

Substance: Per- and polyfluoroalkyl substances (PFAS)

EC number: -

CAS number:

- Annex XV report Third Party Consultation From 22/03/2023 to 25/09/2023

General comments and answers to specific information requests:

Since 1988, SISTO Armaturen S.A. is part of the globally operating KSB Group and the Luxembourg-based SNCI. With a team of approximately 200 employees, SISTO operates from Echternach located in Luxembourg. This is also where development and manufacturing of diaphragm valves takes place. The product portfolio extends over a great range of diverse applications. The diaphragm valve offers various advantages that are indispensable in various industries. These include: high resistance, high hygiene, low maintenance.

SISTO's main focus lies within the pharmaceutical industry; for instance, the company also provided valve support for the vaccine production of multiple manufacturers during COVID crisis. Moreover, SISTO also designs, tests and manufactures valves for building technology, industrial applications, chemical industry and the energy sector.

PFAS (Fluoropolymers) are only used in the diaphragm valve, where the operating conditions absolutely require it and no alternatives are available. Where possible other materials are already in use, since fluoropolymers are expensive. Fluoropolymers withstand high temperatures, aggressive chemicals and high requirements for the leak tightness. For lining or diaphragm materials there are for these cases no adequate alternatives at the moment.

The fluoropolymers we use in our valves have been scientifically evaluated as "polymers of low concern" (PTFE, TFM, FKM, ETFE, ECTFE, PFA, PVDF). They have been shown to be chemically stable, non-toxic, non-bioavailable, non-water soluble and non-mobile. For these reasons, the fluoropolymers are also approved, for example, as materials for food contact or in medical technology.

Hence, we advocate for a broad exemption of fluoropolymers, which are, incidentally, classified as "polymers of low concern" according to the OECD definition, from the PFAS restriction initiative. Since no alternatives are available, a ban would cause a production stop for our valves - which means, that big production lines where our valves are in use come to a stillstand. Besides pharmaceutical industry, this would also relate to the energy sector (e.g. hydrogen production) and chemical industry.

For assessing and responding to the PFAS restriction proposal, SISTO has established a dedicated project team comprised of specialists from different departments. By this procedure the impact of the restriction proposal is internally analysed from different perspectives. The focus of this analysis is especially set on topics as materials, procurement, production, strategy, sales, design and service.

The project roadmap involves a comprehensive analysis of SISTO's affected components and materials. From this, the economic impact can be evaluated. The identification of affected components will be followed by an in-depth examination of potential substitute materials and their associated impacts. Nevertheless, at the moment no 1:1 substitute is existing. Identifying critical applications and products will be a key focus, coupled with an evaluation of socio-economic repercussions. For SISTO, the identification of PFAS substances in products from in-house production is less complicated than for auxiliaries relevant to production. To these belong e.g. machining aids, lubricants, purchased components.

1. Specific information requests:

Sectors and (sub-)uses: Please specify the sectors and (sub-)uses to which your comment applies according to the sectors and (sub-)uses identified in the Annex XV restriction report (Table 9). If your comment applies to several sectors and (sub-)uses, please make sure to specify all of them.

Our industry, which manufactures valves and corresponding actuators, faces a problem with the list of sectors provided. This industrial field is not included in the listed sectors, which makes it hard and even unsuitable to fit valves into the categories given. In previous discussions, it was tough for our industry to give information because the needed categories were missing, and the ones provided only partly matched. Therefore, the predefined classifications only offered a partial fit at best.

Diaphragm valves and its actuators that have parts containing PFAS are used in different areas mentioned in the Annex XV report, and also in application fields beyond that. All of the PFAS substances in diaphragm valves are fluoropolymers. These types of polymers are used in valves where they need to resist chemicals and / or handle high temperatures.

i. Diaphragms:

Fluoropolymer materials like PTFE (polytetrafluoroethylene), TFM (modified polytetrafluoroethylene), FKM (Fluorocarbon elastomers) and PVDF (polyvinylidene fluoride) find application in diaphragms of SISTO valves. These materials exhibit exceptional chemical and temperature resistance, along with low friction. These qualities contribute to reduced energy consumption, extended operational life of valves, and enhanced operational tightness. For multiple fluids there is no alternative which has this combination of excellent thermal and chemical resistance as these materials mentioned above.

ii. Seals:

Fluoroelastomers, also known as e.g. FKM or FPM, serve as specialized seal materials due to their impressive resistance to chemicals, including hydrocarbons, acids, and bases, coupled with their ability to withstand temperatures up to 200 ° C. Their low gas permeability is especially valuable for applications where contaminant-free pumping or prevention of fluid release into the environment is crucial. Beyond chemical and thermal resilience, fluoroelastomers excel in

mechanical properties and aging resistance, ensuring prolonged valve performance. Especially at SISTO actuators FKM is used to withstand high temperatures, where other polymers fail.

iii. Valve linings:

Incorporating fluoropolymer liners, like PTFE, PFA, TFM safeguards internal components of valves against corrosive chemicals and aggressive fluids. An emission of these fluids from the valve is avoided due to these liners. Without any liners the aggressive fluids would chemically attack the metallic body and corrode through.

iv. Coatings:

Fluoropolymer coatings like ETFE (ethylene tetrafluoroethylene) or ECTFE (ethylenechlorotrifluoroethylene) are applied to components such as valve bodies to protect against chemical attacks, corrosion, or abrasion. Usually there are fluids, for which these coatings are the optimal solution and other coating materials are not able to withstand the external influences.

In conclusion, the unmatched chemical resistance and durability of fluoropolymers render them indispensable across valve applications, including:

- i. Chemical processing: Where corrosive chemicals and elevated temperatures are present.
- ii. Oil and gas production: Resisting hydrocarbons, high temperatures, and pressures in drilling and production.
- iii. Power generation: Enduring high temperatures even in the presence of oxygen.
- iv. Pharmaceutical applications: Inert, non-reactive, and sterilizable.
- v. Food and beverage industry: Non-stick and chemically inert for hygiene and product quality.
- vi. Water and wastewater treatment: Handling corrosive chemicals and demanding environments.
- vii. Potable water handling: Ensuring safe pumping and circulation.

Please note that this is not an exhaustive list, as the suitability of PFAS-containing components depends on the specific fluid being used rather than the sector. Hence, an exemption for valve applications or fluoropolymers becomes vital to secure critical material production. Moreover, numerous other sectors rely on valves across the supply chain, making their functioning interdependent. Detailed information can be provided by players within the supply chain rather than valves industry.

For instance, specific applications requiring PFAS include:

- i. Electronics: Pumps and valves in semiconductor manufacturing and automation, necessitating ultrapure, corrosive-resistant water.
- ii. Energy sector: Especially in renewable energy production like hydrogen manufacturing.

- iii. Machinery: Machines manufacturing various materials, demanding fluorinated polymers for high temperatures, non-stick properties, and more.
- iv. Spare parts: Prolonging the lifespan of existing machines containing PTFE parts.
- v. Air conditioning: Fluorinated gases used for safety in production facility air conditioning.
- vi. Chemical industry processes: Reliant on pumps and valves with fluoropolymeric materials for substance production, even if non-PFAs based.

Remember, this list is not exhaustive, but it highlights the diverse applications requiring PFAS.

2. **Emissions in the end-of-life phase:** The environmental impact assessment does not cover emissions resulting from the end-of-life phase. To get a better understanding of the extent of the resulting underestimation, (sub-)use-specific information is requested on emissions across the different stages of the lifecycle of products, i.e. the manufacture phase, the use phase and the end-of-life phase. Please provide justifications for the representativeness of the provided information. In particular:

- a. Please provide, at the (sub-)use level, an indication of the share of emissions (as percentages) attributable to these three different stages. An indication of annual emission volumes in the end-of-life phase at sector or subsector level would also be appreciated.
- b. If possible, please provide for each (sub-)use what share of the waste (as percentages) is treated through incineration, landfilling and recycling. Please provide information to justify the estimates as well as information on the form of recycling referred to.

Manufacturing phase:

Customer requirements related to our products result in a need for fluorinated polymers, which are known to be applied to the diaphragm or body lining. While the lining of the housings and the manufacture of the diaphragms is mainly done in-house, there are also purchased parts containing PFAS (eg. gaskets) which are purchased from specialized manufacturers. In case of liners, the material is used in form of powder, which is processed within isostatic press sintering. Potential waste from processing is used for following processes or it is disposed of professionally. Thus, emissions are mainly relevant at stage of powder production at the manufacturer of the material.

Use phase:

Since fluoropolymers are extremely stable in their chemical structure and thus also resistant to demanding operating conditions, no emissions are to be expected during the use phase.

End-of-life phase:

Due to the usage of fluorinated polymers extraordinary service lifetimes can be realized. In addition, valves are usually maintained by specialist companies. To avoid improper disposal of fluorinated

polymers, a specialized disposal company should always be used for this purpose. An implementation of a traceability system would be appropriate for a proper disposal of PFAS materials. Such a procedure can be raised in accordance with already existing recycling regulations.

3. **Emissions in the end-of-life phase:** With respect to waste management options, additional information is requested on the effectiveness of incineration under normal operational conditions (for different waste types, e.g. hazardous, municipal) with respect to the destruction of PFAS and the prevention of PFAS emissions.

According to requirements from WEEE regulations, a significant number of valves are already being returned to their manufacturers or central collection points. Nevertheless, there is room for improvement by expanding the scope of collection.

Furthermore, establishing protocols for the separate collection of materials containing PFAS is of paramount importance. These materials should be recycled whenever feasible or appropriately disposed of under suitable conditions, enhancing environmental safety. It's noteworthy that based on current knowledge, under specific conditions such as incineration within a defined temperature range, PFAS may not be released into the environment. However, the precise details of this phenomenon are not yet familiar to the pump and valve industry.

Moreover, there's a demand for further research into the recycling and reutilization of fluorinated polymers. This research holds ultimate significance in maintaining a controlled material cycle for fluorine components. Another challenge emerges based on the intended application. In industrial environments, fluorinated polymers often serve for extended periods, sometimes spanning two or three decades. In contrast, substitute materials would necessitate much more frequent replacement due to lower resistance, occurring on a weekly or monthly basis. This discrepancy would lead to a significantly elevated waste stream from these substitutes, along with heightened contamination concerns. The more frequent replacements of substitute materials due to issues like leaks or damages such as wear and tear on sealing components would introduce additional risks for workers and environment. This scenario might require extensive safety measures for maintenance and handling, contingent upon the nature of the conveyed medium.

4. **Impacts on the recycling industry:** To get an understanding of the impacts of the proposed restriction on the recycling industry, information is requested on:
 - a. The impacts that the concentration limits proposed in paragraph 2 of the proposed restriction entry text (see table starting on page 4 of the summary of the Annex XV restriction report) have on the technical and economic feasibility of recycling processes (together with a clear indication on the waste streams to which the described impacts relate).
 - b. The measures that recyclers would need to take to achieve the proposed concentration limits.
 - c. The costs associated with these measures.

Unfortunately, SISTO does not have sufficient knowledge in the field of recycling. We rely on contributions from the recycling sector to get a complete picture.

5. **Proposed derogations – Tonnage and emissions:** Paragraphs 5 and 6 of the proposed restriction entry text (see table starting on page 4 of the summary of the Annex XV restriction report) include several proposed derogations. For these proposed derogations, information is requested on the tonnage of PFAS used per year and the resulting emissions to the environment for the relevant use. Please provide justifications for the representativeness of the provided information.

In the proposal to restrict PFAS (per- and polyfluorinated alkyl substances), the current industries and uses of SISTO products are regrettably not identified or covered by exemptions. As previously stated, diaphragm valves extend from food, over pharmaceutical, to chemical and energy applications. In all of these areas, there is a need for PFAS-containing materials, without which many applications can no longer be performed. This means that the proposed exemptions do not cover specific cases or applications of PFAS, which are essential for many industrial sectors. Therefore, there is a need to reconsider the scope of the proposal to exclude essential applications from the proposal. Within the diaphragm valves, the PFAS materials take up only a small proportion of the total weight. Without this material, however, the entire valve is unusable for the specific application. Consequently, it is more appropriate to evaluate the economic impact. The elimination of the PFAS substances would result in a drop in sales of up to 50% for SISTO, which is enormous. This would also be accompanied by a loss of jobs as a consequence.

The potential restriction on the use of PFASs in large industrial facilities, particularly in valves, would directly impact various sectors. Certain industries rely heavily on the unique properties of PFAS-based materials to ensure smooth operations, safety and efficiency in their production processes. Such a ban would pose significant economic challenges due to the lack of direct alternatives that meet the same technical requirements.

The pharmaceutical industry illustrates this situation. Drug manufacturing requires the highest standards of hygiene and precision, which are currently often enabled by valves containing PFAS. Restrictions on the use of PFAS would lead to problems in maintaining quality, efficiency and sterility in production facilities. As a result, the production of vital medications and patient care would be compromised. As a result, the approval process for materials also takes a particularly long time, which is a problem under the current schedule. Apart from that, there is the problem that no adequate alternatives are available.

6. **Missing uses – Analysis of alternatives and socio-economic analysis:** Several PFAS uses have not been covered in detail in the Annex XV restriction report (see uses highlighted in blue and orange in Table A.1 of Annex A of the Annex XV restriction report). In addition, some relevant uses may not have been identified yet. For such uses, specific information is requested on alternatives and socio-economic impacts, covering the following elements:

- a. The annual tonnage and emissions (at sub-sector level) and type of PFAS associated with the relevant use.
- b. The key functionalities provided by PFAS for the relevant use.

Purpose /sector	Application	Characteristics	Materials (PFAS)
Pharmaceutical & biotechnological industry	Liners, diaphragms	Thermal resistance, chemical resistance, Sterilizable (SIP) & cleanable (CIP), FDA approved	PTFE, TFM, PVDF
Food industry	Liners, diaphragms	Thermal resistance, chemical resistance, Sterilizable, FDA approved	PTFE, TFM, PVDF
Energy industry (Oil, gas, H2 production, etc.)	Liners	High temperature resistance even at air borne oxygen	PTFE, TFM, PFA, FKM
Chemical process industry	Liners, diaphragms, sealings	Thermal resistance, Chemical resistance, Wear resistance	PTFE, TFM, PFA, FKM, ECTFE, ETFE
Actuators	O-ring, gaskets	Thermal resistance	FKM, FPM
Spare parts	Sealings, diaphragms, liners	see all characteristics above	see materials above

- c. The number of companies in the sector estimated to be affected by the restriction.

Restricting PFAS would have a far-reaching impact on our customers. Almost all of our customers would be affected. PFAS span a variety of our product configurations, driven by customer requirements. Thus, numerous customers in the energy, pharmaceutical, food, chemical sectors would be affected. Due to the restriction there will be multiple negative aspects, which are mentioned as follows:

- Degraded product performance → potential emission due worse sealing tightness
- reduced product lifetime → rising of carbon footprint, more waste
- Worse resistance → material failure due to chemical / thermal stress
- omission of product approvals (e.g. pharmaceutical suitability) → very lengthy processes
- multiple production processes, using diaphragm valves, need to be modified → questionable if the process will work under different parameters
- applicability of spare parts will probably not be possible

Our product, the diaphragm valve, is essential for a great range of fluid-related applications. Besides our product, there is also a great variety of different valves and piping components. Therefore, it is very difficult to quantify the number of affected companies within this sector. Nevertheless, it is obvious that not only manufacturers but also the customers of these components will be affected. In the example of a valve, it can be comprehended that this is only a component of an extensive production plant. From this fact, it becomes clear that it is difficult to quantify the number of affected companies.

d. The availability, technical and economic feasibility, hazards and risks of alternatives for the relevant use, including information on the extent (in terms of market shares) to which alternative based products are already offered on the EU market and whether any shortages in the supply of relevant alternatives are expected.

Fluoropolymers used at SISTO are essential for applications, where no adequate substitutions are available for withstanding the tough working conditions. For materials, which could be a potential alternative for partial applications, there is by far not as much data to the resistance of the material against certain fluids, as for the fluoropolymers. So, this carries a certain risk of material failure due to a lack of data / knowledge and a resulting misapplication.

From safety perspective, there is no substitution, which combines the characteristics of high temperature resistance, chemical resistance and excellent sealing performance. That means the approach to replace PFAS substance will go along with worse performance characteristics. In the case of the diaphragm valve, avoiding a leakage is the core task of the usage of fluoropolymers. Materials, which do not fulfil this requirement at aggressive fluids and high temperatures, will fast degrade. This can result in, for example, fire hazards, environmental pollution risks, and ultimately, dangers to the human organism.

In general, the fact is, that fluoropolymers are never the first choice for applications where alternatives are available. This is because of the high prices that are charged for these materials. For combinations of high requirements on temperature, chemical resistance and reliable sealing function, fluoropolymers are a unique solution. Therefore, fluoropolymers find application only under specific circumstances: when all available alternatives would rapidly prove inadequate and, in many cases, pose safety concerns; when the fluorinated polymer guarantees the sustained functionality of the product or component for an acceptable and extended period; or in situations where the conditions are not precisely defined, such as when the composition of wastewater undergoes regular fluctuations.

e. For cases in which alternatives are not yet available, information on the status of R&D processes for finding suitable alternatives, including the extent of R&D initiatives in terms of time and/or financial investments, the likelihood of successful completion, the time expected to be required for substitution (including any relevant certification or regulatory

approvals) and the major challenges encountered with alternatives which were considered but subsequently disregarded.

It is currently not possible to find an estimate for this. The availability of future alternatives depends heavily on the state of development or ongoing R&D projects by the chemical industry. This is where the expertise for developing new materials is available, even though the response often shows that there are currently no adequate alternatives. A change in material significantly impacts the construction and can trigger a time-consuming transition scenario. Introducing a new material necessitates extensive investigations and testing to ensure it meets the required specifications and standards. Furthermore, certifying the new material is another lengthy process, ensuring its approval for use in the construction. Overall, the suitability of a new material is associated with substantial effort and time investment. Even if alternative materials should exist in future, it will only become clear after intensive and long-period testing and certification process whether the supposed alternative can be used.

- f. For cases in which substitution is technically and economically feasible but more time is required to substitute:
 - i. the type and magnitude of costs (at company level and, if available, at sector level) associated with substitution (e.g. costs for new equipment or changes in operating costs);
 - ii. the time required for completing the substitution process (including any relevant certification or regulatory approvals);
 - iii. information on possible differences in functionality and the consequences for downstream users and consumers (e.g. estimations of expected early replacement needs or expected additional energy consumption);
 - iv. information on the benefits for alternative providers.

Due to the higher cost of fluoropolymers compared to standard thermoplastics or elastomers, alternatives are already being used where available. There are currently no alternatives on-hold that could be implemented at the moment for the remaining applications. Fluoropolymers are currently the only solution in diaphragm valves, where high demands are made on temperature, chemical resistance, service life and low wear.

- g. For cases in which substitution is not technically or economically feasible, information on what the socioeconomic impacts would be for companies, consumers, and other affected actors. If available, please provide the annual value of EU sales and profits of the relevant sector, and employment numbers for the sector.

The entire pump and valve industry would be affected by the discontinuation of PFAS respectively fluoropolymers in particular. In the context of diaphragm valves multiple systemically important applications would be eliminated. Since valves as well as the diaphragm valve represents a small element of a complete plant, the effects are by no means negligible. As a consequence, the production in different sectors comes to a standstill.

This concerns the following economic sectors, as already explained at the beginning:

- i. Pharmaceutical products
- ii. Energy production (green energy = e.g. hydrogen)
- iii. Waste disposal
- iv. Food production
- v. Production of chemicals
- vi. Fertiliser manufacturing

Without fluoropolymers within diaphragm valves the production will not be possible anymore and keeping up with competitors outside the EU will no longer be possible as well. It is damaging to one's own economy to an extraordinary degree. The above-mentioned materials are relevant from SISTO perspective, nevertheless the extent is even much greater. In particular, actions to implement the energy transition cannot be realised without fluoropolymers in most cases. Semiconductor production for high-voltage storage in electromobility and hydrogen production are the most common examples besides further.

For PFAS in diaphragm valves (fluoropolymers) SISTO clearly appeals for an exemption. These materials are only used if the operating conditions where no alternative exists. As fluoropolymers are more cost-intensive than other lining materials in our product portfolio, this also shows that there is no cost interest of customers for linings containing PFAS. Fluoropolymers are explicitly used according to the operating conditions, where other materials fail too fast. This will result in shorter service life, which goes along with potential emissions in the production process. Reduced life cycles associated with prophylactic replacement of components also mean higher operating costs and a greater burden on the environment. For the chemical industry, this could for example mean that due to a low chemical resistance toxic substance could be emitted to environment. Depending on the medium, this impact on the environment would pose a direct and far greater danger to living beings. Especially as fluoropolymers are inert, insoluble in water and basically classified as polymers of low concern.

7. **Potential derogations marked for reconsideration – Analysis of alternatives and socio-economic analysis:** Paragraphs 5 and 6 of the proposed restriction entry text (see table starting on page 4 of the summary of the Annex XV restriction report) include several potential derogations for reconsideration after the consultation (in [square brackets]). These are uses of PFAS where the evidence underlying the assessment of the substitution potential was weak. The substitution potential is determined on the basis of i) whether technically and economically feasible alternatives have already been identified or alternative-based products are available on the market at the assumed entry into force of the proposed restriction, ii) whether known alternatives can be implemented before the transition period ends (taking into account time requirements for substitution and certification or regulatory approval), and iii) whether known alternatives are available in

sufficient quantities on the market at the assumed entry into force to allow affected companies to substitute. A summary of the available evidence as well as the key aspects based on which a derogation is potentially warranted are presented in Table 8 in the Annex XV restriction report, with further details being provided in the respective sections in Annex E. To strengthen the justifications for a derogation for these uses, additional specific information is requested on alternatives and socio-economic impacts covering the elements described in points a) to g) in question 6 above.

Purpose /sector	Application	Characteristics	Materials (PFAS)
Pharmaceutical & biotechnological industry	Liners, diaphragms	Thermal resistance, chemical resistance, Sterilizable (SIP) & cleanable (CIP), FDA approved	PTFE, TFM, PVDF
Food industry	Liners, diaphragms	Thermal resistance, chemical resistance, Sterilizable, FDA approved	PTFE, TFM, PVDF
Energy industry (Oil, gas, H2 production, etc.)	Liners	High temperature resistance even at air borne oxygen	PTFE, TFM, PFA, FKM,
Chemical process industry	Liners, diaphragms, sealings	Thermal resistance, Chemical resistance, Wear resistance	PTFE, TFM, PFA, FKM, ECTFE, ETFE
Actuators	O-ring, gaskets	Thermal resistance	FKM, FPM
Spare parts	Sealings, diaphragms, liners	see all characteristics above	see materials above

For the aforementioned applications no alternatives are currently available. The materials in use are currently not substitutable.

8. **Other identified uses – Analysis of alternatives and socio-economic analysis:** Table 8 in the Annex XV restriction report provides a summary of the identified sectors and (sub-)uses of PFAS, their alternatives and the Page 13 of 15 costs expected from a ban of PFAS. More details on the available evidence are provided in the respective sections in Annex E. For many of the (sub-)uses, the information on alternatives and socio-economic impacts was generic and mainly qualitative. In particular, evidence on alternatives was inconclusive for some applications falling under the following (sub-)uses: technical textiles, electronics, the energy sector, PTFE thread sealing tape, non-polymeric PFAS processing aids for production of acrylic foam tape, window film manufacturing, and lubricants not used under harsh conditions. More information is needed on alternatives and socio-economic impacts

to conclude on substitution potential, proportionality, and the need for specific time-limited derogations. Therefore, specific information (if not already included in the Annex XV restriction report or covered in the questions above) is requested on alternatives and socio-economic impacts covering the elements listed in points a) to g) in question 6 above.

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Actuators	O-ring, gaskets	Thermal resistance	FKM, FPM
Spare parts	Sealings, diaphragms, liners	see all characteristics above	see materials above

For the aforementioned applications no alternatives are currently available. The materials in use are currently not substitutable.

9. **Degradation potential of specific PFAS sub-groups:** A few specific PFAS sub-groups are excluded from the scope of the restriction proposal because of a combination of key structural elements for which it can be expected that they will ultimately mineralize in the environment. RAC would appreciate to receive any further information that may be available regarding the potential degradation pathways, kinetics or produced metabolites in relevant environmental conditions and compartments for trifluoromethoxy, trifluoromethylamino- and difluoromethanedioxy-derivatives.

SISTO Armaturen S.A. has no information to this question.

10. **Analytical methods:** Annex E of the Annex XV restriction report contains an assessment of the availability of analytical methods for PFAS. Analytical methods are rapidly evolving.

Please provide any new or additional information on new developments in analytics not yet considered in the Annex XV restriction report.

SISTO Armaturen S.A. has no information to this question.