Johner Institute

PFAS Regulation: New Headaches for Manufacturers

With RA Martin Ahlhaus, Prof. Dr. Christian Johner

Transcript

00:00:05 Speaker 1

Medical Device Insights, a podcast by the Johner Institute for medical device manufacturers, authorities and notified bodies.

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The aftermath of the MDR is far from being digested and there is already the threat of the next disaster, namely another EU legislation, which

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Effects that can have a very big impact even on the medical device industry and that is this issue PFAS.

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This is a matter that is relatively complex from a regulatory point of view, probably also technically, but I got support for this podcast today from the lawyer Martin Allhaus.

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I would like to discuss with him what exactly is required, what should medical device manufacturers

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and what mistakes should you perhaps avoid in the process.

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Mr. Alois, you are very welcome.

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If you say something to yourself very briefly, then we can classify you well, know what else you do and then get straight into the topic.

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Yes, thank you very much.

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Yes, my name is Martin Alois, I am a lawyer and founding partner of the product law firm.

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This is a law firm specializing in product law issues with offices in Augsburg and Berlin.

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We mainly advise companies on questions of product liability and product safety law, also on questions of product-related environmental law, and we also work for companies in the life sciences sector and also advise on all medical device law issues.

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However, my personal focus is more on chemicals law, hence the proximity to the topic of PFAS.

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Substance-related requirements for the marketability of products, especially medical devices, are increasingly in the regulatory focus.

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The EU's Green Deal in particular also addresses these issues, especially with the Chemicals Strategy for Sustainability.

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And it has already clearly addressed the issue of regulation and restriction of PFAS.

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Wow, you've already jumped right into the middle of the topic, that's great, but I think it becomes clear to every listener that we now have exactly the right expert with us, namely a lawyer and a focus on chemicals.

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That's what we need now.

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So for us beginners, what are these PFAS all about?

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What kind of fabrics are these?

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You have already said that it can also be done there, was the E.

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U.

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somehow a bigger idea.

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Could you introduce us to the topic slowly?

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With pleasure.

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So specifically, it's about a ban

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the manufacture, placing on the market and use of so-called per and polyfluorinated alkyl substances in the EU.

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These substances are used in many industrial applications.

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These are substances that are characterized above all by certain durability and resistance, which are therefore also used in particular for oil and water-repellent materials.

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That's where you know them above all.

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For example, with outdoor textiles, you may still have points of contact in your private life.

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However, they are used in many industrial applications.

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They are very widespread and, and this is the main point of reference for this restriction proposal, they are also persistent.

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This means that they do not degrade in the environment or only very, very slowly.

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This means that, according to the restriction proposal, they accumulate in the environment.

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And it is precisely this further accumulation in the environment that the ban that is now being discussed is intended to counteract.

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Specifically, it is to be implemented in the form of a restriction within the framework of the so-called RE-ACH Regulation, i.e. the EU Chemicals Regulation.

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To this end, some authorities of the responsible Member States, in this case Germany, the Netherlands, Denmark, Norway and Sweden,

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submitted a proposal.

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It was opened on 13.

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January to the European Chemicals Agency, which is now coordinating the process.

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And on 7.2.

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the proposal was published.

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This was initially preliminary information.

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Specifically, since 22.

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March a public consultation on this restriction proposal.

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Within the framework of this consultation, all stakeholders, as they say, are now all

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interested parties are invited to comment on this proposal, to evaluate it, to propose changes or to criticise it.

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Mhm, so you just said that it's mainly about chemicals that are difficult to degrade, sometimes that's what you want to be particularly stable.

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I think that's what can bite us a bit afterwards with medical devices.

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You have also already mentioned the Chemicals Regulation, so my assumption is correct that it is a matter of amending this

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I think the REACH Directive works.

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And if so, what exactly does the legislator prescribe now?

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So what does he want to change in there?

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Yes, so it is indeed a matter of adapting the REACH Regulation.

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This is not yet an entirely unusual procedure.

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The REACH Regulation has a restriction procedure in entries in Annex 17, this regulation is very complex and multi-layered, and Annex 17, which deals with very specific restrictions, i.e.

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Bans on certain uses of certain substances.

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There are already a number of entries and an additional entry on PFAS is intended to implement this ban there.

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That is what this proposal is aimed at.

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First of all, the proposal itself is kept quite simple in principle, because in principle the production, placing on the market and use of all PFAS is to be banned in a very general way.

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However, it is not only the use of PFAS as such, i.e. as substances, that is to be banned, but also the placing on the market of substances containing PFAS, mixtures containing PFAS and products containing PFAS.

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And all these bans are to take effect again 18 months after the amendment comes into force.

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This means that there will be an amending ordinance that will:

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will come into force at a certain point in time and the ban will take effect 18 months later.

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So far, so simple.

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Now, however, things get a little more complicated.

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On the one hand, the term PFAS is not entirely trivial.

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That sounds as if we were referring to a very specific substance or a very clearly defined group of substances.

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On the one hand, we do that, and on the other hand, the scope of this group of substances, which it actually is, is very large.

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In fact, well over 10,000 individual substances are covered by this definition.

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This makes it very difficult to determine the specific extent of the impact.

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This means that it is not a trivial challenge to prove the presence or absence of such substances in the products, specifically also in medical devices, or

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to identify from the perspective of a medical device manufacturer in which areas these PFAS actually occur.

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In addition, the proposal itself explicitly emphasises that the available analytical methods currently have all weaknesses, namely because of their specific methodology, the objective.

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Sometimes the focus is on individual substances, i.e. a very focused, only certain PFAS,

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Capture Analysis Method selected.

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There are other analysis methods that look at a total fluorine content.

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Of course, PFAS are also recorded, but not only, other substances are also recorded, so that the reliability of the results is not really tangible.

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And that wouldn't be complex enough, so there's an additional one

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Complicating the whole issue, because the restriction proposal provides for a whole series of exceptions and transitional arrangements.

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And this is where it becomes particularly relevant for medical device manufacturers.

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The proposing Member States have certainly recognised that PFAS cannot be easily replaced in certain areas of application, at least as things stand today.

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This also applies to medical devices and for the corresponding

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applications, exceptions or proper transitional regulations are to be provided.

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These depend on whether, in the opinion of the Member States that have drawn up the proposal, alternatives for the use of PFAS are already within reach or not.

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If they are already tangible, then an additional transitional period of five years is provided, i.e. 18 months until intervention.

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plus another five years.

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That means that in total we are then talking about a 6.5-year transition period.

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And in all those cases in which such alternatives cannot yet be identified or research projects are still ongoing and have not yet produced results, a further twelve years of transitional period are to be added, i.e. 18 months plus twelve years, i.e.

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a total of 13.5 years until the restriction takes effect.

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That sounds comparatively comfortable now.

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However, it is the case that almost all proposed transitional regulations, especially for medical devices, are currently still under review.

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This means that not a single medical device can be reliably claimed for itself today, in any case

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to be able to benefit from such an extended transitional arrangement.

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In addition, the transitional regulations for medical devices currently under discussion only cover a fraction of medical devices at all.

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Objectively, these are very specific transitional regulations and by no means generalising regulations that would cover a large number or wide range or even all medical devices.

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Oi, that was rich in content now.

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I have to summarize that briefly so that we have all this.

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O.K., so what you have described is that it is indeed a matter of adapting the Reach Regulation, including this one annex.

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Then you described that this change seems relatively compact at first, because it simply completely bans all PFAS and their precursor or their production, placing on the market or production.

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This could be easy now, but it is not for several reasons.

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the first reason you mentioned is that it is difficult to distinguish what now belongs to this group of substances.

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You have described that somehow there are more than 10000 substances involved and that you can't decide imaginarily whether a chemical still belongs in there or does it not belong there.

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The second problem you described is that if you meet a requirement or have to prove it, then we also need measurement methods.

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And it is far from clear how it can now be determined whether these regulatory requirements are met or not.

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So, that makes things a bit more difficult.

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What you also indirectly described is that it applies across the board to all substances, regardless of whether you can decide whether they go in there or not, there is no distinction.

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So, as you may otherwise know, benefit-risk assessment, yes, this is not provided for on the individual substance, but actually on a

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group of substances, which makes things even more challenging for medical device manufacturers.

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Then they had described that they actually want to move forward relatively quickly.

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So as soon as it is passed, you only have 18 months in quotation marks until the new version of the regulation takes effect.

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But you also said that it has already been realized that this cannot be replaced and differentiated so seamlessly for all products.

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That's why

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actually 2 cases, namely there is already an alternative substance, then you only have 5 additional years or you don't have this alternative, then you give it 12 additional years to go out with it now.

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And now at the end they said that that would sound like a lot, but that of course it wasn't that much now.

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So I know that now from the clinical trials alone, how long something like this often takes and

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This must then also be researched and proven.

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But that brings us right into the middle of the next question, what are the effects on medical device manufacturers that are now resulting from this?

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In other words, above all from this ban and from this limited transitional period.

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Yes, you had already rightly pointed out that in the cases in which medical device manufacturers, as of today, use PFAS, consciously or unconsciously, this always requires separate clarification,

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a change is certainly needed to take account of this future ban.

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And that ultimately means that the corresponding conformity assessments for medical devices have to be re-approached, because re-evaluations are necessary due to the material changes or even the functional changes that go along with them.

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This means that the entire lead time and planning phase that has to be taken into account must of course be taken into account in addition to the research and development effort.

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can be added.

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And then, as you rightly say, twelve years in the end is no longer a very long period of time.

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There is another factor: the implications for medical device manufacturers are particularly problematic because the proposal does not provide for a general exemption or a generally long transition period for medical devices as such.

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We know this from other regulatory approaches, in which medical devices in general

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be subject to a specific exception or transitional arrangement.

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This is not the case here, but it is

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very specific regulations are provided, for example for implanted medical devices, for things such as hernia meshes, which are specifically addressed as an independent regulatory area, or contact lenses, which are addressed separately with corresponding transitional provisions.

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However, medical devices that are not subject to such a very specific transitional regulation must comply with the requirements 18 months after this restriction comes into force.

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and let's not kid ourselves, this will ultimately lead to a very hard marketing ban for a medical device, because it will simply not be possible to make changes on the material and functional level within 18 months with all the associated requirements.

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This means that we are clearly heading for a traffic obstacle in the field of medical devices if the

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the exceptions and transitional provisions are not provided for here adapted to the individual products.

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This leads to a very special problem area.

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Medical device manufacturers know this, of course.

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We only saw a significant extension of the transitional periods under the MDR in March with Regulation 2023/607.

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That was an ad hoc measure, in particular to

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capacity constraints at the notified bodies.

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Now this PFAS restriction and the associated need for conversion threatens to completely thwart precisely these extended transitional periods.

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Because it is of course clear that these extended transitional periods under the MDR will not help me if I do not comply with the requirements of a PFAS restriction, because then the marketing ban does not result from the MDR,

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but directly from the PFAS ban.

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And so we already have a clear contradiction between this regulatory approach of this regulation to amend the transitional regulation under the MDR and the approach of enforcing a PFAS restriction as quickly and as comprehensively as possible.

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So the effects for medical device manufacturers in particular are very, very tangible here and threaten to

lead to considerable

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yes, to lead distortions in the market, up to supply bottlenecks, unavailability of medical devices and the like.

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If I have shown it correctly, you have now expressed 2, i.e. particularly massive points of criticism.

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The first is the way exceptions are defined.

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Yes, so ultimately in computer science it will be called, they had a closed world assumption, namely we have a finite number of products and then we pick out those that are allowed to benefit from an exception, so to speak,

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But the reality is not a closed world, but we will have new and different products.

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This means that because by default everything does not benefit from an exemption, we lose products that the legislator would probably not have objected to at all if they had benefited from it.

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But the way it has been formulated, namely through a direct assignment, so to speak, and not through rules or risk-benefit considerations, does not give us the selectivity that would actually have been necessary.

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or would have been helpful.

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Criticism number 1.

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Criticism number 2, what you as a counteracting M.D.R.

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extension of transitional periods.

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Namely, of course, it is of no use to us if we do not use the

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very burdened manufacturers an extended transitional period for M.D.R.

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and on the other hand, so to speak, by not placing their products on the market, because we then also prevent them from being placed on the market again with this chemicals or the REACH regulation.

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Oh, that's really terrible again, what's happening.

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What should manufacturers do now?

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Maybe also, what should they not do?

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How should we proceed now?

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What was your recommendation?

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Yes, so first of all, of course, it should be noted that the PFAS restriction has not yet been adopted.

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So there is still time and there is still something to do.

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The proposal is currently on the table and is the subject of a public consultation.

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As I have already said, all those affected, all interested parties can

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comment on this.

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This consultation is open until 25 September.

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September.

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Until then, there is still time to make appropriate submissions for one's own products, one's own portfolio, as a medical device manufacturer, in order to raise concerns, make suggestions, regulatory proposals and even concrete requests for exceptions or extended transitional periods.

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Medical device manufacturers should therefore first examine the proposal in concrete terms.

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Are their products addressed there, have they been treated, how have the proposing member states positioned themselves and is there a need for action against this background?

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As you said, there may be a specific product portfolio or a specific medical device that has simply not yet been evaluated by the proposing Member States, that may not have been known at all,

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and therefore a supplementary submission must be made.

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Experience has shown that what should not be done is to rely solely on the fact that the relevant industry associations will already submit statements on this consultation.

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Of course, all industry associations are doing this, are working at full speed, and in some cases have already done so.

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But product and use-specific issues are usually not dealt with by the associations.

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This means that the individual manufacturer must always make an effort to understand a medical device manufacturer‘s own portfolio and the effects of the proposal and also formulate the corresponding submissions himself.

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It will always be up to the company concerned to position itself here.

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You should also evaluate whether you can send submissions with a request for confidential treatment.

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This means that, in principle, submissions made in the context of a public consultation are also published by ECHA.

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You can already look at the statements that are already available, so you can also familiarize yourself with the submissions that others have submitted.

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Especially in the field of medical devices, however, it is often also linked to the interests of the companies whether and

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in what way information on the composition and modes of operation becomes known.

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This means that the question of the confidential treatment of trade and trade secrets, for example, should be considered very carefully.

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You have the option of requesting confidentiality and secrecy from submissions.

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And if the company's interests are affected accordingly, this should certainly be done.

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Of course, targeted participation in the consultation first of all also requires that you identify your own concern, i.e. first of all determine whether I have PFAS in my medical devices at all, do I use them, how do I use them, where are they possibly present without me even knowing or identifying it before.

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This means that the educational work must first begin.

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I know that the time span until September is comparatively short for this as well.

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In this respect, the most important and overriding advice to medical device manufacturers is certainly first of all to familiarize themselves with the question, are PFAS used in my products, are they present there, would they be detectable and would I therefore be affected by this restriction?

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And as far as I would be concerned as a medical device manufacturer, I should then also take care of the

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appropriate input and participation in the consultation.

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Mhm, so 3 big tips on what I said, I'll summarize very briefly.

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The first thing to do is to determine immediately that the thing affects you, if so, secondly, don't trust exclusively that the industry associations will help you.

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They help, of course, but probably can't proceed so individually now.

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And thirdly, report it to the European Chemicals Agency, I think I stand for it,

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report it, intervene so that they have this on their radar and then, at best, include your product, your product class in the list of exemptions.

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Exactly.

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What I may perhaps add, because we experience this very often in practice, is that blind actionism does not help here either, of course.

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We often see that companies are currently trying to obtain confirmations, i.e. from suppliers,

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Obtain confirmations in the sense of: Please confirm that PFAS are not contained in the materials supplied.

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Of course, I can do that, the only question is how reliable such statements are, when the question of proven analytical methods is currently still completely open.

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That means I can do that, but at the end of the day it doesn't help me.

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That doesn't solve my problem, especially not if the restriction proposal should change over time and in the end

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comes along with content that ultimately does not fit the requested supplier declaration.

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So this step should only be taken when the proposal is actually in the world, as an additional safeguard and then very concretely related to the specification and not now in anticipatory obedience.

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How can you, your law firm or you in person, help manufacturers with this whole process?

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Yes.

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Of course, we can assist in the design of the appropriate product and company-specific inputs as part of the consultation.

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We have already done this in many cases across various industries, including for medical device manufacturers.

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We also have many years of experience in other consultation processes that were aimed at other restrictions, other substance groups.

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So we know very well what the responsible authorities want to see here and what lines of argumentation can be used to

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may then be successful after all, as far as the design of such exceptions and transitional regulations is concerned.

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It is important to note that the presentation of the request for such exceptions is not entirely trivial, you should know that.

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It is not only a matter of presenting the concrete use of the concrete product, but it still requires a supplementary so-called socio-economic consideration.

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It is therefore necessary to consider the advantages and disadvantages of the intervention of the restriction versus the intervention of an exception

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or extended transitional arrangement and evaluate it from various points of view.

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And ideally over the entire product life cycle.

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And that's where it gets really complicated, because this also affects the question of disposal and waste management, which cannot always be answered without further ado on the basis of available information from the individual companies.

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In this context, we can of course support medical device manufacturers.

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Of course, we can also provide support in advance in determining those affected, with the question of how to approach the issue, what precautions must be applied in the area of independent product compliance processes with regard to these and perhaps similar future restrictions, and what adaptations are necessary.

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Because, one must not forget, this PFAS restriction is only a first step.

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The Chemicals Strategy for Sustainability provides for a fundamental

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We have a large number of further measures, including a very fundamental change to the REACH Regulation, which we will see at the end of the year.

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And this approach with a restriction, a prohibition approach for entire groups of substances, with only definite individual exceptions and no major area exceptions, that will rather become the rule.

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This is no longer the exception, it is currently.

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PFAS

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is still a special case at the moment.

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In the future, however, it will become the norm for such restrictions to be implemented for entire groups of substances and for almost all industrial sectors.

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And of course, this also requires a certain amount of adaptation within the company in the area of product compliance processes.

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Oh, you're leaving us with a whole kaleidoscope of emotions.

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On the one hand, perhaps a small feeling of despair, there is much more to come for which we should prepare.

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On the other hand, again with the feeling of hope.

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One can perhaps still avert certain things through submissions, if they are well written, and perhaps also with a feeling of respect, because these submissions of which you have described must be well justified.

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And there is a highly complex risk management or benefit-risk assessment behind it, which is particularly demanding because we have very different variables on the scales.

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It is health.

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Yes, and perhaps of the patient versus the health of the population.

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These are economic aspects.

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It is the aspect perhaps short-term versus long-term.

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Yes, the short-term benefit for the patient and the long-term perhaps harm to the population.

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So, there are a lot of things that have to come together here.

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What you might know a bit from the health technology assessments for some medical devices.

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and there are simply experts needed and you said that you would be available as an expert to formulate exactly such submissions and then also prepare for future Ungebach.

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Mr. Ahlhaus, I thank you from the bottom of my heart for this great insight into this, perhaps a bit frightening world, but it doesn't help.

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Whining doesn't help here and waiting helps even less.

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So, it's time to take action here again and I'm glad that there are people like you who are helping.

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Thank you very much, Mr. Alhaus.

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Very, very gladly.