

SECTION III.

6.) Missing uses – analysis of alternatives and socio-economic analysis

a) **The annual tonnage and emissions (at sub-sector level) and type of PFAS associated with the relevant use.**

- Relevant PFAS are used in packaging machines to ensure thermal and chemical stability for example in heating or cooling processes which are necessary for product safety, especially for pharmaceutical products and food processing.
- Extrapolating the total tonnage of PFAS material use, as well as estimating it, is not practical or feasible for us as a trade association due to the high percentage of special machinery built by our members.

b) **The key functionalities provided by PFAS for the relevant use.**

With the investigation in the network of Packaging Valley Germany e.V., the following areas of use of PFAS were identified among the member companies:

- Piping and tubing of product (w/o product contact),
- piping and tubing to media,
- filters,
- seals,
- O-rings,
- gaskets,
- tubing and pipes,
- expansion joints,
- conveyer belts and reject trays (w/o object contact),
- valves and fitments,
- chutes,
- guiding rails,
- rollers,
- funnels and sliding plates,
- tanks,
- funnels,
- rollers,
- lining,
- blades of knives,
- membranes,
- lubricants,
- surfaces,
- refrigerants.

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

The main relevant applications of the Packaging Valley Germany e. V. member companies were identified in the two customer sectors of food and pharmaceuticals, which is why the consultation of Packaging Valley Germany e. V. focuses on these two areas. Packaging machinery manufacturers have been identified as being severely affected, as have component manufacturers and automation companies involved in packaging technology. Accordingly, only sales from the packaging technology sector were taken into account.

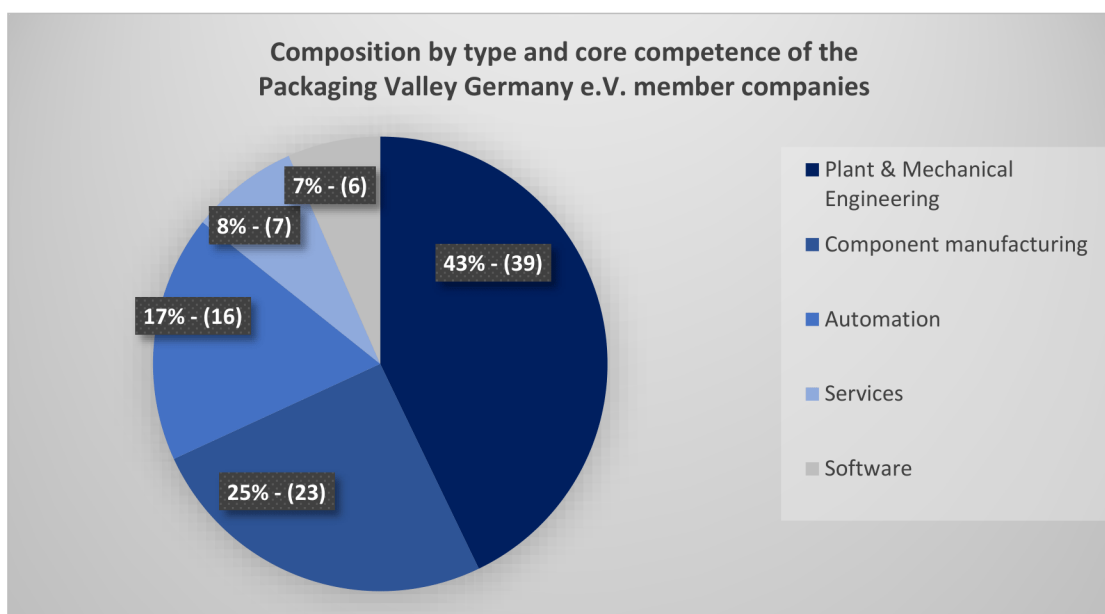


Figure 1: Composition by type and core competence of the Packaging Valley Germany e. V. member companies.

Table 1: Overview of the quantity of member companies of Packaging Valley Germany e. V. by type and core competences.

Packaging Valley member companies - core competence	quantity
Plant & Mechanical Engineering	39
Component manufacturing	23
Automation	16
Services	7
Software	6
Total	91

Food sector: 70 of the member companies of Packaging Valley Germany e.V. provide machines/or solutions for the food industry. The estimated impact of a total PFAS ban on turnover and employees was given as a decrease of 10-30 % for food packaging machines.

Pharma sector: 64 of the member companies of Packaging Valley Germany e.V. provide machines/or solutions for the pharma industry. The estimated impact of a complete PFAS ban on sales and employees was given as a 10-40% decrease in pharmaceutical packaging machinery.

Affected sectors:

- Equipment for industrial production, processing, packaging and filling of food; food contact materials
- Equipment for production, processing, packaging, chilling, filling and freeze-drying of pharmaceutical and nutraceuticals products as well as their ingredients.
- Equipment to clean or sterilize food, pharmaceutical products, nutraceuticals and their ingredients and packaging material as well as the equipment to produce, process, fill or package it.
- Spare parts for already installed equipment of all the above-mentioned sectors.

This information is based on the results of our survey of Packaging Valley member companies. On the basis of the information provided, the overall **impact of a total PFAS ban on member company sales and employment is estimated to be between 5% and 25%**. Considering a total sales of about 7,24 billion Euro and about 20.000 employees of the Packaging Valley member companies in the packaging sector in the EU.

- 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.**
- Shortages in the supply chain are expected.
 - For packaging machine manufacturers, possible **alternatives are widely unknown**.
 - Known alternatives do not run efficient and can so far not fully replace the requirements.
 - Substitutes/Alternative substances cannot be fully assessed by mechanical engineering perspective on their application.
- 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.**

Processes of materials research and development are widely unknown from the perspective of mechanical engineering companies.

- 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.**
- Unknown.
- g) **For cases in which substitution is not technically or economically feasible, information on what the socio-economic 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.**

With a ban on PFAS, productivity losses are expected due to:

- Higher inefficiency of the cleaning cycles (chemical detergents may affect durability or need to be replaced, requiring longer cleaning cycles).
- Higher wear of material cause higher downtimes of machines and impact the carbon footprint of products.
- Modifications of processes and higher costs for material, changes of material, productivity and cleaning.
- Complex processes e.g. high/low temperatures in food/pharmaceutical processing must be revised, modified and revalidated.

Productivity losses affect not only the carbon footprint of the single material but also of the processes and machines. The impact cannot be assessed at this point.

The replaceability of PFAS materials is not yet fully given. Food safety and pharma safety might take losses. Up to now, high temperatures and corresponding cleaning processes have ensured food and pharmaceutical product safety.

Furthermore, new validations will be necessary in the pharmaceutical sector (leads to further downtimes of machines) - the impact on products might change, as well as machine breakdowns can be caused by new processes, which leads to higher drug shortages in the EU.

Due to higher productivity and lower complexity relocation of production facilities abroad become more attractive. Machines in the EU could no longer be operated because spare parts are affected by a PFAS ban or spare parts made from new materials cannot replace the required functions. Lower productivity will make investment in the EU more complicated and less attractive, which may lead to relocation of production in the long term. As a result, the security of supply of pharmaceuticals could decline and the dependence on third countries could increase further.

With an assumed service life of at least 15 to 20 years for machinery and equipment, security of supply is absolutely essential for customers (especially in the pharmaceutical industry), otherwise even existing machinery will be relocated to non-EU countries.

The machine building industry strives to act in the interests of the circular economy. Machines do not end up in landfill, as they typically yield a very high scrap value for their components. End of their lifecycle, machines are usually either reprocessed or recycled, which closes the loops, and the materials and components do not end up in the landscape.

The estimated annual value of EU sales affected is between €0.36 billion and €1.81 billion and the number of jobs affected in the EU is between 1000 to 5000, as declared in more detail in point c) above.