

REQUEST FOR ADDITIONAL INFORMATION

Submission number: NR546252-21

Legal name of applicant: SEBIA

Submitted by: SEBIA

Substance: 4-(1,1,3,3-tetramethylbutyl)phenol, ethoxylated

Uses: Use-1, Use-2, Use-3

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1. AIM & GOAL

The present document synthesises the Applicant's answers to the Socio-Economic Assessment Committee's request for additional information (communication number: AFA-C-2114480948-29-01/F) received on 2019/08/07.

2. REQUEST FOR ADDITIONAL INFORMATION

2.1. Question 1

2.1.1. Committees' question

Following your response to Q20 in the first round of questions, you say that some references will be discontinued due to low sales and some processes will be replaced. During the dialogue you stated that these are not relevant for use 1 and that for use 1 the use of triton tx 100 will increase due to 8% assumed growth rate. However, please provide:

- a. Details of the uses for which usage of triton tx 100 will decrease because references will be discontinued and processes will be replaced.*
- b. What will happen to the kits that are currently produced using references that will at some stage be discontinued?*
- c. Has this been taken into account in the impact assessment?*
- d. For those uses where use of triton tx 100 will decrease because of the above mentioned reason will the decrease outweigh the expected increased usage that will follow from an 8% growth rate?*

2.1.2. Applicant's answer

- a. There might have been a misunderstanding on this issue. Please see below the tables summarizing the consumption of the uses 1, 2 and 3.*

Use-1					
Year	2018	2019	2020	2021	2022
quantities (kg)	67,79	75,24	83,52	91,87	100,14
Evolution of the consumption (%)		11	11	10	9
Use-2					
Year	2018	2019	2020	2021	2022
quantities (kg)	14,50	16,10	17,87	19,65	21,42
Evolution of the consumption (%)		11	11	10	9
Use-3					
Year	2018	2019	2020	2021	2022
quantities (kg)	62,35	69,21	76,82	84,50	92,11
Evolution of the consumption (%)		11	11	10	9

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Triton's overall consumption trend is expected to increase given the company's growth targets of 8% per year. The increase of 11% concerns uses 1, 2 and 3 until 2020. Then, Sébia expects to see its consumption decrease due to the progressive replacement of the Triton X-100 in its kits. Hence, in 2021 the forecasted overall consumption is expected to decrease between 2020 and 2021 (10%) and from 2021 to 2022 (9%). It is well understood that this decrease will rely on the technical feasibility of the alternative.

The consumption of Use-4 will follow the 8% growth rate of the company.

- b. SEBIA has a lot of techniques with Triton. Some techniques have few kit references, and are sold in small quantities (see Appendix Table of the Aoa - confidential) nevertheless these techniques are essential for the benefit of the patients, an important point to be consider is that our devices are necessary to the human health and to diagnose pathologies as early as possible, thus limiting medical costs and risks to patients' health. In this context, all techniques are essential and SEBIA has no intention to date of stopping any of them for any reason whatsoever.*
- c. This has not been taken into account impact assessment. Indeed, even if they are sold in small quantities, some references are somehow appeal products that will appeal the customer because sold anywhere else and as explained in a) these techniques have great benefice for the patients. Discontinuing these references, will result in a direct loss of customers, but also an indirect loss on other references, with customers who will go to the competitors since they will not have any more reason to deal with Sebia. Nevertheless, it is impossible to assess the impact of stopping these products, because the applicant has no idea of the extent of customer loss that could result from stopping these products.*

In addition, Sebia realized that the Triton was going to be banned, less than 2 years ago (among other reasons because the company thought, as well as competitors, that the field of the IVD was excluded from the Authorization scope). Thus, the applicant is at the early stage of thinking / planning / organization, and it is very difficult for us to provide precise data on the technical feasibility of the possible alternatives, on the commercial strategies and the choices that the company will have to make for set up the substitution process in a viable way for the company.

- d. As indicated above, it is not envisaged or conceivable to stop any reference among those taken into account in our file.*

2.2. Question 2

2.2.1. Committees' question

Following Q21, part d from the 1st round of questioning, during the trialogue, we asked the applicant to clarify the use of major and minor equipment and whether this will constrain the number of employees that can be recruited. The applicant clarified that this refers to existing machines only. Please provide:

- a. Further details as to whether the purchase of new equipment would be possible and thus speed up the substitution process or is SEBIA constrained by lack of equipment?*
- b. Why was the purchase of new equipment not included as a substitution cost?*
- c. The applicant stated during the trialogue that it takes time to validate new equipment. At what stage of the substitution process would the new equipment be required*

2.2.2. Applicant's answer

- a. The time required for substitution is only very slightly dependent on production equipment, most of the time required for substitution is dedicated to the formulation of reagents and the validation of these new formulations, production equipment having slightly impact at this stage if not during industrialization and at this stage multiplying equipment does not accelerate substitution.*

The major equipments at Sebia facilities are not "large distribution" machines, they have been bought in a custom-made way for some and made in-house fabrications for others. The process of purchasing and setting up new production equipments is long. Currently, the applicant's facilities cannot host new equipment (construction of a new building needed), and they are not taken into account in the 3 years investment plan. In addition, the introduction of new machines will generate recruitment needs for their exploitation and for their maintenance.

- b. The purchase of new equipment is totally excluded from the substitution plan given the criticality of these equipments, the time required for the validation of new equipment.*

2.3. Question 3

2.3.1. Committees' question

Please provide the number of kits sold by Interlab in relation to Use 2?

2.3.2. Applicant's answer

Interlab sold [REDACTED] kits in 2017.

2.4. Question 4

2.4.1. Committees' question

During the trialogue we discussed whether the applicant could absorb the loss of profits that would result from a non-authorisation of use 4 and questioned whether the argumentation for the other uses applied in this case. The applicant stated that it is likely that the company would absorb the cost and continue to operate but would need to confirm this internally.

2.4.2. Applicant's answer

The turnover related to the Use 4 is lower than the Uses applied for. Therefore, the applicant would probably absorb the loss of profits that would result from a non-authorisation of use 4 in a context of good economic health of the company.

However, the substitution of the Triton, all uses combined, will undoubtedly weaken the economic health of the company (see answers 1 and 5). And therefore, the loss of revenues related to the use 4, will increase this embrittlement.

And in the same way, as for the answer to question 1, the discontinuing of some references will weaken the brand image and make the applicant lose customers directly and indirectly.

Even more, the applicant is the only one to supply on the world market such techniques (range related to the use 4) that tracks cancers, and the benefit for patients must also be taken into account.

2.5. Question 5

2.5.1. Committees' question

In your answer to question 7 in the latest round of questions, you provide calculations of the recruitment costs required for a 7 and a 12 year review period.

- Could you please clarify that the cost difference would be approximately €0.7M for use 1, €0.9M for use 2 and €1.4M for use 3?*
- For example, in use 3 when you move from 12 to 7 years requires 22 extra staff but the extra cost is 1.4 million whereas uses 1 and 2 require more staff, 30 and 25, but the cost is lower?*
- Industrialisation cost seems high for use 3 - why are so many more staff required for use 3 as compared with other uses?*
- Please confirm whether the mentioned expansion of facilities is only required under 7 year substitution phase and not 12?*
- Please provide spreadsheets for discounting over 12 years (currently only given for 7 years).*
- Given that there is not a huge difference in the cost of recruitment over 12 versus 7 years (e.g. for use 1 the extra cost is 700,000/7 years), please provide a justification as to why the extra cost and 7 year substitution is not economically feasible.*

2.5.2. Applicant's answer

*Please see below the updated tables. From each of them, the line total has been deleted and two additional columns (**Additional FTE** and **Additional recruitment cost**) have been supplemented. These parts represent the additional FTE and cost that the applicant might be dealing with in a case of a 7 years versus 12 years review period.*

Use-1											
Review period		12				7				Differential	
	Average gross wage	Time _{12year}	FTE _{12years}	Recruitment cost (NV)	Recruitment cost (NPV)	Time _{7years}	FTE _{7years}	Recruitment cost (NV)	Recruitment cost (NPV)	Additional FTE	Additional recruitment cost
R&D	58000	4,5	27	7 047 000,00 €	6 295 916,00 €	2,6	46,3	7 047 000,00 €	6 518 688,84 €	19,3	222 772,84 €
INDUSTRIALIZATION	58000	7	2	812 000,00 €	807 066,38 €	4,1	3,4	812 000,00 €	893 788,94 €	1,4	86 722,56 €
REGULATORY	45000	6	12,4	3 348 000,00 €	2 218 612,00 €	3,5	21,3	3 348 000,00 €	2 597 085,16 €	8,9	378 473,16 €
Use-2											
Review period		12				7				Differential	
	Average gross wage	Time _{12year}	FTE _{12years}	Recruitment cost (NV)	Recruitment cost (NPV)	Time _{7years}	FTE _{7years}	Recruitment cost (NV)	Recruitment cost (NPV)	Additional FTE	Additional recruitment cost
R&D	58000	4,45	21	5 423 000,00 €	4 828 447,00 €	2,6	36,0	5 420 100,00 €	5 013 756,97 €	15,0	185 309,97 €
INDUSTRIALIZATION	58000	7	2,6	1 058 784,00 €	627 718,00 €	4,1	4,5	1 055 600,00 €	885 659,53 €	1,9	257 941,53 €
REGULATORY	45000	5	11,4	2 562 750,00 €	1 444 972,00 €	2,9	19,5	2 565 000,00 €	1 950 188,78 €	8,1	505 216,78 €
Use-3											
Review period		12				7				Differential	
	Average gross wage	Time _{12year}	FTE _{12years}	Recruitment cost (NV)	Recruitment cost (NPV)	Time _{7years}	FTE _{7years}	Recruitment cost (NV)	Recruitment cost (NPV)	Additional FTE	Additional recruitment cost
R&D	58000	4,35	11	2 777 958,00 €	2 473 395,09 €	2,5	18,9	2 775 300,00 €	2 567 236,71 €	7,9	93 841,62 €
INDUSTRIALIZATION	58000	7,5	14,6	6 354 412,00 €	4 225 956,29 €	4,4	25,0	6 351 000,00 €	5 228 092,39 €	10,4	1 002 136,10 €
REGULATORY	45000	4	4,7	837 375,00 €	342 238,95 €	2,3	8,1	846 000,00 €	643 220,16 €	3,4	300 981,21 €

- Yes. When you sum up the amount of the **Additional recruitment cost**, the cost difference would be approximately €0.7M for use 1, €0.9M for use 2 and €1.4M for use 3.*
- In this simulation the number of staff and the additional costs cannot just be add up because they involve different gross wages during different activity periods. R&D and Industrialisation stages gross wages are different from those of the regulatory stage. While, in this simulation, the period of each stage is shortened (from 12 to 7 years), the number of FTE is higher. The costs are nearly the same because more FTEs are incurred but to do the substation work in*

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*much less time. The biggest difference comes from the additional costs for the industrialization stage of the Use-3 (about 1 M€). It can be explained by the calculation of the NPV provided in the specific tab ("**NPV Use-3 (7years)**") of the enclosed spreadsheet named **Recruitment cost over 7 years versus 12 years_2.xlsx**.*

The applicant would like to note that the assessment of these substitution costs for 7 years is an assumption that was not initially considered because it considers that an alternative cannot be operational in 7 years for all three uses.

- c. This use concerns a range of products (Hb A1c) that require special approvals (NGSP and IFCC) that require more resources. For the other range of products concerned (Hb) it is the validations which are long accounts of the diversity of the variants to take into account. This explains the higher staff required.*
- d. The expansion of facilities is a certitude in the case of a 7 years review period and as stated before, the applicant is in the first stage of reflexion and organising actions to be performed for the substitution process implementation without damaging the viability of the company. Hence, even a 12 years review period granted, it is highly probable that major restructuration will have to be operated.*
- e. Please see attached document named "**NPV Spreadsheet 12 years.xlsx**".*
- f. Admittedly, the cost of substitution reported in the simulation of 12 to 7 years are not so different but it is not only the financial aspect to take into account. These approximately 107 recruitments are to be realized in France, where the products are developed and manufactured. The current workforce of the company in France is about 300 people. That makes a 35% increase in the company size.*

It takes time and money to restructure the business and grow it to this point. For costs, associated with substitution, only recruitment costs were considered. The applicant believes that these costs are underestimated and other cost will inevitably be added, such as the new premises cost previously displayed.

As of the time required, the specific highly qualified job profiles will need to be hired. These profiles take times to be found and hired in the job market. Besides, considering the time required for the construction of a building (2 years without delay), a 7 years review period will not be appropriate.

Finally, all these investments related to the necessity of growth of the company, for jobs which are not directly financially profitable (i.e. investment to guarantee the survival of the company following the prohibition of use of the Triton), will lower Sebia's profitability.