

# SUSPECTED ADULTERATED FOOD SUPPLEMENT: CONTRIBUTIONS OF MICROBIOLOGY TO BRING OUT ANOTHER POTENTIAL RISK FOR PUBLIC HEALTH

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## INTRODUCTION

Food supplements are now of widespread use and consumers may turn to such products for a variety of presumed benefits (weight reduction, enhancing physical performance...). In the same time, public health alerts about those products are regularly rising. Analysis on suspicious food supplements generally focus on the presence of adulterant substances and few are available about their microbiological contaminations<sup>1</sup>. If the presence of undeclared active pharmaceutical ingredients is the result of an intentional addition in the finished product, microbiological contamination is more a consequence of uncontrolled manufacturing process than a real fraud. Contaminated products should be considered more as substandard products than as falsified products. Nevertheless, considering regular case reports from literature about microbiological contamination of food supplements, the risk for consumers is real when using contaminated products because of the presence of pathogenic agents, toxins or endotoxins<sup>2</sup>.

These observations have lead us to carry out both physicochemical and microbiological investigations on suspicious food supplements, particularly when they claim an herbal (or herbal extracts) composition. This approach is now more and more requested by customs or police services which require our knowledge for the analysis of those products in order to provide a better appreciation of the risk for consumers. The synthesis of results obtained for a period of 2 years is presented below and shows that microbiologic contamination is probably widely underestimated in the field of suspicious food supplement, particularly in herbal food supplement.

## METHODS

Since herbal food supplements are very close to herbal medicinal products, method of analysis and recommendations for quality control of those products described in the *European Pharmacopoeia* (Ph. Eur.) are used:

- Microbiological examination of herbal medicinal products for oral use [2.6.31]
- Microbiological quality of herbal medicinal products for oral use [5.1.8; C]

Figure 1: In house experimental design and results analysis strategy

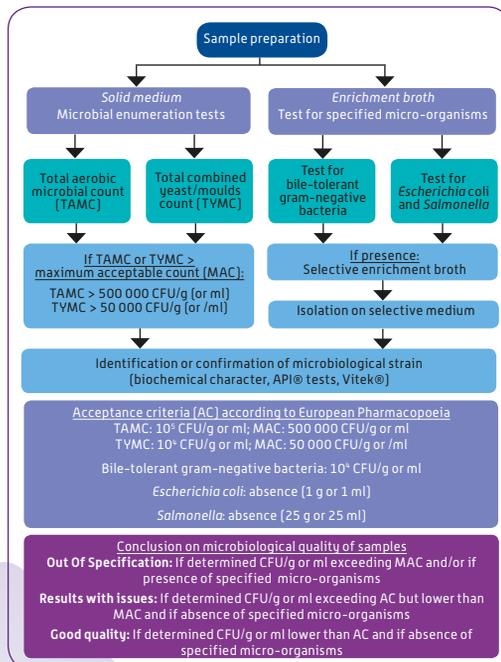


Figure 6: API® test



Figure 7: Pharmaceutical forms investigated



Figure 2: Moulds culture



Figure 3: Microscopic observation



Figure 4: Bacterial isolation



Figure 5: Vitek2® for strains identification



## OVERVIEW OF RESULTS

Over the period October 2012 – July 2014, the microbiological quality of 68 samples was evaluated. Among those samples, only 13 samples were from pharmacies. Microbiological quality of those 13 samples was quite good, only one sample presented a total aerobic microbial count (TAMC) value over the acceptance criteria (AC) but lower than maximal acceptable count (MAC). Concerning other samples (from customs or police), 20% were out of specifications (OOS) and 11% presented results with issues (mainly because of TAMC enumeration between AC and MAC values). Observed out of specifications values were explained by the following results: TAMC enumeration was upper than MAC value for 9/11 samples, total combined yeast/moulds count (TYMC) enumeration was over MAC value for 5/11 samples and bile tolerant gram-negative bacteria enumeration was upper than AC for 6/11 samples. As showed in Table 1, it should be noted that TAMC enumeration was sometimes at very high level, up to 2 000 000 000 CFU/g for a MAC values of 500 000 CFU/g.

None of the specified pathogens defined in the Ph. Eur. was observed. During identification of microbiological strain it was observed contamination with *Bacillus* in half cases. Others identified micro-organisms were *Pseudomonas fluorescens*, *Pantoea spp.*, *Klebsiella pneumonia*, *Ewingella americana* and *Enterobacter cloacae*.

Figure 8: Overview of results

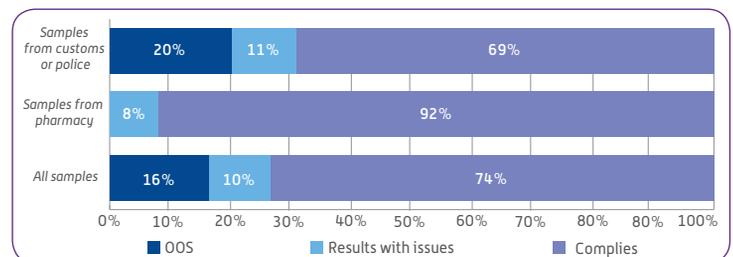


Table 1: Details of OOS results

	TAMC MAC: 500 000 CFU/g (or ml) AC: 100 000 CFU/g (or ml)	TYMC MAC: 50 000 CFU/g (or ml) AC: 10 000 CFU/g (or ml)	Bile-tolerant gram-negative bacteria AC: 10 000 CFU/g (or ml)
Sample 1	68 500	1 500	>10 000
Sample 2	640 000	47 000	>10 000
Sample 3	1 336 667	150	<1 000
Sample 4	2 000 000 000	49 000 000	>10 000
Sample 5	2 200 000	26 000	>10 000
Sample 6	190 000	10 200	>10 000
Sample 7	310 000 000	3 700 000	>10 000
Sample 8	220 000 000	4 200 000	<1 000
Sample 9	28 000 000	260 000	<10
Sample 10	550 000	22 000	<100
Sample 11	550 000	54 000	<100

## CONCLUSION

The results obtained over 2 years period underline the real threat of microbiologic contamination in herbal food supplements and suggest their improper production, handling, packaging and storage, especially for samples from illegal market. Food supplements are considered as foodstuffs, and, unlike drugs that always present a benefits/risks balance, are not supposed to be responsible for adverse effects. Some worrisome case reports also mentioned fatal issues, especially for populations at risk (immunosuppressed or cancer patients)<sup>3</sup>.

Even if it concerns a huge market, global quality of food supplement are not regulated enough and market survey of those products should include microbiological analysis to demonstrate production under acceptable conditions. When relevant, this argument is regularly used by the different public services in France (police, health agencies...) in order to rule on the potential withdrawal of batches or even closure of some manufacturers.

In conclusion, it should be underlined that during our survey, the quality of those products was found rather good when sampled in pharmacy whereas cases of contamination were observed when samples were from outside this regulated supply chain.

## REFERENCES

- <sup>1</sup> Microbiological contamination in counterfeit and unapproved drugs; Pullirsch et al., *BMC Pharmacology and Toxicology* (2014) 15-34.
- <sup>2</sup> *Staphylococcus aureus* and *Zygosaccharomyces bailii* as primary microbial contaminants of a spoiled herbal food supplement and evaluation of their survival during shelf life; Rossi et al., *Food microbiology* (2010) 356-362.
- <sup>3</sup> Severe hepatotoxicity following ingestion of Herbalife® nutritional supplements contaminated with *Bacillus subtilis*; Stikel et al., *Journal of Hepatology* 50 (2009) 111-117.