PFAS Phase Out and Impact on Medical Devices

Are your products impacted? How to best engage with your Notified Body?

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29 January 2025

Objectives

This webinar has been designed to provide you with an overview of what PFAS are, why they are important and what upcoming challenges medical device manufacturers might face

What will participants gain?

- Understanding of the timeline and steps of the restrictions to production and use of PFAS in medical devices
- An introduction on what the next steps may be for manufacturers and how best to engage with the Notified Body

Agenda

01 PFAS overview

02 Upcoming challenges related to PFAS

03 PFAS regulatory landscape and restrictions

04 Impact on MD manufacturers

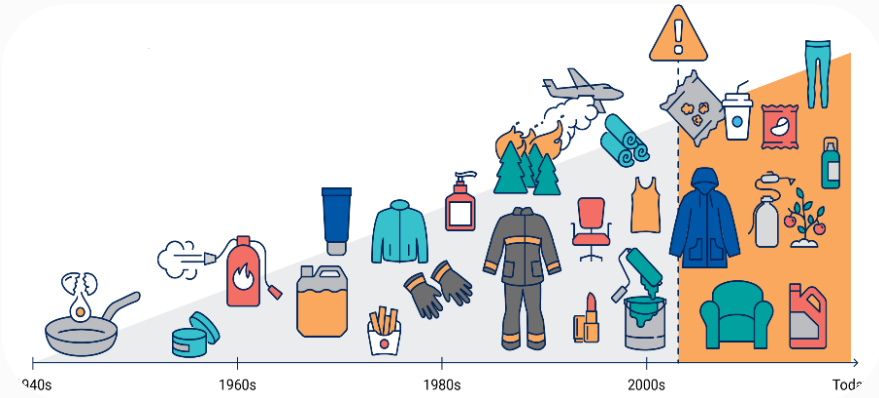
05 Next steps and engagement with BSI

PFAS overview

Definition, properties, applications

Per- and Poly-fluoroalkyl Substances (PFAS)

- PFAS are a large family of synthetic chemicals widely used in industrial processes and consumer products since 1940s [1]
- Defining PFAS has been a complicated, evolving process. Different definitions apply for different regulations, changing what falls in scope
- Per OECD[2], PFASs (Per- and Poly-Fluorinated Alkyl Substances) are defined as substances that contain at least one fully fluorinated methyl (CF_3–) or methylene (–CF_2–) carbon atom (without any H/Cl/Br/I atom attached to it)
- The group comprises approx.10-15,000 individual compounds, both polymeric (e.g., PTFE, aka Teflon, Gore-Tex) and non-polymeric (e.g., PFOA, PFOS, FEP, etc.)



Common PFAS uses

- Water and stain resistant coatings and additives for apparel, carpets, etc.
- Common lubricants, release compounds, etc. in manufacturing processes
- Semiconductor fabrication processes for electronics production
- Lotions, nail polish, shaving cream, makeup for skin conditioning
- Food packaging on coated papers, plastics, wrappers, etc.
- Paints and finishes
- Fire fighting foams (e.g., AFFF)
- **Medical devices**

Poll Question?

Which of the following devices usually contain PFAS?

- Guidewires
- Surgical Gloves
- Contact Lenses
- All of the above

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PFAS key properties in medical devices

With unique physical and chemical properties, PFAS are commonly used as processing aids or as components in many cardiovascular and orthopaedic implantable devices, surgical devices, contact lenses, surgical gloves, catheters for minimally invasive applications, tubings, blood bags, etc.

Hydro- and lipo-phobic

Fluoropolymers can be both water- and grease-repellent. This helps reduce unwanted interactions with biological molecules, promoting biocompatibility and minimising biofouling

Chemically stable

PFAS do not react easily with other substances. This makes them safe for use in many medical applications, including implants and other devices coming into direct contact with body tissues and fluids

Low surface energy

This feature contributes to the anti-fouling and anti-bacterial applications of fluoropolymers, making devices easier to clean and reducing the risk of infections

Upcoming challenges related to PFAS

Poll Question?

What % of Americans do you think have had reported detectable levels of PFAS in their blood?

- 17%
- 27%
- 47%
- 97%

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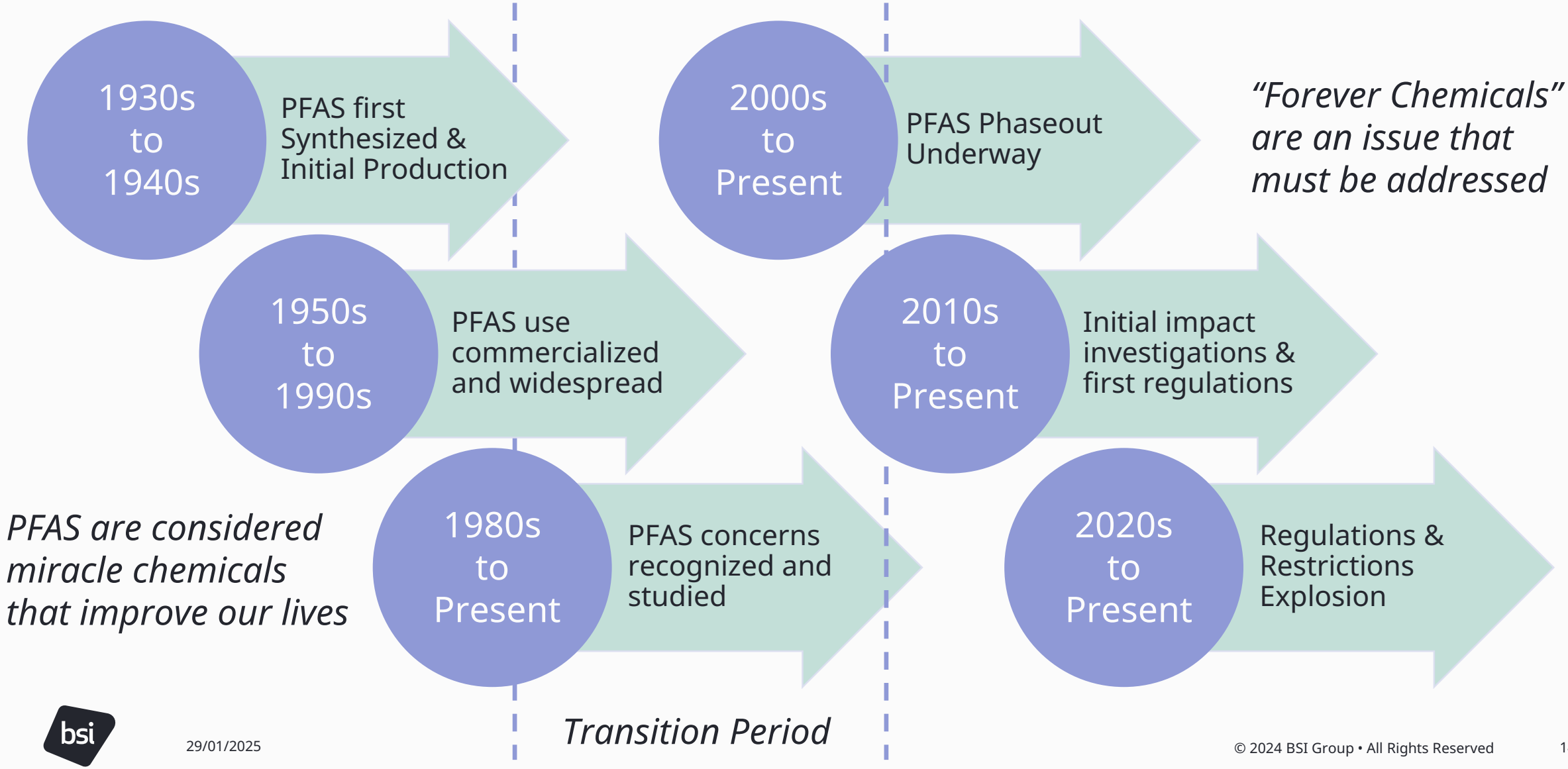
The “Forever Chemicals”

Increasing global concerns over the environmental and health implications of PFAS

- Due to their strong carbon-fluorine bonds, PFAS are highly persistent in the environment and can accumulate in living organisms, earning them the nickname “**forever chemicals**”
- PFAS have been detected as ubiquitous pollutants in soil, groundwater, and drinking water
- Recent studies show that nearly all people in the US have measurable amounts of PFAS in their blood [3]
- Without limiting PFASs emissions, humans will be exposed to steadily increasing levels of PFAS, up to doses exceeding human health thresholds

Evolution of PFAS perception in society



In the beginning…The onset of PFAS regulations

Earliest Regulations

- **2009:** First major EU regulations were the Persistent Organic Pollutants (POPs) regulations limiting PFOS (and salts) in substances and articles[4]
- **2016:** First major US regulations were promulgated by the FDA and banned use of long-chain PFAS in Food Contact Materials (FCMs)[4]
- **2016:** New York State became the first state in the nation to regulate PFOA and PFOS as hazardous substances (adopted formally in March 2017)[5]
- **2019**: First group of PFAS added to the SVHC Candidate List in EU REACH
- Earliest regulations included exemptions and frequent refinements as more information was gathered and assessed

PFAS Regulatory restriction strategies Worldwide

EU: a joint PFAS Restriction Proposal under REACH has been submitted in 2023, aiming for a full ban on all PFAS by ~2028/2030

US: PFAS regulation is evolving at federal and state levels, with laws restricting unnecessary PFAS use in single states, and US EPA setting enforceable limits in drinking water

UK: HSE is considering a ban on a selected group of PFAS

Other Countries: strategies are under development to manage PFAS

The PFAS environmental regulations explosion (2020-Present)

US Regulatory / Enforceable Programs

Toxic Substances Control Act (TSCA)

Retroactive PFAS reporting for manufactured and imported items annually since 2011

Original 2025 reporting deadlines pushed back to 2026

Comprehensive Environmental Response, Compensation & Liability Act (CERCLA) ,"Superfund"

Inclusion of PFOA and PFOS (including isomers and salts) as hazardous substances

National Defense Auth. Act (NDAA)

Phasing in PFAS covered by TRI under EPCRA since 2020

Seven new PFAS added for 2024 reporting year.

Clean Water Act (CWA)

Established enforceable Maximum Contaminant Levels (MCLs) for six PFAS

Guidance/Planned Rules*

- Proposed RCRA regulations to add nine PFAS to RCRA list of hazardous constituents
- AWQC for certain PFAS
- Interim guidance on PFAS destruction and disposal
- New analytical methods for PFAS
- Restrictions on "restarting" manufacturing of 329 PFAS without risk review
- Unregulated Contaminant Monitoring Rule for 29 PFAS
- Effluent Limitations Guideline Plan 15 addressing PFAS leachate in LFs

** Clean Air Act (CAA) considerations – still in the assessment phase related to PFAS air impacts*

Litigation and PFAS supplier exits in US

Litigation

- Billions of dollars in settlements have been provided to consumers alleging harm

- Hundreds of lawsuits are pending across the courts, costs expected to be in the billions

Known Supplier Exits

- **3M**, a leading US supplier of PFAS, was hit with significant lawsuits and is ceasing PFAS production by 2025 (no new orders accepted)

- **Solvay** is discontinuing some of their range of PFAS - changing fluoro-surfactants

- **PPG** already exited medical device PFAS coatings in May 2024

PFAS Restriction Proposal in EU

PFAS Toxicity data and current regulatory restrictions

Currently, toxicity data are available only for few PFASs, primarily legacy PFASs such as perfluorooctanoic acid (**PFOA**) and perfluoro-octane sulfonate (**PFOS**)

357 PFASs are self-classified in **CLP** for one or more human health endpoints considered of most concern (i.e., carc., mut., repr. tox, etc.); however, *harmonized* classification is available for only **41 PFAS**

Under **REACH**, PFASs restrictions and SVHC dossiers (Substances of Very High Concern) have been processed for **14 substances** or substance groups so far

To date, only **6 PFAS** (i.e., PFOA, PFOS, APFO, PFDA,PFNA, and PFHpA) received harmonized classification as "Repr. 1B" according to CLP (and therefore in scope of the CMR restriction under GSPR 10.4 of **MDR**)

EU Restriction proposal: the precautionary principle

- In Feb 2023, five European countries (Denmark, Germany, Norway, Sweden, and the Netherlands) submitted the EU PFAS Restriction Proposal, which seeks to ban the use and manufacture of all PFAS chemicals as identified according to the OECD definition

- According to the proposal, the classical hazard and risk assessment-based strategies cannot be applied, because for most of the PFASs necessary data on harmful properties are not available nor are expected to become available anytime soon

- Arguing that PFASs have a non-negligible potential to harm the environment and human health, the ECHA has identified the need to follow the **precautionary principle**, and the vast number of PFAS chemicals is considered as one chemical group **to prevent regrettable substitution** of restricted PFASs with other PFASs with similar concerns

EU Restriction proposal - Options and derogations

The restriction proposal analyses various risk management options and concludes that a restriction under REACH is the preferred path. Two options are considered:

Restriction Option 1 (RO1)

- A **full ban** of all PFAS with no derogation
- Ban of manufacture, placing on the market and use
- Prohibition entering into force after a transition period of **18 months** after regulation's enforcement

Restriction Option 2 (RO2)

- A full ban of all PFAS with time limited, **use-specific derogations** for either 5 or 12 years, based on analyses of alternatives and socio-economic considerations
- Only few permanent derogations (e.g., active substances in medicinal products), **NOT for medical devices**

EU Restriction proposal - Options and derogations

Restriction Option 2 (RO2)

5 year derogation

- Non-existence of technically and economically feasible alternatives on the market at the entry-into-force (EiF) date, but where **possible alternatives** to PFAS use **have already been identified** and still in the development phase
- Known alternatives are **not available in sufficient quantities** on the market at the EiF date or known alternatives cannot be implemented before the transition period ends

12 year derogation

- Non-existence of technically and economically feasible alternatives on the market at the EiF date, e.g., R&D efforts **did not identify possible PFAS-free alternatives**
- Certification or **regulatory approval** of PFAS-free alternatives **cannot be achieved within five-year** derogation period

Source: https://echa.europa.eu/-/echa-publishes-pfas-restriction-proposal

EU Restriction proposal - Proposed thresholds

Discrete concentration limits (named limit values) for products and applications:

- 25 ppb for any PFAS (except polymeric PFASs) measured with targeted analysis (equals to 25 µg/kg),
- 250 ppb for the sum of PFAS (equals to 250 µg/kg), optionally with prior degradation of precursors, and
- 50 pp**m** for PFASs, including polymeric PFAS (equals to 50 mg/kg).

How to quantify PFAS?

"Total Organic Fluorine" or targeted methods (e.g., EN 17681), are they sensitive enough?

Can unintended external or cross contamination be above limits?

(e.g., from water or machinery)

EU Restriction Proposal - Process steps and timelines

Source: https://echa.europa.eu/-/echa-publishes-pfas-restriction-proposal

- In March 2023, ECHA's Scientific Committees for Risk Assessment (RAC) and for Socio-Economic Analysis (SEAC) began their scientific evaluation of the proposal. More than 5,600 comments received during consultation phase
- The opinions of RAC and SEAC are typically ready within 12 months from the start of the scientific evaluation. However, in view of the complexity of the proposal and the extent of information that is needed from the consultation, RAC and SEAC are now expected to take more time to finalise their opinions - **Restriction estimated to come into force not earlier than ~2029-2030**

EU Restriction Proposal – Latest progress update

A progress update was published on ECHA's website on November 20, 2024

- The opinion development work will **further progress during 2025** and will lead to an opinion of the RAC and a draft opinion of the SEAC. **Another consultation** will be held afterwards
- A **sector-based approach** is followed. Provisional conclusions have been reached on some sectors (none of which is relevant for MedTech)
- Special consideration will be given to some specific PFAS groups/uses, e.g., **Fluoropolymers**, for which specific requirements might be identified
- **Alternative restriction options**, besides a full ban or a ban with time-limited derogations, are also being considered where they could allow to significantly reduce the PFAS emissions. "*An alternative option could allow the continued manufacture / use of PFAS instead of a ban, in particular for uses and sectors where [...] a ban could lead to disproportionate socio-economic impacts*". **Medical devices** are cited as possible example for this case

Source: https://echa.europa.eu/it/-/echa-and-five-european-countries-issue-progress-update-on-pfas-restriction

Impact on Med-Tech Industry

PFAS Phase Out – Impact on Med-Tech industry

Depending on types of products and where PFAS are sourced, the impact of a PFAS phase out on medical device manufacturers can be potentially huge.

“Concerned with the bluntness of the proposal and the lack of any scientific basis in it for distinguishing among PFAS in a way that reflects the significant variability in environmental and toxicological profiles of PFAS. This enormous category of chemicals is being regulated on a definitional basis as opposed to a critical examination of their unique properties and functionalities.”

“Particularly the restriction of PFAS in medical devices and in pharmaceutical manufacturing poses a threat to the continued provision of state-of-the-art medical care for European residents.”

(American Chamber of Commerce on EU Restriction proposal, 2023)

“The PFAS Restriction proposal is of unprecedented scale not only in terms of number of substances in scope, but also their varied physical, chemical and hazardous properties, and the amount of essential medical technologies impacted.”

“The current PFAS Restriction proposal would result in significant impacts on the quality and availability of treatments for patients in the EU. Due to the unavailability of suitable alternatives to PFAS some products would have to be removed from the market.”

(MedTech Europe Position on EU REACH PFAS Restriction proposal, 2023)

Exempted or not, medical devices can be impacted

Even in case medical devices were exempted by the final EU Restriction under REACH, use of PFAS would still represent a challenge for MD Manufacturers

Supply chain disruption

With leading PFAS suppliers ceasing manufacturing of these chemicals to avoid environmental and legal charges, market availability of PFAS is going to be potentially at risk, and supply costs can become prohibitive

Conformity re-assessment

Changes in manufacturing or design driven by restrictions in other sectors or geographies could affect conformity assessment activities

Impact on conformity assessment

Indirect impact

EU Notified Bodies are designated to assess conformity of medical devices with MDR or MDD, not REACH.

Thus, NBs would not be in charge of verifying compliance with a PFAS restriction under REACH.

However, changes to device design, materials or manufacturing process may affect conformity with MDR or MDD.

What's expected?

Manufacturers forced to implement a high number of changes to device design or manufacturing process, some of which considered substantial and requiring regulatory approval

What's to be changed?

- PFAS in manufacturing aids/additives
- PFAS in device component(s)

What types of changes?

- 'Like-for-like' - Move to alternative supplier (same specs)
- Remove PFAS substance only
- Replace PFAS component with alternative material

What areas could be affected?

- Functional performance
- Stability/durability
- Biological safety
- Sterility
- Clinical evaluation - equivalence route used?

For MD under MDR: is the change Substantial?

MDR – Annex IX Section 4.10 (specific to TD Assessment Certificates):

"Changes to the approved device shall require approval from the Notified Body which issued the EU technical documentation assessment certificate where such changes could affect the safety and performance of the device, or the conditions prescribed for use of the device. Where the manufacturer plans to introduce any of the above- mentioned changes it shall inform the Notified Body which issued the EU technical documentation assessment certificate thereof. The Notified Body shall assess the planned changes and decide whether the planned changes require a new Conformity Assessment in accordance with Article 52 or whether they could be addressed by means of a supplement to the EU technical documentation assessment certificate. In the latter case, the Notified Body shall assess the changes, notify the manufacturer of its decision and, where the changes are approved, provide it with a supplement to the EU Technical Documentation assessment certificate."

Additional info provided in NBOG 2014-3

Substantial = must be notified to NB, may require new conformity assessment and regulatory approval

NBOG's Best Practice Guide

applicable for ☒ AIMDD, ☒ MDD, and ☒ IVDD

2014-3

Guidance for manufacturers and Notified Bodies on reporting of Design Changes and Changes of the Quality System

Changes to materials for medical devices or active implantable medical devices (5.1, 5.2)

(4) Changes within a single generic material type or changes in formulation can affect the chemistry, metallurgy or other property, such as stability, of the device.

In each of the above instances, it must be determined if the device is a surgically invasive device intended to be absorbed by the body or to remain in the body for at least thirty consecutive days. If this is the case, and the altered material would be in contact with body tissues or fluids, then an approval of the Notified Body is required.

Even when the material would not be in contact with body tissues and fluids, the question of design specifications arises. If changes to the design specifications are required, they should be done according to section "Change to design" above.

In cases where devices are not intended to be absorbed by the body or to remain in the body for at least 30 consecutive days, but where the altered material is in contact with body tissues or fluids an approval by the Notified Body is required unless the new material meets the existing specifications. As in other cases, changes to performance specifications must be considered as described in section "Changes to design" above.

For MD under MDD certificate: is the change ‘Significant’?

Medical Devices
Medical Device Coordination Group Document MDCG 2020-3 Rev.1

MDCG 2020-3 Rev.1

Guidance on significant changes regarding the transitional provision under Article 120 of the MDR with regard to devices covered by certificates according to MDD or AIMDD

May 2023

Significant = NOT allowed under MDD certificate, thus requiring MDR certification (i.e., loss of “legacy device” status)

4.2 Changes not concerning the design or intended purpose

Changes concerning the manufacturer’s organisation (administrative changes) or changes concerning the manufacturing process should generally not be considered changes in the design or intended purpose within the meaning of Article 120(3c), point (b) MDR, even if they need to be reflected in the information to be supplied with the device (e.g. label or instructions for use).

This includes for example:

- relocation or addition of new manufacturing sites, including when it affects subcontractors or suppliers;
- changing the supplier of a material, substance[18] or component, provided the specifications of the new material, substance or component do not change;
- adding or replacing a new material number for logistic reasons without changing the material;
- new process validation as part of manufacturing improvements or scale-up of manufacturing.

[18] Changes to a medicinal substance – including a change in its manufacturing process – which has undergone medicinal consultation should be notified to the medicines authority responsible for the consultation according to the relevant procedures (see e.g. Annex I, section 10 AIMDD or Annex I section 7.4 MDD) by the notified body.

4.3.2.3 Changes in the design – Charts B to E

Changes concerning software, substances or materials, or sterilisation also concern the design of the device. Specific flowcharts (C, D, E) are intended to assist in assessing whether changes in those areas should be considered significant changes in the design.

For MD under MDD certificate: is the change ‘Significant’?

Medical Devices
Medical Device Coordination Group Document MDCG 2020-3 Rev.1

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Changes related to a substance or material – Chart D

Regarding **changes of substances or materials** the following principles should apply (see chart D):

Non-significant change:

- new or additional supplier/producer of a material within the defined specifications;
- substitution of a chemical substance in order to comply with other applicable laws and regulations e.g. REACH Regulation (EC) No 1907/2006;
- replacing a substance or material, unless considered a significant change as listed below.

Examples:

- change in a material which serves solely as a processing aid which is not available on the finally cleaned device and therefore considered a manufacturing but not a design change;
- addition of an antioxidant to the drug coating of a combination product that reduces the degradation of the drug during production but does not alter its pharmaceutical properties or release kinetics.

  Note: These examples are valid only provided that the risk/benefit ratio of the device is not negatively affected.

Significant change:

- change to a material or substance which is part of an implant and intended for direct or indirect contact with patient tissue or fluid for more than 30 days, or is part of a surgically invasive device which is absorbed;
- addition or change of a material of human/animal origin (e.g. collagen produced from skins by collagen produced from bones);
- change to a material containing a medicinal substance[23] (i.e. excipient or carrier material with influence on the delivery of the medicinal substance), or to the medicinal substance itself;
- change from a material with a low toxicological or biological risk to a material with a higher one;
- new or changed substance or material that adversely affects the safety or performance of the device and therefore negatively affects the risk/benefit ratio of the device.

Notifying changes to BSI

Your partner in progress

Section A - Types of Change

To be completed by Manufacturer (tick all that apply and detail the changes on page 3)

- ☐ Change of name / location / address / company registration number of legal manufacturer, etc.
- ☐ Change in number of employees (detail in the description section the change to employee numbers)
- ☐ Change to QMS activities performed (e.g. addition of design and development, service, installation etc.)
- ☐ Change affects manufacturing of the products (e.g. new technology/process, clean room changes)
- ☑ Change affecting design of the device (e.g. new functionality, new intended use, device materials ...)
- ☐ Change to a QMS critical process (e.g. document control, vigilance, design...)
- ☑ Change to subcontractors/suppliers
- ☐ Change to sterilisation (e.g. changes of provider or change of process, release criteria, method etc.)

Your partner in progress

Section A - Description of Change

Description of Change(s) Provide a detailed description, make comparison of current versus planned. If evidence/information provided to support this change request has been previously submitted to and assessed by BSI please provide relevant details of the BSI review. Should tables, diagrams or formatting be more effective when describing the change, it is recommended to use separate document(s), which should be referenced below and on page 1 in the Attachments section.

○ Substantial ○ Non-Substantial	○ Non Significant ○ Significant
Justification (in all cases)	**Justification** (under MDR Art. 120.3/IVDR Art. 110.3)

Your partner in progress

Change Notification and Work Authorisation Form

Instructions (Hover over fields for further guidance on form)

Complete this form to notify BSI of any plan for substantial changes to the quality management system, the device(s) and/or device-range and to request Regulatory Letters, Summary Technical Reports, or Renewals. If necessary attach additional information making reference to the attachments in this form; attachments are preferable where diagrams, formatting or tables need to be included. Submit to BSI at bsirsnotifications@bsigroup.com (this address is for the initial submission **only**, no further communication should use this email).

When requesting Regulatory Letters or Summary Technical Reports, or Renewals only, please complete the relevant portion of Section A, select the service required from Section C, and complete and sign Section D.

When informing BSI of a planned change, BSI will assess in Section B and determine what (if any) action is required. If a work authorisation is required this will include estimated durations in Section C. The Manufacturer must select the Dedicated or Standard rates as required in Section C and only then complete section D and return to BSI to authorise the work to proceed. **Note: As you complete the form additional fields will appear based on your selections, therefore it is necessary to fill in the form from beginning to end.**

Section A - General Information & Request Details

To be completed by Manufacturer (hover over fields for further information)

Client Name

Address

Contact Person(s)

Email **Phone**

Certification(s) Tick for each certificate type impacted, and list the certificate number(s) in the box that appears. Do include any certificates still in application with BSI that may be impacted.

Example
☑ MDSAP MDSAP 12345
☑ MDR MDR 12345, MDR 24681

☐ ISO 13485		☐ GDPMD/GDPMDS	
☐ MDSAP		☐ ISO 9001	
☑ MDR		☐ IVDR	
☐ UKCA		☐ AIMDD	
☑ MDD		☐ IVDD	

Title of Change

Request(s) (tick all that apply)

- ☑ Notification of Change
- ☐ Regulatory Letter(s)
- ☐ Summary Technical Report(s)
- ☐ Renewal(s)

Manufacturer Single Registration Number

☐ Check if manufacturer is based outside the EU.

The “PFAS storm” and BSI

How is BSI assessing the impact

Actively monitoring regulatory updates and news related to PFAS

Seeking input from manufacturers about expected impact on their pipeline

Mapping forthcoming changes and agree on regulatory submission requirements

Ensuring consistent approach for conformity assessment across teams

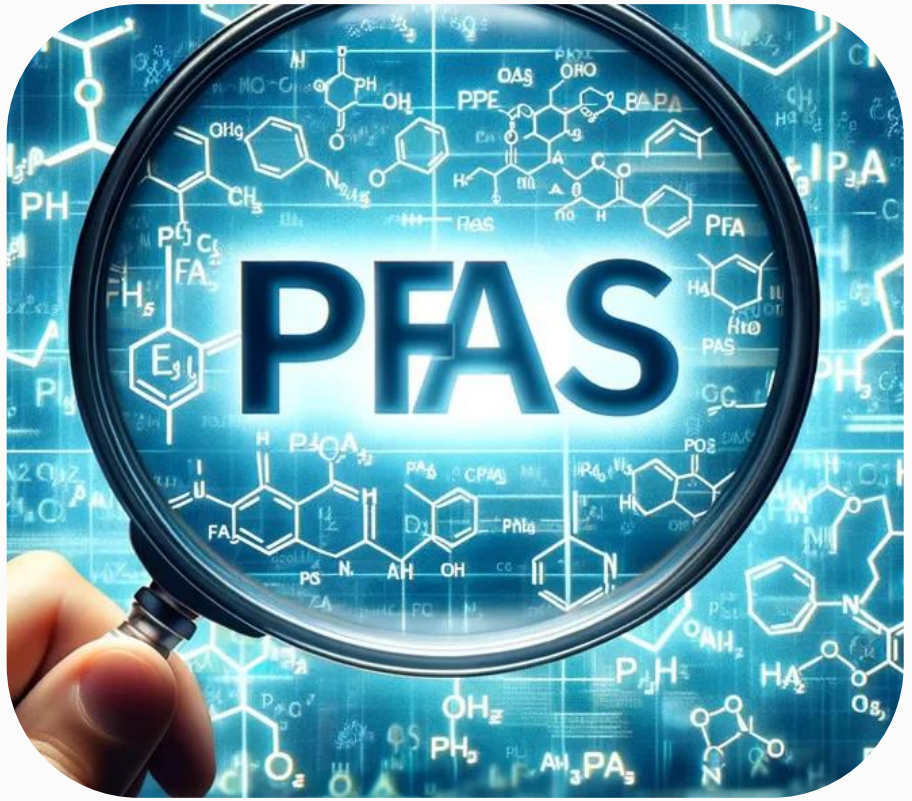
Key considerations for manufacturers

What risk assessment activities are being undertaken to identify devices and/or manufacturing processes that include PFAS materials?

Can these PFAS materials be classified under categories of similar design or functional use? Or in case of process aides, similar utility?

Are considerations focused on replacement materials or redesign? Are there criteria being used to assess impact?

Are you assessing the possibility to pool or group types of materials and requirements to streamline testing/analytic considerations?



How to best engage with us

Talk to us!

- Start early discussions with your Notified Body to better understand the regulatory requirements in relation to changes needed in processes or materials
- Share even preliminary information on potential impact and volume of work foreseen to enable proper planning and avoid delays

Take home message

- Per- and Poly-fluoroalkyl Substances (PFAS) are ubiquitous chemicals used as critical design elements or process aids in manufacture of many medical devices
- Escalating global concerns over environmental and health implications of PFAS are driving proposals of regulatory restrictions and manufacturing discontinuation by PFAS suppliers
- Affected manufacturers will likely be forced to find alternative suppliers or replace PFAS components within the next 2 to 5 years, thus requiring change validation and regulatory approval by NBs
- Starting early discussions with your Notified Body to understand impact on MDR conformity assessment might be beneficial for planning ahead and to avoid issues with certification

Questions

Thank you

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References

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4. *Global Regulations Around PFAS: The Past, the Present and the Future*, Tiffany Thomas, et. al., International Chemical Regulatory and Law Review, Vol. 6, Issue 1, 2023

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