Risk assessment and cost–benefit analysis of salmonella in feed and animal production





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Risk assessment and cost–benefit analysis of salmonella in feed and animal production



Project team

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To the experts in the feed industry, pest control and pork production chain, including pig farmers.

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DESCRIPTION

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Authors	Maria Rönnqvist (Evira), Ville Välttilä (Evira), Katriina Heinola (Luke), Jukka Ranta (Evira), Jarkko Niemi (Luke), Pirkko Tuominen (Evira)
Abstract	Food items of animal origin, such as pork products, have been suggested as the main source of zoonotic salmonella infections in Europe. Contaminated feed can potentially introduce the pathogen into the animal-derived food chains.
	The prevalence of salmonella in different feeds for Finnish pigs was estimated as below 2% (medians) and on average in pigs 0.25% (mean). Feed was estimated on average as the cause of 35% of salmonella infections in fattening pigs and 55% in sows. Around 5% of the 300–400 domestic human salmonella infections reported per year were estimated as attributable to pig feeds. Year 2013 was employed as a reference.
	The present costs for the prevention of salmonella contamination in pig feeds were estimated at 1.8–3.0 million euros per year for the year 2013. The costs due to feed contamination, measures due to detected contamination and the resulting salmonella infections in pigs and humans were estimated at ≤ 2.4 (0.3–6.1) million annually.
	According to a scenario, if salmonella prevalence in Finnish pig feed would be similar to that acquired using data from other EU counties, the prevalence in fattening pigs and people could increase by 55-fold on average. If specific measures to eliminate salmonella from feed were not carried out, the costs due to preventive actions against salmonella were at least \in 1.1–1.8 million per year. Additionally, the costs due to the eradication of feedborne salmonella on pig farms, consequential measures at slaughterhouses, and the health costs to humans could rise to approximately \leq 33 million per year.
	According to the results, the present feed salmonella control, including the preventive actions, is cost-effective and generates benefits to society.
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KUVAILULEHTI

Julkaisija	Elintarviketurvallisuusvirasto Evira
Julkaisun nimi	Rehujen ja tuotantoeläinten Salmonellavalvonnan riskinarviointi ja kustannus-hyöty-analyysi
Tekijät	Maria Rönnqvist (Evira), Ville Välttilä (Evira), Katriina Heinola (Luke), Jukka Ranta (Evira), Jarkko Niemi (Luke), Pirkko Tuominen (Evira)
Tiivistelmä	Eläinperäisiä elintarvikkeita, kuten sianlihaa, pidetään ihmisten salmonellatartuntojen pääasiallisena lähteenä Euroopassa. Salmonella voi levitä eläinperäisten elintarvikkeiden tuotantoketjuun eläinten rehusta. Saastunut rehu voi olla merkittävä salmonellan lähde etenkin maissa joissa salmonellatartunnat ovat harvinaisia tuotantoeläimissä.
	Salmonellan esiintyvyydeksi erilaisissa rehuaineissa ja sianrehuissa arvioitiin alle 2 % (mediaanit) ja sioissa keskimäärin 0.25 % (keskiarvo). Rehun arvioitiin selittävän lihasikojen salmonellatartunnoista keskimäärin 35 % ja emakoiden tartunnoista 55 %. Noin 5 % suomalaisten kotimaassa saamista salmonellooseista, joita raportoidaan vuodessa 300–400, arvioitiin olevan selitettävissä sikojen rehuilla. Vuotta 2013 käytettiin viitteenä.
	Sianrehujen salmonellakontaminaatioiden ehkäisyn kustannuksiksi arvioitiin nykytilanteessa 1,8–3,0 miljoonaa euroa vuodessa (vuoden 2013 tietojen perusteella). Sianrehun saastumisen, havaituista saastuntojen vuoksi tehtyjen toimenpiteiden ja siitä aiheutuneiden sikojen ja ihmisten salmonellatartuntojen arvioitiin aiheuttavan nykytilanteessa yhteensä noin 2,4 (0,3–6,1) miljoonan euron vuotuiset taloudelliset kustannukset.
	Jos suomalaisten sianrehujen salmonellaesiintyvyys olisi samaa luokkaa kuin EU-maista kerätyssä aineistossa, esiintyvyys sioissa ja ihmisissä voisi ennustetussa tilanteessa nousta keskimäärin 55-kertaiseksi. Jos salmonellan hävittämiseksi rehusta ei ryhdyttäisi toimenpiteisiin, ennaltaehkäisyn kustannukset olisivat edelleen vähintään 1,1–1,8 miljoonaa euroa, jonka lisäksi rehun saastumisesta johtuvien sikatilojen saneerausten ja ihmisten sairastumisten aiheuttamat kustannukset nousisivat noin 33 miljoonaan euroon vuosittain.
	Tutkimuksen perusteella sianrehujen salmonellavalvonta ja siihen liittyvät kontaminaatioita ennaltaehkäisevät toimenpiteet ovat kustannustehokkaita ja tuottavat yhteiskunnalle hyötyä.
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BESKRIVNING

Utgivare Livsmedelssäkerhetsverket Evira Publikationens titel Riskvärdering och kostnad-nytta-analys inom tillsynen över salmonella i foder och animalieproduktion Maria Rönngvist (Evira), Ville Välttilä (Evira), Katriina Heinola (Luke), Författare Jukka Ranta (Evira), Jarkko Niemi (Luke), Pirkko Tuominen (Evira) Resumé Animaliska livsmedel, till exempel svinkött, har bedömts vara den huvudsakliga rutten för spridning av salmonellasmittor mellan djur och människor i Europa. Foder kan vara en viktig faktor för spridningen av salmonella till produktionskedjan av animaliska livsmedel. Förekomsten av salmonella uppskattades i genomsnitt i olika fodevaror för svinfoder och foder vara mindre än 2 % (medianer), och i finländska svin 0.25 % (medelvärde). Fodret uppskattades förklara 35 % av salmonellasmittorna hos köttsvin och 55 % av smittorna hos suggor. Cirka 5 % av de salmonelloser som finländarna drabbas av i Finland, av vilka årligen rapporteras 300-400 fall, bedömdes ha sin förklaring i svinfoder. År 2013 användes som referens (år). Kostnaderna för förebyggande av salmonellakontamination i svinfoder uppskattades i nuläget ligga på 1.8–3.0 miljoner euro per år (enlight år 2013 data). Kontamineringen av svinfoder och salmonellasmittorna mellan svin och människor som orsakas av detta uppskattades i nuläget medföra kostnader på sammanlagt cirka 2,4 (0,3-6,1) miljoner euro årligen. Om det i de finländska svinens foder skulle finnas klart mera salmonella än nu, skulle förekomsten hos svin och människor i genomsnitt kunna öka 55-faldigt. Om inga åtgärder skulle vidtas för att utrota salmonella, skulle kostnaderna för förebyggande fortfarande vara minst 1.1-1.8 miljoner euro. Dessutom skulle kostnaderna för saneringar av svingårdar och människornas sjukdomsfall uppgå till i genomsnitt cirka 33 miljoner euro per år. Forskningen visar att salmonellatillsyn av svinfoder och relaterade kontaminationsförebyggande åtgärder är kostnadseffektiva och till nytta för samhället. Februari 2018 Utgivningsdatum Referensord Salmonella, foder, svin, risk, kostnad-nytta, gård Publikationsseriens namn och nummer Eviras undersökningar 3/2018 Antal sidor 129 Språk Engelska Konfidentialitet Offentlig handling Förläggare Livsmedelssäkerhetsverket Evira Layout Livsmedelssäkerhetsverket Evira, enheten för interna stödtjänster ISSN/ISBN 1797-2981/978-952-225-168-8 (pdf)

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GLOSSARY OF TERMS

3 rd countries	Countries outside the EU
Additional guarantees	Finland is allowed to require salmonella-negative testing for imported consignments from exporting countries with no equal salmonella Control Programme and salmonella prevalence (see FSCP).
AIVI, AIVII	Acidic substances, which are used to ensure the proper fermentation of feed, especially when producing feeds that are in a liquid form. They consist of a mixture of formic acid and ammonium formate.
Bayesian inference, probabilistic inference	A method for inferring the probable values of unknown quantities by conditioning on observed data, i.e. updating prior distributions to posterior distributions.
Cost-benefit analysis	A systematic approach to estimating the benefits and the costs of a project such as a control program. The benefits and costs are expressed in monetary terms, taking into account their net amount and changes over time.
DoodleBUGS, OpenBUGS, WinBUGS	Software packages with model specification language for computing posterior distributions using Markov chain Monte Carlo sampling methods.
Dose– response assessment	The determination of the relationship between the magnitude of exposure (dose) to a chemical, biological, or physical agent and the severity and/or frequency of associated adverse health effects (response).
EFSA	European Food Safety Authority
EEA	European Economic Area
ETT	Animal Health ETT r.a., animal health association (Eläinten terveys ETT ry in Finnish)
EU	European Union
Evira	Finnish Food Safety Authority
Exposure assessment	The qualitative and/or quantitative evaluation of the likely intake of biological, chemical, and physical agents via food, as well as exposures from other sources if relevant.

FCC Consortium	Food Control Consultants Ltd. (FCC) is a company that provides experience in matters concerning European veterinary legislation, veterinary public health, laboratories, and supervision in the food industry.
Feed	In this report: Feed may take the form of feed materials, compound feed, feed additives, premixtures or medicated feedingstuffs. (EC) No 767/2009. Feed means any substance or product, including additives, whether processed, partially processed or unprocessed, intended to be used for oral feeding to animals. (EC) No 178/2002.
Feed material (categories), Compound feed (categories), Complete feed (categories)	In the risk assessment model, in this report, complete feed (categories) consist of compound feed (categories), and compound feed (categories) consist of feed material (categories). This is further illustrated in the Figure 1 presented in the Appendix 5. ("Illustration of the terms for material categories in the risk assessment model") in the section 10.5.
Feed material	Feed materials means products of vegetable or animal origin, whose principal purpose is to meet animals' nutritional needs, in their natural state, fresh or preserved, and products derived from the industrial processing thereof, and organic or inorganic substances, whether or not containing feed additives, which are intended for use in oral animal-feeding either directly as such, or after processing, or in the preparation of compound feed, or as carrier of premixtures. (EC) No 767/2009.
	Ingredients that can be used to produce (pig) feed; A feed material is not suitable as such to feed the pig (if it is the only source of nutrition), but in combination, two or more feed materials can make a balance diet for pigs.
Compound feed, Complete feed, Comple- mentary feed	Compound feed means a mixture of at least two feed materials, whether or not containing feed additives, for oral animal-feeding in the form of complete or complementary feed (767/2009). Complete feed means compound feed which, by reason of its composition, is sufficient for a daily ration (767/2009). Complementary feed means compound feed which has a high content of certain substances but which, by reason of its composition, is sufficient for a daily ration of its composition, is sufficient for a daily ration of its composition. No 767/2009.
Feed unit	A term that describes the daily intake of feed for production animals. One feed unit corresponds to 9.7 MJ net energy. Since late 2014, feed units have no longer been officially used in Finland, and energy is only indicated as MJ.
Finnish Farm Registry	The Finnish Farm Registry includes registries of farms and different production animals, including pigs (pig registry).
Finnish Salmonella Control Programme (FSCP)	The Finnish Salmonella Control Programme, which was approved by Commission Decision 94/968/EC, was started in 1995. It covers beef, pork, turkey, and broiler meat, as well as minced meat and egg products, and is intended to keep the annual incidence of salmonella below 1%.
Foodstuff	Any material or substance that can be used as food
GP	General practitioner, physician
Hazard	A biological, chemical or physical agent in, or condition of, food with the potential to cause an adverse health effect

Hazard characteri- zation	The qualitative and/or quantitative evaluation of the nature of the adverse health effects associated with the hazard. For the purpose of microbiological risk assessment (MRA), the concerns relate to microorganisms and/or their toxins.
Hazard identification	The identification of biological, chemical, and physical agents capable of causing adverse health effects and which may be present in a particular food or group of foods.
Human case	A person with salmonellosis
Import	In this report, all meat and meat products, as well as feed, that enter Finland either from EU member states or third countries.
Internal market	A single market that seeks to guarantee the free movement of goods, including production animals and feeds, between EU member states.
Luke	Natural Resources Institute Finland
МСМС	Markov chain Monte Carlo sampling. Monte Carlo simulation based on Markov chain sampling techniques.
ммм	Ministry of Agriculture and Forestry
Pathogenicity	The potential capacity of certain species / strains / lineages of microbes to cause a disease in humans.
Pig	A young swine of either sex; refers especially to swine grown on finishing farms (finishing pig, fattening pig)
Positive list	An open list of animal feed companies that fulfil a specific criteria to ensure the safety of their products, related mainly to salmonella control.
Posterior distribution	A conditional distribution describing the remaining uncertainty about an unknown quantity after observing data
Prior distribution	A conditional distribution describing the initial uncertainty about an unknown quantity before observing data
Production animal	Main animal production lines including pork, beef, chicken, and turkey, as well as production lines and products thereof, meat and table eggs. The salmonella surveillance and risk management actions of these are covered in the Finnish national salmonella control programme (FSCP, MMMEEO 1994).
Risk	A function of the probability of an adverse health effect and the severity of that effect, consequential to a hazard(s) in food
Risk analysis	A process consisting of three components: risk assessment, risk management, and risk communication
Risk assessment	A scientifically based process consisting of the following steps: (i) hazard identification, (ii) hazard characterization, (iii) exposure assessment, and (iv) risk characterization. Risk assessment can be quantitative or qualitative. The result of quantitative risk assessment is presented by way of quantitative, numeric assessments. Qualitative risk assessment can include quantitative parts (numeric values, mathematical methods), but the result is presented in words. Risk assessment is independent of risk management and decision making.

Risk characteri- zation Risk communi-	The process of determining the qualitative and/or quantitative estimation, including attendant uncertainties, of the probability of occurrence and severity of known or potential adverse health effects in a given population based on hazard identification, hazard characterization, and exposure assessment. Mainly a dialogue between risk management and risk assessment during the assessment of the risk. It also includes the communication
cation	of the results of the risk assessment to the authorities, enterprises, researchers, and other stakeholders.
Risk management	A separate process from risk assessment. The results of risk assessment or risk profiling can be used as support for risk management and decision making, for example for the preparation of legislation.
Risk profile	A description of a food safety problem and its context that presents in a concise form the current state of knowledge related to a food safety issue. It also describes potential risk management options that have been identified to date, if any, and the food safety policy context that will influence further possible actions.
	Consideration of the information given in the risk profile may result in a range of initial decisions, such as commissioning a risk assessment, gathering more information or developing risk knowledge at the level of the risk manager, implementing an immediate and/or temporary decision.
Serotype	Serotype refers to distinct variations within a species of bacteria or viruses or among immune cells of different individuals. In serotyping, these microorganisms, viruses, or cells are classified together based on their cell surface antigens, allowing the epidemiological classification of organisms to the sub-species level.
Sow	A female adult pig that has farrowed one or several times
Strict liability	According to Finnish Feed law 86/2008, a party that manufactures, subcontracts the manufacturing of, or imports feed shall compensate for any damage caused to the buyer of the feed due to the failure of the feed to fulfil the requirements laid down in the European Union feed legislation or in 86/2008. Compensation shall be paid even if the damage were not caused intentionally or through negligence.
THL	Finnish National Institute for Health and Welfare
QMRA	Quantitative microbiological risk assessment. A computational approach towards quantitative risk estimates
Technical barrier to trade	Restriction of free trade on the condition that import can be shown by risk assessment to increase the health risk to people, plants, or animals in the importing country.
Zero tolerance	The term zero tolerance regarding salmonella control in Finland refers to the preventive actions taken whenever salmonella is confronted, aiming to eliminate the risk of salmonella-positive eggs or meat reaching the market.
Zoonosis	An infectious disease capable of transmission between (sometimes through a vector) animals other than humans and humans.

1 YHTEENVETO JA JOHTOPÄÄTÖKSET

1.1 Johdanto

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Elintarvikkeiden välityksellä leviävät eläimiin ja ihmisiin tarttuvat bakteerit (nk. zoonoosit) muodostavat merkittävän osan ihmisiin kohdistuvasta tartuntatautien aiheuttamasta tautitaakasta maailmalla. Salmonellabakteerin aiheuttamat sairastumiset ovat erityisen merkittävä kansanterveydellinen ongelma. Kansallisen salmonellavalvontaohjelman tavoitteena on turvata hyvä salmonellatilanne eläimissä ja elintarvikkeissa Suomessa. Vaikka rehut eivät sisälly kansalliseen salmonellavalvontaohjelmaan, niiden vaikutus on arvioitava, jotta saadaan kattava kuva rehuista aiheutuvan salmonellariskin suuruudesta ja vaikutuksista suomalaiselle sianlihan tuotannolle.

Salmonella on edelleen yksi yleisimmistä elintarvikevälitteisten taudinpurkausten ja yksittäisten sairastumisien aiheuttajista. Eläinperäisten elintarvikkeiden, kuten sianlihan, on arvioitu olevan salmonellatartuntojen pääasiallinen lähde Euroopassa. Rehu voi olla tärkeä salmonellan levittäjä eläinperäisten elintarvikkeiden tuotantoketjuun etenkin maissa, joissa salmonellan esiintyvyys eläimissä on vähäistä ja tartunnat eläinten välillä siten harvinaisia.

Suomessa salmonellaa valvotaan tuotantoeläimissä kansallisen salmonellavalvontaohjelman mukaisesti. Tavoitteena on pitää bakteerin esiintyvyys tuotantoeläimissä alle 1 % tasolla. Tavoitteena on myös saada luotettava kuva salmonellan yleisyydestä tuotantoeläimillä ja eläimistä saatavissa elintarvikkeissa. Valvontaohielmaan kuuluu niin sanottu nollatoleranssi, jonka mukaisesti aina salmonellaa tavattaessa ryhdytään toimenpiteisiin, jotka pienentävät todennäköisyyttä, että salmonellan saastuttamia kananmunia tai lihaa pääsee kulutukseen. Suomi on saanut EU:lta myös erityistakuut hyvän salmonellatilanteensa säilyttämiseksi (1995/409/EC). Erityistakuiden vuoksi Suomeen tuotavilta naudan, sian, siipikarjan lihalta sekä näistä lihoista valmistetuilta tuotteilta ja kananmunilta edellytetään salmonellavapauden todistamista, ellei alkuperämaassa ole vastaavaa valvontaohjelmaa ja esiintyvyyttä. Viranomaisvalvonnan lisäksi toimijoiden omavalvonta ja etujärjestöjen toiminta ovat tärkeässä asemassa salmonellan vastustamisessa.

Kansallinen salmonellavalvontaohjelma ei kata rehuja, mutta rehulainsäädännön mukaan rehuissa ei saa esiintyä salmonellaa (Maa- ja metsätalousministeriön asetus rehualan toiminnanharjoittamisesta, MMMa 548/2012). Valvomalla salmonellan esiintyvyyttä eläinten rehuissa pyritään estämään salmonellabakteerin pääsy tuotantoketjuun ja elintarvikkeisiin. Toiminnalla pyritään siten ehkäisemään sekä ihmisten että eläinten salmonellatartuntoja. Rehuvalvontaan kuuluu viranomais- ja omavalvontana toteutettu salmonellanäytteenotto maahan saapuvista rehuista sekä valmistuksen valvonta.

Suomessa sikatilat käyttävät ruokinnassa pääosin teollisesti valmistettuja rehuja, etenkin viljan lisänä tarjottavia täydennysrehuja. Rehut valitaan sikalakohtaisesti, mutta ne sisältävät pääasiassa viljoja hiilihydraatin lähteinä, öljykasvien siemeniä ja hedelmiä ja niistä saatavia tuotteita sekä maatalouden ja teollisuuden sivutuotteita valkuaisen ja rasvan lähteenä, sekä rehun lisäaineita, kuten hivenaineita ja vitamiineja. Vuonna 2013 Suomessa valmistettiin teollisia rehua eläimille yli 1 300 miljoonaa kg, josta sikojen rehuja oli noin 293 miljoonaa kg. Samana vuonna Suomessa toimi noin 1 600 sikatilaa ja oli noin 1,3 miljoonaa sikaa. Sianlihaa tuotettiin noin 186 miljoonaa kiloa.

Salmonellavalvonta aiheuttaa toimijoille kustannuksia sekä lakisääteisten vaatimusten että toimijoiden omavalvonnan toimenpiteiden myötä. Rehun tuontiin liittyvät lainsäädännön perusteella otettavien salmonellanäytteiden kustannukset sekä rehun karanteenivarastoinnin kustannukset, sillä Suomeen tuotavassa rehussa ei saa esiintyä salmonellaa. Rehunvalmistajille salmonellavalvontaan liittyviä kustannuksia hygieniatoimenpiteet (siivoustoimenpiteet aiheuttavat tehdasrakennuksissa sekä salmonellalla kontaminoituneiden materiaalien ja rakennusten puhdistus) ja tuholaistorjunta, salmonella kontaminoituneen rehun käsittely, näytteenotto sekä viranomaisvalvonta. Sikaloissa salmonellaa torjutaan muun muassa hyvällä hygienialla ja torjumalla haittaeläimiä, rehun happokäsittelyllä sekä rehunvalmistajiksi rekisteröityneiden toimijoiden osalta myös omavalvontasuunnitelmaan liittyvien toimenpiteiden avulla. Lainsäädäntö (Rehulaki 86/2008, 23 §) velvoittaa toimijaa, joka tuottaa yli 6 milj. kiloa, kuumentamaan rehun valmistusvaiheessa. Tämä koskee kaikki rehuja pois lukien vitamiini- ja mineraaliseokset ja nestemäiset rehut. Rehutoimijoille tehdyn kyselyn mukaan rehu kuumennetaan keskimäärin 81 - 105 asteeseen. Happokäsittelyllä tarkoitetaan hapollisten aineiden (muurahaishappo ja ammoniumformiaation) lisäämistä etenkin nestemäiseen rehuun oikean pH:n tuottamiseksi. Koska salmonellaan liittyy Suomessa nollatoleranssi (salmonellaa pääsy markkinoille pyritään sisältävien tuotteiden ennaltaehkäisemään), ennaltaehkäisevillä toimenpiteillä on suuri taloudellinen merkitys. Ne ilmenevät säästettyinä salmonellasaneerauskustannuksina tai ehkäistyinä ihmisten salmonellasairaustapauksina.

1.2 Tutkimuksen tavoitteet

Tutkimuksen tavoitteena oli selvittää sianrehujen salmonellavalvontaa ja -torjuntaa Suomessa. Valvontaa tarkasteltiin kahdesta näkökulmasta:

- 1. Sianrehuihin kohdistuvan rehuvalvonnan ja eläintuotannon vaikutus salmonellariskiin Suomessa
- 2. Sianrehuihin kohdistuvan salmonellavalvonnan kustannukset ja hyödyt kotimaisessa sianlihatuotantoketjussa

Ensimmäisessä osahankkeessa tarkasteltiin rehujen välityksellä sikoihin ja sianlihan välityksellä ihmisiin kohdistuvaa salmonellariskiä arvioimalla ensin salmonellan todellinen esiintyvyys rehussa ja sikojen rehusta saamien salmonellatartuntojen suhteellinen määrä. Lisäksi arvioitiin, miten suuri vaikutus sikojen rehulla on ihmisten sianlihan välityksellä saamiin tartuntoihin. Rehuvalvonnan ja eläintuotannon vaikutusta salmonellariskiä nykyisen rehuvalvonnan ja eläintuotannon tasolla erilaisiin tilanteisiin, joissa valvontakäytännöt muuttuisivat.

Toisessa osahankkeessa selvitettiin salmonellavalvonnan ja ennaltaehkäisyn kustannukset ja -hyödyt nykytilanteessa sekä tilanteessa, jossa ennaltaehkäisy- ja valvontakäytännöt muuttuisivat nykytilanteeseen verrattuna. Kustannukset ja hyödyt selvitettiin alkutuotannosta lähtien ottaen huomioon sekä lakisääteiset että vritysten omavalvontana suorittama valvonta ja ennaltaehkäisevät toimenpiteet. Kustannusten osalta selvitettiin sekä sianlihantuotantoketjun salmonellan valvonnasta ja ennaltaehkäisystä aiheutuvat yritysten ja viranomaisten kustannukset että sianrehujen saastumisen ja sen seurauksen asikoihin levinneen salmonellan saneerauskustannukset sekä ihmisten sianlihasta saamista salmonellatartunnoista aiheutuneet kustannukset. Kuluttaiien osalta selvitettiin sianrehuperäisistä salmonellatartunnoista iohtuvien terveydenhuollon, työn tuottavuuden ja kuolemantapausten kustannukset. Hyötyinä tarkasteltiin rehun salmonellasaastumisen ja siitä johtuvan sianruhojen saastumisen sekä ihmisten sairastumisten aiheuttamia kustannuksia, jotka voidaan ennaltaehkäistä salmonellavalvonta-toimenpiteiden avulla. Valvonnan ja ennaltaehkäisevien toimenpiteiden odotetaan vähentävän salmonellan esiintymistä sianlihan tuotantoketjussa ja vähentävän salmonellabakteerin hävittämisestä sikatiloilla ja rehun käsittelyssä aiheutuvia kustannuksia sekä ihmisten sairauskuluja. Kustannustehokkuutta tarkasteltiin vertailemalla nykytilannetta tilanteeseen, jossa rehujen salmonellavalvonta ja -torjunta olisi nykyistä vähäisempää.

1.3 Rehujen ja tuotantoeläinten salmonellavalvonnan riskinarviointi

1.3.1 Vaaran tunnistaminen

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Salmonella on tärkeimpiä elintarvikevälitteisten sairastumisten ja laajojen taudinpurkausten aiheuttajia Euroopassa. Suomessakin rekisteröidään vuosittain pari tuhatta salmonellatartuntaa. Tosin näistä arviolta vain noin 300–400 on kotimaisista lähteistä saatuja. Todellinen tartuntojen määrä voi olla jopa kymmenkertainen rekisteröityyn määrään verrattuna, sillä suuri osa tartunnan saaneista ei hakeudu hoitoon eikä sairauden aiheuttajaa välttämättä tutkita. Salmonellat jaetaan ominaisuuksiensa mukaan kahteen lajiin (*S.enterica* ja *S.bongori*), joista *S. enterica* on jaettu edelleen alatyyppeihin ja serotyyppeihin. Kaikki ihmisten ja eläinten terveyden kannalta merkittävimmät salmonellat kuuluvat ryhmään *S. enterica* subsp. *enterica*, joka koostuu noin 1 500 serotyypistä. Euroopassa, myös Suomessa, yleisimmin raportoidut serotyypit ovat *S*. Enteritidis ja *S*. Typhimurium.

Salmonellat ovat pieniä, sauvanmuotoisia ja pääosin liikkuvia gram-negatiiviseen ryhmään kuuluvia bakteereita, jotka eivät muodosta itiöitä. Ne kasvavat hapellisissa ja

hapettomissa oloissa 7–47° C lämpötilassa, kun pH on 4.5–9.5. Osa salmonellakannoista on sopeutunut poikkeaviin olosuhteisiin, kuten erityisen happamaan elinympäristöön. Salmonellan selviäminen rehuissa riippuu pääosin lämpötilasta, happamuudesta ja käytettävissä olevan veden määrästä. Bakteeri ei yleensä pysty lisääntymään kuivassa rehussa mutta se selviää siinä ja lisääntyy, kun olosuhteet muuttuvat suotuisammiksi. Liemimäisessä rehussa happamuus on oleellinen salmonellan kasvua rajoittava tekijä.

Salmonelloilla on hyvin laaja isäntäkirjo. Suurin osa salmonellakannoista on zoonoottisia, eli ne voivat tartuttaa sekä ihmisiä että eläimiä ja siirtyä näiden välillä. EU-alueella salmonellan esiintyvyys porsastuotantosikaloissa oli vuonna 2008 korkea, 31,8 % sikaloista. Suomessa esiintyvyys on ollut sen sijaan vuosikymmenet hyvin matalalla tasolla. Esimerkiksi vuonna 2013 salmonella osoitettiin vain viideltä sikatilalta. Viime vuosina salmonellan esiintyvyys teurastamonäytteissä, joita otetaan noin 6 000 vuosittain, on ollut myös matala, 0,02–0,05 %:n luokkaa.

Luonnon eläimet, mukaan lukien linnut ja jyrsijät, voivat kantaa salmonellaa ja mahdollisesti levittää sitä eteenpäin esimerkiksi tuotantoeläimiin. Suomessa ja Ruotsissa, joissa salmonellan esiintyvyys tuotantoeläimissä on erittäin vähäistä, salmonellaa on satunnaisesti eristetty maatilojen ympäristöissä liikkuvista villi- ja lemmikkieläimistä. Maissa, joissa salmonellaa tavataan melko yleisesti tuotantoeläimissä, salmonellalöydökset ovat olleet yleisiä myös tilojen ympäristöistä kiinni otetuissa haittaeläimissä. Rehut ovat hyvä kasvualusta salmonellabakteereille. Etenkin valkuaispitoisissa rehuaineissa todetaan ajoittain salmonellaa myös Suomessa, mutta löydökset rehuseoksissa ovat erittäin harvinaisia. Muissa EU-maissa esiintyvyys rehussa vaihtelee riippuen kunkin maan rehunvalmistus- ja valvontakäytännöistä.

1.3.2 Vaaran kuvaaminen

Zoonoottisten salmonellakantojen aiheuttamaa tautia ihmisissä kutsutaan salmonelloosiksi. Taudin oireita ovat kuume, vatsakipu, ripuli, huonovointisuus ja joskus oksentelu. Tauti paranee yleensä ilman hoitoa mutta voi olla jopa hengenvaarallinen henkilöillä joiden vastustuskyky on syystä tai toisesta heikko. Osa salmonellakannoista voi lisäksi kehittyä lääkehoidolle vastustuskykyiseksi. Syötyjen salmonellasolujen määrä on suorassa suhteessa oireiden vakavuuteen ja käänteisesti verrannollinen itämisaikaan, joka on 6–72 tuntia. Oireet kestävät yleensä 4–10 päivää, mutta tauti voi olla myös oireeton. salmonelloosin oireellisen vaiheen jälkeen potilas voi toimia bakteerin kantajana vielä noin 2–4 viikkoa. salmonelloosin jälkitauteina esiintyy nivel- ja suolistotulehduksia sekä Reiterin oireyhtymää, joka vaikuttaa virtsateihin ja ihoon.

Salmonellan kykyä tartuttaa ihmisiä on tutkittu syöttämällä erisuuruisia annoksia bakteereita vapaaehtoisille ja tarkkailemalla sairastuvuutta (annos-vastesuhde). Koska vapaaehtoiskokeiden osallistujat ovat olleet useimmiten nuoria terveitä miehiä, annos-vaste suhdetta on tutkittu myös tilastollisesti vertailemalla taudinpurkauksista saatuja tietoja. Näiden perusteella oireellisen salmonelloosin puhkeamiseen tarvittava annos on yleensä vähintään 10⁵ solun luokkaa, mutta voi olla hyvinkin pieni, kun tartunta saadaan rasvaisista ruoista kuten kastikkeista tai suklaasta. Oireeton tartunta voidaan saada jo muutaman bakteerisolun annoksesta.

1.3.3 Altistuksen arviointi

Tilastollisten mallien sarja, jossa aineistona käytettiin kansallisia keskiarvoja rehuseosten koostumuksesta, rehun käytöstä sikojen ruokinnassa ja sikojen kasvatuksesta, sekä salmonellan esiintyvyystietoja näissä lähteissä, kehitettiin kuvaamaan salmonellasta aiheutuvaa altistusta. Malli luotiin OpenBUGS ohjelmistolla (www.openbugs.net) ja tulokset esitettiin todennäköisyysjakaumina. Mallin rehukategorioita havainnollistava kuva on esitetty liitteessä 5 (kuva 1, osio 10.5).

Tilastollisen mallin avulla arvioitiin salmonellan todellista esiintyvyyttä rehuaineissa ja rehuseoksissa vuoden 2013 rehunvalmistuskäytäntöjen perusteella. Todellisen esiintyvyyden arvio ottaa huomioon havaitun esiintyvyyden lisäksi näytteenottoon liittyvän epävarmuuden sekä menetelmien herkkyyden havaita salmonella näytteessä. Arvio on mallinnettu 25 tonnin rehuerille. Mallin avulla arvioitiin myös salmonellan pitoisuutta silloin kun rehuaineet tai (sian)rehut ovat saastuneita sekä pitoisuuden vähentymistä esimerkiksi rehua kuumennettaessa. Arvio rehun aiheuttamasta tartuntariskistä lihasioille ja emakoille laskettiin yhdistämällä arvio salmonellan esiintyvyydestä arvioon salmonellan pitoisuudesta silloin, kun rehu on saastunutta.

Sikoihin kohdistuvaa salmonellan tartuntariskiä arvioitiin laskemalla todennäköisyys, jollasuomalainensikasaasalmonellatartunnanrehunvälityksellä. Tätätodennäköisyyttä verrattiin muista lähteistä, esimerkiksi ympäristöstä, tapahtuvaan tartuntaan, jotta voitiin arvioida todellista salmonellaesiintyvyyttä suomalaisissa sioissa. Rehujen ja ympäristön suhteellista vaikutusta tartuntoihin tarkasteltiin tilastollisen mallisarjan lisäksi vertaamalla rehusta ja ympäristöä kuvaavista haittaeläimistä osoitettuja salmonellakantoja sioista eristettyihin salmonellakantoihin.

Kuluttajan riskiä saada salmonellatartunta suomalaisesta siasta tai sianlihatuotteesta arvioitiin vertaamalla sioista ja muista lähteistä eristettyjä salmonellakantoja ihmisistä eristettyihin kantoihin ja laskemalla eri lähteiden suhteelliset osuudet. Yhdistämällä arvio mallisarjan avulla laskettuun arvioon sian tartuntojen lähteistä pystyttiin arvioimaan suomalaisten sikojen syömien rehujen osuutta ihmisten saamissa salmonellatartunnoissa.

Riskinarviointia varten kerättiin tilastoja salmonellan esiintyvyydestä rehuaineissa, rehuseoksissa ja sioissa vuosilta 2013–2014. Samojen vuosien perusteella kerättiin tietoa rehuaineiden käyttösuhteista erityyppisissä (mm. täysrehu, täydennysrehu, nestemäinen rehu, kuiva rehu) rehuseoksissa sekä käyttöasteesta sikatiloilla. Rehutehtaille (9 kpl), rahtisekoittajille (13 kpl) ja rehua valmistaville sikatiloille (432 kpl) lähetettiin kysely, joka koski mm. rehun valmistuksessa käytettäviä rehuaineita, rehunvalmistuksen toimintatapoja ja niiden kustannuksia liittyen salmonellan hallintaan vuonna 2013. Kyselytutkimuksen ja hankittujen lisätietojen avulla saatiin aineistoa rehun käsittelytavoista. Salmonellan pitoisuus saastuneessa rehussa, sikojen syömät annoskoot ja sikojen teurasiät saatiin kotimaisesta ja ulkomaisesta kirjallisuudesta. Salmonellan annos-vastesuhde sioille, sekä herkkyys saastunnan tunnistamiseen rehu- ja teurasnäytteissä saatiin niin ikään kirjallisuudesta. Ennusteiden laskemista varten tietoa salmonellan esiintyvyydestä Euroopan eri maissa valmistetuissa rehuissa ja niiden rehuaineissa saatiin vuosittain Euroopan



elintarviketurvallisuusviranomaiselle (EFSA) toimitetuista, julkisesti saatavilla olevista vuosiraporteista. Vuosiraporteista saatiin tietoa kansallisessa viranomaisvalvonnassa ja omavalvonnassa saaduista tuloksista vuonna 2013 ja viranomaisvalvonnan tuloksista vuonna 2014.

1.3.4 Riskin kuvaaminen

Rehujen salmonellasaastumisen riskinarvioinnissa sian riski saada salmonellatartunta laskettiin toisaalta rehujen salmonellaesiintyvyyden ja saastuneiden rehujen salmonellapitoisuuksien, toisaalta teurastamolöydösten perusteella. Ihmisten sianrehusta johtuvaa salmonella-altistusta sianlihan välityksellä arvioitiin yhdistämällä tilastolliseen mallisarjaan pistemäinen arvio kotimaisen sianlihan osuudesta ihmisten kotimaassa saaduista salmonellatartunnoista.

Salmonellan esiintyvyyden arvioitiin olevan vähäistä kaikissa rehuaineissa: 0,01–1,35 % luokkaa (mediaanit). Salmonellan esiintyvyys kotimaassa rehunvalmistukseen käytetyssä viljassa arvioitiin keskimäärin varsin vähäiseksi. Suurimmaksi salmonellan esiintyvyys arvioitiin ei-kotimaisille proteiinipitoisille rehuaineille, mukaan lukien soijasta, rypsistä ja rapsista saadut rehuaineet. Tiheän näytteenoton vuoksi arvioon näiden rehuaineiden salmonellaesiintyvyydestä sisältyi tutkituista rehuaineista vähiten epävarmuutta.

Kotimaisissa rehuaineista ja täydennysrehuista tai täysrehuista koostuvissa sioille tarjottavissa kotimaisissa (täys)rehuissa salmonellan esiintyvyyden arvioitiin vaihtelevan keskimäärin 0,02 % ja 0,10 % välillä. Tuontirehujen salmonellaesiintyvyyden arvioon liittyy suuri epävarmuus, sillä valmiiden täysrehujen ja täydennysrehujen tuonti on vähäistä ja siten näytemäärät näistä pieniä.

Tilastollisten mallien sarjassa oletettiin, että rehuaineiden ja rehuseosten salmonellaesiintyvyys ei muutu käsittelyiden, kuten kemiallisen käsittelyn ja kuumennuskäsittelyn vaikutuksesta. Sen sijaan rehussa esiintyvän salmonellan pitoisuuden oletettiin laskevan saastuneeksi havaitun rehuaineen kemiallisen käsittelyn sekä teollisten rehujen tapauksessa kuumentamisvaiheen seurauksena, jolloin pitoisuus mahdollisesti laskee niin matalalle tasolle, ettei sitä pystytä enää havaitsemaan. Riippuen käsittelyistä, täysrehujen konsentraation arvioitiin vaihtelevan keskimäärin noin -4 ja -1 log₁₀ salmonella/g välillä.

Salmonellan keskimääräinen esiintyvyys lihasioissa ja emakoissa arvioitiin ottaen huomioon todennäköisyys, jolla sioille syötettävä rehu sisältää salmonellaa, rehun annoskoko, sekä lihasian ja emakon todennäköisyys saada salmonellatartunta riippuen saastuneessa rehuannoksessa olevasta salmonellan pitoisuudesta. Esiintyvyydeksi arvioitiin lihasioilla 0,25 % (keskiarvo, 95 % CI: 0,09–0,50 %) ja emakoilla 0,48 % (95 % CI: 0,18–0,99 %). Rehun suhteelliseksi osuudeksi salmonellatartunnoista sioissa muihin lähteisiin kuten ympäristöön verrattuna arvioitiin lihasioilla 34 % (95 % CI: 10–66 %) ja emakoilla 57 % (21–92 %).

Ihmisten sianrehusta johtuvaa salmonella-altistusta laskettaessa käytettiin pistemäisenä keskiarvona arviota 14 % kotimaisen sianlihan osuudesta ihmisten rekisteröidyissä kotimaasta saaduissa salmonellooseissa. Yhdistämällä tämä arvio tilastolliseen mallisarjaan, jossa otettiin altistusta arvioitaessa huomioon myös sianlihan kulutusmäärät, saatiin arvio ihmisiin kohdistuvasta riskistä. Pieni osa, 4,7 % (95 % CI 1,3–9,1 %) kotimaisista ihmisten tartunnoista, joita Suomessa rekisteröidään noin 300–400, olisi arvion mukaan yhdistettävissä sikojen rehuihin.

1.3.5 Oletukset ja rajoitukset

Arvioihin liittyvistä oletuksista, rajoituksista ja erilaisista epävarmuutta aiheuttavista tekijöistä on kuvaus englanninkielisessä osiossa 5.4.5 Assumptions and limitations.

1.3.6 Ennusteet

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Salmonellan esiintyvyys suomalaisessa sianrehussa ja sioissa on erittäin vähäistä verrattuna Euroopan maihin keskimäärin. Jos nykyinen salmonellan suhteen ehdoton linja rehujen valvonnassa lieventyisi vastaamaan käytäntöjä Euroopassa, ajan kuluessa myös salmonellan esiintyvyyden rehujen rehuaineissa ja rehuissa voidaan olettaa lähestyvän muissa Euroopan maissa havaittua esiintyvyyttä. Siksi entistä lievempien rehuvalvontatoimenpiteiden vaikutusta Suomessa arvioitaessa hyödynnettiin muiden Euroopan maiden raportoimia salmonellan esiintyvyyksiä rehuaineissa ("Ennuste-valkuainen") ja rehuissa ("Ennuste-rehu").

Ennusteen perusteella salmonellan esiintyvyys sioissa nousisi noin kaksinkertaiseksi nykytilanteeseen verrattuna, mikäli salmonellan esiintyvyys (sian)rehun tuontirehuaineissa olisi EU-maista kerätyn aineiston tasolla, ja saastuneiden kemiallinen käsittely poistuisi. Esiintyvyys lihasioissa olisi siten 0,53 % (keskiarvo, Q95 %: 0,21–0,95 %). Toisen ennusteen perusteella esiintyvyys sioissa nousisi noin puolitoistakertaiseksi nykytilanteeseen verrattuna, jos kaikki siat ruokittaisiin ilman rehuaineiden kuumennuskäsittelyä. Jos molemmat rehuaineisiin liittyvät ennusteet toteutuisivat, salmonellan esiintyvyys lisääntyisi keskimäärin tasolle 1 %, ja olisi noin nelinkertainen nykytilanteeseen nähden.

Tilanteessa, jossa suomalaisen sioille tarjottavan rehun salmonellaesiintyvyys olisi samaa luokkaa kuin EU-maista kerätyssä aineistossa, bakteerin esiintyvyys sioissa voisi nousta keskimäärin 55-kertaiseksi (keskiarvo, mediaani 50, Q95 %: 10–130) nykytilanteeseen verrattuna. Kirjallisuuden perusteella rehun kuumennuskäsittelyn lämpötila voisi lakisääteisten velvoitteiden poistuessa laskea nykyisestä 81 °C:sta useita kymmeniä asteita jopa prosessin vaatimaan minimiin, 50 °C, mikä otettiin huomioon ennustetta laskettaessa. Esiintyvyyden nousu sioissa nostaisi esiintyvyyttä ihmispotilaissa samassa suhteessa olettaen, että teurastamo- ja lihankäsittelykäytännöt eivät muuttuisi.

Mikäli taloustilanteen tai jonkin muun taustatekijän vuoksi suomalaisten sikojen ruokinnassa käytettäisi pelkästään kotimaisia rehuaineita, esiintyvyys lihasioissa laskisi vain hieman, keskimäärin noin 0,9-kertaiseksi nykytilanteeseen verrattuna. Laskelma perustuu vuoden 2013 tietoihin, joiden perusteella valkuaispitoisia tuontirehuaineita myytiin suoraan sikatiloille vain pieniä määriä.

1.4 Salmonellavalvonnan kustannushyötyanalyysi

1.4.1 Salmonellaa ennaltaehkäisevien toimenpiteiden kustannukset

Kustannushyötyanalyysissa verrattiin nykyisen salmonellavalvonnan aiheuttamia kustannuksia ja hyötyjä vaihtoehtoiseen valvontatilanteeseen. Salmonellavalvonnan tuomien kustannuksien osalta huomioitiin salmonellaa ennaltaehkäisevien toimenpiteiden kustannukset, joita aiheuttavat lakisääteisesti vaaditut toimenpiteet, toimijoiden omavalvontana tekemät toimenpiteet, sekä salmonellakontaminaatioiden aiheuttamat kustannukset. Ennaltaehkäisevien toimenpiteiden kustannukset huomioitiin eri vaiheissa rehuketiusta sianlihantuotantoon rehun tuonnille. rehunvalmistukselle (kaupalliset rehutehtaat ja rahtisekoittajat) ja sikatiloille. Salmonellakontaminaatioiden kustannukset laskettiin edellisten toimintoien teurastamovaiheessa svntvneille lisäksi mvös kontaminaatioille sekä ihmistapauksille. Salmonellavalvonnan tuomat hyödyt nousevat esiin vältettyinä salmonellasaneerauksina rehutehtailla, sikatiloilla ja teurastamoissa, sekä ennaltaehkäistyinä salmonellatapauksina ihmisissä eli säästettyinä kustannuksina.

Ennaltaehkäisevien toimenpiteiden oletettiin vaikuttavan salmonellakontaminaatioiden määrään. Nykyistä salmonellatilannetta verrattiin skenaarioihin, joissa salmonellan esiintyvyys olisi suurempaa, jolloin myös salmonellakontaminaatioiden aiheuttamat kustannukset olisivat suuremmat, vaikka ennaltaehkäisevien toimenpiteitä (ja niiden kustannuksia) olisikin vähemmän.

Ennaltaehkäisevinä toimenpiteinä tai salmonellavalvontaan liitettävinä toimenpiteitä huomioitiin salmonellanäytteenotto, rehunkäsittely, viranomaisvalvonta, tuholaistorjunta sekä hygieniatoimenpiteet ja omavalvonnan kirjanpitoon käytettävä työaika. Salmonellan ennaltaehkäisemiseksi tehtävät toimenpiteet torjuvat myös muita taudinaiheuttajia kuin salmonellaa. Toisaalta esimerkiksi kuumennuskäsittelyä tehdään etenkin rehun koostumuksen saamiseksi tietynlaiseksi, vaikka sillä on vaikutusta myös salmonellan esiintymiseen. Tämän vuoksi asiantuntijoiden avulla arvioitiin salmonellaan kohdistuvaa osuutta näistä kustannuksista. Tuonnin ja rehunvalmistuksen kokonaiskustannuksista erotettiin lisäksi sianrehuun kohdistuva osuus, sillä toimijat valmistavat useiden eläinlajien rehuja. Sianrehuun kohdistuva osuus kustannuksista arvioitiin sianrehun valmistusmäärän suhteessa rehunvalmistuksen kokonaismäärään.

Tuonnin osalta kustannuksiksi laskettiin rehun ja rehuaineiden salmonellanävtteet omavalvontana viranomaisvalvontana sekä karanteenivarastointi. ia Viranomaisnäytteen hinta sisältää myös rehun tai rehuaine-erän valvontatapahtuman päätösmaksunkustannuksen, joka veloitetaan valvontatapahtumaa kohden. Karanteenivarastoinnin kustannus arvioitiin ajanjaksolle, ionka salmonellanäytetuloksen saaminen vaatii sen jälkeen kun itse näyte on otettu. Salmonellanäytteiden osuus arvioitiin täys- ja täydennysrehuille sekä korkeariskisille rehuaineille, käytetään sianrehujen valmistamiseen. Korkeariskiset iota rehuaineet on lueteltu Maa- ja metsätalousministeriön asetuksessa rehualan toiminnanharjoittamisesta (MMMa 548/2012) liitteessä 3. Sianrehuihin kohdistuva

näytemäärä arvioitiin sianrehureseptien sekä sioille valmistetun rehumäärän perusteella.

Toimijoiden rehunkäsittelyn, hygieniatoimenpiteiden, joilla tässä yhteydessä tarkoitetaan tehdasrakennuksissa tehtäviäsiivoustoimenpiteitä, sekä tuholaistorjunnan ja näytteenoton kustannuksia arvioitiin kyselyn tuloksia (kappale 1.3.3) sekä aiempia tutkimuksia hyödyntäen.

Taulukossa 1 on esitetty prosenttiosuus, jonka arvioitiin liittyvän salmonellavalvontaan salmonellaa ennaltaehkäisevästä toimenpiteestä. kustakin Fsimerkiksi salmonellanävtekustannukset kohdistuvat vain salmonellavalvontaan, kun taas tuholaistorjunnasta arvioitiin kohdistuvan salmonellaan vain 14 % rehutehtaiden, ia neliännes sikatiloien osalta. Viranomaisten suorittamien tarkastuskäyntien kustannuksista 25 0∕₀ kohdistuvan salmonellavalvontaan, oletettiin sillä vuositarkastukset käsittelevät muitakin kuin salmonellavalvontaan liittyviä asioita. Myös hygieniatoimenpiteistä, kuten tilojen puhtaanapidosta ja siivouksista, oletettiin kohdistuvan salmonellaan neljännes kaikkien toimijoiden osalta. Rehunkäsittelyssä salmonellavalvontaan oletettiin kohdistuvan viidennes kuumennuskäsittelvn muuttuvista kustannuksista, kuten työaika, energia ja materiaalit ja niistä aiheutuvat kustannukset, ja 80 % muun käsittelyn kustannuksista. Rahtisekoittajien tekemän happokäsittelyn kustannuksista puolet ja tilojen kustannuksista kymmenen prosenttija kohdistettiin salmonellan ennaltaehkäisyyn.

Ennaltaehkäisevä toimenpide	Rehutehtaat	Rahtisekoittajat	Sikatilat
Salmonellanäytteet	100 %	100 %	100 %
Kuumennuskäsittely: Aika ja materiaalit	20 %		
(Muu kuin kuumennuskäsittely, esim. happokäsittely)	(80 %)	(50 %)	(10 %)
Rehunkäsittely: Huolto ja laitteisto	0 %		
Viranomaisvalvonta	25 %	25 %	
Hygieniatoimenpiteet	25 %	25 %	25 %
Tuholaistorjunta	14 %		25 %
Omavalvonnan kirjanpito	50 %	25 %	25 %

Taulukko 1. Salmonellaan kohdistettava osuus eri toimenpiteiden kustannuksista.

Taulukossa 2 on eroteltu sianrehuun ja salmonellavalvontaan kohdistuva osuus toimiioittain salmonellavalvonnan tuomista kokonaiskustannuksesta sekä esitettv salmonellavalvonnan kustannukset. Kustannukset laskettiin kaupallisille rehunvalmistajille, joiden valmistus oli yhteensä noin 300 000 tonnia sianrehua rehutehtaiden osalta ja runsas 30 000 tonnia rahtisekoittajien osalta. Salmonellavalvonnan aiheuttamat ennaltaehkäisevät kustannukset ovat tuonnin, rehunvalmistajien ja sikatilojen osalta yhteensä 1,8–3,0 miljoonaa euroa. Tästä tuontiin liittyvät kustannukset ovat noin 110 000 euroa, rehunvalmistukseen (rehutehtaisiin) liittyvät kustannukset noin 1,2–1,7 miljoonaa euroa ja sikatiloja koskevat kustannukset noin 0,5-1,2 miljoonaa euroa. Rahtisekoittajille kokonaiskustannukset olivat vain noin 5 000 euroa, mikä johtuu ensisijaisesti toimijoiden pienestä tuotantovolyymista suhteessa rehutehtaisiin.

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Tenurivalinistuksessa ja sikationia.						
	Sianrehun valmistukseen ja sikoihin kohdistettava kustannusten osuus, % kaikkien eläinrehujen valmistuksesta		Josta salmonellaan kohdistuva osuus, %		Sianrehuun ja salmonellaan kohdistuvat kustannukset, 1 000 € per vuosi	
	min	maks	min	maks	min	maks
Tuonti	18 %		100 %		105	109
Rehunvalmistus	26 %	25 %	34 %	37 %	1 174	1 701
Sikatilat	100 %		18 %	21 %	512	1 166
Rahtisekoittajat	23 %	27 %	48 %	44 %	5	6
Yhteensä	38 %	44 %	25 %	31 %	1 797	2 982

Taulukko 2. Salmonellaa ennaltaehkäisevien toimenpiteiden kustannukset tuonnissa, rehunvalmistuksessa ja sikatiloilla.

1.4.2 Salmonellalla saastuneen rehun aiheuttamat kustannukset

Taulukossa 3 on esitetty salmonellalla saastuneen sianrehun tai rehuaineen aiheuttamat kustannukset vuosittain sianlihaketjun eri vaiheissa. Näiden kustannusten taustalla on yksittäisiin salmonellatartuntoihin tai ihmisten sairastumisiin liittyvät kustannukset, joiden esiintymisen todennäköisyydessä on hyödynnetty riskiarviointiosiota. Varastossa havaittujen kontaminoituneiden rehuaineiden ja rehujen osalta toimenpiteiden kustannuksiksi arvioitiin keskimäärin 60 000 euroa kontaminoitunutta erää (erän koko noin 25 tonnia) kohti. Summa sisälsi kontaminoituneen varaston siivous-, käsittely- ja varastointikulut sekä lisänäytteenoton. Tehdasalueella havaitun kontaminaation osalta todennäköisiksi kustannuksiksi arvioitiin 1 000-1 500 euroa per tapaus, joskin vaihtelu voi olla suurta. Rehutehtaalla (rehussa tai rehulinjassa) havaitun salmonellakontaminaation saneerauskustannukset voivat olla jopa 0,1-0,4 miljoonaa euroa per 25 tonnin rehuerä, sisältäen puhdistustoimenpiteet, menetetyn rehun arvon, korvaukset asiakkaille rehusta ja rehutehtaan katetuoton menetyksen. Rehun takaisinvedoista voi aiheutua mittavia lisäkustannuksia, mikäli takaisinveto koskee suurta tuotantomäärää. Tämä luku ei kuitenkaan sisällä kontaminaatioista sikatiloille aiheutuvia kustannuksia, jotka riippuvat tilan koosta ja voivat olla huomattavia jo yksittäisen kontaminoituneen sikatilan tapauksessa, saati laajemmissa epidemioissa.

Rahtisekoittajien tekemiin toimenpiteisiin liittyviä kustannuksia olivat auton desinfioiminen ja mahdollinen toiminnan keskeytyminen salmonellalöydöksen vuoksi. Muiden salmonellan torjuntaan kohdistuvien kustannusten arvioitiin rahtisekoittaiien osalta vähäiset. olevan Sikatiloilla salmonellatartunnan saneerauskustannukset vaihtelevat salmonellan leviämisen ja seurausten laajuudesta ja tilan koosta riippuen muutamista tuhansista euroista aina satoihin tuhansiin, ja jopa yli miljoonaan euroon tilaa kohti. Tilan koko vaikuttaa kustannusten suuruuteen olennaisesti. Yksittäisissä tapauksissa on havaittu, että kustannuksia nostaa etenkin se, jos tuotantorakennusten puhdistus- ja desinfektiotoimenpiteet eivät hävitä bakteeria, jolloin toimenpiteet joudutaan tekemään uudestaan. Mikäli salmonellaa havaitaan teurastamolle viedyissä sioissa, johtaa se teurastamon puhdistus- ja desinfiointitoimenpiteisiin sekä toimenpiteisiin tilalla, jolta siat on tuotu.

Ihmistapausten aiheuttamiksi sairauskuluiksi arvioitiin keskimäärin 530–620 euroa per tapaus (sisältäen kaikki tarkastellut vakavuusasteet, mukaan lukien raportoimattomat tapaukset) riippuen siitä, miten laajasti jälkitautien oletetaan esiintyvän. Tämän kustannuksen suuruuteen vaikuttaa se, miten kuolemantapaukset arvotetaan. Vaikka kuolemantapaukset ovat äärimmäisen harvinaisia, ovat niiden kertakustannukset suuria. Sianrehun salmonellakontaminaatiosta johtuvien sairastumisten vuoksi Suomen koko väestön menettämien elinvuosien määrä oli 3–5 DALYa vuodessa riippuen siitä, miten laajasti jälkitauteja oletetaan esiintyvän. Akuuttien terveysvaikutusten osuus oli noin 1 DALYa vuodessa.

Kontaminaatio	2.50%	Mediaani	97.50%
Kaupallinen rehunvalmistus ja tuonti	0	1,7	4,6
Kontaminaatiot tiloilla (eläimet ja rehut)	0	0,3	1,1
Teurastamo	0	0,1	0,4
Ihmisten sairastapaukset	0	0,1	0,2
Yhteensä	0,3	2,1	6,1

Taulukko 3. Rehun saastumiseen liittyvien salmonellakontaminaatioiden aiheuttamat kustannukset (milj. € per vuosi) eri tuotantovaiheissa nykytilanteessa.

1.4.3 Salmonellavalvonnan kustannushyötyanalyysi

Kustannushyötyanalyysin toteuttamiseksi nykytilannetta verrattiin vaihtoehtoiseen rehujen salmonellavalvontatilanteeseen, joiden kustannuksia ja hyötyjä verrattiin nykytilanteeseen. Vaihtoehtoisessa tilanteessa (kustannus-hyötyanalyysin skenaario A) salmonellavalvonta ja ennaltaehkäisy olisivat nykytilannetta vähäisempää, eikä rehuissa salmonellaa havaittaessa ryhdyttäisi toimenpiteisiin kontaminoituneen rehun hävittämiseksi. Toisin sanoen tuonnin, sekä kaupallisen rehunvalmistuksen (rehutehtaat sekä rahtisekoittajat) yhteydessä ei ryhdyttäisi toimenpiteisiin salmonellaa havaittaessa. Salmonellatapausten määrät ihmisissä sekä eläimissä kasvaisivat. Mikäli valvonta olisi vähäisempää, myös salmonellaa ennaltaehkäisevien omavalvontatoimenpiteiden määrä olisi todennäköisesti nykyistä vähäisempi. Taulukossa 4 on esitetty osuus niistä salmonellan torjuntaan kohdistuvista toimenpiteistä, jotka yhä tehtäisiin vaihtoehtoisessa skenaariossa A.

salmonellaa ennaltaehkäisevien toimenpiteiden osuus (%) nykytilanteen kustannustasosta.			
Skenaario A	Kaupalliset rehunvalmistajat		
Osuus salmonellavalvonnan toimenpiteistä, joita oletetaan tehtävän	Rehutehtaat	Rahtisekoittajat	
Näytteenotto omavalvontana	50-90 %	50-90%	
Rehunkäsittely (aika ja materiaali)	95 %	50 %	
Rehunkäsittely (huolto ja laitteisto)	100 %		
Viranomaisvalvonta	0 %	0 %	
Näytteenotto viranomaisvalvontana	0 %	0 %	
Hygieniatoimenpiteet	100 %	100 %	
Tuholaistorjunta	100 %		
Omavalvonnan kirjanpitoon käytettävä aika	80 %	75 %	

Taulukko 4. Kustannus-hyötyanalyysin vaihtoehtoisessa skenaariossa A huomioitavien salmonellaa ennaltaehkäisevien toimenpiteiden osuus (%) nykytilanteen kustannustasosta

Toimenpiteiden määrää, jotka tehtäisiin ilman nykyistä Suomen rehulainsäädäntöä ja sen perusteella tehtävää rehuvalvontaa, arvioitiin rehualan asiantuntijoiden avulla. Selvitysten perusteella muun muassa peruspuhdistustoimenpiteitä ja tuholaistorjuntaa suoritettaisiin kuten nykyisinkin, mutta salmonellanäytteiden otto kohdistettaisiin toimijoiden oman harkinnan mukaisesti suurimmiksi riskeiksi arvioituihin kohteisiin ja näytteiden kokonaismäärä vähenisi hieman nykytilanteeseen verrattuna. Myös rehujen käsittelyn (kuumennus- tai happokäsittely) materiaalija työaikakustannukset voisivat laskea hieman esimerkiksi lämpötilan laskun tai lyhemmän käsittelyajan myötä. Vaihtoehtoisessa skenaariossa viranomaisvalvonnan ja viranomaisten toimesta otettujen salmonellanäytteiden kustannuksiksi oletettiin nolla euroa.

Vaihtoehtoisessa tilanteessa A ennaltaehkäisevien kustannusten suuruudeksi arvioitiin yhteensä 1,1–1,8 miljoonaa euroa vuodessa (taulukko 5). Ennaltaehkäisyn ja valvonnan kustannukset eivät siis laske nollaan, vaan osa toimenpiteistä tehtäisiin myös ilman rehujen salmonellavalvontaohjelmaa.

Salmonella oletettiin hävitettävän, jos sitä leviäisi sikoihin vaihtoehtoisessa tilanteessa A (kuten nykytilanteessakin). Sikatilojen salmonellasaneerauksista ja ihmisten sairastumisista aiheutuneiden kokonaiskustannusten arvioitiin olevan vaihtoehtoisessa tilanteessa keskimäärin runsaat 29 miljoonaa euroa vuodessa, joskin salmonellakontaminaatio rehuissa saattoi johtaa jopa yli 100 milj. euron suuruisiin vuotuisiin kustannuksiin. Ihmisten sairastumisista aiheutuneiden keskimäärin 6.2 miljoonaan euroon vuodessa ja muiden kontaminaatioista johtuvien kustannusten keskimäärin noin 26 miljoonaan euroon vuodessa.

Nykytilanteessa (eli nykyisen lainsäädännön vaatimusten perusteella) salmonellavalvonnan, ennaltaehkäisyn ja salmonellalla saastuneen rehun ja siitä seuraavien saneeraustoimenpiteiden sekä ihmisten sairastumisen kustannusten suuruusluokaksi arvioitiin yhteensä 4,1–5,4 miljoonaa euroa vuodessa. Vaihtoehtoisessa kustannus-hyötyanalyysin skenaariossa A kustannukset puolestaan olivat keskimäärin yhteensä 33,8–34,8 miljoonaa euroa vuodessa.

Taulukko 5. Salmonellavalvonnan aiheuttamien ennaltaehkäisevien toimenpiteiden sekä salmonellalla saastuneesta rehusta seuraavien saneeraustoimenpiteiden ja ihmisten sairastumisten odotetut kokonaiskustannukset nykytilanteessa sekä kustannus-hyötyanalyysin vaihtoehtoisessa skenaariossa A.

Kustannukset, milj. €	Nykytilanne	Vaihtoehto A
Ennaltaehkäisevät toimenpiteet1	1,8–3,0	1,1–2,1
Salmonellakontaminaatiot kaupallisessa rehunvalmistuksessa ja tuonnissa	1,8	0
Salmonella tiloilla (eläimet ja rehut)	0,3	25,5
Kustannukset teurastamolle	0,1	5,8
Ihmisten sairastapaukset	0,1	6
Yhteensä	4,2–5,4	33,8–34,8

¹ Luvut kuvaavat kustannuksia matalalla tai korkealla kustannustasolla laskettuna.

1.5 Johtopäätökset

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Hankkeen tavoitteena oli arvioida rehuista aiheutuvaa salmonellariskiä ja sen taloudellisia vaikutuksia suomalaiselle sianlihan tuotannolle. Riskinarvioinnissa hyödynnettiin tuotantoketjua kuvaavaa tilastollista mallia, jonka avulla arvioitiin salmonellan todellinen esiintyvyys Suomessa sioille tarkoitetuissa rehuissa sekä niihin käytetyissä rehuaineissa. Käyttämällä salmonellan pitoisuustietoja rehussa arvioitiin todennäköisyys, jolla sika saa salmonellatartunnan rehusta ja siten salmonellan esiintyvyys sioissa. Arvion perusteella salmonellan esiintyvyys oli keskimäärin vähäistä niin rehuissa kuin niiden rehuaineissa. Sioissa esiintyvyys oli myös selvästi alle kansallisen 1 % tavoiteylärajan. Arvioitaessa sian saamien salmonellatartuntojen lähteitä käyttäen hyödyksi sioista ja luonnoneläimistä eristettyjen kantojen tyypitystietoja havaittiin, että merkittävä osa tartunnoista voisi olla peräisin rehuista. Arvioon jäi epävarmuutta muiden tartuntalähteiden osuudesta.

Raportoitujen salmonelloosien tyypitystietoja hyödyntämällä arvioitiin, miten suuri vaikutus sikojen rehulla on ihmisten sianlihan välityksellä saamiin tartuntoihin. Yhdistämällä tyypitystiedot mallisarjaan arviota pystyttiin tarkentamaan ja vähentämään arvioon sisältyvää epävarmuutta. Arvion perusteella alle kymmenesosa raportoiduista ihmistapauksista yhdistyi kotimaisiin sianrehuihin ja sikoihin.

Verrattaessa nykytilannetta tilanteeseen, jossa rehun valvontakäytännöt olisivat nykyistä lievemmät ja salmonellan esiintyvyys sen vuoksi rehuaineissa ja rehuissa yleistyisi, myös esiintyvyys sioissa lisääntyisi ja salmonellatartunnat kotimaisista sikaan liittyvistä lähteistä olisivat nykyistä yleisempiä. Sen sijaan tilanteessa, jossa esimerkiksi tuonnin rajoitusten tai taloudellisen tilanteen muutoksen seurauksena sikatilat korvaisivat ulkomaiset valkuaispitoiset rehuaineet kotimaisilla, salmonellan esiintyvyys rehuissa ja sioissa laskisi hieman.

Koska sianrehun salmonellakontaminaatioista, sikojen salmonellatartunnoista ja ihmisten sairastumisista aiheutuvat kustannukset olivat edellä mainitussa skenaariossa A perustilannetta (ks. taulukko 5) suuremmat, ja sianrehujen salmonellavalvontaan ja kontaminaatioiden ennaltaehkäisyyn liittyvät kustannukset olivat nykytilanteessa alle kolme miljoonaa euroa, arvioitiin sianrehujen salmonellavalvonnan (viranomaisvalvonnan ja omavalvonnan) hyötyjen olevan sen kustannuksia suuremmat. Pelkästään ihmisten sairastumisesta aiheutuneet kulut olivat vaihtoehtoisessa skenaariossa A enemmän kuin kontaminaatioiden ennaltaehkäisyn ja valvonnan kustannukset nykytilanteessa. Analyysin lähtökohtana on, että salmonellan torjunta muuttuisi vain sianrehujen osalta. Sen sijaan esimerkiksi tilan sioissa todettu salmonella saneerattaisiin. Nykytilannetta kuvaavassa skenaariossa esimerkiksi vuoden 2009 rehuvälitteinen salmonellaepidemia on ääritapaus, jonka kustannukset olivat simulaatioiden 95 %:n vaihteluvälin ulkopuolella.

Tutkimus vahvisti käsitystä siitä, että rehut ja niiden laatu ovat merkittävä tekijä koko elintarvikeketjussa. Tulokset osoittavat, että riskinhallintatoimenpiteet tuotantoketjun alkupäässä ja koko ketjussa vaikuttavat salmonellan esiintymiseen kuluttajatasolle asti. Sianrehujen salmonellavalvonta ja siihen liittyvät salmonellan leviämistä ennaltaehkäisevät toimenpiteet ovat kustannustehokkaita ja tuottavat yhteiskunnalle hyötyä. Hankkeen tuloksia voidaan soveltaa käytäntöön etenkin arvioitaessa nykyisten salmonellaan liittyvien valvontakäytäntöjen toimivuutta ja muutostarpeita sekä muutoksien mahdollisia seurauksia.

2 INTRODUCTION

Highlights:

- Salmonella is considered a serious food hygiene problem worldwide and pigs a significant reservoir for the disease.
- Food items of animal origin, including pork, are assumed to be the most common source of salmonella in people.
- Feed is potentially an important vector for salmonella infections in pigs, when salmonella is not common in piggeries.
- Risk assessments should be used as key elements when preventive actions against salmonella contamination are planned and executed.

2.1 Salmonella as a food hygiene problem

Food safety is an increasingly important public health issue worldwide (WHO 2007). Currently, many problems are linked to food safety issues, and consumers are more than ever interested in food safety as a whole. Non-typhoid salmonella is the most common bacterial pathogen causing gastrointestinal infection in the USA (CDC 2011). In Europe, it is the leading cause, together with *Campylobacter* spp. (EFSA 2015). Foodborne illness caused by salmonella results in human suffering, and also extensive economic losses in the society. Therefore, concrete actions reducing the risk of foodborne illness as well as building and maintaining an efficient food safety system should be emphasized in risk management.

Humans infected with salmonella can suffer from serious gastroenteritis as well as chronic sequelae. In the worst case, salmonellosis can even lead to the patient's death. Annually, about 1 600–3 000 salmonellosis cases are reported in the Finnish national infectious diseases register (THL 2014). It has been estimated that the reported cases represent only 10–30% of the actual salmonellosis cases (Wheeler, Sethi et al. 1999, STM 1997). Domestic infections are reported to cover about 15% of all the cases registered in Finland, whereas 80% of the cases are reported to be of foreign origin (THL 2014). Food, especially food of animal origin, is assessed to be the most common source of salmonella, even though the source of infections can rarely be defined.

Salmonella are zoonotic bacteria of fecal origin. They can be transferred between humans and animals through salmonella-containing feces, food, drink, or the environment. In the Nordic countries, the strategy for salmonella prevention is to reduce the prevalence of these bacteria at the earliest possible phase in the food chain. In Finland, the surveillance and prevention of salmonella already began in the 1950s. Before joining the European Union in 1995, the salmonella surveillance was further improved in co-operation with Sweden and Norway (Hopp, Wahlstrom et al. 1999). The Finnish national salmonella control programme (FSCP, MMMEEO 1994) covers the salmonella surveillance and risk management actions of the main animal production lines: pork, beef, chicken, and turkey, as well as production lines and products thereof, meat and table eggs. The FSCP has successfully controlled and even reduced (Huttunen, Johansson et al. 2006) the salmonella exposure of the production lines for poultry (Maijala, Ranta 2003), eggs (Lievonen, Ranta et al. 2006), pigs (Ranta, Tuominen et al. 2004), and cattle (Tuominen, Ranta et al. 2007).

Finland has been granted by the EU additional guarantees to sustain the low salmonella prevalence in the country (European Commission Decision 94/968/EC 1994). According to the Agreement on Sanitary and Phytosanitary Measures made in 1995, free trade can be restricted if import can be shown by risk assessment to harm the health of humans, animals, or plants in an importing country. This is termed a technical barrier to trade (WTO 1995). Due to the additional guarantees, a certificate showing freedom from salmonella is required for certain products of animal origin that are imported to Finland. The imported foodstuffs that are included in the FSCP cover about 10% of the Finnish consumption of these products but, according to risk assessment, cause around half of the domestic salmonellosis cases (Mikkelä, Ranta et al. 2011).

2.2 Feed as a source of salmonella

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The FSCP does not cover animal feeds. Nevertheless, according to the feed law $(86/2008, 6 \S)$, feed is not allowed to contain salmonella. Contamination of food production chains and of food with salmonella is aimed to be prevented by monitoring the prevalence of salmonella in animal feed. The monitoring aims at the prevention of both human and animal cases. Imported feeds are considered an important source of salmonella infections in animals, as the bacteria have been detected frequently from imported feeds (Elintarviketurvallisuusvirasto Evira 2015). Less attention has been given to domestic food industry by-products, which can be delivered directly to farms. For instance, salmonella is detected several times a year in the milling industry's by-products, which are used as components in animal feed. Although the relatively small number of salmonella cases in Finland can be regarded as a sign of an effective monitoring and control system, there have been some failures in the system. Large epidemic feedborne salmonella outbreaks have occasionally been experienced. In 1995, a feedborne S. Infantis outbreak occurred in dairy and beef cattle farms. The infection was confronted in 0.7% of Finnish farms. In spring 2009, S. Tennessee was in turn isolated from 4% of the henhouses and 2% of the piggeries in Finland after salmonella contamination had occurred in the feed (Häggblom 2009). Widespread salmonella contamination in feed, such as what happened in 2009 despite the monitoring processes of both the companies themselves and the authorities, shows the vulnerability of the monitoring system (Häggblom 2009). The magnitude and effects of the salmonella risk for Finnish pig production has never been evaluated, although the microbiological quality of the feed has been noted as an important factor in meat production. The effects of prevention are positively reflected in the health of the animals, the prevalence of salmonella in food, and the health of the consumers.

2.3 Salmonella-related risk assessments and cost-benefit analyses

The salmonella-related risk assessments published in Finland have been targeted at poultry, pig, cattle, and egg production included in the FSCP (Maijala & Ranta 2003, Ranta et al. 2004, Tuominen et al. 2007, Ranta et al. 2005, Lievonen et al. 2006). These have covered the risk analysis of the production chains from animal to consumer. Because the aim in these studies has been to evaluate the FSCP, the salmonella risk of feeds has not been evaluated. Different opinions on the impact of feeds on the risk of salmonella infections in humans exist, but it seems obvious that these bacteria can be transferred from feed via the animals to the food products, and therefore expose consumers to the infection (Clark et al. 1973, Liebana & Hugas 2012). The correlation is not necessary direct (Davies et al. 2004).

A cost-benefit analysis prepared by the FCC Consortium and commissioned by the EU (FCC Consortium 2011) evaluated five different salmonella control scenarios in the EU member states. The scenarios varied depending on whether biosecurity at the farm, interventions based on high or low salmonella prevalence, or transport and slaughterhouse measures were taken into account. According to the results, the benefits of salmonella control were, in most cases, lower than the costs. Finland reached one of the highest cost-benefit rations among the countries in the evaluation, but only one of the five control scenarios was economically profitable. This was the scenario with the establishment of a support unit, some increased sampling, and the adoption of feed control measures. Therefore, the options that FCC Consortium evaluated were mainly not economically justified.

In Sweden, the cost for controlling salmonella in high-risk feed materials and compound feed has been evaluated (Wierup & Widell 2014). The total cost for achieving salmonella-safe feed was estimated at $\leq 1.8-2.3$ per ton of feed. Of that cost, 25% relates to the prevention of salmonella-contaminated high-risk vegetable feed materials from entering feed mills and the rest, 75%, is composed of the measures taken to control salmonella contamination within the feed mills. These results suggest that the policy of keeping animal feed free from salmonella is realistic and economically feasible. For fattening pigs, the costs of ensuring salmonella-free feed were 0.6% of the price for compound feed in 2012. This figure is lower than in broilers and dairy cows (0.7%) due to the lower protein content of the pig feed.

In Finland, the economic aspects of salmonella risk have previously been studied mainly in the context of poultry production. However, Maijala and Peltola (2000) have

evaluated the cost of salmonella control in meat production in Finland at €1.1 million, including sampling, veterinary costs, insurance and control costs at the farm, product recalls and the disposal of contaminated meat, feed, and other control measures by authorities, nursing, investigation of the infected people, absence from work, market control, and market price changes. Costs were also compared with the situation without the FSCP, and the benefits were evaluated with and without taking market changes into account. When including the market changes, the benefits were close to \notin 0.3 billion, and when excluding them, the benefits were \notin 6.1 million. By including the market changes, the efficiency figure was 258.1, denoting that one euro invested in the control program pays back €258.1 in saved costs. Maijala (1998) and Maijala and et al. 1998) found the direct cost of the program to be about ≤ 0.5 per household annually. Later, Peltola and co-workers (Peltola et al. 2001) examined the consumer benefits of the FSCP. Consumers were found to be willing to pay an additional ≤ 3.3 -3.8 (a median figure) per month to finance the present level of salmonella control, which cost close to €6 per person per month (€70 per year). On the basis of the consumers' willingness to pay for food safety, the program was seen as beneficial from the economic point of view.

The indirect costs of the FSCP were calculated to evaluate whether the FSCP could act as a technical trade barrier and interfere with imports to Finland, causing welfare losses due to decreased trade (Peltola et al. 2001). The program was found not to affect trade in general. However, some potential effects could be found for pork production, although their significance was questionable.

Kangas et al. (2007) assessed that the expenses of the FSCP to the broiler industry have been about ≤ 0.02 per kilogram of meat annually. The total costs were ≤ 990400 per year. Kangas and co-workers also compared the FSCP with Zoonosis directive 92/117/EC, which only sets measures for breeding flocks of poultry. Based on the analysis, control costs were on average seven times higher when the FSCP was applied compared to the zoonosis directive. On the other hand, public health costs were 33 times higher with the zoonosis directive compared to the FSCP. The loss due to one death was 0.95-1.78 times higher than the costs of the FSCP. One prevented loss of life covered the control costs. Therefore, the FSCP was found to be successful for the broiler chain from the societal point of view.

According to Kilpeläinen et al. (2004), the costs caused by sampling and analysis of salmonella included in the control program were calculated to be 0.18 c/kg in egg production, 10.51 c/kg in broiler production, 4.38 c/kg in dairy production, and 14.9 c/kg in pig production. Furthermore, the program causes different costs to the food industry and to society in general. For instance, the product safety costs in the refining of milk are estimated to be 0.73 cents per liter. All in all, one needs to observe that according to the study by Kilpeläinen et al. (2004), most of the salmonella expenses are caused by mild infections, which do not end up in the outbreak statistics.

In Finland, the FSCP has been regarded as profitable when it covers the whole production chain (Maijala 1998, Maijala & Peltola 2000). The strengths and weaknesses of the program should, however, be investigated using risk assessment methods. At the same time, the best practices that promote food safety and good economic performance should be recognized. Possibly existing futile practices should be given

up and, to replace them, up-to-date and economically rational practices should be developed. At the same time, one should determine whether there are reasons to decrease or increase monitoring, as the current practices may no longer be suited to the modern production pattern and farm structure. Risk assessment and cost-benefit analysis that considers the special features of the Finnish production environment directly answer to the goals proposed in the feed strategy and working group memo on research aiming at improving risk management (MMM 2004, MMM 2010).

2.4 Costs of salmonella related to human cases

A report of the FCC Consortium entitled "Analysis of the costs and benefits of setting a target for the reduction of salmonella in slaughter pigs" (2010) used the cost of illness method (COI) in evaluating the cost of salmonella in humans. The COI method provides an inventory of the money spent on the direct costs of health care, such as hospital services, and the indirect costs, for instance relating to productivity losses. The total costs of human salmonella cases in Finland were evaluated at ≤ 17.2 million in 2008 and the costs per case were on average ≤ 480 for 35 949 cases (FCC Consortium 2010). The costs of chronic sequela were excluded. Focusing on pigs as a source of salmonella, 15% of salmonellosis cases were estimated to be attributed to pork and pork products in the study, and the total costs were ≤ 2.6 million. The share of salmonellosis attributed to pork was estimated to be the same across all countries, meaning that country-specific differences were not taken into account. In Finland, this figure may be relatively high compared to reality.

The multiplier of 11.5 was used in the FCC Consortium report for all European countries, which was based on literature from the UK, the United States, and the Netherlands. Multiplying numbers are used to adjust the officially reported number of cases of salmonellosis. However, some countries have calculated their own multiplying factors. A multiplier of 7.2 was used in Denmark (Pires 2014). In England and in the Netherlands, multiplying factors were estimated to equal 3.8 and 13.4, respectively (van Kreil 2006, Anonymous 2008). In the United States, the multiplier was estimated to be as high as 38.6 (Voetsch 2004).

The FCC used a multiplier of 2.3 to evaluate patients visiting a general practitioner (GP). The analysis assumed that the (severity outcome 1–4) ratio between mild cases (people who do not see a GP) and more severe cases (people who see a GP, are hospitalized, or die) was 80:20. The proportion of patients seeing a GP (severity 2) was assumed to be 18.27% of all cases, the proportion of hospitalized patients (severity 3) 1.68%, and the proportion of fatal cases (severity 4) 0.05%. It was also assumed that the number of days absent from work was 0.5 days for unreported cases, 1.6 days for GP visit cases, and 4.5 days for the hospitalized cases.

In our study, the impacts of salmonella in humans were estimated by using the burden of disease, the unit for which is the disability-adjusted life year (DALY). The DALY is a non-monetary approach to estimate health implications, whereas the cost of illness (COI) provides an inventory of money spent. The DALY method measures the years of life lost due to death or disability. It combines the time lived with the disability and the time lost due to premature mortality in one measure, i.e. information on the quality and quantity of life (WHO 2016).

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There have been studies using the DALY method used in the context of salmonella. For example, Havelaar et al. (2012) estimated that the disease burden of salmonella spp. was 7.7 (at the discount rate of 0%) and 6.7 (1.5%) DALYs per 100 000 inhabitants in the Netherlands. Sequelae and mortality were the major contributors to the total disease burden. The sequelae included irritable bowel syndrome (IBS) and inflammatory bowel disease (IBD), in addition to reactive arthritis. Havelaar et al. (2012) estimated that the percentage of people making GP visits was 15%, the proportion of hospitalized people 3%, and the proportion of fatal cases 0.1% from 35 000 salmonella cases. The DALYs per year were estimated to be 1 270. In 2013, Mangen et al. estimated the DALYs of non-typhoidal salmonella spp. in the Netherlands at 1 190 per year. This estimate was based on the average for the years 2005–2007.

Pires (2014) assessed the burden of diseases caused by foodborne pathogens in 2014 in Denmark. According to the study, around seven persons were in fact infected and ill for each reported salmonella infection. The total burden of salmonella was estimated at 389 DALYs, which corresponded to 6.94 DALYs per 100 000 inhabitants.

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3 DESCRIPTION OF THE FINNISH FEED AND PIG PRODUCTION SECTOR

Highlights:

- Most pig farms use industrially produced compound feed, either complete feed or complementary feed.
- In Finland, 1 391 million kg of feed for production animals was produced in 2013, of which 293 million kg was for pigs.
- The 1 600 pig farms operating in Finland in 2013, housing approximately 1.3 million pigs, produced 186 million kg of pork.
- The Finnish national salmonella Control Programme forms the basis for salmonella control in Finland, setting limits, for example, for the salmonella prevalence in pigs.
- The Finnish feed law (86/2008) sets the basis for the salmonella control of feed production, transport, storage, and use.
- According to salmonella control guidelines, zero tolerance is applied, which means that every salmonella finding results in actions covering the withdrawal of feed or meat products where necessary, tracing back potentially contaminated pigs and feed, increased sampling, and hygiene measures.
- Animal Health (ETT) and the health classification register Sikava promote the health and welfare of food-producing animals and participate in salmonella prevention and control in Finland.

The information needed for the risk assessment and cost-benefit analysis was gathered from several sources, including the reports of the Finnish Food Safety Authority, the customs office, and the Finnish Farm Registry. However, not all information on feed production practices in feed mills and on farms was found from the literature and statistics. To fill in the information gaps, a questionnaire was sent to the feed mills producing pig feed, to pig farms producing their own feeds, and to mobile mixers mixing pig feeds in Finland. The questions covered the whole feed manufacturing process beginning from the pathways by which the feed materials were brought to the process and ending with the distribution of feed. The questionnaire was sent to nine feed mill operators, six of which responded. From the 432 farms that had reported manufacturing pig feed on a list of Finnish feed operators in primary production (https://www.evira.fi/elaimet/rehut/), 61 responded to the questionnaire, while 53 announced that they no longer practiced pork production. The Evira established list relies on information given by the operators. Only two mobile mixers out of 12

filled in the questionnaire. In addition to the questionnaire, information was gathered by interviewing a mobile mixer and the staff of a large Finnish feed mill. In addition to the questionnaire and the interviews, cost information was also collected from the price lists of laboratories and operators related to the feed industry, such as pest control operators and warehouse providers, and from experts of the feed industry and operators related to the feed industry.

3.1 Feed operators

The whole supply chain from farm to food retail is included in feed operations. The production, processing, use, storage, and transport of raw materials for feeds are feed operations. All feed operators, including feed mills, farms, and mobile mixers, must register at Evira based on Regulation (EC) No 183/2005 of the European Parliament and Council laying down requirements for feed hygiene. All operators, including pig farms, are considered as feed manufacturers when they use certain additives or premixes. A list of approved feed businesses in Finland is available on the Evira website (https://www.evira.fi/elaimet/rehut/). This lists feed businesses by name and activity (Table 6).

Activity	Number of businesses
Total number of feed businesses*	2 219
Producer of additives	19
Producer of premixes	13
Producer of feed materials	418
Producer of compound feed	120
Mobile mixer	16
Retail trade	693
Wholesale trade	351
Storage of bulk feed	200
Storage of feed in packages	375
Transport company, bulk feed	480
Transport company, packed feed	436
Importer from EU	349
Importer or representative for third countries	139
Other operator placing feed on the market	471
Exporter	29
Manufacturer of feed intended for particular nutritional purposes	5
Detoxification plant	1

Table 6. Number of approved feed businesses in Finland by activity in 2013.

* One feed business can be involved in several activities.

3.2 Import of feed

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Imported complete and complementary feeds formed a minor part of the pig feeds used in 2013. Less than one million kg of complete feeds and 2.3 million kg of

complementary feeds were imported to Finland. All this feed originated from inside the EU.

According to the reports collected by Evira, a total of 527.5 million kg of feed materials were imported in 2013 for domestic animals (Elintarviketurvallisuusvirasto Evira 2014). Of this, 437.5 million kg were of plant origin, 42.2 million kg of animal origin, 16.6 million kg minerals, 31.1 million kg others, and 16.0 million kg were premixes and feed additives. The feed mills that imported animal feed materials, excluding those manufacturing feed only for fur animals and pets, used altogether about 380.0 million kg of feed materials originating from non-domestic sources. This corresponds to 72% of the total imported amount. The import share of the common market was 75% (Evira 2014). The share of the imports from 3rd countries was 15% of all imported feed. Imports from the EEA countries (European Economic Area) comprised 9% of all feed ingredient imports.

3.3 Feed manufacturing for pigs in Finland

There are three major practices for feeding pigs in Finland. The simplest one is the use of commercially produced complete feeds, as no further processing of the feed on the farm is needed. Another, more common, approach is to use commercially produced complementary feeds and mix them with locally produced cereals and other components. The mixing can be done with the equipment on the farm or a mobile mixer can be utilized. A few pig farms in Finland produce or purchase all the components used to feed their animals locally on their own or from neighboring farms and do not use commercial complete or complementary feeds, mineral complementary feeds excluded.

In total, 293 million kg of pig feed was produced in Finland in 2013. Feed mills in Finland are large on a European scale: in 2008, they were largest in terms of the average production per feed mill (EFSA 2008a). Most feed mills produced feed for pigs and for other production animals. The largest feed mills in Finland produced feed for pigs, poultry, cattle, sheep, horses, fish, and reindeer. The number of production lines varied between the feed mills. The nine feed mills of six operators that produced commercial complete feeds or complementary feeds for pigs produced altogether 87 million kg of complete feeds and 105 million kg of complementary feeds during 2013. According to the questionnaire responses of the feed mills, most of the pig farms in Finland used industrially produced compound feed, either complete feed or complementary feed.

Pig feed can be served to the animals in dry or liquid form (EFSA 2008a). Dry feed is composed of pellets or crumbles, which are fed to pigs from an automated system or by hand. Commercial complete feeds are most often served in a dry form, but they can be modified to be served as liquids. Complementary feeds are available in two types of forms, supposed to be mixed with dry or liquid feed materials. Liquid feed to which the latter form is mixed is mainly composed of protein rich-feed from barley (PFB) and is fermented before serving. In Finland, according to the questionnaire administered within this study, 58% of the pig farms used the feeds in a liquid form, whereas 42% of the farms had only feeding systems for dry feed. Fermented feed was used on 70% of the farms serving the feed in a liquid form.

The feed manufacturing process in the feed mills is composed of several steps during which the feed materials are weighed, ground if needed, and mixed according to the feed formula. The mix is processed to compound feed and stored to be distributed to retail, to mobile mixers, or directly to the pig farms. A schematic diagram of a feed mill is presented in Figure 1. The components in the figure are the following: 1. Intake pit for trucks, 2. pneumatic intake, 3. intake pit for bags, 4. elevators, 5. storage bins, 6. scales, 7. mill, 8. pre-bin for premixes, vitamins etc., 9. mixer, 10. conditioner and pellet press, 11. pellet cooler, 12. storage bin for compound feed, and 13. bulk truck. The Finnish feed law (86/2008, 238) requires that all feed operators who annually produce more than six million kg of feed treat their products with heat during the manufacturing process. Heat treatment must be performed for all feeds except vitamin and mineral mixes and those that are moist or in a fluid form. All four feed mills that produced dry feed for pigs reported in the questionnaire conducted during this study that they used heat treatment during the manufacturing process. According to the guestionnaire, the heating was carried out using steam at the temperature of 81-105 °C. The feed was first heated in a conditioner, then transferred to an expander, and pelleted. The pellets were cooled using a pellet cooler to 10–45 °C. Two of the mills reported using acidifiers to condition the produced feed.

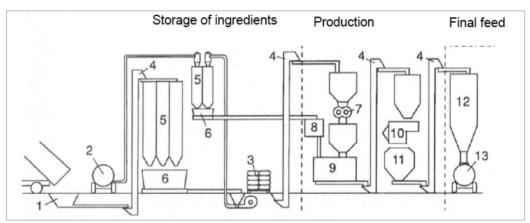


Figure 1. Schematic diagram of a feed-mill that produces pelleted feeds (EFSA 2008b).

A process for the integrated production of ethanol and starch yields as a side product barley fractions suitable for feeding pigs (Fig. 2). The most commonly used barley fractions are protein feed from barley and rank. The barley protein is a mixture of two fractions from ethanol distillation: a protein fraction produced during an early separation process and an insoluble side fraction of fermented starch. Rank is the soluble side fraction of fermented starch, from which some water has been evaporated.

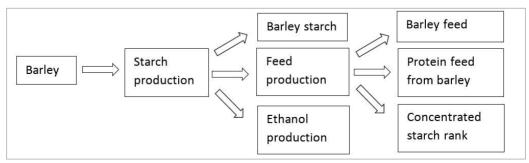


Figure 2. Sidestream barley fractions suitable for the feeding of pigs

About 8% of the pig farms reported in their response to the questionnaire administered within this study that they only use complete feeds to feed their pigs, while only 0.7% of the farms reported that they did not use any commercial feeds, excluding mineral complementary, during 2013. The majority of the farms used commercially produced complementary feeds mixed with feed materials from the farm or from another farm in Finland. Only one of these farms used feed material (soy) imported directly to the farm. None of the farms mixing feed used heat treatment to control growth of the micro-organisms in the feed. Acidifying treatment was used on 38% of the farms that answered the questionnaire. The most common acidic substances used were AIVI and AIVII, which consist of a mixture of formic acid and ammonium formate.

According to the questionnaire, about 10% of the Finnish pig farms used the services of a mobile mixer. These mixers produced in total 33 million kg of pig feed in 2013. The proportion of mixed pig feed from the total amount of produced feed varied from operator to operator, being on average 31.4% (range 0–95.9%). Mobile mixers usually bring some of the feed materials used for the pig feed with them to the client farm. The mixing of the feed takes place in a mill truck and the product is stored in the clients' storage.

In 2013, Finnish feed mills used in total 2 042 million kg of feed materials to produce feeds for production animals. Roughly one fourth of the total amount was used to produce pig feeds. Pig feeds consist of several components, which can be categorized into cereals, protein and oil meals, carbohydrate meals, minerals, and additives, such as vitamins, enzymes, and single amino acids. According to the questionnaire, the three most commonly used feed materials (in terms of quantity used) both in the feed mills and on the farms were barley, oats, and wheat. The most common imported feed material was soy, which was imported in different forms, mostly as textured soy protein granules. A small proportion of imported feed materials was sold to farmers without processing in Finland. According to the feed business operator and farmer interviews conducted during the study, this share varies from year to year, representing at most a few percent of the total quantity imported.

3.4 Pork production in Finland

There were 1 600 pig farms and about 1.3 million pigs in Finland in 2013 (MMMTIKE 2013). Most of the pig farms were located in Western and South-Western Finland: 67% of the farms were situated in the four regions Varsinais-Suomi, Satakunta, Etelä-Pohjanmaa, and Pohjanmaa (Figure 3). The farms were divided according to the type of production as follows: 419 farms were specialized farrowing farms, 707 were specialized finishing farms, 429 were farrowing-to-finishing farms, and 24 were other types of farms, including those for the production of breeding pigs. The total number of pig herds has decreased steadily over the past decades, while their size has increased substantially (Lyytikäinen et al. 2015). There were 7 360 pig farms in Finland in 1995 (MMM TIKE 1997), which was 4.5 times the number in 2013. In recent years, the number of farrowing farms, in particular, has decreased (Table 7). The average herd size has increased from 31 sows per farm in 1995 to 123 sows (median 56) in 2013. The average herd of a finishing farm was 603 (median 353) pigs in 2013. The total number of pigs per farm, regardless of the line of production, was on average 819 pigs (median 434) in 2013.

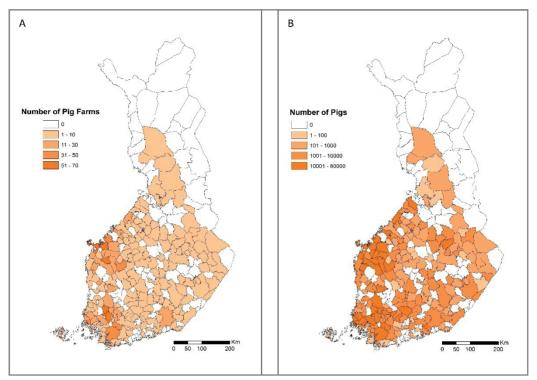


Figure 3. The number of pig farms (A) and pigs (B) per municipality in Finland in 2013. Map: Juha Tuomola, Evira

	1995	2010	2011	2012	2013
Farrowing farms	2 652	623	571	470	428
Finishing farms	2 301	707	689	641	401
Other types of production, including farrowing-to-finishing farms	2 407	722	679	601	524
Total	7 360	2 052	1 939	1 712	1 353

Table 7. The number of pig farms in Finland in 1995 and 2010–2013 (MMMTIKE 2013).

The import of live pigs is focused on importing boars for artificial insemination (ETT 2013). In 2013, Finland imported in total 61 boars from Norway and 158 boars from Denmark.

Table 8 presents the number of slaughtered sows and finishing pigs, as well as the amount of meat produced from 2008 to 2013. In 2013, pork production in Finland totaled 190 million kg (LUKE 2016). Finland has to a large extent been self-sufficient in terms of production. The import of pork was only 33 million kg, while the amount exported was 35 million kg (Tietohaarukka 2016). Finns consumed on average 35.6 kg of pork during 2013 (http://stat.luke.fi/ravintotase). The daily consumption was thus 98 g pork per capita.

Numbe			f pigs		Meat production				Average carcass	
Year	At al	oattoirs			At a	battoirs			weight	
rear	Finishers	Sows	Total	At farms	Finishers	Sows	Total	At farms	Sows	Finishers
1 (1 000 pcs			Million kg			k	g/pcs	
1995	1 982	60	2 066	2	155	8.8	166	-	149	78
2010	2 188	44	2 248	2	194	8.1	203	0.14	183	88
2011	2 206	46	2 267	2	192	8.5	202	0.13	182	87
2012	2 085	43	2 142	2	184	7.7	192	0.12	181	88
2013	2 090	40	2 145	1	186	7.3	194	0.11	181	89

Table 8. Slaughtered pigs in 1995 and 2010-2013 (LUKE 2016).

3.5 Salmonella control of the pork production chain in Finland

In Finland, the prevalence of salmonella in pigs has remained low for several decades due to both mandatory regulatory measures and voluntary actions taken by the industry (Maijala, Ranta et al. 2005). All findings of *Salmonella* spp. in feed, feed mills, animals, or food of animal origin are notifiable by law and action is always taken to eradicate the pathogen where it is observed. Salmonella control of pork is regulated throughout the production chain by legislation.

3.5.1 The Finnish salmonella control programme for pigs

One of the fundamental principles adopted by the EU is the Single Market. This refers to the EU being one market without any internal borders or other regulatory obstacles that would prevent the free movement of goods and services. When joining the EU in 1995, Finland was granted additional guarantees due to ongoing salmonella control to run an independent salmonella control program. The program aimed at maintaining the low prevalence of salmonella in pigs and pig products, in spite of the Single Market. The guarantees allowed Finland to require the same level of salmonella protection in a variety of imported products as that required from the domestic products. In practice, fresh pork and minced pork not intended to be used in processed meat products must be analyzed for salmonella before it is imported to Finland, and proof of a negative test result must be included in the consignments (EY 1688/2005).

The Finnish salmonella control programmes (FSCP), established in 1994 (MMMEEO 1994), includes more strict requirements for salmonella surveillance than the EU legislation (Directive 92/117/EEC). The FSCP covers, for example, all the serotypes of salmonella, not only the most common ones linked to foodborne outbreaks.

The FSCP for pigs includes monitoring of live animals in herds and carcasses at slaughterhouses, as well as monitoring of pig-derived meat products (MMMEEO 1994). One objective of the FSCP is so-called zero tolerance: to take preventive actions aiming to reduce the risk of salmonella-positive meat reaching the market whenever salmonella is confronted (Mead, Lammerding et al. 2010). Whenever salmonella is isolated, contaminated herds are put under restrictions and thorough cleaning and

disinfection of the premises and all possibly contaminated areas are performed, and resampling is carried out. The goal of the programme is to keep the prevalence of salmonella in pigs and in pork at or below the 1% level (at a 95% confidence level). At slaughterhouses, the proportion of salmonella-positive samples per year should be kept at or under 5%. The prevalence is monitored at slaughterhouses and in cutting plants by taking lymph node and surface swab samples. The target is to detect a domestic prevalence of 0.1% at the population level with 95% confidence. Thus, the yearly aim for the number of samples is 3 000 from fattening pigs and 3 000 from sows throughout the year (FSCP 1994).

Several policies applied in Finland support the objectives of the Finnish salmonella control programme. For example, according to the Communicable Diseases Act (1227/2017) and Government Decree on Communicable Diseases (146/2017), the health status of employees working with foodstuffs must be investigated to prevent the spread of communicable diseases, such as salmonella (Jalava, Vuorela et al. 2013).

3.5.2 Combating salmonella in the Finnish feed chain

The Ministry of Agriculture and Forestry is responsible for general guidance and control regarding feed legislation. Evira is responsible for controlling salmonella in feed. This control is based on legislation and described in the annual control plan. It covers the control of feed mills and other feed business operators. Evira carries out spot checks on internal and imported feeds and controls that the market meets the requirements. Feed manufacturing is controlled by official checks and sampling based on Evira's control plan focused on the points considered most risky. Large feed mills (factories) are inspected annually. Inter alia production capacity, the use of certain feeds (e.g. fish meal) affects the frequency of the controls. All the feed manufacturers must have a self-control system for hazard analysis and critical control points (HACCP) and follow it. Sampling and other measures are defined in the HACCP. Evira controls the practicing of the EU Feed Hygiene Regulation (183/2005) through control checks at the operators' facilities. Farms are also controlled by the Sikava's salmonella sampling procedure for pigs, which is further defined in chapter 2.5.4.

Feed quantities that have been found positive for salmonella are treated before being released to the market, destroyed, or returned to the country they came from if they were imported (decree 548/2012). If salmonella is encountered in the feed during production, the manufacturing of the feed is stopped until the production line is cleaned and found to be free of salmonella. Evira and the municipal veterinarian must be informed of the contamination. The origin of contamination is investigated and contaminated feeds are traced and withdrawn. These actions, combined with possible cleaning and disinfection of the salmonella-contaminated farms, as well as breaks in production, can be very costly. Restrictions on animal products purchased and sold follow automatically, similarly to constraints on the use of salmonella-contaminated products. The potential source of the contamination must be investigated. Production farms are freed from the restrictions only after they have been proved free of salmonella by two subsequent official salmonella-negative sampling rounds.

3.5.3 Imported feed

The import of feed and feed materials is controlled by Evira and the Finnish Customs. According to the feed legislation (502/2014), the feed business operator must notify Evira of feed to be imported from the 3rd countries. Notification must include information on the feed and importer, quantity, country of origin, time, place, and the method of import. This concerns trade between the EU member states, termed the internal market. Due to a change in legislation, the official sampling only concerns imports from outside the EU Member States, and not internal trade (MMMa 548/2012). However, sampling must be carried out as self-monitoring measurement. Consignments are only imported through designated entry points. When importing certain high-risk feeds from outside the Member States. Evira must be informed for official sampling. Imported feed is kept under the supervision of the Finnish Customs, in temporary warehouses. The permission of the supervising authority is required prior to the release of feed. Permission is granted due to negative test results in salmonella sampling for laboratory analyses and when other import inspections according to the law are fulfilled. Evira is the national reference laboratory for determining salmonella in feeds. Salmonella samples must be taken from high-risk feed. The sampling frequency is a minimum of one sample per 50 000 kg of feed or, when feed is delivered directly to the farm or mobile mixer without treatment, one sample per 25 000 kg of feed.

The import clearance process usually takes 3 to 4 days, i.e. this is the time before the feed is exempted for use by the authorities. Feed materials may be tested for salmonella by the supplier in the country of origin if this is required by the importer or, in case of re-selling, if required by the exporting country before departure. However, the ship usually departs before the results are obtained. Unloading the feed to temporary warehouses at the harbor usually takes 1 to 2 days, and the samples can already be taken during the unloading, which reduces the extra delay in using feed that has tested negative.

If sample from a feed consignment imported from the EU or from outside the EU (i.e. from 3rd counties) is positive for salmonella, the bacterium is further characterized. The consignment is then to be sent back to the exporting country, destroyed, or treated in such a way that the consignment is no longer salmonella positive. In practice, salmonella-contaminated feed is treated instead of sending it back to the exporting country. Permission from Evira is needed for the treatment to destroy salmonella. This is done by chemical treatment, using formaldehyde based products. Formaldehyde was used in the treatments in 2013, during the period this risk assessment focuses and is based on. In 2017, its use was allowed in Finland until its legal status as an accepted preservative in feed has been decided at the EU level. If salmonella is detected from feed materials or feed, it takes at least a week longer to get the feed into use, whereas the import process normally lasts 4 to 6 days (to obtain the results from the salmonella sampling). Bacterial culture and permission for treatment takes approximately 3 days. Treatment itself takes 1 to 2 days. Finally, new salmonella samples need to be taken to ensure that the feed is salmonella free.

3.5.4 Salmonella management by the industry

The industry has been active in combating animal diseases. The poultry meat sector was the first to start establishing a control program for salmonella in the 1980s.

Animal Health (ETT) is an association maintained by Finnish dairies, slaughterhouses, and egg packers, which was established at the time Finland joined the EU (http:// www.ett.fi/sisalto/ett-english). It coordinates the health care and welfare of production animals at the national level and guides the import of live animals, including their embryos and semen, as well as feed, to prevent the spread of animal diseases and zoonoses. The association has several duties regarding these tasks, including the sharing of information and monitoring of the status of animal diseases. It also maintains a 'positive list' of animal feed companies that fulfil specific criteria to ensure the safety of their feed products.

The stakeholders health and welfare register for swineherds in Finland (Sikava) is a classification register, run by ETT, for pig farms in Finland (Sikava 2014). It has had a quality management system since 2013 and it covers all the requirements of the ISO 9001 standard. In 2013, the system covered about 94% of the swine farms and about 97% of pig production in Finland (Table 9). All operators in Sikava, including the largest slaughterhouses in Finland, have required that their customer farms meet the requirements at the national level or special level herd in Sikava. Most pig farms in the register meet the national level requirements. The farmers of these piggeries have to prove that the animals on the farms are free of salmonella based on fecal samples when joining at the national health classification level, and thereafter once every five years according to ETT instructions (https://www.sikava.fi/sikarekisteri/files/htmlarea/files/Lomakkeet/FIN/salmonellanäyteohje%202014%20(2).pdf).

Level	Number of pig farms in 2014	% of all pig farms in Finland
All	1 615	100
Basic level	68	4.2
National level	1 384	85.7
Special level	58	3.6
Not in Sikava	105	6.5

Table 9. Distribution of pig farms according to health classification level.

As the detection of salmonella in a pig herd initiates costly eradication measures, slaughterhouses have taken out salmonella insurance for pig farms as a group insurance. Each farm producing for an insured slaughterhouse and meeting the self-protection requirements defined by the insurance is insured. The insurance covers the expenses that finding salmonella at the farm causes to the farm as far as the costs are borne by the salmonella clearance plan during the first two months of plan's implementation. A requirement for compensation is that the farms follow the biosecurity recommendations defined by ETT.

Indemnity regulation in feed legislation, which follows the principle of "strict liability", requires that a feed manufacturer, producer, or importer must compensate

for the damage it causes to the feed buyer due to feed that does not meet the legal requirements. These requirements include that the feed is free from salmonella contamination. The damage must be compensated, even if it is not a result of the feed manufacturer's or seller's negligence or intent.

Regulation No 178/2002 of the European Parliament and of the Council declares that the main responsibility for the safety and quality of feed in all stages of production, refinement, and distribution lies with the feed business operator. This responsibility is seen as a requirement for the feed business operator to self-monitor the feed production. The in-house monitoring practices are described in the Decree 548/2012.

The feed business operators, except for those operating as primary producers, are obliged to have a quality control plan, which includes sampling for salmonella testing according to the instructions given to each type of operator. Salmonella-positive findings must be communicated to the inspectors in Evira, who are in charge of further actions carried out in co-operation with the feed business operator.

In-house monitoring also applies to operators in animal production. The Decree of the Ministry of Agriculture and Forestry on the food hygiene of business operators (1369/2011) describes the requirements that each of the operators in animal production are required to follow.

3.5.5 Costs of salmonella control

The costs of salmonella control are carried by the feed industry. Costs can be divided into direct and indirect costs. For the feed mills, preventive costs are mainly caused by heat or acid feed treatment, hygiene measures (outsourced cleaning in the facilities and hygiene measures related to salmonella contaminated materials and facilities), cleaning (and disinfection in special cases), salmonella sampling, pest control, and working time used in self-monitoring. Annual official checks and sampling also cause costs. The same factors cause costs to the mobile mixers and farms that manufacture feed. However, only acid treatment (instead of heat treatment) is used at farms by mixing acid in the compound feed. Salmonella samples are taken from feed, especially feed materials, and as environmental samples in the feed manufacture installations and facilities, such as warehouses. At farms, animals are also objects of salmonella sampling. The import process causes costs, particularly due to salmonella sampling of certain feed materials, but also, for instance, the rental cost of temporary warehouses. The costs caused by official controls must additionally be taken into account. A certain amount of the work of official inspectors, such as municipal and inspection veterinarians, is focused on salmonella control and can be considered as a cost of salmonella control. In addition, slaughterhouses and cutting plants take salmonella samples and have costs caused by official checks and maintaining HACCP and other hygiene measures.

In the case of salmonella contamination, depending on the extent, the cost may be massive. Cleaning, disinfection, and culling of animals are the main direct costs at the production farms. Renovations due to salmonella, when needed, are costly and challenging, as salmonella can persist in the structures of the facilities even after multiple disinfections. Restrictions on animal products purchased and sold cause costs, as production is disturbed. The consequences of the interruption of production and loss of income can be erratic. As regards feed mills, depending on the extent of salmonella contamination, the whole factory may be run down and cleaned. Even in cases where salmonella is not yet detected but suspected, additional hygiene measures are implemented and extra sampling takes place. The consequences caused by strict liability or compensation may raise the cost to millions of euros per case. The total costs for a salmonella case at the Raisio feed mill in 2009 have not been reported publicly, but unofficial estimates suggest that the costs soared to over €20 million due to the cleaning and disinfection of contaminated farms, disposal of infected animals, replacing of the contaminated feed, interruption of production, and income losses. In the Raisio case, salmonella spread to 40 pig and poultry farms via the contaminated feed.

In addition to other hygiene measures implemented upon the detection of salmonella, product recalls and tracing take place at the cutting plants and slaughterhouses. In the event of a human infection, treatment, absence from work, possible sequelae, and studies on the contamination cause costs.

3.6 Methods for health risk modelling

Several methods to model biological phenomena and events can be applied in risk assessments. The choice of method is often based on the quality of the data. A qualitative method is used when the available data can be described and classified, in an unambiguous order if possible, but the nature of the data does not support a mathematical analysis approach. If, however, the available data on a biological phenomenon can be modelled with a quantitative method, such a method is usually chosen, either separately or in combination with qualitative methods. Quantitative simulation methods can be classified as deterministic or stochastic. In the former, calculations contain no random variables and no degree of randomness. Point estimates of input variables/parameters are combined according to a mathematical model to describe the resulting point estimates for the phenomenon (output variables) that is studied, for example the average exposure to a specific pathogen or the worst-case scenario of exposure. Stochastic simulation, which includes random variables, can describe variability and uncertainty over the production chain. Bayesian statistics is a method for quantifying the uncertainty of unknown model variables/parameters based on the observed data and prior distributions. This results in a posterior distribution as a quantitative description of the uncertainty. Several data sets from the food chain can contribute to the result. Therefore, predictions in microbiological risk assessments can be based on both variability and uncertainty, when probabilities are explicitly conditional on the full data sets and the assumed model, as with Bayesian hierarchical models or Bayesian networks. Bayesian methods can be utilized as evidence synthesis in microbiological risk assessment, for example to estimate exposure to certain pathogens.

3.7 Previous risk assessments on salmonella in feed and animal production

Several quantitative risk assessments for salmonella in the pork production chain have been conducted in recent years to support the control of salmonella from farm to fork and the salmonellosis cases in humans due to pork consumption (EFSA 2006, EFSA 2008b, EFSA 2010). These studies have covered some or all of the stages from farm to fork: primary production, including the production of animal feed, industrial processing, and consumer food preparation. The studies have used data collected either from one country or from several, for example from the whole EU area.

Risk assessment studies have traditionally focused on addressing hygiene problems in the first stage of industrial processing, the slaughterhouse (Boughton, Egan et al. 2007, Fosse, Seegers et al. 2008). In addition to the salmonella prevalence in incoming slaughter-aged pigs, cross-contamination between carcasses has been seen as a major factor affecting the salmonella contamination level in the meat. As more knowledge of the contamination routes of salmonella has been gained and more sample data have been collected, it has been possible to evaluate the risks that are linked not only to the slaughter step, but also to primary production at the farm level (Binter, Straver et al. 2011, Doyle, Erickson 2012, Hill, Simons et al. 2015). These assessments have concluded that the prevalence of salmonella in a country's breeding sows is a strong indicator of the prevalence in finishing pigs at slaughter age. Thus, to control the salmonella contamination in meat, one should find solutions to lower the prevalence of salmonella on farrowing farms.

The scientific opinion on a quantitative microbiological risk assessment of salmonella in slaughter and breeder pigs conducted by the EFSA Panel on Biological Hazards concluded that salmonella control in pig farms needs to focus not only on keeping breeding pigs and incoming pigs free of salmonella, but also on controlling the pathogen in animal feed (EFSA 2010). Animal feed has been seen as an especially important route of salmonella contamination in farms when the national prevalence of salmonella is low, such as in Sweden and Finland (EFSA 2008b). Contaminated feed materials may have a significant role in the transmission and introduction of salmonella in feed mills, and thus in the feed chain (Binter, Straver et al. 2011).

Similarly to more recent European studies, a Finnish quantitative risk assessment on salmonella in pork production concluded in 2004 that the magnitude of the salmonella risk to consumers via domestic pork correlates with the prevalence of salmonella on pig farms (Ranta, Tuominen et al. 2004). Imported pork was also seen as a significant source of salmonella contamination in the future, especially if the prevalence in the exporting countries rises or the importers switch to countries with a higher prevalence. Changes in import volumes could also have effects on the risk.



4 AIMS OF THE STUDY

The main aim of this study was to assess the operability of salmonella control practices in Finland. The objective was examined from two aspects: on the one hand regarding the risks, and on the other hand the costs and benefits, as defined by specific objectives 1 and 2 below.

1. What are the impacts of salmonella control practices, targeted at the feed and pork production chains, on the salmonella risk in Finland?

2. How large are the costs and benefits of the pig feed salmonella control programme in Finland?

These goals were addressed in two substudies. The first substudy aimed to assess the salmonella risk to consumers via pork and the risk to pigs via feed. This was achieved by estimating the true prevalence of salmonella in various points of the feed production chain and also the relative number of feedborne salmonella infections in pigs. Using a point estimate of human salmonella infections attributed to pork, the impact of pig feed on the human infections was assessed. The operability of salmonella control in feed and pork production chains was assessed by comparing the salmonella risk at the present level of control with predictions in which the control practices would change.

The second substudy assessed the total costs and the benefits of salmonella control in the present situation and in alternative scenarios. The assessment utilized the results of the first substudy regarding the prevalence of salmonella. Both legislation-based and self-control-based risk management actions were taken into account when the costs and benefits were examined. The costs due to preventive as well as reactive salmonella control actions were included. To assess the cost due to salmonellosis in humans, information was collected on the health care costs, including costs due to death and costs due to the loss of productive working days per person. The benefits were assessed by calculating the avoided disease costs for people not infected and for pigs and feed chains not contaminated by salmonella. The benefits due to avoiding reactive salmonella control costs were also taken into account. The operability of the current salmonella control programme was assessed by comparing the results of each scenario, such as a scenario with a lower level of salmonella monitoring, with the present salmonella control practices.

5 RISK ASSESSMENT ON SALMONELLA IN FEED AND ANIMAL PRODUCTION

5.1 Hazard identification

Highlights:

- Salmonella is one of the most commonly reported foodborne pathogens in the world.
- Many salmonella types, including the most common serotypes S. Enteritidis and S. Typhimurium, infect humans, production animals, and wide range of other hosts.
- As robust bacteria, salmonella are able to persist in various environmental conditions.

5.1.1 Salmonella as a pathogen

Salmonella bacteria are among the most commonly reported food-associated human pathogens in the developed and developing world (WHO 2014b). Together with Campylobacter and Enterohemorrhagic Escherichia coli, they affect millions of people annually. In the European Union, it has been estimated that over 100 000 humans fall ill from salmonellosis each year (EFSA 2015). It has been estimated that more than 80% of all salmonellosis cases are individual cases rather than outbreaks (Smid 2012). The EU notification rate of the disease was 20.4 cases per 100 000 population in 2013 (EFSA 2015). Most cases were reported during summer months, as had been the trend in the EU in 2009-2013. The total numbers of salmonella cases identified in Finland have decreased from more than 3 000 cases at the beginning of the 21st century to less than 2 000 cases in 2013, which corresponds to about 36 cases per 100 000 population in 2013. Due to long-term actions against salmonella in Finland, the number of domestic salmonellosis cases has been low for decades, and most of the cases have been imported from abroad as souvenirs (THL 2014). In 1995–2013, the number of salmonellosis cases originating from domestic food or the environment was on average 390 cases per year, which makes the notification rate 7.2 cases per 100 000 population. The situation is similar in Sweden, where the salmonella prevalence is generally very low and most of the human cases are acquired abroad (Walström, Andersson 2011).

5.1.2 Description of the organism

Salmonella belong to the genus *Enterobacteriacae* (Brenner, Villar et al. 2000). There are only two species of salmonella, *Salmonella bongori* and *Salmonella enterica*. The latter is divided into six subtypes: enterica, salamae, arizonae, diarizonae, houtenae, and indica. Salmonella are divided into 2 500 serovars, defined on the basis of the somatic O (lipopolysaccharide) and flagellar H antigens according to the Kauffman and White principles (Grimont, Weill 2007). All of the most notable salmonella belong to the group *S. enterica* subsp. *enterica*, which consists of 1 500 serovars. In nomenclature, these serotypes are generally referred to as separate species. Serovars can again be subdivided into a large number of phage types, which indicate subsets of one serovar that are susceptible to the same bacteriophages. At the EU level, the two most commonly reported salmonella serovars in 2013, as in previous years, were *S*. Enteritidis and *S*. Typhimurium (EFSA 2015). They represented 39.5% and 20.2%, respectively, of all reported serovars in confirmed human cases. In Finland, most salmonellosis cases are caused by the same two serovars (Kuusi, Jalava et al. 2007).

Salmonella are non-spore-forming, small, rod shaped, and motile Gram-negative bacteria (Wray, Wray et al. 2000). They obtain their energy from oxidation and reduction reactions using organic sources and can thus utilize both fermentative and respiratory metabolism routes (chemo-organotrophs). They are also facultative anaerobes. Several protocols to isolate salmonella from food and animal feces have been described, of which the ISO-6579: 2002 standard is probably the most commonly used. These protocols utilize the biochemical characteristics of the bacteria, which in case of salmonella include oxidase negativity, catalase positivity, and the decarboxylation of lysine and ornithine. Salmonella can also be detected and subtyped using the polymerase chain reaction (PCR) method. The ISO-6579: 2002 standard method can be modified to suit many types of sample materials, including manure and many feeds, such as soy protein meals, rapeseed kibble, and molasses escalope.

The growth temperature range for salmonella is 7–47 °C, which categorizes them as mesophilic bacteria (FSANZ 2013). Under optimal conditions, the generation time for the bacteria can be as short as 25 minutes (Mackey, Kerridge 1988). The optimal temperature for growth is the body temperature of warm-blooded animals, 37 °C (FSANZ 2013). The optimal pH range is 6.5–7.5, but the organism is able to grow in a pH range from 4.5 to 9.5, although its survival is usually shortened below a pH of 5.0. Some salmonella serovars have also been reported to grow outside the pH and temperature ranges that have traditionally been regarded as the limits. Adaptation can especially occur on acidic conditions. This is due to the so-called ATR mechanism (acid tolerance stress response), which induces the bacteria to produce the necessary proteins to tolerate low pH conditions (Alvarez-Ordonez, Fernandez et al. 2010). The minimum water activity in which salmonella can grow is 0.94 (aw = relative humidity/100), and the maximum concentration of NaCl that the organism tolerates is 5% (FSANZ 2013).

The survival of salmonella in feeds intended for pigs depends on many factors, mainly the water activity, pH, and temperature (Fink-Gremmels 2012). As reviewed by Binter et al., some salmonella serotypes are particularly prone to surviving in

the dry conditions present in feed mill environments (Binter, Straver et al. 2011). Some strains are even able to form biofilms, which makes them difficult to eradicate from a feed mill. According to Habimana et al. (2014), long-term exposure to feed processing environmental conditions, such as a dry environment, induced salmonella into a non-cultivable state, even though about 1% of the population remained metabolically active in experimental conditions (Habimana, Nesse et al. 2014). Thus, the monitoring of salmonella from the feed and processing environments could yield false negative results and increase the risk of salmonella-positive feed being distributed to pig farms. This is especially problematic, because the exposure of salmonella strains to the harsh conditions present in the feed production processes alters and often also increases the virulence of those bacterial cells that may have survived the process (Fink-Gremmels 2012). It has been suggested that heat-induced changes in the non-starch polysaccharide fraction of the pig's pelleted diet may also alter the environment in the pig's stomach and intestines towards more favorable conditions for the colonization of salmonella (Brooks 2003).

Liquid fermented feed has been suggested as a preferable alternative to dry pelleted feed for feeding pigs (Missotten, Michiels et al. 2015). Lactic acid in the feed inhibits salmonella growth and appears to alter the conditions in the pig's stomach and gut, so that the animals shed lower amounts of the pathogen, if they even become infected. The preferred pH of the liquid fermented feed is around 4.0, in which state most salmonella strains are not able to grow (Jensen, Mikkelsen 1998). Furthermore, it is stated that the feed must contain at least 100 mmol/l of lactic acid to be able to kill salmonella cells (Beal, Niven et al. 2002). This concentration has no effect on the palatability of the feed, in contrast to a high concentration of acetic acid, which at a level of 40 mmol/l makes feed less palatable for pigs.

5.1.3 Salmonella in animals

Most salmonella serotypes are present in a wide range of hosts, including domestic and wild animals, such as cattle, pigs and rodents, as well as in humans. These unrestricted serotypes can cause illness in many types of host species, although their behavior as commensals is also common. Salmonella infections of pigs with these serotypes are usually asymptomatic, although some of them, such as S. Typhimurium, can cause mild clinical signs, such as diarrhea. These asymptomatic serovars are carried in the tonsils, intestines, and gut-associated lymphoid tissue of pigs. On the contrary to unrestricted serotypes of salmonella, other serotypes are host-related, even to a point they almost never cause infection in other host species (Bell, Kyriakides 2001). These host-restricted serotypes include Typhi and Paratyphi, which infect human hosts. Host-adapted serotypes are most often isolated from a certain host species, for example S. Cholerasuis from pigs. S. Cholerasuis, unlike other serotypes, causes enteritis and septicemia in pigs, leading to serious illness, and even death (Srinand, Robinson et al. 1995). Pigs may also become long-term sub-clinical carriers of the serotype, shedding the pathogen in feces only when stressed, such as during transportation. Salmonellosis can occur at any age, but is most common in growing pigs over eight weeks of age. The most common symptoms in young, 6-12-week-old pigs are fever, poor appetite, coughing, and color changes in the skin (Muirhead, Alexander 1997).

According to EFSA, the proportion of salmonella-positive holdings with breeding pigs in 2008 was as high as 31.8% in the EU + ETA countries (EFSA 2009). In contrast, the incidence of salmonella on pig farms in Finland in 2010 has been estimated to be only 1 per 1 000 farms (0.16%) (Zoonosis Centre Finland 2012). In 2013, salmonella was detected on five Finnish pig farms. Three of the positive samples had been collected from sows. In four cases, the observed serotype was *S*. Typhimurium, while on one farm, *S*. Typhimurium and *S*. Mbandaka was observed. At slaughterhouses, annual randomized systematic sampling of lymph nodes was performed from 3 134 fattening pigs and 3 142 sows in 2013. Salmonella was then isolated from the lymph nodes of three sows and one fattening pig (0.05%). In 2014, 3 113 lymph node samples from sows and 3 128 from fattening pigs were collected. Of these, only one sample from a fattening pig was positive for salmonella. Salmonella was found on one pig farm from fecal and environmental samples in 2014.

The World Health Organization report on global surveillance of antimicrobial resistance in 2014 pointed out an alarming increase in the incidence of antibiotic resistant strains of salmonella (WHO 2014a). Although it is forbidden in the EU to use growth promotors in animal feed and water, feeds can transmit antimicrobial-resistant bacteria to animal production. In some serotypes of salmonella, the genomic element that carries resistance to antimicrobials may spread horizontally among other serotypes.

Wildlife, including wild birds and rodents, are understood as potential introducers and spreaders of salmonella to livestock and the feed and food chains (Meerburg, Kijlstra 2007, EFSA 2008b). Several salmonella serotypes have been isolated from these animals, including S. Typhimurium DT104, strains which are commonly resistant to ampicillin, chloramphenicol, streptomycin, sulfonamides, and tetracycline (Poppe, Smart et al. 1998). Several case studies have shown that wild birds and rodents can carry salmonella in their intestinal tracts, mostly without showing any clinical symptoms of disease. In a Spanish study, the bacterium was isolated from wild bird and rodent droppings found near pig farms (Andres-Barranco, Vico et al. 2014). Interestingly, most of the salmonella strains isolated from birds were classified as of avian origin, and only a few of the strains were similar to those isolated from pigs, while the strains isolated from rodents were more commonly similar to the isolates from pigs. The common strains for pigs, birds, and rodents showed wider antibiotic resistance than the strains common only to birds. In the United Kingdom, a research group isolated S. Typhimurium DT104 from several pig farms over two six-monthly visits (Davies, Wales 2013). Salmonella was isolated from grain stores and feed stores, as well as from wild bird and rodent feces. In Japan, 13 of 28 rodents captured from the manufacturing area of an oilmeal plant carried salmonella in their feces (Morita, Kitazawa et al. 2006). In Sweden, which has a similar low prevalence of salmonella in the pig population to that Finland, salmonella was detected in only one out of 185 rodent samples collected during a study (Backhans, Jacobson et al. 2013). Salmonella enterica, analyzed by the PCR method, was detected from a mouse near a layinghen farm that had experienced a *S*. Typhimurium outbreak at the time of sampling. A similar finding, a salmonella isolation from one out of 282 animals, was obtained from organic pig and broiler farms in the Netherlands (Meerburg, Jacobs-Reitsma et al. 2006). The prevalence of salmonella in Finnish wild birds and rodents is unknown. However, salmonella is sometimes detected from these animals. In a small study conducted in 2016, salmonella was isolated once from a pooled sample of yellownecked mice, which were caught from a farm environment (Rönnqvist et al. 2017).

5.1.4 Salmonella in feeds

Most feed materials used for manufacturing pig feed are considered as prone to salmonella contamination (EFSA 2008a). According to a previous risk assessment, feed is the most important source of salmonella introduced into pig farms and thus into the food chain in countries where the salmonella prevalence is low, such as in Finland (Hill, Simons et al. 2015). The Panel on Biological Hazards concluded in their opinion on salmonella risk assessment in feeds that on the European level, salmonella is quite a common finding in many feed materials. Prevalence data on salmonella in feeds are, however, scarce.

Oil seeds, including soy beans, rapeseed, turnip rapeseed, and sunflower seed, as well as their extracts, have been identified as salmonella contaminated in several studies (EFSA 2008b). A Swedish study assessing the impact of salmonella-contaminated soybeans and other vegetable proteins on the risk of spreading salmonella in animal feed production indicated that the salmonella status of the crushing plants plays an important role in salmonella contamination of feed, despite the heat treatment often used in the production process (Wierup, Haggblom 2010). In two other Swedish studies, salmonella was isolated from one out of 20 pig farms and 3 out of 80 crop production farms (Elving et al. 2015; Elving and Thelander, 2017). The types that were isolated from the surface samples taken from silos were serotype S. Düsseldorf and subtype S. *diarizonae*.

In Finland, high-risk feeds are monitored for salmonella according to legislation. The Finnish Decree of the Ministry of Agriculture and Forestry on the pursuit of activities in the animal feed sector has described a list of categories to which high-risk feed materials belong (548/2012, Annex 3). These feed materials are obliged to be tested for salmonella before they can be imported to Finland. The use of the above-mentioned feed materials also obliges the feed manufacturers to take salmonella samples from the manufacturing process, including the storage areas, dust-removal systems, and the processed feed.

In 2013, the Feed and Fertilizer Control Unit of the Finnish Food Safety Authority Evira reported having taken altogether 3 435 samples from feed materials of plant origin and 291 samples of animal origin. At the same time, 1 064 samples were taken from compound feeds. In addition to the official salmonella sampling, feed business operators took thousands of salmonella samples according to the Finnish feed law (86/2008) and their own in-house control plans.

The Feed and Fertilizer Control Unit reported in total 10 positive salmonella findings (0.26%) from feed materials in 2013. Of these positives, 2/1 280 were detected from rapeseed briquette samples, 7/1 737 from soy meal and briquette samples, and 1/445 from molasses escalope samples. All of the positive batches originated from outside of Finland. The positive batches were contaminated with several salmonella serotypes: *S*. Senftenberg, *S*. Cubana, *S*. Mbandaka, *S*. Havana, and *S*. Typhimurium. Before 2013, during the 21st century, salmonella was also isolated from a few Finnish feed materials: from a mixture of oats and barley, from rapeseed, and from wheat dust as well as from wheat bran. Contrary to what was detected in Sweden in 2000–2005 (Wierup, Haggblom 2010), no salmonella positives were detected from compound feeds in Finland in 2013.

In 2014, the Feed and Fertilizer Control Unit reported two positive salmonella findings in their official feed material control: 1/2 279 samples of imported rapeseed meal and 1/137 samples of domestic wheat bran were positive for salmonella. Domestic wheat bran batches were also found to contain salmonella in in-house monitoring reports, provided by the feed business operators. Several salmonella-positive environmental samples from grain dust were reported. According to these in-house monitoring reports, one fish meal batch, 13 rapeseed meal batches, and two soy meal batches from abroad were also reported salmonella positive.

5.1.5 Salmonella in humans

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In the EU, salmonella are the most frequently reported causes of foodborne outbreaks with known origin (EFSA 2015). According to the World Health Organization, 0.76% of illnesses via food were caused by salmonella in the European region, the foodborne transmission route being the most important for the pathogen (Hald, Aspinall et al. 2016). In 2013, a total of 1 168 foodborne outbreaks of human salmonellosis were reported in the EU region (EFSA 2015). They constituted 22.5% of the total number of reported outbreaks of foodborne illness. Pork and pork products caused 8.9% of the foodborne outbreaks that had been ranked as strong evidence. In Finland, only two salmonella outbreaks originating from food, causing 9 and 4 cases of illness, were reported in 2013. Neither of the outbreaks were directly associated with pork.

According to a microbial subtyping approach originally described by Hald et al. (Hald, Vose et al. 2004), domestic (Danish) pork was the food most likely to cause illness in Denmark (15% of human cases), whereas in Sweden, a country in which the salmonella prevalence resembles that of Finland, domestic (Swedish) pork was estimated to cause less than one percent of the salmonellosis cases in humans (Wahlström, Andersson et al. 2011).

Despite the comprehensive monitoring of animal feed in the Nordic countries, feedborne outbreaks of salmonella occasionally occur. In Sweden in 2003, S. Cubana contaminated a feed plant, due to which the bacteria was spread to at least 49 pig farms (Osterberg, Vagsholm et al. 2006). As a result of statistical analyses performed to identify the risk factors for finding S. Cubana in pig herds after the initiation of the outbreak, an increased risk of farms being salmonella infected was seen for fattening farms and farms feeding soy.

In the early spring of 2009, a feedborne salmonella outbreak occurred in more than 40 layer and pig farms in Finland (Häggblom 2009). The reason for the outbreak was persistent *S*. Tennessee contamination in the production environment of a large feed mill. The outbreak led to massive renovations in the feed mill and costly eradication measures on the suspected and confirmed salmonella-positive farms.

5.2 Hazard characterization

Highlights:

- Salmonella causes gastrointestinal symptoms and sometimes chronic sequelae, but the infection can also be symptomless
- Salmonella is more likely to cause illness if the dose is high and if salmonella is consumed in protein-rich, liquid form foods than otherwise

5.2.1 Salmonellosis

Salmonella serotypes are traditionally classified in two groups according to the disease they cause to humans: typhoidal salmonella and non-typhoidal salmonella. Typhoidal salmonella, S. Typhi and S. Paratyphi A, B, and C, cause enteric fever, a dangerous disease that can lead to death of the infected host (Bell, Kyriakides 2001). In Finland, typhoidal salmonella infections are almost exclusively acquired from abroad and are thus not a hazard in pork products consumed in Finland (Jalava, Vuorela et al. 2013). They are not discussed further in this risk assessment.

Non-typhoidal salmonella serotypes that are able to infect humans cause salmonellosis, a gastroenteritis in which the most typical symptoms are an acute onset of fever, abdominal pain, diarrhea, nausea, and sometimes vomiting (WHO 2013). The disease is in most cases self-limiting, but can progress to systemic infection in patients whose immune status has been lowered. Especially newborn babies, young children, pregnant women, elderly people, and immunocompromised persons belong to the susceptible subpopulation associated with an increased risk of developing a more severe form of the disease. According to a WHO report, S. Typhimurium strains resistant to several antibiotics have been associated with a higher risk of invasive infection, a higher frequency and duration of hospitalization, longer illness, and an increased risk of death as compared to infections caused by susceptible strains (WHO 2014a). The infective dose is usually high, more than 10⁵ cells. However, lower doses have been observed to cause infection when present in certain foods, such as chocolate (Bell, Kyriakides 2001). It thus seems that salmonella in fatty foods may be better protected against the acidic environment of the stomach and become invasive in the intestine, regardless of the damage caused by the acids. The incubation period for the disease is 6-72 hours. The quantity of salmonella cells digested is inversely proportional to the incubation period and directly proportional to the severity of the symptoms. The symptoms last from 4 to 10 days, in some cases even longer. In the acute phase of the disease, a patient suffering from salmonellosis can excrete up to 10° bacterial cells per gram of feces. After the symptomatic phase, patients become asymptomatic carriers of the pathogen for several weeks, and even months (Jalava, Vuorela et al. 2013). Around 50% of patients are carriers of the pathogen after 2-4 weeks. Chronic sequelae, which may emerge after gastroenteritis symptoms, increase the severity of salmonella infections. About 30% of patients infected with salmonella develop reactive arthritis, whereas 3% of patients also suffer from Reiter's syndrome, which affects the urinary system and skin (Dworkin, Shoemaker et al. 2001). Sequelae affecting the joints are connected to human tissue type HLA-B27, as reviewed by Korkeala (Korkeala 2007). Reactive arthritis is a common sequela in the Finnish population: it develops in almost 10% of salmonellosis cases. Death is an uncommon consequence of salmonella infection in countries with high hygiene levels and good health care, but it is still a threat to vulnerable groups.

5.2.2 Dose-response relationship

The infectivity and pathogenicity of salmonella can be characterized in a doseresponse assessment. This describes the relationship between the number of bacteria ingested and the likelihood of a certain outcome, i.e. infection or illness. The doseresponse relationship for salmonella has been investigated in volunteer studies for decades, the first large studies being carried out by McCoullough and Eisele in the 1950s (Bollaerts, Aerts et al. 2008). Volunteer studies have been criticized for using only healthy young adults, whose immune system may be quite resistant towards the illness. Moreover, volunteer studies have only been conducted with high doses of salmonella, which have been extrapolated to all doses, not revealing the possibly different probability of infection with low doses. More comprehensive information on the dose-response relationship can be achieved using outbreak data, assuming that enough is known of the total exposed population and the dose that has been consumed. Although the uncertainty in the estimates is often large, these studies cover several food matrices, age groups, and doses. Bollaerts et al., who used data acquired from 20 salmonella outbreaks in dose-response estimates, observed that the proportion of ill subjects after consuming salmonella-contaminated food is dependent on the food matrix (Bollaerts, Aerts et al. 2008). Protein-rich, liquid-form matrices such as soup and sauce were observed to result in the highest proportion of ill subjects.

Teunis and colleagues suggested that separate dose–response models should be used for infection and illness (Teunis, Kasuga et al. 2010). They used the data acquired from 38 salmonella point-source outbreaks to determine the salmonella dose that would probably result in an infection and illness given that infection occurred. The results varied from less than 1 cfu to 10⁴ cfu for illness, but the dose was somewhat lower, from less than 1 cfu to less than 900 cfu, for infection only.

5.3 Exposure assessment

Highlights:

- A mathematical model of feed flow was constructed based on the national average proportions of feed materials and compound feeds used for pig production
- The exposure to pigs was calculated using both the prevalence estimate of salmonella in feeds as well as the concentration estimate in contaminated feed lots
- Human exposure was estimated by combining the results of the feed model and a point estimate of the proportion of human cases attributable to the domestic pig reservoir as a whole.

5.3.1 Exposure modeling

The risk assessment modeling, which consisted of three parts, was carried out with OpenBUGS and Doodlebugs software (Fig. 4). The results obtained using the model were presented as probability distributions.

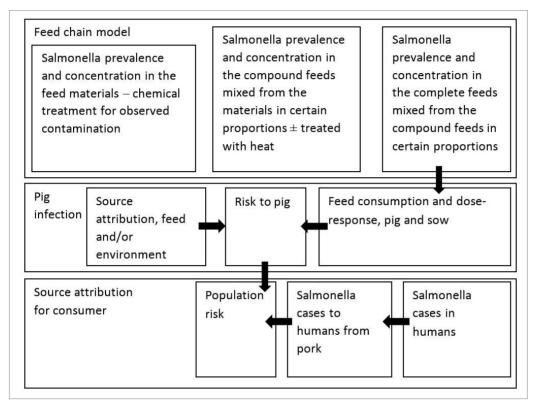


Figure 4. Schematic overview of the risk assessment model.

The feed model was used to estimate the true salmonella prevalence of feed materials, compound feeds, and complete feeds contaminated with salmonella on the basis of 2013 data. It was also used to estimate the concentration of salmonella in these three, and the changes in concentration: 1) for chemical treatment of observed contamination in feed materials and 2) for compound feeds during processing, depending on whether heat treatment to reduce the levels of micro-organisms was used. The prevalence model takes into account the number of salmonella tests from feed materials and compound feeds, as well as the detection probability depending on the concentration, given that contamination exists. The feed chain model relies on two main structures: a stepwise model for the prevalence from feed materials to complete feeds, and a stepwise model for concentrations for contaminated batches. The combined result for the feed risk is a multiplication of the probability of contamination occurring in a batch, i.e. the prevalence in complete feed, and the probability of infection given the dose in such a situation. Note that here, for the risk assessment modeling, a batch is 25 tons (and refers to amount of material one sample represents as explained further in the section 5.3.6 and appendix 3).

The pig model evaluated the probability of infection from the feed consumed during the rearing period. This was weighed against the probability of infection due to other

sources, e.g. the environment: the whole model also estimates the true salmonella prevalence in pigs and sows in Finland, which is then a combination of both feedborne risk and other risks.

To further investigate the relative importance of the two infection routes, a source attribution model utilizing salmonella subtyping results was inserted into the whole model. In the source attribution model, the salmonella subtypes isolated from pigs were compared with the subtypes that have been isolated from the feed chain (including feed materials and some other samples described in section 5.4.5) and with the subtypes that have been isolated from wild animal samples representing the environmental reservoir. The proportion of the feedborne risk from the total risk (feed + other) is a measure for the relative proportion of feedborne infections, but this can be fairly uncertain due to the lack of detailed case reports and follow-up data on actual infection sequences at farms. Also, when all infections are rare, it is even more difficult to estimate their relative sources.

The human salmonellosis cases attributable to pork were calculated using a point estimate of the proportion of human cases attributable to the domestic pig reservoir as a whole. The point estimate was in turn used to approximate the number of human salmonellosis cases attributable to pig feed. The point estimate was based on typing data from human salmonellosis cases (Finnish National Infectious Diseases Register 2014). These typing data were compared to the typing data from salmonella-positive animals and products of animal origin (pigs vs other sources, Evira).

5.3.2 Data used in the exposure assessment

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The data utilized in the risk assessment were gathered from several sources, such as national monitoring databases and the scientific literature (Table 10). As described in chapter 2, to fill in the data gaps, a survey of (compound) feed-producing mills and pig farms was carried out and experts in the field were interviewed.

Table 10. The data in the risk assessment	t model (Figure 4) and their sources.
Data	References
Number of positive findings from feed material (category) or compound feed (category)	National monitoring (years 2013–2014), Evira
Number of tests from feed material (category) or compound feed (category) in total	Decree 548/2012 15–19§ National monitoring (years 2013–2014), Evira Survey of feed manufacturers Survey of pig farmers
Concentration measurements from feed material	Burns et al., 2015 Schelin et al., 2014 Jones et al., 2004 Hansen et al., 1995
Concentration measurements from compound feed (categories)	Samples from contaminated industrial feed have been quantitatively analyzed at the Swedish National Veterinary Institute (Per Häggblom)
Relative portions of the feed material (categories) in compound feed (categories) or compound feed (categories) in complete feed (categories)	Feed recipes collected by national monitoring, Evira Recipes were country averages, which were calculated from 5–10 feed-specific recipes provided by feed manufacturers and feed producing pig farms Survey of pig farmers
Relative proportion of farms using a feeding type (complete feed category) of all pig farms	Survey of pig farmers Finnish pig registry
Daily amount of feed for sows and pigs	Carr, 1998
Number of positive findings in pigs	National monitoring (years 2013–2014), Evira
Number of pigs tested in total	National monitoring (years 2013–2014), Evira
Effect of heat treatment or chemical treatment	Survey of feed manufacturers Himathongkham et al., 1996 National monitoring, Evira Hansen et al., 1995 Pumfrey and Nelson, 1991 Larsen et al., 1993
Length of average rearing period for	Personal communication (Mari Heinonen, Faculty of
pigs and sows	Veterinary Medicine, University of Helsinki)
Average farm size (for pigs or for sows)	Finnish pig registry
Sensitivity of pig lymph node testing	Enøe, 2001
Data for dose–response model	Loynachan et al., 2005
Data for sensitivity model	Koyuncy and Häggblom, 2009
Data for typing based-model	National monitoring (years 2011–2015), Evira and THL. Serotyping of salmonella strains isolated from pig lymph nodes, wild animals and samples representing feed was carried out by Evira. For some serotypes further phage typing was carried out by THL. Salmonella-positive pig and 'feed' samples were from the authorities and the industry, whereas wild animal samples were gathered on a voluntary basis
	from the authorities and the industry, whereas wild animal samples were gathered on a voluntary basi

Table 10. The data in the risk assessment model (Figure 4) and their sources.

5.3.3 Feed recipes used in the feed model

Feed recipes were collected from the national monitoring archive in Evira, combined into average recipes, and commented on by an expert from the feed industry. These recipes were used to evaluate the proportional usage of each feed material in the complete feed manufacturing process. In recipes used in component feeding, the proportions of each ingredient from commercial complementary feeds and farm feed materials were taken into account to calculate the total proportion of each feed material in the served complete feed. Table 11 presents recipes of three examples of the 11 complete feed categories used for the feeding of pigs. The full list of feed material (categories) included is provided in the appendix 5 (section 10.5).

According to the data collected during the project, the feeds used for the feeding of pigs in Finland consisted of roughly 150 feed raw materials, of which 56 were included in the risk assessment. These feed raw materials were further classified according to their similarities and origin into 24 groups (categories) of feed materials, which included, for example, domestic cereals. Feed materials for which a proportion was produced domestically and a proportion was bought outside Finland were handled as separate feed material (categories). Also, complete feeds that were acquired from abroad and purchased as such for feeding the pigs on the farms were regarded as separate, although representing a marginal category. Oils, premixes, minerals, and other materials, such as vitamins, enzymes, or synthetic amino acids, were excluded from the risk assessment, as their manufacturing processes were regarded to pose no salmonella risk for feed manufacturing.

In the model, an additional step of feed mixing was implemented in the model. In a component feeding system, complementary feeds are first produced by a feed mill from feed materials, after which they are transported to the farm to be mixed with, often local, feed materials by the farm itself or by a mobile mixer. These complementary feeds could not be described as feed materials in the model, as they are themselves mixtures of feed materials, and neither could they be described as complete feeds, as they are not fed to pigs as such. Therefore, 'compound feeds' were created as categories. The compound feeds were composed of the feed materials in given proportions. Regarding complete feed brought from abroad, the corresponding 'compound feed' category was simply 100% composed of the complete feed itself. Similar to previous step, where compound feeds were regarded as composed of feed materials, the complete feeds were regarded as composed of themselves. The composition of categories is illustrated in Figure 1 in the appendix 5 (section 10.5). **Table 11.** Typical feed recipes for pigs in Finland. The list consists of 12 of the most commonly used feed materials in each feed. Less used materials, including enzymes and pre-mixtures bought as such from abroad, are listed under the group "others".

Ingredient	Commercial pelleted complete feed for sows (%)	Component dry feed for fattening pigs (%)	Component fermented liquid feed for fattening pigs (%)	
Barley*1	24.1	52.6	40.8	
Bran*1	5.6	0.8	0.2	
Oats*1	25.7	7.2	3.1	
Protein feed from barley*1	0.0	12.6	8.7	
Rank*1	0.0	0.0	12.5	
Rapeseed or turnip rapeseed*1	1.0	0.8	0.2	
Rapeseed or turnip rapeseed*2	0.8	0.8	0.2	
Soy*2	8.0	5.6	3.2	
Sugarbeet*1	3.4	0.0	0.2	
Sugarbeet*2	1.5	0.0	0.0	
Wheat*1	22.6	8.3	6.5	
Whey*1	0.0	3.1	20.1	
Others	7.3	8.2	4.3	

*1Domestic ingredient;

*2ingredient imported from outside Finland

5.3.4 Survival of salmonella in the feed processing environment

The concentration of salmonella in feed that is produced in a feed mill and transported to piggeries or mixed from components on a farm is dependent on both the factors allowing the growth and transfer of the pathogen in the feed materials and compound feed as well as the inactivation treatments of the feed during processing. The effectiveness of the inactivation treatments, such as heat treatment and chemical treatment, are in turn dependent on the temperature, pressure, moisture, time, and the presence and concentration of different chemicals, as well as the number of bacteria in the feed. In control guidelines published by the American Feed Industry Association, the features of the feed such as the fat levels, presence of salts, presence of carbohydrates, pH, and protein content have also been stated to have an impact on the success of decontamination actions (AFIA 2010).

As salmonella bacteria can survive in the soil for as long as two years and are occasionally present in the intestines of birds, reptiles, and mammals, even in countries with a low salmonella prevalence, sporadic contamination of feed materials that are grown on fields is difficult to avoid (Fink-Gremmels 2012). The effect of this low contamination of feed materials on the salmonella status of the finished feed depends on whether the storage conditions of the materials and feed are such that the organism can grow. If the storage temperature is not controlled by heating or cooling, the temperature of the storage is often above the 7 °C at which salmonella can grow. Therefore, the most important factor regulating growth is the moisture level. Feed materials that are stored without further processing after harvesting in silos, such as grains, are targeted to have an aw value lower than 0.94, which is needed for salmonella growth (Eisenberg 2007). Effective ventilation of the storage areas is needed to prevent condensation, which could form on the surfaces. To be able to maintain a

low moisture level in the feed storage areas, water cannot in general be used for cleaning. In some cases, for example in an oilmeal manufacturing plant, water used as steam has been seen as effective means for controlling salmonella. Morita et al. concluded that this method could be used to control the salmonella contamination on the processing floor, which was seen as the greatest risk for contamination of oilmeal feed (Morita, Kitazawa et al. 2006).

Himathongkham et al. observed that the relationship of the logarithmic decline in surviving salmonella when heat treated was linearly dependent on the logarithmic increase in the exposure time (Himathongkham, Pereira et al. 1996). The increasing destruction of salmonella cells was in turn directly dependent on the increase in temperature. Up to a 4-log reduction in S. Enteritidis was observed in the study. when the contaminated feed was treated at a 15% moisture level and at 82.2 °C for more than two minutes. According to the American Feed Industry Association, a 6-log reduction in the concentration of any contamination level of salmonella in feed would guarantee that no salmonella-positive test results could be attained from the treated batch (AFIA 2010). Single severely dehydrated bacterial cells could still survive, but would not be likely to grow in later steps of the feed manufacturing process. The decontamination in heat treatment was modeled based on data from Himathongkham, Pereira et al. (1996), and decontamination in chemical treatment for observed positives was modeled based on data from Hansen et al. (1995), Pumfrey and Nelson (1991), and Larsen et al. (1993). A 3.5-log reduction was estimated to occur in heat treatment for industrial categories of compound feed (j=1-5, first 5 listed in appendix 5), and a 1.3-log reduction in chemical treatment for feed materials observed to be positive.

In Finland, the commercially available pelleted feeds are almost always heat treated. The threshold for the demand for heat treatment of feed is annual production of six million kg (86/2008, 23 §), which in practice only rules out the piggeries that produce feed for their own use and are regarded to be a salmonella risk to a very small number of pigs. Salmonella-contaminated feed materials are treated with formaldehyde based products until salmonella can no longer be detected and are only then released to the market. Formaldehyde was used for decontamination before 1.7.2015 (it was used at the time period this risk assessment is based on), after which its use became restricted due to changes in the biocide legislation (2013/204). Subsequently, permission for the use of formaldehyde as a hygiene improving substance has been applied from the EU, but a decision has not yet been reached in 2017.

The efficacy of acidic chemicals in reducing the level of salmonella in different feed materials has been studied since the 1970s. In a recent study, formic acid was observed to lower salmonella levels in pelleted and compound mash feed $(2.5-\log_{10} reduction)$, rapeseed meal $(1-\log_{10} reduction)$, and in soybean meal (less than $0.5-\log_{10} reduction)$) (Koyuncu, Andersson et al. 2013). The effect was lower at 5 °C and 15 °C compared to room temperatures, increasing the risk of failure in decontamination during cold months when the feed is treated at non-controlled temperatures.

Cross-contamination between salmonella-contaminated feed materials and heattreated or acid-treated feed can be a problem in factories, where the ventilation or the material flows are not properly constructed (EFSA 2008a). Recontamination of

pelleted feeds after heat treatment may result in the growth of salmonella at later stages of the feed production chain, such as in the storage spaces on farms. The salmonella strains that are capable of forming biofilms are especially problematic when combating cross-contamination, because they may not be detected by sampling the feed mill environment, but pathogen cells can occasionally detach from the surfaces to feed and contaminate the batch.

5.3.5 Feed consumption

This risk assessment focused on the feed consumption of sows and fattening pigs, as it was assumed that the piglets that become infected with salmonella will become free of the infection before slaughter age, and thus do not pose a threat to consumer health via consumed pork (Kranker, Alban et al. 2003).

The complete feeds that were utilized in the risk assessment as well as the percentages of their use for sows and fattening pigs on Finnish farms (%) were the following: commercial complete feed for sows (35%) and fattening pigs (11%), on-farm component feeds completed with commercial complementary feeds for sows (dry 26% and liquid 12%) and fattening pigs (dry 27% and liquid 20%), and types of liquid fermented feed (25% for sows, 40% for fattening pigs). There were also complete feeds brought from abroad (less than 0.1% for both sows and fattening pigs), and other farm-made feeds (2% for both sows and pigs).

In Finland, the daily intake of feed for sows and fattening pigs was calculated as feed units (ry) in 2013. One feed unit corresponds to 9.3 MJ of net energy. Because the contamination of feed with salmonella was expressed as colony forming units (cfu) per gram in the risk assessment, kg of feed consumed per day was used instead of feed units in dose–response calculations and risk estimations. The feed consumption in kg for fattening pigs and sows was adapted from Garth Pig Stockmanship Standards (Carr 1998).

5.3.6 Exposure assessment for pigs from feed

The exposure of pigs to salmonella from feed is considered highly dependent on the prevalence of the pathogen in the consumed feeds, which is in turn dependent on the prevalence and concentration of salmonella in the feed materials, as well as the success of the possible inactivation treatments, such as heating. The true prevalence of salmonella in feed material (categories), compound feed (categories), and complete feed (categories) was estimated using the risk assessment model, including the prevalence data collected from the 2013 situation as well as data on the effect of feed processing.

As previously described, in Finland, one sample per 50 000 kg or, when feed is delivered directly to the farm or mobile mixer without any treatment, one sample per 25 000 kg is taken from high-risk feeds according to decree (548/2012). If sampled by the 1/50 000 kg custom, 50 samples would be taken from a 2 500-ton consignment, whereas if the 1/25 000 kg custom was used, the number of samples would be 100. The size of the analytical sample from feeds is 25 grams. The number of samples for prevalence estimation was approximated by 1/25 tons (each sample

then representing one 25-ton batch) for both feed materials and industrial compound feed (categories). The laboratory sensitivity of the salmonella testing was used to describe the total test sensitivity in the estimation. The laboratory sensitivity of the testing has been estimated using data on cultural methods from the literature (Koyuncu, Haggblom 2009), including all test results for contamination levels up to 10³ cfu/25g (excluding palm kernel meal) with different materials and serotypes.

The concentration of salmonella in the feed was also estimated, as more than one salmonella cell is probably needed to infect a pig via feed (Loynachan, Harris DL. 2005). In Finland, one of the few countries intensively testing for salmonella from feeds, the testing is based on the ISO 6579:2002 method, which detects the presence or absence of salmonella cells in a sample, not the concentration. However, a few concentration measurements have been performed from Finnish salmonellacontaminated feed samples (Microbiology Research Unit, Evira). The concentration of salmonella in three samples of contaminated feed, detected with a polymerase chain reaction method, was 2-2.4 cfu (95% confidence level 0.25-17) per 100 g sample. These measurements were used to represent contaminated industrial compound feed (categories). Simultaneously, gathered literature information on the concentration in contaminated feed materials was also used to predict the concentration in contaminated compound and complete feeds. Data from Burns et al. (2015), Jones et al. (2004), Hansen et al. (1995), and MPN-PCR results from Schelin et al. (2014) were included: fifteen measurements with around 20 MPN per 100 g on average, and four censored measurements (cfu g⁻¹/MPN g⁻¹), also utilizing concentrations of Enterobacteriaceae in salmonella-positive samples, were taken into account. The microbial lower limit of 1 cell/sample size in grams and, for the maximum limit, growth to 10⁹ salmonella/g reported by Himathongkham et al. (1996) were utilized. The majority of measurements were from soy products. The measurements were pooled as one data set, and this data set was assigned for each of the feed material categories.

The exposure of pigs from feed changes during the pigs' life, not only due to the changes in the composition of the feed, but also due to the amount of feed the pig consumes at different ages. The salmonella dose for a pig per day from the same contaminated feed is higher for an older pig than for a piglet. An average piglet only consumes its mother's milk in the first week of its life. At the age of 7 days, a piglet starts to eat feed that is suitable for suckling piglets. From the age of 7 days to 28 days, the daily amount of feed typically rises steadily from 0.1 kg per day to 0.3 kg per day per piglet. The composition of the feed for piglets is typically changed at the age of 28 days, when the piglets are weaned. Before the transition to the finishing compartment or to a finishing farm, the piglet consumes about 1 kg of feed per day (Carr 1998). During the last 15 weeks of the assumed 180-day rearing period, the average amount of feed consumed by the pig typically rises gradually from some 1 kg per day to 3.5–4.5 kg per day at the end of the rearing before slaughter. A sow consumes on average 4 kg of feed per day, but the amount and composition varies depending on the stage of production, such as gestation and lactation. In the model, the following average consumptions of feed were used: for pigs, the average feed consumption was modelled as a gradual rise in consumption from 1 kg to 4 kg during the 180 days of the rearing period, with six feeding amounts for the days of each month. For sows, an average consumption of 4 kg feed per day was used throughout their life as a sow, i.e. 720 days.

The probability of pigs becoming infected with salmonella via feed has been observed to increase when the concentration of the pathogen in the feed increases (Loynachan, Harris DL. 2005, Österberg 2010). The dose–response model for pigs that was used in the risk assessment in this work was based on the data produced in the experimental work (of the analyses provided, tonsil samples were included) of Loynachan and Harris (2005), who observed that a dose of 10³ bacterial cells in feed was high enough to cause infection in one out of ten pigs tested, while a 10⁵ dose caused observable infection in six out of ten of the pigs. A more recent study demonstrated that a one log higher dose, i.e. 10⁶ cells, was high enough to infect five out of six pigs tested, and only a considerably higher dose of salmonella, 10⁹ cells, infected all six pigs (Österberg 2010).

Acidic components in the feed and drink of pigs have been shown to decrease the probability of pigs becoming infected with salmonella (Michiels, Missotten et al. 2012, Rasschaert, Michiels et al. 2016). In a study by Rasschaert et al., a feed blend based on medium-chain fatty acids and lactic acid, which was fed to pigs during the whole fattening period, significantly reduced the salmonella prevalence both at the farm and at the slaughterhouse. As quantifiable data on the actual decrease that acidic feeds could induce in the probability of infection is lacking, the effect was not taken into account in the risk assessment model.

5.3.7 Relative exposure for pigs from feed and the environment

Little data is available on the exposure of pigs to salmonella from the environment. Most of the studies on the environmental exposure have been carried out in countries where the salmonella prevalence in pigs is considerably higher than in Finland. According to data collected for a conceptual model on the transmission of salmonella in the pig feed chain, pest animals such as mice, rats, and some wild birds can carry salmonella in their intestine and contaminate the piggery's environment (Binter, Straver et al. 2011). Introduction routes for salmonella contamination on pig farms other than feed are via new animals, people such as temporary caretakers and veterinarians, transportation vehicles, bedding materials, and pets. In the estimation of the relative exposure of pigs from feed and the environment, typing data from salmonella-positive findings from the pigs were compared with those isolated from 'feed' and wild animals (Table 10). There were seven pig and ten sow lymph node findings, and over 100 isolates representing feed and over 100 from wild animals. For example *S*. Agona was frequent for 'feed' and *S*. Typhimurium for wild animals.

5.3.8 Exposure assessment for humans from pork (Source attribution)

Source attribution is a term that describes the partitioning of the human disease burden of one or more foodborne infections to specific sources, where the term "source" includes animal reservoirs and vehicles (EFSA 2008b). Several approaches can be used in source attribution studies, such as outbreak investigations, analytical epidemiology, expert opinions, comparative exposure assessment, and microbial subtyping. In microbial subtyping, each potential source with certain microbial characteristics is described and compared with the characteristics of the serotypes that infected the human cases. Such a study was performed in Sweden, where it was concluded that 0.08% of all sporadic domestic salmonellosis cases were associated with domestic pork (Wahlstrom, Andersson et al. 2011). The attribution of pork was similar to that of cattle (0.1%) and broilers (0.09%).

According to the statistics, an average Finn ate 35.6 kg of pork in 2013 (Lihatiedotusyhdistys 2015). The human salmonellosis cases attributable to pork were calculated by comparing the salmonella subtypes isolated from human cases with those isolated from various sources, including pigs. The data were composed of 58 salmonella subtypes isolated from 191 live production animal samples (pigs, cattle, broilers, turkeys) combined with 4 subtypes (5 samples) from domestic products originating from the same animal species, as well as from 64 subtypes (231 samples) from imported products of animal origin (pigs, cattle, broilers, turkeys) isolated in 2008–2015, and 86 subtypes isolated from 750 domestic human cases in 2012–2014. Four subtypes isolated from eight human cases were unique to the domestic pig reservoir. A total of 424 human cases were caused by 70 salmonella subtypes that had never been isolated from the pig reservoir. The 318 human cases representing 12 subtypes isolated from both the pig reservoir and some other sources were attributed to eight different sources according to the relative share of the subtypes within the reservoir in the estimation. As a result, the proportion of human salmonellosis cases due to domestic pork was estimated at 14%. Finally, the point estimate of the proportion of human cases attributed to pork via live pigs was combined with the estimation of the proportion of pig infections attributable to feed in order to estimate the proportion of human salmonellosis cases attributable to pork via pig feed.

The point estimate (14%) was compared to a result that was obtained from a source attribution model described in another project (Mikkelä et al. 2011). Besides the microbial typing data, comparative exposure assessment was utilized in the final model. In brief, data were collected on the following: the number of herds and individuals of bovines, pigs, broilers and turkeys in Finland in 2013, the number of fecal and slaughterhouse samples taken from these domestic animals and tested for salmonella, the amount of imported raw and cooked meat of these animals and the tests taken from these meats, the salmonella-positive findings and their serotypes, the number of persons who had fallen ill with salmonella, and the serotypes causing the illnesses. The exposure results obtained from the previous farm-to-fork risk assessment models (Maijala, Ranta 2003, Ranta, Tuominen et al. 2004, Tuominen, Ranta et al. 2007), using updated data, were used as inputs in the source attribution model. In combination with the method for the typing data, the overall proportion of human salmonellosis cases attributable to pork was estimated, and it was 12% (3–19%).

5.4 Risk characterization

Highlights:

- The true prevalence in pigs and sows in Finland was estimated as low
- On average, feed was more important for infection of sows in comparison to pigs
- Around 5% of human domestic salmonellosis cases could be associated with pig feed

The objective of the study was to quantify the impact of salmonella-contaminated pig feed on the risk of human salmonellosis caused by the consumption of pork. The quantification was carried out in two parts, of which the first estimated the relative share of salmonella infections in pigs that could have been caused by salmonella contamination in feed. The second part estimated the salmonellosis cases in humans that could have been caused by salmonella-contaminated pork. The risk of a pig becoming infected with salmonella from feed is dependent on the incidence and concentration of the pathogen in the consumed feed, which in turn is dependent on the salmonella contamination in the feed materials, the growth and reduction of bacterial levels in the feed during processing and storage, and cross-contamination between the feed and environmental factors, such as pests, pets, storage spaces, and processing equipment. In this risk assessment, the estimate of the risk of a pig becoming infected with salmonella was formed using data on the salmonella prevalence in feed materials and processed feeds, as well as on pig and sow lymph node samples collected in abattoirs. Data on the concentration of salmonella in feed materials and industrial feeds, as well as changes in the concentration due to treatments, were also included in the estimate.

5.4.1 Salmonella prevalence in feed materials, compound feeds, and complete feeds

The salmonella prevalence and its uncertainty, shown for the 10 groups (categories) of feed materials arranged in the table according to the origin (domestic/nondomestic), is presented in Table 12. The full list of feed materials included in the group "others" is provided in the appendix. As seen from the table, the salmonella prevalence was estimated to be higher in non-domestic protein-rich feed materials than in domestic ones. The prevalence in the grain feed materials, which are used in feed recipes in large quantities, was estimated as rather low. As the non-domestic materials were more often tested than the domestic ones, their estimate of the salmonella prevalence included the least uncertainty. The highest uncertainty was related to those feed materials for which only a small data set was available.

The estimated prevalence of industrial dry complementary feed for sows was 0.2% (mean, 95% CI: 0.1–0.3%) and for pigs 0.3% (95% CI: 0.2–0.4%). These complementary compound feed (categories) are not included in Table 12, as they are not fed to pigs as such but are mixed with farm-produced grains and other components before serving them. This is also the case with the liquid complementary feed, protein feed from barley, in which the salmonella prevalence was estimated at 0.01% (mean, 95% CI: <0.01–0.07%). The mean salmonella prevalence in the served pig feeds i.e. the complete feed (categories), produced and/or on-farm mixed in Finland, was estimated to range from 0.02% to 0.10% (Table 12). The low number of samples in non-domestic complete feed category and the resulting high uncertainty of the prevalence are derived from the very low amount of this feed used on pig farms.

Feed material, non-domestic	L/D*2	Mean	Median	CI 2.5%	CI 97.5%
Rapeseed or turnip rapeseed	D	1.37	1.35	0.99	1.87
Soy	D	0.44	0.43	0.25	0.71
Sugar beet	D	0.18	0.14	0.01	0.56
Feed material, domestic					
Bran	D	0.68	0.65	0.30	1.23
Barley	D	0.01	0.01	<0.01	0.02
Oats	D	0.01	0.01	<0.01	0.02
Rapeseed or turnip rapeseed	D	0.02	0.01	<0.01	0.12
Sugar beet	D	0.05	0.02	<0.01	0.25
Wheat	D	0.01	0.01	<0.01	0.02
Others*4	L/D				
Complete feed (usage % on farms)					
Commercial complete feed for sows (35)	D	0.10	0.10	0.07	0.15
Commercial complete feed for pigs (11)	D	0.08	0.08	0.06	0.12
Farm-made feed ^{*3} + complementary feed for sows (12)	L	0.03	0.03	0.02	0.06
Farm-made feed + complementary feed for pigs (20)	L	0.04	0.03	0.02	0.06
Farm-made feed + complementary feed for sows (26)	D	0.04	0.04	0.03	0.06
Farm-made feed + complementary feed for pigs (27)	D	0.05	0.05	0.04	0.08
Farm-made feed + liquid complementary feed, sows & pigs (25 or 40)	L	0.02	0.02	0.01	0.05
Others*4	L/D				

Table 12. Mean, median, and 95% credible interval for the estimated true batch prevalence^{*1} (%) of *Salmonella* sp. in feed materials and complete feeds for sows and pigs (growers and finishers).

*1 Based on the Bayesian risk assessment model

*2 Feed is served to pigs in liquid (L) or dry (D) form

*3 without an industrial complementary

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*4 The full list of feed material (categories) and complete feed (categories) included is provided in the appendix.

In the risk assessment model, the salmonella prevalence was not assumed to change during the inactivation steps in feed processing, but rather the concentration of the bacteria in contaminated feed batches decreased. Depending on the materials mixed and treatments aiming to minimize the concentration of bacteria in feed materials and compound feeds, the mean for the estimated log concentration of salmonella in contaminated complete feed batches of different categories ranged from less than -4 up to around -1 log₁₀ cfu/g (95% CI limits ranging around from -7 up to 2 log₁₀ cfu/g).

5.4.2 Salmonella prevalence in pigs and sows

Taking into consideration the estimated true prevalence and concentration of salmonella in feeds, the average feed serving sizes for pigs and sows, and the probability of infection using the dose–response plot in relation to the ingested amount of feed, the probability of salmonella infection was calculated using the risk assessment model. The true prevalence, interpreted as the overall probability of infection, was estimated at 0.25% (mean, 95% CI: 0.09–0.50%) for pigs and 0.48% (95% CI: 0.18–0.99%) for sows. For comparison, the sample prevalence was approximately 0.05% (see section 5.1.3).

5.4.3 Relative share of salmonella infections in pigs due to feed or the environment

It was estimated that on average, 34% (posterior mean, 95% CI: 10–66%) of the infections in pigs and 57% (95% CI: 21–92%) of the infections in sows can be attributed to feed and the rest to other sources, such as the environment. The posterior densities for the proportion of infections attributable to feed estimated using the risk assessment model are presented in Figure 5.

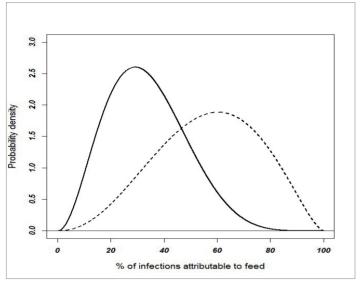


Figure 5. The posterior densities for the proportion of infections attributable to feed estimated using the Bayesian model. The solid line is the proportion estimated for pigs and the dashed line for sows.

5.4.4 Salmonella infections in humans via pig feed

To estimate the human salmonella infections attributed to pig feed via pork, the true prevalence and concentration of salmonella in pig feed, the probability of infection for pigs after consuming the feed, the relative contribution of the environment and feed to the number of infections, and the estimated true prevalence of salmonella in pigs were all integrated in the calculation. The proportion of human salmonellosis cases due to domestic pork, which was estimated as 14%, was included as a pre-calculated point estimate. As a result, 4.7% (mean, 95% CI 1.3–9.1%), of the 300–400 domestic human salmonellosis cases reported per year (Finnish National Infectious Diseases Register 2014) were estimated to be attributable to pig feed.

5.4.5 Assumptions and limitations

The risk assessment model that was used for Bayesian quantification of the uncertainties is described in sections 1–4 of Appendix 3. Some model sensitivity analyses are presented in section 5 of the appendix.

The feed recipes used in this risk assessment were averages from all those recipes that were available at the time of the assessment. Each average recipe was calculated using information from 5 to 10 separate recipes, which were obtained from various

industry sources, including the recipes obtained via the questionnaires. Individual feed recipes used on pig farms and also in feed mills could have varied considerably from the average recipes. Moreover, feed recipes can change over time, for instance due to changes in the relative prices of feed raw materials. Also, the geographical location of the farms, including whether there were barns for lactating cows or bakery activity nearby, may have changed the feed recipes used on individual pig farms. Furthermore, although it is known that some pigs eat feeds of different composition at the beginning and end of the rearing period, only one average recipe was used for the whole rearing due to the lack of representative differences in the two or even three types of recipes and the quantities of each used on farms. Due to the same reason, the average feed recipes for sows were averages of all of the feeds used during the different production phases, such as gestation and lactation.

With the current simplified test sensitivity evaluation, roughly around half of the contaminated feed material batches were estimated to be observed (\overline{s}' ,95% 0.4-0.7). As the laboratory testing was used for sensitivity, and moreover, concentration measurements from observed positives were used for the concentration in contaminated batches, there is notable uncertainty related to the estimated true prevalence in feed batches. Also, the total number of samples was approximated as one per 25 tons (assumed as representative of 25 tons) for all categories of feed material batches. also concerning the monitoring of domestic production (including liquid by-products). enabling a rather simplified straightforward comparison. Since the amount of material that one sample analyzed in the laboratory aims to represent is massive, the true status on the scale of only a few bacterial cells is challenging to identify (e.g. concentrations could alternatively have been modelled). The prevalence of salmonella in most of the feed materials, such as foreign soy, has been calculated using findings from the sampling of the feed material itself, whereas the salmonella prevalence of domestic grains has been calculated using findings from grain dust sampling. In general, also findings have been assumed to represent 25 tons, although positives from ships with further available information on sampling per 50-ton batch were multiplied (assuming 2 500 t shipments where only the number of samples was available). According to the decree (548/2012), some feed materials such as vegetable oils are not included in the sampling of salmonella from feed materials and have been assumed as clean.

The assessment relied on available data concerning the pig farmers and feed producers. The surveys for pig farms and feed producers concerned the year 2013 (the year that was used as the basis for the risk assessment, e.g. for recipes). Therefore, information gained in these was used to complete the missing data for the year 2014 (e.g. feed materials of farm mixtures, as for that year, only yearly amounts reported by feed producers were available). To ease the prevalence estimation, samples of different grain materials were further pooled and used for each of the categories. Similarly, samples of imported complete and complementary feeds for pigs and sows were pooled to represent non-domestic complete feeds for pigs and sows, and (commercial compound) feeds for pig types in general were included as feeds for pigs. Also, distiller's solids/rank and whey were used to represent brewer's yeast and milk/rinse, respectively. As the assessment was based on the categorization of materials, it did not take into account whether all the specific individual materials included were mainly for feeding of the pig types assessed. For example, in the category for soy, various by-products, such as soybean meal, were included. The GMO status and organic production practices were also not considered in the model.

Approximation with 25-ton batches may cause overestimation, and unidentified sampling by operators (e.g. sampling beyond that based on the law or not included in the model, such as sampling by mobile mixers) may cause underestimation of sample sizes. It should be noted that the assessment relied on information gathered in the surveillance, which is not based on an experimental design with random sampling. It should be noted that there was no farm-level information to be exploited in the risk assessment model. As the local grains for on-farm mixed complete feed are not tested, the salmonella prevalence in them was set to be the same as in the grains received in the feed factories, as they were thought to typically have the same origin. Also, all material categories were for simplicity treated similarly in the (sub-)model for the feed material concentration.

The salmonella concentration in positive batches and its changes in feed were taken into account in the risk assessment model only in the phase where feed materials that have tested positive for salmonella are treated with chemicals before releasing them to feed production and in the phase where industrial pelleted feeds are heat treated at the feed mill. Changes in the salmonella concentration in the feed due to storage and transport could not be taken into account, as no follow-up sample data at the farm-level were available. The available concentration data were scarce. Results from different methods (cfu and MPN) were used in the model and treated same way. Measurements were pooled, and pooled data set was assigned for each of the categories, as explained. The inactivation in decontamination treatments was evaluated based on artificial experiments. Inactivation that could occur in feed chain environments other than those mentioned above was not accounted for. In addition, chemical treatment for observed positives at the feed material stage was set for 25ton batches.

Changes in prevalence and concentration between stages of feed production are all defined with the same general fixed formulas of mixing for material categories, and thus there are no stochastic nodes for deviations, e.g. for cross- or (re)contaminations in the environments of the chain. Furthermore, in reality, processing of the feed materials, such as crushing and grinding, and handling, probably affects different materials in differing ways along the production chain of feed for pigs. The chain model with stages describes the pig feed chain and involved actions in a simplified way, conceptually rather than in detail. The potential of salmonella persisting in the sites along the feed production chain has been recognized, but transmission for (re) contamination depends on factors for which no specific information was available for this risk assessment. As described above, findings from feed materials and grain dust sampling were used in the chain model, whereas other findings, e.g. those from outside the manufacturing vessels, such as from the factory floor or receiving pits at the factory site, were excluded. In the typing data model, for sows and pigs, similarly to the feed chain and infection model, lymph node samples were taken into account. For feed, the findings from feed materials, inside storages, dust filters and the dust of materials, considered as related to pig feed production, were included. It is to be noted that the typing-based model does not account for exposure.

In the typing model, there are classes for different serotypes, classes for some phagetyped Typhimurium isolates, and NST as one class of these. Salamae and Diarizonae are also recorded as one category each. For typing data, findings from (batches of) ingredients or pigs were gathered as independent of, for instance, the shipload or farm. In the chain model, feed material batches and pigs have been assumed as independent, e.g. no cross-contamination. No specific data were available on the sensitivity of whole feed testing procedures with differences between feed materials, and the dose-response evaluation for pigs relied on a small data set from experiments using *S*. Typhimurium. Also, as the predicted concentrations in the materials can be small, extrapolation is needed in the sub-models. In the scenarios described in section 5.5, the difference between feed testing procedures is one of the factors causing unquantifiable uncertainty concerning the prediction of an increase in the pig prevalence from using scenario feeding materials.

The evaluated dose–response probabilities related to the salmonella concentration in a contaminated daily feeding amount on average ranged from around a thousandth to around a tenth, depending on the category: the latter for contamination of farmmixed feed, and the marginal one for infection from residual contamination in heattreated feed. However, uncertainties were substantial: 95%CI 10⁻⁹ - 2% for heattreated complete feeds (k=1-2), and 10⁻⁸ - 60% for mixed categories (k=3-12) from lowest lower limit to highest higher limit. Probability over 30 feedings is higher. For heat-treated feed, evaluated test sensitivity (less than percent on average, 95% $2 \cdot 10^{-4}$ – $3 \cdot 10^{-2}$) was marginal. The dose–response model has limitations, such as not accounting for the differences between the serotypes or animals. Furthermore, the whole model for infection from (complete) feed contamination at the farm is only based on the probability of infection given the contamination level and prevalence in feed batches, and does not therefore describe further farm-level salmonella transmission events, cross-contamination, or persistence in the environment.

Estimation of the risk of piglets becoming infected by salmonella was not included in this risk assessment. Because pigs are not widely consumed as piglets, their impact on human salmonella infections from pork is very low. According to a study by Kranker et al. (Kranker, Alban et al. 2003), pigs excrete salmonella for 26 days on average after the initial infection (range 14–101 days). Piglets change feed from one meant for piglets to one meant for pigs at the age of 60 days, after which they are fed on the latter for 108 days before slaughter. Therefore, it seems uncommon for piglets infected with salmonella before the age of 60 days to still excrete the pathogen at the time of slaughter. In the risk assessment, the feedborne infection for a pig or a sow was modeled as an event that is independent from the other animals. Removal of positives (considering e.g. low sensitivity) was not taken into account in the chain modeled. Also, there is no time dimension in the model.

While assessing the relative importance of feed and other sources as a cause of salmonella infections in pigs, the serotyping and phage typing data from the other sources was composed of wild animals only. Therefore, it is uncertain whether other salmonella types could be isolated from the other sources, such as bedding materials. Also, there was uncertainty left about the relative share of pig infections related to e.g. transmission of animals, imported animals, and fur farms. If the true cause of pig infection could be estimated from some sample farms, the attribution to feed could be estimated more directly. In general, the results of the risk assessment are uncertain predictions, limited due to the lack of detailed case reports and follow-up data on actual infection sequences at farms. Also, when infections are rare, it is difficult to estimate their relative sources in general.

5.5 Scenarios

Highlights:

- Replacing domestic protein-rich feed materials with foreign protein-rich feed materials on pig farms increased the prevalence of salmonella in pigs
- An increased use of domestic protein-rich feed materials, such as faba beans, on pig farms lowered the prevalence of salmonella in pigs
- In Finland, a similar salmonella prevalence in pig feed to that reported in other EU countries could lead on average to a 55-fold increase in registered salmonellosis cases in humans

The scenarios were built on the baseline situation referring to the years 2013–2014. The changes in prevalence were compared with the reference results that were estimated from the baseline situation. For the predictions, all the other parameter values, such as data on the salmonella concentration in feed materials, remained unchanged from the preliminary modelling results.

In 2013 and 2014, during the period that was used as the baseline for this risk assessment, the method used for inactivating salmonella in contaminated feed materials and feed was with formaldehyde-based substances. These substances were approved to be used by EU legislation on biocides (EU No 528/2012). From July 2015 onwards, formaldehyde-based substances were no longer allowed to be used for that purpose. At the time of conducting the present risk assessment, it was still uncertain what method shall be used for decontamination in the future. The decontamination step (1.3-log inactivation) for feed materials observed positive was excluded from the risk assessment model in scenarios 3, 4, 5. Heat treatment was set off in the model in scenario 2, and modified in scenario 5. As described, the inactivation steps affect the concentration in contaminated feed, whereas the prevalence data for the occurrence of contamination was modified in all the scenarios except number 2. The starting point was that all factors, such as the feed composition (recipes and their % usage on farms) from feed materials, otherwise remained untouched. The procedure for modelling the scenarios is described in section 6 of Appendix 3.

5.5.1 Scenario 1: The proportional use of domestic protein feed materials on farms increases

The popularity of foreign soy granules as an ingredient in pig feed is in some part explained by the optimal composition of soy as a protein feed ingredient, but the popularity is also dependent on economic factors. If the purchase of soy granules and other protein-rich feed materials was not economically profitable, the use of domestic protein feed materials could rise.

In scenario 1, the salmonella prevalence values for non-domestic rapeseed granules, soy granules, and sugar beet-derived feed materials were replaced by the prevalence estimated for their domestic equivalents. As a result, the overall salmonella prevalence in fattening pigs would change to 0.22% (mean, 95%Q: 0.08–0.46%), corresponding to a 0.9-fold decrease in prevalence on average compared to the reference results (0.25%).

5.5.2 Scenario 2: On-farm mixing of directly purchased feed materials increases

Protein-rich feed materials are used as such in component feeding. By-products of the alcohol industry, e.g. protein feed from barley and rank, are often bought to the pig farm from nearby and they are seldom replaced by foreign equivalents in compound feeds. Other protein sources, such as rapeseed granules, can be self-produced. If they are not, they are bought, depending on the price, from domestic or foreign sources.

The direct feed material imports of pig farms, which means purchasing the feed materials directly from the importing harbors or via other direct import routes, were not a significant route of feed material purchase in 2013 and 2014. However, the share of directly imported feed in the amount of feed used could rise if the economic conditions started to favor them.

In scenario 2, all complete feed was assumed to be produced by mixing feed materials on the farm, i.e. without heat treatment. As a result, the salmonella prevalence in pigs increased on average 1.5-fold compared to the reference results for the fattening pigs. The prevalence in the scenario was simulated at 0.35% (mean, 95%Q: 0.16–0.60%).

5.5.3 Scenarios 3 and 4: Salmonella prevalence in feed materials increases

Currently, the feed business operators pay a lot of effort into buying salmonella-free feed materials. Relaxing the import regulations could lead to similar purchases of feed materials to those used in other EU countries, leading to a similar prevalence of salmonella in the feed material batches. Therefore, in scenario 3, the prevalence of salmonella in non-domestic rapeseed-derived, soya (bean)-derived and sunflower seed-derived feed materials was set to that acquired using the data on feed material prevalence reported by other EU countries (including samples from feed mills, farms and retail, of the above-mentioned feed material categories, excluding Sweden and Norway). Also, in scenario 3, there is no regulation for the chemical treatment of observed positives, and prevalence in pigs would according to the scenario increase on average by 2.2-fold compared to the prevalence in 2013–2014. The prevalence would then be at 0.53% (mean, 95%Q: 0.21–0.95%). If scenario 3 is further combined with the scenario 2, in which feed materials are mixed on the farm without heat treatment, the prevalence would increase to 0.99% (mean, 95%Q: 0.62–1.4%), representing an increase of 4.4-fold on average compared to the reference situation.

5.5.4 Scenario 5: Salmonella prevalence in compound feed increases

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In the extreme case that feed production would significantly decrease in Finland, compound feed would have to be purchased abroad. The salmonella prevalence in compound feed would then probably follow the same distribution to that acquired using the data from other EU counties (including samples from feed mills, of compound feedingstuffs for pigs, and compound feed, farm animals). Also, the treatment temperature for industrial compound feeds was decreased in the scenario from 81 °C

to 50 °C, leading to a predicted decrease in bacterial inactivation from 3.5 log to 1 log. The lower temperature was chosen because it is the lowest temperature that allows the pelleting process and is commonly used in feed processes in some parts of Europe. In the worst scenario, where all Finnish pigs would consume this feed, the salmonella prevalence of which was near the average salmonella prevalence in the EU, the increase in the prevalence in pigs could be as high as 55-fold on average (mean, median 50, 95%Q: 10–130), at 12% (mean, 95%Q: 2–23%).

Changes in the environmental reservoir of salmonella cannot be accounted for in the scenarios, as the scenario predictions rely on available information, and the probability of pig infection from sources other than feed were in all the scenarios therefore assumed to be similar to the reference situation. As described, the risk assessment model does not account for cross- or (re)contamination for the predicted complete feed, although scenario 5 concerns the compound feed.

5.5.5 Examples of the costs of salmonella contamination on pig farms

The costs of salmonella cases on farms in Finland in general are difficult to estimate due to the high variability in the actions needed to eradicate the bacteria from the farm and the varying degree of operating loss at the farm level. Therefore, the costs on farms were estimated using three hypothetical salmonella cases at pig production farms, built together with an expert (Olli Ruoho, ETT). In these three cases, salmonella was assumed to have spread to different extents. The extent in these cases was dependent not only on the farm structure and the feeding system on farms, but also on the success of the cleaning and prevention measures on these different types of businesses: farrowing, finishing, and farrowing-to-finishing farms.

In general, if salmonella contamination on a farm is suspected, restrictive measures are set by the regional state administrative agency (432/2011). The restrictive measures forbid all animal movements from the farm or to the farm under the regulations, covering purchases of sows and selling of growers to finishing farms, among others. This strongly affects the basic operations and particularly the business of the farms. Although restrictive regulations allow the transport of finishing pigs from farms to slaughterhouses, the slaughterhouses may not even be willing to take the healthy animals from salmonella-contaminated farms, unless the farm has two or more separate buildings. In Finland, the animals that have died or are euthanized on the farm are often handled by Honkajoki Oy. This company operates a rendering facility that processes animal-based raw materials such as carcasses of animals that have died on farms, animal-based waste from slaughterhouses, or material that must be rendered at a processing plant that is permitted to process high-risk material. The company uses animal-based raw materials to produce fertilizers and materials suitable for energy production (http://www.honkajokioy.fi/eng/company). In collaboration with service providers, Honkajoki Oy also provides transport services for its customers, including the collection of carcasses.

After enforcing the restrictive measures on a farm, a mapping type of sampling to detect salmonella from the farm premises and the animals is carried out. Depending on the case, samples are usually taken from pig feed, from the feed manufacturing or

storage environment, from the production premises, and as individual samples from boars and sows as well as collective feces samples from pens for weaners, growers, and finishers. Besides the feed samples, which are taken by the officials of Evira's Control Department, sampling is managed by the municipal veterinarian. The number of feed samples, as well as the number of environmental samples that are taken during the sampling, varies according to the feeding system. Usually, the number of feed samples that are collected ranges from 5 to 10. In general, the collective fecal samples are taken per pen or per 10 animals. The environmental samples from the feed manufacturing and storage areas are usually taken from the feed silos, feed mixers, grinders etc. Environmental samples from the production premises are taken, for instance, from the floors of the pens, floor drains, on top of the doors, aisles, feeding trays, and ventilations systems.

There have to be two consecutive sets of negative samples taken by official authorities before restrictive measures are removed. The timing of the first set of samples is often decided on the basis of the possible actions that had been taken to eradicate salmonella from the farm. The second sampling takes place at the earliest two weeks from the first sampling. The mapping type of sampling can be regarded as the first sampling if salmonella is not detected in any of the collected samples. Salmonella sampling is often carried out as self-monitoring between the official samples to obtain information on the success of cleaning measures on the farm and when one wants to check the salmonella status before the official sampling takes place. This is especially the case if salmonella contamination on the farm is prolonged and the restrictive regulations thus apply for several weeks.

Cleaning measures take place to remove salmonella contamination on the farm as soon as the initial actions to prevent further spread of the pathogen, such as cancelling all scheduled animal transfers, have been performed. Although the sampling described in the previous section takes place before the cleaning measures have started, the results of the sampling are not awaited if the suspicion of contamination is strong. In these cases, the cleaning measures are started immediately after sampling.

If the salmonella that has been detected on the farm can be linked to the feed or feed warehouses, destruction of the feed as well as cleaning and disinfection of feed production and storage environments are also started. The feeding system is cleaned and disinfected on the outside, as well as on the interior. Salmonella-contaminated feed is destroyed by the manufacturer or it is buried in the ground. Feed may be treated with organic acids to avoid salmonella contamination. To strip down the feeding installation may take from a day to two weeks, depending on whether a liquid or dry feeding system is used. Feed may be substituted with temporary complete feed, which enables emptying and cleaning of the feed storages. New feed may be distributed by hand, which takes a large amount of time. Pens are disinfected, but the living salmonella-free animals may hamper disinfection, as it is possible that they cannot be moved temporarily elsewhere because of a lack of space. For example, liquid lime can be spread on the floor of salmonella-contaminated pens and on the aisles to inactivate the pathogen. Slurry, which may contain a high concentration of salmonella via the feces of the animals, must be treated during the cleaning. Eradicating salmonella may also require renovations to the construction of the buildings, as salmonella may hide in structures that are difficult or impossible to

clean and disinfect without demolishing the relevant part of the facility. Salmonella is difficult to destroy in the exterior areas of the farm, as the pathogen is known to persist in the ground for one to two years (ETT) and it is quite resistant to acidic and alkaline conditions. It may require (several) outsourced cleaning services to treat the soil near the farm to eradicate the bacteria. In addition to paid cleaning work, a significant amount of the farmer's own time is often used in cleaning and other actions to eradicate salmonella from pig farms.

Salmonella-contaminated animals are removed as soon as possible after they are detected. As a consequence of the lack of space due to interrupted animal movements to and from the farm, even healthy animals may have to be euthanized and transported to the destruction facility, as slaughterhouses may consider it too risky to handle animals from salmonella-contaminated farms. Salmonella bacteria are difficult to remove and they can persist on farms for weeks, being found again and again, causing additional cleaning until samples are negative.

In Appendix 4, three hypothetical salmonella cases are described. Example 1 can be described as a mild case, as the disposal of animals is not involved and costs are low for the farm itself, the feed business operator, the insurance companies, and via the direct and indirect costs described in this report, for society in general. The classification of the other two as intermediate and severe cases is based on the estimated cost of each of the cases to each operator and party involved.

In cases two and three, it was assumed that sows farrow on average 8 piglets every two weeks from each batch. There were eight batches, with seven sows in each. On average, 56 pigs were moved to a weaner unit every other week. In case two, it was assumed that 30 pigs are sold on from the weaner unit to a finishing farm and 26 are moved to the farm's own growing unit. Every other week, 26 finishers were also assumed to have been transported to the slaughterhouse. In case three, all 56 pigs were assumed to be sold to a finishing farm from the weaner unit.

6 CONCLUSIONS FROM THE RISK ASSESSMENT

Highlights:

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- The true prevalence of salmonella in Finnish pigs in 2013–2014 was estimated to be well below the maximum limit of 1% set by the FSCP.
- A relatively high share of the few salmonella infections in Finnish pigs could be feedborne.
- Only a small share of human salmonellosis cases in Finland were estimated to originate from domestic pork.
- An increase in the salmonella prevalence in feed materials, and especially in compound feeds, would probably lead to an increase in the salmonella prevalence in pigs and in human salmonellosis cases.

The objective of this study was to examine the impact of salmonella control practices, targeted at the feed and pork production chains, on the salmonella risk in Finland using data based on salmonella surveillance and information gathered from literature sources. A risk assessment model was used to estimate the current prevalence of salmonella in live pigs and sows, as well as in pig feed materials, compound feeds, and consumed complete feeds. It was estimated that the concentration of salmonella in contaminated feed batches affects the probability of a pig or a sow becoming infected from these batches. As a result, the true salmonella prevalence in feeds, pigs and the salmonella concentration in contaminated feeds were estimated as low.

To evaluate the relative share of salmonella infections introduced to pig herds via feed, salmonella subtypes isolated from samples representing the environment and from feed chain samples were compared with the subtypes isolated from pigs in a sub-model. The addition of the sub-model was necessary, as the lack of data available for quantifying for instance the (re)growth or inactivation, (re)contamination or crosscontaminations, which can affect the true condition of feed batches served to pigs at the farm level and thus the probability of the pigs becoming infected, made the estimate of the risk posed by feed very uncertain when calculated using only the feed chain model. The results suggest that feed is a significant source of salmonella in piggeries, especially when the prevalence in animals and in the environment is low.

The salmonella risk to people via pig feed was calculated using a feed chain model combined with a source attribution point estimate to evaluate the share of human

salmonellosis cases attributed to domestic pork. According to the estimate, the share of the human cases is less than one tenth. By combining the two approaches, bottom up in the feed chain model and top down in the source attribution model for pig infections and a point estimate for human cases, the uncertainty of the estimate of human salmonellosis cases due to domestic pig feed could be somewhat diminished.

An increase in the salmonella prevalence in feed materials, and especially compound feeds, also increased the prevalence in pigs according to the tested scenarios. Although the relative proportion of salmonella infections in pigs due to contaminated feed and human cases from domestic pork is currently low in Finland, alleviation of the control measures for salmonella in the pig feed production chain could potentially lead to an unwanted increase in the number of these cases. Replacing imported feed materials with domestic ones could lead to a decrease in the salmonella prevalence among pigs in a country where this prevalence is generally low, such as in Finland.

7 COST-BENEFIT ANALYSIS

Highlights:

- The cost of measures to prevent a pig feedborne salmonella outbreak in the food chain was €1.8–3.0 million per year.
- The pig feed salmonella control program is cost-efficient, as costs caused by salmonella contaminations are avoided due to the program.
- Besides impacts on the feed and pork production chain, feedborne salmonellosis in humans represent an important part of the economic implications of salmonella

7.1 Cost-benefit analysis: explaining the method

Cost-benefit analysis (CBA) is a systematic approach to assess the economic potential of a "project". The project can be an investment, a management pattern, a policy, or virtually anything that could be implemented to adjust the current state of business. In this report, the project is the control program to reduce salmonella contaminations originating from pig feed. Cost-benefit analysis is always conducted in relation to an option. There should be a with and without option. In our case, the comparison is made between the current control program and an alternative where salmonella control in pig feeds would be substantially lower than in the current situation. Hence, in a CBA, we assess whether implementing the program is justified (i.e. whether the benefits outweigh the costs). These results can be used as a basis for comparing the projects and for decision-making.

The development of CBA dates back to the work of Jules Dupuit and Alfred Marshall, and wider use started in the 1930s in the context of infrastructure, policy, and military projects. The generic process of CBA includes several steps:

Identifying optional projects

- Listing stakeholders and the study area
- Selecting indicators and measuring all costs and benefits that differ between the options
- Electing the decision criteria to be used
- Predicting the outcome of costs and benefits over a relevant time period
- Applying discounting in a multi-period project and calculating the net present value of the options

- Conducting sensitivity analysis
- Adopting the best recommended option and
- Evaluating the outcome

It is important to recognize that when several stakeholders are involved in a project, they may face different costs and benefits due to the project. Some stakeholders may face net losses, while others may face net gains. Externalities may also occur if the decision-maker is not the one who is negatively impacted by the project. However, a project may be societally justified if the overall benefit to society is positive, because income transfers could then be used to make those who lose at least as well off as they would be without the project.

There are some caveats in conducting CBA. CBA should cover both monetary and nonmonetary costs and benefits. However, in some cases, this poses ethical questions or has impacts that are challenging to quantify. For instance, what is the value of a saved human life or business reputation, or how can cash flows be valued that are realized far in the future, for future generations? This may be an issue when evaluating substantially different projects. An error that sometimes occurs is that some of the costs or benefits are either calculated twice or omitted altogether when they should be taken into account.

The results of CBA can be used to guide decision-making. Sometimes, the most valuable contribution of CBA is to foster discussion on the project. The most commonly used decision criteria include net present value (NPV) and the benefit-cost ratio. If NPV is positive or the benefit-cost ratio is larger than unity, then the benefits are larger than the costs and the project can be implemented. When several projects are compared, the best project is that having the largest NPV or benefit-cost ratio, depending on which one is used as the criterion. Because the benefit-cost ratio is relative and NPV is an absolute measure, they may lead to different recommendations if the projects are of different sizes.

Numerous textbooks exist to help with CBA. The World Health Organization has also prepared guidelines on how to conduct CBA (Hutton and Rehfuess 2006).

Sections 7.2 and 7.3 describe the method used in the CBA, and sections thereafter derive and justify the parameter values used in the analysis. We first describe the parameters that characterize the current costs and thereafter describe the scenarios that were analyzed. Unless otherwise stated, the data used to parameterize the model were based on the survey that was described in the risk assessment section of this report and on consultations with industry representatives.

7.2 Costs-benefit analysis of salmonella control in pig feeds

Different ways to examine the economic effects of diseases exist. In this report, the focus is on two types of costs: 1) the costs of preventing a salmonella outbreak and 2) the costs caused by salmonella outbreaks and contaminations due to the salmonella contamination of pig feed. The feed and pork production chain from feed import

to consumers is included. The costs of preventing salmonella include the cost of feed treatment measures, cleaning measures, pest control, measures by authorities (statutory salmonella sampling and official control checks), and self-monitoring measures related to the salmonella control of different operators. Precise cost factors are defined more specifically when reviewing the different operators in the feed and pig sectors. The *benefits* of the salmonella control program are due to *avoided costs* caused by salmonella contaminations. When a more efficient control program is implemented, fewer human infections and contamination events occur along the supply chain, thus reducing the cost of illness in humans and contamination in the food chain. In an efficient program, more costs of contamination are saved than the preventive and monitoring costs of the program when compared to a situation with a less efficient or no program (Figure 6).

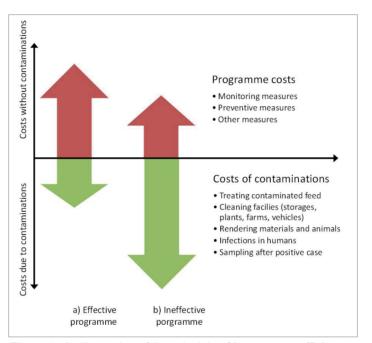


Figure 6. An illustration of the principle of how a more efficient salmonella control program increases monitoring and prevention costs and decreases costs caused by salmonella contaminations in different phases of the supply chain.

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We first calculate the total annual costs (*L*) incurred by control and preventive measures plus costs caused by salmonella contaminations and human infections in Finland in each scenario:

$$L = \sum_{h=1}^{H} P_h C_h + \sum_{i=1}^{24} p a'_i w_i Q_i + \sum_{j=1}^{9} p a''_j w_j Q_j + \sum_{k=1}^{14} P ft_k w_k Q_k d_k + \sum_{r=1}^{2} P a p p_r w_r Q_r \theta_{1,r} + \sum_{m=1}^{4} P_m w_m Q_m \theta_m f d_m$$

where *h* is an index representing one of *H* cost items or measures associated with preventive or monitoring costs; C_h refers to the total costs of measure or item *h* which is implemented fully or partly because of the goal of reducing salmonella

contamination; P_h is the proportion of preventive or monitoring costs C_h that are associated with item h (i.e. if a measure is adopted for multiple reasons, what is the contribution of the salmonella control program to the decision to adopt the measure and thus to the costs); *i*, *j*, *k* and *r* are indices representing feed material, feed (*j*, *k*) or animal types, respectively, where measures associated with the treatment of salmonella-contaminated materials, animals, or humans; $pt''_{,\nu} pt''_{,j\nu} Pft_{k\nu}, Papp_r and P_m$ represent is the probability of salmonella contamination or prevalence of salmonella contamination occurring in *i*, *j*, *k*, *r* or *m*; *w*'s are the cost caused by salmonella contamination, or eradication of the pathogen, in *i*, *j*, *r*, *k* or *m*; *d*_k is the proportion of true infections that will be detected; *d*_m is the proportion of each type of human infection; θ is the proportion of infections related to contamination in feed; and Q's represent the quantity of pig feed materials, pig feed, pigs or humans in the study population. The costs taken into account in each of the six elements in the sum is explained in sections below. (7.4.5, 7.5.1, 7.5.2, 7.5.3, 7.5.4, 7.6).

For feed materials at import and storage prior to feed manufacturing, pa', is the apparent prevalence of salmonella in feed material batches of 25 tons (see appendix 3). For costs incurred at industrial feed manufacturing stage, the apparent prevalence of salmonella in manufactured compound or complete feed (pa") was used. Salmonella contamination in pigs at the farm was obtained as the probability for infection due to feed, using feeding type specific infection probabilities (Pft.). As this was true prevalence, only proportion d_{μ} was considered to result in costly eradication measures. The incidence of salmonella at slaughter pigs was assigned with the observed prevalence of infections (Papp) represented by the prevalence in the lymph node samples (see appendix 3) and the costs for infection (w_i) were relative to the number of pigs that were assumed to be influenced in the batch when a salmonella positive pig was detected. Finally, the annual prevalence of salmonella infections in humans P_m was determined as a proportion of observed infections that could be, according to the source attribution model, be linked to pig feeds. $P_m w_m Q_m \theta$ fd_m therefore represents the product of the prevalence in humans, size of the population in Finland, reporting factor f = 11.5, proportion of infections associated with contamination in feed, and the proportion of infections associated with each type of human infection and cost w_m per infected person (see section 7.6)

Parameters in the loss equation above are important in the cost-benefit analysis. This is because feed is manufactured and handled for different types of animals by using partially the same facilities and resources. Therefore, it is essential to allocate the costs of monitoring and preventive measures to pig feed and other feeds. Furthermore, it is essential to allocate the costs associated with pig feed to those caused by salmonella control (i.e. parameter P_i) and to those caused by other reasons than salmonella control. In addition, in the pig sector, it is essential to identify the number of salmonella infections that need to be resolved.

Preventive and monitoring costs C_i are *independent* of how much salmonella occurs in the food chain. These costs include the statutory measures and additional voluntary measures taken by the stakeholders, who include feed importers, feed processors, and manufacturers (small and large scale), mobile feed mixers, or pigs farms. These costs are explained in more detail in section 7.4 and include:

- Costs of additional cleaning carried out at the harbor warehouse, at the feed factory or warehouse, for equipment and machinery, or at the pig farms
- Sampling and analysis of salmonella samples taken from feed, feed ingredients, or from the environment where feed has been
- Additional storage costs caused by waiting for the analysis results
- Heat or acid treatments carried out to reduce the concentration of salmonella in feeds
- Control of pests and vermin
- Costs due to public monitoring and inspections
- Other costs, if any

This approach was used because commercial feed production operators, in particular, purchase feed materials and produce feed for many types of animals. Monitoring costs related to the production of feed are accounted whereas monitoring costs related to production of feed materials without producing feed are accounted only to the extent that these activities are conducted by feed production operators. Hence, measures that prevent salmonella contamination are also often taken so that they cover feed for different animals. As information on the measures was obtained from a survey that covered multiple species, the cost share attributed to pig feed had to be divided among all produced feed.

By contrast, treatment and eradication costs (w's) depend on the number and severity of salmonella contaminations and human infections observed. These costs include the statutory measures and additional voluntary measures taken by feed importers, feed processors, and manufacturers (small and large scale), mobile feed mixers, pigs farms, slaughterhouses, or measures taken to treat infected humans:

- Additional samples taken to verify salmonella contamination and thereafter freedom from salmonella
- Washing, cleaning, and disinfecting of facilities contaminated with salmonella
- Treatment of salmonella-contaminated feed
- Treatment or culling and rendering of salmonella-contaminated animals
- Business interruptions caused by restrictive measures
- Loss of efficiency on an infected farm

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- Labor effort by authorities and stakeholders in handling salmonella contamination
- Costs caused by salmonella infections in humans (lost working time, visits to the doctor, hospitalization, mortality, sequelae of infection)

More details regarding the parameter values are provided in the sections 7.5 and 7.6. The cost parameters (w's) for feed and feed materials are normalized so that they represent the cost of measures related to 25 tons batch of feed or feed material that is positive with salmonella. For animals they are normalized per infected pig held on a salmonella-contaminated farm and for human infections they represent costs per infected human. Furthermore, w's are multiplied by the amount of animals that can be considered to be influenced by 25 tons of salmonella positive feed, representative number of pig farms in Finland, and the population of Finland.

Because the net treatment and eradication costs can vary substantially from year to year due to changes in prevalence, they are simulated by using the Monte Carlo method. Prevalence parameters are based on the simulation results explained in the previous sections of this report. For the current monitoring programme, the parameters are obtained from the results of simulations reported in Table 12 and in appendix.

7.3 DALY method to assess the costs of human infections

Besides the costs that salmonella contaminations cause to the pig production chain, it is essential to also assess the impacts of feedborne salmonellosis in humans, because they represent an important part of the economic implications. There are different ways to estimate the economic value of Salmonellosis in humans. The disability adjusted life year (DALY) is a non-monetary approach to estimate the health implications, whereas the cost of illness (COI) provides an inventory of money spent. In this study, the impacts of salmonella in humans were estimated by using the burden of disease, the unit of which is the DALY. Costs related to salmonella are estimated per salmonella infection. The DALY also forms and internally-consistent metric that allows healthcare priorities to be weighted. However, it also can be opaque to general audiences, as monetary values are easier to understand. (WHO 2016).

DALY measures the years of life lost due to death or disability. It combines the time lived with the disability and the time lost due to premature mortality in one measure, i.e. information on the quality and quantity of life.

DALY = YLL + YLD

YLL denotes the years of life lost due to premature mortality and YLD describes the years lost due to disability. In the case of an individual death, YLL is calculated as the difference between the standard life expectancy at the age of death and the actual age at death. At the population level, YLL is calculated as follows:

 $YLL = N \times L$,

where N is the number of deaths in a given age category and L refers to the remaining years to the standard life expectancy at the age of death.

YLD can be represented as follows:

 $YLD = n \times DW \times A$,

where n is the number of new incidents, DW is the disability weight and A denotes the average duration of disability. DW is used to make different health effects comparable. Disability weights reflect the severity of the disease on a scale from 0 (healthy) to 1 (disability that is equivalent to death), and they are determined in expert panels using standardized surveys. Estimates on morbidity also take into account the duration of the disease. Sometimes, prevalence data are used to assess the burden of disease. The burden of disease refers to an estimation of the impact of diseases at the population level. (WHO 2016).

7.4 Cost of preventing salmonella in the current situation

The costs of salmonella control were based on the year 2013, which has also been referred to as the current situation. The total costs related to measures to control salmonella were evaluated for different stages of the production chain: the import process, the feed production of commercial feed business operators (including feed mills and mobile mixers), and pork production farms in 2013. As feed business operators produce and process feeds for several species, of these 'total' costs attributed to pig feed was first identified based on the share of manufactured pig feed of all manufactured feed. Secondly, within pig feeds, the proportion of costs directly associated with salmonella control were identified. This is because, apart from salmonella sampling, all the control measures could be carried out even without salmonella risk and the measures may prevent other diseases as well. The share attributed to salmonella, in particular, was individually evaluated by feed sector experts on each control measure.

7.4.1 Import

The costs of salmonella control related to the import process of feed and feed materials are caused by statutory salmonella sampling (both as self-monitoring and official monitoring), fees charged by authorities (the Finnish Food Safety Authority, Evira, the Feed and Fertilizer Control Unit), and quarantine storage of high-risk feeds. There is a fee associated with each control event in addition to salmonella sample costs. The costs of salmonella control of imports were estimated for the largest commercial pig feed production operators, which use the majority of feed imported for pig feed production. The costs and other parameter values reported in subsequent sections were mainly based on the surveys that were conducted within the project and which are described in section 3 of this report.

Salmonella samples

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Salmonella sampling incurs cost to the feed importers, because the Decree of the Ministry of Agriculture and Forestry on the pursuit of activities in the animal feed sector (548/2012) states that high-risk feed materials (listed in 548/2012, annex 3) and feed imported outside of the Member States must be analyzed by official sampling, and because of self-monitoring when importing from the Member States. Feed must be examined at the minimum frequency of one sample per 50 tons of feed or feed material. When imported feed is transported directly to the farm, the sampling is more frequent, being one sample per 25 tons. Import operators must inform Evira prior to the importation when importing from third countries.

In order to assess the sampling costs, the volume of feed materials or feed, sampling frequency, and unit cost per sample were determined. This information was obtained from feed manufacturers. Based on Evira's data, the seven largest operators producing commercial pig feed imported altogether about 380 000 tons of feed materials for all feed they produced (i.e. not only for pig feeds) in 2013. This also included feed materials that were not categorized as high-risk feed and were thus not included in salmonella sampling. The feeds for which the imported feed materials are used were

not reported. The amounts of imported high-risk feed materials used to pig feeds were evaluated based on the amount of manufactured pig feed per operator and the example pig feed recipes used in the risk assessment part of the study (proving a scenario for the feed materials used in certain types of pig feed). The share of imported feed in the recipe was based on the data obtained from Evira. Although the composition and the purchasing of feed materials used to manufacture feed may change depending on the prices of feed materials, it was assumed that the share of imported high-risk feed material in the feed remains the same. Depending on the pig feed type, the share of imported high-risk feed material in feed was between 10% and 45%. For the complete feed, the share ranged from 10% to 15%, and for the complementary feed the share ranged from 33% to 45%. Overall, the share of high-risk feed materials. This corresponded to the imported high-risk feed material attributed to pig feed production amounting about 55 000 tons in 2013.

Based on survey responses from feed manufacturers, one sample per 25 tons of feed material was assumed for self-monitoring instead of the statutory one sample per 50 tons of feed material (data not shown due to data privacy issues). The total number of salmonella samples attributed to raw (pig) feed materials was about 1 600 samples per year. Assuming that one self-monitoring salmonella sample costs \notin 25, the total sampling costs were about \notin 40 000 per year for the pig feeds. All the costs of salmonella samples were attributed to salmonella control. The share of all feed materials attributed to pig feed was about 20%. This only included the feed materials imported for the use of commercial feed materials were imported directly to farms, but these were excluded from the analysis due to their marginal role.

Based on the decree (MMMa 548/2012), official salmonella samples are mainly taken from feed materials imported from outside the EU, and the sampling of internal market trade import is the responsibility of the operator. In 2013, the Evira's feed control unit took altogether 3 074 salmonella samples from imported feed materials, of which 2 338 samples were taken from feed imported from outside the EU. The amount of feed in the sampled batches was 86 584 tons. Altogether 736 samples were taken from feed materials originating from the EU. The sampled batches represented 34 917 tons of feed material. This number of samples mainly concerns salmonellacontaminated feed that has been detected by the operators' self-monitoring activities. Seven feed business operators from which data were obtained for the study were evaluated to account for the majority of use of imported high-risk feed materials, which have been analyzed by the feed control unit. The cost of an official sample (in 2015) was €200, which included the fee for the approval that must be obtained to release each batch of imported feed or feed material for use in Finland. For other samples taken from the same batch, the cost was assumed to be ≤ 130 per sample. Hence, the cost of salmonella sampling of imported feed and feed materials for pig feed by official monitoring was approximately €56 000 per year.

Quarantine storage

Import operators rent warehouses at harbors to store imported feed materials. The statutory salmonella sampling of imported feed batches increases the time that

the feed must stay at the warehouse, because the imported feed batch cannot be dispatched to the next destination before the sampled imported feed is stated to be salmonella-free by the authorities (Evira). According to feed control experts at Evira, this usually takes from 4 to 6 days. Information on the costs of a storage facility for each extra day was obtained from a business operator (Port warehouse operator, personal communication, October 2015). In total, additional storage costs amounting to \notin 7 000 to \notin 11 000 were attributed to pig feeds per year. These were attributed to salmonella control, because only the prolonged duration of storage until sampling results are obtained was taken into account.

Total Salmonella monitoring cost in the import process

The total cost of salmonella control related to the import of feed materials for pig feeds was estimated at $\leq 105\ 000\ to\ \leq 109\ 000\ per\ year$ in Finland (Table 13).

feed materials for pig feeds in 2013.					
Cost item	1 000 € per year				
Self-monitoring by the feed business operator	42				
Official Salmonella monitoring (samples, fees)	56				
Prolonged storage costs	7–11				

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Table 13. Estimated cost of salmonella control associated with the importation of pig feeds and feed materials for pig feeds in 2013.

7.4.2 Feed business operators (feed manufacturing)

Data sources

Total

Feed business operators' costs related to the prevention and monitoring of salmonella consist of salmonella sampling, feed treatment, hygiene measures, self-monitoring, pest control, and official checks, including the official salmonella samples. In 2013, the seven largest feed business operators produced in total 290 000 tons of pig feed. The data used in this study originated from a survey sent to these operators (N = 6 responses). The cost of salmonella control measures for these manufacturers was evaluated based on the questionnaire and complementary information, such as consultation with experts of these operators and Evira, and the study by Wierup & Widell (2014). Because feed companies operate in different ways and some did not or could not respond to all of the questions, average responses weighted by the volume or number of units were used in the analysis. The parameter values used in the country-level analysis took into account that the contribution of each operator to the country-level average costs was determined by the combination of price and quantity information. Because feed factories often manufacture feed for multiple animal species, the cost items were enquired for the full production (i.e. production of feed for all species) of each operator and then allocated to pig feed on the basis of the amount of pig feed out of all feed manufactured.

Salmonella sampling

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Mandatory salmonella sampling is defined in (548/2012). An operator who produces feed materials of certain high-risk feeds must take at least one sample every week

from the production line (an "environmental sample") or one sample per 50 tons, but at least three samples annually. This does not concern operators manufacturing only liquid feed. An operator manufacturing complete feed must take at least one environmental sample from each reception and production line every week, if certain high-risk feed is produced in the same line. Operators using heat treatment must take a sample from six spots (the reception of the materials, the dust removal, the cooler, the dust removal of the cooler, the location of the cooler/cooler intake, the bulk loading line, described in section 3.3).

Commercial feed manufacturers were asked the average number and frequency of self-monitoring salmonella samples. The cost of a salmonella sample reported by the operator was taken into account. When the sample cost information was missing, the price of €25 per sample was used. Altogether, 27% of salmonella sampling costs were related to pig feed, and these costs were €150 000 per year for all operators together. Salmonella sampling costs were 100% related to salmonella control (Table 14).

Feed treatments

Based on the questionnaire, the main treatment used among the feed business operators was heat treatment. One operator used acid treatment and one used "other hygiene treatment" as the main form of treatment.

The cost of feed treatment included labor, materials, the annual cost of installation, and maintenance of the installation. The labor cost of the treatment measures used was assumed to be \notin 26 per effective working hour, including salary, social security, and a proportion of paid leave (Statistics Finland 2016). The costs of materials and electricity used and the maintenance of installations were evaluated based on the questionnaire responses and the previously estimated cost of feed treatment (Wierup & Widell 2014). The fixed costs (depreciation and interest) of installations were calculated as an annuity by using a 7% annual interest rate and 15 years duration for the investment, and the size of the initial investment was based on information provided in the questionnaire. In cases of missing data, comparable data from other respondents were used.

Approximately 25% of feed treatment costs in the surveyed enterprises were attributed to pig feeds. The variable costs attributed to acid and heat treatments of pig feeds in Finland were estimated to range from ≤ 2.3 to ≤ 4.4 million per year and the costs of installation (interest, depreciation, maintenance) were estimated at about €0.1 million per year. The variable costs were dominated by the large proportion of material costs (e.g. energy and acids). The proportion of material and labor costs for handling feeds attributed to the salmonella control of pig feeds was estimated to be within the range of €1.0 to €1.5 million. The share of costs attributed to salmonella control was 20% for heat treatment and 80% for acid treatment, regarding materials and working time, as the duration of treatment and temperature heated may impact on the survival of salmonella. The share attributed to salmonella control was evaluated by experts representing feed sector operators. Although regulations to treat feeds to reduce the risk of salmonella exist, heat treatment has multiple benefits. Feed treatment, in particular, is used to obtain a desired structure for the feed. For this reason, the equipment is needed in any case, and hence it was assumed that 0% of the fixed costs of installations were currently attributed to salmonella control.

Cleaning measures, pest control and official control

The costs of cleaning the feed factory were enquired in the questionnaire. The total costs of cleaning measures for all operators were estimated at €350 000 per year, of which 26% were assumed to be attributed to pig feed and a further 25% (€24 000) to salmonella control in pig feeds. This may be an underestimate because of the low number of responses obtained and because different contracts may exist between the feed factory and outsourced service provider. Feed factories had also typically outsourced pest control. Based on the information obtained from a specialist of the pest control sector, the annual costs varied between €2500 and €3000 when a facility was checked four times a year, and there were about 60 traps per facility (Pest control operator, personal communication, October 2015). The total costs of pest control were estimated at €26000 to €33000 per year, of which 27% were assumed to be attributed to pig feed and a further 14% of these to salmonella control in pig feeds. As the regulations on biocide and chemical use have changed (EY 528/2012), this may have impacted on the cost of pest control when comparing the years 2013 and 2017.

The cost of labor used for self-control measures such as recording salmonella samples and other quality control measures related to pig feeds were estimated at ≤ 18000 , of which 50% were estimated to be associated with salmonella control in pig feeds. This estimate was based on the working time indicated by four respondents (number of hours not shown due to data confidentiality) and the hourly cost of labor. The amount of time used appeared not to be linearly related to the amount of manufactured feed, which may be due to different types of feeds manufactured and company-specific procedures.

The costs of official inspections were mainly evaluated based on the information obtained from the experts (Feed control expert, personal communication, November 2015). The annual official inspections cost on average ≤ 1200 per feed manufacturing unit, but an operator may have several units. The respondents were asked the frequency of the official checks, but complementary information was needed to verify the robustness of these results. The total costs of official monitoring of feed manufacturing in feed companies were estimated at ≤ 25000 per year, which included the company's staff time upon inspections, and ≤ 6000 of which were associated with pig feeds.

Evira takes and analyses salmonella samples as part of the official feed control. There are several control lines such as market surveillance, import control (imports from outside the EU and imports from the common market are managed separately and, as mentioned earlier, the sampling of feed imported from the common market is the sole responsibility of the importing operator) and domestic manufacturing control (including the mobile mixers, in addition to feed manufacturers).

The number of official samples per operator varies from a couple to over a hundred samples per year. The number is based factors such as the volume of manufactured feed and feed type. The total costs of the samples taken from pig feeds in 2013 were estimated at \leq 15 000 per year (34–37% of the costs for all feeds). This number was based on Evira's inspection results for the year 2013.

Summary of costs in feed manufacturing

Monitoring and preventive measures taken at the feed manufacturing stage (excluding measures related to feed imports) and their cost include salmonella sampling as self-monitoring, feed treatments, pest control, hygiene measures, time used in self-monitoring, and official control, including samples. The costs of each measure were either fully or partly attributed to salmonella control. These costs were estimated at €6.4-1.0 million per year in the manufacturing of pig feed, of which €1.2-1.7 million were estimated to be attributed to salmonella control in pig feeds (Table 14).

	Costs of measures attributed to pig feed, 1 000 €	Share (%) attributed to salmonella control	Cost attributed to salmonella control in pig feed, 1 000 €
Sampling as self-monitoring	150	100 %	150
Cleaning measures	94	25 %	24
Pest control	7–9	14 %	1
Time used for other self-control measures (bookkeeping etc.)	18	50 %	9
Feed treatments	5 471–9 157	34–32%	974–1499
Official control	6	25 %	2–3
Official sampling	15	100 %	15
Total	6 358–10 047	37–34%	1 174–1 701

Table 14. Annual costs related to salmonella control of pig feeds in feed manufacturing.

7.4.3 Mobile mixers

Data sources

According to mandatory registration information reported to Evira, there were twelve mobile mixers operating in 2013 and producing pig feed. Only two replies were received from mobile mixers to the questionnaire. Complementary information was obtained by interviewing another mobile mixer operator. The costs were separately evaluated for small-scale and large-scale operators, because according to the information reported to Evira, mobile mixers produced more than 13 000 tons and seven small-scale operators produced less than 9500 tons of feed annually. Altogether, 30 000 tons pig feed was produced by mobile mixers in 2013. Because the operators also manufacture other feeds than pig feed, the costs were allocated to pig feeds according the proportion of pigs feed in their production volume.

Cost of preventing Salmonella for mobile mixers

It was assumed that large-scale operators had four mobile mixer vehicles and smallscale operators had one. The costs of hygiene measures for the mobile mixers, the use of acid, salmonella samples as self-control, and official control, including the operator's own time spent on this, are included in the analysis. Mobile mixers must take at least one salmonella sample as self-monitoring monthly from each vehicle (548/2012) before cleaning it. The price of a salmonella sample was assumed to be €25, as in the previous cases. Material costs and working hours were based on the questionnaire and the interview. One to two hours of cleaning per month was assumed, and half an hour to an hour of the operator's own time per official visit. The cost of labor for cleaning activities, documenting self-monitoring, and working time used for official inspection visits was assumed to be €19.3 per hour (food sector employee's labor costs; Statistics Finland 2016). Of these activities, the share of 25% was attributed to salmonella control (except the share of 100% for samples and 50% for acid use).

Acid was assumed to be used once per month (2 kg per time) for disinfection and two times extra per year for cases when rodent feces were observed in the vehicle (Regulation related to acid treatment described in section 5.3.4). On average, 1.5 official inspections were assumed per year. According to the operators, each visit costs \notin 200.

Table 15 summarizes the annual cost of preventing and monitoring salmonella in mobile mixers.

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	Costs attributed to pig feed, 1 000 €	Share attributed to salmonella control	Cost attributed to salmonella control in pig feeds, 1 000 €		
Sampling as self-monitoring	1.8	100%	1.8		
Cleaning measures	3.7	25%	0.9		
Time used for self-control measures	1–4	25%	0.3–1.0		
Acid treatment	1.0	50%	1.0		
Official control (includes the own time used)	0.9	25%	0.2		
Official sampling	0.7–0.9	100%	2.6-3.2		
In total	9.0-13.0	48–44%	5.0-6.0		

Table 15. Annual cost of preventive and monitoring measures for salmonella in mobile mixers for
pig feed, and shares attributed to salmonella control in pig feeds.

7.4.4 Farms

Data sources

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The survey sent to pig farms enquired about acid treatment costs, the adoption of cleaning and hygiene measures, self-monitoring (including salmonella sampling), and official inspections. The costs of these measures were estimated based on the survey (N = 61 responses) and additional complementary information. The cost of salmonella control run by farms also includes salmonella sampling requested by the Sikava pig health care scheme (described in section 3.5.4).

Cost of acid treatment, hygiene measures, pest control, and Salmonella sampling

Farms vary in size, the feeding system used, and practices applied. Acid treatment of the feed is associated with farms that use liquid feeding. For this study, the farms were divided according to their feeding system. Based on an earlier study, feeding liquid feeding is used on 65% of all pig farms. Based on our questionnaire, 73% of farms used liquid feeding system. However, according to expert views (personal communication), the number of farms using liquid feeding system has been growing over the past years. Hence, 70% of pig farms (1 140 farms) were assumed to use the treatment. For the farms that used a liquid feeding system, the median amount of manufactured feed was 550 tons per farm in 2013 based on the questionnaire and the average amount was about 880 tons per farm. Based on the questionnaire, the average cost of installations for acid treatment was about €2 990 (median €1 500), the cost of materials was €4.40 (median value €1.30), and the cost of maintenance €217 (median €150). The working time for treatment was estimated on average 0.16 hours (median value 0.05 hours) per ton of manufactured feed.

The average costs were ≤ 6500 per year for 880 tons of feed (≤ 0.14 per ton). These costs included materials, labor, and maintenance. The median costs for 550 tons of manufactured feed were ≤ 1340 (≤ 0.40 per ton). The cost of a working hour was assumed to be ≤ 17.22 , which corresponded to a farm worker's labor costs (Statistics Finland 2016). The costs due to acid treatment were only included for the producers who reported this treatment cost. This was almost half of the group of producers using liquid feeding systems. Since the major reason for a treatment is the maintenance of a favorable acid-base balance, only 10% of these treatment costs were assumed to be attributed to salmonella control, resulting in the cost of acid treatment attributed to salmonella control being ≤ 67000 to ≤ 329000 per year for Finnish pig farms.

The frequency, duration, and the targets of cleaning related to feed facilities and feeding were also asked in the questionnaire. Unfortunately, the frequency was often not reported. The median duration of mechanical cleaning was about 160 minutes (average 215 minutes) per month for farms using dry feeding and 40 minutes (average 48 minutes) for farms using liquid feeding. In addition, liquid feeding farms used a median of 120 minutes (196 minutes) to clean the system with a water wash.

The feed material storages were cleaned on average 1.1 times (median 0.5 times) per month, whereas feed storages were cleaned on average 1.5 times (median 1) per month. Poison, traps, and cats were the most commonly used methods for pest control on farms, although a small number of farms did not report any pest control. The total costs of pest control on pig farms were estimated at \in 280 000 per year, of which 10% was assumed to be attributed to salmonella control.

The average time used for documenting self-monitoring (sampling and other quality control measures) was 1.7 hours per month (median 2 hours). This was assumed to concern only those feed manufacturers who must register with Evira, since they have requirements for a self-control program. A quarter of these costs were assumed to be attributed to salmonella control.

The share of costs attributed to salmonella control and the costs of salmonella control related to pig farms are presented in Table 16.

Cost factor	Costs attributed to pigs, 1 000 €	Share (%) attributed to salmonella in pig feed	Attributed to salmonella control 1 000 €
Salmonella sampling (Sikava)	44	100 %	44
Acid treatment	674–3 286	10 %	67–329
Cleaning measures	1 456–3 025	25 %	364-756
Pest control (trap, poison)	280	10 %	28
Self-monitoring (samples, labor)	17–19	25 %	9–10
Total	2 472–6 545	18–21%	512-1 166

Table 16. The annual costs of salmonella monitoring and control in pig farms.

7.4.5 Summary of the cost of salmonella prevention and monitoring

Table 17 summarizes the costs (parameters $P_h C_h$) attributed to measures to prevent and monitor salmonella of feed origin in pig farms and in the feed chain in the current situation. The total costs attributed to salmonella control in feeds were estimated to range from ≤ 1.8 to ≤ 3.0 million per year in Finland.

Table 17. Annual costs attributed to measures to prevent and monitor salmonella of feed origin in pig farms and in the feed chain in Finland¹).

	Attributed to pig feed, 1 000 €		Share attributed to salmonella control on average		Attributed to pig feed and salmonella, 1 000 €	
Import	105	109	100 %		105	109
Feed manufacturing	3 157	4 931	34 %	37 %	1 174	1 701
Pig farms	2 472	6 655	18 %	21 %	512	1 166
Mobile mixers	10	13	48 %	44 %	5	6
Total	5 744	11 707	25 %	31 %	1 797	2 982

¹⁾This table excludes costs due to measures taken when salmonella is observed in the pork supply chain.

7.5 Costs of salmonella contamination in feed, pigs, and the pork production process

Salmonella control is expected to reduce the costs caused by salmonella contamination in feed, pigs, or their environment, and illness in humans caused by salmonella originating from contaminated feed. Therefore, these costs must be estimated for a salmonella control program and for an alternative control policy before being able to assess the benefits of the program. The costs of salmonella contaminations at the import of feed materials, in commercial feed production (at a feed factory), and on pig farms were included in the analyses. In addition, the costs of feedborne infections in humans and the costs of contaminations to stakeholders such as slaughterhouses were taken into account. In the case of contaminations at a slaughterhouse, only the costs of feedborne salmonella were taken into account. The costs of Salmonella contamination of a mobile mixer were excluded from the analysis because of the missing information on salmonella prevalence (no observed cases), but the potential costs of mobile mixer contaminations were estimated to be relatively small. The analysis also approximated the value of disability adjusted life years (DALY) caused by salmonella and its sequelae in humans. Feed-related costs were defined for a batch of 25 tons of feed or on a per-pig basis.

7.5.1 Contamination in feed and feed material import and storage

The cost of salmonella contamination in imported and domestic feed materials (parameters $pa'_iw_iQ_i$) is dependent on the amount of high-risk feed imported and the prevalence of salmonella on it, as the direct costs are caused by treatments and additional sampling in a salmonella case. *Salmonella* in imported feed may also bring additional cleaning costs and delays in the feed production process. The treatment and cleaning of a contaminated warehouse was estimated on average at \leq 46 849 (SD 2237) per contaminated lot, including the acid treatment. Moreover, the costs of extra salmonella samples taken from a contaminated batch were estimated at \leq 3 938 (SD 2809) and the costs of extra rent for the warehouse at \leq 719 (SD 343) per contaminated batch. These values were arrived at by using information obtained on the size of feed batches that were cleaned in 2012–2013.

7.5.2 Contamination in the feed factory

The costs of salmonella contamination at feed manufacturing and manufactured feed are represented by $pa''_{j}w_{j}Q_{j}$. The extent of salmonella cases varies according to the "severity" of contamination and the volume of the production of the feed factory where the contamination is detected. The costs were determined based on a survey conducted with feed manufacturers. *Salmonella* can be detected in the feed, in the production line, or in the surroundings of the line, including the factory yard. If salmonella is detected in environmental samples taken outside the production facility, it does not directly concern feed. However, positive environmental samples also require disinfection and cleaning measures to be taken around the contaminated area. Based on the survey, we assumed these measures to cost ≤ 1 000 to ≤ 1 500.

The more severe case is when salmonella is detected inside the feed factory, in the production line or in the feed. Contamination detected in the production line requires a thorough cleaning of the facility and the production line, and it may require shutting down of the production line(s). Salmonella may contaminate only one production line, but may also contaminate several production lines if they exist. Based on the questionnaire responses, the costs of a salmonella case in the pig feed production line were assumed to range from €167 500 to €390 000 (on average €269 958). This estimate included cleaning and disinfection of the production line and associated warehouse(s), interruption of the production for one week, and additional work, and costs (indemnities paid) to the customers. Due to strict liability, the feed manufacturer is responsible for the cost of salmonella should the feed contaminate pig farms. However, these costs on contaminated farms are included in the subsequent section (costs to farms), even if they are to be paid by the feed supplier. According to expert consultation with a disinfection service provider (Personal communication, October 2015), the disinfection costs were of the relevant magnitude. Even though salmonella sampling and the hygiene measures cause costs, the most costly consequence was the business interruption of the feed factory. These costs represented on average 64% of the assumed costs. Business interruption leads to the loss of sales, which is described by a loss of the profit margin on labor and fixed costs. In addition, the interruption may have spillover effects on the costs of storing the feed and receiving feed materials.

7.5.3 Contamination at a pig farm

Salmonella contamination observed at a farm can have varying consequences. These costs are related to parameters $Pft_k w_k Q_k d_k$, where contamination in feed is accounted and to parameters $P''app''_r w_r Q_r \theta_{1,r}$ which account for costs due to salmonella contamination in pigs. The costs of extra sampling after detection of salmonella, working time and other resources used in cleaning measures, materials, the loss of value of contaminated feed, and potentially euthanized animals, as well as the cost of rendering feed and animals, were taken into account. These costs were estimated on a per-pig basis (i.e. \in per sow and \in per fattening pig). The size of the farm and spread of the salmonella contamination have a major effect on the cost.

The costs of cleaning and disinfecting a piggery and manure storage were ≤ 264 per sow (range $\leq 160-431$; including the costs for piglets) and ≤ 138 (range $\leq 106-190$) per fattening pig. The estimates were based on five realized cleaning cases examined with an expert of ETT Animal Health. If salmonella was detected in pigs, the pigs were assumed to be culled and rendered at Honkajoki Oy. The cost of this was estimated $\leq 1 640$ per farm plus ≤ 49.50 per sow and ≤ 16 per fattening pig. These costs were calculated using the same principles as rendering calculations by Lyytikäinen et al. (2011). The value of rendered feed was assumed to be ≤ 10.35 per sow and ≤ 4.07 per fattening pig (Heinola et al. 2012). The costs of official inspections, sampling, and self-monitoring were assumed to be ≤ 139 per sow and ≤ 62 per fattening pig, but restricted to $\leq 20 000$ per farm. In addition, each salmonella-positive farm was assumed to require altogether one person-month of additional work with ETT Animal Health and national veterinary authorities and one day from the slaughterhouse staff.

Restrictive measures were assumed to last on average 119 days (range 21–259 days) when pigs were found salmonella positive. According to Evira's records on restrictive measures, this was the average realized duration for farms contaminated with salmonella. When only feed or environmental samples from a farm were salmonella positive, the duration of restrictive measures was assumed to be 50% lower. Additional salmonella samples taken from feed incur a cost of €25 per 25-ton batch of feed.

The costs of the lost value of animals and costs due to business interruptions were estimated for fattening pigs by using the results of Niemi et al. (2004) and for sows and piglets by using the model presented by Niemi et al. (2010) (the model structure is described in more detail by Niemi et al. 2017). For fattening pigs, these costs can be approximated as follows (\notin per pig, min \notin 0):

- Salmonella-positive fattening pigs (pigs culled): 102+0.41*duration of restrictive measures
- Salmonella-positive samples (pigs not culled): -12.7+0.47*duration of restrictive measures

For sows (including suckling piglets), these costs can be approximated as follows $(\in \text{ per sow, min } \in 0)$:

Salmonella-positive sows (pigs culled): 665+0.53*duration of restrictive measures

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Salmonella-positive samples (pigs not culled): -0.6+1.3*duration of restrictive measures+4.8*105*duration of restrictive measures²

7.5.4 Detection at a slaughterhouse

Some of the costs (P''app $''_r w_r Q_r \theta_{1,r}$) incurred due to a salmonella contamination in pigs are faced by slaughterhouses and other industry stakeholders. Based on epidemiological results presented in the previous sections, a proportion of salmonella contaminations detected at the slaughterhouse are feedborne. Although feed control is not a part of a slaughterhouse's operation, feedborne salmonella contamination can sometimes go unnoticed at the farm and only be detected at the slaughterhouse, or contamination on a farm may require actions from the slaughterhouse. The costs that a slaughterhouse may face as a consequence of feedborne salmonella contamination must therefore be taken into account. According to cases reported to Evira, there have been four positive findings at a slaughterhouse per seven positive farm cases.

Three major companies slaughter 99% of the pigs produced in Finland. A questionnaire was therefore sent to them. In addition, there are very small companies that slaughter up to a few thousand pigs a year. Slaughterhouses do not receive animals from farms that are under restrictive measures. A contaminated farm must be verified free from salmonella by the municipal veterinarian before animals can again be delivered to the slaughterhouse. In case animals from salmonella-positive farms are to be slaughtered, they are slaughtered at the end of the day and additional washing and liming are applied at the slaughterhouse.

The prevalence of salmonella in meat is monitored through salmonella sampling from lymph nodes and surface swabbing in the slaughterhouses and through the samples taken from the pigmeat on production lines in the cutting house. Evira defines the quantity of required samples based on the volume for each slaughterhouse facility. The actual salmonella and quality control, including sampling, is operated by the staff of the facility. However, inspection veterinarians and meat inspectors work in the slaughterhouses. The inspecting veterinarians monitor that slaughterhouses accomplish their control program. The inspectors are Evira employees, i.e. civil servants.

If salmonella is detected from the lymph node sample or from the meat sample upon cutting the carcass, the inspecting veterinarian informs the Regional State Administrative Agency (AVI) and municipal veterinarian. The source of the contamination is traced. Additional cleaning measures and more frequent salmonella sampling are assumed to take place in the facilities. Meat must be heat-treated and meat product recalls are possible. If salmonella is detected at the slaughterhouse or an animal has been received from a farm where salmonella is suspected, additional cleaning and liming was assumed to be conducted.

If salmonella is found in an environmental sample, additional cleaning measures are assumed to be taken in the facility and re-sampling is done after hygienic measures until salmonella is not found (i.e. three negative sets of samples). The negative sample is confirmed in three days and confirmation of salmonella from a positive sample takes five to six days. The costs of cleaning measures and additional sampling at slaughterhouse facilities were taken into account in the analyses for feedborne contaminations. *Salmonella* control measures not related to feedborne cases were not included in the analysis.

Based on consultation with the slaughterhouses, two equally likely cases were developed: the detection of minor salmonella contamination, where additional measures take place for the minimum time, and a major case where additional measures last for a week. Slaughterhouses were assumed to face costs ranging from ≤ 1070 to ≤ 14620 due to extra working time and materials needed to clear a salmonella case that occurs on a pig farm (Table 18). This estimate was arrived at after consulting the major slaughterhouses in Finland.

Table 18. The range of cost (min, max, € per case) assumed following salmonella detection at a medium and large-sized slaughterhouse, including additional cleaning and sampling.

Cost	Mino	r case	Major case		Description of the measures
Extra sampling	590	2 070	070 2 950 10 330		Minor: Salmonella is detected, extra samples are taken, but no more positive samples are found. One set of extra samples. Major: Five sets of samples assumed (pos. pos.neg.neg.neg) to be taken.
Extra hygiene measures	480	1 430	1 430	4 300	Extra cleaning measures are applied for two/ six nights.
Total	1 070	3 500	4 380	14 620	Includes cost of samples and additional hygiene measures

7.6 Cost of salmonella in humans

7.6.1 Salmonella infections, health outcomes, and feedborne salmonella in Finland

Section 7.6 represents costs parameters $P_m w_m Q_m \theta_m f$. In 2013, altogether 1 997 persons were reported to have a salmonella infection in Finland. On average, the number of reported human cases during 1995–2015 was 2 530 cases per year (THL 2015). The minimum reported number of human cases during a year was 1 632 and the maximum was 3 566. There has been a decreasing trend of salmonella cases in recent years. However, the incidence of salmonella is not fully represented by notified cases. A review by Korkeala (2007) estimated that although the reported incidence has been 2 000 to 3 000 cases per year, the true number of salmonella infections in humans may have been 30 000, because only a small proportion of cases are identified as salmonella infection and thus notified.

Health outcomes of Salmonella in humans

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Salmonella in humans can be acute or asymptomatic. As acute symptoms, Salmonella causes gastroenteritis with a raised body temperature and bloody diarrhea most frequently associated with the pathogen. In the earlier literature, different severity levels of salmonella are used to describe salmonella infections to help identify the consequences and use different parameters. The severity of salmonella in humans can be described as mild, moderate, or severe. A mild infection leads to the full recovery of the infected person. A mild infection may have economic consequences, such as time off from work, but often does not lead to a medical record. In a moderate infection, the individual also fully recovers but feels unwell and probably visits his/ her general practitioner. In a severe infection, the individual has acute symptoms and may become a hospitalized patient.

There are also sequelae linked to salmonella infection. Reactive arthritis, irritable bowel syndrome (IBS), and inflammatory bowel disease (IBD) are the most frequently observed sequelae of *Salmonella*.

Health outcome: Acute symptoms

In 2013, the number of officially reported salmonellosis cases in Finland was 1997. Hence, when using the multiplier of 11.5 = 1/0.087 (FCC 2010) for underreporting, the total number of reported and unreported salmonella infections in Finland was approximately 23 000. Applying the same proportions for different health outcomes as in the FCC (2010) report, 18.3% of all salmonella infections were assumed to require a general practitioner's visit , 1.68% hospitalization, and 0.05% would have been fatal cases. Reported cases were assumed to be more severe (hospitalization and outpatient care) than unreported infections. As we assumed that 20% of the infections required health care and reported cases covered only 8.7% of all infections, 11.3% of the infections result in a general practitioner's visit because of the mild symptoms, although salmonella has not been diagnosed as the cause of the visit. Hence, the ratio reported cases to all infections is assumed to be 11.5. The number of incidents in 2013 overall and per 100 000 inhabitants is presented in Table 19 for all human salmonellosis infections.

Health outcome: Acute symptoms	Proportion of infections (<i>d</i> _m)	Incidents in 2013	Per 100 000 inhabitants in 2013 ²
Mild diarrhea – no health care	80.00%	18 327	337
Mild diarrhea – general practitioner's visit	11.30%	2 596	47.6
Moderate diarrhea – outpatient care	7.02	1 611	29.6
Severe diarrhea – hospitalization	1.68%	386	7.1
Fatal case	0.05%	12	0.2
Total	100.00%	22 966	421.5

Table 19. The estimated number of human salmonella infections with acute symptoms in Finland in 2013 covering all infections, irrespective of their source¹.

¹ Officially reported cases represent 8.7% of all incidents in the table.

² The population of Finland was 5.45 million in 2013.

Based on the results of the risk assessment presented in the previous sections, the total number of salmonella infections related to contaminated pig feed are estimated in Table 20. Infections related to pig feed represent less than 1% of all infections of salmonella in Finland. Per 100 000 inhabitants, this is only three infections in a year.

Table 20. Estimated total number of acute infections (reported and unreported) of human salmonella infections related to pig feed contamination in Finland in 2013.

Health outcome: Acute symptoms	Incidents related to salmonella- contaminated feed	Incidents related to salmonella-contaminated feed per 100 000 inhabitants in 2013
Mild diarrhea – no health care	130	2.4
Mild diarrhea – general practitioner's visit	18	0.3
Moderate diarrhea – outpatient care	11	0.2
Severe diarrhea – hospitalization	3	0.0
Fatal	0	0.0
In total	162	3

A productivity loss equivalent to 0.5 days of absence from work was assumed for the infections that do not require health care (c.f. FCC 2011). Infections requiring a general practitioner's visit but with salmonella being undiagnosed were assumed to require on average 1.1 days of absence from work, in addition to the general practitioner's visit, which could be a doctor or a nurse (based on Pires (2014)) and the lower limit of the duration of diarrhea). Diagnosed cases of salmonella were assumed to require 2.9 days of absence from work, which was based on the average duration of diarrhea (Pires 2014) and two general practitioner's visits (treatment and follow-up visit). Three negative salmonella samples were required to declare a person free from salmonella. In the event of salmonella with severe diarrhea, the duration of hospital admission was assumed to be on average 6.9 days (upper limit of duration by Pires (2014)).

	Table 21. Reditir care in relation to uncrent sever			
	Health outcome	Productivity loss and health care		
	Very mild diarrhea Productivity loss	Absence from work on average 0.5 days		
	Mild diarrhea General practitioner's visit and productivity loss	Absence from work 1.1 days. A general practitioner's visit (a nurse or a doctor)		
	Moderate diarrhea Outpatient care and productivity loss	Absence from work 2.9 days on average. Two visits to a nurse or a doctor (includes a follow-up examination)		
	Severe diarrhea	Absence from work 6.9 days. Hospitalized		

Table 21. Health care in relation to different severi	ty levels of salmonellosis
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Health outcome: Sequelae

Person hospitalized and productivity loss

Hannu (2002), Ekman (2000), and Mattila (1994; 1998) have evaluated the incidence of reactive arthritis (ReA) as a sequela to salmonella. The prevalence varies from 7 to 12% after salmonella outbreaks. We used the average prevalence of the studies, i.e. 8.1%. The probability of developing irritable bowel syndrome (IBS) as a sequela to salmonellosis is based on a study by Mearin et al. (2005). The prevalence after three months was 7.4%. The incidence of inflammatory bowel disease (IBD) as a sequela to salmonellosis was estimated according to Helms et al. (2006) to be 0.5%.

for 6.9 days. Two general practitioner's visits

(includes a follow-up examination)

A Dutch report (Havelaar et al. 2012) suggests that most evidence on ReA is collected from gastroenteritis GE cases requiring medical attention. In our analysis, it was assumed that only more severe GE cases are at risk of developing ReA, and ReA was therefore assumed for reported cases. However, given the uncertainty of who is at risk of developing ReA, we also formed a scenario where all infections that require medical attention can develop ReA. This is 20% of all infections, therefore including 11.3% of unreported infections. For IBD, only reported cases were assumed to develop the sequela. In the case of IBS, we assumed the sequela for reported cases and, in addition, for infections that required medical attention. Table 22 presents the number of sequela cases based on the scenarios that are related to pig feed contamination.

The number of people developing sequelae was estimated based on two scenarios:

- 1. Reactive arthritis (ReA)is developed for 8.1% of reported cases , irritable bowel syndrome (IBS) for 7.4% of 20% (requires medical service) of all infections and inflammatory bowel disease (IBD) for 0.5% of reported cases.
- 2. ReA is developed for 8,1% of 20 % (requires medical service) all infections, IBS for 7.4% of all infections and IBD for 0.5% of reported cases.

Table 22 summarizes the number of sequelae cases related to salmonellosis due to feedborne contamination. The scenarios had different assumptions regarding the development of sequelae for the proportion of unreported infections of human salmonellosis. The total number of cases for ReA, IBS, and IBD was 1.14, 2.40, and 0.07, respectively in scenario 1 and 2.63, 11.99, and 0.07, respectively, in scenario 2 in Finland. These estimates corresponded to 0.02, 0.04, and 0.001 cases per 100 000 inhabitants for ReA, IBS, and IBD in scenario 1 and 0.05, 0.22, and 0.001 cases per 100 000 inhabitants, respectively, in scenario 2.

Table 22. Estimated number of human salmonellosis infections related to pig feedborne contamination developing sequelae in Finland in 2013.

Number of cases annually	Sequelae to reported cases of human salmonellosis	Sequelae to unreported cases of human salmonellosis Scenario 1 ¹	Sequelae to unreported cases of human salmonellosis Scenario 2 ²	Number of cases in total Scenario 1 ¹	Number of cases in total Scenario 2 ²
Reactive arthritis (ReA)	1.14	-	1.49	1.14	2.63
Irritable bowel syndrome (IBS)	1.04	1.36	10.95	2.40	11.99
Inflammatory bowel disease (IBD)	0.07	-	-	0.07	0.07

¹Reactive arthritis (ReA) is developed for 8.1% and inflammatory bowel disease (IBD) for 0.5% of reported cases, and irritable bowel syndrome (IBS) for 7.4% from 20% of all infections.

² ReA is developed for 8.1% from 20% of all infections, IBD for 0.5% of reported cases and IBS for 7.4% of all infections.

7.6.2 DALY estimation

Disability adjusted life years were approximated based on the literature. Our DALY estimation used disability weights and the duration of the disease shown in Table 23. The estimate could be further detailed by considering different age groups with different life expectancies, gender effects, and other details. The duration of diarrhea of different severity is based on Pires (2014).

The last column in Table 23 presents DALY estimates for human salmonella infections originating from a salmonella contamination in pig feed. The total DALY is 1.0 per year excluding sequelae and 2.5–4.7 including sequela. The total estimate corresponds to 0.045–0.085 DALY per 100 000 inhabitants.

Health outcome	DW	Α	Reference	DALY
Diarrhea, mild	0.061	0.0014	Salomon et al. (2013); FCC (2011)	0.01
Diarrhea, overall	0.0817	0.0030	Pires (2014)	0.00
Diarrhea, moderate	0.202	0.0080	Salomon et al. (2013); Pires (2014)	0.02
Diarrhea, severe	0.281	0.0190	Salomon et al. (2013); Pires (2014)	0.01
Fatal case	1	12	Salomon et al. (2013); Pires (2014)	0.97
Reactive arthritis (ReA)	0.21	0.6	Cressey & Lake 2009; Mesle et al. (1998), cited by Haagsma et al. 2008, cited by Pires (2014).	0.15 / 0.34
Irritable bowel syndrome (IBS)	0.042	5	Haagsma (2008); Haagsma (2010), cited by Pires (2014)	0.50 / 2.52
Inflammatory bowel disease (IBD)	0.26	lifelong	Mangen et al. (2004), cited by Pires (2014); Silverstein 1999)	0.78

Table 23. The health outcome, disability weight (DW), duration of disease (A, in years), and DALY estimation for salmonellosis.

7.6.3 Cost of health outcomes of salmonella in humans

Public health care is produced with tax revenues in Finland, and customer charges do not therefore correspond to the real costs of the service. The cost of a doctor's appointment was on average \notin 110, the cost of a nurse visit \notin 47, and the cost of one day hospitalized \notin 213 in Finland in 2011 (Kapiainen et al. 2014). These unit prices are valid for the municipal public health care in 2011. The cost per infection included all examinations, medication, and materials needed.

The cost of lost labor productivity in Finland was on average €350 per day for the employer (State Treasury 2012). The cost of reactive arthritis was evaluated based on Kapiainen et al. (2014) at €1 800. The productivity loss was assumed to be 7 days. The cost of IBD was €1 800 and was based on the average of nine European counties and Israel (Burisch 2013). The productivity loss due to IBD was assumed to be 7 days based on Rocchi et al. (2012). The cost of IBS was based on Rome II criteria and it was assumed to be €500 per case. The cost of the labor productivity loss of about €150 was based on Hillilä et al. (2010). The costs of the productivity lost and health care are summarized in Table 24. Productivity loss was estimated for working age people and for the employment rate of 68.5 in 2013 (Statistics Finland 2013). The number of appointments and labor productivity loss days are defined in Table 24. Death was valued based on the value of €55 000 per lost life year (Asikainen et al. 2014) multiplied by the DALY value for fatal cases and divided by the number of fatal cases. Hence, when applying costs per case to scenarios 1 and 2 above, scenario 1 results in the costs of health outcomes being €530 to €550 per infected person and scenario 2 being €600 to €620 per person.

Health outcome	Cost of health care per case including	Nurse/doctor visit*	Nurse/doctor visit*
	productivity loss, €	Sequelae: Scenario 1 ¹	Sequelae: Scenario 2 ²
Labor productivity loss	180	62	62
Visit to general practitioner	430–494	24 / 32*	24 / 32*
Outpatient care	1 120–1 250	38 / 47*	38 / 47*
Hospitalized	4 150	47	47
Fatal case	666 000	330	330
Reactive arthritis (ReA)	3 500	18	41
Irritable bowel syndrome (IBS)	1 230	11	57
Inflammatory bowel disease (IBD)	4 400	1	1
Acute health outcomes in total		501 / 517	501 / 517
Sequelae in total		31	100
All health outcomes in total		530 / 550	600 / 620

Table 24. Costs of health outcomes, health care activities, and labor productivity loss (\notin per realization), and the cost of health care per health outcome on average for all salmonella infections (\notin per salmonella infection on average).

¹Reactive arthritis (ReA) is developed for 8.1% and inflammatory bowel disease (IBD) for 0.5% of reported cases, and irritable bowel syndrome (IBS) for 7.4% from 20% of all infections.

² ReA is developed for 8.1% from 20% of all cases, IBD for 0.5% of reported cases, and IBS for 7.4% of all infections.

7.7 Other costs of salmonella control to society

Besides the costs taken into account in our study, there are other costs related to salmonella control in the food supply chain. These costs are usually generic in nature and activities dealing with multiple diseases and multiple issues. It is therefore unknown which proportion of these costs are related to prevention, monitoring, and control measures associated with pig-feedborne salmonellosis. Although the detailed costs are unavailable, and therefore not taken into account in this study, we briefly discuss some of the aspects here.

The Ministry of Agriculture and Forestry coordinates public activities that fall under Ministry's remit. These include the steering activities of Evira and preparing legislation related to salmonella control. The food safety unit employs approximately 20 persons who work with a diversity of issues related to food safety.

Evira conducts research and monitoring related to salmonella. Besides the feed control activities included in our analyses, there are generic activities, such as food control, meat inspection, and a zoonosis center, which are relevant to salmonella control in the food chain. According to the financial report of Evira (2017), the costs of activities relevant to the control of salmonella and other hazards in the animal production chain were about \notin 20 million in 2016. Many of these activities are generic in nature and are not explicitly related to salmonella control, but they contribute to improved control of salmonella in the food chain.

The National Institute for Health and Welfare (THL) conducts research, monitoring, and other activities to ensure that salmonellosis is controlled appropriately. For instance, THL is responsible for collecting information on suspected human cases of salmonella. It is not known what proportion of their work is attributed to salmonella control.

Municipal service providers also play an important role in ensuring food safety in Finland. Läikkö-Roto et al. (2014) have estimated that the annual costs of food control to municipal authorities are approximately ≤ 16 to ≤ 18 million, and the full costs of food control to authorities are within the range of ≤ 33 to ≤ 36 million per year. By contrast, Hartikainen et al. (2012) have estimated the municipal costs at about ≤ 26 million per year.

Our rough estimation is that testing for antibodies and serotyping salmonella infections in the event that a human is infected by salmonella in Finland cost 0.2-0.4 million per year. However, this does not include costs due to testing for negative cases, which should also be taken into account as potential costs. The law also requires professionals working in so-called risk duties to be tested for possible salmonella infections. The risk duties include employees who handle food that may spoil easily, such as pork. It is not known how many persons work in duties related to handling pork. However, a recent study (Knuuttila and Vatanen 2017) indicated that food processing, retailing and catering services employ altogether 167 200 persons in Finland. If one third of them would go through salmonella testing per year, this would imply at least 0.2-0.4 million in annual testing costs alone.

Kilpeläinen et al. (2004) estimated that the costs of salmonella control on a pig farm were 14.9 eurocents per kilogram of pork. With the current production quantities of pork in Finland, this would mean approximately \leq 30 million in control costs.

ETT Animal Health is the main stakeholder organization combatting salmonella and other disease contaminations in the livestock supply chain. ETT's expenditures are approximately one million euros per year, some of which is directed to salmonella control.

7.8 Cost-benefit analysis

7.8.1 Salmonella control scenarios

In order to assess the costs and benefits of the pig feed salmonella control program, the costs of *Salmonella* monitoring and preventive measures, as well as the costs of feedborne cases of salmonella in Finland were estimated. The current situation was parameterized as described in the previous sections. In the current situation, there are statutory requirements to prevent salmonella contamination, and operators also apply voluntary preventive measures. Although salmonella control in feeds covers measures only until the pig eats the feed, there are costs throughout the chain that must be taken into account. In others words, costs incurred by feedborne salmonella cases on farms, at slaughterhouse, and human infections must also be taken into account, as they are affected by the efficiency of salmonella control of feeds. In the

case of salmonella contamination in the pork supply chain, the current regulation requires that the pathogen is eradicated immediately.

The estimated total costs of salmonella monitoring and prevention consist of the costs of preventive measures and the costs due to salmonella outbreaks and contaminations. The costs of preventive measures were calculated as the average costs per year in Finland and were as reported in Table 17. The costs of salmonella outbreaks and contaminations, should they occur, were simulated by Monte Carlo simulation model programmed in Matlab R2014b 8.4.0.150421 (Mathworks Inc., USA). All parameters (mean, median, standard deviation, percentiles) describing the prevalence of salmonella in different stages of the supply chain were obtained from the risk assessment scenarios presented in section 5.5 of this report. The costs associated with each contamination were determined as described in sections 7.5 and 7.6 of this report.

The costs of the current salmonella monitoring and control policy were compared with an alternative scenario. Hence, the two main scenarios analyzed were:

- The current pig feed salmonella control program
- A situation where the salmonella prevalence is similar to that presented in section 5.5.4. "Scenario 5: Salmonella prevalence in compound feed increases". In other words, the salmonella prevalence in pig feeds is assumed to be similar to the "EU average". This outcome is assumed to be obtained by the current pig feed salmonella control not being applied by the commercial feed manufacturers (feed mill and mobile mixers), importers, and other operators. This is referred to as scenario A.

Alternative scenarios A assumed a lower level of salmonella monitoring and prevention when the contamination of feed is concerned (Table 25), and they therefore incurred lower prevention and monitoring costs than the current program. In the alternative scenario, no measures were assumed to be taken to eradicate salmonella when feed is contaminated, but in the event that salmonella occurred in pigs or humans, the same measures were assumed to be taken as in the current situation, because these measures are not part of the pig feed salmonella control program.

Cost-benefit analysis scenario A assumes that regarding preventive measures, the statutory measures required by the control program are not required. For example, salmonella sampling (either official by authorities or by self-control) were on a lower level (10–50% below the current level). However, the majority of the control measures were assumed to be realized (Table 26). The share of measures that would be applied in scenario A was determined after consulting four experts in the feed sector. Reduced control measures were expected to increase the prevalence of salmonella. Cost-benefit analysis scenario A corresponded to the Scenario 5 in section 5.5.4: In the worst scenario, *all Finnish pigs* would eat this feed, and the increase could be as high as 55–fold (10- to 130-fold).

Summary of feedborne salmonella control measures applied in the current situation	Current situation	Scenario A ¹				
and in cost-benefit analysis scenario A.						
Import and storage						
Official control	Yes	No				
Self-monitoring (sampling)	Yes	Reduced				
Quarantine storage	Yes	No				
Eradication if Salmonella detected	Yes	No				
Commercial feed manufacturing						
Treatment	Yes	Reduced				
Hygiene measures	Yes	Slightly reduced				
Pest control	Yes	Slightly reduced				
Official control / sampling	Yes	No				
Samples as self-control	Yes	Reduced				
Self-monitoring (documentation)	Yes	Reduced				
Eradication if Salmonella detected ²	Yes	No				
Mobile mixers						
Treatment	Yes	Reduced				
Official control / sampling	Yes	No				
Hygiene measures	Yes	Yes				
Samples as self-control	Yes	Reduced				
Eradication if Salmonella detected	Yes	Reduced				
Pig farms						
Treatment (acid)	Yes	Yes				
Sampling	Yes	Yes				
Hygiene measure ^s	Yes	Yes				
Eradication if Salmonella detected	Yes	Yes, if in pigs				
Slaughterhouses						
Extra measures if salmonella is detected	Yes	Yes				

Table 25. Summary of feedborne salmonella control measures applied in the current situation and in scenario A.

¹ Scenario A corresponds to the worst-case scenario in section "5.5.4 Scenario 5: *Salmonella* prevalence in compound feed increases". In the worst scenario, all Finnish pigs would eat this feed, and the increase could be as high as 55-fold (10- to 130-fold).

²No costs of eradication accounted if salmonella detected in feed. This practice (no eradication if salmonella detected) does not correspond to the EU practice for compound feed.

operators when compared to their application rate (100%) in the current situation.				
Scenario A	Commercial feed manufacturers			
Share of measures still operated	Feed mill operators	Mobile mixers		
Sampling as self-monitoring	50-90%	50-90%		
Treatment (time and materials)	95 %	50 %		
Treatment (installation and maintenance)	100 %			
Official control	0 %	0 %		
Sampling by official control	0 %	0 %		
Hygiene measures	100 %	100 %		
Pest control	100 %			
Time used for other self-monitoring measures (documenting measures etc.)	80 %	75 %		

Table 26. Share of preventive and monitoring measures applied in scenario A by feed business operators when compared to their application rate (100%) in the current situation.

In addition, a sensitivity analysis was conducted regarding the current scenario. In the sensitivity analysis scenarios, the prevalence of feedborne salmonella at different stages of the production chain were increased by using an exponential scale. Hence, in the Exp 1 scenario, the incidence was 2.7-fold higher, in the Exp 2 scenario 7.4-fold higher, in the Exp 3 scenario 20.1-fold higher, and in the Exp 4 scenario 54.6-fold higher when compared to the 2013 prevalence. In sensitivity analysis, the prevalence of salmonella at different stages of the production chain was increased systematically. The sensitivity analysis scenarios only focused on the costs of realized salmonella contaminations. *Salmonella* monitoring was assumed to continue as it is currently, and only the prevalence and the costs of contaminations were assumed to change when compared to the current situation whereas preventive measures were not examined in these four scenarios.

7.8.2 Cost of salmonella control in pig feeds

The annual costs of salmonella contaminations, which were simulated by using Monte Carlo method and costs reported in section 7.5, are presented in Table 27 for the current situation and for scenario A. In the current situation, the simulated cost of salmonella contaminations at import and in feed manufacturing were ≤ 1.3 to ≤ 1.8 million, depending on whether a high or low estimate for the costs was used. The total costs for preventive and monitoring measures ranged from ≤ 1.8 to ≤ 3.0 million per year. Feed-related costs caused by salmonella contaminations and human infections were on average ≤ 2.4 million (95% range of variation 0.3–6.1, median ≤ 2.1 million). Resolving contamination of imports and stored feed materials incurred on average ≤ 1.8 million, and resolving a feed-related costs of pig feedborne salmonella contaminations were estimated on average at ≤ 4.2 to ≤ 5.4 million per year, although in individual cases they could be substantially lower or higher.

In scenario A, the costs of preventive and monitoring measures were reduced to range between €1.1 and €2.1 million per year. The savings, when compared to the current situation, were due to reduced sampling and measures taken in the import process and feed manufacturing. In addition, no costs were incurred to importing bodies or feed manufacturers, even if salmonella was observed in feed or feed materials. However, the prevalence of salmonella would rise, having effects on salmonella eradication measures and their cost at farms and slaughterhouses, and eventually the costs of human cases. These costs were simulated to rise to \notin 32.7 million on average (95% range of variation €1.1 million to €123.9 million). While contaminations in feed incurred no costs, the increased risk of pigs being contaminated increased the costs at farms to €20.5 million on average. In addition, costs to slaughterhouses and industry stakeholders soared on average to €6.0 million per year. Finally, human infections were estimated to result in costs on average of €6.2 million per year. The 95% range of variation due to variation in prevalence for these costs was €0.1-22.0 million when assuming 0.05% fatal cases. However, due to the large value of fatal cases, the full range of variation would be substantially higher when variation in the number of fatal cases would be considered. Hence, the total costs were €33.8 to €34.8 million per year.

The costs in scenario A are approximately \in 30 million higher than the costs estimated for the current situation. When comparing scenario A with the current situation, the rise in costs due to human infections is already larger than the estimated savings in the costs of monitoring and prevention measures.

	Current programme					Scer	nar	io A						
	Low cost control	High cost control		[CI 95%]		Low cost control	High cost control	[CI 95%]						
Prevention and monitoring														
Measures at import and storage	0.1	0.1						0	0					
Measures at feed manufacturing ¹⁾	1.2	1.7						0.6	0.9					
Measures at pig farms	0.5	1.2						0.5	1.2					
Subtotal	1.8	3						1.1	2.1					
Costs caused by contaminations														
Contamination at import or storage	1.8	1.8	[0.0	,	4.5]	0.0	0.0	[0.0	,	0.0]
Contamination at feed factory	0.0	0.0	[0.0	,	0.1]	0.0	0.0	[0.0	,	0.0]
Contamination at farm	0.4	0.4	[0.1	,	1.1]	20.5	20.5	[0.6	,	80.7]
Costs to slaughterhouse	0.1	0.1	[0.0	,	0.4]	6.0	6.0	[0.2	,	26.1]
Costs of human infections	0.1	0.1	[0.0	,	0.3]	6.2	6.2	[0.1	,	22.0]
Subtotal	2.4	2.4	[0.3	,	6.1]	32.7	32.7	[1.1	,	123.9]
Total costs	4.2	5.4						33.8	34.8					

Table 27. Simulated costs of Salmonella prevention and monitoring and Salmonella-contaminated pig feed, pigs, and human infections (€ million per year, 95% range of variation within brackets).

¹⁾ Includes the costs of mobile mixers

7.8.3 Sensitivity analysis

Table 28 reports the results for a sensitivity analysis where the prevalence of salmonella at each stage of the supply chain was increased on an exponential scale (Exp1, Exp 2, Exp 3, Exp 4). As these scenarios assumed the prevention and monitoring of salmonella to continue according to the current situation, even relatively small changes in the prevalence of salmonella in feed material imports could substantially increase the costs of salmonella contaminations. This effect was simulated to be similar to the rise in the prevalence of salmonella in feed.

The results in the previous section suggest that potential savings in prevention and monitoring costs when eliminating the current official salmonella control of feeds would be less than €1 million per year. Comparing these results with the sensitivity analysis indicated that a 2.7-fold increase in the costs of contaminations in feed increased the costs approximately by the amount what could be saved by eliminating salmonella control of pig feed and feed materials. A more than 7.4-fold increase in the costs of human cases was required for the cost change to be larger than the savings in prevention and monitoring measures if eliminating the salmonella control of feeds. Hence, the sensitivity analysis suggests that the rising prevalence of

salmonella contaminations, similar to scenarios 3 and 4 in section 5.5.3, was already likely to increase the costs of salmonella contaminations by more than what could be saved by eliminating the salmonella control program for feed.

Table 28. Sensitivity analysis reporting the average costs (€ million per year on average) caused by salmonella contaminations for each stage of the supply chain and human cases when the prevalence of salmonella in each stage is increased 2.7-fold (Exp 1), 7.4-fold (Exp 2), 20.1-fold (Exp 3) or 54.6-fold (Exp 4). The costs exclude prevention and monitoring costs.

	Current	Increased prevalence scenario				
Scenario	situation	Exp 1	Exp 2	Exp 3	Exp 4	
Change compared to the current situation	1-fold	2.7-fold	7.4-fold	20.1-fold	54.6-fold	
Phase where increased prevalence occurs						
Contamination at import or in the manufacturing of feeds	1.8	4.9	13.4	36.4	98.4	
Contamination at farm	0.4	1.0	2.7	7.4	20.0	
Costs to slaughterhouses	0.1	0.3	0.7	2.0	5.5	
Costs of human infections	0.1	0.3	0.8	2.1	5.7	

8 CONCLUSIONS OF COST-BENEFIT ANALYSES

Highlights:

- The results suggest that preventive and monitoring measures to control salmonella in pig feeds cost approximately €2.8–3.0 million per year. The total costs, which include both prevention costs and costs due salmonella contaminations and human cases, were €4.2– 5.4 million per year.
- The costs of the alternative scenario were estimated on average at about €34 million. The alternative scenario assumes that the costs of current statutory control measures are not applied and therefore control measures are reduced.
- The results suggest that the current salmonella control program is profitable. The benefit-cost ratio of the program was estimated to be higher than one when comparing the current situation with the alternative scenario.

The results suggest that the current salmonella control program is economically profitable, when its benefits (prevented costs of salmonella contaminations) are compared to the costs of the alternative. The results indicate that human health costs can already be substantially larger than potential savings in preventive and monitoring costs related to pig feed salmonella control. In scenario A, the changes particularly impact on pig farms. For an individual farm, the costs of salmonella contamination can be large. In the current situation, salmonella group insurance can cover the costs to a farm, but the price of insurance would probably increase substantially if applying it in cost-benefit analysis scenario A.

The results suggest that preventive and monitoring measures to control salmonella in pig feeds cost approximately $\leq 2.8-3.0$ million per year. However, some of the costs are expected to also be realized in the absence of the current control program. Therefore, the results suggest that the cost saving due to eliminating preventive and control measures could be less than one million euros per year. Hence, the benefitcost ratio of the program was estimated to be substantially higher than one. The rise in the cost in each stage from farm to consumer was more than the potential savings in the costs if mandatory salmonella prevention and monitoring measures in feed were eliminated. The option examined in the cost-benefit analysis is based on the assumption that salmonella control in pig feeds would be adjusted, while the measures for pigs, slaughterhouses and human cases remained similar to the current situation. This means salmonella would still be eradicated if found elsewhere in the pork supply chain than in pig feed. The results also show large variation in the costs. In most years, the costs are less than €5 million, but the average estimate is elevated by individual years resulting in high costs. However, the variation in costs presented in this report refers to variation in the average annual costs rather than fully describing the extreme cases. For instance, the costs of salmonella outbreak associated with a contamination at a feed factory in 2009 are in the margin beyond the 97.5th percentile of the simulated costs.

The sensitivity analysis suggests that a rise in the prevalence of salmonella contaminations similar to scenarios 3 and 4 in section 5.5.3 would already be likely to increase the costs of salmonella contaminations by more than what could be saved by eliminating the salmonella control program for feeds.

The salmonella control program for feeds is an income transfer from feed business operators to consumers. As feed processors could gain from relaxing the regulations regarding salmonella in feed, it is essential that the companies are able to extract a price premium from the markets to cover their extra costs.



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10 APPENDIX

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10.1 Appendix 1. Abstracts from scientific papers

Below are the scientific abstracts of papers published from the project "Risk assessment and cost-benefit analysis of salmonella in feed and animal production."

Food Microbiology, Available online 31 May 2017 Bayesian model for tracing Salmonella contamination in the pig feed chain V. Välttilä, J. Ranta, M. Rönnqvist, P. Tuominen

Salmonella infections in pigs are in most cases asymptomatic, posing a risk of salmonellosis for pork consumers. Salmonella can transmit to pigs from various sources, including contaminated feed. We present an approach for quantifying the risk to pigs from contaminations in the feed chain, based on a Bayesian model. The model relies on Salmonella surveillance data and other information from surveys, reports, registries, statistics, legislation and literature regarding feed production and pig farming. Uncertainties were probabilistically quantified by synthesizing evidence from the available information over a categorically structured flow chain of ingredients mixed for feeds served to pigs. Model based probability for infection from feeds together with Salmonella subtyping data, were used to estimate the proportion of Salmonella infections in pigs attributable to feed. The results can be further used in assessments considering the human health risk linked to animal feed via livestock. The presented methods can be used to predict the effect of changes in the feed chain, and they are generally applicable to other animals and pathogens.

Food Microbiology, Available online 12 April 2017, Short communication Salmonella risk to consumers via pork is related to the Salmonella prevalence in pig feed, M. Rönnqvist, V. Välttilä, J. Ranta, P. Tuominen

Pigs are an important source of human infections with Salmonella, one of the most common causes of sporadic gastrointestinal infections and foodborne outbreaks in the European region. Feed has been estimated to be a significant source of Salmonella in piggeries in countries of a low Salmonella prevalence. To estimate Salmonella risk to consumers via the pork production chain, including feed production, a quantitative risk assessment model was constructed. The Salmonella prevalence in feeds and in animals was estimated to be generally low in Finland, but the relative importance of feed as a source of Salmonella in pigs was estimated as potentially high. Discontinuation of the present strict Salmonella control could increase the risk of Salmonella in slaughter pigs and consequent infections in consumers. The increased use of low risk and controlled feed ingredients could result in a consistently lower residual contamination in pigs and help the tracing and control of the sources of infections.

10.2 Appendix 2. (Appendix to Table 12)

Appendix table. Mean, median, and 95% credible interval for the estimated true prevalence^{*3} (%) of *Salmonella* sp. in feed materials and complete feeds for sows and pigs (growers and finishers)

Feed material	Mean	Median	CI 2.5%	CI 97.5%
Bean	0.17	0.08	<0.01	0.87
Brewer's yeast	0.13	0.06	<0.01	0.67
Flax	2.14	0.97	<0.01	10.7*4
Milk & milk rinse	0.11	0.05	<0.01	0.56
Pea	0.51	0.22	<0.01	2.63*4
Rank/distiller's solids	0.02	0.01	<0.01	0.09
Soy (domestic processing)	0.33	0.29	0.05	0.87
Sunflower	0.16	0.07	<0.01	0.81
Whey	0.01	0.01	<0.01	0.07

Complete feed (usage% on farms)	L/D*2	Mean	Median	CI 2.5%	CI 97.5%
Farm-made feed*1 for sows & pigs	L	0.02	0.02	0.01	0.05
(1 & 1)					
Farm-made feed for sows & pigs	D	0.02	0.01	0.01	0.03
(1 & 1)					
Non-domestic complete feed for sows & pigs	D	3.78	1.65	<0.01	19.3*4
(<0.1 & <0.1)		3.84	1.77	<0.01	19.0*4

*1 Feed is served to pigs in liquid (L) or dry (D) form

*2 without an industrial complementary

*3 Based on a Bayesian risk assessment model

*4The notable uncertainty due to the small number of samples for some categories causes high statistics such as the upper limit here, estimated using the Bayesian model with a fairly uninformative prior distribution over the whole range 0–100%: Note that there have been no salmonella findings, but when the sample size (evidence) is also small, these results substantially rely on vague prior information.

10.3 Appendix 3. Bayesian risk assessment model

The model has been presented in Välttilä et al. (2017), and a summary of the model will be provided in the following sections from 1 to 4. Some model sensitivity analyses are available in section 5. The procedure for modeling further predictions related to scenario situations is described in section 6.

Typing-based model for source attribution (1)

Both a source attribution model utilizing the subtyping data of salmonella isolates (section 1) and a chain model accounting for the exposure (sections 2-4), were used for the risk assessment (full model). In the typing-based model, the frequencies (f) of the subtypes in the sources are estimated

$$(o_{1,1}, o_{2,1}, o_{3,1}...o_{T,1}) \sim Multin(f_1, N_1); (o_{1,2}, o_{2,2}, o_{3,2}...o_{T,2}) \sim Multin(f_2, N_2)$$
 (1)

where $f_1 \otimes f_2$ are for two defined sources: "feed" and the other alternative sources, referred to as the environmental source, or "the environment", respectively, and the data, $o_{t,s}$, are the number of subtype t isolates from source s (isolates totaling N_s). For the frequencies, prior was chosen

 $f_s \sim Dir(\frac{1}{T}, \frac{1}{T}, \frac{1}{T}...); T = no. of different subtypes in total$

Then, the proportion (ϕ_s) of source s of the salmonellas from infected animals can be estimated

$$(a_1, a_2, a_3...a_t) \sim \text{Multin}(F, N)$$
 where $F = f_1 \cdot \phi_1 + f_2 \cdot \phi_2$ (2)

and where data, a_t , are the number of subtype t isolates (totaling N). Also, $\phi_2 = 1 - \phi_1$. A prior $\phi_1 \sim \text{Unif}(0,1)$ was set if the attribution model was used separately. However, in the full Bayesian model, ϕ_{1r} (r indexing pigs & sows) was equated to $-\ln(1-\text{Pf}_r) / [-\ln(1-\text{Pf}_r) -\ln(1-\text{Pe}_r)]$ that is the proportion of infections from feed in the chain model as described in section 2.

Infection and dose-response model for pigs (2)

In the chain model the probability of infection (Pinf) from "feed" or "environment" was interpreted as the true lymph node prevalence (ppt)

$$xp \sim Bin(np, ppa) = Bin(np, ppt \cdot si) = Bin(np, Pinf \cdot si)$$
 (3)

where xp is the number of positives in np samples. An informative Beta(279.7, 652.6) prior was used for the sensitivity (si) of the lymph node testing, with apparent prevalence (ppa). The chain model was also set for pigs and sows each (index r not shown). This probability of infection (Pinfr,) for animal during the period T (modeled rearing/feeding period)

P(at least one infection during T) = 1 - P(none occurs) =

$$1 - e^{-(\lambda_f + \lambda_c)T} = 1 - e^{-(\frac{-\ln(1-Pf)}{T} + \frac{-\ln(1-Pe)}{T}) \cdot T} = 1 - e^{\ln(1-Pf)} \cdot e^{\ln(1-Pe)} = 1 - (1 - Pf) \cdot (1 - Pe)$$
(4)

was based on a continuous-time Poisson process with constant intensity for two causes (λ for intensities, P for probabilities, f indexing feed, and e environment). Ratio of primary infection from feed,

 $-\ln(1-Pf) / [-\ln(1-Pf) - \ln(1-Pe)]$, is the conditional probability, given that infection occurred during T.

Then the probability of feedborne infection (Pf) during T was calculated for a pig representing the whole population of pigs with different feeding types. With mutually exclusive feeding-type specific infection events

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(5)

(8)

 $Pf_r = P(infection from feeds 1|pig type fed feeds 1) \cdot P(pig type fed feeds 1) + ...$

+ $P(\text{infection from feeds } K | \text{pig type fed feeds } K) \cdot P(\text{pig type fed feeds } K)$

 $= Pft_1 \cdot rp_{1,r} + Pft_2 \cdot rp_{2,r} + ... + Pft_K \cdot rp_{K,r}$

where Pft_k are data on share of farms using each feeding type/feeds. For each of these complete feed categories (index k), the probability of infection during the whole rearing period

$$Pft_{k} = 1 - (1 - Pfb_{k,1}) \cdot (1 - Pfb_{k,2}) \cdot (1 - Pfb_{k,3}) \cdot \dots \cdot (1 - Pfb_{k,Y})$$
(6)

where Pfb is the probability of infection during consumption of a batch (Y batches). For the modeled 25 ton batches, farm consumption (average daily feed serving 4kg or 2.5kg, and no. of animals 123 for sows or 603 for pigs) was set to last around a month (30 days, fairly consistent with questionnaire).

The probability of infection from a complete feed batch category k (lasting tc days)

 $Pfb_{k,y} = P(infective dose at least in one day for a batch consumed at yth month) =$

= $P(\text{infective dose at least in one day} | \text{cont. batch}) \cdot P(\text{contaminated batch})$

$$= \left[1 - (1 - Pd_{k,y})^{tc}\right] \cdot pt'''_{k}$$

$$\tag{7}$$

where $Pd_{k,y,n}(c_{rep} "'_{k,n} \cdot ms_y)$ is the dose-response probability, given that the batch is contaminated, and pt''_{k} is the prevalence in batches. Further on, $c_{rep} "'_{k,n}$ is the salmonella concentration in contaminated batch (n replicates, see section 4 for concentration, and 3 for prevalence), and msy the daily feed amount, giving the dose. A logistic regression model was used to estimate the dose-response curve, as an independent sub-module (separated with OpenBUGS cut). Normal(0, 1.0E-3) prior was used for the coefficients.

Model for prevalence in feed (3)

The prevalence in feed material batches of 25 tons was modeled

$$\mathbf{x}' \sim \operatorname{Bin}(\mathbf{n}', \mathbf{pa}') = \operatorname{Bin}\left(\mathbf{n}', \mathbf{pt}' \cdot \overline{\mathbf{s}}'(\mathbf{c}_{\operatorname{rep}' \mathbf{n}})\right)$$

where x' is the number of positives in n' (approximated) samples representing the batches, and pa' apparent prevalence. Sensitivity (\mathbf{s} ') is function of concentration in contaminated ($c_{rep'n}$). A slightly informative prior Beta(0.5,1.5) was used for the true prevalence (pt'), as for the categories with the fewest samples, reliance on a flat prior was considered as unrealistic.

The true prevalence (pt'_{i}) in feed material (i=1...l) was converted to an overall concentration by assuming a Poisson model: $C_i = -\ln(1 - pt'_i)/W_i$ (setting $W_i = W_j = W_k = 25$ tons in all calculations, in this report). These overall concentrations $C_1...C_1$ were mixed with relative weights $M'_{i,j}$,..., $M'_{i,j}$ (data), giving the batch prevalence for mixture, e.g. here a compound feed category j with batch mass W_j

$$pt''_{j} = 1 - e^{-w_{j}(C_{1} - w_{j}, 1 + \dots + C_{1} - w_{j}, 1)}$$
(9)

In the same way, the dependence between the prevalence for compound feed categories (pt''_{j}) and complete feed categories (pt''_{k}) was set. In addition, at the compound feed level (mixtures j=1...] of feed materials i=1...I based on equation 9), the prevalence is simultaneously also inferred from the sample data in the same

way as for feed materials (equation 8). This type of synthesis of multiple evidence is possible in Bayesian hierarchical models.

Model for the concentration in contaminated feed (4)

Levels in random feed material batches contaminated ($c_{rep'n}$ for n=1,...,N; N=20 repetitions) were simulated from Normal(μ' , τ). Measurement data, and priors Gamma(1.0E-3, 1.0E-3) for global precision τ , and Normal(0, 1.0E-6) for mean parameters, were used. Detection probability (s'_n) was modeled (for $c_{rep'n}$) similar to dose–response curve, and sensitivity (s') obtained. Also, chemical treatment was set for feed material

 $c_{rep} *_n = c_{rep'n} \cdot (det_n \cdot \Delta + 1 \cdot det_n)$ where $det_n \sim Bern(s'_n)$ and $s_n = f(c_{rep'n})$ (10)

based on sensitivity model, and Δ is the reducing factor for treatment, concerning observed contamination. Another factor (d_j) was set for the effect of the heat treatment, concerning commercial compound feed categories. The concentration in contaminated batches of mixed categories, now complete feed category k, was modeled simplifying the prediction as (n for repetitions)

$$c_{rep}''_{k,n} = c_{rep}''_{IND_{k,n}}$$
 where $IND_k \sim cat_k (\Pr_{j=1...J})$ and $\Pr_{k,j} = \frac{1 - e^{-W_k \cdot M''_{k,j} \cdot C_j}}{\sum_{j=1}^{J} 1 - e^{-W_k \cdot M''_{k,j} \cdot C_j}}$ 11)

where $Pr_{k,j}$ is (for j) among compound feeds j=1...J, the relative prevalence (see equation 9). Few measurements for commercial compound feed categories were available ($c''_{j,z}$). Here, mu''_{j} is the sample mean and tau''_{j} is the sample precision of $log_{10}(c_{rep}''_{j,n})$ in n simulated repetitions

$$c''_{j,z} \sim \operatorname{Norm} (\mu_j'', \tau_j'')$$
(12)

Sensitivity analyses for the full model (5)

As previously described, scarce concentration data were available to represent contaminated industrial categories of compound feed, and measurements from feed materials were gathered from the literature. To demonstrate the sensitivity of the assessment for information on the concentration, when the calculation was performed relying solely on the literature (3 feed measurements then excluded), the proportion of infections attributable to feed was 25% (mean, 95% CI 2–69%) for pigs and 47% (7–92%) for sows. The scarce measurements from industrial compound feed (categories) suggested a higher concentration compared to that predicted for feed based on heat-treated feed materials. This could have been due, for example, to a higher initial concentration of the feed materials, less effective decontamination treatment, or growth after heat treatment in these contamination events.

The full model was also compared with the sub-model relying on salmonella typing data, as the modules can be run as stand-alone. The proportion of infections estimated as feedborne then became 26% (mean, 95% CI 3–63%) and 41% (5–89%) for pigs and sows, respectively, when only the module using subtyping information was used. As described, the actual infection sequences at the farm level are unidentifiable with the data currently available, and the difference between the estimates using subtyping data in combination with feed chain data and subtyping data alone could be due to various unknown or known factors, e.g. unquantifiable events for bacteria along the chain.

Moreover, tests of sensitivity for data representing salmonella types in feed were performed with the sub-model. Excluding storage findings resulted to attributing 21% (posterior mean, 95% CI 1–57%) of pig and 36% (4–84%) of sow infections to feed. If only sampling (directly) from feed materials was taken into account, the results were 20% (mean, 95% CI 1–54%, median 17, mode 7) and 36% (mean, 95% CI 4–85%, median 33, mode 22) for pigs and sows, respectively, although none of the samples then represented, for example, domestic grain dust sampling. In addition, an alternative treatment of the data was tested, where only one sample of the same salmonella subtype per ship was counted (instead of ship-independent batches). In this way, the proportion of infections estimated as feedborne was 30% (mean, 95%) CI 4-68%) and 48% (6-93%) for pigs and sows, respectively. Findings used in the typing based model were chosen relying on consideration during the risk assessment. In raw information sources (Table 10), there were also other findings, that couldn't be utilized. Pig lymph node findings were S.Typhimurium NST, 2 FT41, and 2 FT1, S.Enteritis and S.Infantis, and sow lymph node findings were S.Typhimurium FT1, FT195 and 5 NST, S.Mbandaka and 2 S.Kisarawe.

Predictions for scenarios (6)

Scenarios were modeled by constructing a parallel replicate of the default Bayesian model network. The parameters in the original network were still estimated as in the default situation using Bayesian inference based on all end points (=data), but those in the parallel network were copied from the original and then used for predicting all variables along the parallel chain. Hence, the parallel chain was simulated as a causal chain without probabilistic inference backwards from end points. Causal effects were included in these predictions, e.g. by changing factors for decontaminating treatments related to the scenario (other than this, the concentration in complete feed categories was predicted to be similar to the default situation), and the prevalence in scenario-related materials was independently estimated using additional data described in section 5.5 (same x/n sample data format and modeling, equations in appendix 3, W=25t). The increase in pig prevalence for the scenarios was obtained by comparison between the prevalence in the default network and the predicted prevalence in the scenario network.

In scenario 5, predicted concentration (1-log reduction from feed material concentration $c_{rep n'} eqn. 9$) was on average less than -1 log₁₀ cfu/g (95%: -4 - 2), test sensitivity 0.3 (95%: 0.2 - 0.4), and true feed prevalence then 3% (95%: 2 - 6%). In scenario 5, it was noticed that if concentration, and therefore test sensitivity, would be lower, the uncertainty for predicted true pig prevalence would increase. (For accurate estimation of true prevalence, test sensitivity obviously needs to be reasonably high). In scenario 3, true prevalence for feed materials were: 3.8% (2.4 - 5.6%) for non-domestic rapeseed, 3.4% (2.3 - 4.8%) for soy (non-domestic processing), and 1.8% (0.9 - 3.1%) for sunflower (test sensitivity as in default model, 95%: 0.4 - 0.7). Then, predicted true feed prevalence ranged from 0.4% (0.3 - 0.5%) for Commercial complete feed for pigs to 0.05% (0.03 - 0.07%) for Farm-made feed + liquid complementary feed, sows & pigs (examining categories in Table 12). In scenario 1, true prevalence ranged from 0.06% (0.03 - 0.10%) for Commercial complete feed for sows to 0.01% (<0.01 - 0.04%) for Farm-made feed + liquid complementary feed, sows & pigs (examining categories in Table 12).

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10.4 Appendix 4. Description of three examples of salmonella contamination on pig farms

Piggery background	Description of the incidents	Duration of the restrictive regulations, days	Number of samples (self- monitoring/ official)	Number of euthanized animals
Case 1 400 finishers in one building The last batch of pigs arrived the week before salmonella was detected on the farm	Salmonella was detected in the drained soya meal silo, which was investigated because of a notification from the feed manufacturer. Samples (environmental, feed etc.) were taken and the restrictive regulations were set by the provincial veterinarian. Contaminated soya was destroyed and other hygiene measures, such as cleaning the silo, were performed. Salmonella did not spread to the animal housing. Salmonella was not re-found after cleaning measures. New samples taken were negative, allowing the removal of the restrictive regulations.	53	135 (110/25)	None
Case 2 Farrowing- to-finishing piggery in one building 50 sows 112 piglets Pigs in weaner unit 168/216 depending on the week Pigs in finishing unit 182/208 depending on the week Separate feed distribution in each unit	Salmonella was detected in a collective sample that was taken from sows (sampling takes place every 5 years in piggeries that are at the national level in Sikava). Samples were taken from the animals, environment, feed, and as feed environmental sampling. More salmonella-positive samples were obtained from the feed, from the warehouse, and in the farrowing unit from the sows and in the pens. Contaminated animals were removed and hygiene measures started. The feed warehouse also required renewal. Salmonella was still found after cleaning measures from the same farrowing unit. More sows and their piglets were removed. As a result of the prolonged salmonella renovations, the lack of space forced the removal of healthy swine and weaners to Honkajoki.	93	630 (630/50)	Sows 9 Piglets 72 Weaners 56 Finishers 280
Case 3 Farrowing farm 50 sows 100 piglets in the farrowing unit 200 pigs in the weaner unit Two bulidings Separate feed distribution in each unit	Salmonella was detected at the slaughterhouse lymph node sample and tracked to the farm. Sampling at the farm revealed that the whole weaner unit was contaminated with salmonella. As a consequence, the whole unit was emptied of animals and carefully cleaned. The source of salmonella was traced to complete feed for weaners, which was removed. The severity of the case was caused by the fact that salmonella was detected from the complete feed, which was manufactured by a feed mill and delivered to several farms	46	245 (230/15)	Weaners 240

10.5 Appendix 5. Illustration of the terms for material categories in the risk assessment model

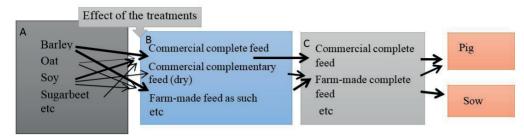


Figure 1. Illustration of the materials in the risk assessment model: complete feed (categories) consist of compound feed (categories), and compound feed (categories) consist of feed material (categories)

A: Feed material (categories):

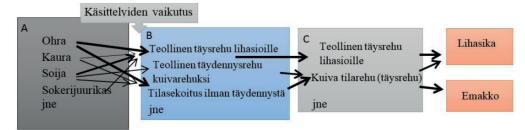
soy(-derived), rapeseed or turnip rapeseed(-derived), sugarbeet(-derived), soy(derived, domestic processing), rapeseed or turnip rapeseed(-derived, domestic), sugarbeet(-derived, domestic), bran, barley, oats, wheat, bean, brewer's yeast, flax, milk & milk-rinse, pea, rank/distiller's solids, sunflower, whey, (for technical reasons included in feed materials:) non-domestic complete feed for sows & pigs, (following 4 categories assumed as clean and excluded:) fish oil, vegetable oil, minerals, premixes

B: Compound feed (categories):

commercial complete feed for sows, commercial complete feed for pigs, commercial complementary feed for sows (dry), commercial complementary feed for pigs (dry), liquid complementary feed, farm-made feed (dry), farm-made feed (liquid), non-domestic complete feed for sows & pigs

C: Complete feed (categories):

commercial complete feed for sows, commercial complete feed for pigs, farm-made feed + complementary feed for sows (liquid), farm-made feed + complementary feed for pigs (liquid), farm-made feed + complementary feed for sows (dry), farm-made feed + complementary feed for pigs (dry), farm-made feed + liquid complementary feed (sows), farm-made feed + liquid complementary feed (pigs), farm-made feed for sows & pigs (liquid), farm-made feed for sows & pigs (dry), (note: at step C, categories with farm-made feed have certain proportion of liquid complementary feed), non-domestic complete feed for sows and pigs



Kuva 1. Riskinarviointimallin materiaalit: täysrehu (C) kategoriat koostuvat rehuseos (B) kategorioista, jotka koostuvat rehuaine (A) kategorioista

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