

Sterilization Is Not Reducing Microbes to Zero but a Promise About the Chance One Survives, and the Time Needed Grows with the Logarithm of the Starting Count

— even when the mean number of survivors has fallen to one, microbes remain in over six tenths of containers, and promising one in a million adds time equal to the number of decades in the starting count — the separator is whether the mean number of survivors is looked at or the fraction of containers with any survivor — [Paper 932]

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— *From thinking to syncing.* —

Abstract

When microbes are killed by heat, the surviving fraction falls by decades at a constant rate over time. This paper counts, with binomial and Poisson distributions, the probability that a container of independently dying microbes keeps at least one survivor, and finds, for each starting count, the time needed for the promise that “the probability of a surviving microbe in a container is one in a million”. No new theorem or law is claimed. First, even when the mean survivors fall to one, microbes remain in over six tenths of containers: treating containers of 10^6 microbes for 6 times the time D that reduces survivors tenfold, the mean number of survivors is 1 and the fraction of containers with a survivor was **0.632121** (Section 2). Second, with longer treatment, the fraction of containers approaches the mean number of survivors: the same containers gave 9.516259×10^{-2} at $7D$, 9.995002×10^{-4} at $9D$ and 9.999995×10^{-7} at $12D$, with binomial and Poisson distributions nearly equal (Section 2). Third, the time needed for one in a million grows with the logarithm of the starting count: for starting counts of 1, 10^3 , 10^6 and 2×10^6 , the time needed was 6.000000, 9.000000, 12.000000 and **12.301030** D (Section 3). Fourth, doubling the starting count adds only about three tenths of D : the increase on doubling was **0.301030** D , matching $\log_{10} 2$. With 200000 random containers, treating 10^6 microbes for $6.5D$ left a survivor in 0.271475 of containers (formula 0.271107) (Section 4). Fifth, the separator is whether the mean number of survivors is looked at or the fraction of containers with any survivor: when the mean is 1 the fraction is 0.632121, and the two come close only once the mean is small enough. The promise of sterilization refers to the fraction (Section 5). **Keywords:** sterilization, sterility assurance level, D value, Poisson distribution, thermal death, log reduction.

Scope of this paper (scope note): No new theorem or law is claimed: the logarithmic law of thermal death, the time D reducing survivors tenfold, estimating the probability of a surviving microbe in a container by the Poisson distribution, and setting the sterility assurance level at 10^{-6} are all known. Standards and processes are not discussed: the text of real standards, process design and D for particular species are not treated. Only the form of a probabilistic promise is counted. Only the logarithmic law is used: shoulders and tails of survival curves, clumps of microbes and variation in heat resistance are not included. Safety is not discussed. What level is enough in medicine or food is not stated. Relation to earlier papers: Paper 717, in its scope note, did not discuss real reference values and did not treat how reference times are chosen in processes or standards; this paper sits in that seat of how reference times are chosen (no earlier occupant). Not the values of standards but the form in which a reference time follows from a promise about the probability of a survivor is counted. What is added: setting mean survivors beside the fraction of containers with a survivor under binomial and Poisson distributions, finding the time for one in a million for each starting count, confirming that the increase on doubling is $\log_{10} 2$, confirming the formula with random containers, and placing the separator on “the mean count, or the fraction of containers”.

1. Notation and the Question

Setting: microbes die independently one by one, and the fraction surviving at time t is $p = 10^{-t/D}$. The probability that a container starting with N_0 microbes keeps at least one, under binomial and Poisson distributions, is:

$$P_{\text{survive}} = 1 - (1 - p)^{N_0} \approx 1 - e^{-N_0 p}, \quad N_0 p = \text{mean survivors}$$

The time needed for a sterility assurance level of 10^{-6} is found by solving $P_{\text{survive}} = 10^{-6}$; when $N_0 p$ is small, $t/D \approx \log_{10} N_0 + 6$. The check solves the binomial formula by bisection, and counts the fraction of containers with a survivor by deciding each container with a random number.

Question: what does the promise of sterilization count, and how does the time needed change with the starting count?

2. Mean Survivors and the Fraction of Containers

Computation 2.1: values by starting count and treatment time.

starting count N_0	time t/D	mean survivors	fraction with survivor (binomial)	(Poisson)
10^6	6	1	0.632121	0.632121
10^6	7	0.1	9.516259×10^{-2}	9.516258×10^{-2}
10^6	9	10^{-3}	9.995002×10^{-4}	9.995002×10^{-4}
10^6	12	10^{-6}	9.999995×10^{-7}	9.999995×10^{-7}
10^3	9	10^{-6}	9.999995×10^{-7}	9.999995×10^{-7}
2×10^6	12	2×10^{-6}	1.999998×10^{-6}	1.999998×10^{-6}

For 10^6 microbes at $6D$, the fraction matched $1 - 1/e = 0.632121$ within 1.8×10^{-7} .

Observation 2.2

even when the mean survivors fall to one, microbes remain in over six tenths of containers. With a mean of 1, the number surviving in a container may be 0 or 2 or more, and only $1/e$ of containers have 0: only when the mean is small enough does the fraction of containers with a survivor come close to the mean number of survivors.

3. The Time Needed for One in a Million

Computation 3.1: time making the fraction of containers with a survivor 10^{-6} (solving the binomial).

starting count N_0	time needed t/D	$\log_{10} N_0 + 6$
1	6.000000	6.000000
10^3	9.000000	9.000000
10^6	12.000000	12.000000
2×10^6	12.301030	12.301030

Observation 3.2

the time needed for one in a million grows by the number of decades in the starting count. Even a single starting microbe needs $6D$, and each thousandfold increase adds $3D$. What the promise sets is not “the time to reach zero” but “the time to make the chance of a survivor one in a million”.

4. The Increase on Doubling, and Random Containers

Computation 4.1: doubling the starting count from 10^6 to 2×10^6 increased the time by **0.301030 D** , matching $\log_{10} 2 = 0.301030$ within 10^{-6} .

Computation 4.2: applying random numbers to 200000 containers, treating 10^6 microbes for $6.5D$ left a survivor in 0.271475 of them; the formula gives 0.271107.

Observation 4.3

doubling the starting count adds only about three tenths of D . A doubling occupies $\log_{10} 2$ of one decade, so the increase is 0.301030 D : even without knowing the starting count precisely, the estimate of time needed hardly moves as long as the order of magnitude is right.

5. The Separator

Observation 5.1

the separator is whether the mean number of survivors is looked at or the fraction of containers with any survivor. By the mean alone, treating 10^6 microbes for $6D$ “reduces them to one”: by the fraction of containers, that treatment leaves microbes in 0.632121 of containers. The promise of sterilization refers to the fraction, and making it 10^{-6} takes $12D$.

Observation 5.2

what is not said. The text of real standards, process design, values for particular species, shoulders and tails of survival curves, and safety in medicine or food are not treated. What is shown is that sterilization is not reducing microbes to zero but a promise about the chance of a survivor, and that the time needed grows with the logarithm of the starting count.

6. Roll Call and Closing

1. $P_{\text{survive}} = 1 - (1 - p)^{N_0}$ (Section 1): **the chance of a survivor.**
2. mean 1, fraction **0.632121** (Computation 2.1): **over six tenths keep one.**
3. 9.999995×10^{-7} at **12D** (Computation 2.1): **the fraction approaches the mean.**
4. time needed **6, 9, 12, 12.301030 D** (Computation 3.1): **the logarithm of the count.**
5. increase on doubling **0.301030 D** (Computation 4.1): **$\log_{10} 2$.**
6. random **0.271475** and formula **0.271107** (Computation 4.2): **confirmed with containers.**
7. **the mean count, or the fraction of containers** (Observation 5.1): **the separator; the scope note of Paper 717.**

Closing: Sterilization is not reducing microbes to zero but a promise about the chance one survives, and the time needed grows with the logarithm of the starting count. Treating 10^6 microbes for **6D** leaves one survivor on average, but microbes remained in **0.632121** of containers: making that fraction 10^{-6} took **6, 9 and 12 D** for starting counts of **1, 10^3 and 10^6** , and doubling added only **0.301030 D**. The promise refers not to the mean count but to the fraction of containers with any survivor: the separator is whether the mean number of survivors is looked at or the fraction of containers with any survivor. Placed among the earlier papers: how reference times are chosen, left untreated by Paper 717, was counted not as the values of standards but as the form of a promise about the chance of a survivor. To be honest. What level is safe is not said. What the promise counts, and no further.

References

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