

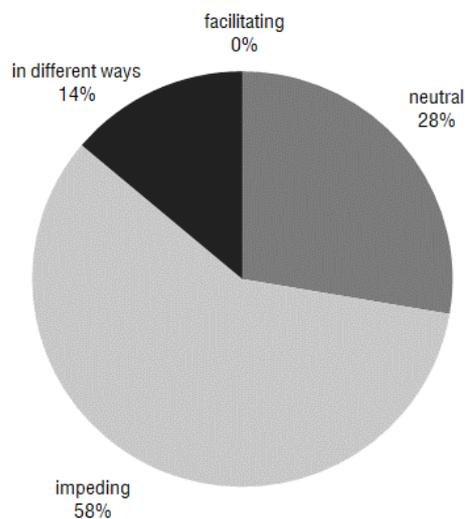
EU regulations impede business operations

Implementation and administration overburden SMEs in the microtechnology industry

Directives and regulations of the European Union are designed to facilitate the free movement of goods and services within the European single market by ensuring uniform requirements in all EU countries. In the perception of the European microtechnology organizations, the impeding effects of EU regulations clearly outweigh the facilitating effects. Particularly SMEs feel overburdened with documentation and reporting obligations and with the expertise needed to interpret and implement regulations.

In the course of its annual economic data survey, the IVAM Microtechnology Network asked microtechnology companies and research institutes in Europe about the practical experiences they made with EU regulations, and the opportunities to exert influence on decision making processes.

General influence of EU regulations and directives on business operations



EU regulations impede rather than facilitate business operations

Only a small proportion of European microtechnology organizations appreciate how EU regulations facilitate trade and collaboration within the EU single market: only 14% say that EU regulations and directives partly have a facilitating effect on their business operations. More than half (58%) of the responding organizations feel that EU regulations and directives are impeding their business operations.

EU regulations affect most of the European microtechnology industry. The industry is largely international: more than 90% of the companies and institutes act on an international level, almost all of them within the European single market.

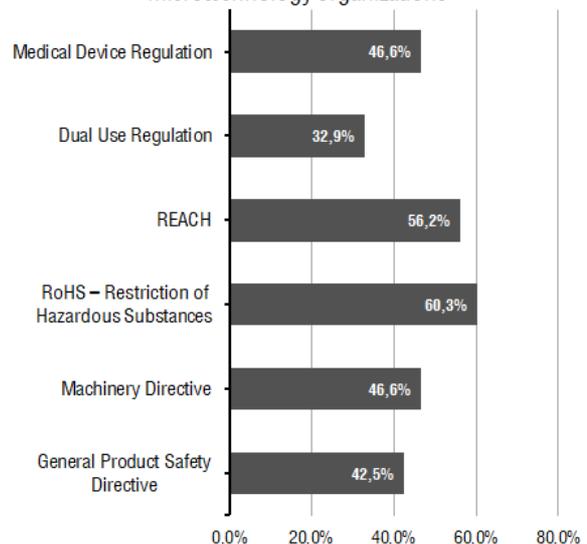
“It is getting more and more complicated to deal with.”

Versatile microtechnology industry affected by a variety of regulations

The European microtechnology industry covers a broad range of technology fields including micro components, MEMS, nanotechnology, advanced materials, and optical technologies. Consequently, the industry is affected by a variety of EU regulations and directives, such as RoHS (Restriction of Hazardous Substances), REACH (Registration Evaluation, Authorisation and Restriction of Chemicals), or the Machinery Directive.

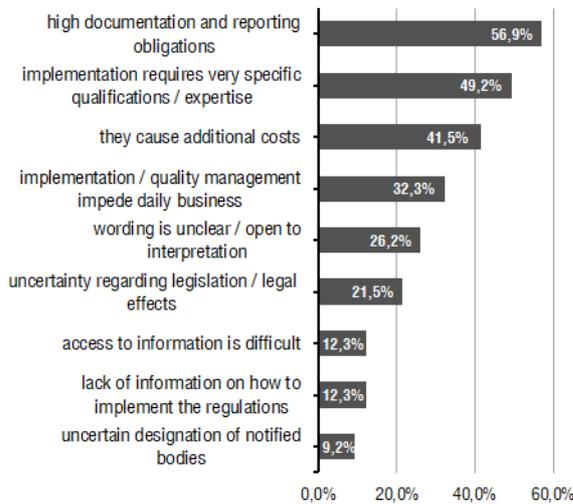
Recently, regulations that apply to device manufacturers have become relevant for the supplier industry as well. The new Medical Device Regulation, for instance, which took effect in May 2017, has considerably increased the requirements of certification and documentation for suppliers of the medical device industry.

EU regulations and directives that affect microtechnology organizations



“[Regulations cause] massive obstruction of innovation, especially in the medical technology market.”

Reasons why EU regulations and directives impede business operations



Documentation and implementation overburden high-tech industry

A major complication from the point of view of the European microtechnology organizations are the high documentation and reporting obligations that EU regulations or directives entail. More than half (56.9%) of the companies and institutes say that the documentation and reporting obligations impede their business operations.

Almost half (49.2%) of the organizations are challenged by the specific qualification and expertise that is required for implementation. Implementation also causes additional costs for a large part (41.5%) of the industry and impedes daily business (32.2%). Even the interpretation of regulations and directives is difficult for more than a quarter (26.2%) of the responding microtechnology organizations.

“Lack of expertise is compensated for with calls for more rules. [...] Innovations are becoming more and more difficult to implement.”

SMEs demand simplified regulations

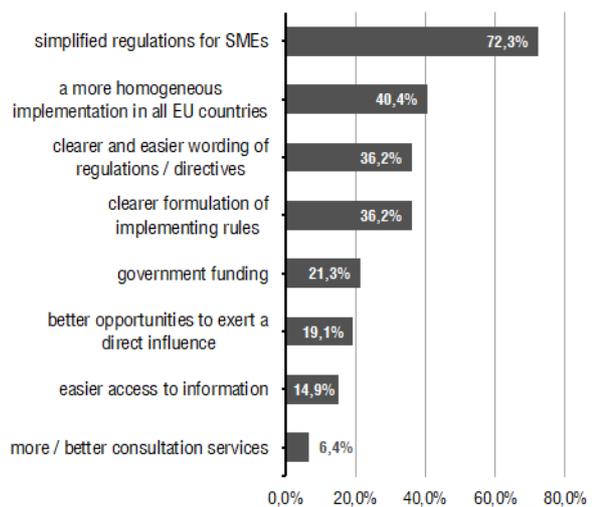
A clear majority of representatives of the European microtechnology industry thinks that EU regulations are too extensive and complex for small companies to be able to comply. Almost three quarters (72.3%) of microtechnology organizations call for simplified regulations for SMEs.

40.4% of microtechnology industry representatives say that a more homogeneous implementation in all EU countries is needed.

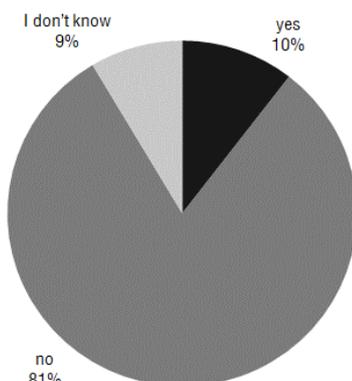
About a third (36.2%) of organizations each believe that a clearer formulation of regulations and a clearer formulation of implementing rules would make it easier to comply with EU regulations.

“Over-regulated, destroys SMEs, favors large companies, formal and out of touch with reality.”

Measures that would make it easier to comply with EU regulations and directives



Proportion of microtechnology organizations that are involved in decision making processes regarding EU regulations

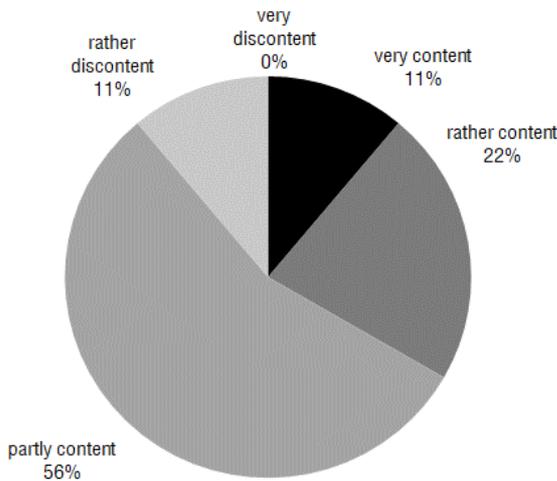


Only few industry representatives try to influence regulations

Although a large part of microtechnology companies and institutes are affected by EU regulations, only few (10%) are trying to influence regulations by getting involved in relevant decision making processes on EU level.

“Basically there is a high inclination to get input e.g. through technology platforms.”

Contentment with the outcome of efforts to exert influence on decision making processes regarding EU regulations



Efforts to influence regulations not wasted, but time-consuming

The prospects of success are rated as partly satisfactory by the involved representatives of the microtechnology industry. More than half (56%) of the involved microtechnology industry representatives are “partly content” with the outcome of their efforts to exert influence on decision making processes regarding EU regulations. A third (33%) are “very content” or “rather content”.

Altogether the efforts to influence regulations are considered to be time-consuming and to have limited effects.

“Time-consuming!”

“The only downside is the long time to success.”

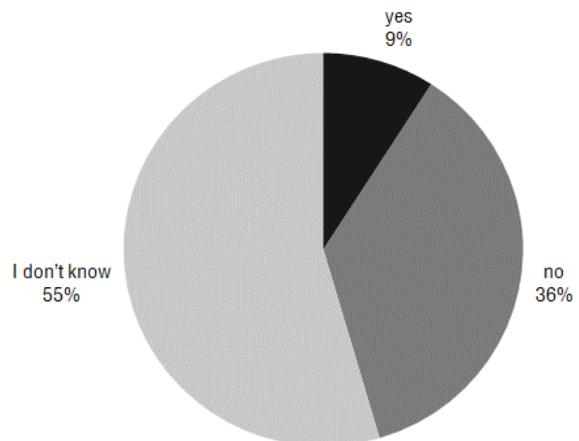
Not enough opportunities to influence regulations

Those industry representatives who are involved in decision making processes are uncertain as to whether there are enough opportunities to exert influence on EU regulations. Only 9% are convinced that there are enough opportunities for individuals to exert influence on the decision making processes regarding EU regulations. More than half (55%) “don’t know”.

The general feeling is that smaller companies or individuals have a very limited influence, even if they try to get involved. Decision making processes are described as complex and not very transparent, personal involvement as not efficient even by industry representatives with a long experience in Brussels.

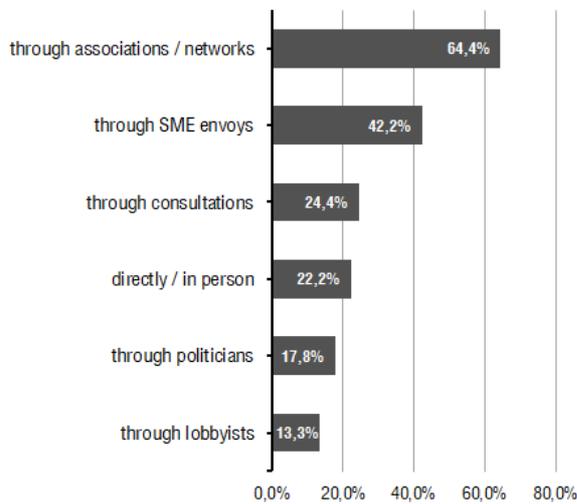
Chances to influence the national implementing rules are judged to be better: 37% of the involved microtechnology industry representatives think that there are enough opportunities to influence decision making processes regarding the national implementing rules; 27% “don’t know”.

Are there enough opportunities for individuals to exert influence on the decision making processes regarding EU regulations?



“Overall, the transparency is not very high. Even after more than 12 years of engagement in Brussels I have problems to be efficient.”

Ways in which microtechnology organizations would like to exert more influence on decision making processes regarding EU regulations



“The attempt to influence as an individual is doomed to failure, so larger associations or national representatives need to become involved.”

Relevant impact only through associations

To date, the microtechnology industry representatives are predominantly involved in decision making processes regarding EU regulations in person (7.6% out of 10% who are involved). Only few are getting involved through instruments or agents such as associations, consultations, SME envoys, politicians, or lobbyists.

However, relevant impact, according to the involved industry representatives, can only be achieved through associations or national representatives. Consequently, a major part of the microtechnology industry wants to associations to become more strongly involved in decision making processes regarding EU regulations. When asked in what ways they would like to have better opportunities to exert influence on the decision making processes regarding EU regulations, 64.4% name industry associations. 42.2% would like to take (more) influence on EU regulations through SME envoys, and 24.4% would like to benefit more from consultations.

Further information:
www.ivam.de/research

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About the IVAM Survey

Once a year, the IVAM Microtechnology Network collects economic data among companies and research organizations that are active in the fields of microtechnology, MEMS, nanotechnology, advanced materials, and optical technologies. In February 2018, 3,800 companies and research institutes in Europe have been asked about their economic situation and expectations, their international activities and their experience with EU regulations. The participants are mostly located in Central, Western and Northern Europe, 73% of participants come from Germany. A large proportion of the participants are representatives of small enterprises: 56% are SMEs, 6% are start-ups, 6% are major enterprises, 32% university or research institutes.