

## The reliability of microbiological analysis

How many samples must be analysed to ascertain at a given confidence level that a batch is not contaminated with for instance *Salmonella*? The answer to this question is given by B. Jarvis (Ross BiosciencesLtd, UK).

Given a batch of milk powder of which less than 1 in 100 samples of 25 g is contaminated with *Salmonella*. How many samples need to be analysed in that case to ascertain at a 90% confidence level that the batch complies with this criterium. Table 1 presents the result of the calculations.

**Table 1.** Number of samples that must be analysed to ascertain at a confidence level of 90, 95 and 99% that the incidence of *Salmonella* in the batch is below the indicated level

True incidence in samples contaminated with <i>Salmonella</i> /25 g	Number of samples that must be analysed		
	Confidence level 90%	Confidence level 95%	Confidence level 99%
1/10	22	28	44
1/20	45	58	90
1/50	114	148	228
1/100	229	298	458
1/200	459	598	919
1/1,000	2,301	2,994	4,603
1/2,000	4,604	5,990	9,208
1/10,000	23,025	29,956	46,049

If the true incidence of *Salmonella* in a batch is less than 1/100 samples of 25 gram, this can be ascertained with 90% confidence if 229 samples of 25 gram are negative for *Salmonella*. To ascertain this level with 99% confidence, 458 samples of 25 gram should be negative for *Salmonella*.

The European legislation with regard to infant milk formula states that in 30 monsters van 25 gram *Salmonella* must be absent. If in reality 1/50 samples were positive, which would be regarded as a relatively high level of contamination, this can only be ascertained with 90% confidence if 114 samples of 25 gram would be negative for *Salmonella*. To ascertain this level of contamination with 99% 228 samples of 25 gram should even be negative for *Salmonella*.

To prevent analysis of excessive numbers of samples, compositing (pooling) of samples is allowed. Instead of 30 x 25 gram it is also allowed to analyse 750 gram. According to the author this is only allowed however, if it has been proven that the analysed amount of powder has no effect on the outcome of the test.

Source:

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### Editorial note:

- 1) Various ready-to-eat products are only rarely contaminated with pathogenic micro-organisms. Routine testing does not contribute to the safety of this type of product.
- 2) Pooling of samples is practiced quite often, but it is not known if analysis of a large amount of product yields the same result as analysis of 30 time a small quantity. It is assumed that the sensitivity of the test is higher when many small samples are analysed. One possible explanation is that if competitive micro-organisms grow to large numbers in the pre-enrichment culture it is more difficult to detect low numbers of *Salmonella*. If many small samples are analysed, both the number of competitive micro-organisms and *Salmonella* will vary, which increases the possibility of detecting *Salmonella*.