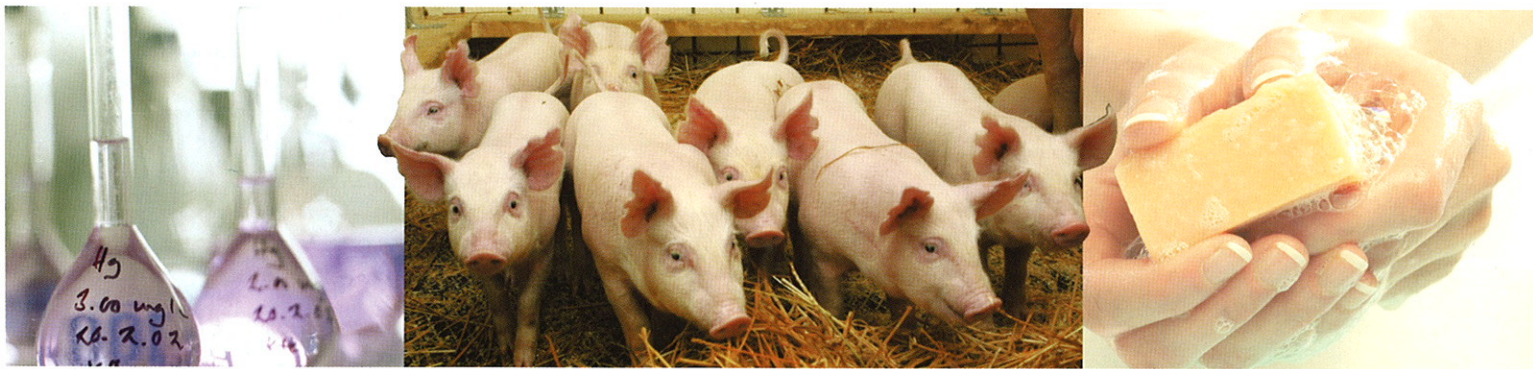


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SALMONELLA IN PORK PRODUCTION IN FINLAND
- a Quantitative Risk Assessment

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| Julkaisun nimi | Salmonella suomalaisessa sianlihatuotannossa – kvantitatiivinen riskinarviointi |
| Tiivistelmä | <p>Tämän riskinarvioinnin tavoitteena oli kuvata ja mahdollisuuksien mukaan laskea kvantitatiivisesti Suomessa myytävän sianlihan ja sianlihaa sisältävien elintarvikkeiden aiheuttama salmonellatartuntariski kuluttajille. Samalla haluttiin selvittää vuodesta 1995 alkaen voimassa olleeseen, EU:n hyväksymään kansalliseen salmonellavalvontaohjelmaan liittyvien riskinhallintatoimenpiteiden vaikutusta ko. riskiin. Valvontaohjelmaan kuuluvat naudat, siat ja siipikarja. Valvontaohjelman perusteella Suomelle on myönnetty ns. lisävakuudet, jotka antavat Suomelle mahdollisuuden vaatia, että tietyt kyseisiin elintarvikkeisiin kuuluvat tuontiartikkelit on tutkittu lähimmäisissä salmonellan varalta, poikkeuksena maat, joissa on vastaavantasoinen valvontaohjelma.</p> <p>Arviointi tehtiin valvontaohjelman tulosten ja muun käytettävissä olevan aineiston perusteella. Mallinnuksen lähtökohdaksi valittiin vuoden 1999 tiedot. Arviointi katsoi tuotantoketjun teurassioista kuluttajaan, ja se toteutettiin neljän kvantitatiivisen osamallin avulla. Sianlihaa sisältävät elintarvikkeet jaettiin kolmeen luokkaan: tuoreeseen lihaan verrattaviin tuotteisiin, tuotteisiin, joiden valmistusmenetelmä ei vastaa +70 °C:n kuumennusta, sekä tuotteisiin, joiden valmistusmenetelmän katsottiin vastaavan +70 °C:n kuumennusta. Kvantitatiivinen riskinarviointi koostuu neljästä osamallista: Teuraseläinmallista, Tuontimaamallista, Prosessointimallista ja Kuluttajamallista.</p> <p>Ensimmäinen, Teuraseläinmalli arvioi salmonellan todellista esiintyvyyttä teuraaksi lähetettävissä lihasioissa valvontaohjelmaan kuuluvien imusolmukelöydösten ja käytetyn laboratoriomenetelmän avulla. Vuonna 1999 teurassikoja todettiin tutkimuksissa positiivisiksi 0,15 %, mallin tulosten mukaisen todellisen esiintyvyyden ollessa 0,24–1,28 % (95 %:n vaihteluväli; keskiarvo 0,6 %). Arvio todellisesta esiintyvyydestä on korkeampi kuin todettu esiintyvyys, koska mallin avulla arviointiin myös toteamattomien tartuntojen määrä. Positiivisiksi todettuja eläimiä ei saa toimittaa teurastamoon muutoin kuin poikkeuksin (esim. salmonellan tuhoava kuumennuskäsittely). Teurastamalla salmonellalla saastuneeksi todetusta ruhosta</p> |

aiheutuvat toimenpiteet vaikuttavat epäsuorasti salmonellan esiintyvyyteen teuraspopulaatioissa, mutta tätä vaikutusta ei mallinnettu. Jos salmonellan todellinen esiintyvyys teurassioissa lisääntyisi 1 %:iin, ihmisissä todettujen salmonelloositapausten määrä voisi lisääntyä noin kolminkertaiseksi nykyiseen verrattuna.

Tuontimaamalli arvioi salmonellan todellista esiintyvyyttä eri maista tuotavassa sianlihassa ja -tuotteissa maiden itsensä ilmoittamien sianlihasta ja sianlihaa sisältävistä elintarvikkeista tehtyjen tutkimustulosten, Suomessa tehtyjen pistokoe- luonteisten lisätutkimusten sekä laboratorioherkkyyden perusteella. Lisäksi otettiin huomioon sianlihan ja sitä sisältävien elintarvikkeiden tuontimäärät maittain ja arvioitiin tuontilihan käyttötarkoitus. Lähtökohtana oli, että Suomeen valvontaohjelman mukaisesti tuotu tuore liha on salmonellakielteiseksi todettua, ellei sitä käytetä raaka-aineena kypsennettyihin tuotteisiin. Lisävakuudet koskevat käytännössä vain noin 11 % tuoduista sianlihasta ja sianlihaa sisältävistä elintarvikkeista. Jos salmonellavalvontaohjelma lakkautettaisiin ja lisävakuudet sen myötä poistettaisiin, kuluttajien sairastuminen salmonelloosiin ei tuontimaiden jakauman pysyessä ennallaan siksi lisääntyisi arvion mukaan juuri lainkaan. Jos tuonti sen sijaan kattaisi 50 % kulutuksesta ja tuontimaat muuttuisivat asiantuntijoiden arvioimalla tavalla, sianlihan aiheuttamien salmonelloositapausten määrä lisääntyisi todennäköisesti 2,4-kertaiseksi nykyiseen verrattuna.

Teuraseläin- ja Tuontimaamalla hyödynnettiin Prosessointimallissa, joka arvioi salmonellalla saastuneiden, sianlihaa sisältävien annosten määrän Suomessa simuloiden salmonellatartunnan kulkua teurastamoissa, leikkaamoissa ja jalostuslaitoksissa. Laskennallisia salmonellalla saastuneita ruoka-annoksia olisi vuosittain 0,34–2,7 % (90 %:n luottamusväli; keskiarvo 0,84 %) teollisuudesta kulutukseen lähtevässä tuotannossa, ennen lopullista kuluttajilla ja ravintoloissa tapahtuvaa säilytystä ja kypsennystä.

Mallin neljäs osa, Kuluttajamalli, arvioi sianlihasta aiheutuvien ihmisten salmonellatapausten määrää Suomessa. Elävistä sioista ja valvontaohjelman mukaisista näytteistä eristettyjä salmonellaserotyyppejä verrattiin kotimaassa saatuihin, ihmisistä eristettyihin kantoihin. Suomessa tarjolla olevasta sianlihasta tai sitä sisältävistä elintarvikkeista johtuvien tapausten pääteltiin olevan enimmillään noin 4,5 % kaikista vuonna 1999 rekisteröidyistä 2866 salmonellatapauksesta. Suomalaisesta sianlihasta kuluttajalle aiheutuneiden salmonelloosien määrä kaikista sianlihan kuluttajalle aiheuttamista tapauksista oli mallin tulosten mukaan noin 55 %. Tuontisianlihan ja muiden sianlihaa sisältävien tuontielintarvikkeiden, jotka vastaavat noin 8 % näiden tuotteiden kokonaiskulutuksesta, arvioitiin aiheuttavan noin 45 % kaikista sianlihasta tai sianlihaa sisältävistä tuotteista kuluttajille aiheutuneista salmonelloositapauksista Suomessa. Tulokseen vaikuttaa epävarmuus tuontilihan todellisesta prevalenssista.

Mallin avulla voidaan vetää seuraavia johtopäätöksiä:

1. Salmonellan esiintyvyys sianlihan tuotannossa on Suomessa matala, ja alittaa selvästi tavoitetason 1 % myös todellisena esiintyvyytenä arvioituna.
2. Salmonellan esiintyvyydellä alkutuotannossa on selvä merkitys kuluttajalle aiheutuvan riskin suuruuteen. Tämä suhde ei ole kuitenkaan lineaarinen.
3. Vaikka kotimainen sianliha aiheuttaa mallin perusteella yli puolet sairaustapauksista, ulkomaisen sianlihan vaikutus kulutusmääriin suhteutettuna on todennäköisesti kotimaista suurempi.
4. Nykyiset lisävakuudet eivät suojaa kuluttajaa salmonelloosilta kovin tehokkaasti, koska ne kohdistuvat vain pieneen osaan tuonnista (11 %) ja kulutuksesta (0,88 %). Tuontimaiden vaihtuessa niiden merkitys lisääntyy, jos tuontimaassa salmonellaa esiintyy enemmän kuin Suomessa.
5. Kotimaisen salmonellan esiintyvyyden nouseminen sianlihassa 1 %:iin vastaisi kuluttajiin kohdistuneena vaikutuksena (kuluttajien sairastumisina) ilman lisävakuuksia tuotavan lihan määrän lisääntymistä 50 %:iin kulutuksesta tuontimaiden jakauman pysyessä lähes ennallaan.

| | |
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Beskrivning

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| Publikation | Salmonella i finsk svinköttsproduktion – en kvantitativ riskvärdering. |
| Referat | <p>Målet för föreliggande riskbedömning var att beskriva och i mån av möjlighet göra en kvantitativ bedömning av risken för att salmonellainfektion överförs till konsumenter från svinkött och livsmedel som innehåller svinkött och som saluförs i Finland. Samtidigt ville man utreda vilken inverkan på risken ifråga de riskhanteringsåtgärder haft som vidtagits i anslutning till det av EU godkända nationella programmet för salmonellakontroll som varit i kraft sedan 1995. Kontrollprogrammet omfattar nötboskap, svin och fjäderfä. På grundvalen av kontrollprogrammet har Finland beviljats s.k. tilläggsgarantier, som ger Finland en möjlighet att kräva att vissa importartiklar som hör till gruppen av livsmedel ifråga har salmonellakontrollerats i utgångslandet. Ett undantag utgör länder som har ett kontrollprogram av motsvarande standard.</p> <p>Bedömningen utfördes utgående från de resultat kontrollprogrammet givit samt annat till buds stående material. Till utgångspunkt för beskrivningen valdes uppgifterna för 1999. Bedömningen täckte hela produktionskedjan från slaktsvin till konsumenten och genomfördes med hjälp av fyra kvantitativa delmodeller. Livsmedel som innehöll svinkött indelades i tre klasser: produkter som är jämförbara med färskt kött, produkter vilkas produktionsmetoder inte motsvarar upphettning till +70°C samt produkter vilkas produktionsmetoder ansågs motsvara upphettning till +70°C.</p> <p>Den kvantitativa riskbedömningen omfattar fyra delmodeller: Slaktdjursmodellen, importlandsmodellen, processningsmodellen och konsumentmodellen.</p> <p>Med hjälp av de fynd som vid genomförandet av kontrollprogrammet påträffas i lymfkörtlarna på köttsvin som skall sändas till slakt och den använda laboriemetoden bedömer den första modellen, slaktdjursmodellen den faktiska förekomsten av salmonella. Vid undersökningar av slaktsvin 1999 konstaterades 0,15% vara positiva, medan den faktiska förekomsten enligt modellens resultat uppgick till 0,24–1,28% (variationsintervall 95%; medelvärde 0,6%). Den faktiska förekomsten har bedömts vara högre än den konstaterade förekomsten, vilket beror på att den bedömning som utförs med hjälp av modellen också beaktar</p> |

antalet icke konstaterade fall av infektioner. Djur som konstaterats vara positiva får inte levereras till slakteriet annat än i undantagsfall (t.ex. upphettningsbehandling som förgör salmonellan). De åtgärder en kropp som på slakteriet konstateras vara salmonellainficerad förorsakar påverkar indirekt förekomsten av salmonella i slaktdjurspopulationen, men för den här effekten gjordes inte någon beskrivning. Om den faktiska förekomsten av salmonella hos slaktsvin skulle öka till 1 %, kunde antalet fall av salmonella som konstaterats hos människor öka till omkring det tredubbla jämfört med nuvarande situation.

Importlandsmodellen utvärderar den faktiska förekomsten av salmonella i svinkött och svinköttsprodukter som importeras från olika länder utgående från resultat av undersökningar av svinkött och livsmedel som innehåller svinkött som meddelats av länderna ifråga själva, av ytterligare undersökningar av stickprovsnatur som gjorts i Finland, samt från labororiesensitivitet. Ytterligare beaktades importvolymerna av svinkött och livsmedel som innehåller svinkött från respektive land samt gjordes en bedömning av importköttets bruksändamål. Utgångspunkten var att det färskt kött som importerats till Finland regelrätt enligt kontrollprogrammet har konstaterats vara salmonellanegativt om det råmaterial inte används till tillredda produkter. I praktiken gäller tilläggsgarantierna endast cirka 11 % av det importerade svinköttet och importerade livsmedel som innehåller svinkött. Enligt den bedömning som gjorts skulle insjuknandet i salmonellos knappt alls öka bland konsumenterna om programmet för salmonellakontroll slopas och därmed också tilläggsgarantierna. Det här innebär att fördelningen av import länderna ändras inte. Om däremot importen skulle täcka 50 % av konsumtionen och importländer förändras på ett av experterna antaget sätt skulle antalet av svinkött orsakade fall av salmonellos sannolikt öka 2,4-falt i jämförelse med nuvarande situation.

Slaktdjurs- och importlandsmodellen utnyttjades i processningsmodellen, som uppskattar antalet av salmonella infekterade portioner som innehåller svinkött i vårt land genom att simulera salmonellainfektionens vandring genom slakterier, köttstyckningsanläggningar och förädlingsanläggningar. Den kalkylmässiga årliga mängden matportioner som infekterats av salmonella uppgår enligt uppskattningen till 0,34–2,7 % (konfidensintervall 90 %; medelvärde 0,84 %) av den produktion som levereras av industrin för konsumtion före den slutliga förvaringen och beredningen hos konsumenter och i restauranger.

Den fjärde delmodellen, konsumentmodellen gör en bedömning av omfattningen av salmonellafall människor i Finland som orsakats av svinkött. Salmonellaserotyper från levande svin och från prover som tagits enligt kontrollprogrammet och isolerats jämfördes med stammar som erhållits från människor i vårt eget land och isolerats. Antalet fall som orsakats av svinkött eller livsmedel som innehöll svinkött som saluförts i vårt eget land bedömdes uppgå som mest till cirka 4,5 % av samtliga 2866 registrerade salmonellafall i 1999. Enligt de resultat modellen gav uppgick andelen fall av salmonellos som orsakats konsumenter av finländskt svinkött till cirka 55 % av samtliga fall av salmonellos som orsakats av svinkött. Importen av svinkött och andra livsmedel som innehåller svinkött, som motsvarar cirka 8 % av totalkonsumtionen av dessa produkter, bedömdes orsaka cirka 45 % av alla fall av salmonellos i Finland som orsakas konsumenterna av svinkött eller produkter som innehåller svinkött. Osäkerhet av prevalens från olika import länder spelar en viktigt roll i den estimat.

Med stöd av modellen kan följande slutsatser dras:

1. Förekomsten av salmonella inom svinköttsproduktionen är låg i Finland och underskrider också vid en bedömning av den faktiska förekomsten klart den målsatta nivån 1%.
2. Förekomsten av salmonella i primärproduktionen har en uppenbar betydelse för hur stor konsumentens risk är. Förhållandet ifråga är dock inte lineärt.
3. Trots att det inhemska svinköttet enligt modellen orsakar över hälften av sjukdomsfallen, är det utländska köttets verkningar i relation till den konsumerade volymen sannolikt större än de inhemska.
4. De nuvarande tilläggsgarantierna skyddar inte alltför effektivt konsumenten för salmonellos, eftersom de bara är inriktade på en liten del av importen (11 %) och konsumtionen (0,88 %). Sker det byten av importländer ökar deras betydelse om det förekommer mera salmonella i importlandet än i Finland.
5. En ökning av den inhemska förekomsten av salmonella i svinkött till 1% skulle i form av en till konsumenterna fokuserad effekt (insjuknade konsumenter) utan tilläggsgarantier motsvara en ökning av volymen importkött till 50% av konsumtionen om fördelningen av import länderna knappast ändrar.

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| Title | Salmonella in Pork Production in Finland – A Quantitative Risk Assessment |
| Abstract | <p>The goal of this risk assessment was to describe and as far as possible quantify the risk of salmonella to consumers from pork and pork products sold in Finland. At the same time, we wanted to determine what effects the EU-approved Finnish Salmonella Control Programme, which began in 1995, has had on this salmonella risk. The programme covers cattle, pigs and poultry. Based on this salmonella control program, Finland has also been granted so-called additional guarantees, which allow her to require that certain imported foods be examined in the country of origin for salmonella, with exceptions granted to countries which have a similar salmonella control program.</p> <p>This risk assessment is based on data gathered for the control programme as well as on other available data. Data from 1999 was chosen as the starting point for the modelling. The assessment covered the entire production process from slaughter to consumer, and was done with the help of four quantitative submodels. For the purposes of this study, pork products were divided into three groups: products comparable to fresh meat, products which are not heated to 70°C, and products whose preparation includes heating to 70°C, or the equivalent. The quantitative risk analysis is composed of four submodels: the Slaughter Prevalence Inference Model (SPIM), the Import Prevalence Inference Model (IPIM), the Secondary Production Simulation Model (SPMS), and the Consumption Inference Model (CIM).</p> <p>The first submodel, the Slaughter Prevalence Model, estimates the true prevalence of Salmonella in finishing pigs using the lymph node data and other laboratory methods which are part of the salmonella control program. In 1999, 0.15% of samples from slaughter pigs tested positive; according to the model, the true prevalence was 0.24%-1.28% (95% probability interval, mean 0.6%). The estimate of true prevalence is higher than the tested prevalence, since the model also estimates the number of undetected cases. Animals which have tested positive may not be brought to the slaughterhouse except in exceptional circumstances (for example, to be used in products which are heat-treated to destroy salmonella). Procedures to deal with contaminated carcasses identified at the slaughterhouse may indirectly influence the prevalence of salmonella in the slaughter population,</p> |

but this effect was not modelled. If the true prevalence of salmonella in the slaughterhouses would increase to 1%, the number of human cases might triple compared to the present situation.

The Import Prevalence Inference Model estimates the true prevalence of salmonella in the pork and pork products imported from different countries on the basis of the tests conducted and reported by the exporting countries themselves, on additional spot-checks made in Finland and on the sensitivity of the microbiological testing methods used. In addition, this risk assessment took into consideration the quantities of pork and pork products imported from each country, as well as its intended use. The starting point was that in keeping with the Finnish salmonella control programme, imported fresh meat is certified as salmonella negative, unless it is being used as raw material in heat-treated products. In practice, the additional guarantees only affect about 11% of imported pork meat and pork-products. Therefore, according to our estimate, the incidence of salmonella in consumers would not increase measurably if the salmonella control programme were abolished and with it the additional guarantees – assuming the distribution of exporting countries remains nearly the same. On the other hand, if the proportion of imported meat increased to 50% of total consumption, and if this imported meat came from the countries deemed likely by experts, then the number of human salmonella cases caused by pork meat would most likely increase 2.4-fold over the current situation.

The results of the Slaughter Prevalence Inference Model and the Import Prevalence Inference Model were used in the Secondary Production Simulation Model, which estimates the number of salmonella-contaminated servings of pork in Finland by simulating the path of a salmonella infection through the slaughterhouse, cutting plant and processing plant. Prior to the final storage and processing done by consumers or in restaurants, the proportion of contaminated servings of pork leaving production destined for consumers is on average 0.34%-2.7% (90% probability interval, mean 0.84%).

The fourth part of the model, the Consumption Inference Model, estimates the number of human salmonella cases in Finland which are caused by contaminated pork. The salmonella serotypes isolated from living pigs and from samples taken under the salmonella control programme are compared to the serotypes isolated from humans. We estimate that a maximum of 4.5% of the total number of salmonella cases registered in Finland in 1999 (2,866) are caused by pork or pork products served in Finland. According to the model, about 55% of these salmonella cases are caused by domestic pork, while the other 45% are caused by imported pork, which constitutes about 8% of total pork consumption in Finland. The result is partly due to the inherent uncertainty in estimates of import prevalence due to lacking information.

Using these models, we can draw the following conclusions:

1. The prevalence of Salmonellain Finnish pork production is low, and remains clearly below the 1% threshold level, even when estimated as true prevalence.
2. The prevalence of *Salmonella* in primary production has a clear significance on the size of consumer risk. This relationship is not linear, however.
3. Although according to the model domestic pork accounts for over half of human cases, when related to the quantities consumed, the effect of imported pork is greater than that of domestic pork.
4. Additional guarantees in their present form do not directly protect consumers from salmonellosis very effectively, since they cover only a small proportion of all imports (11%) and consumption (0.88%). However, if the countries Finland imports from change from the present, the significance of these measures will increase if the Salmonellaprevalence in these export countries is higher than it is in Finland.
5. A rise in the prevalence of salmonella in domestic pork to 1% would have the same effect on consumers (human salmonellosis cases) as if 50% of consumption were covered by imported pork not subject to additional guarantees, assuming that the distribution of exporting countries remain approximately the same.

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1. Some abbreviations and acronyms

Additional guarantees

Finland is allowed to require the same level of safety from imported consignments as is provided by the National *Salmonella* Control Programme (FSCP).

Apparent infected animal

An animal detected *Salmonella* positive in faecal and/or lymph node and/or meat samples (hence, apparent prevalence).

Bayesian inference, probabilistic inference

Method of inferring the probable values of unknown quantities by conditioning on observed data, i.e. updating prior distributions to posterior distributions.

CIM

Consumption Inference Model. The model is for joint estimation of the average final CFU/g at the time of consumption per contaminated serving at retail, and the true number of human cases of illness, accounting for under reporting. Uses probabilistic inference (MCMC sampling, WinBUGS).

EELA

National Veterinary and Food Research Institute.

Elite breeding herd

Herds producing breeding animals for the domestic market as well as for export. Herd owners participate actively in the national pig breeding program by sending animals to performance test stations and producing AI boars. An elite breeding herd must comply with the requirements of the National Health Scheme for domestic swine breeding herds.

ETT

Association for the Prevention of Animal Diseases.

Exporting country

Any country exporting meat and meat products to Finland.

Farrowing herd

Herd producing piglets to be sold to finishing herds.

Finfood

Finnish Food Information Centre.

Finishing herd

Herd obtained by purchasing piglets from farrowing herds and rearing them until slaughter.

Fresh meat, fresh pork

All meat, frozen or not, without added ingredients, including minced meat.

FSCP

Finnish *Salmonella* Control Programme. The national *Salmonella* control programme, which was approved by Commission Decision 94/968/EC on December 1994 and started in 1995. It covers beef, pork and poultry production and is intended to keep the annual incidence of *Salmonella* below 1%.

Import

All meat and meat products which enter Finland either from EU member states or third countries.

IPIM

Import Prevalence Inference Model. The model is for estimating the true contamination prevalence in imported fresh meat and meat products. Uses Bayesian probabilistic inference (MCMC sampling, WinBUGS).

KTTK

Plant Production Inspection Centre.

LTK

Finnish Meat Research Institute.

Marginal distribution

Distribution of one or a few random variables derived from a joint distribution containing a larger number of random variables. $(f(x) = \int f(x, y)dy)$.

MC

Monte Carlo Simulation. Method of generating random numbers from a defined distribution, i.e. from a probabilistic model.

MCMC

Markov chain Monte Carlo Sampling. Monte Carlo simulation based on Markov chain sampling techniques.

MMM

Ministry of Agriculture and Forestry.

MP

Meat product. Raw meat preparations, processed meat products and some food produced from slaughter animals. Products containing food of animal origin or gelatine are not considered meat products if they do not contain meat, minced meat, raw meat preparations or processed meat products.

PMP

Processed meat product. A meat product processed by heating, ripening, drying, smoking or by combination of such processes so that the cutting surface has no properties of fresh meat. **Note!** In this report processed meat products are considered to behave like any meat product processed with at least 70°C heating.

Posterior distribution

Conditional distribution describing the remaining uncertainty about an unknown quantity after observing data. ($f(x | data, prior)$).

Prior distribution

Conditional distribution describing initial uncertainty about an unknown quantity before observing data. ($f(x | prior)$).

@RISK

Spreadsheet software for Monte Carlo simulation (Palisade corporation).

RMP

Raw meat preparation. A meat product that is not ripened, is made wholly or partly of meat or minced meat, and is not processed by heating, ripening, drying or smoking or by combination of such processes. With added salt, spices, additives or other foods. **Note!** In this report raw meat preparations are considered to be meat products not processed with at least 70°C heating.

Slaughter animal

Swine at the slaughterhouse.

Slaughter weight pig

A pig which has reached the required weight for slaughter.

SPIM

Slaughter Prevalence Inference Model. The model is for estimating the true prevalence in a slaughter population. Uses Bayesian probabilistic inference (MCMC sampling, WinBUGS).

SPSM

Secondary Production Simulation Model. The model simulates the production chain from slaughtering and processing to the total number of contaminated servings. Modelled by probabilistic forward simulation (Monte Carlo sampling, @RISK).

True infected animal

A truly infected animal, detected or not (hence, true prevalence).

WinBUGS

Software with model specification language for computing posterior distributions using MCMC sampling methods (<http://www.mrc-bsu.com.oc.uk/bugs/>).

1. Yhteenveto ja johtopäätökset

1.1 Johdanto

Suomella on ollut vuodesta 1995 alkaen EU:n hyväksymä kansallinen salmonellavalvontaohjelma. Ohjelman tavoitteiksi asetettiin salmonellan esiintymisen pitäminen alhaisena niin kotieläimissä kuin eläimistä saatavissa elintarvikkeissa. Tätä kautta voitaisiin varmistaa ruuan turvallisuus kuluttajille. Tavoitteiksi asetettiin myös luotettavan kuvan saaminen salmonellan yleisyydestä tuotantoeläimillä ja eläimistä saatavissa elintarvikkeissa sekä se, ettei teurastettavissa eläimissä esiintyisi enempää kuin korkeintaan 1 % salmonellaa kansallisella tasolla.

Valvontaohjelmaan kuuluvat tärkeimmät kotimaiset tuotantoeläimet: naudat, siat ja siipikarja sekä niistä saatava liha ja kananmunat. Ohjelma antaa Suomelle mahdollisuuden vaatia, että osa tuotavasta naudan-, sian- ja siipikarjanlihasta, kanamunat ja elävä siipikarja on lähtömaassa tutkittu salmonellan varalta, ellei lähtömaassa ole EU:n vahvistamaa vastaavantasoisia valvontaohjelmaa kuin Suomessa (nk. lisävakuudet). Käytännössä ainoastaan Ruotsi ja Norja ovat tällaisia maita. Lisävakuudet eivät koske lihatuotteita eivätkä tuoretta sian- ja naudanlihaa, joka tuodaan raaka-aineeksi vähintään 70 °C :een kuumennettavaan lihavalmistukseen.

Salmonellavalvontaohjelmaa on nyt noudatettu kahdeksan vuotta. Tällä riskinarvioinnilla haluttiin selvittää Suomessa myytävän sianlihan ja sianlihatuotteiden aiheuttama tartuntariski kuluttajille, sekä salmonellavalvontaohjelmaan liittyvien riskinhallintatoimenpiteiden vaikutusta tähän riskiin. Arviointi tehtiin valvontaohjelman tulosten ja muun käytettävissä olevan aineiston perusteella. Lisäksi arvioitiin, miten tämä riski muuttuisi, jos kansallista salmonellavalvontaohjelmaa ja siihen liittyviä lisävakuuksia ei olisi tai jos Suomeen tuotavan sianlihan ja sianlihatuotteiden määrä lisääntyisi selvästi. Työ on tehty maa- ja metsätalousministeriön pyynnöstä.

1.2 Riskinarviointimalli

1.2.1 Vaaran tunnistaminen

Salmonelloosi on *Salmonella enterica* -bakteerin aiheuttama tauti. *S. enterica* -serotyyppejä tunnetaan noin 2500. Kaikki serotyypit voivat aiheuttaa tautia ihmiselle, joskin taudinaiheutuskyvyssä on eroja eri serotyyppien välillä. Salmonella lisääntyy elintarvikkeissa, jos säilytys- ja kuljetuslämpötilat ovat sille otolliset. Salmonella tuhoutuu yleensä prosesseissa, joissa sen lämpötila ylittää 70 °C, joten se voi säilyä elossa matalan lämpökäsittelyn läpikäyneissä elintarvikkeissa. Kuumennuksen teho on riippuvainen tuotteen kosteudesta. Joissakin tapauksissa salmonellan tuhoamiseen tarvitaan jopa 130 °C.

Vuosina 1995–2000 salmonellaan sairastuneiden ihmisten määrä on vaihdellut varsin vähän Suomessa ollen keskimäärin 3000 tapausta vuosittain (50–66 tapausta / 100 000 asukasta / vuosi). Salmonellatartuntoja aiheuttaa Suomessa vuosittain noin 100 salmonellaserotyyppiä. Yli puolet kaikista tartunnoista on 1990-luvulla ollut *Salmonella* Enteritidis ja *Salmonella* Typhimurium -serotyyppien aiheuttamia. *Salmonella* Enteritidis -tartunnoista suurin osa (89–91 %) oli peräisin ulkomailta, *Salmonella* Typhimurium -tartunnoista puolestaan suurin osa (71–81 %) on kotimaisia tartuntoja. Vuosina 1995–1999 oli ulkomaista alkuperää olevien salmonelloosien osuus 65–81 % kaikista tartunnoista (KTL 2002).

Suomalaisista sikaloista salmonellaa on löytenyt erittäin harvoin. Kansalliseen salmonellavalvontaohjelmaan sisältyvistä teuraslihasikojen imusolmukkeista salmonellaa on löytenyt keskimäärin 0,16 %:ssa näytteistä, pintasivelynäytteistä vieläkin harvemmin. Leikkaamoista otetuista näytteistä salmonellaa on löytenyt keskimäärin 0,02 %:ssa näytteistä. Vuosina 1999 ja 2000 salmonellaa kartoitettiin kaupan olevassa sianlihassa (Hatakka et al. 2000, Hatakka et al. 2001). Salmonellaa ei todettu yhdessäkään näytteessä (näytteitä tutkittiin 171 ja 165 kpl).

Kaikissa merkittävässä sianlihaa tuottavissa maissa salmonellaa esiintyy sioissa varsin yleisesti. Sianlihan on arvioitu 1990-luvulla vastanneen Tanskassa 10 %, Hollannissa 15 % ja Saksassa 20 % kaikista ihmisten salmonellatartunnoista (Hald & Wegener 1999). Joissakin ruokamyrkytystapauksissa tartunnan lähde on jopa pystytty jäljittämään yhteen tiettyyn teurastamoon (Wegener & Baggesen 1996) tai sikalaan (Maguire et al. 1993). Suomessa on valvontaohjelman voimassaoloaikana pystytty osoittamaan sianliha kerran (vuonna 1997) ruokamyrkytyksen aiheuttajaksi (Kukkula 1998).

1.2.2 Vaaran kuvaaminen

Salmonellabakteeri voi kasvaa 5–46 °C:ssa, vaikkakin sen optimikasvulämpötila on 35–37 °C. Kasvun minimi vesiaktiivisuustaso on 0.95, mutta solut voivat säilyä kuivassa materiaalissa hengissä pitkään. 9 % suolapitoisuus ja pH alle 4.0 tai yli 9.5 estävät salmonellan kasvun (Jay 2000; Ray 2001).

Salmonellainfektio on sioilla useimmiten oireeton. Oireita, jos niitä on, todetaan yleisimmin vieroituksen jälkeen noin 4 kuukauden ikään asti. Useimmat siat toipuvat täydellisesti. Osa sioista voi silti erittää salmonellaa ajoittain aina teurastusvaiheeseen asti. Oireettomia kantajia ei voida todeta normaalissa lihantarkastuksessa, joten ne voivat saastuttaa lihaa ja lihatuotteita (Schwartz 1999).

Myös ihmisten salmonellatartunta voi olla oireeton. Salmonella aiheuttaa ihmisillä kuitenkin usein ruuansulatuskanavan oireita (ripulia, vatsakipua, kuumetta, päänsärkyä ja oksennusta). Ensimmäiset oireet ilmaantuvat yleensä 12–48 tunnin kuluttua tartunnan saamisesta ja kestävät 3–4 päivää. Harvinaisissa tapauksissa tartunta johtaa potilaan kuolemaan. Huomattavasti tätä yleisempiä ovat sen sijaan nk. jälkioireet kuten nivel- ja silmätulehdukset. Reaktiivista niveltulehduksta todetaan 1–15 %:lla akuutin salmonelloosin sairastaneista henkilöistä. Niveloireet alkavat yleensä 7–15 päivän kuluttua ruuansulatuskanavan oireiden alkamisesta. Useimmat potilaat paranevat 3–5:ssä kuukaudessa. 16 %:lla näistä tapauksista oireet muuttuvat kuitenkin kroonisiksi (Leirisalo-Repo et al. 1997; Ekman 2000).

Eräs keskeisiä ongelma-alueita mikrobiologisten riskien arvioinnissa on annos-vasteen arviointi, niin myös salmonellan osalta. Useimmat annos-vastekokeet on tehty joko eläimillä tai terveillä nuorilla aikuisilla, joten tuloksia ei suoraan voi käyttää normaaliväestön, puhumattakaan riskiryhmien annos-vasteiden arvioimiseksi. Yleisesti oletetaan, että vasta annokset 10^7 – 10^9 salmonellasolua aiheuttavat sairastumisen. Eräissä ruokamyrkytyksissä on kuitenkin raportoitu sairastumisia jopa alle 10^3 solun annoksella. Tässä riskinarviointimallissa on käytetty normaaliväestölle sovitettua ns.

beta-Poisson annos-vastemallia (WHO/FAO 2002). Siinä käytettävä arvio tarjoiluhetken keskimääräisestä salmonellapitoisuudesta (pesäkettä muodostavaa yksikköä /g, PMY/g) on arvioitu laskemalla kulutusta kuvaavassa päättelyketjussa (inferenssimallissa) nykytilanteen havaintoaineistoon (1999) perustuva nk. posteriorijakauma.

1.2.3 Altistuksen arviointi

Salmonellan esiintymistä alkutuotannossa voidaan arvioida useista eri lähteistä kerätyn tiedon perusteella.

Rehut

Rehuilla on merkitystä salmonellan leviämislle sikaloihin, mutta rehun salmonellavalvonta ei sisälly suoraan kansalliseen salmonellavalvontaohjelmaan. Rehun aiheuttamia salmonellaepidemiaa sioissa ei ole raportoitu salmonellavalvontaohjelman voimassaoloaikana. Rehujen osuutta sikojen salmonellatartuntoihin ei mallinnettu tässä riskinarvioinnissa, koska tarvittavia tietoja saastuneen rehun vaikutuksesta suomalaiselle sianlihan tuotannolle ei ole saatavissa.

Elävät eläimet

1990-luvun loppupuoliskolla tutkittiin vuosittain satoja sikaloita ulostenäyttein salmonellabakteerin varalta teurastamoiden terveysohjelmien puitteissa. Vuosina 1998–2000 ei näistä näytteistä todettu positiivisia sikaloita lainkaan, ja sitä ennenkin taso oli matala: vuonna 1996 positiivisiksi todettiin 0,06 % ja vuonna 1997 0,16 % tutkituista sikaloista.

Keskeinen osa valvontaohjelmaa on teuraaksi tulevien emakoiden ja lihasikojen imusolmuketutkimukset salmonellan varalta. Niissä on todettu salmonellaa 0,06–0,30 %:ssa emakoista ja 0,09–0,19 %:ssa lihasioista tehdyissä tutkimuksissa vuosien 1996–2000 aikana.

Salmonellan esiintymistä sikatiloilla ei tässä projektissa kuitenkaan mallinnettu. Yksi syy oli juuri salmonellan vähäinen esiintyminen. Muita syitä olivat tilakohtaisten tutkimusten epäsäännöllinen näytteenotto sekä se, että näytteenottomenetelmät eivät kauttaaltaan ole yhteneväisiä ja standardisoituja. Suurimmasta osasta sikaloita ei näytteitä oteta ollenkaan ja toteutuneet salmonellatutkimukset on kohdistettu vain tietyn tyyppisiin sikaloihin (terveysohjelmiin pyrkiviin). Teurastamoilla tehtävät imusolmuketutkimuksetkaan eivät anna tarkkaa kuvaa salmonellan esiintyvyydestä tiloilla (näytemäärä/tila on pieni ja näytteenotto painottuu suuriin sikaloihin) eivätkä siitä, missä vaiheessa elämäänsä sika on saanut tartunnan.

Sianliha ja sianlihaa sisältävät elintarvikkeet

Altistuksen arvioinnissa salmonellan tartuntareittiä on mallinnettu tässä riskinarvioinnissa teurastamolta alkaen ja päätyen kuluttajalle tarjottaviin annoksiin. Altistuksen arvioinnista saatu tieto yhdistetään lopulta riskin kuvaamisessa annosvaste- yms. tietojen kanssa riskin arvioimiseksi (vuosittain sianlihasta peräisin olevien ihmisten sairaustapausten määrä).

Tässä riskinarviointimallissa keskitytään ainoastaan lihasikoihin ja niiden imusolmukelöydöksiin. Tämä johtuu siitä, että emakoista saatava liha edustaa ainoastaan 5–6 % koko sianlihan tuotannosta. Lisäksi emakoiden liha käytetään kokonaisuudessaan kuumennettaviin tuotteisiin, joiden salmonellariski kuluttajalle on pieni. Emakoiden voidaan myös olettaa olevan lihasikoja harvemmin salmonellan erittäjiä siinäkin tapauksessa, että niiden imusolmukkeista eristetään salmonellaa.

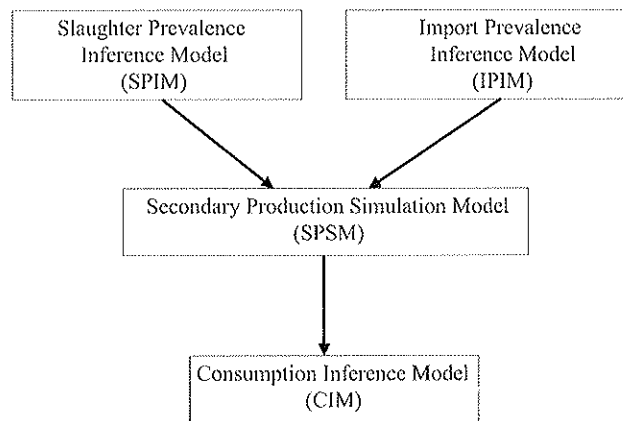
Keskittymällä imusolmukelöydöksiin (eikä esim. pintasivelylöydöksiin niihin liittyvine jatkotoimenpiteineen) ja olettamalla jokaisen testiposiitiivisen lihasian ruho salmo-

nellan kokonaan saastuttamaksi haluttiin rakentaa malli ns. pahinta mahdollisuutta silmällä pitäen (worst case scenario). Pahinta mahdollisuutta edustaa myöskin leikkaamo- ja prosessointiristikontaminaation malli, joka ennustaa varsin jyrkästi sitä suuremman kontaminaation mitä enemmän raaka-aineen salmonellapitoisuudelle valittu kynnystaso mallissa ylittyy. Ristikontaminaation suuruudesta on hyvin vähän mitattua tietoa, joten teurastamoja, leikkaamoja ja lihankäsittelylaitoksia käsittelevä osa mallia perustuu hyvin karkeaan kuvaukseen.

Mallin laskelmia varten jauheliha sisällytettiin samaan luokkaan tuoreen lihan kanssa. Mallia varten tehtiin myös oletus, että lihavalmisteen kuumennetaan tuotantoprosessinsa aikana vähintään 70 °C:een. Loput lihatuotteet katsottiin raakalihavalmistetuiksi.

Altistuksen mallintaminen

Koko riskinarviointimallinnus sisältää neljä WinBUGS tai @Risk -ohjelmilla tehtyä osamallia (Kuva 1), joiden tulos ilmaistaan todennäköisyysjakautumina.



Kuva 1.
Sianlihasta kuluttajalle aiheutuvan salmonellariskin arviointimalli osamalleineen.

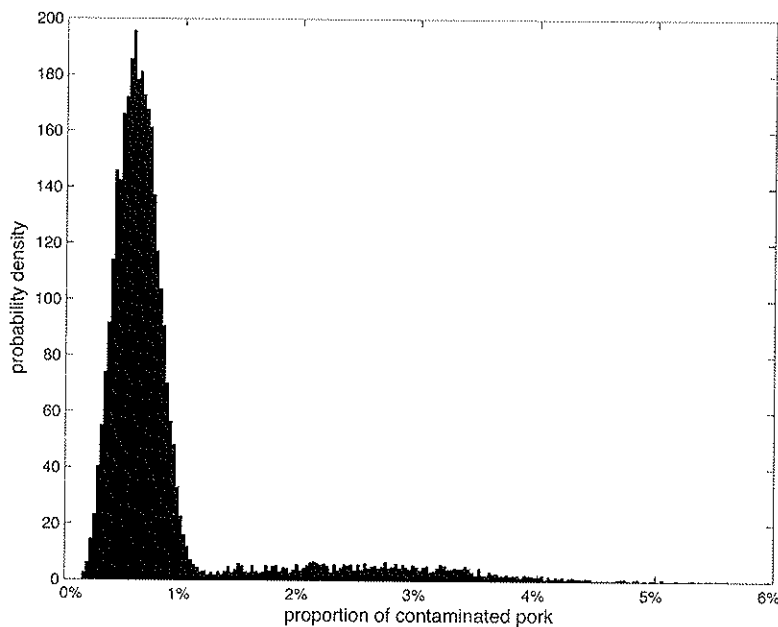
Ensimmäinen osamalli, **Teuraseläinmalli** (Slaughter Prevalence Inference Model, SPIM), arvioi vuoden 1999 tietojen perusteella teuraaksi tulevien infektoituneiden lihasikojen todellista määrää. Mallissa on otettu huomioon tutkittujen imusolmukenäytteiden ja niistä todettujen positiivisten löydösten määrä sekä laboratoriomenetelmän herkkyys.

Toinen osamalli, **Tuontimaamalli** (Import Prevalence Inference Model, IPIM), arvioi salmonellan todellista esiintyvyyttä eri maista tuotavassa sianlihassa. Malli ottaa huomioon maiden itsensä ilmoittamat tutkimustulokset salmonellan esiintymisestä sianlihassa ja sianlihatuotteissa, Suomen valvontaohjelman edellyttämät salmonellan varalta tehdyt lisätutkimukset sekä laboratoriomenetelmän herkkyuden. Tässä riskinarvioinnissa selvitettiin sianlihan tuontimäärät ja -maat ja salmonellan esiintyvyys eri tuontimaissa, sekä arvioitiin tuontilihan käyttötarkoitus vuonna 1999.

Tuotantoa- ja prosessointia kuvaava kolmas osamalli, **Prosessointimalli** (Secondary Production Simulation Model, SPSM), arvioi kahden edellisen osamallin ja muiden tietojen pohjalta vuosittain salmonellalla saastuneiden sianliha-annosten määrän Suomessa sisältäen sekä tuoreen lihan että lihatuotteet. Osamallin avulla voidaan simuloida yleisellä tasolla salmonellatartunnan kulkua läpi teurastamo-, leikkaamo- ja jalostusvaiheiden. Mallissa on huomioitu tilastotietoja teurastettujen lihasikojen määristä ja teuraspainoista, sekä tutkimustietoja luuttomaksi leikattujen ruhojen painoista. Asiantuntijoiden arvioiden perusteella on saatu syöttötiedot lihavalmisteen ja tuoreen lihan väliselle ristikontaminaatiolle sekä lihantuotannon ja kaantumisen tuoreeseen lihaan (sisällytetty myös jauheliha), raakalihavalmistuksiin

ja kypsennettyihin lihavalmisteisiin. Kansanterveyslaitoksen Finravinto 97 (National Public Health Institute 1998) tutkimuksen perusteella on arvioitu keskimääräinen annoskoko sianlihaa syöväällä aikuisväestöllä. Mallin perusteella Suomessa myynnissä olevassa sianlihassa esiintyisi salmonellaa keskimäärin 0,85 %:ssa (Kuva 2).

Vaikka riskinarviointimalli pyrkii kuvaamaan vain yleisellä tasolla salmonellatartuntaa, siinä on silti monia sellaisia kohtia, joiden osalta arvioinnin kuluessa on jouduttu turvautumaan asiantuntijoiden arvioihin. Asiantuntijoiden käyttäminen puuttuvien tietojen lähteenä on yleistä mikrobiologisessa riskinarvioinnissa. On mahdollista, että asiantuntijoiden arviot osuvat harhaan, mutta toisaalta nykytekniikan antama mahdollisuus käyttää todennäköisyysjakaumia keskimääräisen arvion sijasta mahdollistaa jonkin verran epävarmuuksien huomioon ottamista.



Kuva 2.
Salmonellan esiintyvyys Suomessa myynnissä olevassa sianlihassa vuoden 1999 tilanteen perusteella oli 0.85 %, 95 %:n vaihteluväli [0.3 %, 3.0 %]

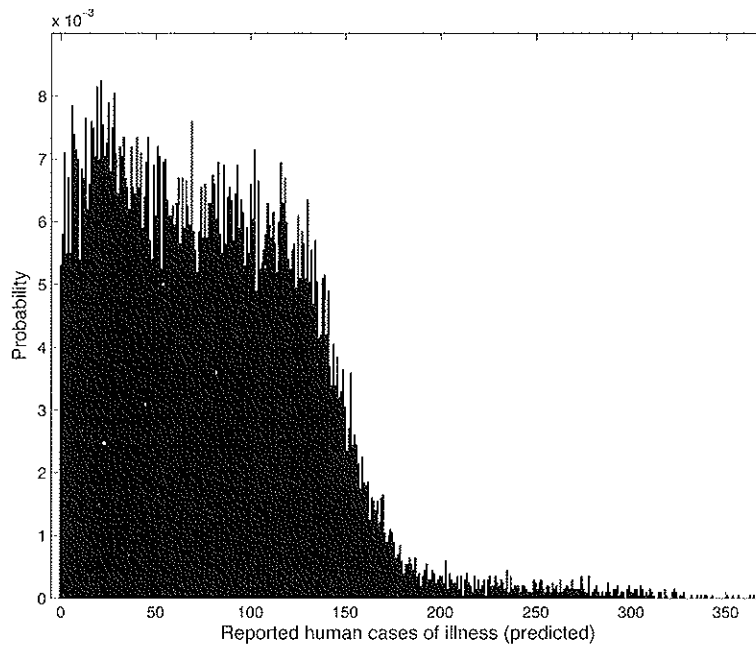
1.2.4 Riskin kuvaaminen

Se, miten monta salmonellasolua ruokailija saa syöntihetkellä, riippuu salmonellasolujen määrästä lihassa, ruoan kypsennysasteesta sekä keittiössä tapahtuvasta ristikon-taminaatiosta. Määrän arvioiminen on siten vaikeaa. Riskinarviointimallin neljännessä osassa, **Kuluttajamallissa** (Consumption Inference Model, CIM), hyödynnettiin siksi ns. Bayesin inferenssimallia, joka perustuu arvioituun sianlihasta peräisin olevaan sairaustapausten määrään (minimi- ja maksimimäärät) havaintovuoden (1999) tilastoitujen sairaustapausten perusteella (KTL 2001). Maksimimääräksi valittiin niiden kotimaista alkuperää olevien salmonelloosien lukumäärä, joita vastaavat serotyypit oli eristetty joistakin valvontaohjelman mukaisista näytteistä. Naudan-, sian- ja siipikarjan osuudet näistä ihmisten salmonelloositapauksista arvioitiin jakamalla tapaukset eri eläinlajeista ja elintarvikkeista tehtyjen eristysten suhteessa. Näin sianlihan aiheuttamien sairaustapausten määrän arvioksi saatiin 0–129 sairaustapausta vuonna 1999.

Sianlihasta peräisin olevasta arvioidusta sairastapausten määrästä (minimi ja maksimi) ja Prosessointimallilla simuloidusta annosten määrästä laskettiin annetulla annosvastemallilla (WHO/FAO 2002) arvio siitä, kuinka monta pesäkettä muodostavaa yksikköä annoksessa olisi keskimäärin (CFU/g) syöntihetkellä. Kotimaisen ja englantilaisen arvion (Ruutu 2001, Wheeler 1999) perusteella arvioitiin samalla myös se osuus, joka sairastapauksista päättyy terveystapauksien (KTL) rekisteriin (10–30 %). Näin annosvastemalli kalibroitiin havaintovuoden (1999) tietojen perusteella, eikä

syöntihetken salmonellakontaminaation tasolle tarvinnut antaa suoraa epävarmuusjakaumaa riippumattomasti erillisenä asiantuntija-arviona, mikä olisi johtanut helposti ylisuureen tapausennusteeseen suuren epävarmuutensa vuoksi. Kuluttaja-osamallin avulla saatua arviota keskimääräisestä kontaminaatiosta syöntihetkellä käytettiin myöhemmin avuksi simuloitaessa erilaisia skenaariotilanteita.

Tuloksissa esiintyvä suuri hajonta kuvaa lähtötietoihin liittyvää epävarmuutta. Siten ääripäiden tulokset eivät ole todennäköisiä. Ennusteen 95 % todennäköisyysväli sianlihan aiheuttamien tilastoitujen kotimaisten (eli kotimaassa saatujen) sairaustapausten määrälle Suomessa vuoden 1999 aineiston perusteella oli [4,193] ja keskiarvo 79 (kuva 3).



Kuva 3.
Ennustejakauma vuosittain raportoitujen sianlihan ja sianlihatuotteiden aiheuttamien salmonelloositapausten määrälle. Tulos perustuu vuoden 1999 tietoihin (100 000 MCMC iteraatiota).

Kun kotimaassa tuotettujen raaka-aineiden salmonellan esiintyvyys simuloitiin lähes olemattomaksi (0.00001 %), saatiin saastuneiden annosten esiintyvyydeksi keskimäärin 0,34 %, 90 %:n vaihteluväli [0,12 %,0,58 %], jota voidaan siis pitää tuontilihan ja lihavalmisteen aiheuttamana sianliha-annosten salmonellan esiintyvyytenä. Keskiarvoja verrattaessa noin 40% salmonellaa sisältävistä sianliha-annoksista olisi siten peräisin tuodusta sianlihasta, joka kattaa noin 8 % kulutuksesta. Toisaalta tuontilihan todellisen prevalenssin arvio sisältää puuttuvista tiedoista johtuvia epävarmuuksia jotka osaltaan johtavat korkeampaan arvioon.

Kuluttajamallilla arvioitiin myös tuontilihan ja -lihavalmisteen aiheuttamaa sairaustapausten määrää suorittamalla simulointi siten, että kotimaisen sianlihan salmonellan esiintyvyys asetettiin hyvin alhaiseksi (0.00001 %). Sianlihaa sisältävien tuontielintarvikkeiden aiheuttama sairaustapausten määrä vuoden 1999 aineiston perusteella oli 36 (95 %:n vaihteluväli [1,85]) sairaustapausta eli ne olisivat aiheuttaneet noin 45 % kaikista sianlihasta tai -tuotteista aiheutuneista salmonelloositapauksista.

1.3 Riskinhallintatoimien vaikutus

Riskinhallintatoimien vaikutuksen tutkimiseksi simuloitiin mallilla kolme eri skenaariota. Yhdistämällä kaikki neljä osamallia saatiin todennäköisyysjakauma sille, kuinka monta suomalaista vuosittain sairastuu sianliihasta peräisin olevaan salmonellaan (Kuva 3). Koska tavoitteena oli tutkia kansallisen salmonellavalvontaohjelman vaikutusta kuluttajien riskiin, oli vertailtavien skenaarioiden sijoituspaikka teurastamo ja tuonti. Sen vuoksi tuotantoketjun loppuosan tarkentamista ei katsottu erityisen tarpeelliseksi. On siten huomioitava, että mallin tuottamia arvioita itse sairaustapausten määrästä on pidettävä suuntaa-antavina.

Skenaariot:

1) Valvontaohjelmaan perustuvia tutkimuksia ei vaadita sianlihan tuonnin yhteydessä

Jos kansallisen salmonellavalvontaohjelman edellyttämiä tutkimuksia ei vaadittaisi tuontieristä, mallin ennuste 95 % todennäköisyysväliksi sianlihan aiheuttamille raportoiduille kotimaisten sairastapausten määrälle on [4,202] ja odotusarvo noin 82. Odotusarvo on vain noin 1,04 kertaa suurempi kuin vastaava luku (79) lisävakuuksien voimassa ollessa. Tämä johtuu siitä, että tuontierien tutkimukset koskevat vain tuoretta lihaa ja sitäkin rajoitetusti.

2) Salmonellaa esiintyy nykyistä enemmän kotimaisissa teuraslihasioissa

Vuonna 1999 salmonellan todellinen esiintyvyys teurastettavissa lihasioissa oli todennäköisimmin 0,50 %, eikä siinä ole tapahtunut muutoksia vuosina 1996-2000. Jos esiintyvyys teuraspopulaatioissa nousisi 1 % :iin, ihmisillä todettujen sairastapausten odotettu määrä nousisi noin 248:aan henkilöön, (95%:n vaihteluväli [13,543]), eli noin kolminkertaiseksi. Jos esiintyvyys teuraspopulaatioissa nousisi 5%:iin, ihmistapausten odotettu määrä olisi noin 948 (95 % vaihteluväli [52,2090]), sairastapausta eli yli kahdeksan kertaa enemmän nykytilanteeseen verrattuna. Tämä tulos johtuu oletetusta ristikontaminaatiomallista ja sen oletetusta kynnyсарvosta.

3) Tuonti kattaa 50 % kulutuksesta

Lopuksi tutkittiin tilannetta, jossa sianlihan ja sianlihatuotteiden tuonti nousisi valvontaohjelman voimassa ollessa niin paljon, että se kattaisi peräti 50 % kotimaisesta kulutuksesta (osuus kulutuksesta v.1999 oli 8 %). Salmonellan esiintyvyyden arvioimiseksi Suomessa ja tuontilihassa käytettiin vuoden 1999 tietoja. Kokonaiskulutuksen oletettiin pysyvän nykytasolla, jolloin vastaavasti kotimainen tuotanto pienenesi. Arvio tuontimaista ja tuonnin jakautumisesta tuoreeseen lihaan (johon sisältyi myös jauheliha), raakalihavalmisteisiin ja (kypsennettyihin) lihavalmisteisiin kyseisessä skenaariossa perustui lihateollisuudelle osoitettuihin asiantuntijakyselyihin. Niiden mukaan tuoreen lihan ja pohjoismaiden ulkopuolisen tuonnin osuudet kasvaisivat, jolloin lisävakuuksien merkitys lisääntyisi. Kyseisessä tilanteessa mallin antama ennuste sianlihan aiheuttamille salmonelloositapausten odotetulle määrälle olisi noin 189 (95 %:n vaihteluväli [10,414]) eli 2,4-kertainen nykytilanteeseen verrattuna. Jos lisävakuudet poistettaisiin, sairastapausten odotettu määrä olisi noin 241 (95 %:n vaihteluväli [13,538]) eli noin 3,1-kertainen.

1.4 Johtopäätökset

Suomalaisilla sioilla esiintyy siis erittäin vähän salmonelloosia. Sianlihan alkutuotantoa ei mallinnettu, koska vähäisten tapausmäärien ja suomalaiseen tuotantoon soveltuvan salmonellatiedon puutteen perusteella ei voitu vetää luotettavia johtopäätöksiä. Sen sijaan valvontaohjelmaan kuuluvien imusolmuketutkimusten ja -löydösten perusteella mallilla estimoitiiin salmonellan todellinen esiintyvyys teuraaksi tulevilla lihasioissa, mikä oli noin 0.6 % (keskiarvo), (95 %:n vaihteluväli [0,24 %, 1,28 %]).

Mallilla saadun arvion mukaan Suomessa tarjolla olevien salmonellalla saastuneiden sianliha-annosten todellinen osuus kaikista annoksista on keskimäärin 0,84 % olettaen että ne ovat satunnaisia otoksia koko lihantuotannosta. Niistä voisi olla noin 60 % peräisin kotimaisesta ja noin 40 % ulkomaisesta sianlihasta. Mallin avulla voidaan todeta, että vaikka mukaan luettaisiin myös piilevät salmonellatartunnat, salmonellan esiintyvyys Suomessa jää alle 1 %:n, ja että kansallisen valvontaohjelman sianlihalle ja sianlihatuotteille asettama tavoitetaso saavutetaan myös näin arvioituna. Toisaalta nähdään, että kotimaisen sianlihan salmonellapitoisuudella on suuren kulutusmääränsä vuoksi tärkeä kokonaismerkitys kuluttajariskiinkin.

Vuosina 1995–2000 Suomessa on raportoitu noin 3000 salmonelloositapausta ihmisillä vuosittain. Niistä on ollut ulkomailla tartunnan saaneita noin 65–81%. Kotimaassa saaduista salmonelloositapauksissa sianliha osoittautui välittäjäelintarvikkeeksi kerran vuonna 1997. Tässä riskinarvioinnissa käytettiin raportoitujen sairaustapausten ja serotyypierottelun perusteella sianlihasta peräisin olevien raportoitujen tapausten määrän alarajana tarkasteluvuonna (1999) nollaa tapausta ja ylärajana 129 tapausta. Mallista saadun ennustejakauman perusteella sianlihas-ta peräisin olevaan salmonellaan odotetaan raportoitavan sairastuvaksi Suomessa noin 79 (keskiarvo), 95 %:n vaihteluväli [4,193], ihmistä vuosittain, jos tilanne säilyy samankaltaisena kuin vuonna 1999. Niistä maahan tuotu sianliha aiheuttaa mallin mukaan noin 36 (keskiarvo), 95 %:n vaihteluväli [1,85], sairaustapausta. Keskiarvoja verrattaessa ulkomaisen sianlihan aiheuttamia sairaustapauksia olisi siten noin 45 % kaikista sianlihan aiheuttamista salmonellooseista. Absoluuttisia tapausmääriä on kuitenkin pidettävä vain suuntaa antavina epävarmuutta lisäävien tekijöiden vuoksi. Tapausmäärien mahdollisesti sisältämän virheen vaikutusta voidaan vähentää jos skenaarioiden välinen vertailu perustuu suhteellisiin, ei absoluuttisiin, tapausmäärien eroihin.

Salmonellavalvontaohjelman perusteella saadut lisävakuudet kohdistuvat vain osaan tuontilihasta. Vakuuksien alaisen tuontilihan määrä oli vuonna 1999 ainoastaan noin 11 % kaikesta sianlihan ja sianlihatuotteiden tuonnista, tuonnin kokonaisuudessaan vastatessa vain noin 8 % sianlihan kokonaiskulutuksesta. Siten tuontisianlihan aiheuttamien salmonelloositapausten määrä suhteessa suomalaisen sianlihan aiheuttamiin tapauksiin saattaa olla suuri. Toisaalta arvio salmonellan esiintyvyydestä ulkomaisessa lihassa perustuu osin puutteellisiin tietoihin mikä lisää epävarmuutta tältä osin.

Malliin sisältyy epävarmuutta ja oletuksia, jotka on esitelty tässä raportissa.**Mallin avulla voidaan vetää kuitenkin seuraavat johtopäätökset:**

1. Salmonellan esiintyvyys sianlihan tuotannossa on Suomessa matala, ja alittaa selvästi tavoitetason 1 % myös todellisena esiintyvyytenä arvioituna.
2. Salmonellan esiintyvyydellä alkutuotannossa on selvä merkitys kuluttajalle aiheutuvan riskin suuruuteen. Tämä suhde ei ole kuitenkaan lineaarinen.
3. Vaikka kotimainen sianliha saattaa aiheuttaa mallin perusteella yli puolet sairaustapauksista, ulkomaisen sianlihan vaikutus kulutusmääriin suhteutettuna on todennäköisesti kotimaista suurempi.
4. Nykyiset lisävarusteet eivät suojaa kuluttajaa salmonelloosilta kovin tehokkaasti, koska ne kohdistuvat vain pieneen osaan tuonnista (11 %) ja kulutuksesta (0,88 %). Tuontimaiden vaihtuessa niiden merkitys lisääntyy, jos tuontimaassa salmonellaa esiintyy enemmän kuin Suomessa.
5. Kotimaisen salmonellan esiintyvyyden nouseminen sianlihassa 1 %:iin vastaisi kuluttajiin kohdistuneena vaikutuksena (kuluttajien sairastumisina) ilman lisävarusteita tuotavan lihan määrän lisääntymistä 50 %:iin kulutuksesta, olettaen tuontimaiden jakauman pysyvän lähes ennallaan.

2. Summary and conclusions

2.1 Introduction

Since 1995, Finland has had an EU-approved national *Salmonella* Control Programme aiming to keep the prevalence of *Salmonella* low both in domestic animals as well as in food products derived from animals, thus ensuring the safety of food for consumers. Another aim of the control programme is to produce a reliable picture of the incidence of *Salmonella* in production animals and animal-derived food products, and also to ensure that the incidence of *Salmonella* in slaughtered animals remains no higher than 1% at the national level.

The programme covers the most important domestic production animals: cattle, pigs and poultry, as well as their meat and eggs. The control program allows Finland to demand that a portion of imported beef, pork and poultry meat, eggs and live poultry are examined for *Salmonella* in the country of origin if that country does not have an EU-approved salmonella control programme comparable to Finland's (so-called additional guarantees). In practice, only Sweden and Norway have such programs. These additional guarantees do not apply to meat products or to fresh pork and beef which are imported as raw materials to be used in meat products heated to at least 70°C.

The Finnish *Salmonella* Control Programme (FSCP) has now been in effect for eight years. This risk assessment analyses the risk of infection to consumers of pork and pork products sold in Finland, as well as the effects the risk management measures included under the programme have on this risk. This risk assessment has been based on data gathered for the control programme as well as on other available data. In addition, we analyzed how these risks would change if the national *Salmonella* control programme and the additional guarantees did not exist, and how it would change if the amount of imported pork and pork products would increase greatly. This work has been done at the request of the Ministry of Agriculture and Forestry.

2.2 The Risk Assessment Model

2.2.1 Hazard Identification

Salmonellosis is caused by the *Salmonella enterica* bacteria. About 2500 serotypes of *S. enterica* are known. All serotypes can cause infection in humans, although there are differences between different serotypes in how easily they can cause infections. *Salmonella* bacteria can multiply in food products if the temperature during storage and transportation allows. *Salmonella* is usually destroyed in processes where the temperature exceeds 70°C, so it may persist in products processed at lower temperatures. In

addition, the effectiveness of heat treatment depends on the humidity of the product: in some cases, temperatures as high as 130°C are needed to destroy *Salmonella*.

In 1995-2000, the number of human *Salmonella* infections in Finland remained relatively steady at about 3000 cases per year (50-66 cases per 100,000 inhabitants/year). About 100 *Salmonella* serotypes are responsible for *Salmonella* infections each year. In the 1990s, over half of all infections were caused by the serotypes *Salmonella* Enteritidis and *Salmonella* Typhimurium. The vast majority of the *Salmonella* Enteritidis infections (89-91%) came from abroad, while the majority of *Salmonella* Typhimurium infections (71-81%) were of domestic origin. In 1995-1999, 65-81% of all salmonellosis infections came from abroad.

Salmonella has only rarely been found on Finnish pork farms. *Salmonella* has only been found from an average of 0.16% of lymph node samples of slaughtered pigs analyzed under the Finnish *Salmonella* Control Programme, and even less from surface swab samples. In samples from cutting plants, *Salmonella* has only been found in an average of 0.02% of samples. In 1999 and 2000 the presence of *Salmonella* in pork at retail was studied (Hatakka et al. 2000, Hatakka et al. 2001), but *Salmonella* was not found in any of the samples tested (171 and 165, respectively).

Salmonella is rather common in all the major pork producing countries. It has been estimated that in the 1990s, *Salmonella* originating in pork was responsible for 10% of human *Salmonella* infections in Denmark, 15% in Holland, and 20% in Germany (Hald & Wenger 1999). In some salmonellosis cases, it has even been possible to trace the infection source to a single slaughterhouse (Wegener & Baggesen 1996) or pig farm (Maguire et al. 1993). During the time the Finnish *Salmonella* Control Programme has been in effect, there has been one case (1997) where it could be shown that pork caused a case of salmonellosis (Kukkula 1998).

2.2.2 Hazard Characterization

Salmonella can grow in temperatures of 5-46°C, although the optimal temperature is 35-37°C. The minimum water activity for growth is 0.95, but cells can survive long periods in dry material. 9% NaCl prohibits the growth of *Salmonella* as well as a pH outside the range of 4.0-9.5 (Jay 2000; Ray 2001).

In pigs, *Salmonella* infections are usually symptomless. Symptoms, if any, are typically seen in pigs from weaning to about 4 months of age. Most pigs make complete clinical recovery but a portion may remain carriers and intermittent shedders until the end of the finishing period. Symptomless carriers cannot be detected in standard meat inspections, so they can contaminate meat and meat products (Schwartz 1999).

Salmonella infections in humans can also be symptomless. However, in humans *Salmonella* often causes febrile gastroenteritis, i.e. diarrhea, stomach ache, fever, headache, nausea and vomiting. The first symptoms usually appear 12-48 h from infection and continue for about 3-4 days. In rare cases, infection can result in the patient's death. Much more common are various so-called sequelae such as arthritis and ophthalmia. Reactive arthritis is observed in 1-15% of patients with acute salmonellosis. Onset typically occurs from 7 to 15 days after the beginning of gastrointestinal symptoms and most patients recover within the first 3 to 5 month. However, in 16% of patients the symptoms become chronic (Leirisalo-Repo et al. 1997; Ekman 2000).

One of the problem areas in assessing microbiological risks is estimating the dose-response, and this is true for *Salmonella* as well. Most dose-response tests have been conducted with either animals or healthy, young adults, thus the results cannot be directly applied to the assessment of dose-responses for the normal

population, let alone for specific risk groups. It is generally assumed that it takes a dose of at least 10^7 - 10^9 cells/g to cause salmonellosis. However, data from outbreaks of salmonellosis have indicated that sometimes doses even below 10^3 cells/g are able to cause gastroenteritis. In this risk assessment model, we used a Beta-Poisson dose-response model adapted for the normal population (WHO/FAO 2002). The average concentration (colony forming units/g, CFU/g) *Salmonella* contamination at the time of consumption was estimated by computing, on the basis of presently available data (1999), a so-called posterior distribution from the Consumption Inference Model (CIM).

2.2.3 Exposure Assessment

The prevalence of *Salmonella* in primary production can be estimated on the basis of data coming from various sources.

Feed

Feed plays a role in the spread of *Salmonella* to pig farms, but *Salmonella* control of feed is not directly a part of the Finnish *Salmonella* Control Programme. Epidemics of *Salmonella* in pigs caused by feed have not been reported during the time the programme has been in effect. The role of feed in *Salmonella* infections in pigs was not modelled in this risk assessment, as the information necessary for determining the effects of contaminated feed on Finnish pork production is not available.

Living animals

During the late 1990s, hundreds of pig farms were inspected annually for the *Salmonella* bacteria by analysing faeces samples under the slaughterhouse health programmes. In 1998-2000, not a single positive case was found among these samples, and even prior to 1998 the level was very low. In 1996, 0.06% and in 1997 0.16% of the samples analysed were positive.

An essential part of the FSCP is analysis of the lymph nodes of slaughtered sows and finishing pigs to detect *Salmonella*. In tests during the years 1996-2000, *Salmonella* was found in 0.06-0.30% of sows and 0.09-0.19% of finishing pigs.

The prevalence of *Salmonella* on pig farms was not modelled in this project. One reason for this is the generally low prevalence of *Salmonella* in Finland. Other reasons were the irregularity of sampling from any given farm, as well as the fact that sampling methods are not thoroughly uniform and standardized. No samples are taken from the majority of pig farms, and the *Salmonella* studies that have been undertaken have only targeted certain types of pig farms (namely, those wishing to join health programmes). Also, the lymph node analyses undertaken at slaughterhouses do not give an accurate picture of the prevalence of *Salmonella* on farms (the number of samples taken per farm is low and the testing focuses on large pig farms), nor do these analyses reveal the age at which the pig has been infected.

Pork and food products containing pork

When assessing exposure, we have modelled the infection route starting from the slaughterhouse and ending in the consumer serving. Finally, the information obtained from exposure assessment is combined with information depicting the risk such as dose-response data, to come up with the annual number of human *Salmonella* infections originating from pork.

Only data from finishing pigs and their lymph node test findings were used in the model since the amount of meat received from sows is small (5-6%) compared to the total amount of pork meat production. In addition, sow meat is always heat-

treated and only used for processed meat products, and is therefore less likely to be contaminated with *Salmonella* at retail. Moreover, detecting *Salmonella* in a sow's lymph nodes might be less likely to indicate *Salmonella* excretion (as opposed to being a chronic carrier) than detecting *Salmonella* in a finishing pig.

By concentrating on lymph node findings (as opposed to surface swab findings with associated further measures) and by assuming that each finishing pig carcass that tests positive is thoroughly contaminated by *Salmonella*, we wished to construct a model representing a worst-case scenario. The model of cross-contamination between cutting and processing plants also represents a worst-case scenario. This model predicts that contamination rises rather sharply depending on how much the threshold chosen for the *Salmonella* levels of the raw material is exceeded by. There is very little measured data on the amount of cross-contamination, so the part of the model dealing with the slaughterhouse, cutting plant and meat processing plant is based on a very rough description.

For the calculations, minced meat was included in the same class as fresh meat. We also assumed that during production processes, meat products are heated to a minimum of 70°C. The rest of the meat products were considered as raw meat preparations.

Exposure Modelling

The entire risk assessment modelling consists of four submodels made with WinBUGS or @Risk software (Figure 1), whose results are presented as probability distributions.

The first submodel, the **Slaughter Prevalence Inference Model** (SPIM) was used to estimate the true prevalence of *Salmonella*-infected finishing pigs at the time of slaughter on the basis of 1999 data. The model takes into account the number of lymph node *Salmonella* tests of pigs, the number of positive findings, as well as the sensitivity of the microbiological testing method.

The second submodel, the **Import Prevalence Inference Model** (IPIM), evaluates the true *Salmonella* prevalence in imported pork and pork products. The IPIM takes into account the reported test results from the main exporting countries, the additional testing results required by the Finnish *Salmonella* Control Programme and the sensitivity of the microbiological testing methods. This risk assessment charted the quantities and countries of origin of imported pork and the prevalence of *Salmonella* in the different exporting countries, and evaluated the intended use of imported pork in 1999.

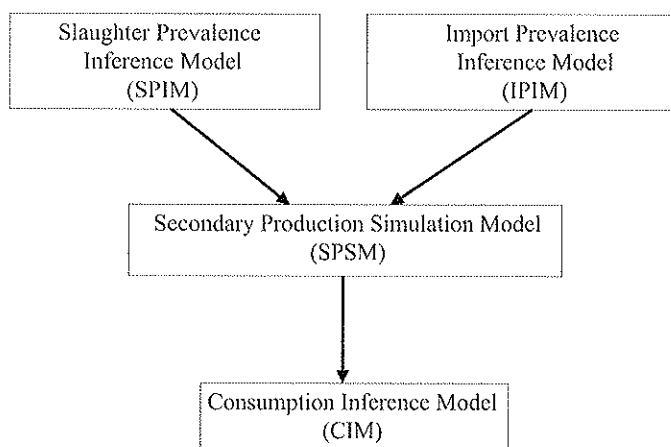


Figure 1.
The risk assessment model with its submodels for assessing the risks to the consumer of *Salmonella* in pork.

The third submodel covers production and processing. Called the **Secondary Production Simulation Model (SPSM)**, it uses the output of the SPIM and the IPIM as an input, combining them with other data to model the annual number of *Salmonella*-contaminated servings of pork, both raw meat and processed meat products, in Finland. This submodel can be used to simulate on a general level the path of a *Salmonella* infection through the stages of the production chain (slaughterhouse, cutting plant and processing plant). The model uses statistics about the number and slaughter weights of slaughtered finishing pigs as well as research data on the boneless weights of carcasses. Expert opinions were used to form input data for cross contamination between processed meat products and fresh meat as well as for the distribution of meat production into pork intended to be sold as fresh for consumers (including minced meat), raw meat preparations and processed (heat-treated) products. On the basis of the National Public Health Institute's Finfood 97 study (National Public Health Institute 1998) we have estimated the average serving size for the adult population. According to the model, on average, 0.85% of all pork sold in Finland was contaminated with *Salmonella* (Figure 2).

Although the risk assessment model attempts to model *Salmonella* infection only on a general level, it nevertheless contains many areas where we have been forced to resort to expert opinion. Using expert opinion as a source for information for which no relevant data exists is a common practice in microbiological risk assessment. It is always possible that the expert opinions are off the mark, but on the other hand the possibility offered by modern information processing technology of using probability distributions instead of average estimates provides some means to account for uncertainties.

2.2.4 Risk characterization

The number of *Salmonella* cells consumed by the consumer from a specific serving depends on the number of *Salmonella* cells in the meat, the temperature to which it has been heated and the chance of cross-contamination in the kitchen. It is therefore difficult to estimate this quantity. In the fourth part of the risk assessment model, the **Consumption Inference Model (CIM)**, we therefore utilized a so-called Bayesian inference model which estimates the number of human cases of illness caused by *Salmonella* from pork based on records of reported domestic human cases of illness

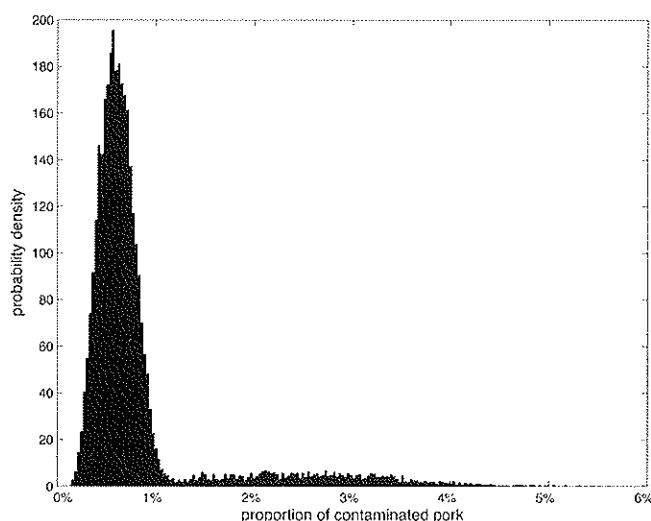


Figure 2.
The prevalence of *Salmonella* in pork in Finland, based on the 1999 situation, was 0.85%, interval of 95% [0.3%, 3.0%]

from the 1999 statistics (KTL 2001). To estimate the maximum number based on these records, we first chose those salmonellosis cases of domestic origin which had a corresponding serotype isolated from a FSCP specimen. Then, the relative shares of beef, pork and poultry as a cause for human salmonellosis cases was estimated by dividing the number of human cases in the proportion of serotype isolates made from different domestic animal species and food products. Thus we arrived at an estimate of 0-129 pork-borne human cases of illness in 1999.

Using the estimate of the number of pork-borne human cases of illness (minimum and maximum value) and the number of servings provided by the SPSM simulation, we applied a specific dose-response model (WHO/FAO 2002) to estimate how many colony forming units (CFU/g) such a serving would average at the time of consumption. On the basis of domestic and British estimates (Ruutu 2001, Wheeler 1999) we also estimated that 10%-30% of all human cases are detected and registered by health authorities (National Public Health Institute KTL) Thus we calibrated the dose-response model to the level of the data collection year (1999), and thereby did not need to fix a direct and independent probability distribution for CFU/g as a separate expert opinion, which would have lead to a sizable overestimate. We later utilized the estimate of average contamination at the time of consumption derived by the CIM submodel in simulating various scenarios.

The large variation in the results reflects uncertainty concerning input information. Thus the results at either extreme are improbable. The predictive distribution of the number of reported human cases of illness, under conditions similar to 1999, was 79 (mean), 95% interval of posterior probability [4,193] according to the CIM (Figure 3).

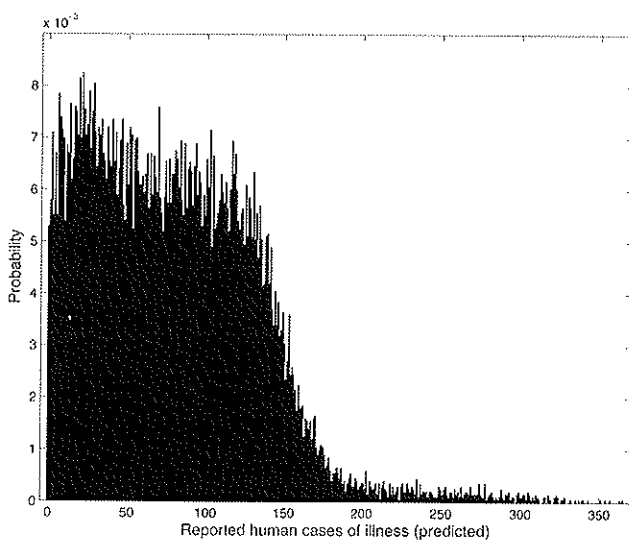


Figure 3.
Predictive distribution of the number of annually reported pork-borne human cases of salmonellosis. Result based on data from the year 1999, (100,000 MCMC iterations).

When the *Salmonella* prevalence of domestically-produced raw materials was simulated to be nearly non-existent (0.00001%), we obtained an average prevalence of contaminated servings of 0.34% (90% interval [0.12%, 0.58%], which can thus be considered to be the *Salmonella* prevalence caused by imported pork and pork-containing meat products. Thus, if we compare averages, about 40% of pork servings contaminated by *Salmonella* would come from imported pork, which accounts for about 8% of Finland's total pork consumption. However, the result is partly due to the inherent uncertainty in estimates of import prevalence due to lacking information.

We also used the model to estimate the number of human cases of illness caused by imported pork by carrying out a simulation where the *Salmonella* prevalence of domestically produced pork was set to be nearly non-existent (0.00001%). The result of this simulation was that, based on 1999 data, the number of human cases of illness caused by imported food products containing pork was 36, 95% interval [1,85], cases, meaning that they would be responsible for about 45% of all pork-borne salmonellosis.

2.3 Effects of interventions

In order to study the effects of the Finnish *Salmonella* Control Programme on the *Salmonella* risk to Finnish consumers, we used the model to simulate three different scenarios. By combining all four submodels, we obtained a probability distribution for how many Finns annually contract pork-borne salmonellosis (Figure 3). Since the objective was to study the effect of the FSCP and its consequences (the additional guarantees) on consumer risk, the scenarios compared were located at the slaughterhouse and import. We therefore did not consider it particularly necessary to specifically focus on the end stages of the production chain. We must therefore bear in mind that the estimates provided by the model should be considered suggestive.

Scenarios:

1) Additional guarantees under the FSCP are not required in conjunction with imported pork

If *Salmonella* testing under the FSCP would not be required for imported pork, the model predicts a mean of 82 reported human cases of pork-borne illness (95% interval [4,202]). This predicted number of cases is only 1.04 times larger than the corresponding number of cases (79) when additional guarantees are utilized. This is because testing under the additional guarantees only applies to fresh meat, and even then only to a limited extent.

2) Increased prevalence of *Salmonella* in domestic pork

In 1999, the real prevalence of *Salmonella* in finishing pigs was most probably 0.50%, and there were no changes in this figure in 1996-2000. If prevalence in the finishing pig population would rise to 1%, the predicted number of human cases of illness would rise to approximately 248 (95% interval [13,543]), or roughly triple the present level. If prevalence in the finishing pig population would rise to 5%, the predicted number of human cases would be approximately 948 (95% interval [52,2090]), or over eight times the present number of cases. These effects are due to the assumed cross-contamination model and its threshold value.

3) Imports account for 50% of consumption

Finally, we studied a scenario where, under the additional guarantees, imports of pork and processed meat products containing pork would rise so much that they would cover 50% of total consumption (in 1999, the actual figure was 8%). To estimate *Salmonella* prevalence in Finland and in the imported pork, we utilized 1999 data. The total consumption was estimated to remain on the present level, meaning that domestic production would be reduced correspondingly. The estimate of which countries the imported pork would originate from and how the imports would be distributed between pork intended to be sold as fresh for consumers (including

minced meat), raw meat preparations and processed (heat-treated) products in this scenario was based on expert opinion solicited from the meat processing industry. According to these expert opinions, the proportion of fresh meat imports and imports from outside of the Nordic countries would increase, whereby the importance of the additional guarantees would also increase. In this scenario, the predicted expected number of pork-borne human cases of illness would be approximately 189 (95% interval [10,414]), or 2.4 times the present number. If the additional guarantees would be removed, the predicted expected number of illness cases would be approximately 241 (95% interval [13,538]), or 3.1 times the present number.

2.4 Conclusions

The prevalence of salmonellosis in Finnish fresh pork is very low. We decided not to model the occurrence of *Salmonella* in primary production, since the small number of cases and lack of *Salmonella* data applicable to Finnish production would not have allowed us to draw reliable conclusions. Instead, we used the model to estimate, on the basis of lymph node analyses and findings from the FSCP, the real *Salmonella* prevalence of finishing pigs. This estimate is 0.6% (mean) (95% interval [0.24%,1.28%]).

According to the estimate provided by the model, the real proportion of *Salmonella*-contaminated servings among all consumed servings in Finland was 0.84% (mean) assuming these were drawn randomly from the total production. Of these, about 60% may come from domestic pork and about 40% from imported pork. The model allows us to conclude that even if we include latent *Salmonella* infections, the prevalence of *Salmonella* in Finland does not exceed 1%, and that the FSCP's objective of keeping *Salmonella* prevalence in pork and processed meat products containing pork at below 1% is thus met even under these conditions. On the other hand, we can see that *Salmonella* prevalence in domestic pork has a large effect on consumer risk due to its high total consumption.

In Finland, the annual incidence of registered cases of human salmonellosis in 1995–1999 was about 3000. The proportion of cases where the salmonellosis was contracted abroad was 65%–81%. Domestic pork was reported to be the cause of human salmonellosis outbreaks in one case in 1997. In this risk assessment, based on reported human salmonellosis cases and serotype isolates, we used zero as the minimum number of human cases of illness caused by pork and 129 as the maximum number of cases in 1999. Based on the model, the predictive distribution of the number of reported human cases of illness is 79 people annually (mean), with 95% interval of posterior probability [4,193], assuming circumstances remain similar to those in 1999. Of these 79 cases, the model predicts about 36 (mean) to be caused by imported pork, with 95% interval of posterior probability [1,85]. If we compare these averages, we can see that imported pork would be responsible for about 45% of all pork-borne human salmonellosis cases. However, due to uncertainty factors, we should consider these absolute figures to be only indicative. We can minimize the effects of possible errors in the absolute (baseline) number of cases by focusing on relative differences between outcomes under different scenarios.

Additional guarantees as a consequence of the FSCP only target a portion of all imported meat. In 1999, the proportion of all imported pork that fell under the additional guarantees was only some 11% of the total imports of pork and processed meat products containing pork, while imports amounted to no more than 8% of total pork consumption in Finland. Thus the number of salmonellosis cases caused by

imported pork relative to cases caused by domestic pork might be rather high. On the other hand, our estimate of *Salmonella* prevalence in non-domestic pork is based partly on insufficient information which increases the uncertainty of this estimate.

As we have detailed in this report, the model does contain uncertainties and assumptions. However, the model does allow us to draw the following conclusions:

1. The prevalence of *Salmonella* in Finnish pork production is low, and remains clearly below the 1% threshold level, even when estimated as true prevalence.
2. The prevalence of *Salmonella* in primary production has a clear significance on the size of consumer risk. This relationship is not linear, however.
3. Although according to the model domestic pork accounts for over half of human cases, when related to the quantities consumed, the effect of imported pork is greater than that of domestic pork.
4. Additional guarantees in their present form do not directly protect consumers from salmonellosis very effectively, since they cover only a small proportion of all imports (11%) and consumption (0.88%). However, if the countries Finland imports from change from the present, the significance of these measures will increase if the *Salmonella* prevalence in these export countries is higher than it is in Finland.
5. A rise in the prevalence of salmonella in domestic pork to 1% would have the same effect on consumers (human salmonellosis cases) as if 50% of consumption were covered by imported pork not subject to additional guarantees, assuming that the distribution of exporting countries remain approximately the same.

3. Introduction

3.1 Project history

Finland joined the EU in 1995. Since then there has been a national *Salmonella* control programme in Finland, approved by the EU. The aims of the programme are to keep the occurrence of *Salmonella* low both in domestic animals and food of animal origin, and thus to ensure the safety of food for consumers with respect to *Salmonella*. The overall strategy of the programme has been expressed in the following way: 1) *Salmonella* infection and contamination should be prevented at each level of the production chain; 2) The critical steps with respect to *Salmonella* infection and contamination are controlled; 3) Each time *Salmonella* is detected, measures are taken to eliminate it. In addition, the programme also intends to monitor reliably the prevalence of *Salmonella* infection in domestic animals at the time of slaughter, and the contamination level of fresh meat at the abattoir. The target prevalence of infection/contamination was set at a maximum of 1% annually at the national level and 5% annually at the slaughterhouse level.

The EU provides Finland with so-called additional guarantees, enabling Finland to require that meat imported from other countries is tested for *Salmonella* in the country of origin (commission decision 95/409/EC) if the meat is not intended for processed meat products. However, a certificate is not required if the dispatching country has a similar EU-approved *Salmonella* control programme as the Finnish one, though in practice only Sweden and Norway (a non-EU country) fulfil these requirements.

3.2 Objectives

The objectives of this risk assessment on *Salmonella* in pork production are the following:

1. To model the *Salmonella* risk caused by pork and pork products to Finnish consumers using data from 1999.
2. To study the effect of the additional guarantees resulting from the Finnish *Salmonella* Control Program on public health.
3. To study the effect of three scenarios of a hypothetical increase in *Salmonella* prevalence on public health.

4. Background information

4.1 Pork production in Finland

In 2000, there were 4,300 pig herds and about 1.3 million pigs in Finland. The number of pig herds is steadily decreasing, whereas the herd size is increasing

(Table 1). In 2000, the mean number of sows and finishing pigs per herd was 43 and 296, respectively.

In a farrowing-to-finishing unit, the respective numbers were 42 and 172 (MMMTIKE 2002).

Pig production is largely concentrated in South-Western and Western Finland. The pork production chain is described in Figure 4.

The population of Finland is 5,147,349 inhabitants (1999). Table 2 shows the overall production and consumption of pork in Finland.

The mean consumption of pork per inhabitant per year is 33-34 kg.

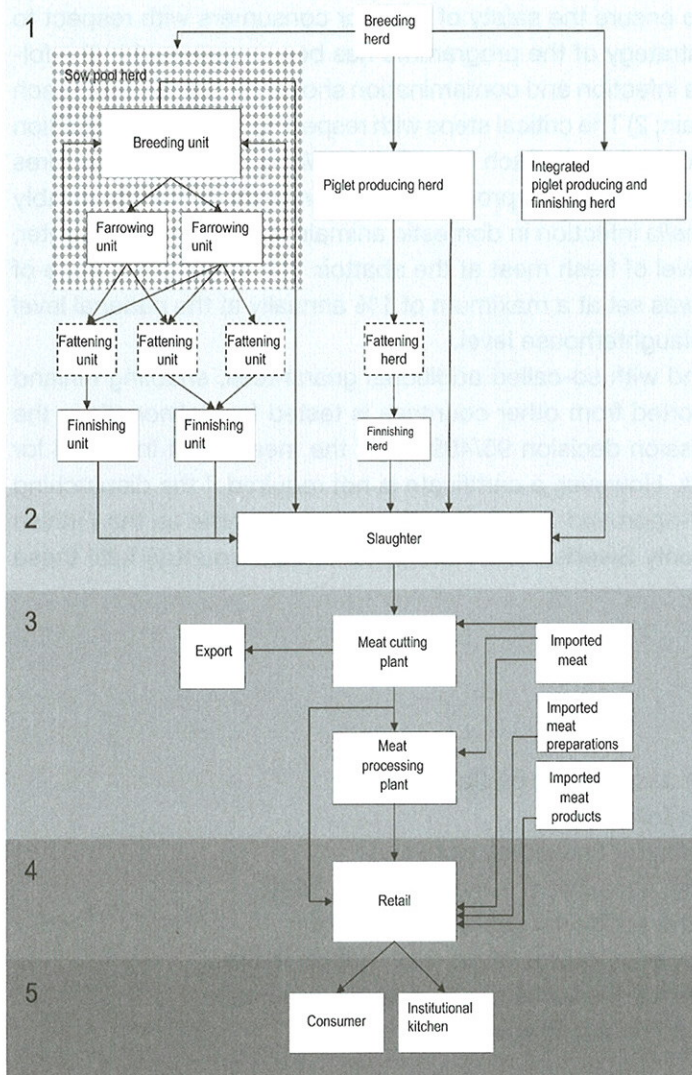


Figure 4. The pork production chain in 1999: 1. Primary production, 2. Slaughtering, 3. Processing, 4. Retail, 5. Consumption.

Table 1.

Number of pig herds and pigs in Finland in 1998-2000 (MMMTIKE 2002¹ and Finfood 2002²).

| Year | 1998 | 1999 | 2000 |
|--|-------|-------|-------|
| No. of pig herds ¹ | 5,296 | 4,831 | 4,300 |
| Total no. of pigs ¹ (thousands) | 1,401 | 1,351 | 1,298 |
| - of which sows ² | 187 | 180 | 184 |
| - of which finishing pigs ² | 421 | 431 | 405 |

Table 2.

Production, consumption, import and export of pork (mill. kg) in 1998-2001 (Finfood 2002).

| Year | 1998 | 1999 | 2000 | 2001 |
|-------------|------|------|------|------|
| Production | 185 | 182 | 173 | 176 |
| Consumption | 176 | 177 | 171 | 168 |
| Import | 13 | 15 | 15 | 12 |
| Export | 20 | 22 | 18 | 19 |

4.2 The Finnish *Salmonella* control programme for pigs

The Finnish *Salmonella* Control Programme (FSCP) comprises the control of cattle, pigs, and poultry, as well as of the meat and eggs obtained from them (Veterinary and Food Department, Ministry of Agriculture and Forestry 10.10. 1994, revised on 13.12. 1994). *Salmonella* inspections are carried out on the production farms and in the abattoirs and meat cutting plants. The goal of the FSCP is to keep the prevalence of *Salmonella* in the production animals, as well as in the meat and eggs obtained from them, at a level of no more than 1% throughout the country. At abattoirs and cutting plants the goal is to keep the incidence below 5%. National authorities are responsible for the programme.

The control programme for pork is comprised of the following parts:

- annual screening of the elite breeding herds for *Salmonella* (MMM Decision 24/EEO/1997)
- screening of young boars entering artificial insemination stations (MMM Ministerial letter 4/93, 26.11.1993)
- monitoring finishing pigs and sows at the abattoir (MMM Decision 8/EEO/95 concerning 1999; currently 20/EEO/2001)
- monitoring pig and sow carcasses after slaughter before chilling (MMM Decision 8/EEO/95)
- monitoring crushed meat at meat cutting plants (MMM Decision 8/EEO/95)

In addition, salmonellosis in pigs is a notifiable disease (MMM Decision 1346/1995, 23/EEO/95), which means that any time a veterinarian suspects salmonellosis due to clinical signs, faeces samples have to be taken for bacteriology. If *Salmonella* is detected, movement restrictions are placed on the herd, and actions, including sanitary measures, are taken by an official veterinarian to eliminate the infection from the herd.

The elite breeding herds, which send groups of pigs to phenotype test stations, are screened by analysing two pooled faecal samples annually. One pooled sample comprises faeces of weaned pigs and/or young breeding animals collected from five pens. The local official veterinarian collects the samples during one of four annual control visits. The corresponding provincial veterinarians are responsible for keeping an official list of the elite breeding herds, veterinary visits and annual screening samples. There were 110 elite breeding herds in 2001 in Finland (FABA 2002).

Salmonella infection in finishing pigs and slaughtered sows is monitored by analysing five ileocaecal lymph nodes per carcass. Samples are collected from all slaughterhouses in the country, and the sample size per plant is proportioned to the annual volume of slaughter. In 2000, the number of EU-approved establishments for pig slaughter was 15, and the number of small-scale slaughterhouses was 68 (National Food Agency). From the small-scale slaughterhouses, a minimum of two samples from both finishing pigs and sows must be collected. In total, about 3000 samples from both finishing pigs and sows are collected and analysed annually. The range of the tested finishing pigs and sows was 0.1-3.5% and 3.8-75% out of 2,064,492 and 68,721 slaughtered swine. Samples from five animals are pooled. If *Salmonella* is detected, samples from each individual animal are retested to detect the infected individual. In addition, faeces samples are collected from pigs in the corresponding herd to verify the *Salmonella* infection.

Carcasses are monitored for *Salmonella* contamination before chilling by analysing surface swab samples. The testing method was changed at the beginning of 2002. Until the end of 2001, two different swabbing areas of each carcass were combined into one sample. The swabbing areas were the lateral and medial surface of the hind leg and the corresponding area of the pelvic cavity, forming a 700 cm² area, and the sternum and the abdominal/chest cavity corresponding skin surface, forming another 700 cm². The number of surface swab samples analysed is the same as the number of lymph node samples.

Salmonella contamination at cutting plants is monitored with meat crush samples. Twenty-five grams of meat or meat crush is collected from relevant places in the cutting plant and analysed for *Salmonella*. The total number of samples is about 3000 annually. The number of samples per plant depends on the plant's capacity (Table 3). There were approximately 200 cutting plants in 2000 in Finland, and their number has stayed about the same since then.

If *Salmonella* is detected in surface swab or meat crush samples, the establishment tries to find out the origin of the contamination. Moreover, monitoring to find out the extent of the contamination, and hygienic measures to get rid of the contamination are taken into use according to the establishment's approved own-checking scheme.

Table 3.

Samples taken for *Salmonella* analysis according to cutting plant capacity (MMM 2002).

| | Cutting plant capacity | | | Small scale cutting plant |
|--------------------|------------------------|----------------------------|--------------------|---------------------------|
| | > 100 000 kg / week | 20 000 - 100 000 kg / week | < 20 000 kg / week | |
| Sampling frequency | 1 sample / day | 1 sample / week | 1 sample / month | 2 samples / year |

Before 2003, all kinds of samples were analysed using the modified method of ISO 6579:1993 (EELA 2201) or the NMKL method (No 71:1991, 4th edition).

According to the FSCP-based additional guarantees, Finland may require fresh pork to be analysed for *Salmonella* before it is imported to the country, if it is not intended to be used for processed meat products. Proof of a negative test result has to accompany the consignment. Foodstuffs of animal origin delivered from EU member states are checked at the place of destination in Finland for certificates proving they are free of *Salmonella*. Imported consignments from non-EU countries must have a veterinary border inspection post at the specified border inspection agency, and a similar *Salmonella* certificate is required. If *Salmonella* is detected, the consignments must be returned to the country of origin or destroyed. Costs are almost fully carried by the industry. Meat products containing pork as well as fresh pork intended for (heat-treated) processed products are allowed to be imported without *Salmonella* testing.

4.2.1 Other measures to combat *Salmonella*

In addition to the FSCP, other measures are also being taken to control *Salmonella* in the food production chain. According to the Feed Act (MMM 396/1998), all imported, marketed and manufactured feed materials and compound feeds are under the control of the Plant Production Inspection Centre (KTTK). It controls the production and the veterinary border inspection post controls the import of animal-originated feedingstuff. The frequency of sampling for *Salmonella* varies, depending on the estimated risk of *Salmonella* contamination based on the results of previous controls. In import control, every consignment of feedingstuffs with a potential risk for *Salmonella* is sampled and investigated regularly by the official control of the KTTK. Feed materials of both plant and animal origin are examined for *Salmonella*. In marketing control, every batch of feed materials from other countries is sampled and investigated regularly by the official control or by the own-check control of producers which is regulated by legislation. Official control includes random sampling except in the case of feedingstuffs of plant origin where every consignment with a *Salmonella* risk is sampled for analysis (MMM 396/1998).

In order to prevent the spread of animal diseases, the Animal Disease Act (MMM 55/1980) requires certain hygienic measures in preparation of certain feedingstuffs of animal origin. It also effects the international trade of feedingstuffs between Finland and other countries. In addition, the Act on Veterinary Border Inspection (MMM 1192/1996) applies to imports to Finland and to the EU via Finland from other countries. Meat and bone meal factories are controlled according to EC directive 90/667.

In addition to this official control of feeds, voluntary control is also practiced according to the recommendations of the Association for the Prevention of Animal Diseases (ETT). This association keeps an open register of feed importers, manufactures and mixers whose standards are higher than the official standards for the *Salmonella* freedom of feeds, e.g. who test every batch of imported feedingstuff for *Salmonella*. ETT also instructs and directs those importing live animals.

In Finland the control and handling of foodstuffs is mainly based on three acts: the Act on Hygiene of Foodstuffs of Animal Origin (MMM 1195/1996), the Food Act (MMM 361/1995) and the Health Protection Decision (MMM 763/1994). The acts and decrees based on them also deal with zoonotic agents in foodstuffs. The purpose of the Hygiene Act is to ensure the quality of foodstuffs of animal origin and to prevent the spread of infection from animals to humans via foodstuffs. The Act applies to the handling of foodstuffs of animal origin, sets quality requirements for food hygiene, and legislates control and inspection before foodstuffs are sold in retail outlets. Detailed provisions and recommendations for these activities, including the requirements involved, are laid down in the Decisions of the Ministry

of Agriculture and Forestry which are issued on the basis of the Hygiene Act. For example, instructions about individual zoonotic agents are given in the rules on meat inspection laid down in the Decision on Meat Hygiene (16/EEO/2001).

4.3 Modelling of health risks in a production chain

When any biological system is modelled, a first consideration is choosing the level of description. If quantitative results are required, this choice is closely related to the quality of available data. Often, a quantitative risk assessment of a large and convoluted system combines both expert opinions and data sources. These two sources of information can be treated coherently in a probabilistic framework of analysis which takes into account all the uncertainties involved.

A hierarchical model consists of conditional probability distributions organized in the shape of a tree. Each node in the tree denotes a random variable, and the variables are related according to the tree structure. The conditional distribution of each "child variable" depends on the random (uncertain) values of its "parent variables." This hierarchy provides a useful and intuitive description of many phenomena, e.g. production processes, and can be straightforwardly implemented as a simulation algorithm once all the "parents" and "children" in the tree have been specified. When completed, it can also be called an expert system, or a belief network.

Some of the variables in the model are drawn from data, whereas some are unknown, i.e. unobserved. Probabilistic inference means constructing probability distributions of the unknown variables, given the known variables within a specified model. In other words, we can make inferences based on some events we have not directly observed, based on observations we have been able to make. An unobserved variable might be, for example, the future number of *Salmonella* positive carcasses, or it can be the current true number of *Salmonella* positive carcasses. Since neither of these can be observed directly or known accurately, there remains uncertainty about them; a probability distribution aims to summarize this uncertainty.

In the Bayesian approach, a probability denotes (subjective) uncertainty, which means that the probabilities are always conditional on a given piece of information. There are different sources of uncertainty, however: there are uncertainties about our knowledge, as well as uncertainties about biological and physical processes. Finally, in all situations, a probability model describes and summarizes our total uncertainty about the quantities in question. In this way, probability theory works as extended logic where probabilities of one (100%) and zero (0%) mean full certainty (true/false).

When no variables in the hierarchical model are fixed as data points, the probabilities describe our *a priori* uncertainty. This prior uncertainty can be visualized as a distribution, or as a chain of distributions describing the entire biological/physical system of interest. Thus, each distribution depends on the random result of a previous distribution in the chain description. The resulting joint distribution may not have an easy analytical solution, but it can always be visualised using sufficiently large random samples drawn successively from the chain of distributions. This is the conventional Monte Carlo approach. Typically, this approach requires that each of the conditional distributions in the chain is a known standard probability density from which we can obtain random numbers, for example by using @RISK or some other tools. If the distributions involved are not among the list of known probability densities, it is still possible to visualize them with numerical sampling techniques, but one may need to do some programming first. Generally, it is sufficient if the densities

can be written up to the normalizing constant, or if the full conditional densities can be solved. In such cases sampling is based on various versions of Markov chain Monte Carlo techniques (MCMC), all of which require more specialized algorithms and tools which are not available in basic spreadsheet software. Such techniques become especially useful if some model variables are observed as data points. We can then compute a conditional distribution (a so-called posterior distribution) of the remaining unknown variables, given the observed values of the other variables. This is probabilistic inference in operation, and as such is a form of empirical science, learning from observations. Before a posterior distribution can be computed, we still need to define prior probability densities – in other words, the full hierarchical model. These priors can be based on past experience, or they can be elicited by interviewing a group of experts. Typically, many Monte Carlo models in risk analysis are based on the study of prior probabilities only. We were able to extend the analysis towards actual probabilistic inference by utilizing observed data from various points of the production chain simultaneously with the priors drawn from expert opinion.

Computing posterior probability distributions is usually not straightforward, so specialized algorithms are needed. WinBUGS software was used for computing the slaughter prevalence inference model (SPIM), the import prevalence inference model (IPIM) as well as the consumption inference model (CIM). The results of these analyses could be further used as inputs in a more straightforward simulation of the production chain, which we did using @RISK software.

For more information on the software, numerical methods and modelling typically used in Finnish universities, see the report of the Centre for Scientific Computation (2000), available at <http://www.csc.fi/raportit/mallinnus/>. For more information on expert systems, Bayesian analysis and modelling see e.g. the books by Congdon (2001), Cowell et al. (1999), French & Smith (1997), Gelman et al. (1995), and Robert & Casella (1999).

5. Risk assessment on *Salmonella* in pork production

This risk assessment on *Salmonella* in pork production follows the principles of the Codex alimentarius commission (CAC/GL-30, 1999). Therefore, this risk assessment process has been divided into four parts:

1. Hazard identification
2. Hazard characterization
3. Exposure assessment
4. Risk characterization

The modelling is focused on pork that is sold in Finland, and different serotypes are not distinguished. This assessment excludes pork produced for own-consumption or distributed via direct sale. The results of the tested sows were excluded because their meat covers only 5-6% of total production, and all the meat from sows is to be heated and therefore regarded as *Salmonella*-free. Its impact on consumer health was considered marginal. Pork production modelling has been divided into four models: the Prevalence Inference Model (SPIM) describing the prevalence in the slaughter population; the Import Prevalence Inference Model (IPIM) describing the prevalence in imported meat; the Secondary Production Simulation Model (SPSM) describing slaughter & meat processing and the Consumption Inference Model (CIM) describing the resulting number of cases of illness related to the amount of meat consumed and the level of contamination.

5.1 Hazard identification

Salmonella are Gram-negative, facultative anaerobe, small motile rod-shaped bacteria, belonging to the genus *Enterobacteriaceae*. They are widely distributed in nature, with humans and animals being their primary reservoirs. At least 2,422 different serovars of *Salmonella* are known and have been placed in two species, *S. enterica* and *S. bongori* (Popoff et al. 1996). *S. enterica* is divided into six subspecies: enterica, salamae, arizonae, diarizonae, houtenae and indica (Popoff & Minor 1992). Serotyping of *Salmonellae* is done by identifying the O- and H- antigens (phase 1 and 2) in order to name the serovar. Names for *Salmonella* serovars were maintained only for the subspecies enterica serovars, which account for more than 99.5% of isolated *Salmonella* strains.

Salmonella may cause enteritis or a general infection in animals and humans. Most serovars are not species specific. For epidemiological purposes, they can be

placed into three groups: (1) Those that infect humans only: *S. Typhi*, *S. Paratyphi A* and *S. Paratyphi C*. These cause typhoid and paratyphoid fevers, which are the most severe of all diseases caused by *Salmonellae*; (2) Host-adapted serovars (some are human pathogens and may be contracted from foods). *S. Gallinarum*/*Pullorum* causes diarrhea in poultry, *S. Dublin* causes diarrhea in cattle, *S. Abortus equi* causes abortions in horses, *S. Abortus ovis* causes abortions in sheep and *S. Choleraesuis* causes disease in swine; and (3) Unadapted serovars with no host preference. These are pathogenic both for humans and animals, and include most foodborne serovars (Jay 2000). In this risk assessment, only *Salmonella* belonging to group 3 are discussed.

All mammals, birds and reptiles may act as carriers of *Salmonella* without symptoms. An infected animal sheds *Salmonella* in the faeces, thus enabling the bacteria to spread into the environment. Wild animals, such as birds, mice and rats, may spread the infection to feed and production animals unless proper pest control is employed on the farm. The duration of shedding of *Salmonella* depends on the animal species and the serovar; moreover, the infection might persist in the animal for the rest of its life.

Prevalence has been stable in infections of domestic origin since the 1970s (500-1,300 domestic cases per year). In travel-associated infections, there was a steep increase in the late 1980s (due to a massive increase in holiday travel to the Mediterranean area) followed by a steep decrease due to economic recession (and a drop in holiday travel) in the 1990s. In 1998 about 950,000 Finns travelled abroad, which was approximately 15% less than in 1990. However, the total number of salmonellosis cases in 1998 (2,740 cases) was 63% less than in 1990 (7,353) and 7% less than in 1997 (2,961). The number of cases of domestic origin has been decreasing in the last few years.

Physicians have to notify clinical cases caused by *S. Typhi* and *S. Paratyphi B*. Laboratories, of which there are approximately 75, have to notify all confirmed *Salmonella* cases to a register for infectious diseases. All foodborne outbreaks with more than 5 confirmed cases not belonging to a single family are reported (MMM 2002).

Samples are taken from persons suffering from diarrhea and their close contacts and from asymptomatic persons working in risk professions. The surveillance method used is bacteriological culturing in 99% of faecal specimens. The *Salmonella* species identification is done by biochemical methods and by the agglutination of cultures by *Salmonella* antisera. Phagetyping is done according to the systems developed at PHLLS in Great Britain (*S. Paratyphi*, *S. Typhimurium*, *S. Enteritidis*) (MMM 2000).

In Finland, occupational control of food industry and hospital workers includes over 50,000 samples annually. In 1982-1996, almost 808,000 faecal samples were studied for these purposes, usually obtained from clinically symptomless persons. In the annual testing of these workers, on average 0.11% (range 0.06-0.20) have been infected with *Salmonella*. The same situation also applies to new workers, 0.12% (range 0.07-0.21), whereas 3.1% (range 2.16-3.73) of those having vacationed outside the Nordic countries were infected. Table 4 shows the total incidence of human salmonellosis in some European countries in 1997. According to investigations of asymptomatic food handlers, at any moment 0.1% of Finnish adults are *Salmonella* positive. In asymptomatic citizens investigated 2-10 days after a stay outside the Nordic countries, the figure is 3% (Siitonen, personal communication). It is estimated that about 10% of all human *Salmonella* infections are diagnosed and reported in Finland (Ruutu 2001).

Table 4. Salmonellosis reported in humans in some countries of the European Union in 1999. Incidence rate, including both domestic and cases acquired abroad, per 100,000 inhabitants for all cases and share of *S. Enteritidis* and *S. Typhimurium* (Document No. VI/8495/98. Rev. 2 of the European Commission).

| Country | Total incidence* | Incidence of | |
|-------------------|------------------|-----------------------|-----------------------|
| | | <i>S. Enteritidis</i> | <i>S. Typhimurium</i> |
| Denmark | 95.0 | 69.6 | 16.0 |
| Finland | 58.0 | 21.3 | 12.8 |
| Sweden | 48.5 | 21.2 | 4.6 |
| England and Wales | 61.8 | 43.8 | 8.9 |
| France | 33.5 | 11.4 | 11.8 |
| Germany | 128.4 | 70.6 | 37.2 |
| The Netherlands | 16.4 | 7.5 | 5.1 |

* Including domestic and abroad acquired salmonellosis.

5.1.1 Pork as a source of human salmonellosis

Pork and pork products have been an important source of human salmonellosis in Europe. In the late 1990s, the proportion of human salmonellosis cases attributable to pork and pork products was estimated to be approximately 10% of all cases in Denmark, 15% in The Netherlands, and 20% in Germany (Hald & Wegener 1999). In the USA, Bean and Griffin (1990) reported that pork was the vehicle for 252 food-borne outbreaks between 1973 and 1987 (7% of the total of food-borne disease outbreaks with a known vehicle). Maguire et al. (1993) reported a large outbreak of human salmonellosis (*S. Typhimurium* DT 193) traced to a local pig farm in a small town in northern England.

In Finland, the annual incidence of registered cases of human salmonellosis in 1995-1999 was 54-65 cases per 100,000 inhabitants. The proportion of domestic cases was assessed to be 19-35% (Zoonoses in Finland 1995-1999). Serotypes *S. Enteritidis* and *S. Typhimurium* were responsible for over 50% of all cases. Domestic pork was reported to be the cause of human salmonellosis outbreaks in 1997, when several outbreaks of the serotype *S. Typhimurium* DT 124 (an uncommon serotype at the time) were traced to pork originating from a single small meat cutting plant (KTL 2002). A special feature of the outbreaks was that the pork was roasted and served as a whole carcass (weighting 40-60 kg).

Denmark reported 3,259-5,015 registered human cases in 1994-99, with 3,268 cases in 1999 (Dansk Zoonosecenter 1999). In 1999, the annual rate was 61.5 cases per 100,000 inhabitants. An investigation of *S. Typhimurium* strains isolated from food-producing animals and humans in 1992 showed that DT12 was the predominant *S. Typhimurium* phage type in pig herds, and this was also the phage type occurring most frequently in humans (Baggesen and Wegener 1994). Furthermore, in the summer of 1993, an outbreak of human salmonellosis caused by *S. Infantis* was traced to pork at a single abattoir (Wegener and Baggesen 1996). These observations suggest that pork played a major role as a source of human salmonellosis in Denmark.

In Sweden, the annual incidence of registered cases of domestic human salmonellosis in 1980-1999 varied between 3 and 14 per 100,000 inhabitants. The most common serotypes, *S. Enteritidis* and *S. Typhimurium*, were responsible for approximately 60% of all findings in 1997-1999 (SVA 2001b). According to a survey, no outbreaks of human salmonellosis were traced back to Swedish pork in 1996 and 1997 (Thorberg et al. 1999). The prevalence of *Salmonella*-positive lymph node

samples in Swedish slaughter pigs corresponds to that in Finnish slaughter pigs (SVA 2001b). The annual number of *Salmonella* outbreaks in pig herds in Sweden has been less than five during the last 15 years (SVA 2001b).

In Norway, the annual incidence of registered cases of human salmonellosis in 1999 was 33.2 per 100,000 inhabitants, of which 17% were domestic cases. Serotypes *S. Enteritidis* and *S. Typhimurium* were responsible for 69% of cases (Norwegian Zoonosis Centre 2001). Domestic pork has not been reported to be a source of human salmonellosis.

5.1.2 *Salmonella* in slaughter weight pigs

Swine can be infected with a variety of *Salmonella* serotypes that do not cause disease in swine but do represent a source of infection for pork products. *Salmonella*-infected pigs are most often subclinical carriers of *Salmonella* and will only intermittently excrete the organism in their faeces. Shedding of the organism can be exacerbated by a long list of stressors, including mingling of pigs, transportation, concurrent disease, and food deprivation (Schwartz 1999). Wood and Rose (1992) have demonstrated that *S. Typhimurium* persists in swine internal organs and lymph nodes in low numbers for at least 28 weeks following experimental infection.

During transportation to the abattoir, *Salmonella*-free pigs may be infected from previously contaminated trucks that have not been thoroughly cleaned, or from *Salmonella*-infected pigs loaded on the same truck (Fedorka-Cray et al. 1994), Rajkowski et al. 1998). The prevalence of infection within a group of pigs continues to increase with increasing length of stay in the pens prior to slaughter (Morgan et al. 1987), although Davies et al. (1999) claimed that only a prolonged lairage of several days may result in an increased risk of *Salmonella* contamination. In one experiment (Fedorka-Cray et al. 1994), *Salmonella*-free pigs were mixed with a population of pigs that were shedding $2.69 \log_{10}$ CFU *Salmonella*/g faeces. *Salmonella* was recovered from pooled faecal samples from mixed pigs on day 2 after exposure to the infected group. Low numbers of *Salmonella* were detected in the ileocolic lymph nodes, ileum, caecum or spleen of all mixed pigs.

5.2 Hazard characterization

5.2.1 Microbe

Salmonella can grow in temperatures of 5-46°C, although the optimal temperature is 35-37°C. The minimum water activity for growth is 0.95, but cells can survive long periods in dry material. 9% NaCl prohibits the growth of *Salmonella* as well as pH outside the range of 4.0-9.5 (Jay 2000; Ray 2001). *Salmonella* is destroyed when the temperature exceeds 70°C. However, the matrix, especially the humidity, affects this. Sometimes even temperatures over 100°C are needed to destroy *Salmonella* in dry feedstuffs. There are variations in the ability of different strains and serotypes to survive in the environment, e.g. in dry heat and pH resistance (Jay 2000).

The heat resistance for *Salmonellae* (D-value at 60°) is between 33 s and 9.5 min (reviewed by Borch et al. 1996).

The virulence mechanisms of *Salmonella* continue to be unravelled. Although enterotoxin and a cytotoxin have been identified in pathogenic *Salmonella*, they seem to play only a minimal (if any) role in the gastroenteritis syndrome (Jay 2000). Virulent strains of *S. enterica* initiate infection in non-phagocytic cells by attaching to the intestinal mucosa.

5.2.2 Pig hosts

Only some serotypes are associated with disease in swine, usually as a cause of enterocolitis. Enterocolitis caused by *S. Typhimurium* is most commonly seen in pigs with concurrent debilitating illnesses, in conditions of poor hygiene that allow exposure to high doses of the organism, or where immunologically naive pigs are exposed to sufficiently large doses. Most salmonellosis outbreaks occur in intensively reared weaned pigs and although disease in adults and suckling pigs is infrequent, infection is not (in most countries). Disease occurs worldwide but varies markedly in estimated prevalence, morbidity and mortality (Schwartz 1999).

Salmonellosis manifested as enterocolitis is most frequent in pigs from weaning to about 4 months of age. The initial clinical sign is watery yellow diarrhoea, initially without blood or mucus. The disease may spread rapidly to involve most pigs in a pen within a few days. The initial diarrhoea in an individual pig usually lasts 3-7 days, but it typically may recur for second and third bouts. Affected pigs are febrile, have decreased feed intake and are dehydrated, paralleling the severity and duration of the diarrhoea. Mortality is usually low. Most pigs make complete clinical recovery but a portion may remain carriers and intermittent shedders for at least 5 months, i.e. until the end of the finishing period (Schwartz 1999).

During acute disease, pigs will shed up to 10^7 *S. Typhimurium* / gram faeces. The minimum disease-producing dose has not been established in field situations, but disease is difficult to reproduce experimentally at low doses. Most authors report successful experimental disease production with doses of 10^8 - 10^{11} cells unless pigs are artificially stressed (Schwartz 1999).

5.2.3 *Salmonella* in pork

Data collected from various countries indicate that *Salmonellae* are present in 0-48% of carcasses and 0-30% of retail pork products. The high level of infection demonstrated in some of the studies, and the initial prevalence in slaughter pigs, are likely the result of abattoir cross-contamination in crowded holding pens prior to slaughter as well as to mechanical transfer of contamination among carcasses by dehairing machines, scalding tanks, and polishers. Although much of the *Salmonella* contamination of pork products occurs within abattoirs during processing, infected pigs leaving the farm are considered the original source of abattoir infections (Schwartz 1999).

According to Berends et al. (1997), there is a strong correlation between the number of live animals that carry *Salmonella* spp. in their faeces and the number of contaminated carcasses (in general between 5-30% of carcasses) at the end of the slaughter-line in the Netherlands. Live animals that carry *Salmonella* spp. are 3-4 times more likely to end up as a positive carcass than *Salmonella*-free animals. In the Netherlands, about 70% of all carcass contaminations are the result of the animals being carriers themselves, and 30% because other animals were carriers. This is so because evisceration alone can contribute up to 90% of the number of carcasses contaminated with Enterobacteriaceae as well as up to 90% of the load with these organisms (Berends et al. 1997). The importance of live pigs as the ultimate source of *Salmonella* contamination was also stressed by Davies et al. (1999), and by Giovannacci et al. (2001), who noticed that none of the *Salmonella* strains in two French pork slaughter and cutting plants persisted for long periods in the pork-processing environments.

5.2.4 Human host

Infections in humans with the non-human adapted *Salmonella* sp. are characterised by febrile gastroenteritis, i.e. diarrhea, stomach ache, fever (up to 40°C), headache,

nausea, vomiting and malaise. The first symptoms appear after 12-24 h (range 5-72 h) and continue for about 3-4 days (range 2-7 days) (Baird-Parker 1990; Flowers 1988; European Commission 2000).

In addition to causing morbidity resulting from gastrointestinal symptoms, patients can have a variety of extraintestinal symptoms. In approximately 5% of cases, sequelae arise (e.g. septicemia, endocarditis, multiple abscesses, polyarthritis, osteomyelitis) (European Commission 2000). One of these complications is arthritis, which can be either septic or sterile (reactive). Septic arthritis is rare, but reactive arthritis (ReA) is observed in 1-15% of patients with acute salmonellosis. The onset typically occurs from 7 to 15 days after the beginning of gastrointestinal symptoms and most patients recover within the first 3 to 5 months. Nevertheless, many patients continue to have mild joint symptoms after the acute phase of ReA and in 16% of the patients the disease even remains chronic, mainly in patients who are HLA-B27-positive (Leirisalo-Repo et al. 1997; Ekman 2000, Hannu et al. 2002). Furthermore, there are new results suggesting increased mortality within one year after contracting salmonellosis (Helms et al. 2003).

5.2.4.1 Dose-response

Studies with volunteers have demonstrated that the larger the inoculum size the greater the attack rate. Generally, 10^7 - 10^9 cells/g are needed to cause salmonellosis in healthy adults (Jay 2000). However, data from outbreaks of salmonellosis have indicated that sometimes low doses of *Salmonella* (even below 10^3) are also able to cause gastroenteritis. In data from 33 outbreaks, the log₁₀ CFU dose varied between 1.23 and 9.90 (WHO/FAO 2002).

Especially immunosuppression or a lack of stomach acidity has been used to explain the susceptibility of newborns, infants, the elderly, and immunocompromised individuals (Miller et al. 1995). Given the data on *Salmonella* outbreaks in the WHO/FAO risk assessment (WHO/FAO 2002) there was insufficient evidence to conclude that "susceptible" individuals have a higher probability of illness compared with the "normal" population. Therefore, in this risk assessment, no differences are made according to the susceptibility of the target population, i.e. all calculations are done for the normal population. It should be not forgotten, however, that the severity of illness may be higher in susceptible individuals, thereby increasing the risk (risk is a combination of probability and severity).

In addition, it has been suggested that excess mortality is associated with drug-resistant *Salmonella* Typhimurium (Helms et al. 2002). Patients with pansusceptible *S. Typhimurium* infections were 2.3 times more likely to die 2 years after infection than persons in the general Danish population. The likelihood was bigger with multiresistant strains; with quinolone resistant strains the mortality rate was 10.3 times higher than the general population.

It has also been suggested that a high fat or protein content of food lowers the infective dose, due to the protection of *Salmonella* from gastric acidity. Some outbreaks, e.g. caused by chocolate, have been reported with a low infection level (Fontaine et al. 1980; Blaser & Newman 1982; Kapperud et al. 1990).

Unfortunately, data on dose-response in humans is difficult to obtain due to ethical and practical reasons. Therefore, it is not surprising that there is no consensus on which dose-response model is most applicable to *Salmonella* dose-response modelling. Holcomb et al. (1999) compared six dose-response models with the maximum likelihood method for use with food-borne pathogens, including *Salmonella typhosa*. They concluded that there was a need especially to predict infection at low doses. In the work on microbiological risk assessment on food

by WHO, five dose-response models were studied in detail. They concluded that, at present, a single model representation for the relationship between dose and response is not vastly superior to any other model (WHO 2002).

5.3 Exposure assessment

Basic information on the exposure situation in Finland is given in section 5.3.1. The exposure model is described in sections 5.3.2, 5.3.3 and 5.3.4. Two models, the Slaughter Prevalence Inference Model SPIM and the Import Prevalence Inference Model IPIM, use Bayesian inference for prevalence estimation whereas the actual results are simulated by the Secondary Production Simulation Model SPSM. The outputs of the SPSM are used in risk characterization while the Consumer Inference Model CIM is used to estimate consumer risk.

5.3.1 Basic information on exposure

5.3.1.1 Occurrence of contamination in primary production

There are several sources of information about the status of *Salmonella* in primary production. According to the results of the FSCP, voluntary *Salmonella* control, diagnostic autopsies carried out at EELA and feed control, the occurrence of *Salmonella* is rare. Still, for this assessment we decided not to model the occurrence of *Salmonella* in primary production using the available data, mainly because data collection from the herds was fairly non-standardized and infrequent, and for the majority of herds there was a total lack of information. In addition, the sampling strategy at slaughterhouses aims at monitoring the *Salmonella* prevalence in slaughter pigs, not at detecting *Salmonella*-infected herds. Moreover, there are no reports about feed-borne *Salmonella* epidemics, which could have been used for exposure assessment. Hence, this includes an overall description of the occurrence of *Salmonella* in primary pig production.

Table 5 shows the numbers of herds studied microbiologically for *Salmonella* in 1996-2000. Notice that this summary table consists of data collected for different purposes (control of elite breeding herds vs. voluntary control of production herds) and from animals of different age (sows vs. young growing pigs vs. slaughter weight pigs).

Table 5.

Number of herds studied microbiologically for *Salmonella* infection during a five year period using two pooled faeces samples from sows (1996-97) or from growing pigs (1998-2000). Sampling is based both on FSCP and on voluntary health control organised by the industry. Samples originate both from farrowing herds and finishing herds. (EELA 2000 and 2001).

| Year | Total no. of herds studied | No. of positive herds |
|------|----------------------------|-----------------------|
| 1996 | 1,654 | 1 |
| 1997 | 1,262 | 2 |
| 1998 | 803 | 0 |
| 1999 | 365 | 0 |
| 2000 | 273 | 0 |

In addition to the above-mentioned surveys, *Salmonella* was found in faeces samples of one herd in 1999, and of one herd in 2000. These herds were traced back from slaughter houses where positive lymph node samples had been detected in animals

originating from these two herds.

Furthermore, in 1999 *Salmonella* was detected in a piglet which was delivered to EELA for a diagnostic autopsy (Table 6). However, *Salmonella* was not re-detected in faeces samples of the corresponding herd. Testing animals submitted to a diagnostic autopsy can be considered risk group testing using parallel testing (both intestinal contents and mesenteric lymph nodes are cultivated), which increases the sensitivity of the testing method compared to the usage of either method alone. However, diagnostic samples are not representative of the whole pig population. A *Salmonella* culture is routinely performed on intestine contents and mesenteric lymph nodes (in more than 99% of cases) using the modified ISO 6579:1993 method (EELA 3476).

Table 6.

Number of *Salmonella*-positive pigs autopsied in EELA in 1996-2000.

| Year | No. of autopsies | No. of <i>Salmonella</i> positive carcasses |
|------|------------------|---|
| 1996 | 735 | 0 |
| 1997 | 582 | 0 |
| 1998 | 630 | 0 |
| 1999 | 984 | 1 |
| 2000 | 928 | 0 |

5.3.1.2 Sensitivity of the bacteriological culture of mesenteric lymph nodes and caecum contents

Salmonellae are known to invade and disseminate from the intestine to mesenteric lymph nodes and other organs. Reed et al. (1986) demonstrated that after an experimental oral infection or inoculation into isolated intestinal loops, *S. Typhimurium* was detected in mesenteric lymph nodes at 24 hours and 2 hours, respectively.

Keteran et al. (1982) reported that *Salmonella* was detected in mesenteric lymph nodes of 67/115 (58.2%) and 16/51 (31.3%) of healthy sows and slaughter hogs, respectively ($p < 0.005$). This result indicates a difference in infection rates of sows and slaughter hogs, although age and time spent in holding pens might have biased the results. Furthermore, the isolation rate from contents of caecum and mesenteric lymph nodes seems to fluctuate in different studies, as neither isolation site is positive in bacterial cultivation more often than the other (Table 7).

Most of the original culture methods were developed for the diagnosis of clinical salmonellosis in humans and other animals. In pigs, clinical salmonellosis is, with the exception of the *S. Choleraesuis* infection, uncommon. The sensitivity of the culture method may also be affected by the phase of the infection. For clinical samples, direct culture may suffice, whereas samples from chronically infected pigs or from the environment will almost certainly require pre-enrichment and selective enrichment. Pooled faecal samples are preferred over rectal swabs for the detection of *Salmonella*-carrier pigs. It has been shown that in survey studies both rectal swabs and carcass swabs provide an underestimation of the level of infection (Fedorka-Cray 2000).

During acute disease, pigs will shed up to 10^7 *S. Typhimurium* / g faeces. Such an excretion can be easily detected by cultivation. However, subclinically infected pigs typically excrete *Salmonellae* intermittently and often in low doses, which is one reason for the low sensitivity of culture methods. Analysis of 31 samples of caecum content of Danish slaughter pigs using the modified semisolid Rappaport-Vassiliadis agar (MSRV) resulted in a sensitivity of 0.58 (Baggesen & Wegener 1993). Davies et

al. (1999) used a similar culture method for faecal samples (n=80) and ended up with a sensitivity of 0.70. They also stressed that the weight of faecal samples had a marked linear effect on the detection of *Salmonella*. Enøe et al. (2001) reported a sensitivity of the culture method for *S. Typhimurium* ranging from 27%-33% and 32%-39% for mesenteric lymph node samples and samples of caecal contents, respectively. They analysed samples from 163 herds and 1,704 individuals. The microbiological examination was done according to NMKL 71 (4th edition) including non-selective pre-enrichment, followed by selective enrichment. This study describes the method of testing objectively since it is based on several independent test methods and a large sample size.

Table 7.

Proportion of *Salmonella* (*S.spp.*) findings in different samples from the same individual pig or groups of pigs in five different studies.

| Caecum contents | Mesenteric lymph nodes | Comments | Reference |
|-----------------|------------------------|---|-------------------------|
| 42% (n=237) | 58% (n=321) | | Harvey et al.(1999) |
| 9.7% (n=1072) | 13.7% (n=966) | Faeces analysed instead of caecum contents; four-day delay between the samplings. | Kim et al. (1999) |
| 35.8% (n=150) | 25.4% (n=150) | Corresponding to five herds. | Lawhorn (1999) |
| 15.2% (n=99) | 20.7% (n=121) | | Limpitakis et al (1999) |
| 71% (n=37) | 45.2% (n=37) | Experimental oral inoculation | Wood et al. (1989) |

5.3.1.3 Occurrence of contamination in secondary production

Swine slaughter is an open process with many opportunities for the pork carcass to be contaminated with potentially pathogenic bacteria. The slaughter process includes some process steps where the bacterial number may be reduced, but

Table 8.

Results of the FSCP regarding samples collected at slaughterhouses in 1996-2000 (EELA 2000 and 2001).

| | Year | Lymph node tested pigs | | | Carcasses swabbed | | |
|----------------|------|------------------------|----------|------|-------------------|----------|------|
| | | Total | Positive | % | Total | Positive | % |
| Fattening pigs | 1996 | 2,683 | 5 | 0.19 | 2,964 | 5 | 0.17 |
| | 1997 | 3,209 | 6 | 0.19 | 3,196 | 0 | 0.00 |
| | 1998 | 3,247 | 5 | 0.16 | 3,224 | 2 | 0.06 |
| | 1999 | 3,143 | 5 | 0.15 | 3,187 | 1 | 0.03 |
| | 2000 | 3,242 | 3 | 0.09 | 3,264 | 0 | 0.00 |
| | Mean | 3,105 | 5 | 0.16 | 3,167 | 2 | 0.05 |
| Sows | 1996 | 2,627 | 8 | 0.30 | 2,711 | 6 | 0.22 |
| | 1997 | 3,165 | 4 | 0.13 | 3,137 | 3 | 0.10 |
| | 1998 | 3,070 | 3 | 0.10 | 3,041 | 1 | 0.03 |
| | 1999 | 2,984 | 4 | 0.13 | 2,968 | 1 | 0.03 |
| | 2000 | 3,120 | 2 | 0.06 | 3,123 | 0 | 0.00 |
| | Mean | 2,993 | 4 | 0.14 | 2,996 | 2 | 0.08 |

does not contain any point where hazards are completely eliminated (Borch et al. 1996). Different categories of a slaughter pig regarding *Salmonella* infection and skin contamination were presented by Berends et al. (1997). They found a strong correlation between the number of live animals that carry *Salmonella* spp. in their faeces and the number of contaminated carcasses at the end of the slaughter-line. They estimated that 5-15% of all carcass contamination with *Salmonella* spp. occurs during polishing after singeing. The remainder is the result of current evisceration practices in the Netherlands (55-90%) and, to a lesser extent, further processing (5-35%), i.e. dressing, splitting and meat inspection.

During the slaughter process, both the pig and the environment can act as a contamination source for the meat (reviewed by Borch et al. 1996 [74]). In Finland, there is no data available on the microbial cross-contamination of pork due to pig carcasses and the environment during the slaughter process. However, carcass swabs are taken before chilling and analysed for *Salmonella* (Table 8).

The number of crushed meat samples collected per plant depends on the volume of meat, but does not necessarily exceed one sample per day (Table 3). In 1999, one *Salmonella*-positive sample was detected out of 3,502 crushed meat

Table 9.

Number of crushed meat samples and test positive samples from domestic pork examined at meat cutting plants according to the FSCP in 1996-2000 (EELA 2000).

| Year | Total | Positive | % |
|------|-------|----------|------|
| 1996 | 3,358 | 0 | 0.00 |
| 1997 | 3,741 | 1 | 0.03 |
| 1998 | 4,427 | 2 | 0.05 |
| 1999 | 3,502 | 1 | 0.03 |
| 2000 | 3,472 | 0 | 0.00 |
| Mean | 3,700 | 1 | 0.02 |

samples (Table 9). The sampling instructions for meat cutting plants are not highly standardized, and the spot where the sample is taken may vary between different plants. Furthermore, the quantitative consequence of positive crushed meat on the amount of contaminated meat is not clear. Because of these reasons, crushed meat samples were not included in the input of the SPSM.

5.3.2 Slaughter Prevalence Inference Model (SPIM)

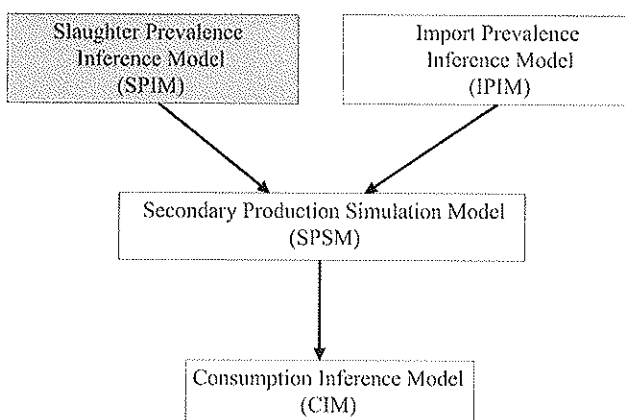


Figure 5.
The Slaughter Prevalence Inference Model (SPIM) in the whole risk assessment model.

5.3.2.1 Summary of the SPIM

The primary production of pork was not the starting point of this risk assessment. Instead, the true prevalence in slaughter animals was derived from the lymph node tests of the finishing pigs, which are part of the FSCP follow-up system (Table 8).

This Bayesian inference submodel, the Slaughter Prevalence Inference Model, SPIM (Figure 5) was used to estimate the true prevalence of *Salmonella*-infected finishing pigs at the time of slaughter, and was made with WinBUGS[®] software. The sensitivity of the lymph node *Salmonella* testing of pigs according to Enøe et al. (2001) was taken into account.

A joint posterior distribution was derived. It gave the 95% posterior probability interval of true prevalence [0.2%, 1.3%] with a mean of 0.6%, and the true number of infected slaughtered finishing pigs [9,36] with a mean of 19, among the 3,143 lymph node tested finishing pigs. The posterior distribution of the true prevalence was used as a prior probability distribution in the simulation model (SPSM).

5.3.2.2 Inputs of the SPIM

Number of lymph node tested animals (N_s) and the number of detected positives (N_{pos})

In Finland, lymph nodes instead of faeces samples are tested at slaughter to detect carrier pigs (Table 8). As can be seen, the apparent prevalence of test positive animals has been low and fairly stable during the time when the programme has been in force. Only data from finishing pigs were used in the model since the amount of meat received from sows is small (5-6%) compared to the total amount of meat. In addition, sow meat is always heat-treated and only used for processed meat products, and is therefore less likely to be contaminated with *Salmonella* at retail. Moreover, detecting *Salmonella* in a sow's lymph nodes might be less likely to indicate *Salmonella* excretion (as opposed to being a chronic carrier) than in the case of detecting *Salmonella* in a finishing pig. The apparent prevalence of lymph node test positive finishing pigs in 1999 was taken from the FSCP (Table 8).

Sensitivity of lymph node testing (p_{sen})

To describe uncertainty about the sensitivity of the lymph node test used to detect an infected finishing pig at slaughter, a uniform prior distribution (27-33%) was used, based on the results of Enøe et al. (2001). This sensitivity can be seen as very low compared to some other estimates. However, the estimate of Enøe et al. (2001) takes into account the different stages of infection that can take place in an animal at the time of slaughter (acute and spreading, chronic but not spreading, intermittently spreading). In some other studies both higher and lower figures have been reported for sensitivity, which points out the importance of the stage of infection and of the different serotypes of *Salmonella* on the results. Because all positive results are confirmed by EELA, the specificity of the test was assumed to be (virtually) 100%.

True prevalence (p)

For the unknown true prevalence, a uniform prior distribution over the range [0,1] was used as an uninformative prior distribution, because this is a 'standard' choice when an informative prior would be difficult to elicit, or when the prior should be 'objective' in the sense that it gives equal weight to every possible value before the data are observed. The true prevalence (p) is the parameter we wish to estimate using the SPIM so that the posterior (not the prior) distribution of p will be the 'output' of the model.

All the inputs for the SPIM are presented in Table 23 in Appendix.

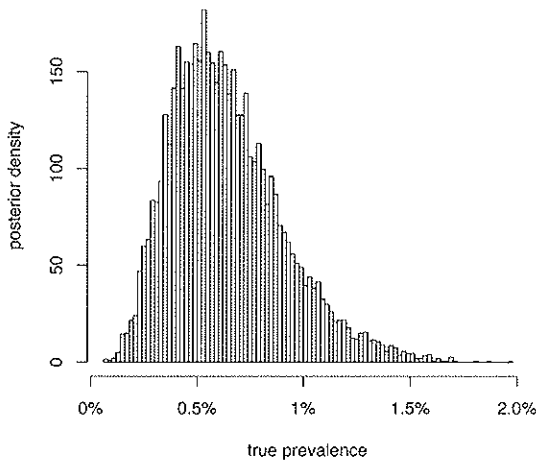


Figure 6.
Marginal posterior probability density of the true slaughter population prevalence (p) in 1999. The number of MCMC iterations was 20,000.

5.3.2.3 Output of the SPIM

As an output, a joint posterior distribution of the true prevalence, the sensitivity of the test, and the true number of infected pigs among those tested in 1999 was derived. The 95% posterior probability interval of true prevalence was [0.2%, 1.3%], with a mean of 0.6%. The 95% posterior interval of the true number of infected pigs among those tested in 1999 was [9,36] with a mean of 19. The output of the SPIM was used later as input in the Secondary Production Simulation Model (SPSM).

5.3.2.4 Mathematics of the SPIM

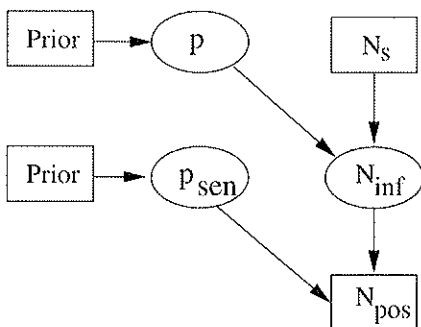


Figure 7.
A graph of the conditional distributions in the SPIM.

The set of conditional distributions in the model, together with the given set of data and prior distributions, define a posterior distribution (Figure 7) which was computed using WinBUGS software. The number of detected positives N_{pos} has a conditional binomial distribution with parameters p_{sen} (sensitivity of the testing method) and N_{inf} (true number of infected pigs in the sample). Similarly, N_{inf} has a conditional binomial distribution with parameters p (true prevalence) and N_s (sample size, i.e. number of tested pigs). Finally, p has uniform (0,1) prior density, and p_{sen} has uniform (0.27,0.33) prior density. Using a generic notation, π , for a probability density, the joint posterior of p , p_{sen} and N_{inf} can be written as:

$$\pi(p, p_{sen}, N_{inf} | N_{pos}, N_s) \propto \pi(N_{pos} | p_{sen}, N_{inf})\pi(N_{inf} | p, N_s)\pi(p)\pi(p_{sen}).$$

The inputs and conditional distributions can be seen in Table 23.

5.3.2.5 Sensitivity and limitations of the SPIM

According to the FSCP, the sample size is chosen so as to detect at least one test positive sample with 95% confidence, if the population prevalence of positive

animals exceeds 0.1%. The annual sample size does not imply a clear increase in the true prevalence of infected pigs unless the number of test positives is 15 or more (Table 10). Figure 6 suggests that the true prevalence of infected finishing pigs was most likely 0.5% in 1999. There was no evidence of differences in prevalence from 1996 to 2000, Table 8. Hence, for the risk assessment model, it does not matter which year is chosen to obtain the data. The sensitivity selected has an effect on the estimate of true prevalence, as can be seen in Table 10, which shows results under alternative assumptions about test sensitivity. These were computed using exactly the same model (SPIM), but replacing the prior distribution of the sensitivity according to the scenario.

Table 10. The 95% posterior probability intervals of the true prevalence p (%), and of the true number (#) of infected finishing pigs N_{inf} in the sample of 3143 in 1999 and in other scenarios assuming different test sensitivity and a different observed number of test positives (Rautiainen et al. 2002)

| P_{sen} | No. of detected positives in a sample (#) | | | | |
|-----------|---|-----------|-----------|-----------|-----------|
| | 0 | 5 | 10 | 15 | |
| 0.27-0.33 | 0.00-0.38 | 0.24-1.28 | 0.59-1.99 | 0.96-2.71 | p (%) |
| 0.27-0.33 | # 0-10 | # 9-36 | # 20-58 | # 33-80 | N_{inf} |
| 0.5 | 0.00-0.24 | 0.14-0.75 | 0.35-1.16 | 0.58-1.57 | p (%) |
| 0.5 | # 0-5 | # 6-19 | # 13-31 | # 21-44 | N_{inf} |
| 0.8 | 0.00-0.14 | 0.09-0.47 | 0.22-0.73 | 0.36-0.98 | p (%) |
| 0.8 | # 0-2 | # 5-10 | # 10-17 | # 15-24 | N_{inf} |

5.3.3 Secondary Production Simulation Model (SPSM)

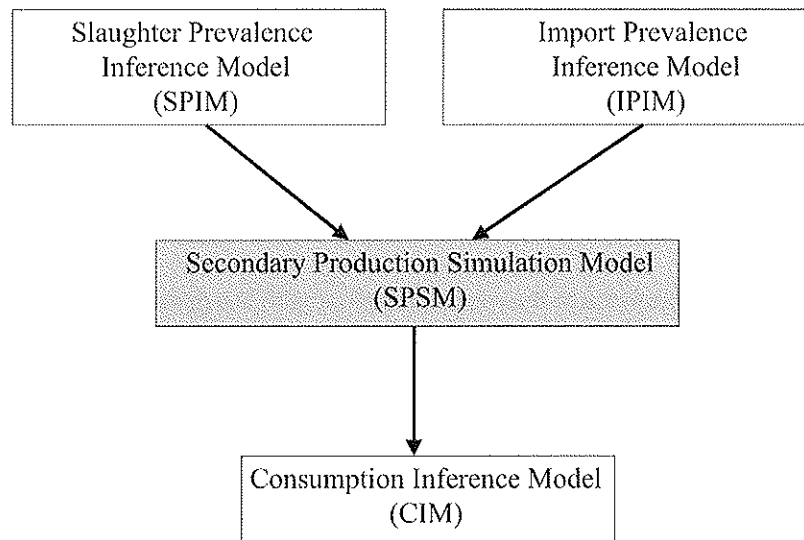


Figure 8. Secondary Production Simulation Model, SPSM in the whole risk assessment.

5.3.3.1 Summary of the SPSM

In order to model the annual risk of *Salmonella*-contaminated pork, the slaughter process and the subsequent processing of the pork were modelled. The Secondary Production Simulation Model (SPSM) covers the production chain from slaughtered swine up to the amount of contaminated pork and meat products containing pork

on sale in Finland. The contamination prevalence in imported pork and pork products in the Finnish market was estimated by the Import Prevalence Inference Model (IPIM) and it was used as an input in the SPSM. Likewise, prevalence in the Finnish slaughter population was estimated by the Slaughter Prevalence Inference Model (SPIM) and used as an input in the SPSM. As a result, the SPSM provides a predictive distribution of the expected number of contaminated servings at the retail level as if the servings were drawn randomly from the total pork production which has the estimated contamination prevalence. The number of such servings is not the same as the number of contaminated servings actually eaten, because that depends on the final cooking and storage in homes and restaurants, which is not modelled in the SPSM. Since the actual composition of all possible servings and their final usage is not modelled in detail in SPSM, the Consumption Inference Model (CIM) was constructed separately to calibrate predictions of the number of human cases of illness based on reported cases in 1999. However, the predictive distribution obtained from SPIM was taken as a prior distribution of the number of 'all initially contaminated servings' in the CIM. The input data and prior distributions of the SPSM are seen in Table 24.

Several assumptions were made. Firstly, we focused on 1999, since complete data were available for this year, and the year was also suitable for other *Salmonella* risk assessments. Secondly, only FSCP data from finishing pigs were included in the model. Thirdly, we assumed that all meat from a lymph-node-test-positive finishing pig would be contaminated with *Salmonella*. Therefore, the model is likely to produce an overestimated amount of contaminated meat and (initially) contaminated servings. However, this is computed similarly for all scenarios and should not drastically influence relative comparisons between scenarios.

In the final part of the SPSM model, the estimate of the proportion of all pork (both domestic and imported) sold as fresh, raw meat preparations and processed meat products was utilized to quantify these classes separately. *Salmonella* contamination within each class was estimated by taking into account possible cross-contamination between raw material and end-products. The number of contaminated servings (before final storage and preparation) was then obtained using the estimated average serving size and the simulated total amount of contaminated meat. The number of contaminated servings thus depends directly on the amount of contaminated meat, i.e. the contamination prevalence in meat. Thus the number of contaminated servings caused by imported pork relative to those caused by domestic pork might be rather high. On the other hand, our estimate of salmonella prevalence in non-domestic pork is based partly on insufficient information which increases the uncertainty of this estimate.

According to the model, on average, 0.85% of all servings in 1999 could have been initially contaminated with *Salmonella* in Finland, assuming these are drawn randomly from the total production before final storage and heating. Of all such positive servings, 60% of the pork could have been of domestic origin, and the remaining 40% foreign. However, only about 8% of the total consumption was of imported meat.

5.3.3.2 Inputs of the SPSM

The data used for the SPSM was obtained from the FSCP, official statistics and two inference submodels, the SPIM and IPIM, which were made using WinBUGS® software. In addition, expert opinions were used to elicit prior probability distributions on model quantities for which there was only limited or no information. A summary of the variables, parameters, data and prior distributions used in the SPSM are presented in Table 24 in Appendix.

Number of slaughtered finishing pigs (N)

The number of pigs slaughtered in 1999 (2,064,492) consists of all the pigs slaughtered in Finnish slaughterhouses. This number excludes sows slaughtered in slaughterhouses (68,721) and both sows (457) and pigs (28,981) slaughtered in low-capacity slaughterhouses (EELA 1999).

Mean slaughter weight of finishing pigs (w)

The slaughter weight that was used for finishing pigs in the model was calculated from the data of two large meat companies. A mean slaughter weight of 82.1 kg was used.

Proportion of meat in a carcass (rM)

The amount of boneless meat was derived from an expert opinion, and is based on the statistics of some slaughterhouses which included information on the proportion of meat in an average slaughter carcass (82%).

Proportion of domestic pork intended for fresh sale (rFM), proportion of domestic pork intended for meat preparations (rRMP), proportion of domestic pork intended for processed (heat-treated) products (rPMP)

Domestic pork was divided into three categories according to the use for which it was intended. One of the categories was pork intended to be sold as fresh for consumers. Finnish meat industry experts assumed that this proportion would be in the range of 30%-44%. The second of the three categories was domestic meat intended to be used as raw material in the production of raw meat preparations. The proportion of this category was assumed to be in the range of 9%-30%. The proportion of domestic pork intended for processed (heat-treated) products was determined from the other two proportions so that the total is 100%.

The true prevalence of infected finishing pigs at slaughter (p)

This was taken as a fitted distribution resulting from the SPIM.

Cross-contamination effect at slaughterhouse and meat cutting (CC)

In the model it was assumed that all meat obtained from infected animals is contaminated whereas all uninfected animals will produce completely *Salmonella*-free meat – unless they become contaminated during slaughter and processing. Infected animals arriving for slaughter can infect other animals due to close contacts. Additionally, meat originating from initially uninfected animals can become contaminated in the slaughter process and during meat cutting. The combined effect of these cross-contaminations was modelled by cross-contamination probability, which depends on the initial infection prevalence among all animals arriving for slaughter: the higher the initial prevalence, the higher the probability of cross-contamination for each initially uninfected animal. This probability was modelled as a simple parametric function and its shape is determined by a single parameter (CC) Figure 9. Given the value of this probability and the number of initially uninfected animals, the additional number of contaminated animals was modelled by binomial distribution.

Cross-contamination in the production of meat products

It was assumed that heat treatment during industrial meat processing eliminates *Salmonella* completely. However, expert opinion was elicited about cross-contamination, evaluating how products which have already been heat-treated may

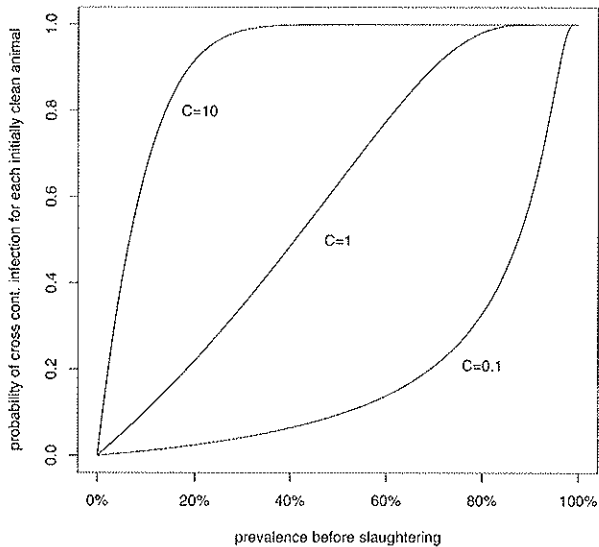


Figure 9.
Probability of cross-contamination as a function of initial prevalence.

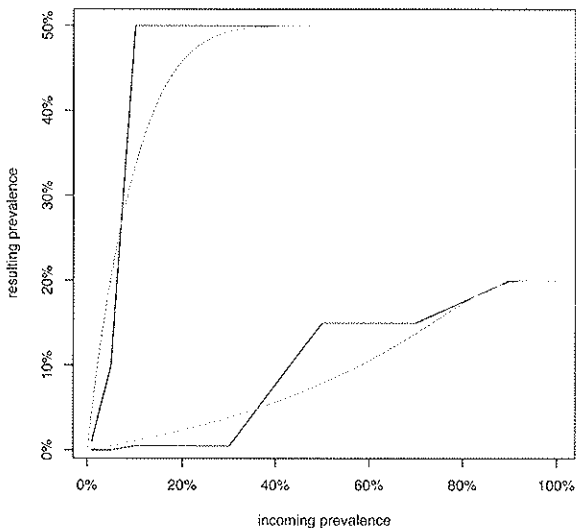


Figure 10.
The proportion of cross-contaminated heated pork products in relation to the contamination level of fresh pork according to most differing expert opinions. Approximating curves overlaid.

still get contaminated by raw material in the processing plant. A calculation was then made according to an opinion given by experts representing meat industry companies producing the majority of meat in Finland, showing that if the *Salmonella* prevalence in fresh pork remains lower than a threshold of 1%, practically no cross-contamination would take place. The resulting products would thus be completely free of *Salmonella*. If, on the other hand, the prevalence in fresh pork exceeds 1%, cross-contamination would take place according to the curves shown in Figure 10. According to expert opinion, cross-contamination extends rapidly if the *Salmonella* prevalence of fresh pork increases markedly. The same threshold model was used to describe cross-contamination in raw meat preparations. In this case, however, it was assumed that if fresh meat contamination is below 1%, it remains the same after processing, because no heat treatment is applied. In Figure 10, the limits of the expert opinions (straight lines) are shown with approximating curves. To account for the uncertainty of the opinions, a value is drawn from a uniform distribution between the two curves, for each level of incoming prevalence in fresh pork (i.e. in raw material for production) shown in the horizontal axis.

Amount of imported fresh meat for direct sale (FM), raw meat preparations for direct sale (RMP1), fresh meat for producing raw meat preparations (RMP2), processed meat products for direct sale (PMP1), and fresh meat for producing processed meat products (PMP2)

Data concerning pork and meat products containing pork entering Finland were mainly gathered from the statistics of the National Board of Customs (Table 11, Table 13). Because the classification differs from the one used in food regulation, however, some generalizations had to be made. The countries of origin and the amount of imported pork were reported in these statistics. The amount of fresh meat imported with *Salmonella* certificates (1,556,638 kg of boneless meat) and the number of such consignments (449 consignments), however, was derived from the EU domestic market register (EVI 1999). This contains the total amount of member state imports (8,517,131kg) and the total number of consignments (2299 consignments) which the local authorities have reported. Also, the number of certificated meat consignments (449 consignments) is reported. The proportion of fresh meat imported according to the additional guarantees (1,661,300 kg), by each importing country, was derived from this information. After converting it to boneless meat, the amount used in the model was estimated to be 1,549,644 kg. Further on, the certified meat was divided between the exporting countries according to the statistics of the Customs.

Before Finland joined the EU, the amount of imported pork was minor (2 million kg in 1994, Finfood 2002). Since 1995, however, the amount of imported pork and pork-containing products has increased a great deal, and was over 15 million kg in 2000 (Table 2). Most of this increase has been in imports of fresh pork (Table 11).

Table 11.

The import (kg) of fresh pork in 1996-2000 listed according to the country of origin (National Board of Customs)

| Country | Year | | | | |
|--------------------------|-------------------|------------------|-------------------|------------------|-------------------|
| | 1996 | 1997 | 1998 | 1999 | 2000 |
| Australia ^a | 2,100 | 4,200 | 8,100 | 6,100 | 1,300 |
| Austria | - | - | 2,400 | - | - |
| Belgium | 120,900 | 9,800 | 439,200 | 613,000 | 2,292,200 |
| Brazil ^a | 13,000 | - | - | 38 | 5,000 |
| Denmark | 7,022,100 | 6,893,400 | 8,938,700 | 10,307,400 | 8,821,000 |
| France | - | - | 2,100 | - | 2,100 |
| Germany | 46,100 | 126,300 | 193,700 | 661,300 | 1,209,200 |
| Hungary ^a | 600 | 44,800 | - | - | 600 |
| Ireland | 20,400 | 2,400 | 3,200 | - | 2,800 |
| Italy | - | - | 400 | - | 1,800 |
| Japan ^a | - | - | - | - | 14 |
| New Zealand ^a | - | - | - | 400 | 600 |
| Spain | - | - | 10,000 | 3,300 | - |
| Sweden | 3,140,100 | 1,558,100 | 901,300 | 943,200 | 534,400 |
| The Netherlands | 6,700 | 2,700 | 22,000 | 38,800 | 87,300 |
| UK | 35,600 | 1,500 | - | 1,500 | 4,200 |
| Uruguay | - | 20 | - | - | - |
| Total | 10,407,600 | 8,643,200 | 10,521,100 | 12,575,00 | 12,962,500 |

^a A non-EU country

Table 12 and Table 13 show the amount of imported pork and pork-containing meat products listed according to the country of origin in 1999. The amount of pork in sausages is an estimate, where the total amount of sausages has been multiplied by 0.67 to correspond to the amount of pork (this assumption is based on an expert opinion). The table shows that Denmark is clearly the largest exporter of pork and pork products to Finland.

Table 12.

The import of fresh pork in kg (including organs and blood) in 1999 listed according to the country of origin (National Board of Customs).

| Country | Total fresh pork | Of which boneless | % boneless | Of which carcasses | Of which organs & blood | Total non-boneless pork excl. organs |
|--------------------------|-------------------|-------------------|-------------|--------------------|-------------------------|--------------------------------------|
| Australia ^a | 6,122 | - | - | - | - | 6,122 |
| Belgium | 612,946 | 608,234 | 99.2 | - | - | 4,712 |
| Brazil ^a | 38 | 38 | 100.0 | - | - | - |
| Costa Rica ^a | 33,305 | - | - | - | 33,305 | - |
| Denmark | 10,433,453 | 6,199,612 | 59.4 | 112,025 | 126,042 | 4,107,799 |
| Germany | 667,739 | 530,572 | 79.5 | - | 6,440 | 130,727 |
| New Zealand ^a | 393 | - | - | - | - | 393 |
| Spain | 3,248 | 3,248 | 100.0 | - | - | - |
| Sweden | 1,003,240 | 700,623 | 69.8 | - | 60,050 | 242,567 |
| The Netherlands | 38,830 | 31,709 | 81.7 | 96 | - | 7,121 |
| UK | 1,500 | 1,500 | 100.0 | - | - | - |
| Total | 12,800,814 | 8,075,536 | 63.1 | 112,121 | 225,837 | 4,499,441 |

^a A non-EU country

Prevalence in imported fresh meat and meat products (p_i^r, p_i^p)

The true prevalence of contamination in imported meat was taken as a probability distribution obtained from the IPIM for each exporting country. The IPIM provides these distributions for fresh meat and processed meat products only, but in the SPSM we simulated the amounts of contaminated meat in five import categories according to the different uses of imported meat. Therefore, the prevalence in imported fresh meat (from the IPIM) was applied as an initial prevalence in the categories, which were imports as fresh meat or as raw meat preparations. The prevalence in imported meat products (from the IPIM) was applied only when computing the prevalence of contaminated meat in meat products imported for direct sale.

Thus the final prevalence of the meat imported for direct sale was taken to be same as the corresponding prevalence obtained from the IPIM. However, for other categories, which were imports for producing either raw meat preparations or processed meat products in Finland, the cross-contamination effect was computed to translate the initial prevalence in the corresponding raw material into a final prevalence in the product.

Table 13.

The import of raw pork preparations (salted, cured, dried or smoked), preserved pork and sausages in kg in 1999 listed according to the country of origin (National Board of Customs).

| Year 1999 | | | | |
|--------------------------|-----------------------|----------------|----------------|---|
| Country | Raw pork preparations | Preserved pork | Sausages | Heat treated pork preparations total ^b |
| Austria | - | 13,529 | - | 13,529 |
| Belgium | 809 | 14,493 | - | 14,493 |
| Brazil ^a | - | - | - | - |
| Denmark | 464,140 | 394,263 | 522,315 | 744,214 |
| France | 7,514 | 2,073 | 6,147 | 6,191 |
| Germany | 11,685 | 63,049 | 294,375 | 260,280 |
| Greece | - | - | - | - |
| Hungary ^a | - | - | 280 | 280 |
| Ireland | - | - | 9,520 | 9,520 |
| Italy | 18,595 | 971 | 14,940 | 10,980 |
| New Zealand ^a | - | 1,620 | - | 1,620 |
| Norway | - | - | - | - |
| Spain | 5,074 | 2,111 | 9,640 | 8,570 |
| Sweden | 27,367 | 447,020 | 110,832 | 521,277 |
| Thailand ^a | - | 400 | - | 400 |
| The Netherlands | 1,474 | 41,294 | 18,247 | 53,519 |
| UK | 3,000 | 3,360 | - | 3,360 |
| USA | - | 20 | - | 20 |
| Total | 539,658 | 984,203 | 986,296 | 1,645,021 |

^a A non-EU country

^b Corresponding to preserved pork + 67% of the sausages

Prevalence in imported meat and meat products from Sweden

In the IPIM, Sweden was excluded from the 'population model for exporting countries', because there are no *Salmonella* testing requirements for meat imported from Sweden and the prevalence was assumed to be the same as in Finland due to a similar control programme and similar findings. Since we have no model for Swedish primary production, the distribution of the prevalence in the slaughter population in Finland was taken as a baseline for imported Swedish pork. To estimate contamination in fresh pork imported from Sweden, the slaughter population prevalence was first generated from an identical but independent distribution of the Finnish slaughter prevalence. Then, this was multiplied with a constant parameter, which accounts for the average cross-contamination of meat production in Finland described earlier in the SPSM. This coefficient was crudely estimated by dividing the expected *Salmonella* prevalence of Finnish pork after cross-contamination by the expected prevalence in the slaughter population before cross-contamination. The value of the coefficient for fresh meat and raw pork preparations was 1.049, and 0.312 for processed products.

Export (FMexp, RMPexp, PMPexp)

Export from Finland to other countries consists of the amount of exported fresh pork (FMexp), processed meat products (PMPexp) and raw meat preparations (RMPexp) containing pork.

Table 14.

The amount of imported fresh pork (counted as boneless) and pork products (1999) used in the model.

| Country | Fresh pork including organs | | | Pork products | |
|-----------------|-----------------------------|----------------------|------------------------|-----------------------|--------------------|
| | For fresh sale | For raw preparations | For processed products | Raw pork preparations | Processed products |
| Denmark | 1,195,575 | 62,925 | 8,435,550 | 464,140 | 744,214 |
| Sweden | 118,345 | 6,229 | 835,004 | 27,367 | 521,277 |
| Germany | 79,451 | 4,182 | 560,576 | 11,685 | 260,280 |
| Belgium | 75,491 | 3,973 | 532,634 | 809 | 14,493 |
| The Netherlands | 4,631 | 244 | 32,674 | 1,474 | 53,519 |
| Others | 5,357 | 282 | 37,795 | 34,183 | 65,730 |
| Total | 1,478,849 | 77,834 | 10,434,232 | 539,658 | 1,645,021 |

Note:

The boneless weight of a pork carcass is 82% of the carcass weight; 65% of pork (including organs) is imported boneless, thus the mean weight of a lot is $3700 \text{ kg} * (0,65+0,82*0,35) = 3,467 \text{ kg}$;

The No. of lots with a salmonella certificate is 449;

The amount of boneless meat imported with additional guarantees for sale and for raw preparations is $449 * 3467 \text{ kg} = 1,556,683 \text{ kg}$;

95% of meat imported under additional guarantees is sold fresh, 5% as raw preparations

For pork products, see the table 15.

Table 15. shows the export of pork and pork-containing meat products from Finland in 1999. The amount of non-boneless pork has been multiplied with 0.82 rM to get the amount of boneless pork.

5.3.3.3 Outputs of the SPSM

The amount of imported *Salmonella*-contaminated fresh meat is the product of the corresponding country-specific prevalence and the amount of imported fresh pork. Therefore, the highest import risk is not necessarily from the country with the highest estimated prevalence. The amount of all contaminated fresh meat and raw pork preparations (country-specific mean values) ranged from 2,480 kg to 146,110 kg. Likewise, the amount of contaminated (processed) pork products (country-specific mean values) varied from 84 kg to 1,509 kg. The country-specific prevalences were obtained as probability distributions from the IPIM and the imported amounts were treated as fixed data based on the year 1999.

The SPSM provided simulations of the amount of contaminated pork and the total amount of pork, including both domestic production and pork entering Finland. These predictive distributions could then be used further as prior distributions in the CIM. The predictive distribution of the proportion of contaminated pork sold in Finland had a peak clearly below 1% prevalence (Figure 11). However, the tail of the distribution reached much higher values. It turned out that this tail was due to the tails of the distributions of prevalence in imported raw meat preparations and imported processed meat products. This in turn was due to the shape of posterior distributions of the initial true prevalence in these imports and the assumed cross-contamination model which had a threshold value. If the initial prevalence can be over this threshold value with small probability, the cross-contamination model is likely to transform these events into a high output prevalence (although in most cases it would be low because the initial prevalence would be below threshold).

Table 15.
Export of Finnish fresh pork and pork products in kg in 1999 (National Board of Customs).

| Fresh pork including organs and blood | Of which boneless | % boneless | Of which organs & blood | Total counted as boneless | Raw pork preparations | Preserved pork | Sausages | Processed pork products total ^a |
|---------------------------------------|-------------------|------------|-------------------------|---------------------------|-----------------------|----------------|-----------|--|
| 25,053,829 | 4,018,586 | 16 | 5,256,431 | 22,213,643 | 18,946 | 481,350 | 1,986,994 | 1,812,636 |

^a Corresponding to preserved pork + 67% of the sausages

This cross-contamination model was based on expert opinions containing large uncertainty, though it was still justified based on our knowledge of cutting and meat processing. The numerical values were very uncertain, however, which undermines the validity of the quantitative output. More data would be needed about the cross-contamination effects both at the slaughterhouse and processing stages. However, these are difficult or impossible to obtain because, ideally, prospective observations of the natural course of undetected *Salmonella* contamination would be needed.

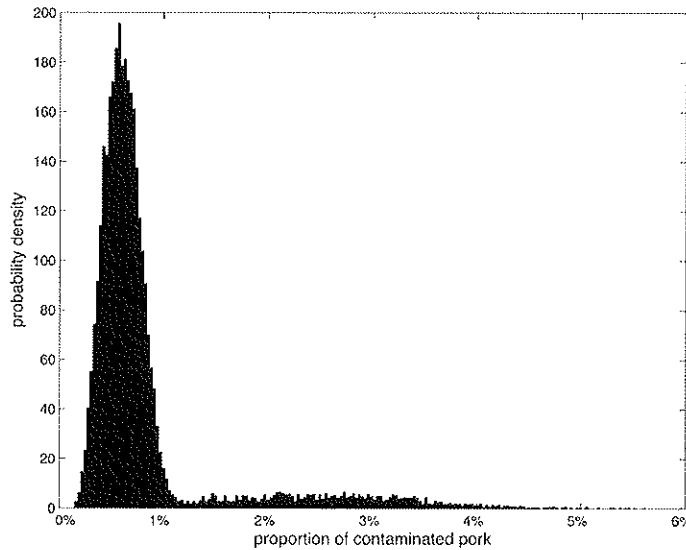


Figure 11.
Predictive distribution (from the SPSM) of *Salmonella* prevalence in pork that is sold in Finland based on data from 1999. Mean 0.0085. Interval of 90% probability [0.003371, 0.027]. (20,000 Monte Carlo iterations).

In the SPSM, we obtained an estimate of the influence of imported pork and pork products on the number of contaminated servings in the current situation. This was done by fixing a very low value (0.00001%) for the prevalence of *Salmonella*-infected domestic finishing pigs, instead of using the distribution received from the SPIM. Under the SPIM result, the proportion of contaminated servings among all consumed servings was 0.85% (mean). However, assuming the domestic prevalence to be 0.00001% the proportion of contaminated servings was 0.34% (mean). Thus, the ratio of the expected proportion of contaminated servings due to foreign origin and the expected proportion of all contaminated servings was 0.4.

5.3.3.4 Mathematics of the SPSM

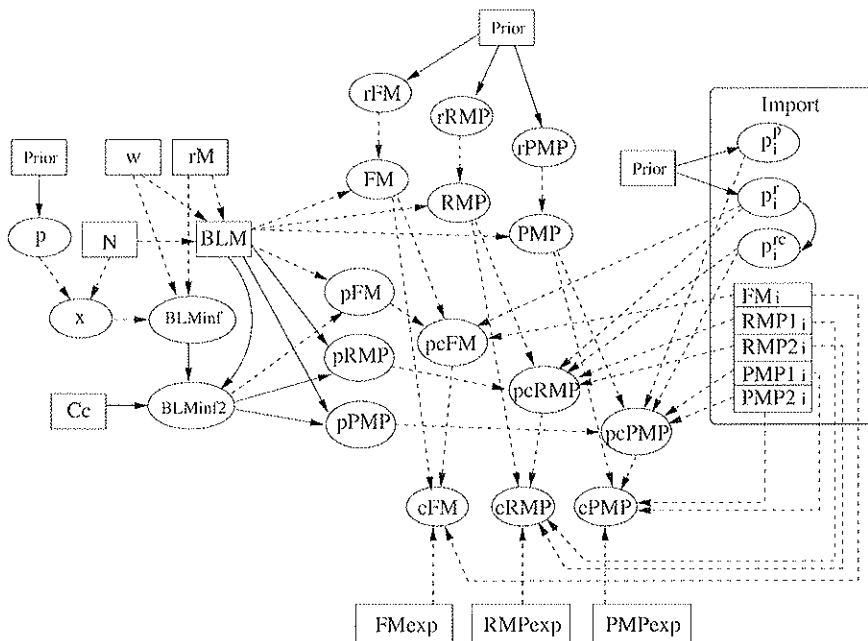


Figure 12.

A schematic presentation of the conditional distributions in SPSM.

The set of conditional distributions in the simulation model defines a prior predictive distribution of the output quantities (Figure 12). The simulation was done using Monte Carlo sampling with @RISK software. The simulation proceeds in a straightforward manner in the direction of the conditional distributions defined, starting with the initial quantities which are given prior distributions according to expert opinion or according to the results of previous inference modules. For example, the true prevalence in the slaughter population was given a distribution according to the SPIM, but the percentage of domestic meat consumed as fresh pork, raw pork preparations and processed pork products was assigned a prior distribution according to expert opinion. All the conditional distributions and formulae are summarized in Table 24 below.

5.3.3.5 Sensitivity and limitations of the SPSM

The predicted prevalence (mean 0.85%) of *Salmonella* positive pork can be compared to the information on the retail level obtained by a study done by local food control laboratories, EELA and National Food Agency. In 1999, 171 fresh pork samples were collected by local authorities all over the country and analysed for *Salmonella*, but *Salmonella* was not detected in any of these samples. Similarly, 165 samples from domestic pork were collected and analysed in 2000, and again *Salmonella* was not detected (Hatakka et al 2000 and 2001). Comparison of these results to the apparent *Salmonella* prevalences of 0.03% and 0.00% in crushed meat samples gathered from the cutting plants in 1999 and 2000 (Table 9), show convergent low prevalence levels. If the true prevalence would be 0.85%, then there is a 23% probability that none of the 171 samples are truly contaminated. Even if some of them were, the testing method is not likely to detect all truly contaminated samples. The model prediction is apparently in fair agreement with these findings, although it is probably somewhat of an overestimate. It is important to notice that we assumed the whole carcass of an infected finishing pig would be contaminated with *Salmonella*.

It is also important to notice that the certificates of negative *Salmonella* tests cover only 11% of imported pork, i.e. pork intended for fresh sale (fresh pork or raw meat preparations). 74% of imported (fresh) pork is used for making processed products and is not subject to additional *Salmonella* testing. 15% of imported pork is either processed (heated) pork products or raw pork preparations and neither of these are subject to additional *Salmonella* testing.

Predictions of the number of contaminated servings were studied by using different threshold values in the processing cross-contamination model: 100%, 2%, 1.5%, 1%, 0.5% and 0% (Figure 13). If the threshold value were 100%, the initial contamination in the fresh pork would always be below this and the cross-contamination model would never be activated in the simulations. Likewise, if the threshold value were set to 0%, the model would always be activated. The default value used was 1%. Between extreme threshold values (100% & 0%) the difference in absolute numbers of contaminated servings ranges from 3 million to over 15 million (when comparing means of the distributions). Therefore, the expected number of human cases may also be about 5 times higher if computed assuming the highest possible cross-contamination compared to the lowest.

The model is sensitive to the assumed cross-contamination effect due to meat processing, which nevertheless was based on expert opinion. The opinions were reflected by the general model function but it was not possible to develop a more detailed model. In SPSM, the effect of cross-contamination increases sharply when the initial prevalence of *Salmonella* in fresh pork reaches and exceeds 1%. The same cross-contamination model was assumed for imported pork and for domestic pork. An exporting country with poor prevalence data will be estimated with a wide distribution of true prevalence, due to uncertainty. A high initial *Salmonella* prevalence in imported pork may lead to a huge cross-contamination effect in the model, and consequently to a large share of human cases of illness caused by imported pork. This can be tested in the model by comparing the default simulation to a scenario with no cross-contamination effect at all. (The latter is simply obtained by giving a high threshold value (100%) for the cross-contamination to become effective). The

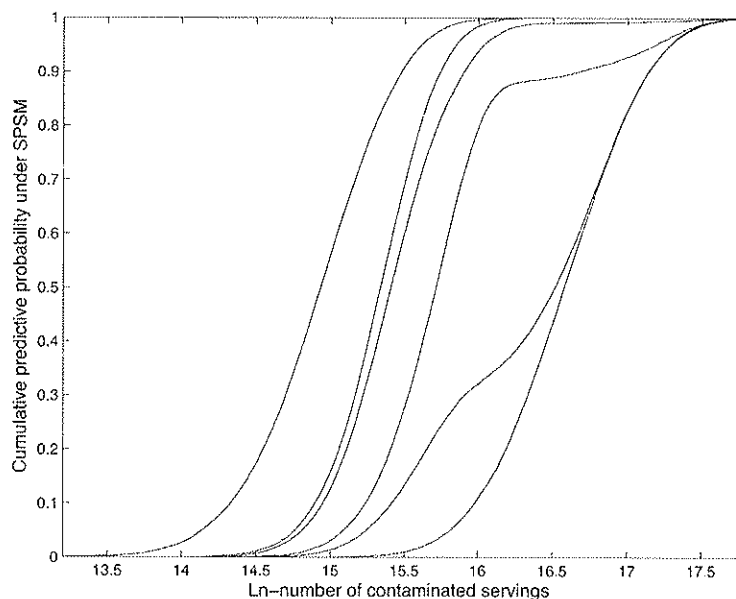


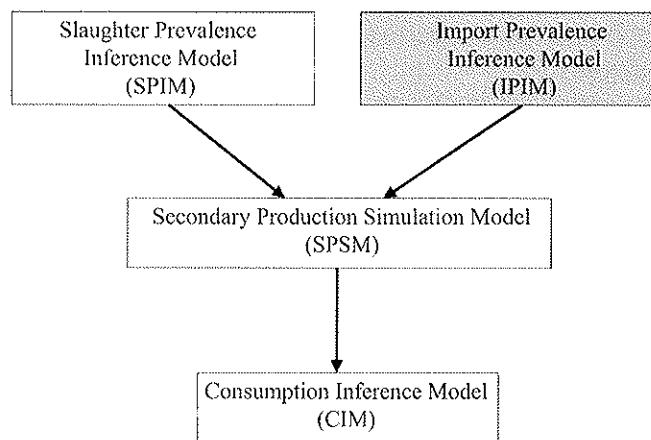
Figure 13.

Cumulative probability of the logarithm of the number of contaminated servings.
Curves from left to right: threshold value 100%, 2%, 1.5%, 1%, 0.5% and 0%.

share of *Salmonella* contaminated servings due to imported pork in volumes similar to 1999 then becomes minor which indicates that much of the import risk is due to the assumed cross-contamination effect and the threshold value of 1%. Similarly, if all imported pork were intended for fresh sale, the effect of cross-contamination parameter would disappear, because the cross-contamination model does not concern any meat intended for fresh sale. However, in this case all fresh pork imports would take place under the required additional certificates, which would cause a selective effect towards a lower prevalence.

5.3.4 Import Prevalence Inference Model (IPIM)

Figure 14.
The Import Prevalence Inference Model (IPIM) in the whole risk assessment model.



5.3.4.1 Summary of the IPIM

To assess the risk of salmonellosis caused to consumers from the pork on sale in Finland, we also had to evaluate the true *Salmonella* prevalence in imported pork and pork products. This true prevalence was estimated using the Import Prevalence Inference Model (IPIM), which is a hierarchical Bayesian model (Figure 14).

The IPIM was based on reported testing results from the main exporting countries. The true prevalence for each country was modelled as a 'population model' by describing the 'population of countries exporting to Finland', i.e. the uncertainty due to variability in the true prevalence between countries. The parameters of this population model were estimated from the reported data for different countries, and predictions for those countries with no data were then based on this estimated population model. It was considered sufficient for predicting the prevalence in countries without data, as long as the profile of the exporting countries remains the same as in 1999.

Because of the FSCP, Finland has permission to require additional *Salmonella* guarantees showing negative test results (per consignment) before importing fresh meat, with some exceptions. The *Salmonella* examinations required to prove test negative were also included as data, although the number of such additional tests was based on an estimate. The sensitivity of the microbiological test was evaluated as an expert opinion based on a few references.

Sweden, as a country with low *Salmonella* prevalence and a similar control programme as the FSCP, need not fulfil the testing procedure requirements concerning pork export to Finland. Because there were no data available on a Swedish *Salmonella* risk assessment on pork, in this assessment Swedish pork prevalence was estimated on the basis of the Finnish results.

According to the model the true prevalence in imported fresh meat varied among exporting countries from 0.18% (mean), 95% probability interval [0.12%,0.25%], to 5.65% (mean), 95% probability interval [3.93%,7.70%]. The true prevalence in imported pork products varied from 0.01% (mean), 95% probability interval [0%,0.11%], to 0.59% (mean), 95% probability interval [0%,4.0%]. The outcome of the IPIM was used as a probability distribution of the true prevalence in imported meat in the simulation model (SPSM). The less data from an exporting country, the wider the distribution will be.

5.3.4.2 Inputs of the IPIM

All the inputs to the IPIM are presented in Table 25 in Appendix.

Number of tests reported in each exporting country (n_i^0) and the number of test positives (d_i^0)

Information on the basic prevalence in the different countries is drawn from the zoonotic report included in the annual report of trends and sources of zoonotic agents in animals, feedstuffs, food and man in the European Union and Norway in 1999 (Table 16). Although the data from different countries are not directly comparable because there are differences in the sampling systems and laboratory methods in use, as well as in the reporting systems, the model had to be run with the existing data.

The numbers of *Salmonella* tests and positive samples reported in every exporting country are shown in Table 16. These were available for fresh meat and meat products, and it was assumed that “fresh meat” results can be used for prevalence estimation for all categories of fresh meat, including raw meat preparations. Test results of “meat products” were used for prevalence estimation for processed meat products. Retail level data were used in order to estimate the actual prevalence after processing, but if this was not available, test results at slaughterhouse were used instead. With these assumptions and constraints, the data (number of tests and the corresponding results) were used to estimate the true prevalence for each country, separately for fresh meat and meat products.

Number of tests done for certificates (n_i^a) and the number of test positives (d_i^a)

The number of *Salmonella* tests due to the additional guarantees was evaluated according to the requirements (i.e., the number of tests which should have been done). If *Salmonella* is detected, the whole import consignment of pork is discarded. Therefore, there is a selection effect which can be quantified based on the number of additional tests with corresponding negative results required for the certificates. The amount of pork imported to Finland from other countries with the guarantee coming from certificate requirements in 1999 was 1,661,300 kg according to the National Food Agency. No pork of the same category was imported from other countries according to the Ministry of Agriculture and Forestry (MMMELO 2002).

Because the exporting countries were not available in the National Food Agency extract we used, we had to make some assumptions. First, we assumed that the countries which exported certificated pork in 1999 were the same as those which had exported fresh pork in the same year. Second, we assumed that the proportions among certificated pork exporters were the same as in the total fresh pork import. So, the proportion of pork imported with the *Salmonella* certificate (1,661,300kg) from each exporting country was assumed to be the same as the country's proportion of all exporting countries (Table 11). Imported meat and meat products entered Finland for different purposes: 1. fresh meat for sale as fresh, 2. fresh meat for raw meat preparations, 3. fresh meat for processed meat products, 4. raw meat preparations for

Table 16.

Occurrence of *Salmonella* contamination of pork and corresponding meat products in the main meat exporting countries and Finland (EC 2001).

| Country | Sample | Sampling site | Units investigated | Salmonella detected | Sampling method |
|-----------------|---------------|-------------------|--------------------|---------------------|-----------------------|
| Denmark | Raw meat | At slaughterhouse | 16,399 | 164 (1.0%) | - |
| | | At retail level | 2,261 | 27 (1.2%) | - |
| | Meat products | At retail level | 2,078 | 0 | 25 g |
| Sweden | Raw meat | At slaughterhouse | 4,973 ^a | 0 | a: Incl. beef samples |
| | Meat products | At retail level | 423 | 0 | |
| Belgium | Raw meat | At slaughterhouse | 154 | 43 (27.9%) | Surface swabs |
| | | | 152 | 41 (27.0%) | Ground meat |
| Germany | Raw meat | At slaughterhouse | 7,890 | 111 (1.4%) | - |
| | | At retail level | 1,624 | 48 (3.0%) | - |
| The Netherlands | Raw meat | At retail level | 533 | 33 (6.2%) | 25 g |
| Finland | Raw meat | At slaughterhouse | 6,155 | 2 (0.03%) | Surface swabs |
| | | At retail level | 171 | 0 | 25 g |

sale, 5. processed meat products for sale (Table 14). The certificates concern the first two categories only. The amount of pork in each import category had to be estimated as well as the number of additional tests required in the first two categories.

The estimate that 1,556,638 kg of the imported pork was imported boneless was based on the Customs register; we converted the initial imported amount of 1,661,000 kg to boneless meat. The amount of imported boneless meat from each country corresponded to a certain number of consignments, since the average weight of a consignment was 3,700 kg (Table 17). According to an expert opinion, one consignment of meat corresponded on average to 185 parcels of 20 kg each. According to official instructions (MMM 897/1997), one consignment in that case shall be tested with 38 samples (0,75x50 samples). The final estimate of the number of tests for each country was determined by multiplying the number of consignments by 38 (Table 17). Concerning carcass meat, we assumed that the number of half carcasses (weighting 42 kg on average) in one consignment was 88, and thereby estimated that the number of samples per consignment was 40 (MMM 897/1997).

Concerning the meat that is actually imported with certificates, the number of positive samples (d_i^a) in the additional tests is assumed to be zero because whenever a result is positive the whole consignment is rejected and thus cannot be imported.

Combined data on testing (n_i and d_i)

The combined data consist of the number of tests concerning fresh meat and meat products at the retail or slaughter house level, the number of positive results thus reported in each exporting country, and the additional number of (negative) tests required for the certificates concerning some import categories. Therefore, the number of tests is either $n_i = n_i^0 + n_i^a$ or $n_i = n_i^0$ depending on whether we assume additional

Table 17.

The number of *Salmonella* tests conducted in EU countries exporting to Finland according to the additional guarantees in 1999.

| Exporting country | Imported according to additional guarantees, non-carcase meat | | | Imported according to additional guarantees, carcase meat | | |
|---------------------|---|--------------------------|-----------------------------|---|--------------------------|-----------------------------|
| | Amount of meat ^a | No. of lots ^b | No. of samples ^c | Amount of meat | No. of lots ^b | No. of samples ^d |
| Denmark | 1,231,091 | 333 | 12,643 | 112,025 | 30 | 1,200 |
| Sweden ^e | 132,950 | 36 | - | - | - | - |
| Germany | 89,255 | 24 | 917 | - | - | - |
| Belgium | 84,806 | 23 | 871 | - | - | - |
| The Netherlands | 5,106 | 1 | 38 | 96 | 1 | 1 |
| Others together | 6,018 | 1 | 38 | - | - | - |
| Total | 1,549,226 | 418 | 14,508 | 112,121 | 31 | 1,201 |

^a Total meat, of which 65% is boneless and the rest bone meat

^b The average weight of a consignment is 3,700 kg (when bone meat is included)

^c The total no. of parcels (20 kg) / lot meat is 185; the number of samples / consignment is $0.75 \times 50 = 38$ (MMM 1997)

^d The total no. of halved carcasses (42 kg) / lot is 88 (expert opinion); the number of samples / consignment is 40 (MMM 1997)

^e Sweden has a similar salmonella control programme as Finland, thus no additional testing is required

testing or not. The combined number of positive results is simply $d_i = d_i^0$, because $d_i^a = 0$.

Information about apparent *Salmonella* prevalence in meat products was received from only one country (Denmark) but information on raw meat apparent prevalence was available for four countries (Denmark, Germany, Belgium, Netherlands). The combined data can be used when estimating the true prevalence under the additional guarantees. Effectively, the prevalence is estimated to be lower the more negative test results are known to exist concerning those imports. The number of positive results in these additional samples was not needed because the whole import consignment is rejected whenever a positive sample is detected. Therefore, information about the number of tests with negative results is sufficient to quantify the prevalence in imported meat under the additional guarantees. The original country-specific data on other test results reported is included in the calculations as background information. If no additional tests are required for *Salmonella* certificates, then the estimation rests on this background information only.

True prevalence (p_i)

This generic parameter represents either the prevalence in raw meat or in meat products in the i th country, depending on which we are estimating (the model structure is the same). No prior information was assumed concerning the true prevalence (either raw meat or meat products) in each country. Therefore, a hierarchical prior distribution $p_i \sim \text{Beta}(\alpha, \beta)$ was assumed with independent and identical hyperprior distributions for α and β . This results in a uniform prior predictive distribution of p_i . Moreover, the hierarchical construction allows us to estimate the posterior distribution of parameters α, β from the country-specific data. This posterior distribution can then be used for predicting p_i for those countries with missing data (p_{pred}).

Sensitivity of the testing method (p_{sen})

Sensitivity of the testing method was accounted for in the model, but it was assumed to be the same for all countries. The sensitivity of the microbiological test method for *Salmonella* in pork was given a Beta(281.3,8.7) distribution with a mean of 0.97 and a standard deviation of 0.01. Effectively, the distribution was then defined over the range [95%,100%] (Peterz et al 1989, Wiberg, personal communication 2002, Feldsine et al 2003).

Exception to the IPIM: Sweden

Sweden was excluded from the IPIM 'population model for exporting countries', because there is no *Salmonella* testing requirement for meat imported from Sweden, and prevalence for fresh pork and beef cannot be distinguished from each other in the information available on the fresh meat surveys at the slaughter level (Table 16). Therefore the prevalence in Swedish pork was assumed to be the same as in Finland due to a similar control program. This can be based on the results of the Swedish *Salmonella* Control Programme (see Table 18 and Table 8).

Table 18.

Results of the Swedish *Salmonella* control programme regarding samples collected from finishing pigs at slaughterhouses in 1996-2000 (SVA 2001a and SVA 2001b).

| Lymph node tested finishing pigs | | | |
|----------------------------------|-------|----------|------|
| Year | Total | Positive | % |
| 1996 | 2,699 | 1 | 0.04 |
| 1997 | 3,382 | 6 | 0.18 |
| 1998 | 3,914 | 3 | 0.08 |
| 1999 | 3,495 | 9 | 0.26 |
| 2000 | 3,436 | 9 | 0.26 |
| Mean | 3,385 | 6 | 0.16 |

5.3.4.3 Outputs of the IPIM

The true prevalence of imported fresh meat (mean) varied from 0.18% [0.12%, 0.25%] to 5.7% [3.9%, 7.7%]. The true prevalence of imported pork products (mean) varied from 0.01% [0%, 0.11%] to 0.59% [0%,4.0%].

The estimate of the amount of imported contaminated meat (fresh meat or meat product) is the product of the corresponding prevalence estimate and the estimated amount imported. This calculation is done in the SPSM using the prevalence estimates obtained from the IPIM.

The estimated prevalence in imported pork products was based only on the examinations conducted in Denmark because of a lack of statistics concerning other exporting countries, but the estimated prevalence in imported fresh pork was based on statistics of four countries.

5.3.4.4 Mathematics of the IPIM

The set of conditional distributions in the model together with the given set of data and prior distributions define a posterior distribution (Figure 15) which was computed using WinBUGS software.

Table 19.

The estimates of true prevalence of *Salmonella* in fresh pork and pork products imported from different countries in 1999 based on the IPIM.

| Without additional quarantees | | | | | | |
|-------------------------------|------|------|--------|-------|------------------------|----------------------------|
| Fresh pork | | | | | | |
| | Mean | 2.5% | Median | 97.5% | No. tests ^a | No. positives ^a |
| Denmark | 0.01 | 0.01 | 0.01 | 0.02 | 2,261 | 27 |
| Germany | 0.03 | 0.02 | 0.03 | 0.04 | 1,624 | 48 |
| Belgium | 0.27 | 0.20 | 0.27 | 0.34 | 154 | 43 |
| The Netherlands | 0.06 | 0.05 | 0.06 | 0.09 | 533 | 33 |
| Other countries | 0.09 | 0.00 | 0.07 | 0.35 | --- | --- |
| Pork products | | | | | | |
| Denmark | 0.00 | 0.00 | 0.00 | 0.00 | 2,078 | 0 |
| Other countries | 0.01 | 0.00 | 0.00 | 0.04 | --- | --- |
| With additional quarantees | | | | | | |
| Fresh pork | | | | | | |
| | Mean | 2.5% | Median | 97.5% | No. tests ^b | No. positives ^a |
| Denmark | 0.00 | 0.00 | 0.00 | 0.00 | 16,105 | 27 |
| Germany | 0.02 | 0.01 | 0.02 | 0.03 | 2,541 | 48 |
| Belgium | 0.04 | 0.03 | 0.04 | 0.06 | 1,025 | 43 |
| The Netherlands | 0.06 | 0.04 | 0.06 | 0.08 | 572 | 33 |
| Other countries | 0.01 | 0.00 | 0.01 | 0.05 | 38 | 0 |
| Pork products | | | | | | |
| Denmark | 0.00 | 0.0 | 0.00 | 0.00 | 2,078 | 0 |
| Other countries | 0.01 | 0.0 | 0.00 | 0.04 | 423 | 0 |

^a Reported by the dispatching countries.

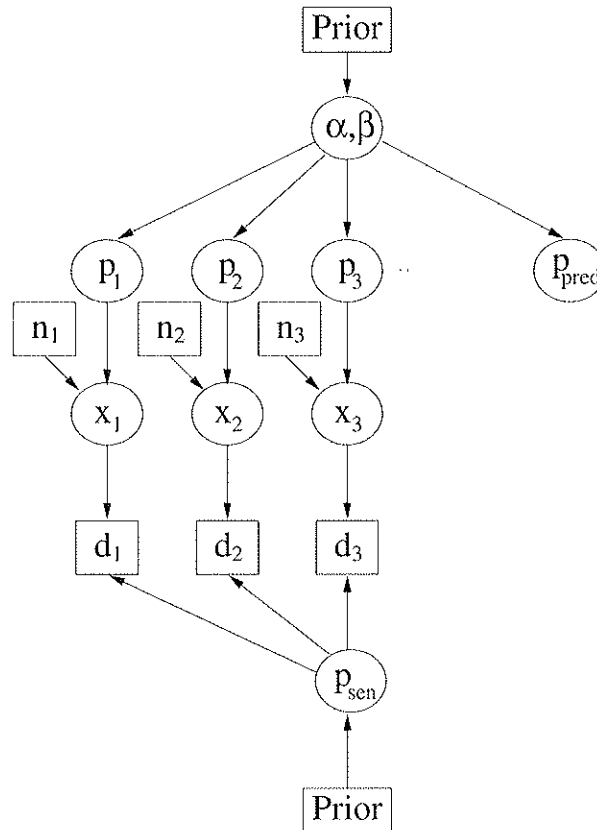
^b Reported number of tests + tests required by the additional quarantees.

The observed number of positives d_i for the i th country with a known sample size n_i has a conditional binomial(x_i, p_{sen}) distribution, where x_i is the true number of contaminated samples among those taken, and p_{sen} is the sensitivity of the testing method. The x_i has a conditional binomial(n_i, p_i) distribution, where p_i is the true prevalence for the i th country. Finally, p_i has a conditional beta(α, β) distribution describing the uncertainty due to variability between country-specific prevalences. The hyper parameters α, β both have an $\exp(0.001)$ density which effectively was chosen in order to have uniform prior predictive density for each p_i . Using π as a generic notation for a probability density, the joint posterior density of $\alpha, \beta, p_i, x_i, p_{sen}$ can be written as

$$\pi(\alpha, \beta, p_i, x_i, p_{sen} | n_i, d_i) \propto \pi(\alpha)\pi(\beta)\pi(p_{sen}) \prod_i \pi(d_i | p_{sen}, x_i)\pi(x_i | p_i, n_i)\pi(p_i | \alpha, \beta).$$

Figure 15.

Graphical description of the conditional distributions in the Imports Inference Model (IPIM). p_i denotes the true prevalence in the imports from the i th country, p_{sen} the sensitivity of the testing method, x_i the true number of contaminated samples and d_i the number of detected positive samples among a total number of samples n_i taken. p_{pred} is the predicted true prevalence for a country with no data about n_i and d_i .



For countries with no data on n_i and d_i , the posterior predictive distribution of p_i is then computed on the basis of the marginal joint posterior distribution of the hyper parameters α and β . This predictive distribution is thus affected not only by the absolute values of the estimates of different p_i , but also on the heterogeneity of prevalences between different countries. The model effectively assumes that the country-specific true prevalences are like samples from a common population distribution. Estimating the parameters of this population distribution allows predictions to be made about generic members of the same population.

When the FSCP is not assumed to be in force, nor the additional guarantees, the sample size n_i is taken to be equal to n_i^0 which is the number of samples reported from each country, if this is known. When the FSCP and additional guarantees are assumed to be in force, there are a number of additional tests done per each country (determined by the import volume) and these are required to be test negatives before importing to Finland is permitted. Test positive consignments are rejected. Once the number of negative test results is known or estimated, this information can be used in the model. The number of such additional test negative results n_i^a was then added to the previously given number of samples n_i^0 so that the new sample size becomes $n_i = n_i^0 + n_i^a$, and the new joint posterior was computed based on this n_i and d_i . Effectively, this additional information decreases uncertainty about the true prevalence, and the estimate of the true prevalence also becomes lower. This quantifies the effect of selection imposed by the requirement of negative test results. Yet, the baseline information given by the country-specific initial data set (n_i^0, d_i) is preserved.

The model is mathematically the same for imported fresh meat and meat products. The only difference is that the data (n_i, d_i) then describes either the results of fresh meat or meat products at the retail level for each country. The additional tests required due to the additional guarantees only concern fresh meat imports excluding the raw material for processed meat products.

5.3.4.5 Sensitivity and limitations of the IPIM

For some of the dispatching countries there were no reports available about the *Salmonella* prevalence in fresh pork. Some countries had only very few samples analysed and reported. These two things caused uncertainty about the true prevalence, which lead to wide confidence intervals in some country-specific distributions of prevalence in the IPIM.

The Swedish import prevalence was estimated in a different way than the others. There are no additional tests required for Swedish imports because certificates are not required as they are for other countries since Sweden has a control program similar to FSCP and the prevalence can be assumed to be similar to the Finnish prevalence. Therefore, Sweden is not in an exchangeable position with respect to other countries in the IPIM, and this is against the IPIM model assumptions. It was considered best to estimate Swedish prevalence using the estimated Finnish slaughter prevalence as a starting point rather than the IPIM-model with other importing countries.

The number of countries exporting to Finland included in the IPIM was only 5, because these were responsible for 99% of the import volume. All the other countries were grouped together into one class. There was missing information on the number and results of tests for some countries. The estimation of the population distribution of the country specific prevalences may be unreliable because it depends on a very small set of countries. In particular, for pork products at the retail level there were data from only one country and the predictions for the other countries then depend on this information. Also, the population distribution obtained may only adequately predict countries which are sufficiently within the range of prevalences of those observed. The model does not incorporate complex spatial or temporal dependencies between all countries around the globe, but presents a simple probabilistic hierarchy to model a small set of import data and for making predictions for countries with missing data.

5.4 Risk characterization

The goal of this risk assessment was to quantify the risk of human infections caused by *Salmonella* in pork. This depends on the estimated number of contaminated servings, but also on the level of contamination per such serving. The estimate of the number of contaminated servings depends on the results of the previous inference models (SPIM, IPIM) and the simulation model (SPSM). The estimated mean level of contamination at the time of consumption in all servings which originally would have been contaminated after processing in the food industry depends on the results of the Consumption Inference Model (CIM) which includes an assumed dose-response model and its parameters. The CIM also uses data on the reported number of human cases and underreporting. Effectively, the CIM was calibrated to the current situation (based on the year 1999) by estimating the mean CFU/g and the true number of cases using these data and the results of previous modules. The predictive distribution of the number of reported human cases of illness caused by *Salmonella* in pork is shown in Figure 17.

5.4.1 Consumption Inference Model (CIM)

5.4.1.1 Summary of the CIM

The number of human cases of illness due to *Salmonella* from pork was assessed by a hierarchical Bayesian model, based on the records of the reported number of

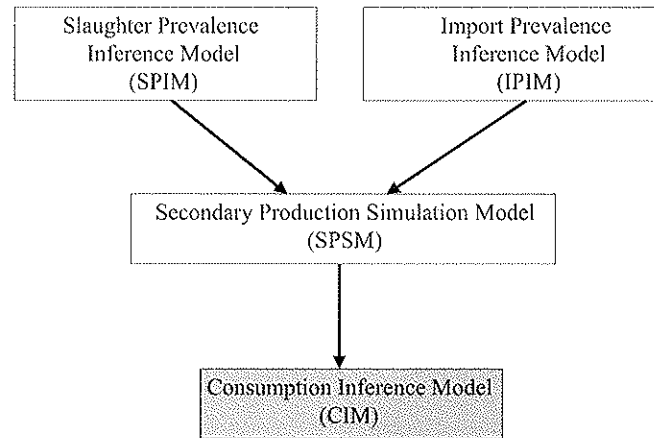


Figure 16.

The Consumption Inference Model, CIM, in the whole risk assessment.

domestic human cases of illness and the phagetype information. The meta level model utilizes a given dose response model that is assumed to be fixed. Effectively, the CIM combines information from two directions: the observed records of human cases of illness and the predicted number of contaminated servings resulting from the SPSM. As a result, the model estimates the average CFU/g level per contaminated serving jointly with other uncertain quantities. The resulting information can be further used when predicting the number of human cases under different scenarios. All the input data, prior distributions and conditional distributions used in the CIM are listed in Table 26.

The dose-response model specifies a probability distribution for the number of human cases of illness for each specified set of values for: (1) the parameters in the model; (2) the number of contaminated servings; (3) the size of the servings; and (4) the average CFU/g levels in such servings. Uncertainty about the exact number of contaminated servings was described by a probability distribution resulting from the secondary production simulation model (SPSM). This represents the expected number of servings that could be contaminated, at least before final preparation and storage. The parameters of the dose-response model were taken from the literature and treated as fixed constants. The serving size was quantified as a distribution deduced from the consumption data. The CFU/g levels at the time of actual consumption are highly uncertain. There are no reliable data sources available and also the expert opinions present large uncertainties. Therefore, this most uncertain

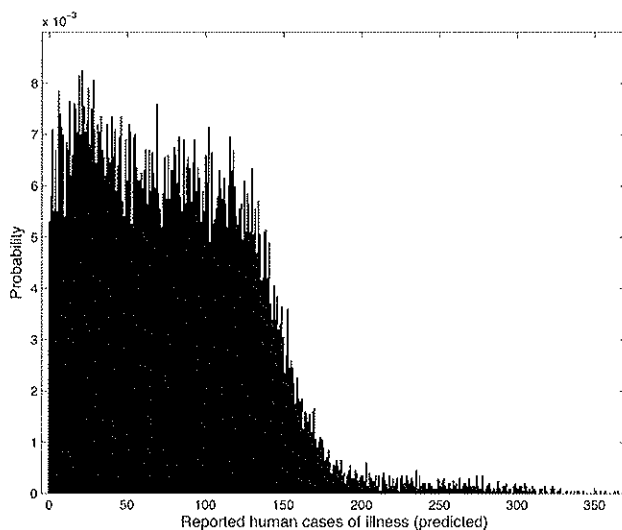


Figure 17.

Predictive distribution of the number of reported human cases of illness. Result based on data from 1999, 100,000 MCMC iterations. Mean 79, interval of 95% posterior probability [4,193].

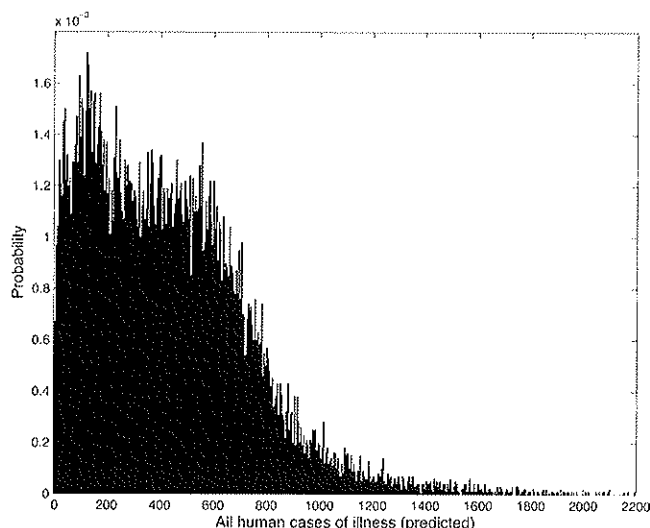


Figure 18.
 Predictive distribution of the number of all human cases of illness. Result based on data from 1999, 100,000 MCMC iterations. Mean 431, interval of 95% posterior probability [22,1153].

quantity was described by an uninformative (uniform) prior distribution so that it is estimated, on the basis of the other quantities, from a posterior distribution.

For the observed years, e.g. 1999, the total number of reported human infections of *Salmonella* is known. From that we can deduce an estimate (min, max) for the number of infections due to pork. This can be done, for example, on the basis of the serotypes and phagetypes detected in pork, and from the human infections. Therefore, we can treat the estimate of human infections due to pork as a censored data value and compute a posterior distribution for CFU/g, given the range and the prior densities for the number of contaminated servings and the size of the servings. Furthermore, we can take into account the underreporting of human infections simultaneously within the same inference model. This approach accounts for many of the uncertainties while, at the same time, utilizes the only truly observed consumption related data: the reported human infections.

The predictive distribution of the number of reported human cases of illness, under the conditions similar to 1999, was 79 (mean), with the 95% interval of posterior probability [4,193] according to the CIM. For the predictive distribution of the number of all human salmonellosis due to pork, the CIM gave 431 (mean) with the 95% interval of posterior probability [22,1153].

5.4.1.2 Inputs of the CIM

All the inputs to the CIM are presented in Table 26 in Appendix.

Number of contaminated servings (nser)

The number of contaminated servings is calculated simply by dividing the total amount of contaminated meat by the average serving size. The total amount (kg) of contaminated meat is given by the SPSM as a predictive probability distribution which is taken as a (fitted) prior distribution in the CIM (Figure 19). Different interventions and scenarios considered in this assessment have an effect on this total amount only, and hence on the number of contaminated servings.

Number of pork-borne reported cases of human infections (ncobs)

The number of reported human cases of illness caused by *Salmonella* from pork is not directly available in Finland. Therefore, the ratio of any serotypes isolated from FSCP-linked pigs and pork samples to the isolates of the reported human cases was used as an estimate of pork-caused human salmonellosis. For this calculation,

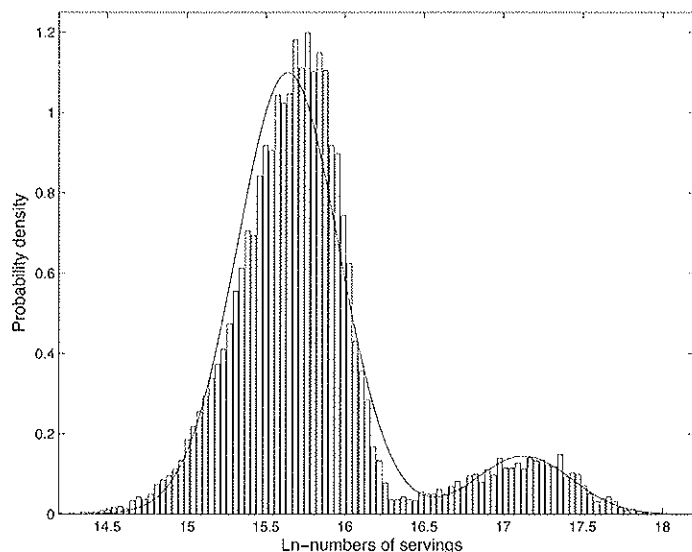


Figure 19.
Fitted probability density and the simulated predictive density of the log-number of contaminated servings from the SPSM.

data from 1999 were used. All the serotypes of the isolates from the FSCP (i.e. for regular monitoring) were taken into account because they were considered to refer to the prevalence in pork for consumption. Of these, the share for pigs and pork (in respect to no. of isolates) was 129. Thus, 129 was used as maximum number of human cases of illness caused by pork (i.e. 2.5 cases per 100,000 inhabitants). Zero was chosen to be a minimum. Such data can be interpreted to be 'censored' so that even if we do not know exactly the right number of reported cases of illness due to pork, we are sure that it is not smaller than 0 or larger than 129. In other words, it is observed as an imperfect measurement.

Serving size of pork (ssize)

The mean size of a meat serving is estimated to be 122 g for an adult person from 25 to 65 years of age. This estimate is based on The 1997 Dietary Survey of Finnish Adults (KTL 1998) and an expert opinion.

Level of contamination (cfu)

The level of contamination at the time of consumption is an important factor in consumer risk. It depends e.g. on the characteristics of the strain, the microbiological ecology of the food, the initial contamination of raw material including consideration of regional differences and seasonality of production, the level of sanitation and process controls, the methods of processing, packaging, distribution and storage of the foods as well as any preparations steps such as cooking and holding (Codex Alimentarius Commission 2000). One approach would have been to ask experts about all these issues and build a model for all these steps. The experts could have been asked to estimate the level of contamination at the time of consumption (including storage, preparation, cross contamination etc.).

Unfortunately, very little such data exists in Finland concerning these various steps in food preparation and storage and it was not possible to quantify the actual CFU/g level (at the time of consumption) even as an expert opinion. Therefore, Bayesian inference was used in the CIM for computing the likely average contamination level based on the available information on the number of reported human cases of illness, the selected dose-response model, the average serving size and the number of contaminated servings. Hence, it was possible to start with an uninformative prior distribution for the average CFU/g, e.g. a uniform distribution over a suitably wide

range to cover all the plausible values. As a result, a posterior distribution of CFU/g is obtained as an output, representing the plausible average values according to information on the aforementioned other quantities.

Dose-response model (α, β)

A Beta-Poisson dose-response model was chosen with parameters $(\alpha, \beta) = (21.159, 0.2767)$ for the normal population taken from the WHO/FAO report (WHO/FAO 2002). The Beta-Poisson model chosen has been presented by the USDA/FDA in the *Salmonella* Enteritidis Risk assessment. It is based on human feeding trial data for *Shigella dysenteriae*. Fazil et al. (2000) compared it to outbreak data, and on a purely empirical basis they concluded that this curve tends to capture the upper range of these data.

Expected reporting of human cases of illness (p_{sel})

Laboratories have to notify all confirmed *Salmonella* cases of any serotype, usually based on bacteriological culturing. Samples are taken from persons suffering from diarrhea, including their close contacts, and from asymptomatic persons working in risk professions. *Salmonella* species identification is done by biochemical methods and by agglutination of cultures by *Salmonella* antisera. Phagetyping is done for *S. Paratyphi*, *S. Typhimurium*, *S. Enteritidis*.

Wheeler et al. (1999) conducted a study on the reporting rate of some foodborne diseases. According to them, 72.7% of the *Salmonella* cases visited the physician, 36.5% were positive for *Salmonella* in laboratory analysis and 31.8% were reported in the national register. In Finland, it has been estimated that approximately 10% of all the *Salmonella* infections are reported into the national registers (Eiintarvike-erityistilanne-työryhmän muistio 1997). Since this information is relatively weak, the distribution for the reporting activity of the range of 10-30% was used. This may still be an overestimate since the origin (domestic/foreign) of many of the reported infections cannot be identified. In the CIM, the variable *ncobs* describes the number of such cases that are reported and identified as domestic origin, and linked to pork according to the assumptions presented earlier.

5.4.1.3 Outputs of the CIM

The association between cfu and the number of contaminated servings

The marginal posterior distribution of average CFU/g and the number of contaminated servings, based on the estimated number of reported cases of illness, is shown in Figure 20.

As a result, the most probable values appear along the "boomerang" shaped distribution. Large values of CFU/g together with a small number of contaminated servings is just as probable as small values of CFU/g together with a large number of contaminated servings. This is the summary information we get from the CIM as an output. When simulating predictions under the same assumptions and background scenario (such as was the case in 1999), the number of human cases of illness could be simulated with parameters taken from this joint distribution. However, the marginal posterior density of the number of servings becomes different from the original prior distribution due to the probabilistic inference based on the given data and priors. Furthermore, differences are also due to errors in density fitting with the simulation result of the SPSM that needs to be done in order to define a density function of *nser* for the WinBUGS computation. Therefore, in order to preserve both the exact predictive density of *nser* (taken from the SPSM), and the inferential result concerning *nser* and *cfu* jointly (taken from the CIM), the predictions of human cases were

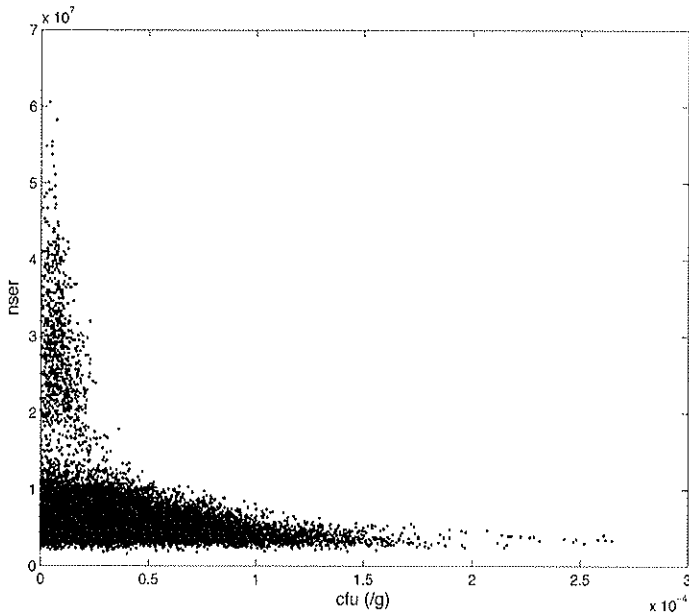


Figure 20.
MCMC sample from the marginal joint posterior distribution (CIM) of average cell counts at the time of consumption (CFU/g) and the number of contaminated servings (nser) (100 000 MCMC iterations). Marginal mean of cfu is 0.00004, Std 0.00003, and the interval of 95% posterior probability [0.000002, 0.0001].

computed using stochastic pointwise coupling. Technically, this is implemented by pointwise ordering of the MCMC sample according to the sampled values of nser, and then replacing the nser-values with similarly ordered values sampled from a scenario distribution of nser (Figure 21). The default situation (in the SPSM) is also considered as such a scenario.

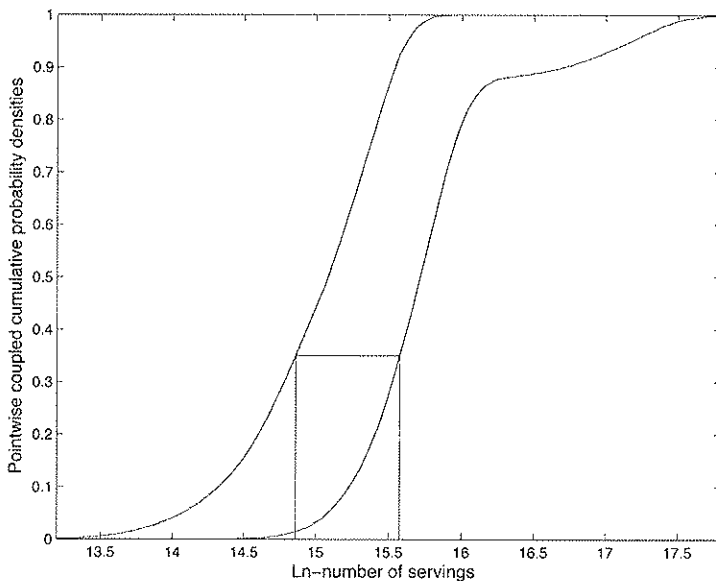


Figure 21.
Pointwise coupling of two random variables. Values connected with lines occur simultaneously.

The number of human cases of illness

The resulting number of human cases in the CIM depends on the total number of consumed contaminated meals and the dose-response model. The former quantity is provided by the previous steps of the simulation model (the SPSM), and the latter can be chosen among several equally plausible models. We have chosen a Beta-Poisson dose-response model whose parameters were taken from Fazil et. al (2000).

5.4.1.4 Mathematics of the CIM

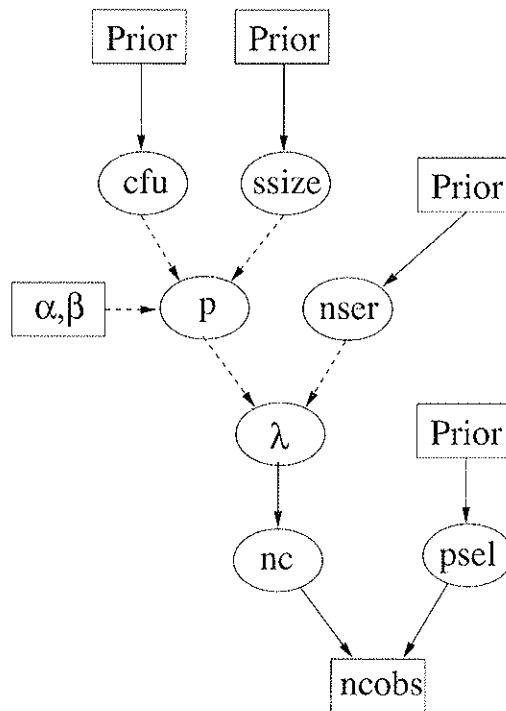


Figure 22.
A schematic
presentation of
the conditional
distributions
in the CIM.

The set of conditional distributions in the model together with the given set of data and prior distributions define a posterior distribution which was computed using WinBUGS software (Figure 22).

The observed reported number of human cases of illness $ncobs$ due to *Salmonella* in pork has a conditional binomial($nc, psel$) distribution, where $psel$ is the probability that a case of illness is detected and reported. The number of all cases of illness, nc , has a conditional Poisson distribution with parameter $p \cdot nser$ where $nser$ is the number of contaminated servings, and p is the probability of illness according to a dose-response model. The Beta-Poisson dose-response model was chosen with fixed parameter values (α, β) so that $p = 1 - (1 + cfu \cdot ssize / \alpha)^{-\beta}$. The size of a serving ($ssize$) was given a prior density of $N(122, 10^2)$ and the average CFU/g per serving was given an uninformative prior density of $uniform(0, 0.1)$. The log-number of servings was given a prior distribution obtained as a fitted distribution based on the simulation results of the SPSM. This prior was a mixture of two normal distributions $0.89 N(15.64, 0.32^2) + 0.11 N(17.13, 0.30^2)$ in order to capture the bimodality of the simulation result which was due to the threshold value of the cross contamination model.

Using π as a generic notation for a probability density, the joint posterior density can then be written as

$$\pi(nc, ssize, cfu, nser, psel | ncobs, \alpha, \beta) \propto \pi(ncobs | psel, nc) \pi(nc | cfu, ssize, \alpha, \beta, nser) \pi(cfu) \pi(ssize) \pi(nser) \pi(p)$$

The posterior predictive distribution of cases was then computed using the marginal joint posterior density of $ssize$, cfu , $psel$, and $nser$. However, the marginal posterior distribution of $nser$ becomes different from the original distribution, which was derived as a Monte Carlo sample from the SPSM. For comparability between scenarios and the default prediction, all predictions were computed using stochastic pointwise coupling of the scenario distributions of $nser$ -variable and the posterior marginal distribution of $nser$. Effectively, this construction keeps the distribution of $nser$ unchanged, i.e. as it is simulated from the SPSM, but utilizes the information gain

that is learned from the CIM model concerning the plausible values of cfu jointly with nser, given the data and the priors.

Notice that the observed value (data) of ncobs can be a single point, or it can be treated as a censored observation reflecting uncertainty about the exact value. In the former case, the likelihood contribution is just the corresponding binomial probability, but in the latter case the minimum and maximum values determine the censoring and the likelihood contribution will be the sum of binomial probabilities over those values between minimum and maximum.

5.4.1.5 Sensitivity and limitations of the CIM

Sensitivity analysis is a method used to examine the behaviour of a model by measuring the variation in its outputs resulting from changes to its inputs. As we said above, the portion of the domestic human salmonellosis cases due to pork is a rough estimate, and indeed is probably overestimated. This estimate can be compared to e.g. Danish estimates from the same year. According to the Danish MAF (2000), domestic pork contributed to 270-305 cases of illness (mean 5.5 cases per 100,000 inhabitants) in 1999, while at the same time the mean prevalence of *Salmonella* in Danish pork at slaughterhouses was 1.0% (in Finland there was mean 2.5 cases per 100,000 inhabitants, and 0.03% prevalence at slaughterhouses).

The model is limited to describe the average levels of CFU/g in the total population of initially contaminated servings at the retail level, at the actual time of consumption. It would be interesting to describe the levels separately in different groups of pork products because there may be important differences between them. However, this would ideally require an estimate of the reported number of human infections resulting from each group of products, which is difficult to estimate. The same problem concerns e.g. different types of restaurants and different habits of preparing food. Alternatively, a direct survey of contamination at the time of consumption would be needed but this would be expensive because large samples would be needed due to the current low prevalence of *Salmonella* contamination. However, the interventions that are assessed here only affect the numbers of resulting contaminated servings and not the final levels of CFU/g. Hence, it can be sufficient for our present purposes to quantify average levels of CFU/g for the total population. The estimate of CFU/g depends on the estimated number of contaminated servings (from the SPSM) and the estimated number of reported human cases of illness, together with the chosen dose-response model. Since the Bayesian estimation is based on conditioning the posterior distribution on observed data, all of these unknown variables and parameters can be quantified simultaneously, but the quality of the result will depend on the quality of the data. On the other hand, this is directly reflected by the form of the joint posterior density thus obtained.

We were uncertain about the true number of human *Salmonella* cases due to pork in 1999. In spite of being a recognized source of *Salmonella* for humans abroad, domestic *Salmonella* epidemics have rarely been traced to pork (with one exception in 1997) even though they are suspected anytime when relevant, and laboratory capacities are generally available for local epidemiological investigations. Hence, our expert opinion of the maximum number of cases (129) might be an overestimate as stated earlier. However, the relative differences between the predicted number of cases under alternative scenarios can be more reliable than the corresponding predicted absolute number of cases. However, the uncertainty about the reported human cases due to pork was included in the model by treating this value as a censored (i.e. uncertain, imprecise) "observation" instead of choosing an exact value. This was accomplished by specifying the minimum and maximum value.

Validation and comparison against an observed value of CFU/g is not currently possible, because there are no data about levels of CFU/g at the actual time of consumption. However, by definition, a contaminated serving must have at least one colony forming unit of *Salmonella* bacteria. If the average size of a serving is 122 g, the average level of contamination should be at least $1/122=0.008$ CFU/g for such servings. The posterior mean was 0.0000393 CFU/g. This is either because the SPSM is overestimating the number of contaminated servings or because the contamination level of the servings at the actual time of consumption drops nearly to zero for nearly all servings, or because of both of these reasons. The SPSM aims to estimate the amount of contaminated meat as a total that would be contaminated *before* final storage and preparation. These final steps were not included explicitly in the model. Also, the amount of contaminated meat was estimated by counting the whole meat weight of each 'infected' animal in the simulations. Furthermore, due to a lack of data, the model may be unrealistically overestimating cross-contamination effects. Therefore, the predicted amount of contaminated servings at retail very likely overestimates the number of contaminated servings at the actual time of consumption. If preparation and heating are mainly done properly, the actual average contamination level at the time of consumption in those servings can be much smaller than 0.008, as indicated by the posterior mean. Notice that the Bayesian CIM model is inferring plausible values for all uncertain quantities jointly, based on those values given, but accounting for the prior distributions. Therefore, if the number of resulting human cases is given as data (or censored data) the model calibrates the rest of the parameters according to that information. Hence, the cfu-parameter becomes effectively calibrated because the number of servings has a more informative prior distribution.

6. Interventions and scenarios

In order to study the effect of the Finnish *Salmonella* Control Programme on the prevalence of salmonellosis in Finnish consumers, the following scenarios were simulated:

1. A situation (similar to 1999) with the prevalence in domestic slaughter pigs estimated from the SPIM.
2. The *Salmonella* prevalence in domestic slaughter pigs increases to 1%.
3. The *Salmonella* prevalence in domestic slaughter pigs increases to 5%.
4. The import of pork increases considerably, up to 50% of consumption.

These scenarios were simulated either assuming that additional guarantees (for imported fresh pork intended for fresh sale) were applied or not.

6.1 Scenario 1: current situation (similar to 1999)

6.1.1 The effect of additional guarantees on the present situation

We studied the effect of the additional guarantees, which Finland was granted due to the FSCP, on the number of human cases of illness in the present situation (1999). This could be done in the IPIM by reducing the number of *Salmonella* tests done in the exporting countries due to the additional guarantees to zero. The prediction mean of reported human cases according to the CIM in the circumstances of 1999 would then be 82 (95% interval 4-202), Figure 23. This mean number of cases is only 1.04 times larger than the corresponding number of cases would be when additional guarantees are utilized. According to the model, the ratio between cases of foreign origin and all human salmonellosis cases caused by pork in the present situation (1999) is approximately 45%. The results are shown in Table 22.

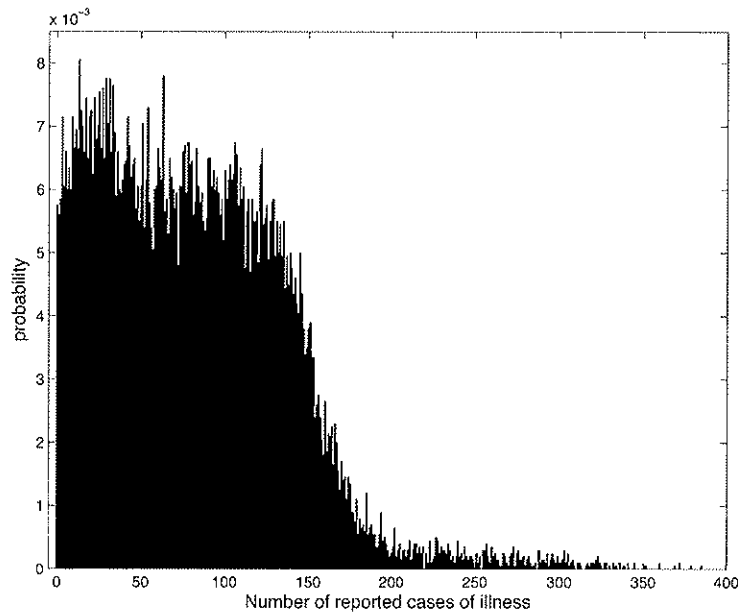


Figure 23.
Predictive distribution of the number of reported human cases of illness caused by *Salmonella* from pork and pork products when no additional *Salmonella* testing, required by the additional guarantees, would be performed. Mean 82. Result based on data from 1999, 100,000 MCMC iterations. Interval of 95% probability [4,202].

6.2 Scenarios 2 & 3: the effect of increased domestic pork *Salmonella* prevalence on the number of human cases

In the SPSM it is possible to give a fixed number for the prevalence of *Salmonella*-infected finishing pigs at slaughter instead of a distribution based on the results of the FSCP. Thus, we can give any prevalence for domestic production in order to study its effect on the *Salmonella* risk to humans. The present (1999) true *Salmonella* prevalence is most likely 0.50%. We decided to study two scenarios, one with a domestic prevalence of 1% and another with 5%. In these scenarios it was assumed that both the total consumption and the volume and type of import would be unchanged. A prevalence of 1% or 5% *Salmonella*-infected pigs can be considered high compared to the present situation in Finland, but not in an international perspective. One possible source of a *Salmonella* epidemic could be contaminated industrial pig feed.

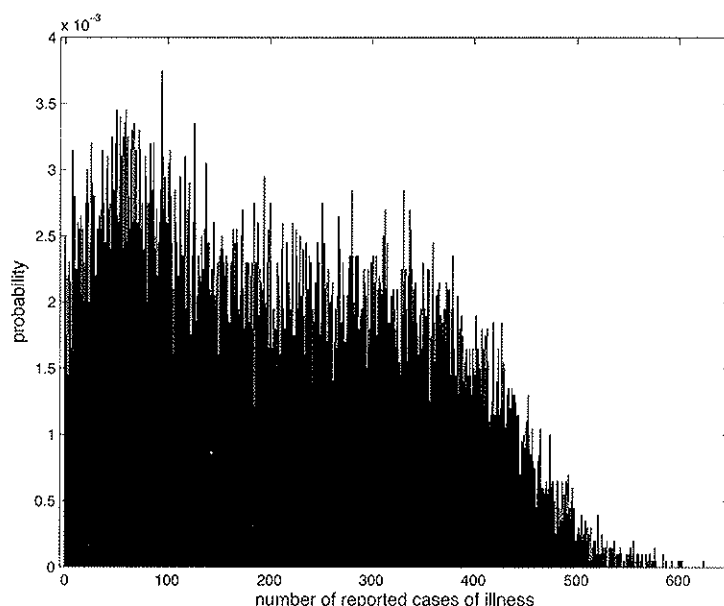


Figure 24.
Predictive distribution of the number of reported human cases of illness caused by *Salmonella* from pork and pork products, when the prevalence of *Salmonella* infected finishing pigs at slaughter would increase to 1% (Scenario 2). Mean 248. Result based on data from 1999, 100,000 MCMC iterations. Interval of 95% probability [13,543].

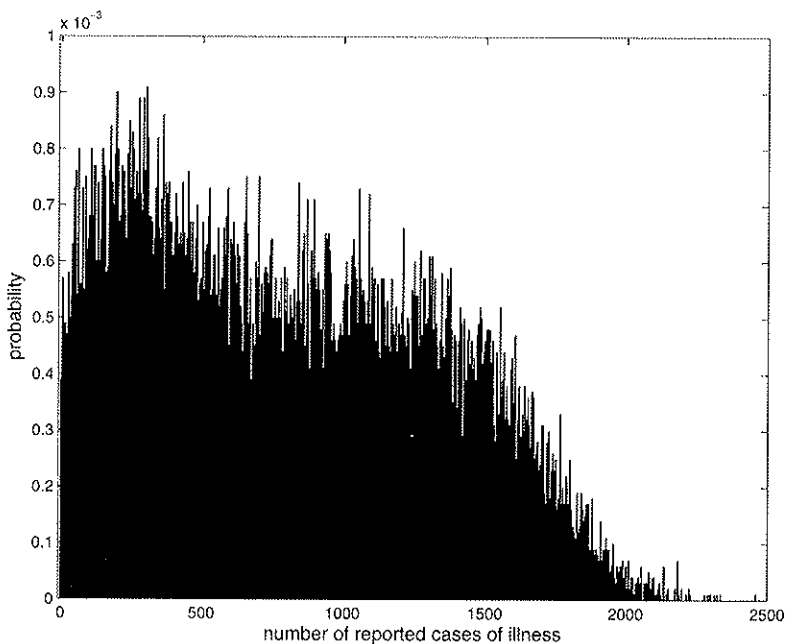


Figure 25.

Predictive distribution of the number of reported human cases of illness caused by *Salmonella* from pork and pork products, when the prevalence of *Salmonella*-infected finishing pigs at slaughter would increase to 5% (Scenario 3). Mean 948. Result based on data from 1999, 100,000 MCMC iterations. Interval of 95% probability [52,2090].

According to Figure 24 and Figure 25, it can be seen that a marked increase in the domestic *Salmonella* prevalence of finishing pigs would cause a marked increase in the number of human cases. When the prevalence of *Salmonella*-infected finishing pigs increases 2-fold and 10-fold compared to the present situation (1999), the number of reported human cases of infection is 3.1 (248/79) and 12.0 (948/79) times higher, respectively, in scenarios 2 and 3. For pork, the FSCP does not include any direct intervention to reduce *Salmonella* occurrence in pork during slaughter or meat cutting. Moreover, according to the model, the probability of cross-contamination of processed heat-treated products during meat processing increases very rapidly when the *Salmonella* prevalence is 1% or higher. Therefore, the prediction depends quite heavily on the assumed model of cross-contamination. The results with or without additional guarantees are shown in Table 22.

6.3 Scenario 4: the effect of increased import on the number of human cases

The effect of an increased import share on *Salmonella* risk was studied assuming additional guarantees are either required or not. An expert opinion was elicited about the imported amounts in each exporting country (Table 20) and the share of usage of pork (Table 21) in a hypothetical situation where imports would correspond to as much as 50% of the total consumption in the next 5-10 years. Total consumption was assumed to be the same as in 1999. The scenario (i.e. selection of countries exporting to Finland) was based on two expert opinions, and the experts represented marketing knowledge of the industry.

The above-mentioned results were used as inputs in the SPSM to simulate a scenario where the import of pork and pork products would correspond to 50% of total consumption. Pork would then be responsible for (mean) 189 [10,414] reported human salmonellosis cases (Figure 26).

Table 20.

Dispatching countries in 1999, and in the next 5-10 years according to a scenario.

| Exporting country | The share of import of pork and pork products when the total import corresponds to | |
|-------------------|--|---|
| | 20% of the total consumption ^a | 50% of the total consumption ^b |
| Denmark | 76.9% | 60 % |
| Sweden | 10.6% | 5 % |
| Germany | 6.5% | 10 % |
| The Netherlands | 0.7% | 10 % |
| Belgium | 4.3% | 5 % |
| Others | 1.0% | 10 % |
| total | 100 % | 100 % |

^a Corresponding to the actual figures of boneless pork in 1999 (see tables 13b and 14).

^b According to two scenarios and expert opinions

Table 21.

The share of imported pork and pork products in 1999, and in the next 5-10 years according to a scenario.

| | The total import corresponds to | |
|------------------------|---|---|
| | 20% of the total consumption ^a | 50% of the total consumption ^b |
| Fresh pork | | |
| for fresh sale | 10.4% | 15 % |
| for raw preparations | 0.5% | 15 % |
| for processed products | 73.6% | 30 % |
| Pork products | | |
| raw preparations | 3.8% | 10 % |
| processed products | 11.6% | 30 % |
| total | 100 % | 100 % |

^a Corresponding to the actual figures of boneless pork in 1999 (see tables 14 and 17).

^b According to two scenarios and expert opinions

It is interesting to notice that domestic pork prevalence would need to reach 1% before it would be responsible for the same number of human illnesses as the consumption covered with 50% imports. Another interesting result is that the additional guarantees coming from the FSCP would not in such a case be able to prevent an increased risk of *Salmonella* infection to consumers due to imported pork and pork products.

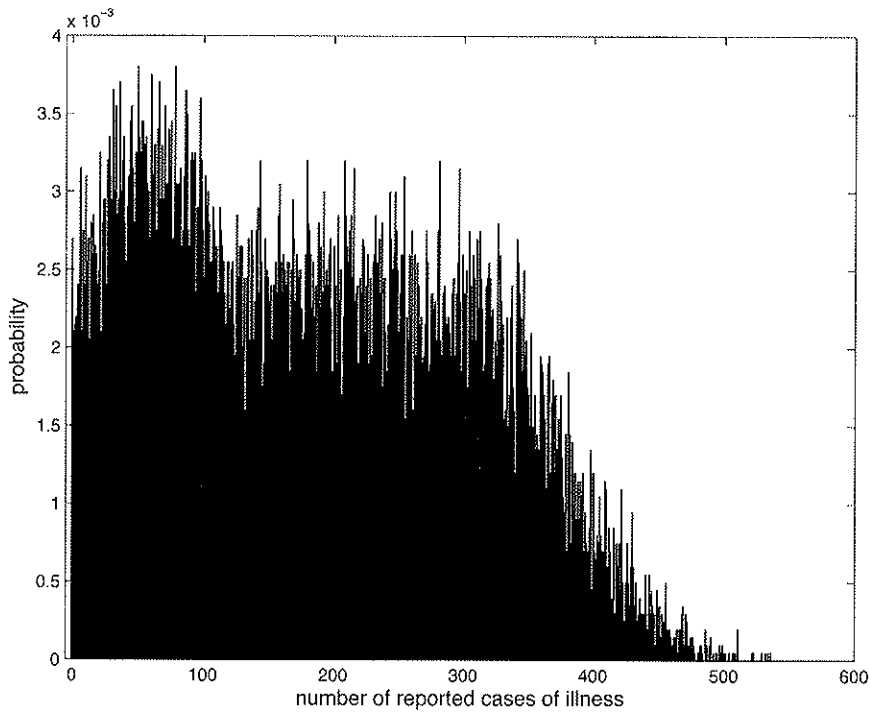


Figure 26.

Predictive distribution of the number of reported human cases of illness caused by *Salmonella* from pork and pork products, when the import of pork and pork products would correspond to 50% of total consumption. Mean 189. Result based on data from 1999 and expert opinion about the exporting countries and the share between the usage of pork, 100,000 MCMC iterations. Interval of 95% probability [10,414].

Table 22.

Predicted numbers of human cases of illness under different scenarios.

| | | mean REPORTED CASES | 95% low | 95% up | mean ALL CASES | 95% low | 95% up |
|--|----------------------------|---------------------------|---------|--------|----------------------|---------|--------|
| Default | import certificates YES | 79 | 4 | 193 | 431 | 22 | 1,153 |
| | import certificates NO | 82 | 4 | 202 | 444 | 23 | 1,192 |
| No cross contamination | | | | | | | |
| | import certificates YES | 32 | 1 | 75 | 176 | 9 | 443 |
| | import certificates NO | 34 | 1 | 79 | 187 | 10 | 464 |
| Import 20% of consumption | | | | | | | |
| | import certificates YES | 104 | 5 | 232 | 567 | 30 | 1,421 |
| | import certificates NO | 109 | 5 | 241 | 590 | 31 | 1,477 |
| Import 50% of consumption | | | | | | | |
| | import certificates YES | 189 | 10 | 414 | 1,024 | 55 | 2,507 |
| | import certificates NO | 241 | 13 | 538 | 1,309 | 70 | 3,250 |
| FIN 0,00001% prevalence | | | | | | | |
| | import certificates YES | 36 | 1 | 85 | 194 | 10 | 500 |
| | import certificates NO | 38 | 1 | 88 | 204 | 10 | 520 |
| FIN 1% prevalence | | | | | | | |
| | import certificates YES | 248 | 13 | 543 | 1,348 | 71 | 3,333 |
| | import certificates NO | 252 | 13 | 551 | 1,368 | 73 | 3,373 |
| FIN 5% prevalence | | | | | | | |
| | import certificates YES | 948 | 52 | 2,090 | 5,149 | 272 | 12,837 |
| | import certificates NO | 950 | 52 | 2,090 | 5,160 | 278 | 12,875 |
| FIN 1% prevalence, import 20% of consumption | | | | | | | |
| | import certificates YES | 260 | 14 | 566 | 1,412 | 75 | 3,476 |
| | import certificates NO | 264 | 14 | 574 | 1,431 | 75 | 3,515 |
| FIN 1% prevalence, import 50% of consumption | | | | | | | |
| | import certificates YES | 288 | 15 | 646 | 1,567 | 83 | 3,894 |
| | import certificates NO | 340 | 18 | 772 | 1,847 | 98 | 4,645 |
| FIN 5% prevalence, import 20% of consumption | | | | | | | |
| | import certificates YES | 894 | 49 | 1,958 | 4,856 | 262 | 12,044 |
| | import certificates NO | 901 | 50 | 1,970 | 4,892 | 256 | 12,140 |
| FIN 5% prevalence, import 50% of consumption | | | | | | | |
| | import certificates YES | 699 | 38 | 1,512 | 3,794 | 202 | 9,309 |
| | import certificates NO | 752 | 42 | 1,631 | 4,082 | 219 | 10,013 |

7. Constraints of the model

Mathematical models have limitations which depend on the structure of the model and the reliability and representativeness of the information used. The sensitivity of the results can be studied with simulations of different hypotheses.

In this work, we have also aimed to model the interventions included in the FSCP. However, it was difficult to draw general conclusions about some of them, as there are no appropriate studies on them, and information on the effects of some interventions is impossible to model because information is lacking or limited.

Also, the low prevalence of *Salmonella* in Finland has an impact on the evaluation: because no clinically-infected pig herds have been diagnosed, and we have no experience on their sanitation, we consequently have no knowledge on the effects of interventions, such as the effect of restrictions on a pig farm. Although these effects are considered great, they were not modelled because of a lack of data. Only five faeces-positive farms were detected in the years 1996-2000. So the interventions directed at *Salmonella*-positive farms could not be modelled reliably. The same lack of knowledge also concerns interventions taken in slaughterhouses and cutting plants. There are no such statistics or studies available that allows their modelling.

Cross-contamination is considered to have great importance in food processing. In this model, cross-contamination was specified in two stages. A single parameter controls the impact of cross-contamination at the slaughter and meat cutting level by defining the slope of the mathematical function. The parameter is hypothetical, and was implemented to leave space for future research results. In simulations the parameter was given the value 0.05, which increased the amount of contaminated fresh meat to 0.032% in the basic situation (prevalence and production structure as in 1999).

When fresh meat is contaminated with *Salmonella*, it may also contaminate the end product (raw meat preparation or processed meat product). This second cross-contamination was modelled by an expert opinion. The effect of the cross-contamination was tested inter alia by presuming that there were no cross-contamination at all. In this case the proportion of the contaminated pork and pork products would be 0.3%, CI 95% [0.1%,0.6%]. When the cross-contamination model was included, and the raw material prevalence was supposed to be 1%, the proportion of *Salmonella*-contaminated pork and pork products would be 0.85%, CI95% [0.3%,3%]. These results show that the effect of cross-contamination might have been regarded as too great. On the other hand, cross-contamination cannot be excluded from the model either.

In the model, all *Salmonella* in the raw material of processed meat products are eliminated during heat-treatment. The products may contain some *Salmonella* even after processing, but only cross-contamination from raw material to ready products

is taken into account.

In the IPIM, imported meat may contaminate only meat imported from the same country, as if all meat was handled separately as raw material either from domestic production or meat imported from other countries. This structure was chosen because there is lack of statistics and knowledge needed for modelling.

The model presumes that all processed products behave like those processed at least at 70°C. Raw meat preparations and minced meat are assumed to behave like fresh meat. This is probably unreliable, as there is probably a greater impact of cross-contamination, for example.

8. Discussion

The prevalence of *Salmonella* in Finnish fresh pork is very low and the situation has remained stable for many years. The amount of contaminated pork on sale depends on the *Salmonella* prevalence in both domestic and imported pork. If the prevalence in domestic pork could be reduced to zero, the number of human cases could be half of what it is now (the number of estimated contaminated servings would drop from 6.9 million to 3.6 million out of a total of 1000 million servings). Not all contaminated servings contain an infectious dose, and the theoretical expected number of contaminated servings is obtained from the estimated prevalence in industrial production.

The estimated proportion of contaminated servings among all consumed servings was 0.85% (mean), but assuming the domestic prevalence to be 0.00001%, the proportion was 0.34% (mean). Thus, the ratio of the expected proportion of contaminated servings due to foreign origin and the expected proportion of all contaminated servings was 0.4. The number of corresponding amounts of human cases is nearly the same due to the near linearity of the posterior expected values in the CIM with respect to the number of contaminated servings, given the data used in the CIM.

If the share of imported pork would increase to 20% or 50% of the total amount of consumed pork, the number of reported human cases could double. This is caused by the higher prevalence in imported pork, which was based on country-specific data on the retail level. Some of the country-specific estimates were quite uncertain due to a small number of reported test results or because there was no information available. Additional testing, required with negative results before import is permitted, has a selective effect on the contamination level in imports. Such additional testing also reduces uncertainty about contamination. However, these additional tests currently apply to only a small proportion of imports: fresh meat imported to be sold as fresh or raw material for raw meat preparations. In other words, they have no impact on imported raw meat preparations, imported processed meat products and imported fresh meat used for processed meat products in Finland. Therefore, the direct effect on the total is limited and tightly connected to the amount of a certain type of import. Indeed, the significance of these tests grows if the share of fresh pork imports increases (Figure 27).

According to the IPIM, uncertainty is lower the more information we get about *Salmonella* prevalence in exporting countries, and the risk of *Salmonella* is lower due to the selection effect. Ideally, all imports and thus the additional samples required would only concern one exporting country with a known low estimate of *Salmonella* prevalence and with the rejection of all consignments tested positive. This would mitigate both the uncertainty and the contamination.

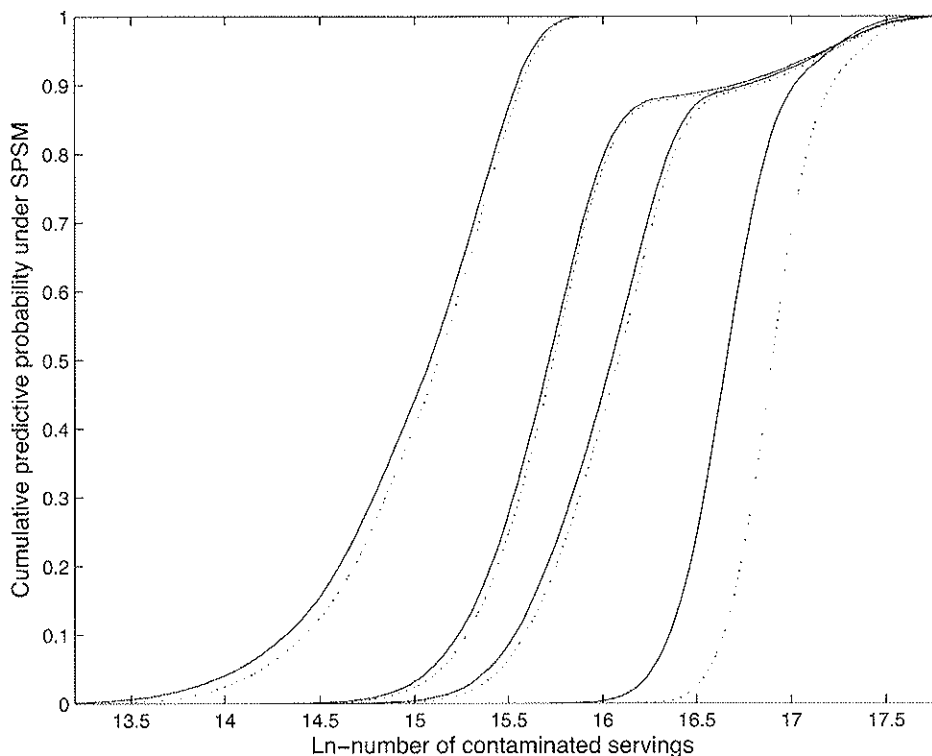


Figure 27.

The cumulative predictive probabilities of the logarithm (ln) of the number of contaminated servings annually. From left to right: assuming domestic prevalence to be 0,000001%, default scenario, share of import 20% and share of import 50%. Dotted lines show the corresponding results under no additional testing required.

Over the course of writing this risk assessment, we identified several needs for further studies, surveys and examinations. Also, statistics should be developed to satisfy the needs of risk assessments. There is a lack of knowledge concerning Finnish production, and there is also a need for international research in the same areas. The sensitivity of both analytical and sampling methods used in different stages should be studied more. The importance of risk factors should be examined and classified according to their impact on consumer risk. Cross-contamination may, after all, be the most important risk factor, but we do not have profound quantitative knowledge of this.

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10. Appendix

Table 23.

Summary of the Slaughter Prevalence Inference Model (SPIM)

| Code | Meaning | Distribution / formula / value | Source of information | Assumption |
|-----------|---|---------------------------------------|---------------------------------|--|
| N_s | Sample size (number of tested pigs) | 3,143 | Given as data concerning 1999 | Random sampling of slaughter pigs for lymph node testing. Sows are not included to the calculations. |
| p | True prevalence in the slaughter population | Uniform(0,1) prior distribution | Uninformative prior chosen | No prior knowledge assumed |
| N_{inf} | True number of infected pigs among those tested | Binomial(N_s, p) | | Random sample of pigs from the slaughter population. |
| p_{sen} | Sensitivity of the lymph node testing method | Uniform(0.27,0.33) prior distribution | Knowledge of the testing method | |
| N_{pos} | Number of detected lymph node positive pigs | 5 | Given as data concerning 1999 | |

Table 24.
Summary of the Secondary Production Simulation Model (SPSM)

| Code | Meaning | Distribution / formula / value | Source of information | Assumption |
|------------|---|---|---|---|
| N | The number of slaughtered and inspected fattening pigs in 1999 | 2,064,492 | EELA 1999 | |
| w | The mean slaughter weight of fattening pigs | 82.1 kg | Expert opinion | Based on 1999 situation |
| rM | The proportion of meat in a carcass | 0.82 | Expert opinion | Based on 1999 situation |
| rFM | Proportion of domestic pork intended for fresh sale | Uniform(0.30,0.44) | Expert opinion | Based on 1999 situation. Not to be heat treated (< 70 °C) |
| rRMP | Proportion of domestic pork intended for raw meat preparations | Uniform(0.09,0.3) | Expert opinion | To be heat treated (>70 °C) |
| rPMP | Proportion of domestic pork intended for processed meat products | 1-rFM-rRMP | | |
| FM | Domestic pork intended for fresh sale (kg) | rFM*BLM | | |
| RMP | Domestic pork intended for raw meat preparations (kg) | rRMP*BLM | | |
| PMP | Domestic pork intended for processed meat products (kg) | rMP*BLM | | |
| p | The true prevalence of infected fattening pigs at slaughter | Beta(5,726;888,1232) | Slaughter Prevalence Inference Model (SPIM) | |
| x | The true number of infected fattening pigs at slaughter | p * N | | |
| BLM | Total amount of domestic boneless pork | rM * w * N | | |
| BLMinf | Total amount of domestic boneless pork from infected animals | rM * w * x | | |
| BLMclean | Total amount of domestic boneless pork from noninfected animals | rM * w * (N - x) | | |
| prev_cont | The prevalence of contaminated domestic pork before cross contamination | BLMinf / BLM = p | | All meat from infected animals is counted as contaminated |
| Cc | A parameter for cross-contamination at slaughter & meat cutting | 0.05 | Expert opinion | Cross contamination depends on the initial prevalence |
| BLMclean2 | Total amount of contaminated domestic pork after cross-contamination at slaughter & cutting | BLMinf+Poisson(BLMclean*(1-exp(-cc*prev_cont/(1-prev_cont)))) | | |
| BLMclean2 | Total amount of non-contaminated domestic pork after cross contamination at slaughter & cutting | BLM-BLMclean2 | | |
| prev_cont2 | The prevalence of contaminated domestic pork after cross contamination at slaughter | BLMclean2 / BLM | | |

| Code | Meaning | Distribution / formula / value | Source of information | Assumption |
|-------------------|--|--|--|--|
| pFM | The final prevalence in domestic fresh pork | prev_cont2 | | |
| pRMP | The final prevalence in raw meat preparations after cross-contamination at meat processing (not heat-treated products) | If prev_cont2 < 0.01, then prev_cont2, else Uniform(Min,Max) | | Below threshold value there is no cross contamination, in which case the output prevalence is the same as in raw material. |
| pPMP | The final prevalence in processed meat products after cross-contamination at meat processing (heat-treated products) | If prev_cont2 < 0.01, then 0, else Uniform (Min,Max) | | Below threshold value there is no cross contamination, heat treatment eliminates salmonella. |
| Min | Minimum value of contamination prevalence after meat processing | $(1 - \text{Exp}(-0.5 * \text{prev_cont2} / (1 - \text{prev_cont2}))) * 0.2$ | Fitted smooth curve derived from expert opinion | |
| Max | Maximum value of contamination prevalence after meat processing | $(1 - \text{Exp}(-10 * \text{prev_cont2} / (1 - \text{prev_cont2}))) * 0.5$ | Fitted smooth curve derived from expert opinion | |
| EXPORTS | | | | |
| FMexp | Amount of fresh pork exported (kg) | 22,213,643 | National Board of Customs. | |
| PMPexp | Amount of (heat-treated) processed meat products exported (kg) | 18,946 | National Board of Customs. | |
| RMPexp | Amount of raw meat preparations containing pork exported (kg) | 1,812,636 | National Board of Customs. | |
| IMPORTS | | | | |
| FM _i | Amount of fresh pork imported (from the ith country) to be sold as fresh (kg) | | National Food Administration, MMM, National Board of Customs | Amount of imported meat under additional guarantees from other EU countries according to the statistics of National Food Agency was imported with a similar profile as the total amount of fresh meat (statistics of the Customs). Amounts of imported meat from other than Members, were known (statistics of MMM). |
| RMP2 _i | Amount of fresh pork imported (from the ith country) to be used for producing raw meat preparations (kg) | | National Food Administration, MMM, National Board of Customs | The same proportion of imported fresh meat was assumed to be used for raw pork preparations as the experts assumed was prepared from Finnish meat in 1999. |
| PM2 _i | Amount of fresh pork imported (from the ith country) to be used for producing (heat-treated) processed meat products (kg) | | National Food Administration, MMM, National Board of Customs | The imported fresh pork excluding FM _i and RMP2 _i was assumed to be used for processed meat products. |
| RMP1 _i | Amount of raw meat preparations, containing pork, imported (from the ith country) to be sold as raw meat preparations (kg) | | Expert opinion and National Board of Customs | Some assumptions had to be done in specifying the products and their contents. |

| | | | National Board of Customs | in specifying the products and their contents. |
|-------------|--|--|--|---|
| p_i^f | Contamination prevalence in imported fresh pork and raw meat preparations containing pork (from the <i>i</i> th country) | Beta (parameters estimated from the IPIM) | Import Prevalence Inference Model (IPIM) EC 2001 | Salmonella prevalence in fresh meat and raw meat preparations are the same. |
| p_i^p | Contamination prevalence in imported (heat-treated) processed meat products (from the <i>i</i> th country) | Beta (parameters estimated from the IPIM) | Import Prevalence Inference Model (IPIM) EC 2001 | Information on the prevalence of the meat products on retail level, corresponds to the definition of products processed (>70°C) |
| cFM_i | Amount of contaminated fresh pork imported (from the <i>i</i> th country) to be sold as fresh (kg) | $FM_i \cdot p_i^f$ | | |
| $cRMP2_i$ | Amount of contaminated fresh pork imported (from the <i>i</i> th country) to be used for producing raw meat preparations (kg) | $RMP1_i \cdot p_i^f$ | | |
| $cPMP2_i$ | Amount of contaminated fresh pork imported (from the <i>i</i> th country) to be used for producing (heat-treated) processed meat products. | $PMP2_i \cdot p_i^f$ | | |
| $cRMP1_i$ | Amount of contaminated raw meat preparations, containing pork, imported (from the <i>i</i> th country) to be sold as raw meat preparations (kg) | $RMP1_i \cdot p_i^f$ | | |
| $cPMP1_i$ | Amount of contaminated (heat-treated) processed meat products, containing pork, imported (from the <i>i</i> th country) to be sold as processed meat product (kg) | $PMP1_i \cdot p_i^p$ | | |
| pFM_i^f | Final contamination prevalence of fresh pork imported (from the <i>i</i> th country) sold as fresh | p_i^f | | |
| $pRMP2_i^f$ | Final contamination prevalence of raw meat preparations produced from imported fresh pork (from the <i>i</i> th country) | If $p_i^f < 0.01$ then p_i^f , else $\text{Uniform}(\text{Min_imp}, \text{Max_imp})$ | | If the Salmonella prevalence of the raw material is lower than 1%, no change. If the Salmonella prevalence of the raw material exceeds 1%, cross contamination curve defines the final contamination prevalence |
| $pRMP2_i^f$ | Final contamination prevalence of (heat-treated) processed meat products produced from imported fresh pork (from the <i>i</i> th country) | If $p_i^f < 0.01$ then 0, else $\text{Uniform}(\text{Min_imp}, \text{Max_imp})$ | Expert opinion | Heat-treatment kills all the Salmonella bacteria. However, cross contamination may occur, if salmonella prevalence before processing exceeds 1% |
| Min_imp | Minimum value of contamination prevalence after meat processing (imported) | $(1 - \text{Exp}(-0.5 \cdot p_i^f / (1 - p_i^f)))^{0.2}$ | Fitted curve from expert opinions | |
| Max_imp | Maximum value of contamination prevalence after meat processing (imported) | $(1 - \text{Exp}(-10 \cdot p_i^f / (1 - p_i^f)))^{0.5}$ | Fitted curve from expert opinions | |
| $pRMP1_i^f$ | Final contamination prevalence of raw pork preparations imported (from the <i>i</i> th country) sold as raw pork preparations | p_i^f | | As in fresh pork |
| $pRMP1_i^f$ | Final contamination prevalence of (heat-treated) processed meat products, containing pork, imported (from the <i>i</i> th country) sold as processed meat products | p_i^p | | As in processed meat products |

| Code | Meaning | Distribution / formula / value | Source of information | Assumption |
|--------------------|--|--|-----------------------|--|
| TOTALS | | | | |
| fresh_pork | Total amount of fresh pork sold | $FM - FM_{exp} + \sum FMI_i$ | | |
| raw_pork_products | Total amount of raw meat preparations containing pork sold | $RMP - RMP_{exp} + \sum RMP1_i + \sum RMP2_i$ | | |
| heat_pork_products | Total amount of processed meat products containing pork sold | $PMP - PMP_{exp} + \sum PMP1_i + \sum PMP2_i$ | | |
| pcFM | Contamination prevalence in fresh pork sold | Amount weighted average of prevalences | | |
| pcRMP | Contamination prevalence in raw meat preparations containing pork sold | Amount weighted average of prevalences | | |
| pcPMP | Contamination prevalence in processed meat products containing pork sold | Amount weighted average of prevalences | | |
| cFM | Amount of contaminated fresh pork sold | $fresh_pork * pcFM$ | | |
| cRMP | Amount of contaminated raw meat preparations containing pork sold | $raw_pork_products * pcRMP$ | | |
| cPMP | Amount of contaminated processed meat products containing pork sold | $heat_pork_products * pcPMP$ | | |
| Total_sold | Total amount of pork sold (domestic + imported) | $fresh_pork + raw_pork_products + heat_pork_products$ | | |
| Total_sold_cont | Total amount of contaminated pork sold | $cFM + cRMP + cPMP$ | | This is used for calculating the expected number of contaminated servings by dividing the total by the average serving size. |

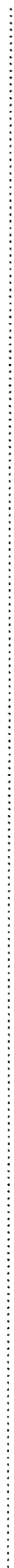
Table 25.

Summary of the Import Prevalence Inference Model (IPIM)

| Code | Meaning | Distribution / formula / value | Source of information | Assumption |
|-----------------|---|--|-----------------------|---|
| α, β | Population parameters for the true proportions p_i of contamination in the population of importing countries | Exp(0.001) | | No prior knowledge assumed. Uninformative uniform prior implied for p_i . |
| p_i | True proportion of salmonella contaminated meat from the i th import country (raw meat or meat products at retail level) | Beta (α, β) | | A common distribution describes prevalence levels in all importing countries. |
| n_i^0 | Number of salmonella tests reported in the i th importing country, concerning raw meat (alternatively meat products) at retail level, except for Belgium at slaughterhouse. n_i^0 can be interpreted as a prior sample. | Given as data, Table 16 | EC 2001 | Comparable randomized testing at retail level in each country |
| n_i^a | The estimated number of salmonella tests done due to additional quarantees in each import country when additional quarantees are assumed to be in force. | Given as data, Table 17 | MMM 897/1997 | Randomized testing of each imported lot |
| n_i | Number of salmonella tests done concerning the imported meat from the i th country. | $n_i^0 + n_i^a$ or just n_i^0 | EC 2001 | The number of tests applied depend on whether additional quarantees were obtained or not. |
| p_{sen} | Sensitivity of the testing method used. | Beta (281.3, 8.7) | Expert opinion | The sensitivity of the testing method is approximately the same in all countries. |
| x_i | True number of contaminated samples among the total of n_i samples. | Binomial(n_i, p_i) | | |
| d_i^0 | Number of positive results reported among the n_i^0 (prior) tests. | Given as data, Table 16 | | |
| d_i^a | Number of positive results among the tests required if additional quarantees are assumed to be in force. | 0 (because lots with positive results are rejected) | EC 2001 | Certificates of negative testing results required before import. |
| d_i | Number of positive results concerning the imported meat from the i th country. | $d_i^0 + d_i^a$ or just d_i^0 (i.e. d_i^0 in both cases) | EC 2001 | Lots with positive results are rejected. |

Table 26.
Summary of the Consumption Inference Model (CIM)

| Code | Meaning | Distribution / formula / value | Source of information | Assumption |
|-----------------|---|--|---|--|
| Ln(nser) | Ln-Number of contaminated servings, calculated as the theoretical expected number of contaminated servings produced in industry. (This is not the same as the number of contaminated servings at the actual time of consumption). | $0.8910 * N(15.6371, 0.3233^2) + 0.1090 * N(17.1295, 0.3004^2)$ | Prior based on SPSM | |
| Ssize | average size of a serving | $N(122 \text{ (g)}, 10^2)$ | Prior based on the dietary survey of Finnish adults 1997, National Public Health Institute (KTL 1998) | |
| cfu | Average CFU/g per contaminated serving at the time of consumption | $U(0,0.1)$ | Uninformative prior over 0-0.1 | Possible mean cfu/g at the time of consumption among all initially contaminated servings is <0.1 |
| α, β | Parameters of the dose response model | 21.159, 0.2767 | WHO report | Dose-response model describes adequately total population. |
| p | probability of illness | $1 - (1 + cfu * ssize/a)^{-b}$ | WHO report | Beta-Poisson dose-response model |
| λ | expected number of cases of illness | $p * nser$ | | |
| nc | True number of human cases of illness due to pork | Poisson(λ) | | Approximates binomial(nser,p) when nser is large and p is small. |
| psel | Probability of a case of illness being diagnosed and reported | beta(20,80) | Prior based on expert opinion, Elintarvike-erityistilanne-työryhmän muistio 1997, UK tutkimus. | |
| ncobs | number of reported cases of illness | binomial(nc,psel), treated as censored observation between 0-129 | | Assumed to be between 0-129 based on the phagetype information on reported human cases. |





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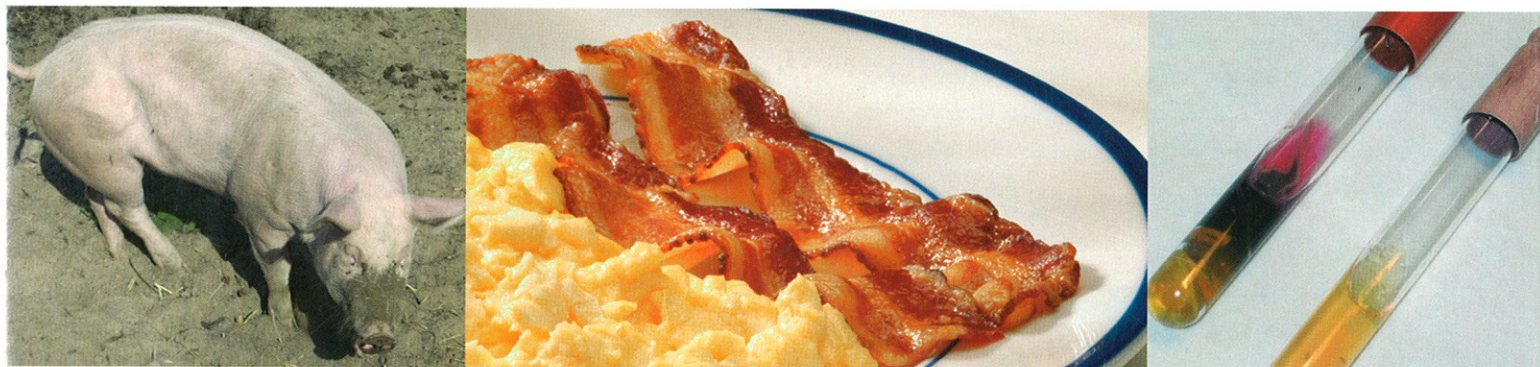
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