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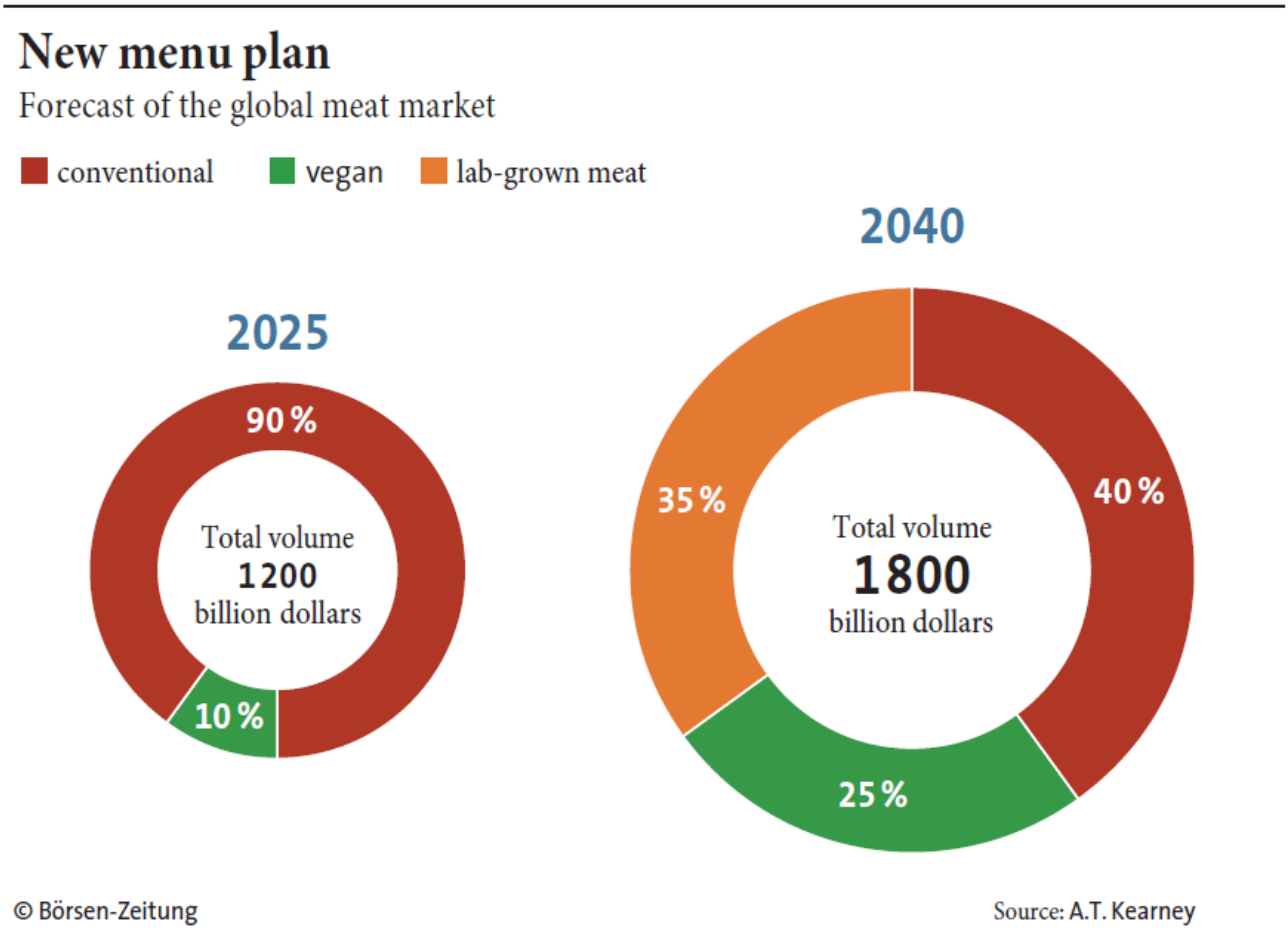
AN INTERVIEW WITH WOLFGANG SCHÖNIG, MORRISON & FOERSTER

"At any rate, it won't fail because of money."

Veggie Day is no longer a lifestyle choice; moderate meat consumption and meat substitutes are being considered key elements for climate protection. Many companies have entered the meat substitute business, but they are encountering legal hurdles, explains the legal expert Wolfgang Schönig in an interview. Their financing is nevertheless ensured and they arouse a huge appetite among venture capitalists.



Dr. Schönig, CO2-neutral meat production is considered one of the key aspects in the fight against climate change. Can we really make a big difference through our food choices?

According to expert estimates, conventional meat production takes up around 75% of the agricultural land used worldwide and is responsible for over 15% of the greenhouse gases emitted globally. This is a rising trend. Alternatives, such as plant-based meat substitutes or meat produced in cell cultures, are significantly more resource-conserving and climate-

friendly by comparison, mainly because no greenhouse gases are produced, and the high water and energy consumption of conventional animal husbandry is eliminated. For the agri food industry, this is not so much an option, it's a necessity, as the industry will have to meet strict CO2 reduction requirements by 2030 as part of the EU's so-called Green Deal.

How often does environmentally friendly meat end up on your plate?

The market for meat substitutes is growing rapidly, and this is happening without strict regulatory requirements for the industry in terms of the CO2 reductions already in place. The market here probably anticipates the compelling need and sees the opportunities – both for plant based alternatives and for cell-cultured meat. It is important to remember that the world's population will grow to nearly 10 billion by 2050, all of whom will need sufficient protein foods. So it's not so much a lifestyle choice, but an essential contribution to curb CO2 emissions and preserve our lives. It also presents immense economic opportunities.

> *"American companies such as Beyond Meat and Upside Foods are currently among the leading manufacturers and developers of meat substitutes."*

Which providers are ahead in the race?

American companies such as Beyond Meat and Upside Foods are currently among the leading manufacturers and developers. The Israeli manufacturer Redefine Meat is currently intensively pursuing its market entry in Europe. But EU-based start-ups like Mosa Meat are also working on alternative products for consumers in Europe. There are countless other examples. In any case, there will be no lack of money, as venture capitalists are in the process of setting up huge funds for this sector, including in Germany. The current focus, however, is more on plant-based meat substitutes. Products made from cultured meat are not yet as widespread, mainly because of regulatory uncertainties, but Singapore is an exception.

What is the legal framework for lab-grown meat? Is it possible to market meat from cell cultures in Europe?

The possibility of marketing cell-cultured meat definitely exists. However, as far as can be seen, no application for an authorization procedure has yet been received in the EU. The European legal framework is divided into two parts. If a new product or a new single protein

is GMO-free, the Novel Food Regulation applies. If a product contains genetically modified organisms, it is subject also to the GMO Regulation. In this case, the Novel Food Regulation largely takes a back seat. This applies to both cell-cultured meat and plant-based meat alternatives.

Which products fall under the Novel Food Regulation?

Any food that was not used for human consumption to any significant extent before May 15, 1997 is covered by the regulation. This includes, for example, insects or proteins generated from them. Plant-based meat substitutes, whether vegan or vegetarian, may also fall under the regulation.

That is unusual; they have been on the market for a long time.

It is true that legumes, such as soybeans or peas that contain protein isolates, have long been used in the production of plant-based meat substitutes, and are generally not novel foods as defined by the Novel Food Regulation. However, a fairly intense innovation competition is underway to identify new, better proteins for use in meat substitute products. The origin or the process of isolating the proteins can then make the individual protein or even the final food "novel" in the sense of the regulation. In the EU, for example, a new regulation was recently passed for – GMO-free – proteins isolated from mung beans and rapeseed, which can also be used in meat substitutes.

What about cell-cultured meat?

In my opinion, meat or proteins produced from meat cell or tissue cultures fall under this regulation. However, there are no clear guidelines on this yet.

What are the requirements for approval under the Novel Food Regulation and the GMO Regulation?

Under both regulations, a product requires authorization before it can be marketed for consumption in the European Union. The procedures are complex. A few key points: In each case, manufacturers must be able to demonstrate that consumption of the product does not pose a health risk. If genetically modified foods are involved, it must also be ruled out that unintentional modifications are possible. The requirements are very complicated.

Specifically in what aspects?

Insofar as a Novel Food is intended to replace an existing food, it may not be inferior to the conventional product in terms of nutritional value. In no case may the products be

marketed in a misleading manner. In the case of GMO products, there are also mandatory labeling requirements.

In what sort of time frame does the admission process take place?

Approval under the Novel Food Regulation takes between 12 and 18 months. Approval under the GMO Regulation, on the other hand, takes considerably longer and is significantly more cost-intensive, due in particular to the complex verification of the product's safety.

In Singapore, chicken nuggets made from cell-cultured meat were launched on the market for the first time months ago. Are the approval criteria in that country less strict?

In Singapore, cell-cultured meat also has to go through a highly regulated approval process. The approval of the chicken nuggets took two years, and Eat Just, the company that developed the chicken nuggets, had to provide the authorities with data on the quality and safety of the product, as well as on the production process.

In the end, however, it worked out.

Yes, but what currently sets Singapore apart from other countries is, on the one hand, the willingness to actually bring such products to market. Singapore wants to become the global leader in food tech innovations. Accordingly, generous government subsidies are available there. On the other hand, consumers in Singapore are very open to this new type of food.

In Europe, by way of comparison, people like to talk about "food neophobia," i.e., an aversion to anything new. The very negative attitude in Europe toward genetic engineering further restricts the industry's options with regard to meat substitute products.

Is the regulatory framework in place in Europe to advance meat substitutes?

Major issues include how to determine product designations and advertising references for meat substitute products – whether plant-based or not. For milk substitute drinks, the European legislator has recently clarified that they must not be labeled as milk; with regard to meat substitute products, a uniform regulation is still lacking at the European level. It would also be desirable for the EU to develop clear guidelines for the approval process for cell-cultured meat.

How far has the EU advanced?

There is a lot of guidance on the websites of the competent authorities, especially the European Food Safety Authority (EFSA), for the approval for alternative proteins in general. Not long ago, a separate set of rules was even developed for the approval of insect-based

products. For cell-cultured meat, however, corresponding guidelines are still missing. I think this should be addressed soon. In addition, and perhaps more importantly, in my view another question that urgently needs clarification is how to deal with new genetic engineering methods in the European food industry.

> *"Ultimately, the issue is how to feed the growing world population in a climate-friendly way (...)."*

Isn't genetic engineering in food production still highly controversial among European consumers?

The inventors of one of these methods called CRISPR, often referred to as "the gene scissors," won this year's Nobel Prize for their invention. These new technologies can enable quantum leaps in development and are of considerable importance when it comes to cost-effectively obtaining proteins in sufficient quantity and quality for meat substitute products so that the transformation to meat substitutes, which advance is urgently needed against the backdrop of the climate crisis and population growth, can also succeed. This applies to plant-based proteins just as much as to cell-cultured meat from the bioreactor.

What is the problem?

Currently, these technologies are subject to GMO regulation with all of the red tape that comes along with it. A clear distinction must be made as to whether GMO technology is used to introduce foreign genetic material into an organism or only to make changes within the genome of an organism that, in theory, could also occur naturally. At least for the latter area – the so-called non-transgenic area – there is now ample evidence for the safety of these technologies, at least as far as plant development is concerned. In many countries, therefore, the technologies are handled much more liberally in this field of application than in the EU – where any deviation from the status quo is still often met with the stigma of "Frankenfood."

So it's all about cultural idiosyncrasies?

GMO regulation is increasingly becoming a competitive disadvantage, especially for small innovative start-ups that simply cannot afford the high costs under the regulation. There are currently consultations at the EU level on the extent to which these new techniques for plants could be less regulated in the future. Certain labeling references are also up for debate, even if the technology no longer qualifies as a GMO in the future. This is a good development, but this process is taking too long. And the consultations are essentially behind closed doors and not transparent enough.

Won't some consumers still find it difficult to appreciate all of this as food?

As far as cell-cultured meat or optimized plant proteins produced using new genetic technologies are concerned, this is certainly a challenge. The industry is already doing massive educational work here. However, I would like to see the issue to be given the space it deserves in the public political debate as well. Ultimately, it's about how the growing world population will be fed in a climate-friendly way and whether Europe wants to play a significant role. Clearly, the topic is controversial and requires courage, not only from the industry but also from public stakeholders. However, it is one thing to set up climate targets for the agricultural and food industry by way of the EU's Green Deal, but as another thing, a framework of conditions must also be created so that the targets can be achieved. In my opinion, this cannot be done without new technologies.

Dr. Wolfgang Schönig (46) is a partner in the Berlin office of Morrison & Foerster, a corporate law firm founded in San Francisco in 1883. He supports his clients in the protection of intellectual property, with a particular focus on providing IP law advice to companies in the digital and telecommunications, high-tech, life sciences, and pharmaceuticals industries. His main areas of advice include research and development collaborations, complex licensing agreements, technology transactions, know-how protection strategies, and employee invention law. He also has extensive litigation experience enforcing patents, trademarks and other intellectual property (IP) rights, often in a cross-border context. In addition, the lawyer and his team regularly evaluate the legal conformity of advertising campaigns, check the availability of trademarks, and develop appropriate filing strategies. And he does all this with dedication: "My passion is IP. I enjoy helping clients exploit the full potential of their intellectual property," he says, outlining the scope of his work. Before joining Morrison & Foerster in May 2015, Schönig worked at Clifford Chance as counsel beginning in 2006.