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Risk assessment of the removal of the requirement for storing shell eggs refrigerated in the table-egg production

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Reg. Vurdering af risikoen for human salmonellose ved fjernelse af kravet om opbevaring af konsumæg på køl

From Ana Sofia Ribeiro Duarte, Tine Hald

29 August 2023
asrd

Risikovurdering af de fødevaresikkerhedsmæssige konsekvenser hvis kravet om opbevaring af konsumæg på køl fjernes

Ved e-mail af 25. november 2021 (J.nr. 2021-28-25-00420) anmodede FVST DTU Fødevareinstituttet om at foretage en vurdering af risikoen for human salmonellose ved fjernelse af kravet om opbevaring af æg på køl for konsumægs-produktionen (Annex I).

Specifikt anmodede FVST om svar på følgende:

Beregne risikoen for et øget antal syge personer ved fjernelses af kølekravet for æg for hvert af de følgende scenarier (A, B og C). Anbefalingen om opbevaring ved en konstant temperatur gælder stadig i hvert scenarie.

A. Små ægproducenter

Når primærproducenten selv leverer æg fra egen primærproduktion inden for leveringsgrænsen på 312.000 æg om året, fjernes kravet om at opbevare æggene ved højst 12 °C i egen detailvirksomhed. Eksempler på sådanne detailvirksomheder er såkaldte "gårdbutikker", restaurant/café, eller primærproducentens egen bod på lokalt, offentligt marked. Temperaturkravet på 12 °C bevares for ægproducentens eget ægpakkeri med begrænset, lokal omsætning.

B. Små ægproducenter

Når primærproducenten selv leverer æg fra egen primærproduktion inden for leveringsgrænsen på 312.000 æg om året, fjernes kravet om at opbevare æggene ved højst 12 °C i

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egen detailvirksomhed. (se eksempler i A) og for primærproducentens eget ægpakkeri med begrænset, lokal omsætning

C. Både små og store ægproducenter

Kravet om køl fjernes fra hele konsumægsproduktionen, uanset produktionens størrelse og distributionsmønster. Det vil sige, at det nationale krav om opbevaring af æg ved højst 12 °C distributionskæden fjernes.

På et møde d. 5. januar mellem FVST og DTU blev det aftalt at starte med Scenarie C og på basis af resultaterne af dette vurdere, om det vil være nødvendigt at gennemføre de øvrige scenarier.

På samme møde blev det aftalt, hvilke data FVST skulle levere til brug for risikovurderingen. Endelige data blev modtaget på e-mail d. 2. maj 2022.

Selve risikovurderingen med beskrivelse af data, metoder, og resultater er udarbejdet på engelsk. Nedenfor følger et kort sammendrag på dansk.

Dansk resumé

Resultater af risikovurderingen

Denne risikovurdering estimerer det samlede antal *Salmonella*-tilfælde pr. år, hvis kravet om opbevaring af æg på køl fjernes fra alle led i jord-til-bordkæden (scenarier B og C). I beregningerne indgår det samlede antal æg, der produceres årligt af små og store ægproducenter. Tre tilberedningsscenarier blev vurderet: Ikke varmebehandlede æg, let varmehandlede æg og gennemvarmebehandlede æg.

Risikoen for sygdom efter at have indtaget gennemvarmebehandlede æg forblev ubetydelig, hvis køling fjernes fra alle produktionsled inklusiv hos forbrugeren (scenarie C).

I scenarie B ved indtag af ikke varmebehandlede eller let varmebehandlede æg blev det estimeret, at der vil gå tre til fire år før, at en smittet flok vil forårsage et sygdomstilfælde, hvis køling fjernes fuldstændigt fra produktionsforløbet for små producenter. Dette medførte ikke nogen målbar stigning i det gennemsnitlige antal årlige *Salmonella* tilfælde.

For store ægproducenter estimeres det, at der i gennemsnit vil gå 8-9 mdr. (0,7 år) før, at en smittet flok vil forårsage et sygdomstilfælde ved indtag af ikke varmebehandlede eller let varmebehandlede æg.

De absolutte estimater for det årlige antal sygdomstilfælde varierer med 99% sandsynlighed mellem 0 og maksimalt 5 tilfælde pr. smittet flok på tværs af alle scenarier for ikke-varmebehandlede eller let varmebehandlede æg (Tabel 4, side 19).

På nationalt plan og under hensyntagen til den nuværende prævalens af *Salmonella* blandt store producenter, varierer de absolutte risikoestimater for det årlige antal sygdomstilfælde med 99% sandsynlighed mellem 0 og 35 tilfælde, med et gennemsnit på 10 tilfælde, hvis æggene er indtaget ikke-varmebandlede, og 8 tilfælde, hvis æggene er indtaget let varmebehandlede.

Alle ovennævnte estimater er beregnet under forudsætning af, at 100% af forbrugerne enten spiser ikke varmebehandlede æg eller 100% af forbrugerne spiser let varmebehandlede æg. Disse estimater blev derefter skaleret, så de svarer til antallet af *Salmonella*-tilfælde estimeret årligt via smittekilderegnskabet (SKR).

De årlige *Salmonella*-SKR viser et "baselinegennemsnit" på 16 tilfælde pr. år, med minimum 2 og maksimalt 34 tilfælde pr. år. Sammenlignes baselineniveauet med scenariet, hvor man fjerner køling både for ikke og let varmebehandlede æg, vil der i langt de fleste tilfælde ikke være nogen forskel i risiko. Dog sås et højere maksimalt antal estimerede *Salmonella* tilfælde, særligt fra ikke varmebehandlede æg, når køling blev fjernet.

Det skal bemærkes, at både SKR-resultaterne og risikovurderingsestimaterne er usikre, ligesom de er baseret på forskellige metoder og antagelser. Risikovurderingen antager for eksempel for hvert scenarie, at alle forbrugere behandler deres æg på samme måde. SKR-resultaterne er baseret på antallet af rapporterede *Salmonella* -tilfælde og afspejler derved i princippet alle eksponeringsbetingelser, herunder forskelle i forbrugeradfærd og –præferencer, men kan ikke vurdere effekt af temperatur på vækst af *Salmonella* bakterier.

Med henblik på at tage højde for forskellige tilberedningsmetoder blev der derfor også udarbejdet en risikomodel, i hvilken det blev antaget, at 5% af de konsumerede æg spises ikke varmebehandlede, 15% spises let varmebehandlede, og 80% spises gennemvarmebehandlede. Dette resulterede i risikoestimater på 0 tilfælde pr. år forårsaget af æg fra store producenter, når de opbevares på køl, og maksimalt 7 tilfælde pr. år, hvis køling blev fjernet.

Risikoestimaterne er som nævnt forbundet med usikkerhed på grund af en række antagelser og mangel på repræsentative data.

Antagelser, der kan føre til overvurdering af risiko, inkluderer:

- At alle salmonellatilfælde, der kan tilskrives æg, stammer fra et enkelt produktions-forbrugsscenarie og at der ikke er taget højde for, hvilken andel af tilfælde, der stammer fra små eller store producenter og om æggene ikke var varmebehandlede eller let varmebehandlede. Der blev gjort et forsøg på at redegøre for forskelle i tilberedningsmetoder, hvilket resulterede i et betydeligt fald i antallet af estimerede tilfælde pr. år. Andelen af æg, der indtages rå eller tilberedes hhv. let eller ikke gennemvarmebehandlede kendes imidlertid ikke, så disse proportioner er udelukkende baseret på antagelser.
- Estimaterne er baseret på det forudsatte maksimale produktionsniveau for individuelle store flokke (45.000.000 æg pr. år), hvilket formentlig er en stor overvurdering af den samlede årlige produktion af æg fra store flokke i Danmark, men det reelle antal kendes ikke.
- Risikoen vil også påvirkes af prævalensen af inficerede høns indenfor flokken og hvor mange kontaminerede æg en inficeret høne lægger. Sidstnævnte var ikke medtaget i modellen, i hvilken det blev antaget at alle æg fra en inficeret høne er kontaminerede. Denne antagelse er også brugt i andre lignende risikovurderinger.

Antagelser, der kan føre til undervurdering af risikoen, inkluderer følgende:

- At overvågningsprogrammet fungerer, som det er designet til at gøre, så smittede flokke påvises hurtigst muligt og der tages aktion på resultaterne. Sker den forsinkelse i påvisning af smittede flokke, vil sandsynligheden for at smittede æg når frem til forbrugeren alt andet lig stige.

Endelig gøres der opmærksom på følgende forhold, som er af betydning for fortolkningen af resultaterne af risikovurderingen:

- Det understreges, at disse resultater er baseret på den aktuelle *Salmonella*-prævalens i konsumægsproducerende flokke. Enhver fremtidig stigning i prævalensen af *Salmonella*-positive flokke må forventes også at øge antallet af humane tilfælde af *Salmonella*-infektioner i Danmark.
- Selvom kølekravet fjernes kan det anbefales, at æg opbevares ved en temperatur under 24°C. Temperaturer over 25°C fører til, at æggeblommemembranen hurtigere brister og at eventuelle salmonellabakterier, der er tilstede får bedre vækstvilkår. Dette er nærmere beskrevet i undersøgelser og risikovurderinger udarbejdet i vore nabolande. I en tysk undersøgelse for æg opbevaret ved 18-20°C blev der estimeret en 18 dages holdbarhed (Gross et al., 2015). I overensstemmelse med dette har Sverige og EFSA angivet holdbarhed på 18 dage ved 23°C og 7-12 dage ved 24-30°C (EFSA, 2009; NYBERG, 2017).
- Opbevaring på køl reducerer risikoen for, at bakterier trænger ind gennem æggeskallen (EFSA, 2009; Nyberg, 2017). Bakterier kan trænge gennem æggeskallen, når der skabes et undertryk i ægget på grund af ændring i opbevaringstemperaturen, typisk når æggene går fra et varmere til et køligere miljø. Det vurderes at blive sværere at kontrollere store variationer i temperatur, når æg opbevares ved stuetemperaturer, især hjemme hos forbrugeren. Bemærk endvidere, at effekten af kontaminering af ægget på grund af skalpenetration ikke er medtaget i denne vurdering.

Konklusion af risikovurderingen:

Risikovurderingen blev udført ved at estimere antallet af salmonellatilfælde ved køling af æg (**baseline**) og sammenligne disse med antallet af salmonellatilfælde, når æg opbevares udenfor køl (**scenario C**).

Estimatet i **baseline** blev skaleret for at matche resultatet fra det årlige *Salmonella* SKR. Da antallet af estimerede *Salmonella* tilfælde i **scenario C** ikke er meget højere end i **baseline**, konkluderes det, at sandsynligheden for en stigning i sygdomsrisikoen ved fjernelse af kølekravet til æg er meget lille. Vi opfordrer desuden til, at der tages hensyn til de ovennævnte yderligere forhold (tilse opbevaring af skalæg ved konstant temperatur og under 25°C), hvis kølekravet fjernes, og at både producenter og forbrugere rådgives herom.

Risk assessment of the removal of the requirement for storing shell eggs refrigerated in the table-egg production

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1. Short description of materials and methods

1.1 Flock size

The data provided on type of laying-hen flocks and corresponding production sizes are presented in Table 1 and Table 2.

Table 1: Production codes and types, production size categories (stor/lille) and number of herds per production code

Production code	Production type	Production size	Number of herds
3121	Frilandshønsehold, konsumæg	Stor	18
3122	Stimulusberiget burhønsehold, konsumæg	Stor	5
3123	Skrabeægshønsehold, konsumæg	Stor	57
3124	Økologisk hønsehold, konsumæg	Stor	93
3134	Stalddørssælgere på det lille program	Lille	215
3136	Stalddørssælgere der kører stort program fordi de har over 1000 dyr	Stor	11
Total			**399**

Based on the data in Table 2, we simulated 399 individual observations of flock size by randomly sampling, from a uniform distribution, *n* numbers between the minimum and maximum limits of *"max_prod_size"*, where *n* corresponded to *"n_hold_max_prod_size"*. The simulated data represented an artificial sample of 399 flocks of sizes obtained by a random draw within the interval limits of the corresponding flock size category. A Geometric distribution was then fitted to the observations corresponding to large egg producers (production codes 3121, 3122, 3123, 3124, 3136), and another Geometric distribution was fitted to the observations of small, barn-yard-egg producers (production code 3134), as presented in Figure 1 and Figure 2, respectively.

Table 2: Intervals for maximum flock size in each production code, and number of flocks per size category.

Maximum flock size	Number of flocks	Production code
1001-4999	4	3121
1-1000	2	3121
15000-19999	2	3121
20000-29999	6	3121
30000-39999	2	3121
40000-49999	1	3121
75000-99999	1	3121
>=120000	2	3122
100000-119999	1	3122
20000-29999	2	3122
>=120000	1	3123
100000-119999	4	3123
10000-14999	4	3123
1001-4999	3	3123
1-1000	2	3123
15000-19999	3	3123
20000-29999	4	3123
30000-39999	2	3123
40000-49999	12	3123
50000-74999	13	3123
5000-9999	4	3123
75000-99999	5	3123
10000-14999	27	3124
1001-4999	7	3124
1-1000	7	3124
15000-19999	19	3124
20000-29999	8	3124
30000-39999	8	3124
40000-49999	3	3124
50000-74999	4	3124
5000-9999	10	3124
>=500	6	3134
1-29	25	3134
200-499	35	3134
30-39	18	3134
40-49	9	3134
50-59	13	3134
60-89	43	3134
90-199	66	3134
>=500	8	3136
200-499	1	3136
90-199	2	3136
TOTAL	399	-

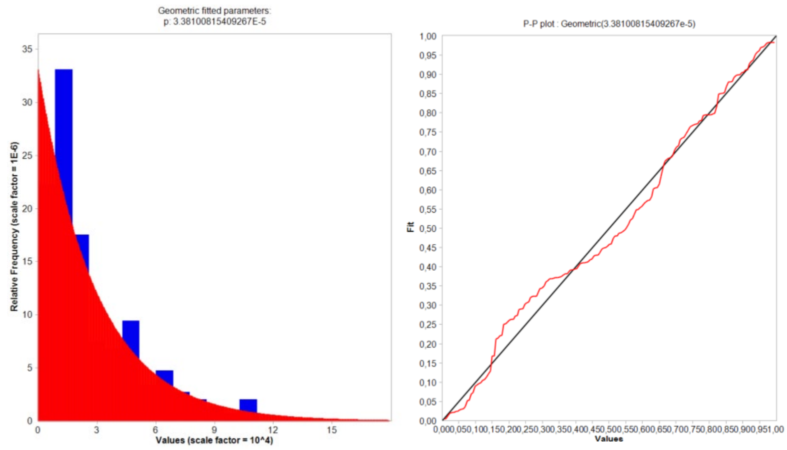


Figure 1: Density plot and P-P plot of Geometric distribution (p= 0.00003) fitted to the flock size of large egg producers (>500). ***Left plot****:* The blue bars show the distribution of flock sizes, among large flocks of egg producers in Denmark, and the red curve shows the fitted geometric distribution, with flock size on the x-axis (scale 10^4) and frequency of flock sizes on the y-axis (scale 10^{-6}). ***Right plot****:* The straight line shows the correspondence between the flock sizes (values on the x-axis) and the cumulative probabilities of different flock sizes (y-axis) according to the fitted distribution, while the red line shows the distribution of the flock size data. Since the data pattern follows approximately the straight line, the data can be assumed to be well-represented by the fitted probability distribution.

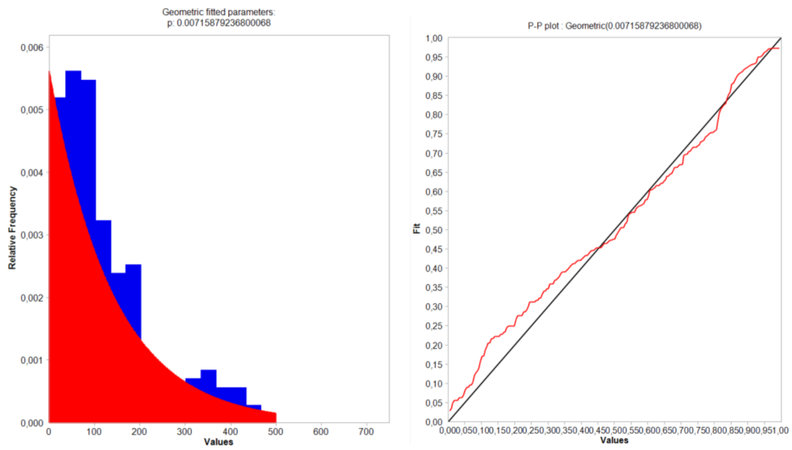


Figure 2: Density plot and P-P plot of Geometric distribution (p=0.007) fitted to the flock size of small egg producers (<500). ***Left plot****:* The blue bars show the distribution of flock sizes, among small flocks of egg producers in Denmark and the red curve shows the fitted geometric distribution, with flock size on the x-axis and frequency of flock sizes on the y-axis. ***Right plot****:* The straight line shows the correspondence between the flock sizes (values on the x-axis) and the cumulative probabilities of different flock sizes (y-axis) according to the fitted distribution, while the red line shows the distribution of the flock size data. Since the data pattern follows approximately the straight line, the data can be assumed to be well-represented by the fitted probability distribution

These two distributions were used as input to randomly simulate the variability of size of a laying hen flock, for large and small producers, respectively. The following assumptions underlie the distribution fitting: the distribution of flock sizes between the given minimum and maximum values was assumed to be uniform i.e., any flock size in the interval was equally likely to occur. For flock sizes >=500 and >=120 000, the limits of the uniform distribution were assumed as a single value, 500 or 120 000, respectively.

1.2. *Salmonella* prevalence in laying hen flocks

The provided number of flocks tested for *Salmonella*, and the number of *Salmonella* infected flocks, among large and small producers, for the years 2017-2021 are provided in Table 3, including the distribution of serotypes among positive flocks. The data were used to estimate the prevalence of *Salmonella* positive laying hen flocks from 2017-2021 (Figure 3) and the prevalence of the flocks positive for different serotypes of *Salmonella* (Figure 4).

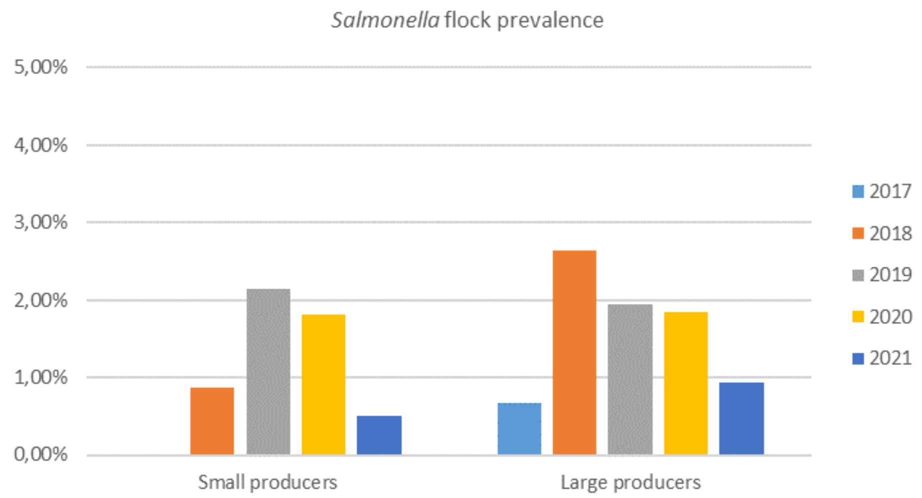


Figure 3: Estimated prevalence of *Salmonella* in large and small laying hen flocks, years 2017-2021.

Table 3: Number of tested and positive laying hen flocks under the *Salmonella* monitoring program, in years 2017-2021.

Year	*Tested flocks*	*Positive flocks*	*Serotypes*
Large producers			
2017	446	3	S. Derby (1)
			S. Typhimurium (1)
			S. Enteritidis (1)
2018	454	12	S. Enteritidis (6)
			S. Typhimurium (4)
			S. Newport (1)
			S. Give (1)
2019	411	8	S. 4.12:I:- (1)
			S. Coeln (1)
			S. Derby (1)
			S. Give (1)
			S. Kottbus (1)
			S. Liverpool (1)
			S. Typhimurium (2)
2020	432	8	S. 4,5,12:i:- (3)
			S. Ajiobo (2)
			S. Enteritidis (2)
			S. Infantis (1)
2021	429	4	S. Enteritidis (2)
			S. Coeln (1)
			S. Anatum (1)
Small producers			
2017	104	0	-
2018	115	1	S. Typhimurium (1)
2019	140	3	S. Typhimurium (1)
			S. Enteritidis (1)
			S. 4,5,12:i:- (1)
2020	166	3	S. Typhimurium (1)
			S. Enteritidis (1)
			S. Hadar (1)
2021	196	1	S. Newport (1)

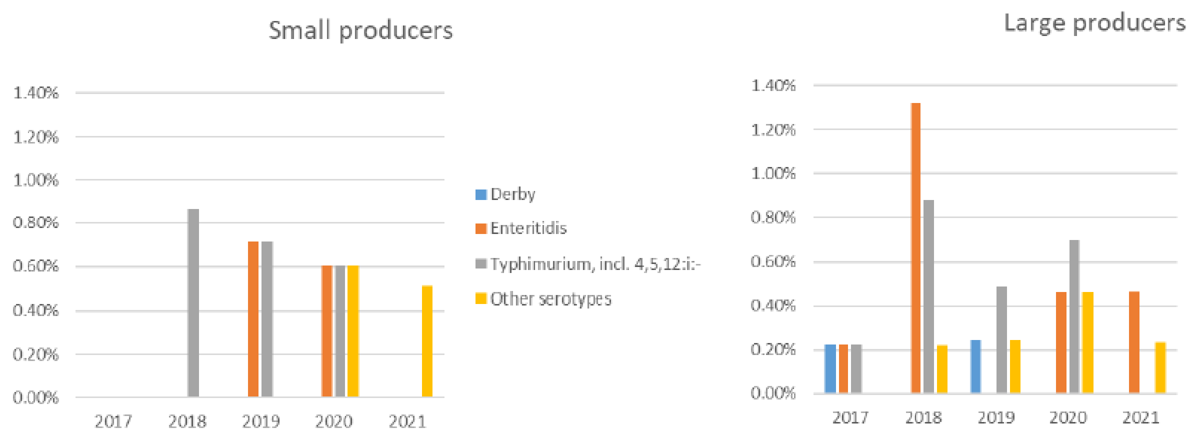


Figure 4: Estimated prevalence of *Salmonella* serotypes isolated from large and small laying hen flocks, in years 2017-2021.

Due to the low number of isolates per serotype obtained every year, it was not possible to statistically assess the difference in prevalence between serotypes. Therefore, the risk assessment was done for *Salmonella* including all serotypes.

The average number of tested and positive flocks among all years were used as inputs in the exposure assessment to estimate prevalence of *Salmonella*-infected flocks, for small- and large producers. The estimated average *Salmonella* prevalence was 1.1% and 1.6% among small and large producers, respectively. The average *Salmonella* flock prevalence estimated including all flocks tested from 2017 to 2021, without distinction for flock size, was 1.5%.

1.3. Description of the risk assessment

The exposure assessment was performed by adapting and combining two independent previously developed exposure assessment models, namely the "Risikovurdering af ændret salmonellaprøveprogram for konsumægsbesætninger, der alene sælger ved stalddøren" (performed by DTU Fødevareinstituttet for FVST, 2018) and the exposure assessment developed for the "Scientific Opinion on the public health risks of table eggs due to deterioration and development of pathogens" (EFSA, 2014).

1.3.1. *Salmonella* contamination at the farm

In 2018, DTU Food developed a stochastic risk assessment that modelled *Salmonella* infection in barn-yard flocks under a combined serological and bacteriological surveillance program (Risikovurdering af ændret salmonellaprøveprogram for konsumægsbesætninger, der alene sælger ved stalddøren). Here we used the exposure model developed for the bacteriological part of the program, adapted to model infection in both barn-yard and large producers. The model input parameters were to the extent possible estimated based on monitoring data or literature data. Assumptions were made, when data was not available.

Briefly, the model simulates a possible course of infection in a flock, i.e. the epidemiological unit is one flock. The model is run with 10,000 iterations, where relevant input parameters are changed. Output parameters are summed over all iterations, so that average values are obtained that can be used in the following calculations to simulate the situation at national level. The following outputs from the model were selected:

- The number of infected flocks that are not detected per year
- The average number of eggs produced per flock before detection (assuming a maximum of 312,000 eggs per flock for barn-yard producers and 45,000,000 for large producers)
- The average number of eggs laid by infected hens per herd
- The average prevalence (%) of contaminated eggs laid by infected hens

These outputs were combined to estimate the final output of the flock-level model: average percentage of contaminated eggs (produced by barn-yard or large producers, respectively) that goes undetected by the surveillance program.

1.3.2. - *Salmonella* transmission from farm to consumer

The model used is published in the Scientific Opinion on the public health risks of table eggs due to deterioration and development of pathogens (EFSA, 2014), hereby referred to as the EFSA model.

The EFSA model does not include the farm phase. Figure 5 shows the possible scenarios for the pathway of table eggs from farm to consumer in Denmark.

Four scenarios were considered:

1) barn-yard producers (no refrigeration);

2) small producers with packing at the farm (maximum at 12°C) and selling in "gårdbutik" or local market (maximum 12°C);

3) large producers with packing at the farm (maximum at 12°C) and selling to retail/food industry (maximum at 12°C);

4) large producers with packing at packing centres (maximum at 12°C) and selling to retail/food industry (maximum at 12°C).

In Figure 5, bold arrows represent transport of eggs during which phase there is no refrigeration. All transport is assumed to last less than 48 hours and occur under constant ambient temperature. This assumption is adopted from the EFSA model, however, the distribution used to model temperature during transport was changed to approximate ambient temperatures in Denmark, with a most likely value of 14°C. Note that in Denmark transport with duration above 8h must occur under temperatures ≤12°C. This was not specified in the model, where transport temperatures were assumed to follow the same distribution across all simulated scenarios and at all stages of the pathway.

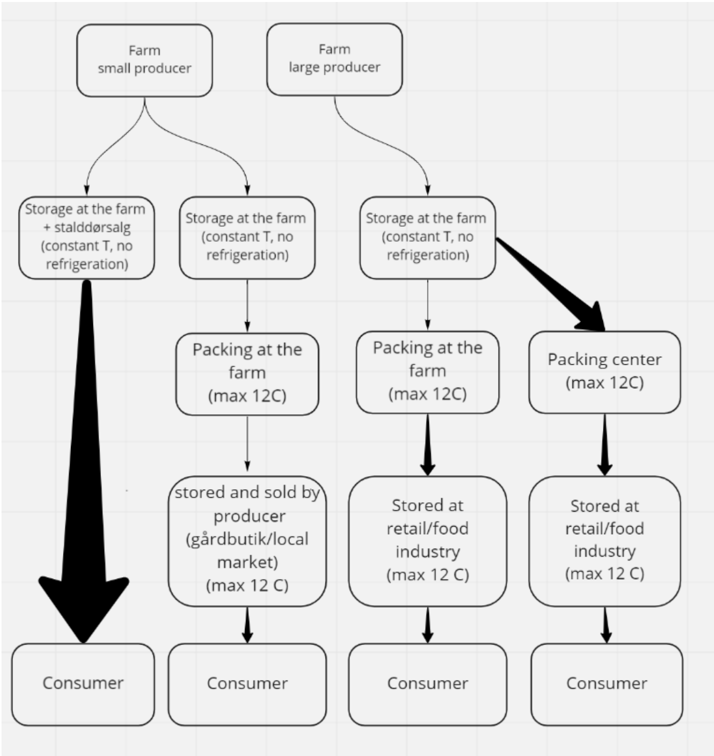


Figure 5: Exposure pathway scenarios for the egg production chain in Denmark. Bold arrows represent transport of eggs during which there is no refrigeration.

The baseline scenarios for each pathway represent the current practices in the egg-production chain (Figure 5). Ambient temperature was modelled as Pert distributions with parameters minimum, most likely and maximum temperature (see Annex II). Egg sales from small producers were modelled to follow one of two scenarios - 100% "stalddørssalg" (directly from the stable door) and 100% "gårdbutiksalg" (from a farm shop). It was assumed that no farms sells in both fashions.

Furthermore, it was assumed that all eggs laid by infected hens have positive egg contents due to primary contamination. Note that this represents a worst-case scenario of the probability of occurrence of primary contamination. Secondary contamination of eggs due to cross-contamination was not considered in the model.

The consumer phase modulates the risk of disease due to the consumption of contaminated eggs prepared in different ways (uncooked, lightly-cooked, well-cooked). All consumption behaviours were considered and two different scenarios with probabilities of occurrence of each behaviour were applied – scenario X: 1% uncooked, 5% lightly-cooked, 94% well-cooked; scenario Y: 5% uncooked, 15% lightly-cooked, 80% well-cooked. Additionally, the risk was estimated considering worst-case scenarios with 100% consumption of uncooked eggs and 100% consumption of lightly-cooked eggs (scenario Z). Different subgroups of the consumer population, including vulnerable groups, are considered in the dose-response model in the EFSA risk assessment.

1.3.3. Risk increase due to removal of refrigeration

Alternative refrigeration scenarios for each production pathway were modelled from farm to consumer by changing the temperature from refrigeration to ambient temperature (see Annex II for more details), at the relevant steps. The output of this assessment was the estimated mean number of illnesses for the total number of eggs consumed from a single infected farm in a year, in a production scenario where refrigeration is substituted by ambient temperature, assuming the maximum annual production (312 000 and 45 million eggs for small and large producers, respectively). Note that not all producers will reach the maximum annual production limit, meaning that the number of eggs produced is largely overestimated. However, it was not possible to obtain any numbers of actual produced eggs in Denmark divided by flock categories.

In order to obtain actionable information for changing the refrigeration procedures on a national level, the outputs from the EFSA model with removal of refrigeration were compared to the outputs from the same model with current refrigeration conditions, to estimate the increase in the number of annual cases due to removal of refrigeration, with consumption scenarios X and Y.

The risk estimated with consumption scenario Z (assuming 100% occurrence of one cooking behaviour) was used to translate the results in terms of increase in the average annual number of egg-attributed human *Salmonella* cases in comparison with those estimated among the five recent years with the Danish *Salmonella* source-account (Figure 6). For this, the average number of illnesses/total eggs consumed from a single farm in a year obtained with consumption scenario Z was multiplied by the average number of farms in Denmark and by the present value of *Salmonella* flock prevalence, to estimate the expected number of annual cases at the national level. The baseline risk estimate was scaled to match the baseline source-account result, so that the alternative risk estimate obtained with removal of refrigeration could be interpreted in terms of expected number of egg-attributed cases.

The present number of egg-attributed cases was represented by the Poisson distribution in Figure 6, with mean corresponding to the average number of cases from five recent years obtained with the Danish annual *Salmonella* source-account.

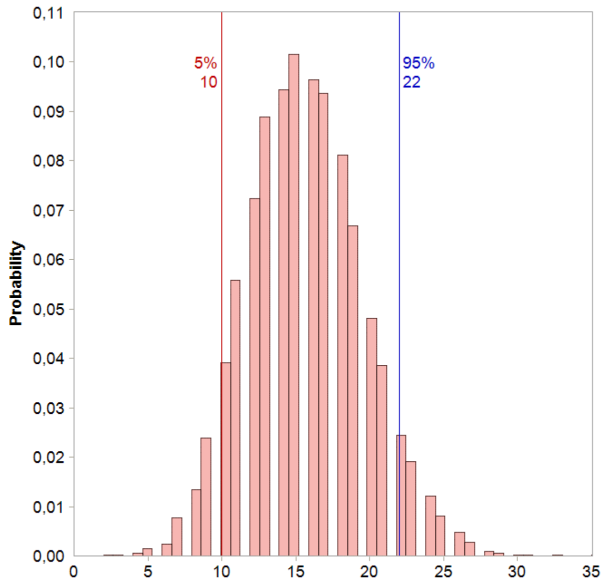


Figure 6: Distribution of the baseline estimated annual number of egg-attributed human salmonellosis cases in Denmark based on the Danish *Salmonella* Source Account (min=2, mean=16, max=34, standard deviation=4)

2. Results

2.1. *Salmonella* contamination at the farm

The percentage of contaminated eggs produced in a year, which go undetected in the monitoring program, was estimated for individual barn-yard producers ("stalddørssælgere") and individual large producers. The estimated average percentage of eggs laid by undetected infected hens for a maximum annual production of 312,000 eggs by a barn-yard flock is 0.027% (with 90% probability between 0.02% and 0.038%) corresponding to 84 undetected contaminated eggs per flock per year, and the estimated average percentage of eggs laid by undetected infected hens from a large flock for a maximum production of 45 million eggs is 0.0009% (with 90% probability between 0.0007% and 0.0014%) corresponding to 405 undetected contaminated eggs per flock per year. These estimated average percentages were used as inputs in the subsequent exposure model of farm to consumer, to represent prevalence of *Salmonella* in egg-contents.

Additionally, based on the data provided, the prevalence of infected flocks was also estimated for both production types and the values were used as input to estimate the number of illnesses in the subsequent risk model. The mean prevalence of infected flocks was 1.6% for large producers and 1.1% for small producers.

2.2. Risk assessment from farm to consumer

The EFSA model was run with the baseline storage conditions (refrigeration) and with a scenario of complete removal of refrigeration. When storage temperature is changed to ambient temperature (see Annex II) at the relevant steps in each pathway, the risk increases for eggs consumed lightly-cooked or uncooked. Table 4 shows the estimated mean number of illnesses per total consumed eggs from single infected farms, according to each production pathway in a scenario, where eggs are stored at ambient temperature. The estimates are for the three consumption behaviours, with consumption scenario Z (i.e. assuming 100% of one behaviour at a time): uncooked, lightly-cooked and well-cooked eggs. The plots represent the simulated temperature profiles along the egg production chain for each production pathway.

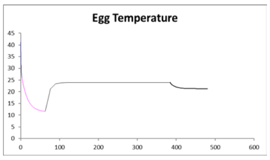
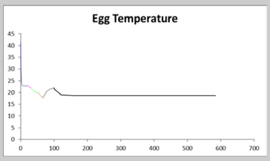
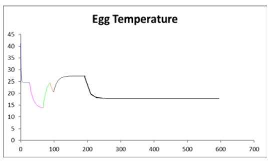
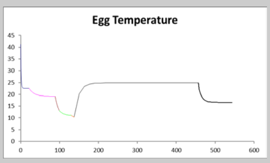
The results (Table 4) show that by completely removing refrigeration from the egg production pathways, including packing-center, "gårdbutik", retail and consumer household, the risk of illness per total eggs consumed in a year from a single infected farm remain negligible for eggs consumed **well-cooked** (99% probability of 0 cases/year from a single farm).

For eggs consumed **lightly-cooked or uncooked**, considering the average number of cases per total eggs consumed in a year originating from a single infected farm (Table 4), the estimated number of years before an illness occurs, when refrigeration is 100% removed from the production pathway, and consumption behaviour is assumed as 100% uncooked, lightly-cooked or well-cooked is:

- 3 years, for small producer/barn yard sale, eggs consumed uncooked;
- 4 years, for small producer/barn yard sale, eggs consumed lightly-cooked;
- 3 years, for small producer/"gårdbutik" sale, eggs consumed uncooked;
- 4 years, for small producer/"gårdbutik" sale, eggs consumed lightly-cooked;
- 0.7 years, for large producer/packing at the farm, eggs consumed uncooked;
- 0.8 years, for large producer/packing at the farm, eggs consumed lightly-cooked;
- 0.7 years, for large producer/packing centre, eggs consumed uncooked;
- 0.8 years, for large producer/packing centre, eggs consumed lightly-cooked;

In comparison with the baseline storage conditions, these results represent a general increase in the risk of illness, by removal of refrigeration, for eggs consumed uncooked or lightly-cooked, originating from single infected farms, including small producers and large producers. The most prominent increase in risk upon removal of refrigeration is observed for eggs consumed lightly-cooked, which changed from a negligible risk to a risk comparable to that of uncooked eggs.

Table 4: Estimates of the <u>mean number of illnesses per total eggs consumed from a single infected farm</u>, for farms from different production pathways and for three consumption behaviours, when refrigeration is completely removed from the pathway.

		Mean # illnesses/total eggs consumed from single infected farm (1% - 99% percentiles)			
Production pathway	**Temperature profile**	**100% Uncooked**	**100% Lightly cooked**	**100% Well cooked**	**Refrigeration removal**
1. Small producer –> barn-yard sale		2.9 x 10^{-1} (0 – 2)	2.4 x 10^{-1} (0 – 2)	5.3 x 10^{-5} (0 – 0)	Proportion of eggs refrigerated in household = 0%
2. Small producer –> packing at the farm –> "gårdbutik"		3 x 10^{-1} (0 – 2)	2.4 x 10^{-1} (0 – 2)	1.3 x 10^{-5} (0 – 0)	Temperature for packing at the farm = room T Proportion of eggs refrigerated at "gårdbutik" and in household = 0%
3. Large producer –> packing at the farm –> retail		1.4 (0 – 5)	1.2 (0 – 4)	1.0 x 10^{-4} (0 -0)	Temperature for packing at the farm = room T Proportion of eggs refrigerated at retail and in household = 0%
4. Large producer –> packing centre –> retail		1.4 (0 – 5)	1.2 (0 – 4)	1.0 x 10^{-4} (0 – 0)	Temperature at packing centre = room T Proportion of eggs refrigerated at retail and in household = 0%

Note: total eggs produced in a year is assumed to be 45 million for a single large producer and 312 thousand for a single small producer, which represents a scenario of maximum egg production, since not all egg producers will reach these production numbers in a year.

2.3. Risk increase due to removal of refrigeration

The estimates of mean number of illnesses due to consumption of eggs produced by single infected farms obtained without refrigeration, for eggs consumed uncooked or lightly cooked, were used in order to estimate the expected number of annual human salmonellosis cases attributed to eggs in Denmark with removal of refrigeration.

The reference present annual number of human cases attributed to eggs was considered as the Poisson distribution in Figure 6, with mean corresponding to an average of 16 cases, according to five recent years of the Danish annual *Salmonella* source-account. This annual mean was furthermore multiplied by the proportion of the number of hens and the proportion of the flock prevalence attributed to large and small flocks, to estimate the number of cases attributed to eggs from all small and all large flocks in Denmark (Figure 7). According to the data provided, the proportions of laying hens is 1% from small farms and 99% from large farms. For an overall national *Salmonella* flock prevalence of 1.5 % (estimated including all flocks tested from 2017 to 2021), small flocks contribute with 0.3%, whereas large flocks contribute with 1.2%. According to these results, we estimate that the majority of egg-attributed cases are caused by eggs from large producers, and that eggs from small producers presently represent a negligible risk. The annual mean of 16 egg-attributed cases was thus assumed to represent human cases solely due to consumption of eggs from large producers.

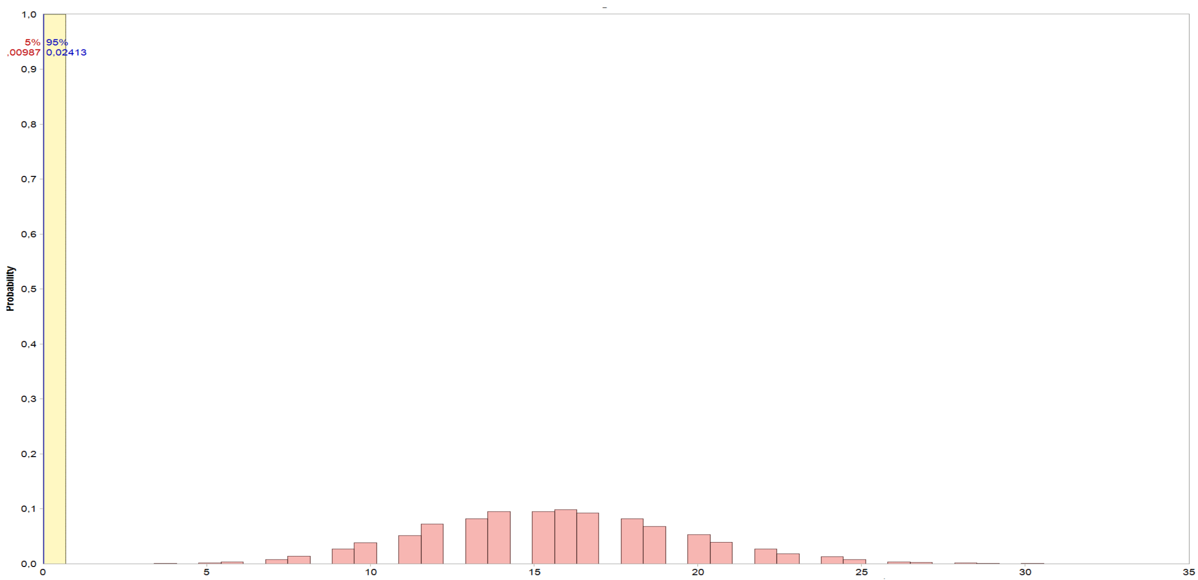


Figure 7: Probability distribution of the estimated number of cases (x axis) attributed to eggs from small flocks (yellow bar) and from large flocks (orange bars) produced in Denmark. This plot shows that with 90% probability the number of annual cases attributed to small producers is zero, whereas the probability of annual cases attributed to large producers follows a wider distribution, represented by the orange bars.

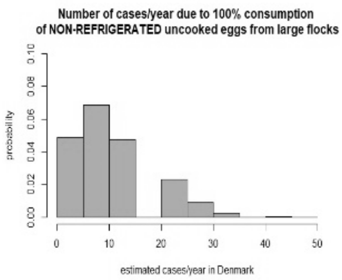
According to the risk model results for large producers (including scenarios with packing at the farm and at a packing centre), if eggs are stored at room temperature, an average of 1.4 illnesses and 1.2 illnesses per total eggs consumed from a single infected farm is expected in a year (Table 4), if all eggs were consumed uncooked or lightly cooked, respectively. These averages were multiplied by the average of 434 large flocks tested for *Salmonella* in years 2017 to 2021 in Denmark and by the *Salmonella* flock prevalence among large producers (1.6%), to estimate the expected number of annual cases at the national level. The average expected number of annual cases at the national level resulted in 10 total illnesses/year for 100% consumption of uncooked eggs and 8 total illnesses/year for 100% consumption of lightly-cooked eggs. Table 5 provides further details on estimates specific for each production-consumption scenario.

Table 5: Estimates of the mean number of illnesses per total eggs consumed from all large producers in a year in Denmark, when refrigeration is completely removed from the pathway.

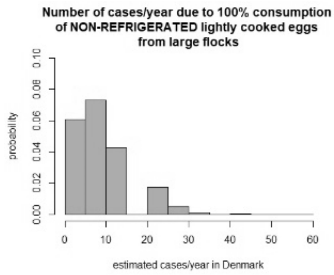
<table>
<tr><th rowspan="2">Production pathway</th><th colspan="2">Mean illnesses/total eggs consumed from large flocks in Denmark, with 1.6% flock prevalence*

(1% - 99% percentiles)</th></tr>
<tr><th>100% Uncooked</th><th>100% Lightly cooked</th></tr>
<tr><td>Large producer –> packing at the farm/packing centre –> retail</td><td>10

(0 – 35)


</td><td>8

(0 – 28)


</td></tr>
</table>

*Note: *Risk due to consumption of eggs from small producers is assumed negligible, thus results assume that risk is solely due to consumption of eggs from large producers; the total eggs produced in a year is assumed to be 45 million for a single large producer; estimates for an average of 434 large producers; 1% and 99% percentiles are for the variability distribution of number of illnesses/total eggs consumed/year*

Table 5 shows the estimated number of annual cases due to consumption of uncooked or lightly cooked eggs, from large producers, nationally, in a scenario without refrigeration. The absolute estimates of the number of cases due to consumption of all eggs produced by a single infected farm are low at the single farm level and vary between a minimum of 0 and a maximum of 5 cases per year across all scenarios, at the national level. Considering an average of 434 large flocks and the present average *Salmonella* prevalence among those flocks (1.6%), the absolute estimates at national level vary between 0 and 35 cases/year, assuming that all eggs are consumed either uncooked or lightly cooked. This represents the estimated risk if refrigeration is removed, obtained with the EFSA risk model. In order to compare this result to the number of egg-attributed cases estimated annually with the *Salmonella* Source-Account model (Figure 6), a correspondence between the outputs of both models was performed. Consequently, the present number of egg-attributed cases represented the baseline risk under refrigerated storage, against which an estimate of the egg-attributed cases corresponding to the scenario without refrigeration was compared (Figures 8 and 9).

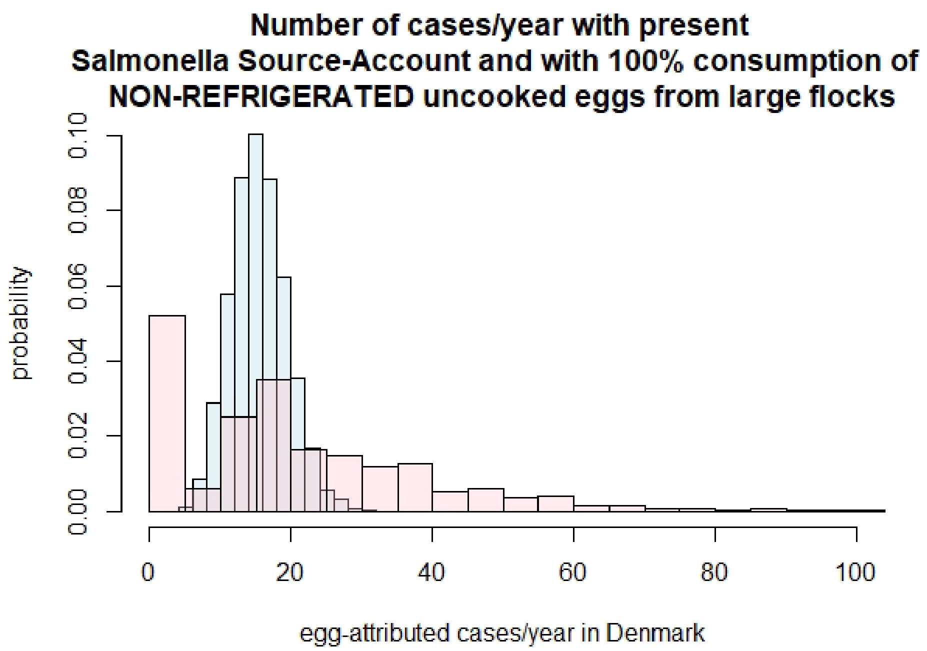


Figure 8: Probability distribution of the estimated number of egg-attributed *Salmonella* cases per year (x axis) with a baseline scenario (blue histogram) and with a scenario where refrigeration is removed from the pathway (pink histogram). This plot shows estimates that assume a single consumption behaviour – all eggs consumed **uncooked**.

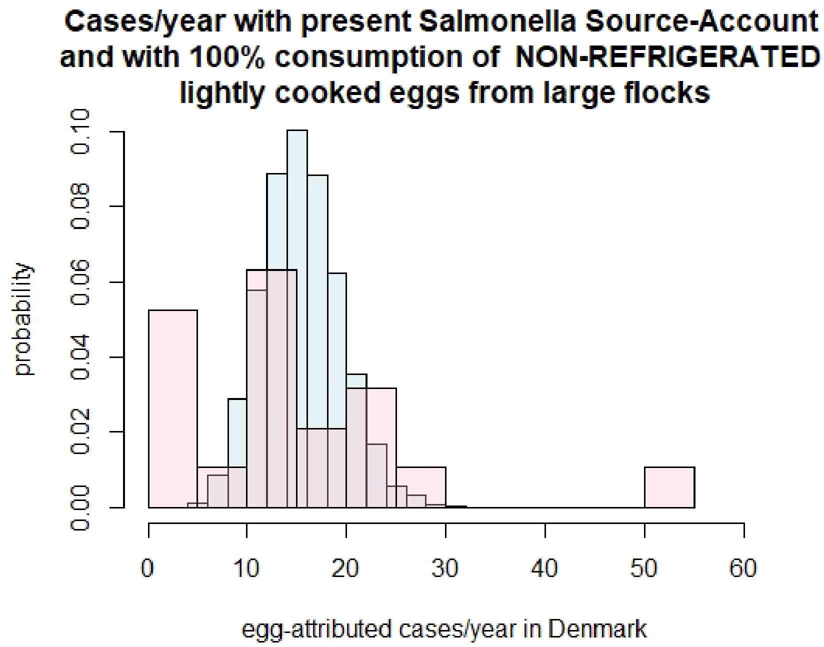


Figure 9: Probability distribution of the estimated number of egg-attributed *Salmonella* cases per year (x axis) with a baseline scenario (blue histogram) and with a scenario where refrigeration is removed from the pathway (pink histogram). This plot shows estimates that assume a single consumption behaviour – all eggs consumed **lightly cooked**.

Risk due to well-cooked eggs is estimated as negligible. In order to obtain more accurate estimates for risk due to consumption of uncooked and well-cooked eggs, data would be needed on the proportion of egg-related cases that can be attributed to each consumption behaviour. Despite the lack of data, two scenarios were further assumed to account for the fact that not all eggs will be prepared in the same manner. The following probabilities of occurrence of each behaviour were considered: scenario X with 1% uncooked, 5% lightly-cooked, 94% well-cooked; scenario Y with 5% uncooked, 15% lightly-cooked, 80% well-cooked. Both scenarios resulted in an estimate of 0 cases per year at national level for consumption of eggs stored under refrigerated conditions. Upon removal of refrigeration, with scenario X there was no increase in risk, and with scenario Y there was an increase from 0 to 7 cases per year, at national level.

3. Conclusion

This risk assessment estimated the total number of human illnesses due to *Salmonella* per year resulting from the consumption of eggs produced by infected small and large producers, in a scenario where refrigeration is removed from every step of the farm-to-fork pathway (Scenarios B and C). Three consumption behaviours were considered: uncooked-, lightly-cooked- and well-cooked eggs.

The risk of human illness due to the consumption of well-cooked eggs remained negligible under complete removal of refrigeration from the farm-to-fork chain.

Under Scenario B, by completely removing refrigeration from the production pathway for small flock producers and from the consumers' homes, 3 to 4 years were estimated as the number of years before an illness occurs due to a single infected flock. This represented no increase in the average number of annual cases.

For a similar simulation considering large-flock producers only, an average of 0.7 years before an illness occurs due to consumption of uncooked or lightly cooked eggs from a single infected large flock were estimated. The absolute estimates of the number of illnesses per individual infected flock varied with 99% probability between 0 and 5 cases per year across all scenarios, for eggs consumed uncooked or lightly cooked (Table 4).

At the national level, the absolute estimated average number of egg-attributed human *Salmonella* cases/year, expected from removal of refrigeration along the farm-to-fork pathway varied with 99% probability between 0 and 35, with average of 10 cases/year for eggs consumed uncooked and 8 cases/year for eggs consumed lightly-cooked.

All the above mentioned estimates were obtained assuming a single consumption behaviour in each scenario: 100% uncooked eggs or 100% lightly-cooked eggs. Those estimates were further scaled to correspond to the number of egg-attributed *Salmonella* cases estimated annually with a source-account model as part of *Salmonella* surveillance. The baseline estimates according to the annual *Salmonella* source-account results were an average of 16 cases/year, with minimum of 2 and maximum of 34 cases/year. Comparisons between baseline and non-refrigeration scenarios, both for uncooked and lightly-cooked eggs, showed mostly an overlap between the two risk outputs, but also a higher variability in the distribution of the number of cases per year, with an increase in the probability of occurrence of a higher number of cases per year, when refrigeration is removed, mostly marked for uncooked eggs.

Note however, that both the source-account results and the risk estimates are uncertain, and differ in their nature. While the source account results are based in the number of reported cases, which occur under different exposure conditions, including different consumption behaviours, the above mentioned results obtained with the risk model are based on the assumption of a single consumption behaviour at a time. However, the source-account model is not able to consider the effect of different temperature conditions.

In order to account for the impact of different consumption behaviours (i.e., egg-preparation methods) on risk, probabilities of consuming uncooked, lightly-cooked and well-cooked eggs were also simulated. The estimates were 0 cases/year caused by eggs from large flocks, when stored refrigerated, and a maximum of 7 cases/year when refrigeration was removed and the probabilities of each consumption behaviour were 5% uncooked, 15% lightly-cooked and 80% well-cooked eggs.

The risk estimates presented are uncertain due to several assumptions and data gaps in the modelling process. Assumptions that may lead to risk overestimation include:

- It is assumed that all egg-related salmonellosis cases in Denmark originate from a single production-consumption scenario, i.e. the risk model does not account for proportions of cases that originate from small or large producers, and from different consumption behaviours. An attempt was made to account for differences in consumption behaviour, which resulted in a considerable decrease in the number of estimated cases per year. However, the probabilities of different behaviours were solely based on best guesses due to lack of data.
- Furthermore, estimates are based on the assumed maximum production level by every individual large flock (45,000,000 eggs/year), which represents a considerable overestimation of the total annual egg production by many large flocks in Denmark.
- Also, the risk is influenced by the within-flock prevalence of infected hens in infected flocks and the probability that an infected hen lays contaminated eggs. The latter was not included in the model in which it was assumed that all eggs from an infected hen were contaminated. Due to lack of data, this assumption has been used in other similar risk assessments.

Identically, assumptions that may lead to underestimation of the risk include the following:

- It is assumed that the monitoring program is working perfectly and detecting flock contamination as it is designed to do. Should there be a delay in the detection of infected flocks, the probability of contaminated eggs reaching the consumer will increase, all else kept equal.

Finally, we would like to emphasise some additional considerations to follow the interpretation of this assessment:

- It is emphasized that the results are based on the current *Salmonella* prevalence in table-egg producing flocks (and their eggs). Any future increases in flock prevalence must be expected to also increase the number of human salmonellosis cases in Denmark.
- Cooling extends the time period before the egg-yolk membrane breaks, and cooled storage remains recommended after the yolk-membrane integrity time is reached. The time of the yolk membrane breakdown for an average storage temperature of 18-20°C was estimated in a recent study performed in Germany at 18 days (Gross et al., 2015). Accordingly, EFSA had previously indicated a decrease from 18 days at 23°C to 7-12 days at 24-30°C (EFSA, 2009; Nyberg, 2017). It is thus recommended that eggs are stored cool when ambient temperature rises above 24°C.
- Refrigerated storage reduces the risk of bacteria penetrating eggshells (EFSA, 2009; Nyberg, 2017). Bacteria can penetrate the eggshell when a negative pressure is created in the egg due to a change in the

storage temperature, typically from warmer to cooler. It is emphasized that it may become more challenging to control for minimal temperature oscillation when eggs are stored at ambient temperatures, especially at the consumer home. Note that the effect of contamination of the egg due to shell penetration was not considered in this assessment.

In short, the risk assessment was done by estimating the number of salmonellosis cases with cooling of eggs (the baseline), and similarly the number of salmonellosis cases without cooling of eggs (risk estimate for large producers where small producers have an insignificant contribution to the risk). The estimate in from the baseline model was scaled to match the result of the annual *Salmonella* source-account (both estimates are with cooling of eggs). Since the number of estimated cases in scenarios, where cooling was removed, was only slightly higher compared to the baseline and do not exceed the number of cases estimated in the source-account model (which is more data-driven), it is concluded that the risk increase associated with removing the cooling requirement for eggs is very small. We emphasize that further considerations should be taken into account (mentioned above), if the cooling requirement is removed and the consumer and producers must be advised accordingly.

4. References

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Annex I – Anmodning om risikovurdering af 25. november 2021

Ministeriet for Fødevarer, Landbrug og Fiskeri
Fødevarestyrelsen

J.nr. 2021-28-25-00420/PES
25. november 2021

Kære Advice.

Vi har brug for en vurdering af risikoen ved at fjerne kravet om opbevaring af æg på køl for konsumægsproduktionen.

For nærværende er kølekravene for opbevaring af æg som følger:

1. Der er ikke krav om køl ved stalddørssalg, altså salg direkte fra primærproducent til den endelige forbruger.
2. Der er ikke krav om køl ved opbevaring hos ægproducenten, men anbefaling om konstant temperatur. Dette gælder både for æg, som efterfølgende leveres til primærproducentens egne detailvirksomheder (på bedriften eller på lokalt, offentligt marked), og for æg, som efterfølgende leveres til ægpakkeri.
3. Der er ikke krav om køl ved transport af æg, så længe transporten varer under 8 timer.
4. Der er krav om køl på ægpakkeri – max. 12 °C.
5. Der er krav om køl i detail-leddet, altså også i primærproducentens egen detailvirksomhed på bedriften eller egen bod på lokalt, offentligt marked – max. 12 °C.
6. Endelig *anbefales* det, at æg opbevares ved en konstant temperatur.

Dato for mindste holdbarhed for æg er 28 dage efter lægningen, og æg må ikke markedsføres direkte til forbrugeren eller til egne detailvirksomheder eller ægpakkerier senere end 21 dage efter, at æggene er lagt.

En lille producent defineres således:

1. Har højst 1.000 høns, der undersøges for salmonella hver 9. uge med 2 par sokkeprøver, der analyseres som én samleprøve eller 60 gram gødning, der analyseres som 2 samleprøve
2. Producerer højst 312.000 æg

Øvrige producenter undersøges for salmonella hver 2. uge med 2 par sokkeprøver analyseret som én samleprøve eller 2 x 150 gram gødning analyseret som én samleprøve.

Vi ønsker at få beregnet risikoen for øget antal syge personer ved fjernelses af kølekravet for æg for hvert af de følgende scenarier. Anbefalingen om en konstant temperatur gælder stadig i hvert scenarie.

A. **Lille producent**
   Når primærproducenten selv leverer æg fra egen primærproduktion inden for leveringsgrænsen på 312.000 æg om året, fjernes kravet om at opbevare æggene ved højst 12 °C for primærproducentens egen detailvirksomhed på bedriften, f.eks. såkaldt "gårdbutik" eller restaurant/café på bedriften, eller

primærproducentens egen bod på lokalt, offentlig marked. _Temperaturkravet på 12 °C bevares for ægproducentens eget ægpakkeri med begrænset, lokal omsætning_

B. **Lille producent**
Når primærproducenten selv leverer æg fra egen primærproduktion inden for leveringsgrænsen på 312.000 æg om året, fjernes kravet om at opbevare æggene ved højst 12 °C for primærproducentens egen detailvirksomhed på bedriften, f.eks. såkaldt ”gårdbutik” eller restaurant/café på bedriften, primærproducentens egen bod på lokalt, offentlig marked _og for primærproducentens eget ægpakkeri med begrænset, lokal omsætning_

C. **Kravet om køl fjernes fra hele konsumægsproduktionen, uanset produktionens størrelse og distributionsmønster**. Dvs. det nationale krav om opbevaring af æg ved højst 12 °C i visse dele af distributionskæden fjernes

Jeg medsender notat fra jer, hvori I vurderede risikoen ved ændring af reglerne for stalddørssalg af æg.

Annex II – Exposure model inputs for egg storage temperature

The egg storage temperatures in the exposure model of farm to consumer were modelled as stochastic inputs following the Pert distributions below, with parameters (minimum, most likely, maximum):

- ambient temperature at farm and during packing (in no refrigeration scenarios): *Pert (4°C; 15°C; 25°C)*
- during transport to retailer: *Pert (0°C; 14°C; 25°C)*
- during transport from retail/farm to consumer's home: *Pert (-5°C; 14°C; 25°C)*
- room temperature at consumer's home and retail (in no refrigeration scenarios): *Pert (14°C; 19°C; 25°C)*
- refrigeration temperature: *Pert (0°C; 4.5°C; 12°C)*

The percentage of refrigeration at retail or at the consumer's home was set to a constant of 0% or 100% depending on the simulated scenario.