the number of infected animals, a loss of containment in the waste water treatment plant, and burning all of the fat produced in the plant's boilers. Although these incidents would increase the risk of release of potentially infective material, in no instance were levels elevated to a degree whereby they would be considered to pose a significant risk.

The study has shown that the possible releases of BSE infectivity into the environment from the normal operation of the Rendac rendering plant at Sumar are extremely small and would not pose any significant risk to people living in the vicinity.

1. Introduction

1.1 Background

Rendac BV (Rendac) is the major processor of animal by-products in the Netherlands and processes all of the Specified Risk Material (SRM) produced in the Netherlands as well as any fallen stock. (SRM represents the tissues that have the highest levels of infectivity in a bovine infected with BSE, see section 1.3 below) Rendac has two processing facilities in the Netherlands, one at Son and the other at Sumar. Until recently all SRM produced in the Netherlands was processed at the Sumar plant although currently the SRM is being processed at Son.

The study was commissioned by the Provinsje Fryslân as inhabitants in the vicinity of the plant have expressed their concern about the possible health risk from exposure to the BSE infective agent that may be present in waste products or accidental releases from the facility.

1.2 Objectives

The objective of this study was to identify and, so far as possible, quantify the risks to public health from the BSE infective agent arising from the activities at the Rendac Bergum rendering plant.

In particular the study has sought to:

- Quantify the expected number of bovines with positive BSE infectivity that will have been slaughtered and the amount of SRM processed at the plant;
- Assess the likely effect of the process at the plant on the infectivity;
- Identify all possible pathways by which people could be exposed to any infectivity arising from the plant. This includes both normal operational discharges (e.g. treated liquid effluent) and accidental releases (e.g. spills of untreated material);
- Quantify the magnitude of infectivity that could be present in each pathway;
- Assess the exposure of the population to the BSE infective agent.
- Assess the risk to public health resulting from this exposure

Det Norske Veritas (DNV) has applied a standard risk assessment approach to this study drawing on the experience from previous BSE risk studies, both for rendering plants and for other facilities. The data and assumptions from these previous studies have been updated, both to take account of any recent research and information and to make the study specific to the plant and conditions in the Netherlands.

There is significant uncertainty about many aspects of the risk from BSE. In order to deal with this uncertainty, input parameters have been expressed as ranges or probability distributions wherever possible, and the risk evaluated using Monte Carlo simulation.

The project has employed event tree analysis to graphically present the likely fate of potentially infective materials through the various processes within the plant. This information has then been used to identify where releases to the environment might occur. The subsequent risk of ingestion of potentially infectious material by humans has then been evaluated and results have been set in context by comparing them with background risks from other sources.

1.3 Specified Risk Material

Specified Risk Material has been defined by the Scientific Steering Committee of the EC to include all tissues that may contain detectable levels of infectivity. It includes: the skull, including the brain and dura mater, the pituitary gland, the eyes, the tonsils, the intestines from the duodenum to the rectum, the vertebral column, including the dorsal root ganglia, spinal cord and dura mater, of bovine animals aged over 12 months, and ovine and caprine animals which are aged over 12 months or have a permanent incisor tooth erupted through the gum. The spleens of ovine and caprine animals.
In the EU regulations (Regulation EC 999/2001 amended by EC 1248/2001, 1326/2001 and 270/2002) this has been adopted as follows:
Tissues designated as specified risk material:
Bovine animals of all ages:
- the intestines from the duodenum to the rectum;
- the mesentery.

Bovine animals over 12 months:
- the skull including the brain and eyes,
- the tonsils,
- the vertebral column excluding the vertebrae of the tail and the transverse processes of the lumbar vertebrae, but including dorsal root ganglia and spinal cord.

Caprine and ovine animals of all ages:
- the spleen.

Ovine and caprine animals aged over 12 months or which have a permanent incisor erupted through the gum; Bovine animals over 12 months:
- the skull including the brain and eyes,
- the tonsils,
- the spinal cord.

2. Potential for transmission of BSE to humans

Bovine Spongiform Encephalopathy (BSE) or 'mad cow disease' is a fatal neurological disease of cattle, first identified in 1986. Most known cases of the disease have occurred in Great Britain, but 26 cases have been identified up to the end of 2001 in the Netherlands, with the first case identified in 1997. The disease reached a peak in the United Kingdom in 1992 when over 36,000 cases were reported (Wilesmith et al., 1992). However, with the advent of control measures this number has now reduced to 751 in 2001 with the trend continuing downwards.

The distinctive feature of BSE is the development of sponge-like holes in brain tissue, resulting in impaired mental function and ultimately death. The incubation period for the disease from origin of infection to development of clinical signs is typically 5 years, but can be as short as 20 months.

The nature of the BSE agent remains unclear. However, it is known that the agent does not evoke an immune response in the host and is resistant to inactivation by heat, chemical disinfection or radiation. The dominant theory is that the agent is a distorted form of protein known as a prion protein. This molecule is believed to transform other similar proteins to distort in the same way, leading to a slow spread of infection from the origin of infection (e.g. the digestive tract), through lymph nodes in the gut wall, and finally into the central nervous system (Prusiner et al., 1996).

The condition known as new variant Creutzfeldt-Jakob disease (vCJD) is believed to be a human form of BSE (Will et al., 1996). This is a deteriorating mental condition, typically leading to death within 6 months. This condition differs from conventional CJD in that it tends to occur in younger patients (aged 16–42), produces different symptoms, and produces a different pattern of lesions in the brain of patients.

To date in the UK there are reported to have been 110 deaths from vCJD, 89 confirmed and 21 probable cases (source: web site of CJD Surveillance Unit, University of Edinburgh: www.cjd.ed.ac.uk). France, Italy and Ireland are the other European countries to report cases of vCJD (5 as at April 2002), and none have been found in the Netherlands (source: web site of The European and Allied Countries Collaborative Study Group of CJD).

2.1 Infectivity of CNS Tissue in Cattle with BSE

The infectivity of the BSE agent has been considered in detail by the Scientific Steering Committee (SSC) of the European Commission and their assessment presented in their opinion adopted at their meeting on the 13-14 April 2000 'Oral Exposure of Humans to the BSE Agent: Infective Dose and Species Barrier'. This opinion is used as the basis for this risk assessment.

The infectivity (i.e. the potential to cause infection) of tissue from an animal with BSE is expressed in terms of its Infectious Dose 50 (ID_{50}) value. This is the dose (i.e. the quantity which each person would need to consume) to cause infection in 50% of the exposed

population. This term acknowledges that some people may become infected from much smaller doses, while others may be uninfected after consuming much larger doses.

2.1.1 Infectious Dose

The SSC concluded that the various approaches to assessing the infectivity from a clinically infected brain yielded a range of values from 10^1 to 10^3 cattle oral ID_{50}/g. They noted that the higher value may represent a worst case scenario if the oral route is more efficient than data suggests and a particularly high titre of infected brain is sampled. They conclude that such a high dose cannot be ruled out. The lower value is based in part on the results of the attack rate experiment carried out by the UK Ministry of Agriculture Fisheries and Food (MAFF). It is noted that this experiment is incomplete and that it is not possible to obtain a final value for the infectious dose. The SSC gives some weight to the calculations of Diringer (1999) using the results of published and peer reviewed experiments. This results in an estimated infectious dose of 50 cattle oral ID_{50}/g of clinically infected brain.

From this data it is proposed to adopt a distribution of values ranging from 10 to 10^3 cattle oral ID_{50}/g with a median value of 50 cattle oral ID_{50}/g and a 95 percentile of 100 (see appendix V).

2.1.2 Species Barrier

The infectivity of BSE for humans is believed to be lower than in cattle due to the species barrier. The species barrier in this context is defined as the factor by which the effective infectivity in one species is reduced when given to a second species. Thus, if the cattle–human species barrier was 100, it would mean that 100 times more infective material would be required to infect a man than a bovine.

In their opinion, the SSC concluded that the size of the species barrier between BSE in ruminants and BSE in humans (vCJD) is not known. They considered that a worst case scenario considering no species barrier (i.e. = 1) should be included, although available evidence indicates that values greater than 1 are likely to be more realistic. They recommended that, until more scientific data are available, for risk assessments of human exposure to potentially BSE infected products, a species barrier of about 1 should be considered as a worst case scenario and that the range from 10^4 to 10^1 be considered. This supports the assumptions made by DNV in previous risk assessments in which the species barrier was represented as a distribution using values of 10, 100, 1000 and 10,000 with equal probabilities, and a 1% probability of it being 1 (DNV, 1997 a,b). The same distribution has been used in this assessment.

3. Risk assessment structure

The risk assessment has been conducted using a tiered approach whereby the quantities of potentially infective material entering the process have been identified and then followed through either to inactivation or potential release to the environment. The report contains a number of sections which reflect this structure.

The risk assessment has considered the sources of infectivity, the treatment of materials within the plant and the pathways whereby infectivity may be released to the surrounding environment. These pathways have been modelled using event trees that describe fractions of potentially infective material which can either be released, inactivated or removed from the site for disposal elsewhere. Although the boundary of this risk assessment is defined by the perimeter of the plant, the study does include the risks associated with transport of material to the plant, but not the fate of incinerated material or other off site forms of waste disposal.

The amount of infectivity entering the rendering process has been described using data obtained from the Institute for Animal Science and Health (ID-Lelystad) together with evidence from scientific opinion and published papers.

In order to detail the processes of relevance to the study a series of linked event trees has been constructed describing three major areas:

1. **Rendering Process** – An event tree showing a high level overview of the rendering system is presented showing the progression of product (MBM and fat) or waste materials through the process.

2. **Waste Processing -** Waste processing event trees then describe the treatment of waste materials using input data derived from stages in the Rendering Process.

3. **Environmental Pathways -** The waste streams described are then expressed in relation to the fate of material potentially released from the processes involved in the management of waste from the plant.

The report firstly describes activities as they would be expected to run under normal operating conditions. However, the possibility of abnormal release is also described where areas identified as being of potential risk for major release are examined by adapting the model to reflect breakdown in containment and/or inactivation of the agent.

3.1 Hazard Identification

The Structured What-IF Technique (SWIFT) is a thorough, systematic, multi-disciplinary team-orientated method of identifying hazards, based on a combination of brainstorming, structured discussion and checklists. The SWIFT process ensures that a knowledgeable cross-section of individuals familiar with both the risk assessment structure and operating conditions within the facility under study identify areas where attention should be directed.

The SWIFT workshop took place over 12 –13 September at RIVM, Bilthoven. In attendance were representatives of Provinsje Fryslân, Rendac Bergum, ID-Lelystad, DNV and RIVM.

The team included people with specialist knowledge of the plant and its operation, those with knowledge of local BSE issues, those with an understanding of potential exposure pathways, and others familiar with the risk assessment systematic structure. The SWIFT study involved a systematic discussion of each potential pathway by which people could be exposed to infectivity from the facility.

The SWIFT study has been used in identifying areas where there may be hazardous activities associated with the rendering process (see Appendix I for a summary of SWIFT findings). The issues raised are referred to in a number of sections within the report, and the information on Abnormal Releases (Appendix II) uses some of the scenarios identified to examine the consequences of major incidents on the potential release of infectious material.

3.2 Acceptability of Risk

There are no universally applicable criteria to define whether or not risks are tolerable; this is a social and political judgement which can be guided by but not replaced by technical advice. It is therefore impossible to be precise about whether a risk is tolerable because:

- The value judgements about what is tolerable vary between individuals and between societies, alter with time, accident experience and changing expectations of life, and depend on the perceived risks and benefits of the hazardous activity.
- The risk estimates themselves contain uncertainties, often estimated to be an order of magnitude band in absolute terms, although less when comparing risk options.

The simplest framework for risk criteria is a single risk level which divides tolerable risks from intolerable ones (i.e. acceptable activities from unacceptable ones). Such criteria give attractively simple results, but they need to be used very carefully, because they do not reflect the uncertainties both in estimating risks and in assessing what is tolerable. For instance, if applied rigidly, they could indicate that an activity which just exceeded the criteria would become acceptable as a result of some minor remedial measure which in fact scarcely changed the risk levels.

A more common approach to dividing tolerable and intolerable risks is to use two criteria, known as ‘maximum tolerable’ and ‘negligible’ levels. These divide risks into three tiers:

- An intolerable region (above the ‘maximum tolerable’ criterion), within which the risk is generally intolerable whatever the benefit may be. Risk reduction measures or design changes are considered essential.
- A middle band (between the ‘maximum tolerable’ and ‘negligible’ criteria) where risk reduction is desirable. In the UK, risks in this region are considered to be tolerable only when they have been made ‘as low as reasonably practicable’ (ALARP). This requires risk reduction measures to be implemented if they are reasonably practicable, as evaluated by cost-benefit analysis.
- A negligible region (below the ‘negligible’ criterion) within which the risk is generally tolerable, and no risk reduction measures are needed.

This approach, which is used both in the Netherlands and in the UK, is illustrated in Figure 3.1. The risk criteria used in the Netherlands to assess the impact of hazardous installations

were set out in an Ordinance known as 'Besluit Risico's Zware Ongevallen' (BRZO) that was issued in 1988 and amended in 1990 and 1992 (BRZO, Staatsblad 1988, 432; W-BRZO-I, Staatsblad 1990, 443; -BRZO-II, Staatsblad 1992, 291) and amplified in the report 'Omgaan met Risico's' (Tweede Kamer 1988-89, 21, 137, No 5). This defined a Maximum Permissible Risk as being an individual risk of 10^{-6} per year for new situations and 10^{-5} per year for existing situations, with a Negligible Risk defined as 10^{-8} per year. An 'Individual Risk' was defined as the risk of fatality to a hypothetical individual exposed 24 hours per day at a given location.

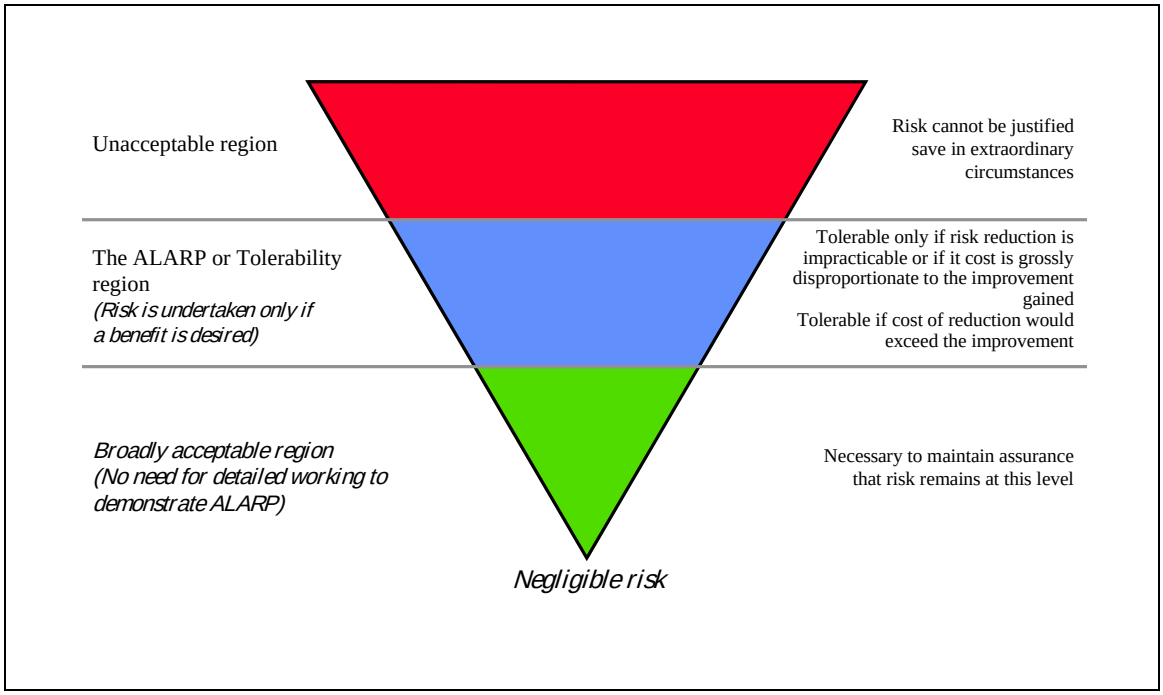


Figure 3.1: HSE Risk Criteria Framework

For comparative purposes, Table 3.1 shows the necessary activity to sustain a risk of 1 in a million per year.

Activity/exposure	Type of risk
Smoking 1.4 cigarettes	Cancer, heart disease
Spending 1 hour in a coal mine	Black lung disease
Living 2 days in New York or Boston	Air pollution
Travelling 150 miles by car*	Accident
Travelling 10 miles by bicycle	Accident
Flying 1000 miles by jet	Accident
Living 2 months in Denver on vacation from New York	Cancer caused by cosmic radiation
Living 2 months with cigarette smoker	Cancer, heart disease
One chest x-ray taken in a good hospital	Cancer caused by radiation
Eating 40 tablespoons of peanut butter	Liver cancer caused by aflatoxin
Drinking 30 12-oz cans of diet soda	Cancer caused by saccharin
Risk of accident by living within 5 miles of nuclear reactor for 50 years	Cancer caused by radiation

Table 3.1: Activities Associated with One in a Million Incremental Risk of Death in a Year
** UK 1992 road accident data*
Source: Richard Wilson as cited by Joseph Rodricks, 1992; Edmund Crouch and Richard Wilson, Risk/Benefit Analysis, 1982.

4. SRM Processed at Rendac Bergum

The total infectivity entering the rendering process is obtained by combining the total number of animals for processing, the assumed prevalence of BSE in the cattle, and the estimated infectivity per infected animal. The first stage in the assessment is to assess the total amount of BSE infectivity that may be present in the material processed. This then provides the input to the event tree model that considers the effect of the disposal route on the infectivity and the pathways by which people could be exposed.

The Rendac plant at Sumar processes a range of raw materials, including poultry waste, blood, feathers, hog hair, and waste products from the catering sector (i.e. fat, waste water, etc. as opposed to pig swill), as well as Specified Risk Material (SRM). The overall plant capacity is 600,000 tonnes per year, but the plant is not run at full capacity. The data used in this assessment will be for 2001 where possible. However, there are areas where 2001 figures were not available for the study and in these cases less current information has been used, and this has been made clear in the text. In 2001 the plant processed some 580,000 tonnes of material, the composition of which is shown in Table 4.1. This study is only concerned with the slaughter by-products that are considered to include all the SRM and fallen stock.

Material Rendered	Quantity (tonnes)
Slaughter by-products	453,455
Blood	64,709
Feathers	39,263
Pig hair	17,315
Fats / oils	7,945
Total	582,687

Table 4.1: Quantities of Raw Material Processed in 2001

In the past all of the SRM produced in the Netherlands were processed at Sumar; this is not currently the case and at present most of the SRM is being processed at the Son plant (see also appendix IV). However, for the purposes of this study it will be assumed that all of the SRM produced in the Netherlands is being processed at Sumar. Bovine Specified Risk Material (SRM) in the Netherlands comprises the skull including the brains and eyes, the tonsils, the spinal cord, the vertebrae of animals aged over 12 months, and the intestines from the duodenum to the rectum and the mesentery of bovine animals of all ages (see also 1.3).

The Rendac Bergum plant also processes fallen stock from farms in the locality on a second, smaller SRM line. This smaller line is only in operation when the main line is not being used for SRM and is used to partially process fallen animals before transferring the half-product to Son for complete processing. The processing of SRM in the secondary line is described in Appendix IV.

4.1 Testing for BSE Infectivity

Cattle in the Netherlands are tested for BSE if they fall into one of the following three groups:

- Animals over 30 months of age at time of slaughter (This category includes animals over 24 months, not completely healthy at slaughter or emergency slaughtered)
- Fallen stock over 24 months of age
- Animals showing clinical signs of disease consistent with BSE.

The numbers of animals tested in each category and the resulting proportion found positive are shown in Table 4.2

Category	Number tested	Positive for BSE	
		Number	Percentage
Over 30 months*	500,000	11	0.002
Fallen stock (>24 months)	30,599	3	0.01
Clinical cases		6	

Table 4.2: Numbers of Animals Tested in 2001 and Found Positive for BSE in the Netherlands (This category includes animals over 24 months, not completely healthy at slaughter or emergency slaughtered)*

All bovines over 30 months are tested at the slaughterhouse. Any positive cases are removed from the production line and sent to Rendac for processing. These animals will not have had clinical signs of BSE and thus the level of infectivity would be less than for a clinical case. However, for the purposes of this risk assessment, it will be assumed that they have the same level of infectivity as a clinical case (see also 4.2).

Fallen stock are tested on arrival at the Rendac facility. These are animals that have died on the farm or been put down by a veterinary surgeon. Rendac operates a collection service that collects fallen stock from farms and delivers them to the plant. The complete carcasses are processed with other SRM. As for the previous case it is assumed that the level of infectivity will be the same as a clinical case.

Animals diagnosed with clinical signs of BSE on a farm will be send to ID-Lelystad for laboratory testing and afterwards the carcass is send to Rendac for processing and subsequent incineration. If the case is confirmed as BSE positive, the complete herd is also slaughtered and tested for BSE. We do not assume any additional infectivity from the rest of the herd unless other BSE positive animals are identified.

4.2 Infectivity Input to Rendering Plant

From Table 4.2 it can be seen that 20 BSE positive cases were identified in the Netherlands in 2001. It will be assumed for this study that 100% of the infectivity from these 20 animals will be sent to the rendering plant at Sumar for processing together with other SRM.

Most of the infectivity in a clinically infected animal is found in the brain and spinal cord and some other CNS tissues. Residual infectivity associated with SRM products other than brain and spinal cord is assumed to constitute a small fraction of that contained in CNS tissues, which typically represents some 750 grams of infected material per infected animal. For the purposes of this study the weight of infective material will therefore be taken as a total of 750g per animal. Thus the infectivity coming into the Rendac plant will be the number of infected animals multiplied by the infectivity values given in Section 2 multiplied by the amount of infected material (750 g).

Table 4.3 shows the total infectivity entering the Rendac Bergum plant assuming that all the SRM produced in the Netherlands is processed at the plant. The median value of the infectivity entering the process is 3,110 human oral ID_{50} units per year, with a range from 53 to 114,000. The wide range is primarily due to the uncertainty in the cattle to human species barrier (calculation explained in appendix V).

	human oral ID_{50} units		
	P5	**P50**	**P95**
Infectivity entering process (per year)	53	3,110	114,000

Table 4.3: Infectivity entering rendering process

The total infectivity is based on 20 BSE positive animals (Table 4.2), and it has been assumed that all cases will have the infectivity of a fully clinical case, although particularly in cases detected early in the infection this is unlikely to be the case. It is generally accepted that the highest titres of infectivity are found in clinically affected animals in the terminal stages of the disease. The rapid BSE test used, may also detect cases several months (estimated 3 to 5) before the final stage of the disease, in which case the infectivity level will be lower (Butler, 1998). How much lower is difficult to assess, but it could be in the range of 10-fold lower.

Based upon related experimental work in hamsters (Beekes et al., 1996) and pathogenesis studies in mice, sheep and cattle, it can be assumed that there are two stages in the replication. Initially there is a zero phase, during which the agent multiplies in peripheral nerves between gut and CNS, followed by the period of logarithmic increase when it reaches the CNS which is roughly in the last 50% of the incubation period.

The assumption that all detected animals are infected at the clinical level is therefore a conservative estimate. This also addresses the issues that there may be low levels of activity associated with animals that fall below the detection levels of the test, false negatives (the test is reported to be effective in detecting 95% of cases within the detection limits), and any infectivity associated with peripheral tissues other than brain and spinal cord.

5. Process description

In order to quantify the infectivity associated with the rendering process, it is necessary to describe how materials are processed and assign values according to which routes the infective material may follow, either in relation to processing activities or as waste products. This section provides an overview of how material is rendered and identifies waste streams associated with different aspects of the process. For reasons of commercial confidentiality, the process described below is presented as a simplified version of the actual situation

Information on the process whereby SRM is processed within the Rendac Bergum facility has been supplied to DNV and used in conducting the risk assessment. Where possible data has been used in describing the process. However, there are a number of activities where precise data were not available and in those cases estimates have been made. All data and estimates used have been reviewed by the project steering group and accepted as the best available information for the assessment.

An important attribute of the prion protein is that it is hydrophobic, and will tend to attach to solids (Gale, 1998). Thus any infective material will tend to associate with the MBM as opposed to tallow (fat) or liquid effluent streams. This aspect of prion behaviour forms a fundamental assumption used in modelling how potentially infective material will behave within the rendering process and environmental pathways. In this study it has been assumed that any suspended solids associated with the fat stream or liquid effluent would have the same infectivity as the MBM, and removal of suspended solids by effluent treatment will remove infectivity. For the purposes of this study it will be assumed that rendering results in production of MBM, fat and water in the ratio of 24:12:64 respectively (data supplied by the plant).

5.1 Effects of Rendering on Infectivity

For the purposes of this study it is assumed that the only points in the rendering process where activity is reduced through treatment are during the Sterilisation stage and where materials are burned in the boiler. This is considered to be a cautious assumption as there are other steps including Vaporisation and microbial degradation processes within the sewage treatment plant, where there will very probably be a further significant reduction in infectivity.

Inactivation studies carried out by Schreuder et al. (1998) using a laboratory scale simulation of the Rendac Bergum process have shown that the rendering process will lead to a reduction in infectious load of at least 1 in 200 and probably 1 in 1000. This is significantly greater than that found by Taylor et al. (1995) in a study to assess the effectiveness of different types of rendering processes. Taylor showed that some types of rendering could reduce infectivity by a factor of 50 to 100. However, the experimental procedure was not able to demonstrate any greater reductions due to a low titre of infectivity in the starting material.

The studies of Schreuder et al. are more relevant to the Rendac Bergum facility and their results will be used here. We propose to adopt a conservative estimate of a 200 fold reduction of infectivity in the MBM as the best estimate with a 95 percentile figure of 1000.

Taylor et al. (1995) also tested for the presence of infectivity in the fat stream. They tested unfiltered tallow from 2 processes and found no detectable infectivity. In one of the processes the level of infectivity in the MBM was similar to that in the raw material (i.e. there had been no significant reduction in infectivity) and yet there was still no infectivity detected in the tallow. From this result it has been assumed that any infectivity remaining after rendering would be associated with the MBM, and that any solids in the condensate or tallow streams would be assumed to have the same infectivity as the MBM.

This position is supported by the Scientific Steering Committee of the EC in their revised Opinion on the safety of tallow (SSC, 2001). In this Opinion the SSC concludes that 'There is no evidence that tallow derived from ruminant animals would constitute a TSE risk. The SSC considers that possible TSE risks associated with tallow will result from protein impurities that may be present in the end product, …' In the accompanying report, the limitations of the techniques for assessing residual TSE infectivity are recognised, and it is stated that it is not possible to absolutely exclude any risk of BSE infectivity being present in tallow.

No further consideration is given to this issue in this study as a low level of infectivity in the fat stream would be of little significance since all of the fat produced by Rendac Bergum is either burned in the boilers or sent for incineration.

Burning MBM associated with fat in the boiler has been assumed to result in a reduction factor of one million in accordance with previous advice from SEAC (DNV, 1997b).

5.2 Main Processing Line

5.2.1 Overview

The production process for SRM is geared to process the raw materials into MBM and fat. Raw materials are consecutively reduced, cleared of metal, ground, evaporated and sterilised, with all end product materials destroyed by incineration. SRM is processed via an independent line within the Rendac Bergum plant and the system is designed to ensure segregation of this material from other processing streams that may be subject to lower levels of containment and disposal.

A somewhat simplified model has been produced for the purpose of this study with the process broken down into a number of steps, namely: Reception, Metal detection / size reduction hall, Vaporisation, Sterilisation and de-fatting, and Milling and storage. The reason for the simplification is to present events at the level of complexity required to make the assessment meaningful, without introducing excessive complexity and breaching commercial confidentiality associated with the process, but includes all the details relevant for the purposes of the study.

The flow of materials through the rendering process is relatively complex, with recirculation and reintroduction of materials at various points. However, the study assumes that only materials entering or leaving the containment offered by the process are of concern. For example, there are points in the process where wash water is generated, but provided that this then enters the process it is not subjected to specific scrutiny as an individual branch in the event tree model as it remains within the containment of the main process. Any materials that are simply recirculated will be ignored for the purposes of the model since they do not

lead to either a net increase in the potential infectivity processed, nor to release of these materials to the environment. These areas are referenced in the text where they occur.

Table 5.1 summarises the stages in the process where materials are either removed as part of a waste stream or as products.

	Product					
Activity	Waste water	Air	Vapour	Metal	MBM	Fat
Reception	✓*	✓				
Metal detection / size reduction		✓		✓		
Vaporisation	✓	✓	✓			✓
Sterilisation & de-fatting	✓	✓	✓			✓
Milling and storage		✓		✓	✓	

Table 5.1: Products Produced in Processing SRM
**Material passed to sewage treatment only in the event of a spillage outside the reception building (see Appendix II, Abnormal release Scenarios).*

As the distribution and flow of MBM through the process is central to modelling potentially infective material within the plant, values have been assigned to product and waste streams to reflect the associated proportion of solid material. Detailed descriptions of the data used and assumptions made are shown in Appendix III.

The following sections describe each of the main process activities in detail, together with their associated waste and product streams.

5.2.2 Reception

Dedicated vehicles are used to collect SRM and these follow a defined route within the plant before being unloaded in a dedicated bay. The reception area is enclosed within a building and serviced by dedicated drains in order that any wash or spillage in this area is fed into the process. Drains outside this building feed to the plant's own waste water treatment plant.

It is considered unlikely that a major spillage would occur outside the reception building, but if this were to happen measures are in place to prevent materials entering the sewage treatment plant through the use of inflatable barriers in the drainage system. This material would then be pumped from the drains and fed back into the process. This measure is in place to avoid potential release of infective materials, but also as protection against large amounts of organic matter entering the water treatment plant directly and upsetting the microbial degradation of waste that occurs in the treatment process. This possibility has also been described as a scenario under the section of the report that identifies and describes the consequences of Abnormal Releases (Appendix II).

Raw materials are deposited into one of three bunkers by a lifting plateau, before the trucks are cleaned and disinfected in the wash bay, with all cleaning and waste materials entering the process. Waste material will mainly be associated with wash water that is fed into the

process via the dirty water tank, with any solid material entering the bunkers for processing. The veterinary / public health inspectors on site supervise activities in the Reception area including the cleaning and disinfection of vehicles.

5.2.3 Metal Detection & Size Reduction Hall

Raw materials are transported from the bunkers by sealed transport screws to pre-breakers where it is crushed. Metal detectors are then used to divide the reduced material into metal-free and metal-containing lines, before these are transported to separate weighing bunkers. The metal-free material is then further reduced in fine breakers and routed to the rough tank.

The metal-containing material is heated in a pre-cooker to 145^{o}C and 4 bar gauge for about 1 hour. The cooked material is passed through a filter plate in the pre-cooker from where it is mixed with the metal free material in the rough tank. The combined material is mixed with fat, recycled from later in the process, before being further reduced in disintegrators. The slurry produced is then transported via a fine tank to the three-stage evaporation installation.

The metal material remaining in the pre-cooker is removed regularly (about once a week) treated with a caustic solution and transported off site as production waste, with the wash solution fed back into the process. Although it is considered highly unlikely that there will be significant infectivity associated with the cleaned metal fraction, it has been included in the study model. It has been assumed that 1kg/tonne of raw material solids will be associated with the metal stream. It is likely that both the cooking and the caustic treatment would result in some reduction in infective load, but this has not been considered. In the cooking process there were no indications for the occurrence of concentration through evaporation or smearing of dried out material, that may reduce the effectiveness of autoclaving as described by Taylor et al. (1999). Therefore this has also not been considered. The only other waste product from this stage is air, as described in Section 6.3.

5.2.4 Vaporisation

The processing of the reduced material takes place in the Vaporisation stage where it is separated into solids and fat. The solid portion is sent to the autoclave via a weighing bunker for further processing, and the separated fat is treated into a finished product or reintroduced into the process via fat recycling tanks.

Fat generated by the process is either removed as fat product or recirculated to act as a carrier for the MBM and maintain the consistency of the product. However, as the recirculated material does not involve the release of potentially infective material, this aspect does not form part of the model. Of the 800 tonnes of fat removed from the process each week, approximately 97% is generated from the Vaporisation stage and the remainder from the Sterilisation phase.

Fat is removed from the process during Vaporisation and Sterilisation. Approximately 25% (200 tonnes) of the fat produced is burned in the plant's boilers, although it is planned in the future to burn all of the fat on site. The risk associated with this possibility is described as one of the Abnormal Release Scenarios (Appendix II).

In the evaporator the slurry is further dried to the desired moisture content, and the vapour produced transported to the second stage. The dried slurry is then passed to decanters, where it is separated into (coarse) fat and dry solids (half-product). During Vaporisation half-product fat is produced and vapour driven off the mixture to form condensate.

Vapour produced during Vaporisation and Sterilisation consists of two fractions; condensate and non-condensables. The condensate is cooled to produce waste water that is routed to the waste water treatment plant, whereas the non-condensate remains in the vapour phase and is washed before being sent to be burned in the boilers. This was introduced as an odour control measure, but will also reduce the risk of infectivity being discharged by this route. It has been assumed that 90% of the solid material associated with the condensate will be derived from the Vaporisation stage, with the remaining 10% from Sterilisation.

The washed solid from the non-condensate is likely to comprise a small fraction of the material going to the water treatment plant. Since this portion will be treated in the same manner as the solid material derived from condensate and is likely to comprise a relatively small portion of such, for the purposes of this study it has been included as an unspecified part of the condensate fraction.

5.2.5 Sterilisation & De-fatting

Half-product from the decanters is transported to autoclaves via weighing bunkers using screws where it is sterilised and further dried. The autoclaves are fitted with a heat mantle and mixing apparatus. For the purposes of this study it will be assumed that Sterilisation is the only point in the rendering process where the level of infectivity will be reduced through treatment (Section 4.3). Sterilisation also results in the production of vapour and fat from the process, with the vapour fraction forming condensate and non-condensate fractions.

Sterilisation occurs under steam pressure where materials are heated to 133 ºC and 3 bar pressure for 20 minutes. After each batch, the contents of the autoclave are removed and brought to a drain bunker using transport screws. The remaining fat from the autoclaved half-product is gravity separated in the drain bunker. Fat from the drain bunker and extraction presses is then pumped from a fat tank via a vibrating sieve into fat recycling tanks, with any meal caught in the vibrating sieve reintroduced into the drain bunker. The half-product is then transported to the mechanical fat extraction presses where the remaining fat is removed. The meal product, known as crackling, is then transported to the cool bunker.

A number of safeguards and controls are in place to ensure that the sterilisation process is conducted in accordance with the required time, temperature and pressure. These include a series of alarms, automated procedures controlling the sterilisation procedures, and physical interlocks which ensure that the cycle has to be completed before vessels can be opened.

Surplus fat from the decanters that is not brought back into circulation is purified in a decanter, with the separated solids transported back to the fat extraction presses. The fat produced at the Sterilisation stage (3% of the total fat removed from the system) is pumped via precipitation tanks and a filter into storage tanks before incineration. The same proportion of the fat produced as in Vaporisation (approximately 25%) is burned in the plant's boiler house.

5.2.6 Milling & Storage

Crackling is transported from the cool bunkers and combined with blood meal. Any remaining metal is then removed from the coarse parts of the product before it is further reduced in hammer mills via dosage bunkers. Fine parts are weighed before remaining hair is extracted using a flat sieve. The product is then brought up to the desired moisture content and transported via mixing silos to the storage silos, which feed two granule press installations. Any particles contained in the cooling air is extracted in cyclones and transported to the air treatment installation for purification. The granulated meal is transported off from separate silos via a loading bay. Where required, non-granulated meal can be transported from the storage tanks in bulk.

6. Product and Waste Processing

Throughout the rendering process there are stages where materials are removed either as product or waste materials. Figure 6.1 shows the event tree that has been used to model these events, which are described in the following sections. All event trees and associated data tables are contained in Appendix III.

6.1 MBM and Fat

MBM and fat are the products of the rendering process and would normally be sold for incorporation into other products, including fertiliser and animal feeds. However, due to the nature of the material used to produce these products they are sent for disposal by incineration. The scope of this study does not include the fate of the products of incineration, although this will almost certainly further reduce the potential infectivity by several orders of magnitude.

6.2 Waste Water Treatment

All waste water produced on the Rendac Bergum plant is treated in the dedicated treatment plant on site. Sources of waste water from the process have been taken as condensate from Vaporisation and Sterilisation, together with wash water used to remove particulates from air and non-condensates. In addition, waste water is received from the other process facilities on the site.

The flow of liquid into the sewage treatment plant is approximately 600,000 m^3 per year. Less than 40% of this amount is related to the processing of slaughter byproducts etc. and has a suspended solid content of 0.01-0.02%. The remaining liquid flow comes from cleaning water and rainfall. For the model an assumed value of 0.02% solid content in 600.000 m^3 was taken. Of this solid material the fat content has been measured to be approximately 150-300 mg/l (assumed value 150 mg/l). The difference between the suspended solid content and that accounted for by the fat fraction is therefore 30 tonnes per year. However, the total tonnage of solid material removed as sludge from the water treatment plant is approximately 1,000 tonnes per year. This discrepancy is accounted for by the addition of other materials including dust, leaves, solids from other processing lines (e.g. feathers and hair lines), and the products of microbial growth within the waste water treatment plant. Sludge from the treatment plant is removed by tankers and would normally be fed into a deep well oxidation facility, where it is oxidised under conditions of high temperature and pressure. In times when the deep well oxidation facility is out of commission the material can be disposed of by dumping at landfill sites or spreading on the land as fertiliser in accordance with current legislation.

For the purposes of the study a simplified model of waste water treatment has been adopted, where a series of filters remove a large portion of the solid material from the process with the remainder discharged to the canal at a suspended solid concentration of 5mg/litre (Figure 6.2).

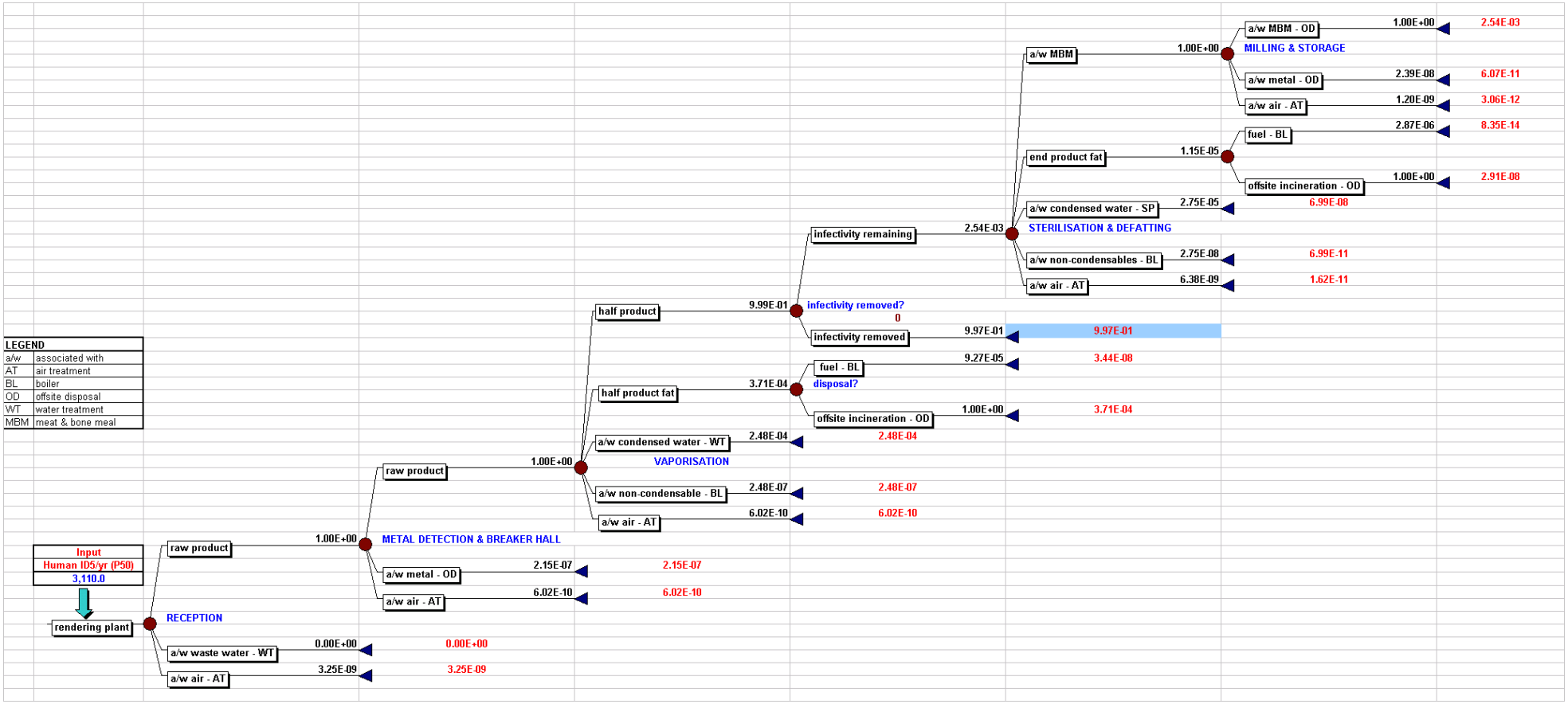
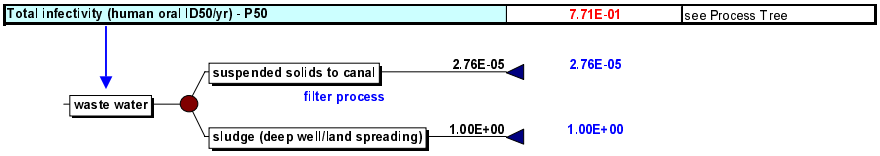


Figure 6.1: Event Tree for Rendering Process (For further explanation see also appendix II)



Output - Infectivity Pathways and Fractions					
ref	Parameters	Probability	Human Oral ID_{50} Units	Dilution Factor	Infectivity
WT10	Fraction of infectivity released to canal	2.76E-05	2.13E-05	6.00E+05	3.54E-11
WT11	Fraction of infectivity to deep well oxidation/land spreading	1.00E+00	7.71E-01	3.00E+01	2.57E-02
	totals	1.00E+00	7.71E-01		

Figure 6.2: Event Tree for Waste Water Treatment

6.3 Air Treatment

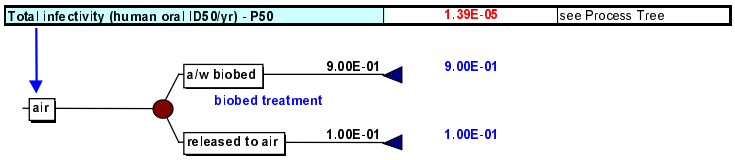
All activities associated with the rendering process involve the removal of air from the plant and surrounding areas. This measure is designed both to remove potential aerosols and control odours. Table 6.1 summarises the volumes of air removed from the areas of the plant and the volumes these would represent over a year, assuming the system operates 24 hours a day, 365 days a year.

Activity	Volume (m^3/hr)	Volume (m^3/yr)
Reception	40,000	3.5×10^8
Metal detection / size reduction hall	7,500	6.6×10^7
Vaporisation	7,500	6.6×10^7
Sterilisation & de-fatting	80,000	7.0×10^8
Milling and storage	15,000	1.3×10^8
TOTAL	150,000	1.3×10^9

Table 6.1: Sources of Air Released from the Rendering Process

Solid material is removed from the air using firstly a series of scrubbers and then passing through a water bath of approximately 1 metre depth beneath the biofiltration beds. The solids removed by this washing process are assumed to enter the water treatment process, and are likely to comprise a small fraction of the material going to the water treatment plant. Since this portion will be treated in the same manner as the solid material derived from condensate and is likely to comprise a relatively small portion of such, for the purposes of this study it has been included as an unspecified part of the condensate fraction.

The fraction of solid material that will pass through the scrubber and water bath located beneath the biobed is not known precisely. However, it has been assumed that under normal operating conditions this is likely to be extremely low, and 1 $\mu g/m^3$ has been assumed as a highly conservative estimate. Fractions of this material have been allocated to the air streams originating from different processes in accordance with the volumes of air processed, reflecting stages before and after sterilisation has taken place. It has also been assumed that 90% of the particulate matter will adhere to the biobed material. The biobed material itself is used for 2 –3 years before being buried in the grounds of the plant. Figure 6.3 shows the event tree and probability values for air treatment.

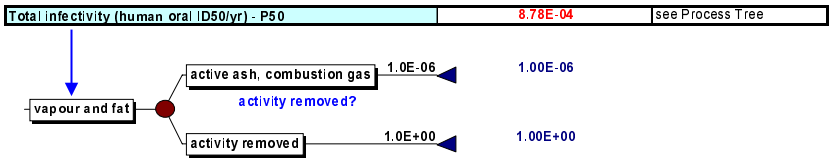


Output - Infectivity Pathways and Fractions				
ref	Parameters	Probability	Human Oral ID_{50} units	Comments
AW03	Fraction infectivity associated with biobed	9.00E-01	1.25E-05	
AW04	Fraction infectivity released to air	1.00E-01	1.39E-06	
	totals	1.00E+00	1.39E-05	

Figure 6.3: Event Tree for Air Treatment

6.4 Combustion in Boilers

Non-condensable gases produced during Vaporisation and Sterilisation are burned in the boiler, together with 25% of the fat produced. It has been assumed that a reduction of one million fold will be produced when material is burned in this way (Section 4.3). Negligible quantities of soot were reported to remain in the boiler and it has been assumed that all particulate material will pass up the stack. Figure 6.4 shows the event tree and probability values for combustion in the boiler.



Output - Infectivity Pathways and Fractions				
ref	parameters	probability	Human Oral ID_{50} units	comments
CW01	Fraction of infectivity to combustion gas	1.00E-06	8.78E-10	
Cw02	Fraction of infectivity removed	1.00E+00	8.78E-04	
	totals	1.00E+00	8.78E-04	

Figure 6.4: Event Tree for Combustion

7. Results

The infectivity flow through the process has been modelled using a set of linked event trees. The model has been evaluated using a probabilistic risk assessment approach to reflect the uncertainties in the input parameters. Selected variables have been defined as a distribution of values and the result calculated many times using a Monte Carlo simulation tool (@risk from Palisade Corporation). The full results for the study are also shown in Appendix III, with the main result summarised in Table 7.1 below and discussed in the accompanying sections.

The risk is presented as the expected discharge of infectivity into the environment expressed in terms of human oral ID_{50} units. A worst case assumption would be that exposure to one human oral ID_{50} unit would result in a 50% chance of infection and similarly exposure to 0.1 of an ID_{50} would result in a risk of infection of 5%. This is based on the underlying assumption that there is a linear dose response relationship and that there is no safe threshold. This is likely to be very pessimistic, especially for very low exposures.

7.1 Normal Operation Conditions

Table 7.1 shows the total amount of infectivity associated with the product and waste streams from the Rendac Bergum plant, based upon the input data provided for this study. Values are shown as the median (P50), 5 percentile (P5) and 95 percentile (P95) values. Values referred to in the report are median values unless otherwise stated.

	human oral ID_{50} units		
Parameter	**P5**	**P50**	**P95**
Infectivity entering process	53	3,110	114,000
Infectivity removed			
Infectivity removed during rendering	53	3,100	113,640
Infectivity removed in boilers	1.5×10^{-5}	8.8×10^{-4}	3.2×10^{-2}
Total infectivity removed	53	3,100	113,640
Infectivity to offsite disposal			
Infectivity associated with MBM product	1.3×10^{-1}	8	289
Infectivity associated with fat product	2.0×10^{-2}	1	42
Infectivity associated with metal	1.1×10^{-5}	6.7×10^{-4}	2.5×10^{-2}
Total infectivity to offsite disposal	1.5×10^{-1}	9	332
Infectivity to environment			
Infectivity released to canal	3.6×10^{-7}	2.1×10^{-5}	7.8×10^{-4}
Infectivity associated with WTP sludge	1.3×10^{-2}	7.7×10^{-1}	28
Infectivity released to air	2.4×10^{-8}	1.4×10^{-6}	5.1×10^{-5}
Infectivity associated with biofilter	2.1×10^{-7}	1.3×10^{-5}	4.6×10^{-4}
Infectivity released with combustion gas	1.5×10^{-11}	8.8×10^{-10}	3.2×10^{-8}
Total infectivity released to environment	1.3×10^{-2}	7.7×10^{-1}	28

Table 7.1: Summary of Infectivity Associated with Product / Waste Streams

7.1.1 Infectivity Removed

The model indicates that approximately 99% of the infectivity associated with processing the material is inactivated as a consequence of the rendering process. This includes material inactivated through the Sterilisation phase, together with further reduction that occurs as a consequence of burning fat and non-condensables in the boiler.

7.1.2 Infectivity to Offsite Disposal

The levels of infectivity associated with MBM and fat are 8 and 1 human oral ID_{50} units per year, representing final concentrations based on the estimated quantities of product produced of 7×10^{-8} and 2×10^{-8} human oral ID_{50} units/kg. The infectivity associated with waste metal (total value 7×10^{-4} human oral ID_{50} units per year) is very low.

7.1.3 Infectivity to Environment

The most significant source of infective material to be disposed to the environment is the sludge from the waste water treatment plant with 1 human oral ID_{50} units per year. This would normally be sent to deep well oxidation but may be put in landfill or spread on the land as fertiliser if this option is not available. The levels of infectivity associated with this material can be explained as the majority of suspended solid has been assumed to come from condensate associated with the vaporisation phase, which occurs prior to sterilisation. It has been assumed that the vaporisation process does not result in any inactivation of infectivity. Given that this infectivity will be distributed within 1,000 tonnes of sludge the final concentration is relatively low at around 1×10^{-6} human oral ID_{50} units/kg.

The total amount of infectivity released to the canal is very small at 2×10^{-5} human oral ID_{50} units per year. This infectivity is released in a total discharge of 600,000 m^3 giving an extremely low concentration of 3×10^{-11} human oral ID_{50} units/m^3.

Very low amounts of material are associated with the biofilter (1×10^{-5} human oral ID_{50} units per year) and burial of this material is therefore considered to be of very low risk. Similarly the fraction released to the air (1×10^{-6} human oral ID_{50} units) is not considered to be significant, even before a massive dilution factor is applied.

Risks associated with combustion gases are extremely low with a total emission value of 9×10^{-10} human oral ID_{50} units. This figure is largely due to the large reduction in infectivity through burning material in the boilers.

7.1.4 Risk Assessment

In order to put these values into context we can consider the risk to a person drinking the effluent from the waste water treatment plant before it is discharged to the canal. The following example examines the risks associated with drinking the effluent discharged to the canal, an unlikely eventuality in itself.

1. Discharge to canal has 2 x 10^{-5} (P50) or 8 x 10^{-4} (P95) ID_{50} units per year in a discharge of 600,000 m^3.

2. A typical person drinks 2 litres water per day (730 l/year).

3. If a person were to have the discharge to the canal as their sole supply of drinking water, then their exposure would be:

   - P50: (2 x 10^{-5} / 600,000) * 0.73 = 2 x 10^{-11} human oral ID_{50} per year.
   - P95: (8 x 10^{-4} / 600,000) * 0.73 = 1 x 10^{-9} human oral ID_{50} per year.

4. This person's risk of infection would therefore be 1 x 10^{-11} per year, well below the negligible level of 1 x 10^{-8} per year, or 5 x 10^{-10} per year if the discharge was at the P95 level for the whole year (which is highly improbable).

The calculation indicates that if a person drank one glass of the effluent (0.5 litres), and the effluent was at the 95 percentile level, then they would consume 7 x 10^{-13} ID_{50} units and have a risk of infection of 3 x 10^{-13}. If this person were to drink only the effluent from the plant for a whole year (at 2 litres per day) then their risk of infection would be 1 x 10^{-11} per year (or 5 x 10^{-10} per year assuming that the effluent remained at the P95 value for the complete year). The risk of infection, even for this extreme scenario, is well below the negligible risk level of 1 x 10^{-8} defined by the authorities in the Netherlands (see section 3.2).

7.1.5 Abnormal Release Scenarios

Hazardous substances are often released when normal operating conditions are disrupted in some way, or the loading entering the system changes. The scenarios selected were done so in discussion with experts in the field and from a review of the issues raised at the SWIFT workshop (see Appendix I).

- Loss of containment during transportation;
- Spillage outside the Reception building;
- Increase in number of infected animals;
- Loss of containment in waste water treatment plant;
- Burning all of the fat produced in the plant's boilers.

These scenarios are described in detail in Appendix II. Although these incidents would increase the risk of release of potentially infective material, in no instance do they increase levels to a degree whereby they would be considered to pose a significant risk.

8. Conclusions and Recommendations

8.1 Conclusions

The objective of this study was to identify and, so far as possible, quantify the risks to public health from the BSE infective agent arising from the activities at the Rendac Bergum rendering plant.

After inactivation by the rendering process, most of the remaining infectivity, will be found in the Meat and Bone Meal (MBM) product: 8 human oral ID_{50} units per year. (7×10^{-8} human oral ID_{50} units per kg MBM). All of this MBM is sent offsite for disposal by incineration. Infectivity from the plant can enter the environment through one of three routes, via sludge used in landfill or spread on the land as fertilizer, via waste water discharged to the canal, or as particles released to the air.

The study has concluded that these releases of infectivity into the environment from the normal operation of the rendering plant at Sumar are extremely small and would not pose any significant risk to people living in the vicinity.

8.2 Recommendations

In general the plant was found to be well managed and the process under good control. However, there are areas where controls could be improved and the following recommendations have been made by the working group:

- The risks associated with spreading potentially infective materials on land should be evaluated and the suitability of this as a means of disposal addressed;

- Emergency response measures in place for dealing with road traffic incidents should be formalised and documented as part of the plant's quality system.

Should there be significant changes to the way the process is undertaken or to waste management controls, the assessment should be revisited in order to ensure containment levels are maintained.

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Appendix I

SWIFT findings

Det Norske Veritas			
SWIFT: BSE Risk Study of Rendac Bergum BV		**2001-09-14**	
System: 1. Main process			
Subsystems: 1.1. Reception			
What If	**Causes**	**Consequences**	**Safeguards**
1. Spillage of material			
2. Vehicle wash water	2.1.	2.1.	2.1. Dedicated vehicles for SRM.
3. Raw materials are emptied into incorrect bunkers e.g. SRM in poultry line.	3.1.	3.1. E.g. Dogs eat contaminated meal.	3.1. Bunkers can be blocked
			3.2. Ensure correct materials into correct stream.
			3.3. veterinary / public health inspectors monitor incoming raw materials
4. Wrong raw material			
5. Contamination			
Subsystems: 1.2. Metal Detection			
What If	**Causes**	**Consequences**	**Safeguards**
1. Wash water	1.1.		1.1. Return to process (evaporator)
Subsystems: 1.3. Size reduction Hall			
What If	**Causes**	**Consequences**	**Safeguards**
1. Pipe failure		1.1. Material spills on ground.	1.1. This would get washed back into process.
2. Ventilation air			2.1. All air goes to scrubber and biofiltration

3. Explosion of pressure cooker (Pre cooker operates at 4 bar, 4.5 bar steam)	3.1.	3.1. Loss of containment of process material.	3.1. Spill would be contained within building
			3.2. Pressure vessels are inspected.
		3.2. Damage to building	
		3.3. Safety fault at 4.5 bar	
Subsystems: 1.4. Vaporisation			
What If	**Causes**	**Consequences**	**Safeguards**
1. 3 Vaporisers operate at 80/150 deg C			
2. De fatting			2.1. Turbidity measurement
3. Vapour stream condensed (air and water)			
4. Spillage from vapouriser		4.1. Loss of containment of process material.	4.1. Spill would be contained within building
5. Bleeding gases from vaporiser			5.1. Bleed gases can be cleaned to avoid contamination of burner.
6. Failure of decanter. Wet slurry goes to decanter (6) to separate fat.		6.1. Loss of containment of process material.	6.1. Spill would be contained within building
			6.2. There is a loud noise if centrifuge is not well centred.

Subsystems: 1.5. Sterilisation & De fatting			
What If	**Causes**	**Consequences**	**Safeguards**
1. 12m^3 vessels. 5% of material (water) evaporates when vessel is opened.			1.1. Cyclones remove particles
2. Material is screwed out			
3. Drain bunker removes fat by gravity, then mechanical separation. Fat is cleaned, meal is cooled down in water cooled screw before milling & pelletising. Cooling water is well water.		3.1. Cooling water goes to canal. No risk of contamination.	3.1. Vent air is burned in boiler house.
Subsystems: 1.6. Milling			
What If	**Causes**	**Consequences**	**Safeguards**
Subsystems: 1.7. Silos and Pelletiser			
What If	**Causes**	**Consequences**	**Safeguards**
Subsystems: 1.8. Fat Stream			
What If	**Causes**	**Consequences**	**Safeguards**

Appendix II

Abnormal Release Scenarios

II. Abnormal Release Scenarios

Section 7 of the report described the estimated release of infective materials under normal operating conditions at the plant. However, it is recognised that very often hazardous substances are released when these normal operating conditions are disrupted in some way, or the loading entering the system changes. A number of scenarios are therefore described that represent a selection of the sorts of events that could occur and how these would alter the levels of infectivity potentially released to the environment.

The scenarios selected were done so in discussion with experts in the field and from a review of the issues raised at the SWIFT workshop (see Appendix I).

- Loss of containment during transportation
- Spillage outside the Reception building
- Increase in number of infected animals
- Loss of containment in waste water treatment plant
- Burning all of the fat produced in the plant's boilers

II.1 Loss of Containment During Transportation

Trucks are used to transport BSE positive animals and tissues to Sumar. These animals may have come from abattoirs or farms, located all over the Netherlands. In the event of an accident there is the possibility that there will be a release of material and this could have consequences for those in the surrounding area.

It will be assumed that there is an equal probability that infected material may be present in any of the deliveries to the plant. An event tree (Figure II.1) has been used to estimate the probability of an accident leading to a release of infective material and Table II.1 shows the input data used to derive the associated probability values.

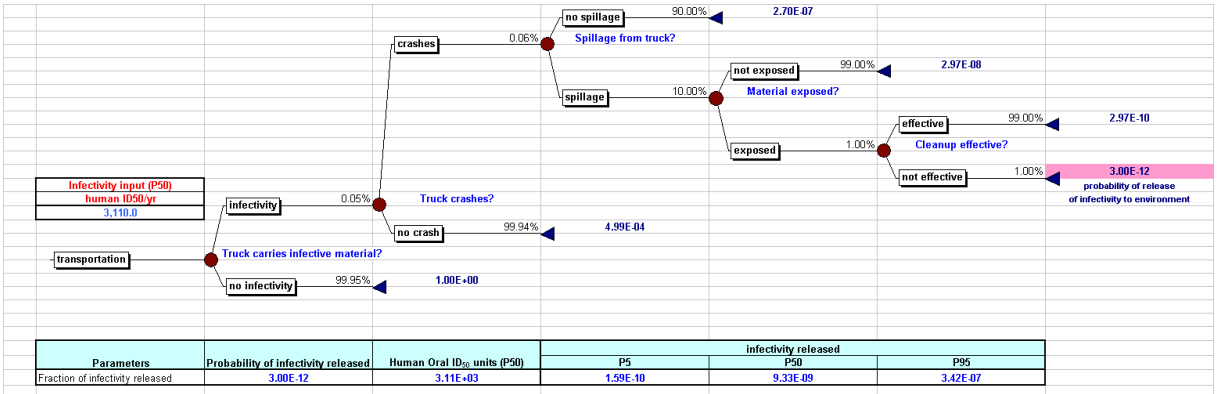


Figure II.1: Event Tree for Transportation of SRM

Parameter	Value	Units	Assumption
Material Transported by Road			
Total tonnage transported by road hauliers in the Netherlands in 2000	431,149,000	tonnes	Data from the Information Service on Traffic and Transport
Total number of truck accidents in the Netherlands	22,865	Nr /year	As above
Truck accidents per tonne transported	5.3×10^{-5}		Number of accidents divided by the tonnage transported
Total tonnage of SRM transported by plant	453,455	tonnes	Data supplied by plant
Inferred number of truck accidents by Rendac Bergum vehicles	24	Nr/ year	Number of tonnes transported by Rendac multiplied by number of accidents per tonne
Infectivity on truck			
Number of journeys per year by Rendac vehicles	40,040		140 journeys per day, assuming operating 5.5 operating days per week
Number of infected carcasses per year	20		Base assumption
Proportion of journeys transporting infected carcasses	5.0×10^{-4}		Number of infected animals divided by the total number of journeys
Proportion of trucks that crash	6.0×10^{-4}		Number of truck accidents divided by number of journeys per year
Proportion of accidents that result in break in containment	10%		Assumes 10% of crashes result in loss of containment
Proportion of crashes where there is a release of infective material	10%		Assumes that in the event of loss of containment, 10% of the infectivity is released
Proportion of material not recovered and disposed of securely during clean up	1%		Assumes that clean up is 99% effective in collecting and disposing of spillage materials

Table II.1: Input Data and Assumptions for Road Transport Model

The model was run using the same range of input values for infectivity as for the 'normal operating conditions' scenario. Data supplied by the Information Service on Traffic and Transport was used to calculate the number of road accidents per tonne of material transported in the Netherlands. A factor of accidents per tonne transported was then generated and applied to the tonnage of material transported to the plant (453,455 tonnes). As the number of deliveries to the plant per day was known (165), it was assumed that the total number of deliveries per year would be 165 x 5.5 (operational days in the week) x 52 (weeks).

As leak proof containers are used to transport material, the risk of breaking the containment in the event of an accident is assumed to be the same as that recorded for accidents resulting

in personal injury in the Netherlands (10%). Similarly as the infectious material in the carcass will be largely contained within the skull and spinal column, the probability of a release of potentially infective material from within the carcass is considered to be similarly small, and again the factor of 10% has been applied. Finally, even in the event of an accident the material spilled will be cleaned up by plant staff, and as the material is likely to be composed of large pieces of tissue the cleanup process has been assumed to be 99% effective.

Table II.2 shows that the amount of material released through transportation of carcasses to the plant is likely to be very low at 9×10^{-9} human oral ID_{50} units. As more than 99% of infectivity is removed by the rendering process, this implies that the risk associated with transportation of product from the plant will be considerably lower.

Parameter	**human oral ID_{50} units**		
	P5	**P50**	**P95**
Infectivity transported to plant	53	3,110	114,000
Infectivity released from accidents	1.6×10^{-10}	9.3×10^{-9}	3.4×10^{-7}

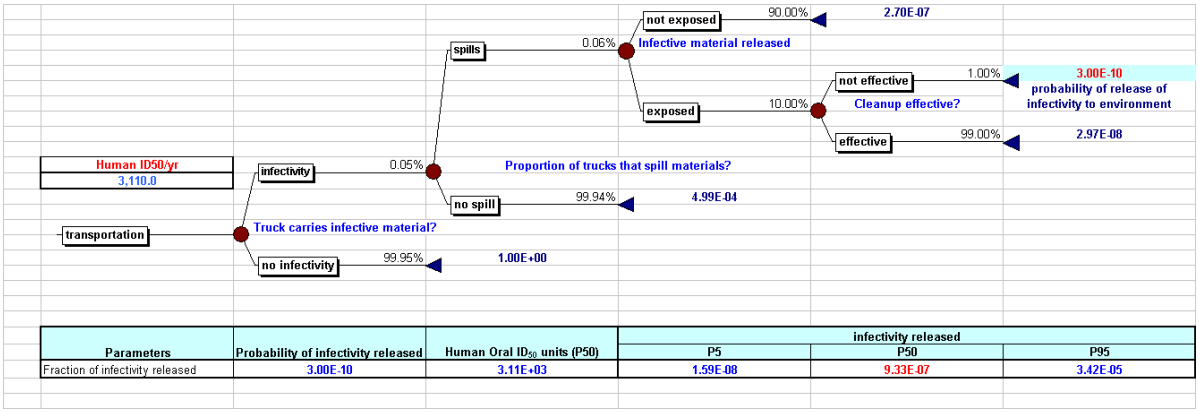
Table II.2: Summary of Infectivity Associated with Road Transport of SRM to the Rendac Bergum Plant

This result may be open to misinterpretation in that the release of such a small amount in the event of an accident is impossible to predict accurately. However, with only 20 carcasses being transported on almost 45,000 journeys, combined with the chance of there being a break in containment followed by a release of material that is not cleaned up, transportation is considered to represent minimal risk. However, it cannot be ignored that the possibility of release of material to the environment does exist and emergency plans should be in place. These should be designed to ensure that the potential nature of the load is clearly identified to those dealing with an accident, and adequate emergency response personnel and equipment are available.

II.2 Spillage Outside the Reception Building

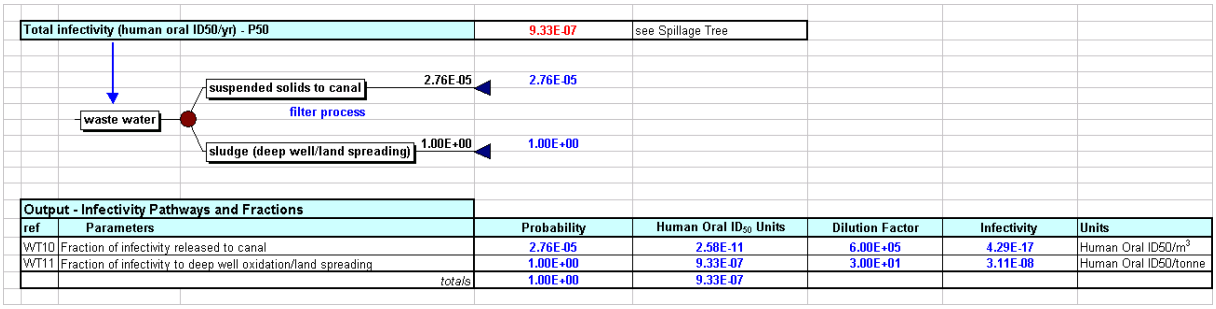
Although containment measures within the plant ensure that spillages are fed back into the process, the possibility exists that a spillage outside the reception building would result in untreated material entering the water treatment plant directly. Whilst this is considered unlikely and measures are in place to manage such an eventuality, such an event has been modelled to show the likely effect on discharge to the canal.

The scenario considers that the event occurs on the same number of occasions as a road traffic accident and is based upon the same model. It is assumed that by definition material is released from the containment of the vehicle, but all other parameters are the same. There is also an additional step where the filtration system in the plant will remove infectivity, and this value has been set to the same as for the main process model. Figures II.2 and II.3 show the event trees used for the spillage scenario and Table II.3 shows median, P5 and P95 values for the scenario described.



Parameters	Probability of infectivity released	Human Oral ID_{50} units (P50)	infectivity released		
			P5	P50	P95
Fraction of infectivity released	3.00E-10	3.11E+03	1.59E-08	9.33E-07	3.42E-05

Figure II.2: Event Tree for Spillage Outside Reception Building



Output - Infectivity Pathways and Fractions						
ref	Parameters	Probability	Human Oral ID_{50} Units	Dilution Factor	Infectivity	Units
WT10	Fraction of infectivity released to canal	2.76E-05	2.58E-11	6.00E+05	4.29E-17	Human Oral ID50/m^3
WT11	Fraction of infectivity to deep well oxidation/land spreading	1.00E+00	9.33E-07	3.00E+01	3.11E-08	Human Oral ID50/tonne
	totals	1.00E+00	9.33E-07			

Figure II.3: Event Tree for Environmental Pathways

Parameter	human oral ID_{50} units		
	P5	P50	P95
Infectivity entering process	53	3,110	114,000
Infectivity released to canal	4.4×10^{-13}	2.6×10^{-11}	9.5×10^{-10}
Infectivity associated with WTP sludge	1.6×10^{-8}	9.3×10^{-7}	3.4×10^{-5}

Table II.3: Summary of Infectivity Associated with Product / Waste Streams for Spillage of Material Outside the Reception Building

From the results it can be seen that this would result in an additional discharge to the canal (over and above that of the normal process) of 3×10^{-11} human oral ID_{50} units. This figure remains insignificant in relation to the risk posed by the discharge. The infectivity associated with the sludge is increased by 9×10^{-7} human oral ID_{50} units. These values indicate that there are very low levels of risk associated with a spillage of material outside the Reception building.

II.3 Increase in Number of Infected Animals Processed

The amount of infective material entering the rendering process is clearly an important aspect in assessing the potential risk for release to the environment. The figures used in the study probably represent an over-estimate of the levels of infectivity as it assumed that all animals were infected at the clinical level, even though at least 11 of the 20 animals were detected at the subclinical level. In order to assess the likely loading on the system, the number of clinically infected animals processed was increased to 100, five times the number in 2001. Table II.4 shows median, P5 and P95 values for the scenarios where 100 carcasses are processed.

From the results it can be seen that even when levels are increased to 100 cases, the result is the equivalent of an increase in all parameters of half of one log order of magnitude. In relation to releases to the environment this would result in values for discharge to the canal of 2×10^{-10} human oral ID_{50} units per m^3 once the dilution factor has been applied. This figure remains insignificant in relation to the risk posed by the discharge. Similarly the values for infectivity released to the air, in combustion gas and associated with the biofilter do no increase to levels of concern (7×10^{-6}, 4×10^{-9} and 6×10^{-5} human oral ID_{50} units respectively), even before further dilution factors are applied.

Parameter	human oral ID_{50} units		
	P5	**P50**	**P95**
Infectivity entering process	265	1,550	570,000
Infectivity removed			
Infectivity removed during rendering	264	15,501	568,119
Infectivity removed in boilers	7.5×10^{-5}	4.4×10^{-3}	1.6×10^{-1}
Total infectivity removed	264	15,501	568,119
Infectivity to offsite disposal			
Infectivity associated with MBM product	6.7×10^{-1}	39	1,447
Infectivity associated with fat product	9.8×10^{-2}	6	211
Infectivity associated with metal	5.7×10^{-5}	3.3×10^{-3}	1.2×10^{-1}
Total infectivity to offsite disposal	7.7×10^{-1}	45	1,659
Infectivity to environment			
Infectivity released to canal	1.8×10^{-6}	1.1×10^{-4}	3.9×10^{-3}
Infectivity associated with WTP sludge	6.6×10^{-2}	4	141
Infectivity released to air	1.2×10^{-7}	6.9×10^{-6}	2.5×10^{-4}
Infectivity associated with biofilter	1.1×10^{-6}	6.3×10^{-5}	2.3×10^{-3}
Infectivity released with combustion gas	7.5×10^{-11}	4.4×10^{-9}	1.6×10^{-7}
Total infectivity released to environment	6.6×10^{-2}	4	141

Table II.4: Summary of Infectivity Associated with Product / Waste Streams for Processing 100 Positive Cases

II.4 Loss of Containment in Waste Water Treatment Plant

It is possible that there could be an increased discharge to the canal through failure in the waste water treatment plant. This might be brought about by a system failure or extreme environmental conditions, although a series of alarms, and contingency measures including surplus capacity, are in place making this an unlikely eventuality. However, for the purposes of the scenario it has been assumed that the event occurs once in the year and lasts for one day. During that day the discharge is 200 times greater than normal at 1 g/l of suspended solid. The result of this increase is the equivalent of an increase in the annual average release to the canal of 7.7 mg/l. The results are shown below in table II.6.

Parameter	human oral ID_{50} units		
	P5	P50	P95
Infectivity entering process	53	3,110	114,000
Infectivity released to canal	5.5×10^{-7}	3.2×10^{-5}	1.2×10^{-3}

Table II.5: Summary of Infectivity Associated with an Increase of 200 Fold in the Suspended Solids Discharged to the Canal on One Day

Even when the amount of material is increased 200 fold for an entire day, the levels of infectivity entering the canal are insignificant at 3×10^{-5} human oral ID_{50} units.

II.5 Burning All Fat Produced in the Boilers

The current situation is that approximately 25% of the fat removed from the rendering process is burned in the boilers as fuel. However, in the future it is planned to increase this amount to all of the fat produced. Table II.4 shows median, P5 and P95 values for the scenarios where all of the fat is burned.

Parameter	human oral ID_{50} units		
	P5	P50	P95
Infectivity entering process	53	3,110	114,000
Infectivity removed in boilers	2.0×10^{-5}	1.2×10^{-3}	4.4×10^{-2}
Infectivity released with combustion gas	2.0×10^{-11}	1.2×10^{-9}	4.4×10^{-8}

Table II.6: Summary of Infectivity Associated with Burning All Fat Produced by the Rendering Process

From the results it can be seen that even when all fat is burned in the boilers the result is the equivalent of an increase in the amount of infectivity associated with combustion gas of less than one half of one log order of magnitude. In relation to releases to the environment this would result in a release to the air of 1.2×10^{-9} human oral ID_{50} units. This figure remains insignificant in relation to the risk posed by the discharge.

Appendix III

Rendering plant model and input data

Input Data - Infectivity						
ref	parameter	low P5	ML/mean	high P95	*exp*	assumptions
DI01	Number of infected cattle rendered	n/a	**20**	n/a	**20**	Assume fixed
DI02	Weight of infected material per animal (g)	n/a	**750**	n/a	**750**	Assume fixed
DI03	Species barrier	n/a	n/a	n/a	**1000**	Discrete distribution based on probability of 1% for value of 1, equal probability for values of 10, 100, 1000 and 10000
DI04	Infectious dose	n/a	n/a	n/a	**55.0**	Lognormal distribution with mean of 54.64 and std dev of 24.09, truncated at 10 and 1000

note - "exp" equals expected or mean value based on probabilistic distribution specified

Output Data - Infective Material						
ref	parameter	low P5	med P50	high P95	*mean*	assumptions
DI10	Total weight of infective material (g)	n/a	n/a	n/a	**15,000**	
DI11	Total infectivity (human oral ID50) base	**53**	**3,110**	**114,000**	**30,700**	base case - 20 cattle, 750 g per animal infected material
DI12	Total infectivity (human oral ID50) new	**53**	**3,110**	**114,000**	**30,700**	new values if analysis differs from base case

note - this model fixes P5, P50, P95 and mean values for the base case (incl 20 cattle, 750 g of infected material per cattle). If latter two parameters change, or tree parameters change, all infectivity data changes proportionally.

CLIENT:	Provinsje Fryslan, The Netherlands
PROJECT:	Assessment of Risk to Public Health from the Rendac Bergum BV Rendering Plant
MODEL:	Process Plant Risk Assessment
SHEET:	2 - Process Data (PD)
DATE:	19-Mar-02
REV:	DNV 716056

Process Data Input to Process Tree Model

bold values calculated from input (input not bold)

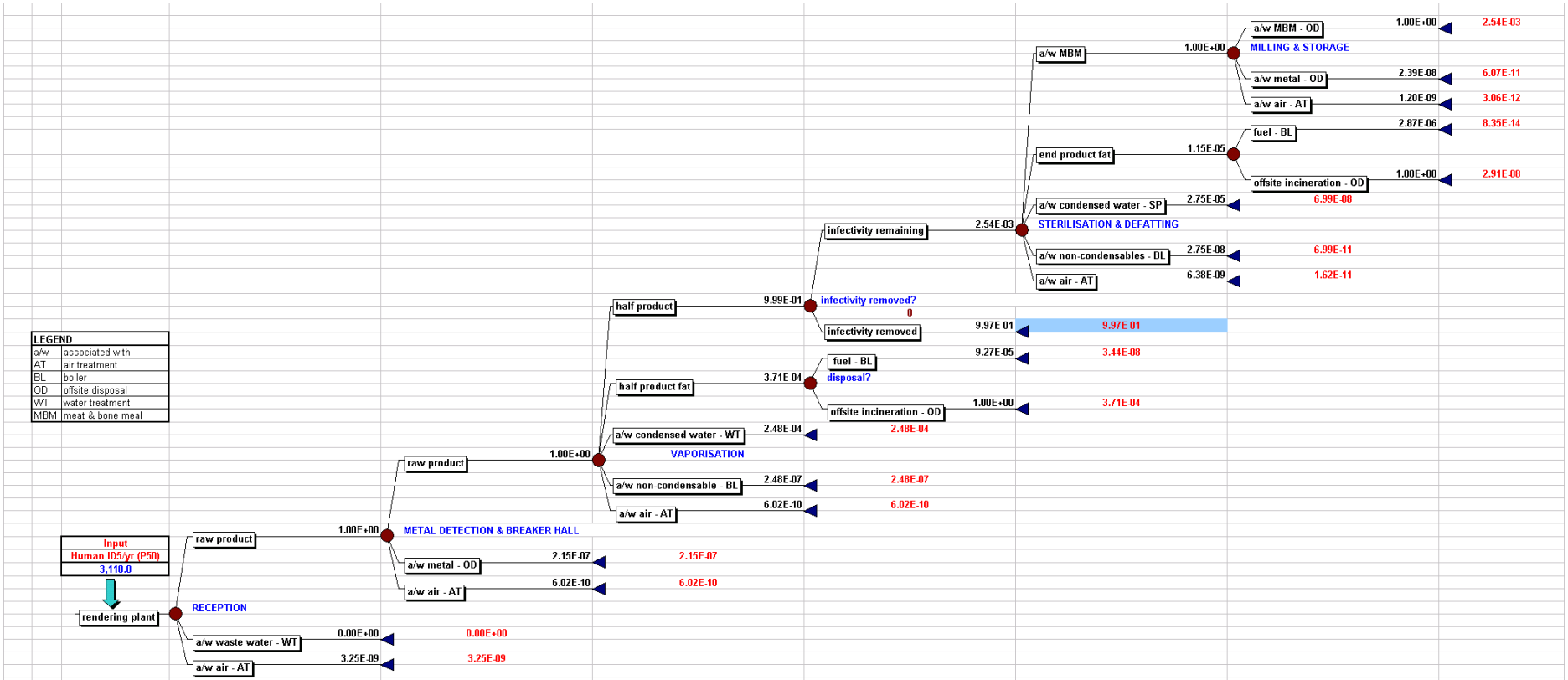
Ref	Parameter	Value	Units	Assumption
	Solid Input into Rendering Process			
PD01	Input of SRM material in tonnes	453,455	tonnes/year	2001 data supplied by plant.
PD02	Percentage of MBM	24.0%		Assumes approximate breakdown of raw materials of 24% MBM, 12% fat and 64% water
PD03	Total solid material rendered	**108,829**	tonnes/year	24% of total SRM input to process
	Solid Associated with Waste Water			
PD04	Total volume waste water produced per year	600,000	m^3/year	Volume of waste water input to and discharged from water treatment plant. Supplied by plant.
PD05	Total suspended solid in waste water entering treatment plant	0.02%		Data supplied by plant. Includes fat and MBM.
PD06	Total amount of solid entering water treatment plant	**120.0**	tonnes	Comprises fat and solid fraction (i.e. MBM)
PD07	Concentration of fat in waste water entering treatment plant	150	g/m^3	Data supplied by plant
PD08	Amount of total attributable to fat	**90.0**	tonnes	Concentration of fat multiplied by volume
PD09	Total amount of solid entering water treatment plant associated with MBM	**30.0**	tonnes/year	Amount of solid assocaited with MBM entering water treatment plant (N.B. excludes fat fraction)
PD10	Suspended solid content (MBM) of water stream entering water treatment plant	**0.050**	kg/m^3	Total suspended solid content based upon 30 tonnes of solid and input volume of 600,000m^3.
	Solid Associated with Condensables			
PD11	Proportion of solid associated with condensables	99.90%		Assumes 99.9% of solid associated with condensate fraction.
PD12	Total solid entering water treatment plant from condensables	**29.97**	tonnes/year	99.9% of 30 tonnes (total solid input to water treatment)
PD13	Proportion solid entering water treatment plant associated with condensables	**2.75E-04**		Solid from condensables / total solid entering process
	Reception			
PD14	Proportion of suspended solid	0%		No release from reception under normal operating conditions
PD15	Amount of solid associated with waste water	**0.0**	tonnes/year	
PD16	Proportion of total solid	**0.E+00**		
	Vaporisation			
PD17	Proportion of solid associated with vaporisation	90.0%		Assumes 90% of suspended solid to water treatment produced during at vaporisation
PD18	Amount of solid	**26.97**	tonnes/year	Fraction of suspended solid associated with vaporisation multiplied by total solid from condensables
PD19	Proportion of total solid	**2.48E-04**		Suspended solid produced at vaporisation divided by total tonnage of solid entering process
	Sterilisation			
PD20	Proportion of solid associated with sterilisation	10.0%		Assumes 10% of suspended solid to water treatment produced during sterilisation
PD21	Amount of solid	**2.997**	tonnes/year	Fraction of suspended solid associated with sterilisation multiplied by total solid from condensables
PD22	Proportion of total solid	**2.75E-05**		Suspended solid produced at sterilisation divided by total tonnage of solid entering process
	Solid Associated with Non-condensables			
PD23	Proportion of solid associated with non-condensables	0.10%		Assumes 0.1% of solid associated with non-condensables
PD24	Total solid entering water treatment plant from non-condensables	**0.030**	tonnes/year	0.1% of 30 tonnes (total solid input to water treatment)
PD25	Proportion solid entering water treatment plant associated with non-condensables	**2.75E-07**		Solid from non-condensables / total solid entering process
	Vaporisation			
PD26	Proportion of solid associated with vaporisation	90.0%		Assumes 90% of suspended solid to water treatment produced during at vaporisation
PD27	Amount of solid	**0.027**	tonnes/year	Fraction of suspended solid associated with vaporisation multiplied by total solid from non-condensables
PD28	Proportion of total solid	**2.48E-07**		Suspended solid produced at vaporisation divided by total tonnage of solid entering process
	Sterilisation			
PD29	Proportion of solid associated with sterilisation	10.0%		Assumes 10% of suspended solid to water treatment produced during sterilisation
PD30	Amount of solid	**0.003**	tonnes/year	
PD31	Proportion of total solid	**2.75E-08**		Suspended solid produced at sterilisation divided by total tonnage of solid entering process
	Discharge to Canal			
PD32	Suspended solid content of water discharged to canal	5.00	mg/l	Data from plant
PD33	Total suspended solid released to canal	**3.00**	tonnes/year	Based upon 5 mg/l and 600,000 m^3 discharged to canal
PD34	Proportion of total solid released to canal	**2.76E-05**		Suspended solid released to canal divided by total tonnage of solid entering process

	Solid Associated with Fat Stream			
PD35	Total tonnage of fat produced per year	**41,600**	tonnes/year	800 tonnes/week x 52 weeks/year.
PD36	Proportion of solid in fat	0.10%		Data supplied by plant
PD37	Total solid associated with fat stream	**41.60**	tonnes/year	0.10% of 41,600 tonnes
PD38	Proportion solid associated with fat stream	**3.82E-04**		Suspended solid content of fat divided by total tonnage of solid entering process
	Vaporisation			
PD39	Proportion of total fat produced at vaporisation	97.0%		Figure supplied by plant
PD40	Total amount of solid associated with fat	**40.35**	tonnes/year	Fraction of suspended solid associated with fat produced during vaporisation multiplied by total solid associated with fat
PD41	Proportion of total solid associated with fat produced during vaporisation	**0.037%**		Solid produced at vaporisation divided by total tonnage of solid entering process
PD42	Proportion of fat to boilers	25.0%		25% of fat burned in boilers
PD43	Amount of solid in fat to boilers	**10.09**	tonnes/year	25% of solid associated with fat produced during vaporisation
PD44	Proportion of solid to boilers	**9.27E-05**		Solid produced at vaporisation burned in boilers divided by total tonnage of solid entering process
PD45	Proportion of fat to incineration	75.0%		75% of fat sent to incineration
PD46	Amount of solid in fat to offsite incineration	**30.26**	tonnes/year	Amount of fat sent for offsite disposal
PD47	Proportion of solid to incineration off site	**2.78E-04**		Solid produced at vaporisation sent to incineration divided by total tonnage of solid entering process
	Sterilisation			
PD48	Proportion of total fat produced at sterilisation	3.0%		Figure supplied by plant
PD49	Total amount of solid associated with fat	**1.25**	tonnes/year	Fraction of suspended solid associated with fat produced during sterilisation multiplied by total solid associated with fat
PD50	Proportion of total solid in total fat	**1.15E-05**		Solid produced at sterilisation divided by total tonnage of solid entering process
PD51	Proportion of fat to boilers	25.0%		25% of fat burned in boilers
PD52	Amount of solid in fat to boilers	**0.31**	tonnes/year	25% of solid associated with fat produced during sterilisation
PD53	Proportion of solid to boilers	**2.87E-06**		Solid produced at sterilisation burned in boilers divided by total tonnage of solid entering process
PD54	Proportion of fat to incineration	75.0%		75% of fat sent to incineration
PD55	Amount of solid in fat to offsite incineration	**0.94**	tonnes/year	Amount of fat sent for offsite disposal
PD56	Proportion of solid to incineration off site	**8.60E-06**		Solid produced at sterilisation sent to incineration divided by total tonnage of solid entering process
	Solid Associated with Air			
PD57	Total volume air treatment per year	**1.31E+09**	m^3/year	Data supplied by plant
PD58	Suspended solid content of air	0.001	mg/m^3	Estimated value of solid reaching biofilter (1 microgram/m^3, probably very conservative estimate as majority will be associated with waste water.
PD59	Total suspended solid content of air	**0.00**	tonnes/year	Total volume multiplied by solid content
PD60	Proportion of total solid associated with air treatment	**1.20E-08**		Solid associated with air divided by total tonnage of solid entering process
	Reception			
PD61	Proportion of total suspended solid	27.00%		Proportion of air from reception
PD62	Amount of solid associated with air	**3.54E-04**	tonnes/year	27% of total solid associated with air
PD63	Proportion of total solid	**3.25E-09**		Solid associated with reception air divided by total tonnage of solid entering process
	Breaker hall			
PD64	Proportion of total suspended solid	5.0%		Proportion of air from breaker hall
PD65	Amount of solid associated with air	**6.55E-05**	tonnes/year	5% of total solid associated with air
PD66	Proportion of total solid	**6.02E-10**		Solid associated with breaker hall air divided by total tonnage of solid entering process
	Vaporisation			
PD67	Proportion of total suspended solid	5.0%		Proportion of air from vaporisation
PD68	Amount of solid associated with air	**6.55E-05**	tonnes/year	5% of total solid associated with air
PD69	Proportion of total solid	**6.02E-10**		Solid associated with vaporisation air divided by total tonnage of solid entering process
	Sterilisation			
PD70	Proportion of total suspended solid	53.0%		Proportion of air from sterilisation
PD71	Amount of solid associated with air	**6.94E-04**	tonnes/year	53% of total solid associated with air
PD72	Proportion of total solid	**6.38E-09**		Solid associated with sterilisation divided by total tonnage of solid entering process
	Milling			
PD73	Proportion of total suspended solid	10.0%		Proportion of air from milling
PD74	Amount of solid associated with air	**1.31E-04**	tonnes/year	10% of total solid associated with air
PD75	Proportion of total solid	**1.20E-09**		Solid associated with milling divided by total tonnage of solid entering process
	Biobed			
PD76	Fraction of solid remaining with biobed	90.0%		Estimated value
	Solid Associated with Metal			
PD77	Total tonnage metal per year	26.0	tonnes/year	0.5 tonnes/week x 52
PD78	Solid associated with metal	1.00	kg solid / tonne metal	Estimated value
PD79	Total solid associated with metal	**2.60E-02**	tonnes/year	Total volume multiplied by solid content
PD80	Proportion of total solid associated with metal	**2.39E-07**		Solid associated with metal divided by total tonnage of solid entering process
	Breaker hall			
PD81	Proportion of total solid associated with metal	90.0%		Proportion of metal from breaker hall
PD82	Amount of solid associated with metal	**2.34E-02**	tonnes/year	90% of total solid associated with metal
PD83	Proportion of total solid	**2.15E-07**		Solid associated with breaker hall divided by total tonnage of solid entering process
	Milling			
PD84	Proportion of total solid associated with metal	10.0%		Proportion of metal from milling
PD85	Amount of solid associated with metal	**2.60E-03**	tonnes/year	10% of total solid associated with metal
PD86	Proportion of total solid	**2.39E-08**		Solid associated with milling divided by total tonnage of solid entering process
	Reduction Factors			
PD87	Reduction factor for rendering	**393.53**	fold reduction in infectivity	200 best estimate with 95 percentile of 1000 (resulting mean value)
PD88	Proportion of activity reduced in boilers	99.99990%		Assumes million fold reduction in activity (99.9999%)
	Dilutions			
PD89	Discharge to canal water	600,000	m^3 water	Data supplied by plant
PD90	Discharge to air from air treatment	1,310,000,000	m^3 air	Data supplied by plant

CLIENT:	Provinsje Fryslan, The Netherlands
PROJECT:	Assessment of Risk to Public Health from the Rendac Bergum BV Rendering Plant
MODEL:	Process Plant Risk Assessment
SHEET:	2 - Rendering Plant Process Tree (PT)
DATE:	30-Apr-02
REV:	FinalRev4
REF:	DNV 716056

Input - Branch Probabilities

ref	Parameters	Branch Probabilities	Comments
	RECEPTION		
PT01	Fraction of infectivity associated with raw product	1.00E+00	
PT02	Fraction of infectivity in waste water outside reception building	0.00E+00	
PT03	Fraction of infectivity associated with air	3.25E-09	
	METAL DETECTION & BREAKER HALL		
PT04	Fraction of infectivity associated with raw product	1.00E+00	
PT05	Fraction of infectivity associated with metal	2.15E-07	
PT06	Fraction of infectivity associated with air	6.02E-10	
	VAPORISATION		
PT07	Fraction of infectivity associated with half product	9.99E-01	
PT08	Fraction of infectivity in half product fat	3.71E-04	
PT09	Fraction of infectivity as fuel to boiler	9.27E-05	
PT10	Fraction of infectivity to offsite disposal	1.00E+00	
PT11	Fraction of infectivity associated with condensed water	2.48E-04	
PT12	Fraction of infectivity associated with non-condensate	2.48E-07	
PT13	Fraction of infectivity associated with air	6.02E-10	
	STERILISATION & DEFATTING		
PT14	Fraction of infectivity associated with MBM	1.00E+00	
PT15	Fraction of infectivity in end product fat	1.15E-05	
PT16	Fraction of infectivity as fuel to boiler	2.87E-06	
PT17	Fraction of infectivity to offsite disposal	1.00E+00	
PT18	Fraction of infectivity associated with condensed water	2.75E-05	
PT19	Fraction of infectivity associated with non-condensate	2.75E-08	
PT20	Fraction of infectivity associated with air	6.38E-09	
	FRACTION INFECTIVITY REDUCED		
PT21	Fraction of infectivity reduced	2.54E-03	
PT22	Fraction of infectivity remaining	9.97E-01	
PT23	**MILLING & STORAGE**		
PT24	Fraction of infectivity associated with MBM	1.00E+00	
PT25	Fraction of infectivity associated with metal	2.39E-08	
PT26	Fraction of infectivity associated with air	1.20E-09	



Output - Infectivity Pathways and Fractions

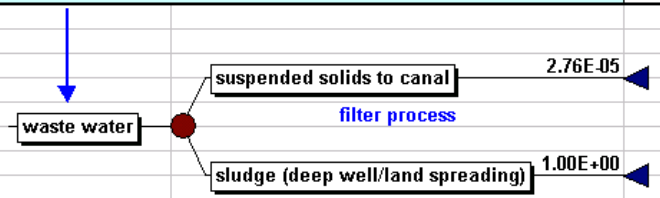
ref	Parameters	fractions	Human Oral ID_{50} units	comments
PT30	Fraction of infectivity removed	9.97E-01	3.10E+03	
	Total infectivity inactivated during rendering	9.97E-01	3.10E+03	
PT31	Fraction of infectivity to waste water treatment	2.48E-04	7.71E-01	
PT32	Fraction of infectivity to air treatment	4.47E-09	1.39E-05	
PT33	Fraction of infectivity to boiler (combustion)	2.82E-07	8.78E-04	
	Total infectivity to waste processing	2.48E-04	7.72E-01	
PT34	Fraction of infectivity associated with MBM product	2.54E-03	7.90E+00	
PT35	Fraction of infectiviy associated with fat product	3.71E-04	1.15E+00	
PT36	Fraction of infectiviy associated metal	2.15E-07	6.69E-04	
	Total infectivity to offsite disposal	2.91E-03	9.05E+00	
PT37	*Total infectivity remaining*	3.16E-03	9.82E+00	
	totals	1.0000E+00	3110.00	

CLIENT:	Provinsje Fryslan, The Netherlands				
PROJECT:	Assessment of Risk to Public Health from the Rendac Bergum BV Rendering Plant				
MODEL:	Process Plant Risk Assessment				
SHEET:	3 - Waste Water Treatment Plant Tree - WT				
DATE:	30-Apr-02	REV:	FinalRev4	REF:	DNV 716056

Input - Branch Probabilities

ref	Parameters	Branch Probabilities	Comments
WT01	Fraction of infectivity associated with discharge to canal	2.76E-05	
WT02	Fraction of infectivity in sludge to deep well oxidation	1.00E+00	

Total infectivity (human oral ID50/yr) - P50	7.71E-01	see Process Tree



Output - Infectivity Pathways and Fractions

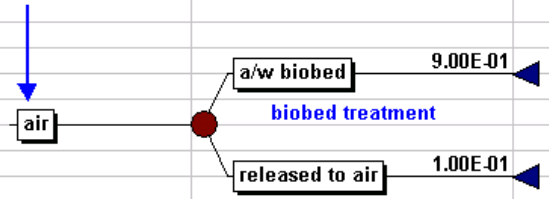
ref	Parameters	Probability	Human Oral ID_{50} Units	Dilution Factor	Infectivity	Units
WT10	Fraction of infectivity released to canal	2.76E-05	2.13E-05	6.00E+05	3.54E-11	Human Oral ID50/m^3
WT11	Fraction of infectivity to deep well oxidation/land spreading	1.00E+00	7.71E-01	3.00E+01	2.57E-02	Human Oral ID50/tonne
	totals	1.00E+00	7.71E-01			

CLIENT:	Provinsje Fryslan, The Netherlands				
PROJECT:	Assessment of Risk to Public Health from the Rendac Bergum BV Rendering Plant				
MODEL:	Process Plant Risk Assessment				
SHEET:	4 - Air Waste Tree - AW				
DATE:	30-Apr-02	REV:	FinalRev4	REF:	DNV 716056

Input - Branch Probabilities

ref	Parameters	Branch Probabilities	Comments
AW01	Fraction of infectivity remaining in biobed	9.00E-01	
AW02	Fraction released to air	remaining	

Total infectivity (human oral ID50/yr) - P50	1.39E-05	see Process Tree



Output - Infectivity Pathways and Fractions

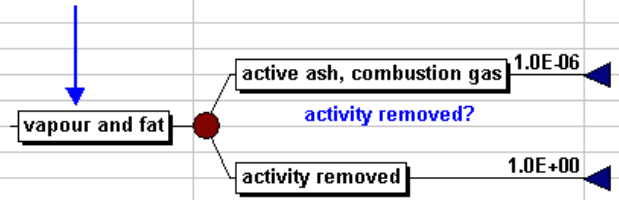
ref	Parameters	Probability	Human Oral ID_{50} units	Comments
AW03	Fraction infectivity associated with biobed	9.00E-01	1.25E-05	
AW04	Fraction infectivity released to air	1.00E-01	1.39E-06	
	totals	1.00E+00	1.39E-05	

CLIENT:	Provinsje Fryslan, The Netherlands				
PROJECT:	Assessment of Risk to Public Health from the Rendac Bergum BV Rendering Plant				
MODEL:	Process Plant Risk Assessment				
SHEET:	5 - Combustion Waste Tree - CW				
DATE:	30-Apr-02	REV:	FinalRev4	REF:	DNV 716056

Input - Branch Probabilities

ref	Parameters	Branch Probabilities	Comments
CW01	Fraction infectivity associated with combustion gases	1.00E-06	
Cw02	Fraction of infectivity reduced	1.00E+00	

Total infectivity (human oral ID50/yr) - P50	8.78E-04	see Process Tree



Output - Infectivity Pathways and Fractions

ref	parameters	probability	Human Oral ID_{50} units	comments
CW01	Fraction of infectivity to combustion gas	1.00E-06	8.78E-10	
Cw02	Fraction of infectivity removed	1.00E+00	8.78E-04	
	totals	1.00E+00	8.78E-04	

CLIENT:	Provinsje Fryslan, The Netherlands
PROJECT:	Assessment of Risk to Public Health from the Rendac Bergum BV Rendering Plant
MODEL:	Process Plant Risk Assessment
SHEET:	6 - Output Summary (*Case BC - Base Case*)
DATE:	30-Apr-02 REV: FinalRev4 REF: DNV 716056

SUMMARY

ref	Parameter	Human Oral ID_{50} baseline	P5	P50	P95	Comments
	Total Infectivity Entering the Process	3,110	53	3,110	114,000	
OS1	Infectivity removed during rendering	3.10E+03	5.3E+01	3.1E+03	1.1E+05	
OS2	Infectivity removed during combustion in boilers	8.78E-04	1.5E-05	8.8E-04	3.2E-02	
	Total infectivity removed	*3.10E+03*	*5.3E+01*	*3.1E+03*	*1.1E+05*	
OS3	Infectivity associated with MBM product	7.90E+00	1.3E-01	7.9E+00	2.9E+02	
OS4	Infectivity associated with fat product	1.15E+00	2.0E-02	1.2E+00	4.2E+01	
OS5	Infectivity associated with metal	6.69E-04	1.1E-05	6.7E-04	2.5E-02	
	Total infectivity to offsite disposal	*9.05E+00*	*1.5E-01*	*9.1E+00*	*3.3E+02*	
OS7	Infectivity released to canal	2.13E-05	3.6E-07	2.1E-05	7.8E-04	
OS6	Infectivity associated with water treatment sludge (deep well oxidation/land spreading)	7.71E-01	1.3E-02	7.7E-01	2.8E+01	
OS8	Infectivity associated with biobed	1.25E-05	2.1E-07	1.3E-05	4.6E-04	
OS9	Infectivity released to air	1.39E-06	2.4E-08	1.4E-06	5.1E-05	
OS10	Infectivity released with combustion gas	8.78E-10	1.5E-11	8.8E-10	3.2E-08	
	Total infectivity released to environment	*7.71E-01*	*1.3E-02*	*7.7E-01*	*2.8E+01*	
	check:	3,110	53	3,110	114,000	

P:\2001\Consult\RUK\6050-6100\716056\Dutch rendering\Final Models PJH\[Base Case - RenderingPlantFinalModelRev5.xls]InfectivityData

Appendix IV

Second process line

IV.1 Background

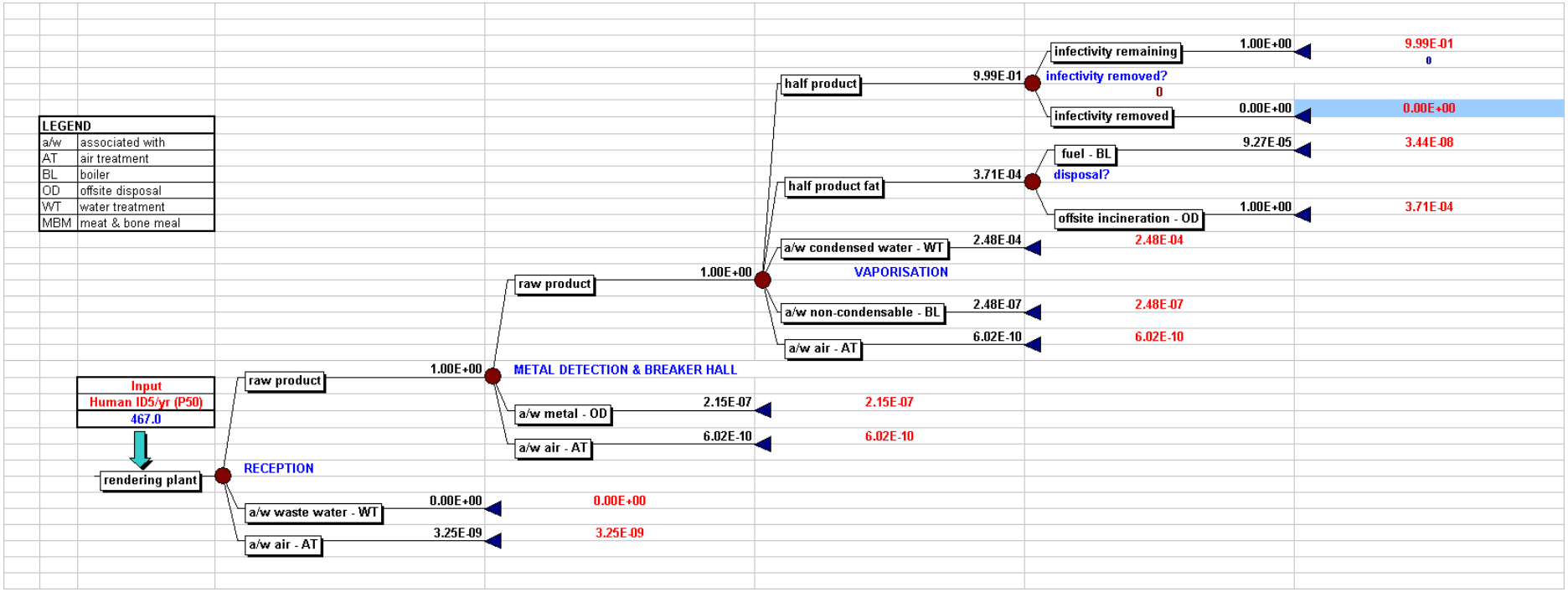
The second process line at RendacBergum is used to process locally collected fallen stock when the main line is not being used to process SRM.

Material is processed in the same way as for the main line but the process is simplified in that no metal is removed and the process ends at the Vaporisation stage. As the second line does not process materials to the same degree as the main line, the treatment is not considered to provide any degree of inactivation. Once processed the material is transferred by tanker to Son where sterilisation takes place and subsequent disposal.

Reception activities and size reduction are conducted in the same manner as for the main process with the same checks in place to safeguard against the escape of materials into the environment. After breaking, materials are dried using steam with the condensate and non-condensate fractions handled in the same way as before. Once the product has been dried, fat is removed and either recirculated in the process, burned in the boilers or sent offsite for disposal.

The second processing line has been described using the same model as for the main process with the exception that no metal is removed and the process ends with Vaporisation (Figure IV.1).

Figure IV.1: Event Tree for Second Process Line



IV.2 Infectivity Entering the Process

It will be assumed that as the smaller line only processes fallen stock, all infectivity associated with the fallen stock found positive for BSE in 2001 are processed, i.e. 3 animals. Table IV.1 shows the total infectivity entering the second processing line assuming that all the BSE positive fallen stock in the Netherlands is processed at the plant. The amount of material processed is also much less than for the main plant with approximately 41,600 tonnes processed. Since the amount of waste material associated with the second line will be much less than for the main line, all input values to waste stream have been scaled to the same proportions as the input values (Table IV.2 at end of section).

	human oral ID_{50} units		
	P5	**P50**	**P95**
Infectivity entering process	8	467	17,100

Table IV.1: Infectivity Entering Rendering Process

IV.3 Results

Table IV.3 shows the total amount of infectivity associated with the product and waste streams from the Rendac Bergum plant, based upon the input data provided for this study. Values are shown as the median (P50), 5 percentile (P5) and 95 percentile (P95) values.

	human oral ID_{50} units		
Parameter	**P5**	**P50**	**P95**
Infectivity entering process	8	467	17,100
Infectivity removed			
Infectivity removed during rendering	0	0	0
Infectivity removed in boilers	2.3×10^{-6}	1.3×10^{-4}	4.8×10^{-3}
Total infectivity removed	2.3×10^{-6}	1.3×10^{-4}	4.8×10^{-3}
Infectivity to offsite disposal			
Infectivity associated with half product	8	466	17089
Infectivity associated with fat product	2.9×10^{-3}	1.7×10^{-1}	6
Infectivity associated with metal	0	0	0
Total infectivity to offsite disposal	8	466	17096
Infectivity to environment			
Infectivity released to canal	5.4×10^{-8}	3.1×10^{-6}	1.2×10^{-4}
Infectivity associated with WTP sludge	2.0×10^{-3}	1.2×10^{-1}	4
Infectivity released to air	3.5×10^{-9}	2.1×10^{-7}	7.6×10^{-6}
Infectivity associated with biofilter	3.2×10^{-8}	1.8×10^{-6}	6.8×10^{-5}
Infectivity released with combustion gas	2.2×10^{-12}	1.3×10^{-10}	4.8×10^{-9}
Total infectivity released to environment	2.0×10^{-3}	1.1×10^{-1}	4

Table IV.3: Summary of Infectivity Associated with Product / Waste Streams for Second Processing Line

IV.4 Infectivity Removed

As this material is not subject to Sterilisation, it has been assumed that no inactivation takes place within the process. However, some infectivity will be removed by burning fat and non-condensates in the boiler (1.3×10^{-4} human oral ID_{50} units).

IV.5 Infectivity to Offsite Disposal

The levels of infectivity associated with half product and fat are 466 and 0.2 human oral ID_{50} units per year respectively. The half product is transferred to Son for processing and subsequent disposal.

No metal is removed during processing in the second line.

IV.7 Infectivity to Environment

The most significant source of infective material to be disposed to the environment is in the eventuality that the sludge from the waste water treatment plant is spread on land as fertiliser (0.1 human oral ID_{50} units per year).

The total amount of infectivity released to the canal is very small at 3×10^{-6} human oral ID_{50} units per year.

Very low amounts of material are associated with the biofilter (2×10^{-6} human oral ID_{50} units per year) and burial of this material is therefore considered to be of very low risk. Similarly the fraction released to the air (2×10^{-7} human oral ID_{50} units) is not considered to be significant, even before a massive dilution factor is applied.

CLIENT:	Provinsje Fryslan, The Netherlands
PROJECT:	Assessment of Risk to Public Health from the Rendac Bergum BV Rendering Plant
MODEL:	Small Process Line
SHEET:	2 - Process Data (PD)
DATE:	20-Mar-02
REV:	DNV 716056

Process Data Input to Process Tree Model

Ref	Parameter	Value	Units	Assumption
	Solid Input into Rendering Process			
	Input of SRM material in tonnes to second line	800	tonnes/year	2001 data supplied by plant.
	Input of SRM material in tonnes to main line	453,455	tonnes/year	2001 data supplied by plant.
	Reduction fator for second processing line	1.76E-03		Fraction of material processed in small line relative to ain line. Used as reduction factor for product and waste streams.
	Percentage of MBM	24.00%		Assumes approximate breakdown of raw materials of 24% MBM, 12% fat and 64% water
	Total solid material rendered	192	tonnes/year	24% of total SRM input to process
	Solid Associated with Waste Water			
	Total volume waste water produced per year by second line	1,059	m^3/year	Volume of waste water input to and discharged from water treatment plant. Supplied by plant.
	Total suspended solid in waste water entering treatment plant	0.02%		Data supplied by plant. Includes fat and MBM.
	Total amount of solid entering water treatment plant	2.12E-01	tonnes	Comprises fat and solid fraction (i.e. MBM)
	Concentration of fat in waste water entering treatment plant	150	g/m^3	Data supplied by plant
	Amount of total attributable to fat	1.59E-01	tonnes	Concentration of fat multiplied by volume
	Total amount of solid entering water treatment plant associated with MBM	5.29E-02	tonnes/year	Amount of solid assocaited with MBM entering water treatment plant (N.B. excludes fat fraction)
	Suspended solid content (MBM) of water stream entering water treatment plant	0.05	kg/m^3	Total suspended solid content based upon 30 tonnes of solid and input volume of 600,000m^3.
	Solid Associated with Condensables			
	Proportion of solid associated with condensables	99.9%		Assumes 99.9% of solid associated with condensate fraction.
	Total solid entering water treatment plant from condensables	0.05	tonnes/year	99.9% of 30 tonnes (total solid input to water treatment)
	Proportion solid entering water treatment plant associated with condensables	2.75E-04		Solid from condensables / total solid entering process
	Reception			
	Proportion of suspended solid	0.00%		No release form reception under normal operating conditions
	Amount of solid associated with waste water	0.00	tonnes/year	
	Proportion of total solid	0.00%		
	Vaporisation			
	Proportion of solid associated with vaporisation	90.00%		Assumes 90% of suspended solid to water treatment produced during at vaporisation
	Amount of solid	0.05	tonnes/year	Fraction of suspended solid associated with vaporisation multiplied by total solid from condensables
	Proportion of total solid	0.02%		Suspended solid produced at vaporisation divided by total tonnage of solid entering process
	Sterilisation			
	Proportion of solid associated with sterilisation	0.00%		Assumes 10% of suspended solid to water treatment produced during sterilisation
	Amount of solid	0.00	tonnes/year	Fraction of suspended solid associated with sterilisation multiplied by total solid from condensables
	Proportion of total solid	0.00E+00		Suspended solid produced at sterilisation divided by total tonnage of solid entering process
	Solid Associated with Non-condensables			
	Proportion of solid associated with non-condensables	0.10%		Assumes 0.1% of solid associated with non-condensables
	Total solid entering water treatment plant from non-condensables	0.00	tonnes/year	0.1% of 30 tonnes (total solid input to water treatment)
	Proportion solid entering water treatment plant associated with non-condensables	2.75E-07		Solid from non-condensables / total solid entering process
	Vaporisation			
	Proportion of solid associated with Vaporisation	90.00%		Assumes 90% of suspended solid to water treatment produced during at vaporisation
	Amount of solid	0.00	tonnes/year	Fraction of suspended solid associated with vaporisation multiplied by total solid from non-condensables
	Proportion of total solid	2.48E-07		Suspended solid produced at vaporisation divided by total tonnage of solid entering process
	Sterilisation			
	Proportion of solid associated with sterilisation	0.00%		Assumes 10% of suspended solid to water treatment produced during sterilisation
	Amount of solid	0.00	tonnes/year	
	Proportion of total solid	0.00E+00		Suspended solid produced at sterilisation divided by total tonnage of solid entering process
	Discharge to Canal			
	Suspended solid content of water discharged to canal	5.00	mg/l	Data from plant
	Total suspended solid released to canal	0.01	tonnes/year	Based upon 5 mg/l and 600,000 m^3 discharged to canal
	Proportion of total solid released to canal	2.76E-05		Suspended solid released to canal divided by total tonnage of solid entering process

Solid Associated with Fat Stream			
Total tonnage of fat produced per year	73	tonnes/year	800 tonnes per week x 52.
Proportion of solid in fat	0.10%		Data supplied by plant
Total solid associated with fat stream	0.07	tonnes/year	0.10% of 41,600 tonnes
Proportion solid associated with fat stream	3.82E-04		Suspended solid content of fat divided by total tonnage of solid entering process
Vaporisation			
Proportion of total fat produced at vaporisation	97.00%		Figure supplied by plant
Total amount of solid associated with fat	0.07	tonnes/year	Fraction of suspended solid associated with fat produced during vaporisation multiplied by total solid associated with fat
Proportion of total solid associated with fat produced during vaporisation	0.037%		Solid produced at vaporisation divided by total tonnage of solid entering process
Proportion of fat to boilers	25.00%		25% of fat burned in boilers
Amount of solid in fat to boilers	0.02	tonnes/year	25% of solid associated with fat produced during vaporisation
Proportion of solid to boilers	0.009%		Solid produced at vaporisation burned in boilers divided by total tonnage of solid entering process
Proportion of fat to incineration	75.00%		75% of fat sent to incineration
Amount of solid in fat to offsite incineration	0.05	tonnes/year	Amount of fat sent for offsite disposal
Proportion of solid to incineration off site	0.028%		Solid produced at vaporisation sent to incineration divided by total tonnage of solid entering process
Sterilisation			
Proportion of total fat produced at sterilisation	0.00%		Figure supplied by plant
Total amount of solid associated with fat	0.00	tonnes/year	Fraction of suspended solid associated with fat produced during sterilisation multiplied by total solid associated with fat
Proportion of total solid in total fat	0.00E+00		Solid produced at sterilisation divided by total tonnage of solid entering process
Proportion of fat to boilers	25.00%		25% of fat burned in boilers
Amount of solid in fat to boilers	0.00	tonnes/year	25% of solid associated with fat produced during sterilisation
Proportion of solid to boilers	0.00E+00		Solid produced at sterilisation burned in boilers divided by total tonnage of solid entering process
Proportion of fat to incineration	75.00%		75% of fat sent to incineration
Amount of solid in fat to offsite incineration	0.00	tonnes/year	Amount of fat sent for offsite disposal
Proportion of solid to incineration off site	0.00E+00		Solid produced at sterilisation sent to incineration divided by total tonnage of solid entering process
Solid Associated with Air			
Total volume air treatment per year	2.31E+06	m^3/year	Data supplied by plant
Suspended solid content of air	1.00	mg/m^3	Estimated value of solid reaching biofilter, probably very conservative estimate as majority will be associated with waste water.
Total suspended solid content of air	2.31E-03	tonnes/year	Total volume multiplied by solid content
Proportion of total solid associated with air treatment	1.20E-05		Solid associated with air divided by total tonnage of solid entering process
Reception			
Proportion of total SS	27.00%		Proportion of air from Reception
Amount of solid associated with air	6.24E-04	tonnes/year	27% of total solid associated with air
Proportion of total solid	3.25E-06		Solid associated with reception air divided by total tonnage of solid entering process
Breaker hall			
Proportion of total SS	5.00%		Proportion of air from breaker hall
Amount of solid associated with air	1.16E-04	tonnes/year	5% of total solid associated with air
Proportion of total solid	6.02E-07		Solid associated with breaker hall air divided by total tonnage of solid entering process
Vaporisation			
Proportion of total SS	5.00%		Proportion of air from vaporisation
Amount of solid associated with air	1.16E-04	tonnes/year	5% of total solid associated with air
Proportion of total solid	6.02E-07		Solid associated with vaporisation air divided by total tonnage of solid entering process
Sterilisation			
Proportion of total SS	0.00%		Proportion of air from sterilisation
Amount of solid associated with air	0.00E+00	tonnes/year	53% of total solid associated with air
Proportion of total solid	0.00E+00		Solid associated with sterilisation divided by total tonnage of solid entering process
Milling			
Proportion of total SS	0.00%		Proportion of air from milling
Amount of solid associated with air	0.00E+00	tonnes/year	10% of total solid associated with air
Proportion of total solid	0.00E+00		Solid associated with milling divided by total tonnage of solid entering process
Biobed			
Fraction of solid remaining with biobed	90.00%		Estimated value
Solid Associated with Metal			
Total tonnage metal per year	0.00	tonnes/year	0.5 tonnes/week x 52
Solid associated with metal	1.00	kg solid / tonne metal	Estimated value
Total solid associated with metal	0.00E+00	tonnes/year	Total volume multiplied by solid content
Proportion of total solid associated with metal	0.00E+00		Solid associated with metal divided by total tonnage of solid entering process
Breaker hall			
Proportion of total solid associated with metal	90.00%		Proportion of metal from breaker hall
Amount of solid associated with metal	0.00E+00	tonnes/year	90% of total solid associated with metal
Proportion of total solid	0.00E+00		Solid associated with breaker hall divided by total tonnage of solid entering process
Milling			
Proportion of total solid associated with metal	10.00%		Proportion of metal from milling
Amount of solid associated with metal	0.00E+00	tonnes/year	10% of total solid associated with metal
Proportion of total solid	0.00E+00		Solid associated with milling divided by total tonnage of solid entering process
Reduction Factors			
Reduction factor for rendering	393.53	fold reduction in infectivity	200 best estimate with 95 percentile of 1000 (resulting mean value)
Proportion of activity reduced in boilers	99.99990%		Assumes million fold reduction in activity (99.9999%)
Dilutions			
Discharge to canal water	1,059	m^3 water	Data supplied by plant
Discharge to air from air treatment	2311144	m^3 air	Data supplied by plant

Table IV.3: Input Data for Second Process Line

Appendix V

Calculation of infectious dose

The following is a summary of the calculations used for total infectious dose.

V.1 Calculation method

Total infectivity is defined by the following

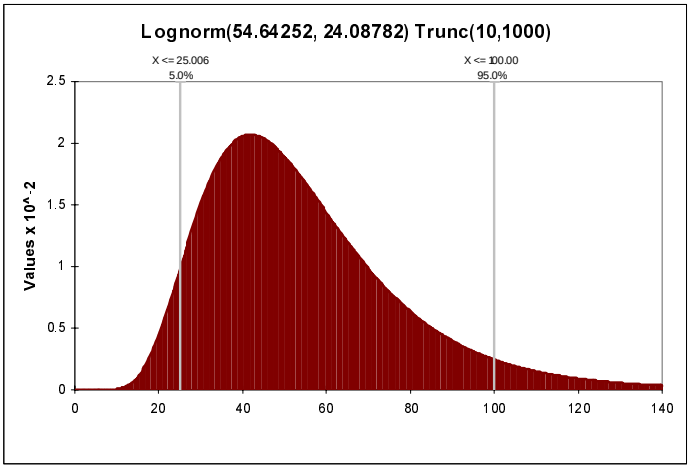
TOTINF = NOC * WTINF * INFDOSE / SPECBARR

where

TOTINF = total infectivity measured in human oral ID_{50} units per year
NOC = number of cattle processed per year (assumed to be 20)
WTINF = weight of infected material per animal (assumed to be 750 gm)
INFDOSE = infectious dose, measured in cattle oral ID_{50} units (variable, see below)
SPECBARR = species barrier (highly variable, see below)

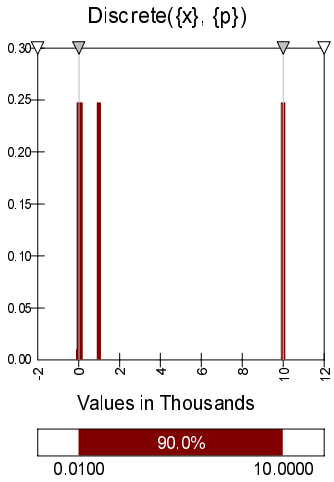
V.2 Infectious Dose

The infectious dose is generally assumed to follow a lognormal distribution, as seen below. Consistent with previous studies, we have assumed a distribution which has a median value of 50, and is truncated at 10 and 1,000. The P95 value of this distribution (95% of all values are less than this number) is 100.



V.3 Species barrier

From published data and previous practice, the probability that the species barrier is 1 is very low (assumed to be 1%), and there is an equal probability (24.75%) that the species barrier could take on higher values (10, 100, 1,000, or 10,000). This distribution is plotted below (note that at this scale it is difficult to distinguish between 1, 10 and 100).



V.4 Values for Total Infectious Material

Because two of the parameters are highly variable there is no single calculated value for the total infectious material. The final answer can be as low as:

TOTINF = 20 * 750 * 10 / 10,000 = 15

or it can be as high as

TOTINF = 20 * 750 * 10,000 / 1 = 15,000,000

when the minimum and maximum values of species barrier and infectious dose are taken into account.

A more realistic answer is obtained when all possible combinations are considered, and practical minimum (P5), practical maximum (P95), mean and median values are calculated. This is done by using the Monte Carlo method, which selects parameter values at random, but in a manner so that the characteristics of the input distributions are preserved.

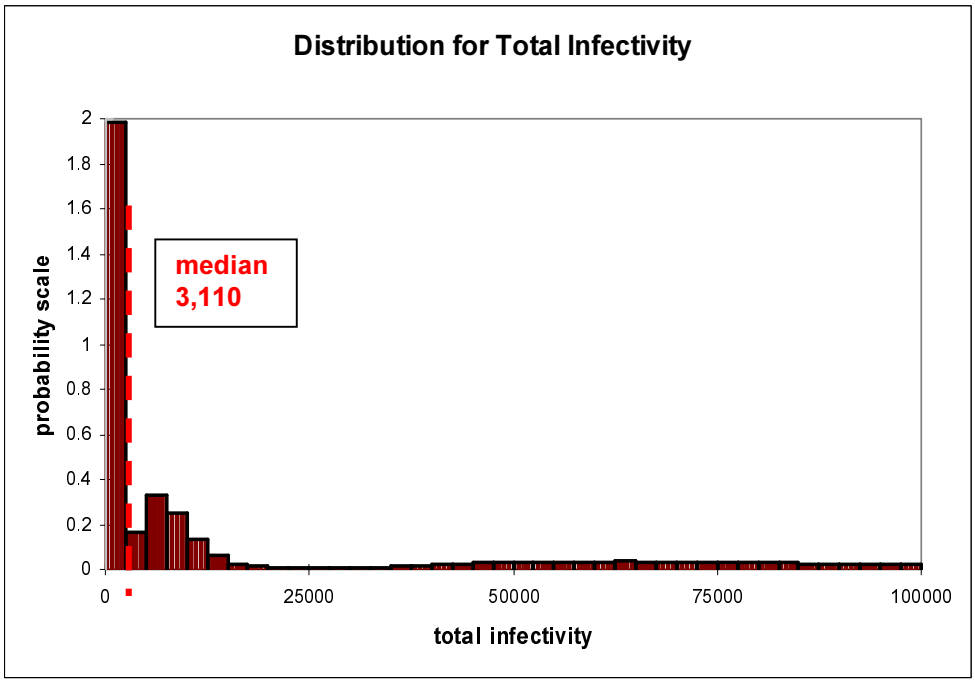
The final output distribution is seen below. The statistics of the output distribution are as seen in the table:

measures	**values**
P5	53
Median (P50)	**3,110**
Mean	30,700
P95	114,000

The median value is plotted in the graph. Note that only part of the graph is shown here, as maximum values can reach as reach into the millions, as discussed above. Hence the curve has

a very long ‘tail’; this accounts for the high mean or average values, and the fact that 50% of the values calculated are higher than the median value of 3110.

The median value has been used as this is considered to be a good representation of the central tendency of the data, whilst remaining relatively conservative in relation to the vast majority of values generated. This is consistent with other studies in this area.



Appendix VI

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