SUBSTITUTION PLAN

Legal name of applicant: *REACHLaw Ltd in its legal capacity as Only Representative for Suzhou Xiangyuan New Materials Co., Ltd.*

Submitted by: *REACHLaw Ltd.*

Substance: *2,2'-dichloro-4,4'-methylenedianiline (MOCA), EC No.: 202-918-9 CAS No.: 101-14-4*

Use title: *Industrial use of MOCA as a curing agent/chain extender in cast polyurethane elastomer production*

Use number: *1*

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LIST OF ABBREVIATIONS

AoA	Analysis of Alternatives
BDO	Butane-1,4-diol
CAS	Chemical Abstract Service
DETDA	Diethyl toluenediamine
DMTDA	Dimethylthiotoluenediamine
EC	European Commission
ECHA	European Chemicals Agency
EEA	European Economic Area
EU	European Union
EUR	Euro
HQEE	2,2'-p-phenylenedioxydiethanol
ISO	International Organization for Standardization
LF	Low-Free
LFM	Low-Free MDI
LFMDI	Low-Free MDI
LFTDI	Low-Free TDI
MbOCA	MOCA
MBOEA	4,4'-methylenebis(2-ethylbenzenamine)
MCDEA	4-[(4-amino-2-chloro-3,5-diethylphenyl)methyl]-3-chloro-2,6-diethylaniline
M-CDEA	4-[(4-amino-2-chloro-3,5-diethylphenyl)methyl]-3-chloro-2,6-diethylaniline
MDI	4,4'-diphenylmethane diisocyanate
MOCA	2,2'-Dichloro-4,4'-methylenedianiline
NCO	Isocyanate group
NDI	1,5-naphthalene diisocyanate
OH	Hydroxyl group
PPDI	1,4-Phenylene diisocyanate
PPE	Personal Protective Equipment
PU	Polyurethane
QMS	Quality Management System
R&D	Research and Development
REACH	Registration, Evaluation, Authorisation and Restriction of Chemicals
SAGA	Suitable alternative generally available
SEA	Socio-Economic Analysis
SME	Small and medium-sized enterprise
SVHC	Substance with Very High Concern
TDI	Toluene diisocyanate
UK	The United Kingdom

INTRODUCTION

BACKGROUND TO THE COMMISSION REQUEST

In a letter dated 10th March 2020, the European Commission requested REACHLaw as only representative (OR) for the non-EU supplier Suzhou Xiangyuan New Materials Co., Ltd. (Suzhou) to draw up a "substitution plan" for this authorisation application and submit it to ECHA by the 10th September 2020. The request is based on legal reasons relating to a decision taken by the General Court in March 2019 (T-837/16[1]) and is specific for utilizations of MOCA cured polyurethanes where "*suitable alternatives in general"* are available. Utilization is explained as "*certain applications of the use applied for*". The letter gives criteria for when it can be considered that "suitable alternatives in general" are available. Specifically an alternative is considered to be "generally available" if it is safer than MOCA and is technically and economically feasible for someone on the EU market (i.e. another moulder). For utilizations where we conclude that a suitable alternative is not generally available, we were requested to submit the reasoning as an addendum to the Analysis of Alternatives report.

As OR for a non-EU supplier, we did not have the information needed to prepare the requested reports. We prepared a questionnaire for Suzhou downstream users to collect the information from the actual users of MOCA and ran an information campaign to inform them. We also contacted MOCA distributors and asked them to pass this information on their customers. This report is based on the information collected from them.

Via the survey, we collected information on the specific types of polyurethanes (PUs) manufactured with MOCA and the sectors where the PU parts/components are used (utilizations following the terminology of the Commission letter) and the contribution MOCA based products makes to their turnover, whether they manufacture products to customer specification (custom made low volume production) or the same kinds of products at high volumes. The survey also collected information on alternatives to MOCA to manufacture PUs for their specific utilization, whether there were suitable alternative generally available for that utilization, information on the alternatives they had tested and the status of their substitution plans. For the question "*For the polyurethane products for which you still use MOCA, please select the preferred alternative for MOCA. Please provide the information ONLY for your most important market sector (highest % in the market sector question)",* half responded that there was no alternative generally available for the products where they still use MOCA. The other half either selected an alternative from the picklist available or reported more generally "*No suitable alternative available to you but your competitors in the same market sector are using an alternative to MOCA".* For the purpose of fulfilling this request from the Commission according to their requirements, we differentiate the companies into two groups, one group is designated as having "suitable alternative generally available" (SAGA) and the other for those that have not (no SAGA).

This means we will present the substitution timelines in this report solely for SAGA designated companies. For those companies who responded that there is not a SAGA for their specific PU products/parts for the specific sectors these are supplied, we will include their rationale in a separate document that will be an addendum to the Analysis of Alternatives report already submitted.

Note that while some responders supply products to the same general sectors, due to the broadness of the sectors and the diversity of PU parts/components supplied, some responders may have a SAGA while others will not. This distinction is also coming from customer requirements in the sectors. Another complication is that a given responder may consider there is a SAGA for some products and no SAGA for others in their product portfolio.

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[1] Judgment of the General Court (Fifth Chamber) of 7 March 2019, Kingdom of Sweden v European Commission concerning Commission Decision authorising the use of lead sulfochromate yellow and of lead chromate molybdate sulfate red, Case T-837/16 available at http://curia.europa.eu/juris/liste.jsf?language=en&num=T-837/16

OTHER RELEVANT COURT RULINGS POST SUBMISSION OF THIS APPLICATION

As outlined above, the request to submit a substitution plan for this application is a consequence of a decision taken by the General Court on the lead chromate case (T-837/16). Since we submitted this application on the 11.11.2016, there have also been other rulings by the General court (T-268/10 RENV[2]) and the Court of Justice (C-650/15 P[3]) relating to the definition of intermediate use that are relevant in decision making on this application.

In light of these rulings, we consider that **MOCA use in the manufacture of cast polyurethanes is intermediate use as per Article 3(15) of the REACH Regulation**.

Consequently, we ask the Commission to include in its decision on this application whether Suzhou DUs' use is intermediate use and therefore exempt from authorisation. As there is no other possibility for the concerned downstream users and Suzhou as their non-EU supplier to get legal certainty, we are requesting the Commission to **also** consider the ruling of the Court of Justice when taking its decision on this application. When MOCA was proposed for inclusion on the candidate list, it was stated in the Annex XV dossier[4] that MOCA use in the manufacture of polyurethanes was not an intermediate use based on a definition of intermediate uses given in the ECHA Guidance from 2010.[5]

Specifically

> *According to the guidance on intermediates (ECHA 2010) document a substance should not be regarded as intermediate as soon as the main aim of the chemical process is not to manufacture another substance, but rather to achieve another function, specific property, or a chemical reaction as an integrated part of producing articles (semi-finished or finished). In accordance with this statement, the end use described above and the use as curing agent described in section 2.2.1 cannot be regarded as use of MOCA as intermediate. Similarly, it appears not possible to consider the use of MOCA as a cross-linking agent as use of the substance as intermediate.*

Based on this understanding, this upstream application was submitted to cover downstream users of MOCA as a chain-extender/curing agent in the manufacture of polyurethanes. All current downstream users of MOCA are covered by this upstream application under transitional arrangements. However in October 2017, the European Court of Justice has ruled in Case C-650/15 P that ECHA in its 2010 definition on intermediates has added a condition that is not in the legal text.[3] Specifically

> *Article 3(15) of that regulation contains no additional criterion allowing a differentiation to be made according to whether that purpose was primary or secondary in nature or examination of whether or not the chemical process by which one substance is transformed into another is indistinguishable from the end use for which that substance is intended.*

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[2] Judgment of the General Court (Fifth Chamber, Extended Composition) of 25 September 2015, Polyelectrolyte Producers Group GEIE (PPG) and SNF SAS v European Chemicals Agency (ECHA). Case T-268/10 RENV available at http://curia.europa.eu/juris/liste.jsf?language=en&num=T-268/10%20RENV

[3] Judgment of the Court (First Chamber) of 25 October 2017, Polyelectrolyte Producers Group GEIE (PPG) and SNF SAS v European Chemicals Agency, Case C-650/15, available at http://curia.europa.eu/juris/document/document.jsf?text=&docid=195945&pageIndex=0&doclang=EN&mode=lst&dir=&occ=first&part=1&cid=596449

[4] The documents are available on the ECHA website at https://echa.europa.eu/fi/registry-of-svhc-intentions/-/dislist/details/0b0236e180e49371

[5] ECHA Guidance on Intermediates, V.2, 2010, available at https://echa.europa.eu/guidance-documents/guidance-on-reach

In this ruling, the Court found that by failing to classify acrylamide, in the context of the process of transformation into polyacrylamide for grouting purposes, as an ‘intermediate’, the General Court in its ruling on T-268/10 RENV[2], by adding a condition that is not laid down in Article 3(15) of the REACH regulation, misinterpreted that provision.

Considering this ruling in the context of MOCA use in the manufacture of polyurethane, MOCA use also fulfils the definition of intermediate use and the statement to the contrary given in the Annex XV dossier is based on criteria that are not in the legal text. Following the rationale given in the court decision,[3] three conditions need to be fulfilled for the use of a substance to be capable of being regarded as use of an intermediate. The first of those conditions concerns the intended purpose at the time of the manufacture and use of a substance as an intermediate, which consists of transforming that substance into another. The second condition concerns the technical means by which that processing takes place, namely a chemical process known as ‘synthesis’. The third condition restricts the scope of the definition of ‘intermediate’ to uses of a substance which remains confined to a controlled environment, which may be either the equipment within which synthesis takes place, or the site in which the manufacturing and synthesis takes place or to which that substance is transported, ‘site’ being defined in Article 3(16) of the REACH Regulation as a ‘single location’ in which infrastructure and facilities are installed.

Applying these criteria to the use of MOCA in the manufacture of PU, it can be seen that as the intended use at the time of the manufacture and use of MOCA is to transform it into another substance, the first of these three conditions is satisfied. MOCA is used in the manufacture of another substance during which it is itself transformed into that other substance, namely polyurethane. The use of MOCA to manufacture polyurethane at downstream user sites also fulfil the other two criteria; namely that the reaction can be described as synthesis and is confined to a controlled environment.

Consequently, we consider that use of MOCA by Suzhou downstream users is intermediate use and that authorization is not required. The reasoning is given below.

Using industry terminology, MOCA is a chain-extender / curing agent in the manufacture of cast polyurethanes. The MOCA amine groups react with the terminal NCO groups of the pre-polymer as given in the reaction scheme in Figure 2 (AoA-SEA report). As there is always an excess of the pre-polymer, MOCA is consumed in the reaction. The polyurethane has no free MOCA reactant present.

MOCA reacts immediately with the pre-polymer mixture in the reaction vessel. The pot life (also known as the gel time) is a measure of the reactivity of the pre-polymer’s terminal isocyanate groups with the MOCA diamine groups and within 10 minutes, the viscosity of the mixture has increased to the extent that it can no longer be easily poured. The viscosity increase is due to the reaction of MOCA amines with the NCO groups of the pre-polymer that extends the pre-polymer chain length. The liquid polyurethane as poured in the moulds is “green” in that it has not yet taken the shape of the mould. Once in the mould, the liquid polyurethane starts to take the shape of the mould during the curing. The curing time depends on the size and shape of the mould and the pre-polymer/MOCA combination used.

In addition, although MOCA would not be described as a “monomer” using industry terminology, it would fulfil the REACH definition of monomer when it is used to manufacture polyurethane. The use of monomers to manufacture polymers is intermediate use.[6] The rationale is given below.

Looking at the chemistry of the pre-polymer system, the isocyanate group (N=C=O) of the toluene diisocyanate (TDI) reacts with an OH end of the polyol creating the linking **urethane** group (Figure 2 of the AoA-SEA report). This can be written in simple form for the TDI/polyol system as follows:

[6] ECHA Guidance on monomers and polymers V. 2.0, 2012 available at https://echa.europa.eu/guidance-documents/guidance-on-reach

TDI- (polyol-TDI)n

The dashes represent the urethane groups created by the N=C=O/OH reaction. An excess of TDI creates a stable prepolymer. This prepolymer is then reacted with MOCA where the MOCA amine groups react with the terminal isocyanate groups to give **urea** linkages.

This gives a MOCA linked polyurea/urethane elastomer shown in a simple form

[Prepoly -MOCA -Prepoly -MOCA -Prepoly -MOCA -Prepoly -MOCA -]n

The dashes here represent the urea group linking the MOCA diamine to the terminal isocyanate groups of TDI of the prepolymer. In a complete reaction "n" is unlimited. The result is a solid urethane/urea elastomer. The reacted MOCA units also functions as a curative as the aromatic character allows for chain stacking and hydrogen bonding between the urea linkages.

The Guidance[6] outlines that REACH defines a monomer as a substance which is capable of forming covalent bonds with a sequence of additional like or unlike molecules under the conditions of the relevant polymer-forming reaction used for the particular process. The definition of polymer and monomer are given in Articles 3(5) and 3(6).

5. A polymer is a substance consisting of molecules characterised by the sequence of one or more types of monomer unit. Such molecules must be distributed over a range of molecular weights. Differences in the molecular weight are primarily attributable to differences in the number of monomer units.
A polymer comprises the following:
(a) a simple weight majority of molecules containing at least three monomer units which are covalently bound to at least one other monomer unit or other reactant;
(b) less than a simple weight majority of molecules of the same molecular weight.
In the context of this definition a 'monomer unit' means the reacted form of a monomer substance in a polymer;
6. monomer: means a substance which is capable of forming covalent bonds with a sequence of additional like or unlike molecules under the conditions of the relevant polymer-forming reaction used for the particular process

The guidance has the following clarifications on the term sequence;

Sequence: "*a continuous string of monomer units within the molecule that are covalently bonded to one another and are uninterrupted by units others than monomer units*."

Considering the definition of polymer, it can be seen that polyurethane has polymer molecules with monomer units coming from TDI, the polyol and MOCA covalently bound via urea and urethane linkages.

In conclusion, for the reasons outlined above, MOCA use in the manufacture of polyurethanes as described in this application fulfil the criteria to be considered as intermediate use.

BACKGROUND TO THE SUZHOU UPSTREAM APPLICATION

We submitted the Suzhou upstream application as OR applicant for the use of MOCA as a chain extender/curing agent in the manufacture of cast polyurethanes by industrial users almost 4 years ago now. This application was intended to cover all industrial users (referred to as moulders in the application reports) in the Suzhou supply chain that were under this use description. It was one of a number of upstream applications that were prepared and submitted during this period. At that time, there was little guidance available to upstream applicants on how to deal with the uncertainty that is intrinsic to these kinds of applications. While our application has a narrow use description, the polyurethanes manufactured with the TDI/MOCA system are diverse (e.g. roller covers, wheel covers, pads, belts, punches, polishing wheels, anvil covers) and are used in diverse sectors ranging from aerospace, automotive, ceramic, paper and pulp, packaging, steel, iron and aluminum industries. Some of the users have portfolios covering 1000's of polyurethane products (referred to as generalist moulders in the application reports) while others have a more limited portfolio and manufacture these in high volumes (referred to as specialist moulders in the application reports). Due to the diversity of the PU products, we differentiated between the polyurethanes based on the size of the products manufactured; small, medium and large. The rationale was based on the differing requirements in the manufacture of parts of different sizes; larger parts being more sensitive to the system pot life. The application was based on input from 21 users and covered at that time 68 % of the tonnage supplied to the EU. The number of users estimated at that time was 89.

Comments submitted by alternative system providers during the public consultation on our application gave insight on the complexity of polyurethanes and the number of systems that are available for their manufacture. A system refers to the combination of diisocyanate (e.g. TDI, MDI, NDI, PPDI), polyols (e.g. esters, ethers, carprolactones, carbonates) and chain extender (e.g. diamines, diols) used. Many system components are proprietary and sold under tradename (e.g. Adiprene®, Vibracure®, Ethacure®, Lonzacure®, Desmodur®, Addolink®). In particular, the report submitted by Chemtura prepared by Amec Foster Wheeler Environmental & Infrastructure UK Limited (referred to as the Amec report from here on)[7] outlines that while there may be alternative systems generally available to the TDI/MOCA system, the selection of the system, system components, ratio of components, process conditions (mixing rate, temperature, curing temperature, curing time) means that considerable optimization is needed to achieve equivalent properties (and in turn material performance). The report outlines that 'Critical properties' required of end (cast polyurethane) products manufactured with ester and ether based polyols with the TDI/MOCA system include:

- For ester-based systems: wear resistance, load bearing, tear strength, heat resistance, oxidative resistance, radiation stability, weathering resistance, crystallisation rate, and adhesion to substrates; and
- For ether-based systems: hysteresis, resilience, low temperature flexibility and hydrolytic stability.

The report further outlines that different utilizations will require different combinations of these properties and that alternative PU products will need to be usable within both of these system types, and to provide equivalent properties against each of the properties that are important for a given utilization and that the relative importance of each parameter varies from utilization to utilization. It further outlines that some MOCA-based PUs are for highly technically demanding utilizations and that PUs manufactures with alternative systems need to be equally effective in such utilizations. It highlights that TDI/MOCA polyurethanes have a proven track record and customer confidence in the performance of the PUs at the sites of use.

The report outlines that at that time (2016) despite the number of alternative systems available, 17 % of the sector in the EEA remain dependent on the TDI/MOCA system to manufacture PUs.

[7] Comment 1166 submitted in the public consultation available on the ECHA website at https://echa.europa.eu/applications-for-authorisation-previous-consultations (application ID 0094-01)

The joint opinion from the ECHA scientific committees on the application concluded that the broad scope of the authorisation gave rise to uncertainty as to the availability of the alternatives for the utilizations of MOCA covered by the application. The opinion outlines that an assessment of the requirements of the products (e.g. safety standards, qualification schemes, etc.) would have been needed to address this uncertainty. While the opinion agreed that there are products/parts where substitution is not possible by the sunset date, it states that the committee found it likely that there are utilizations where substitution is already feasible. Due to this uncertainty, the opinion recommended a short review period and conditions for the review report that a more precise name and description of the use applied for and a narrower scope in terms of the different articles/parts manufactured.

Based on the request from the Commission, this Substitution Plan report will document the information collected from the 12 users who selected from the options given in the questionnaire relating to their preferred alternative, that there are alternatives available for their specific utilizations but currently not suitable for them.

Here we would like to highlight that the interpretation of suitable alternatives generally available is likely to be subjective and each company may have understood it differently. We do not challenge the choice taken by the company and document the rationale they have given in their response supplemented by information already available in the public domain.

To enable the ECHA committees and the Commission understand the relevance of PU material properties for the parts/components they are used, we give some illustrative examples of PU parts and how they are ultimately used by the end-users in Appendix 2. The information is taken from the public domain and gives details of product types and how they are used.

Note on the representative of this report for all MOCA users covered by the application

Based on information collected in 2016 and documented in the ECHA scientific committee opinion, 89 downstream users were estimated to be covered by this authorisation application. There was uncertainty as to the exact number of users as this information is challenging to collect for upstream applicants. The supply chain includes distributors and they did not necessarily give details of their customers. Now in 2020, we received responses from 24 users. 13 of the respondents have submitted or are in the process of submitting their own downstream authorisation application. These users account for 148 tons. The users who provided responses to the survey are primarily from Italy and Spain. There were 2 users from Portugal and one each from Denmark, Ireland, France, Belgium, Germany and the UK. Their total reported tonnage used in 2018 is ca. 210 tons. The total tonnage supplied by Suzhou to the EU28 in 2018 was 574 tons meaning that the users of 364 tons did not complete the survey. We note that we got only one response from the UK and this may be due to Brexit where UK users are likely to be under a different regulatory framework at the end of the transition period. This potentially accounts for the use of 60 tons leaving the use of 304 tons in the EU27 unaccounted. Based on the information from Suzhou on tonnage supplied, we estimate that potentially 90 % of this unaccounted 304 tons is supplied to two distributors and that potentially none of their customers provided responses. We have contacted them multiple times and also requested an extension of one month from the Commission to allow their customers to respond. It is possible that they also supply to users in the UK, which may account for more of the missing tonnage. It may also be that they were concerned that Suzhou would get access to their customer information despite the assurances given that all information would be anonymised. However we can only speculate as this information is unavailable to us. This illustrates the challenges of collecting information for upstream applications.

OVERVIEW OF THE QUESTIONNAIRE RESPONSES

We received 24 responses and 12 indicated they have identified suitable alternatives in general for their uses of MOCA ("utilizations" using the terminology given in the Commission request). The twelve companies were designated as SAGA companies. The remaining twelve indicated that they have not identified a suitable alternative in general for their utilizations. These twelve were designated as no-SAGA companies. These designated SAGA users are located in six countries. Of these 12, 6 are preparing downstream user applications. The SAGA companies account for 92 tons of the 564 supplied to the EU 28 in 2019. A breakdown of the tonnage reported is given in Appendix 3.

Their responses were anonymised and compiled to prepare this report. As was already described in the AoA report, PU parts/components (e.g. roller covers, wheel covers, pads, belts, punches, polishing wheels, anvil covers) manufactured with the TDI/MOCA system are supplied to end users in diverse sectors ranging from aerospace, automotive, ceramic, paper and pulp, packaging, steel, iron and aluminum industries. Some of the users have portfolios covering 1000's of polyurethane products (referred to as generalist moulders in the application reports) while others have a more limited portfolio and manufacture these in high volumes (referred to as specialist moulders in the application reports). Due to the diversity of the PU products, the AoA-SEA report differentiated between the polyurethanes based on the size of the products manufactured; small, medium and large. The rationale was based on the differing requirements in the manufacture of parts of different sizes; larger parts being more sensitive to the system pot life.

In this Substitution Plan report, we document their rationale for why they have not yet been able to implement substitution of the TDI/MOCA system for their PU parts/components and the actions they are taking to phase out their use of MOCA. Details on the types of PUs manufactured are also given based on the questionnaire responses.

Utilizations of MOCA by sector of end use of the PU products

The questionnaire collected information on the sectors TDI/MOCA PU products are supplied to. The 9 sectors listed in the questionnaire were based on information in the public domain where PU parts/components are widely used. The responses are summarized in **Figure 1**. Respondents could select "other" for sectors not on the list and report sectors in the free field. The responses under "other" were wind, agrifood, food, wheels maintenance, packaging, industrial supplies, and electrical. For each sector, companies may supply multiple different products, e.g. for glass and glass edge sector, the products include polishing wheels, rollers, wheels. Likewise the same product type, e.g. a roller may be supplied to several sectors such as ceramics, glass, mining, offshore, paper, steel industries. The breakdown by company is given in Appendix 4.

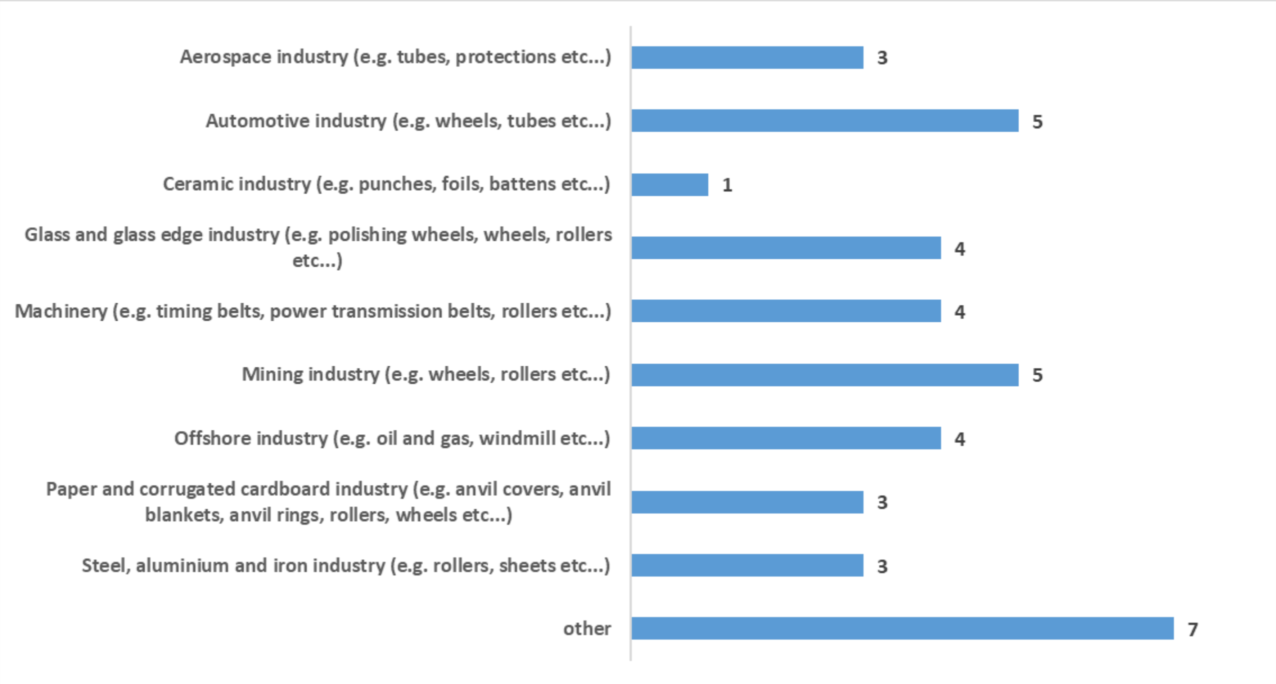

Figure 1 The number of companies who reported supply of TDI/MOCA PU parts/components to each sector given in the questionnaire

Four companies reported to supplying to just 1 sector. Seven companies reported supplying to between 2 and 5 sectors. One company reported supplying products to 6 sectors. One company reported supplying PU products to all 9 listed sectors and one additional sector under "other". The difference in PU portfolios between the companies illustrates that some companies manufacture the same kinds of products in high volumes (e.g. transmission belts, anvil covers, polishing wheels, wheel covers) while others manufacture products to demand and to customer customisation. These offer a wide variety of products in lower volumes (e.g. custom-made covers for rollers for a specific steel mill, custom made pads for pipe laying off-shore).

The questionnaire collected information on the PU product types to each of the sectors. Respondents could select from a picklist of product types and there was a free text field to report types not on the list. They were also asked to indicate the product types supplied to each sector. The product types listed are given in **Figure 2**. All respondents reported the sectors they supply PU parts to while the information collected on the product types supplied to these sectors was less complete. A given product type can be supplied to many sectors (e.g. rollers, wheels). The market sectors reported where PU products are supplied to are diverse. Two of the 12 are specialist companies, who manufacture specific parts/components (timing belts for power transmission and polishing wheels for glass polishing) at high production volumes. Others reported supplying multiple different PU product types to diverse market sectors (e.g. rollers to aerospace, automotive, glass and glass edge, mining industry, mining, offshore, paper and cardboard industry, steel, aluminium and iron industry). The specifications for the material properties for the PU parts depend on where and how that part will be used in end-use machines/installations. Some product types are specific (e.g. belts for power transmission) and the sector "machinery" covers their use in power transmission and conveyance systems. This covers diverse sectors as they are used in for example, office machinery (printers), electronic data processing equipment, textile machinery, wood processing machinery, machine tools, compressors, printing machinery, hydraulic gear pumps, building machinery.

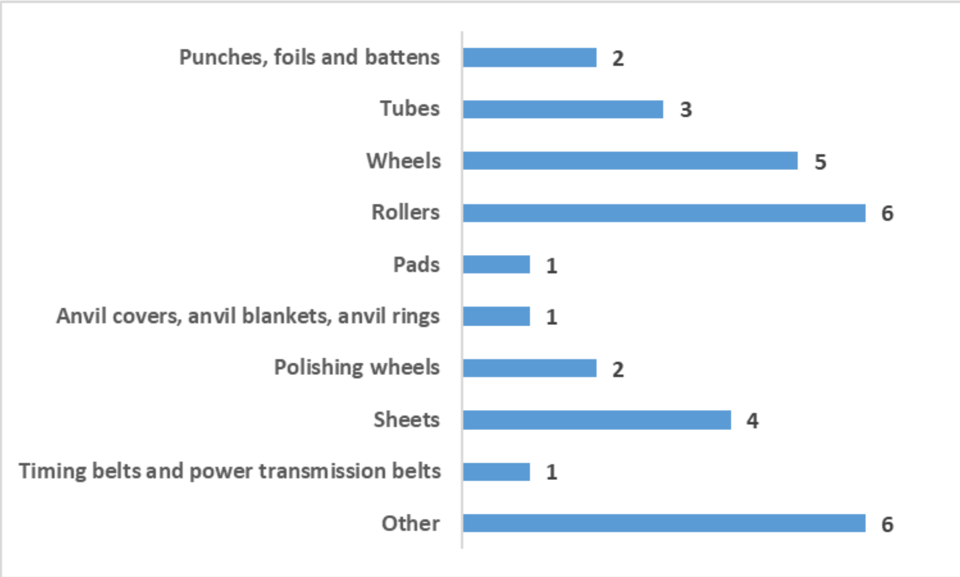

Figure 2 Summary of the types of PU products supplied by the respondents

As can be seen from Figures 1 and 2, TDI MOCA polyurethane products are diverse and each of the different product types can be supplied to diverse sectors.

1. FACTORS AFFECTING SUBSTITUTION

As outlined in the introduction, 17 % of the polyurethane industry in the EEA relied on TDI/MOCA in 2016. This means that more than 80 % of the sector use different systems. As can be seen from **Figure 1**, the respondents who selected available alternatives from the options given in the survey are quite different in terms of the sectors they supply to but are common in that they are all relatively small sites with less than 50 employees. As outlined above, some would be "generalist" moulders with vast portfolios of PU products they can offer their customers at low production volumes. Others would be "specialist" moulders with a limited portfolio that is manufactured at high volumes. Most offer PU products manufactured with alternative systems. An obvious question is why they have not already implemented complete substitution given that they have experience with alternative systems. As will be outlined in this section, the reasons are both technical and economic.

The TDI/MOCA system is very versatile and through variation of the polyol, the component ratios and process parameters like heating and cure times, the material properties of the cast polyurethane can be tailored for specific utilizations. Key material properties relating to PU product performance include hardness, tensile strength, heat resistance, cut resistance, tear resistance, compression set, resilience, abrasion resistance, hydrolysis resistance, oil resistance and elongation at break. This means that TDI/MOCA PUs do not refer to one specific PU but rather a very large family of PUs with properties that are tailored to where the product (e.g. wheel covers, roller covers, pads, belts) will be used (e.g. industrial installations in mining, metal processing, energy, paper and packaging sectors, conveyance systems, offshore installations). The TDI/MOCA system is also very versatile and can also be used to manufacture both small and large PU parts due to its long pot life.

As given in the Amec report[7], the main advantages of the TDI/MOCA polyurethane system are:

- Long pot-life – giving adequate time to mix, pour and fill the mould;
- Robust processing – the cast PU product is not affected by small errors in stoichiometry;
- Reliable processing – there are no significant issues with moisture control and the low viscosity;
- Allows ready flow into moulds;
- Performance – tough, durable elastomers are easily obtained;
- Catalysis – the ability to catalyse the reaction is important for production efficiency;
- Multifunctional – it can be used with TDI-ester prepolymer & TDI-ether prepolymer systems;
- Economical – favourably priced compared with other curatives; and
- Track Record – TDI prepolymer/MbOCA systems have a long history of successful use and customer confidence.

All polyurethane moulders have specifications and performance criteria for the different PUs products they manufacture. These specifications and performance criteria come from customer requirements from the end-user sectors where the PU products are integrated as parts or components in complex assemblies or installations. For example, pads used in offshore installations have requirements for compression set and durability. Roller coatings used in the steel industry have requirements for abrasion resistance, durability, cut resistance, coefficient of friction and rebound resilience. Timing belts used in power transmission and conveyance systems in industrial installations, have requirements for tensile strength, abrasion resistance and ageing resistance. Wheel coatings in conveyance, load carrying, transportation have requirements for load bearing capacity, wear resistance, abrasion, tear and cut resistance, coefficient of friction, tensile strength, durability and compression set. Customers have criteria based on product performance in their specific installations that include material specifications and also factors like downtime for repairs and replacement, reliability and durability. The established record of performance and customer confidence of TDI/MOCA PUs means that alternative systems will take time to gain the same level of confidence.

As outlined in the Amec report[7] and in papers in the public domain[8], there are no "drop-in" replacement systems that meet the cost-benefit profile of MOCA across the board. Choosing the right replacement is a matter of the needs of the utilization and the ability of the various alternatives to best meet these needs. More than one alternative system will be needed to replace the TDI/MOCA system. The number of alternative systems being developed is continuously expanding[9] and system providers work with their customers (moulders) to develop tailored systems for their specific utilizations. Moulders need in turn to work with their customers (the end users of the PU parts/components) to field test if needed and ensure that the part performs to specification. In practice, this means that the choice of alternative systems to replace the TDI/MOCA system needs to be tailored and optimised by each company to achieve the same PU performance in their product portfolio. More than one alternative system may be needed to cover the entire portfolio of TDI/MOCA products offered by a given company and some companies report that they offer more than 3000 products. The complexity means that expertise needs to be gained on the alternative systems and each product tested and qualified with the alternative system. Existing production lines may need to be adapted for the specificities of the alternative systems and the extent of the adaption will depend on the system. Additional production lines may need to be installed for testing and to enable a phased transition from one system to another.

This brings in economic factors. As outlined in the Amec report[7] and earlier in Chemtura comments submitted in the public consultation relating to the ECHA recommendation to include an entry for MOCA on Annex XIV[10], the concentration of free MOCA in cast polyurethane products is well below the 0.1 % (w/w) threshold when the ratio of reactants is controlled. This is the case for all industrial manufacture done to technical specification for PU material properties. This is a key point as it means that the Commission cannot regulate the import of TDI/MOCA PU products to the EU under Art. 69(2) based on the MOCA content. Non-EU based moulders can therefore continue to market TDI/MOCA PU products in the EU. This means that EU moulder necessarily have to compete in price, performance and track-record with these non-EU based competitors when they transition to non-TDI/MOCA systems. This is corroborated by the Amec report where Chemtura estimated that MOCA represented approximately 70 % of the chain extender sales in North America and Australia and approximately 85 % of the sales in Asia in 2016. In addition, while many system providers promote non-TDI/MOCA systems in the EU[11], some providers also promote TDI/MOCA for use in the rest of the world (see e.g. a technical brochure[12] in Appendix 4). This latter point brings a strong economic factor into the substitution planning of the companies. How much investment is needed to adapt the production process? How do the production costs compare? Will their customer base be willing to stay with them while they phase out their current product portfolio? Will customers engage in testing of the "new" PU products made with the alternative systems? Will customers be willing to pay more for the "same" product? Will their parent companies be willing to make the investment in a new plant for the alternative system?

In this section, we document the factors limiting substitution for the **12** companies who responded that while they have identified available alternatives, these cannot be taken into implementation by them at their sites.

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8 From a paper available on the PMA website: Choosing the best alternatives to MOCA cured TDI polyurethanes available at http://www.pmahome.org/files/1914/6282/8261/351_Chemtura.pdf

9 Polyurethane makers prepare for a phase out, CE&E News, 2016 available at https://cen.acs.org/articles/94/i23/Polyurethane-makers-prepare-phase.html

10 See comment 5 in "Responses to Comments Document (RCOM) on ECHA's Draft 4th Recommendation for 2,2`-dichloro-4,4`-methylenedianiline (EC number: 202-918-9)" available on the ECHA website at https://echa.europa.eu/documents/10162/4da7a7e6-19c0-4f57-94fb-aaad0fc0450d

11 e.g. https://solutions.covestro.com/en/highlights/articles/stories/2019/moca-free-solution

12 http://ure.ext.lanxess.com/wp-content/uploads/sites/26/2019/11/LXS-Global-Hot-Cast-Polyurethanes-Brochure.pdf

Preferred alternative systems
In response to the question;

> *For the polyurethane products for which you still use MOCA, please select the preferred alternative for MOCA. Please provide the information ONLY for your most important market sector (highest % in the market sector question)*

Respondents could select from the following options in the picklist

1. TDI/Ethacure 300 (DMTDA)
2. TDI/Addolink 1604
3. TDI/MCDEA
4. TDI/Vibracure A157
5. TDI/DETDA
6. TDI/MBOEA
7. MDI/Vibracure A260
8. MDI/BDO
9. MDI/HQEE
10. Another polyurethane system
11. No alternative generally available (i.e. no suitable alternative available for your nor your competitors in the same market sector)
12. No suitable alternative available to you but your competitors in the same market sector are using an alternative to MOCA

Eight selected a specific system from the list, two selected option (12) and two selected option (10). Two of the four who selected option 10 gave details of the alternative in the free text field. The answers are compiled in **Table 1**.

Preferred alternative system	Number of responders	Increased production costs
TDI/Ethacure 300 (DMTDA)	3	10-65 %
TDI/MCDEA	1	600 %
MDI/BDO	1	0
MDI/HQEE	1	30 %
No suitable alternative available to you but your competitors in the same market sector are using an alternative to MOCA	2	No answer given
Other MDI Vibracure 2101+LFM products (1) LFMDI Duracast / Vibracure A260 (1) No answer (2)	4	40 % 25 % 80 % No answer given

Table 1 Compiled preferred alternatives selected by the respondents

Ten of these responded that the production costs were higher with the preferred alternative. Of these, nine gave the percentage increase in costs. These are also given in **Table 1**. They are consistent with cost information in the public domain.[13, 7] They survey also had fields to report the main reasons for the increased costs. Raw material and process costs were the main reasons given. These are also consistent with information in the public domain.

Ongoing substitution activities. The questionnaire also collected information on the status of their substitution activities. None reported that they can successfully substitute by November 2021 (corresponding to a four year review period with the sunset date as the starting date).

Three reported that they have successfully substituted some of their TDI/MOCA PU portfolio to a different system (see **Table 2**). One of these has installed a new production line for the MDI/BDO system for PU parts used in farm machinery. One reported that they had successfully substituted with a Lanxess system for automotive sealants. One reported successful substitution with MDI/MCDEA for parts used in the paper and steel sectors. Substitution for other PU products in their portfolio has not been successful.

% PU product portfolio already successfully substituted	Substituted TDI/MOCA with	Sectors where these PUs products manufactured with alternative systems
20	MDI / BDO	Feeding, farm machinery
20	MDI/MCDEA	Stationery and steel
20	LFM E370 LFM E760 Vibracure 2101 NDI / BDO	Tubes to the automotive Industry (to make sealings)

Table 2 Details from companies that report successful substitution of part of their PU portfolios and the sectors where these parts are supplied to

The questionnaire collected information on R&D activities conducted on alternative to MOCA both before and after the sunset date as free text entries. All of the companies reported substitution activities and eight had R&D activity ongoing before the sunset date. Since the sunset date, all but one company have ongoing R&D activities. The exception reported that they have tested the available alternative systems pre-2017 and explained that no suitable systems for their product portfolio had become available since then. They stated that they will test new systems as they become available.

Since the sunset date, many reported performing tests with MDI/BDO, MDI/HQEE, TDI/Ethacure 300 and other alternatives on site and in the lab, collaboration and site visits from suppliers, tests on prototypes at customer sites. One company reported that they are now concentrating their substitution efforts on an MDI system from a main systems provider. The static physical properties of the polyurethane and the dynamic properties of the PU parts made with the alternative system met their requirements. The pot life of the substitute was shorter than the MOCA formulation utilised in their production. However, processing has not met their requirements, as the reject level has been too high. Imperfections in the finished parts have included voids/bubbles, lack of green strength (demould strength) and incorrect shape formation. They outlined that their appraisal is continuing and their supplier has recommended new additives to test. However, to date, none of the change made to formulation has resolved the challenges. They outlined that the cost of the replacement formulation is significantly higher. They are also now working with another

13 http://www.pmahome.org/files/5013/9830/9213/341_Life_Beyond_MOCA.pdf

major systems provider and have done one trial with onsite assistance from them. The PU has met their static physical properties requirement. However, the dynamic test results done on prototypes have been variable. The pot life is shorter and the processing requirement, so far has not been met. The cost ratio is similar to the TDI/MOCA and their overall assessment is continuing. One company reported that they have ongoing testing with MDI/BDO (internal tests, tests with selected customers). They have purchased new equipment to test prototypes for properties relevant for their end use and they have also conducted customer trials for one product family. Another reported that testing is ongoing and prototypes for specific products have been provided to customers for testing when the properties met requirements. They also recently started collaboration with a university on alternatives but this has now been delayed due to the covid 19 situation. Another reported ongoing testing with the MDI/BDO and MDI/HQEE systems. Another reported they are testing polycarbonate prepolymers.

Before the sunset date, many reported testing MDI/BDO, MDI/MCDEA, TDI/Ethacure 300. One reported they installed a production line for MDI/BDO. Two reported tests with TDI/Ethacure 300. One reported working with the provider on testing and development of a production line for MDI/MCDEA. One company reported that they have been testing alternatives for more than two decades and have tested more than fifteen systems, using both manual and machine casting techniques. Technical experts from the systems providers have come to their site to conduct trials with the alternative systems. Many of the alternatives tested did not meet their PU hardness requirement. For many, the catalysed formulations had too short a pot life and moulding times were off-specification. Not all of the alternatives tested passed their benchmark dynamic test evaluation. None of the options passed their processing suitability requirements. None were economically viable replacements for TDI/MOCA at their production facility. The difficulties encountered included voids, bubbles, lack of green strength, poor shape formation, crack development, flow lines, short shot, residue formation, marks on the exterior and surface crystallisation. The majority of the replacements, did not meet their compound cost ratio, they were more expensive than the standard TDI/MOCA system components.

The questionnaire also collected information on the substitution costs to date. Seven respondents gave estimates for how much they have spent on substitution activities to date. Two of the values reported were under 100 000 EUR, three were between 100 and 200 000 EUR and two reported 700-800 000 and greater than 1 million EUR respectively.

The questionnaire also collected information on the number of alternatives tested by the 12 responders are compiled in **Figure 3**. Three reported them have tested 1, six between 3 and 5 alternatives, one reported 7 and one reported having tested more than 15 alternatives.

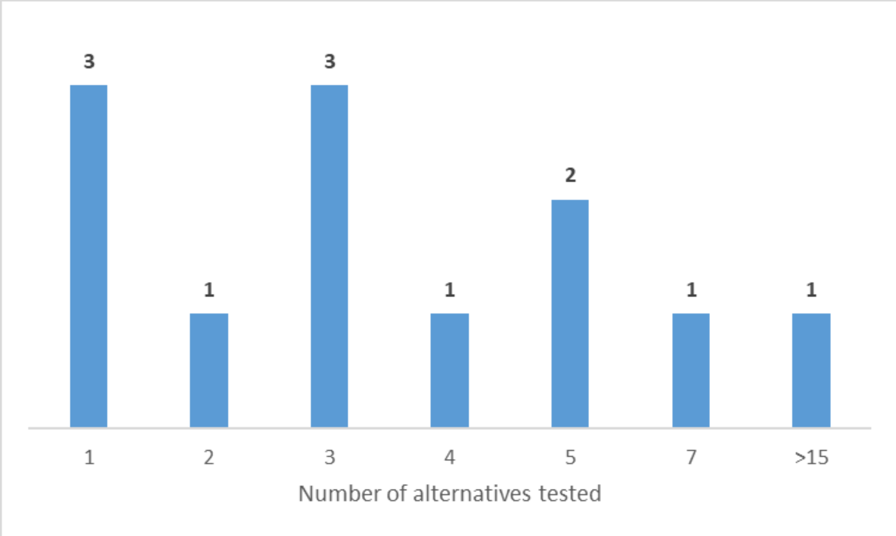

Figure 3 The number of alternatives tested by the responders

Key factors preventing substitution: Eleven of the twelve companies gave answers in the free text fields in response to a question on the three main factors that prevent them from substituting MOCA or makes substitution difficult. The free text responses were consistent in that nine gave **product quality/performance** of the PU and **process challenges** (potlife life and processing) as the two key challenges followed by **cost considerations** (6 of the 11 responses). Two companies gave testing and qualification as factors. The compiled responses are summarised in **Figure 4Error! Reference source not found.**.

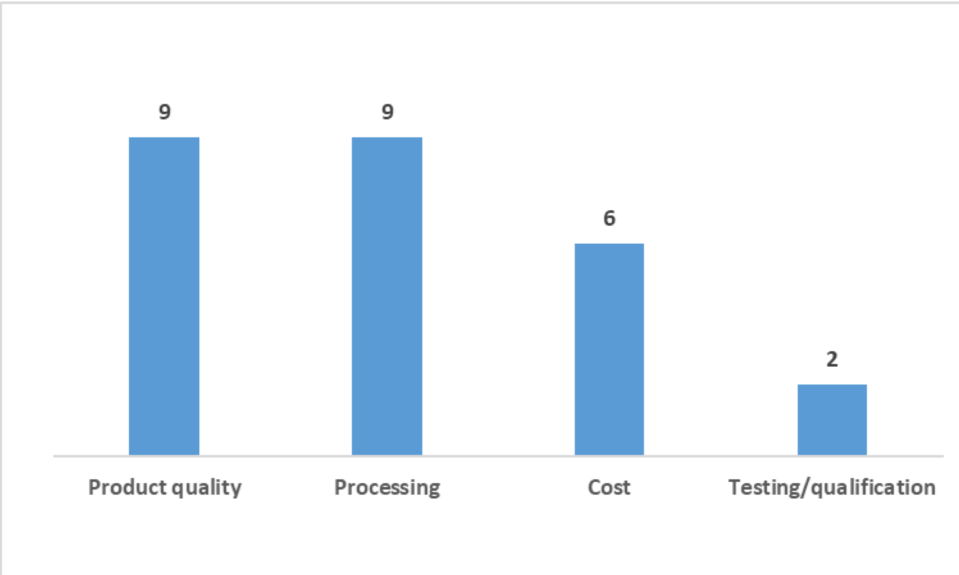

Figure 4 Compiled responses for the three main factors reported by the respondents that prevent them from substituting use

The reasons given by the responders for why available alternative systems are not suitable for them included product technical performance, the higher costs of the alternative systems, increased production costs, process changes needed to manufacture PUs with the alternatives (adapting existing machines and/or purchasing new machines; adapting existing ovens and/or purchasing new ovens; purchasing new moulds). One responder gave an estimate that replacing 5 machines would cost 1.25 million EUR. Another company with a large product portfolio gave an estimate of 1.2 million for the cost of changing all the moulds. Some of the companies have a vast portfolio of PU products that can be made on demand to customer specifications for PU performance. Prototypes of each would need to be tested with the alternative system. Some make PU parts for installations that are used in harsh environments (e.g. offshore energy) and parts made with alternative systems will need to be field tested before use in that sectors. Given the diversity of the parts/components, this will be a lengthy process and also requires engagement and commitment from customers to test prototypes on site. Some companies have a more limited portfolio and have dedicated production lines for high production volumes of one product type (e.g. timing belts for power transmission). This means that factors like scrap rate are critical to profitability. Scrap rate is the ratio parts rejected (off-specification) on a given production line and production lines have acceptability criteria for scrap rates. One responder outlined that none of the alternative systems has been found to be feasible in their fixed installation that is highly automated and designed for the TDI/MOCA system. In their case, switching to an existing alternative would require new machinery, in the current facility, that can process MOCA free urethane (estimated cost ca. 4 million EUR). This investment is not feasible for them. One company product outlined that they offer PU products used in precision engineering and they need to ensure that the alternative system will fulfil the product technical specifications of their customers. They outlined that more than 50 % of their turnover comes from products exported outside the EU and that they need to ensure that switching production to the alternative does not risk losing their biggest market.

To assess the credibility of the responses given, we looked at considerations given in the Amec report[7] relating in particular to costs and affordability. The report gave the following as the main sources of additional costs for taking an alternative system into implementation

1. Additional raw material costs
2. Direct and indirect cost of trials/testing

At that time (2016), the report gave the following as relative prices for curatives

- DMTDA (Ethacure 300) = 2.08 times the price of MOCA for equivalent stoichiometric amount;
- VIBRACURE® A157 / Polacure 740M = 6.7;
- Lonzacure M-CDEA = 10.9;
- Addolink® 1604 HM = 5.4;
- Polyol blends or amine curatives and polyols = 3.4; and
- 1,4-butanediol (BDO) = 0.30

All except BDO are more expensive than MOCA. The relative price difference for HQEE was claimed confidential but was stated to more expensive than MOCA. In terms of overall system costs, the report outlined that the relative costs of the different prepolymer systems also need to be considered. As a (w/w) %, the pre-polymer accounts for 90 % of the overall system, the report considered the impact of changing the prepolymer system on overall costs. For MDI based systems, they took into account the price differences between LF version and the conventional version of both TDI and MDI prepolymers. LF is a designation for a prepolymer with a low free monomer content (< 1 % free monomer compared with ca. 20 % for conventional MDI prepolymers and ca. 2-4 % for conventional TDI prepolymers). The costs for LF versions are significantly higher than the conventional versions. For companies already using LFTDI, there would not be a significant increase in cost for switching to LFMDI. This means that companies using a conventional TDI prepolymer system, raw material costs are significantly higher if a like for like alternative is used or switching to a LFMDI prepolymer system.

In terms of direct costs, the Amec report[7] gave typical costs of machines and outlined a typical plant would have several machines, most fewer than 10 with only big companies have 20 or more. Each machine was estimated to cost between €180,000 and €300,000. Whether or not new machines need to be purchased will depend on the alternative system and whether more than one alternative system is needed. The report did not consider costs for new moulds or additional ovens to maintain capacity for systems that have longer cure times. For scenarios where the same machine can be used, costs associated with process optimisation for the new system, pilot testing and a phased transition to all lines were considered.

The Amec report[7] proposed that increased cost could be offset with savings on PPE, ventilation and extraction systems assuming that that these would not be needed with the alternative systems. This would only be the case where the sites solely use low free prepolymers (< 0.1 % (w/w free diisocyanate monomer). This is unlikely to be generally the case as the current restriction on the use of diisocyanates[14] allows the use of prepolymer with free diisocyanate > 0.1 % (w/w) provided the workers are trained on their safe handling.

In terms of affordability in terms of costs on final product, the Amec report[7] outlines that there is no standard threshold at which it can be concluded costs would be unaffordable for the moulders. Their high level assessment suggested that the costs could potentially be absorbed in certain sectors/applications, while **for others the costs may not be affordable**. In these cases, the report outlines a combination of three options. As a first option, it states they could absorb the costs, either temporarily or permanently, with an associated reduction in their profit margin. As the second option, it states they could pass the additional costs on to downstream users where these are likely to be acceptable (i.e. in some specialist applications with demanding functionality and/or where the parts form part of much larger systems). For the third option, it states that, the customers of the moulders could import TDI/MOCA PU products from outside the EU, in cases where the concentration of MOCA in articles is below 0.1 %, and hence not subject to the REACH SVHC substances in articles provisions, if this is technically feasible (and affordable).

The report also considered the changes to the PU costs may depend on the products and their end uses. The report gave three broad categories:

- Relatively simple geometries with the part manufactured from 100% PU. These parts are heavily dependent on PU price as it could represent 70% of the part cost.
- More complex geometries which are a combination of metal & PU for which the impact of PU cost is around 30-35% of the part cost.
- Specialised high tech parts for which PU impact is less than 10% of total part cost.

The report[7] gave some illustrative examples of some of the end user applications that may be negatively affected by increased costs. Three of the four given are relevant for this application; tyres and wheels, industrial applications and mining, oil & gas applications. The report outlines that the ability to pass on increased costs will depend on the end use of the component and whether the PU product is a minor component of a large assembly or not. It concluded that in the majority of cases the PU components themselves form part of much larger systems, suggesting any price increase, would be further diluted before the final end use.

Consequently based on the Amec report[7], the costs and drivers reported by the respondents are credible and in line with the main factors that impacts substitution at their sites; PU quality/performance, cost and process.

Considering the Amec report options listed for moulders where the costs are not affordable, the third option implies that the moulders switch their role from manufacturer to distributor of imported TDI/MOCA PU products. Further, it does not consider that the moulders already face competition from non-EU moulders and that there is an obvious fourth option; they cease manufacture of their PU products currently manufactured with TDI/MOCA. In this case, whether they remain economically viable will depend on the contribution their TDI/MOCA PU portfolio makes to turnover. For companies where the contribution is high, they may cease operation entirely. The questionnaire collected information on the contribution TDI/MOCA

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[14] Details on the proposed restriction on the use of diisocynate is available on the ECHA website at https://echa.europa.eu/fi/registry-of-restriction-intentions/-/dislist/details/0b0236e180876053

PU products make to global turnover. The compiled responses are given in Appendix 6. For companies where the contribution is low, they may be able to diversify their production to other products. Again, it is important to note that TDI/MOCA PU product imports cannot be regulated by the Commission based on the MOCA content as it is well below the threshold for Art 69(2) restrictions meaning that the EU based moulders must offer PU products that are competitive in terms of cost and quality with imports. It is very unlikely they will find a market for an equivalent but much more costly PU product and extremely unlikely they will find a market for a PU product with poorer performance and a higher price. This means that companies are very unlikely to be able to pass on costs to their customers. The competitive nature of the market also means that the companies have a fine line between engaging with their current customers to test prototypes made with alternative systems and not raising concerns that they are not a reliable long term supplier of PU products.

All of the above reiterates the competition these companies face on cost and quality due to imports from non-EU based moulders. Of the three companies interviewed for the Amec report[7] who reported that they had successfully substituted to the LFMDI/HQEE system, two did not feel that they could pass on the increased costs of the final products coming from substitution to their customers.

In summary, TDI/MOCA continues to be used by these companies to manufacture PU parts/components for a combination of technical and economic factors that are inter-related. Alternative systems do not perform well in the existing process technology meaning the product quality is not acceptable. Adaption of the fixed installations requires investment (machines, ovens, controllers, moulds) and together with the increased production costs (raw materials, heating) that may not be economically viable. The PU market is competitive and companies need to ensure that they do not lose the share of the market, in particular to non-EU based competitors who continue to use TDI/MOCA systems.

Utilizations/groups of utilizations

It was not possible to group the TDI/MOCA PU products into meaningful utilizations following the terminology of the Commission letter. As can be seen from **Error! Reference source not found.** and **Figure 2**, the TDI/MOCA system is versatile and yields PU products with a range of material properties that are tailored to their intended use. This is in turn why they are so widely used in diverse sectors. They are hidden in components used for transport (e.g. wheel covers, pads for gripping) conveyance systems (e.g. timing belts, roller covers, wheel covers, wheels), glass polishing units (e.g. polishing wheels), rotary die cutters (e.g. anvil covers), ceramic moulds (e.g. punches)) and very widely used for their excellent performance. There is probably not an industry sector where PU components/parts are not used.

For the purpose of the request received for this application with the scope already defined in 2015 when the application was being prepared, we differentiate between the users based on their ability to implement substitution. We define the following three utilization groups:

1. Utilizations where a decommissioning of the existing plant is needed
2. Utilizations where the product portfolio is extensive meaning that substitution is lengthy
3. Utilizations where available alternatives in general are not economically feasible for the users

We allocated the twelve designated SAGA companies to one of these three groups based on the answers given in their questionnaires supplemented by information in the public domain. One company was allocated to group 1. They are "specialists" and make one product type in high production volumes in a fixed installation that was customised for the TDI/MOCA system. They have spent more than 20 years testing alternatives and have concluded that existing alternative systems cannot be run on their installation and that ultimately the implementation of a suitable alternative will require decommissioning the existing plant and commissioning a new one. As this is not economically feasible for them, they will continue to work with systems providers and test new systems as they come on the market.

Three companies were allocated to groups 2 and 3 as they have PU products that would be under both groups. They are "generalists" and all have very broad portfolio of products meaning that it is a lengthy process to phase out TDI/MOCA for all products. Available alternatives are not currently economically or technically feasible for them to implement based on cost and performance.

One company was allocated to group 2 and seven companies were allocated to group 3.

For the company solely allocated to group 2, while they have one product type, they have a portfolio of more than 3000 product codes. The products are used in high precision engineering and the company outlined that they need to ensure that PU products made with alternative systems will fulfil the technical specifications of their customers for the complete range of products offered.

For the seven companies allocated solely to group 3, all outlined that affordability is the main driver. Due to interplay between technical and economic factors, they are unable to take available alternatives into implementation at their sites. As the PU market is very competitive, they do not consider they will be able to compete with non-EU based suppliers in price and performance of products made with alternative systems. Non-EU suppliers will continue to use the TDI/MOCA system giving them a strong competitive advantage. Their ability to substitute is depend on factors that they cannot influence; the regulatory status of MOCA outside the EU, the absence of restrictions on imports on TDI/MOCA PU products and the costs of the alternatives offered by systems providers. They will continue to work with alternatives providers to test alternative systems as they come on the market and will phase out MOCA use once the available alternatives are affordable for them (or ultimately discontinue the product range given the regulatory uncertainty). In contrast EU based competitors can already have implemented substitution with the "suitable alternatives generally available" for the same utilisation. These companies have determined substitution is affordable for them. It may be that these companies are larger, already use the alternatives for other speciality products or can absorb a lower profit margin. A 2015 study by the Commission on the impacts of REACH on innovation, competiveness and SMEs notes that that "*SMEs have been more acutely affected than large enterprises by the compliance costs*"[15], supports that affordability seems to be related to company size. This was further discussed in the 2018 Commission study on the impacts of authorisation[16] that highlighted that affordability may be a barrier to substitution for SMEs in the authorisation process. Similarly, a 2016 report[17] noted that the actual adoption of identified alternative substances in the industrial process could pose higher challenges to SMEs in terms of affordability than bigger companies. The authors state that SMEs are less likely to have the resources for implementing the necessary process/product design modifications. In summary, these companies that are all SMEs have issues with affordability that they need to overcome to implement substitution.

Note that due to the diversity of PU products offered, many of the companies will also have products that do not have a SAGA. This is in particular the case for large sized PU products where there are currently no suitable alternatives that are economically feasible in the EU.

[15] European Commission (EC). (2015).Monitoring the Impacts of REACH on Innovation, Competitiveness and SMEs. Luxembourg: Publications Office of the European Union. Available at: http://ec.europa.eu/DocsRoom/documents/14581/attachments/1/translations/en/renditions/native p.200

[16] European Commission (EC) (2018) Impacts of REACH authorisation, Final report; Publications Office of the European Union. Available at https://op.europa.eu/s/ofW7

[17] Tickner, J. and M. Jacobs. (2016). Improving the Identification, Evaluation, Adoption and Development of Safer Alternatives: Needs and Opportunities to Enhance Substitution Efforts within the Context of REACH, Report for the European Chemicals Agency (ECHA). Available at: https://echa.europa.eu/documents/10162/13630/substitution_capacity_lcsp_en.pdf/2b7489e1-6d96-4f65-8467-72974b032d7b

2. LIST OF ACTIONS AND TIMETABLE WITH MILESTONES

Ten of the twelve designated SAGA companies responded that they follow the following four general steps to replace MOCA in the manufacture of their polyurethane products:

- Early stage R&D
- Upscaling to production and internal testing
- Customer trials
- Phase out of MOCA

For a given product line, the steps are sequential and going from one step to the next will have a GO/NO GO decision point. For example, only candidates that pass early stage R&D may move into the upscaling production and internal testing stage. Only alternatives that pass the upscaling to production and internal tests may move to the customer trial stage. If an alternative fails during early stage R&D, the project will remain in this stage and another alternative will be tested. If an alternative fails during stage 2 or 3, the project will return to stage 1.

The remaining two designated SAGA companies indicated that they do not follow the four general steps indicated above. Both indicated that, while they have conducted trials on different alternatives to MOCA, the significant investments needed to implement the alternatives and the higher production costs of alternatives means they are more likely to stop their production of MOCA-based PU products. Based on the reported contribution TDI/MOCA PU products to global turnover reported by each of these companies (ca. 10 % and 40 %), stopping production may negatively impact viability of the company more dependent on these products for its turnover.

Due to the current situation where EEA moulders need to compete heavily in terms of product price and performance with non-EEA moulders and the absence of drop-in alternatives to MOCA, the substitution of MOCA still requires years of work. Based on the answers of the questionnaire, all twelve designated SAGA companies have unanimously expressed that it was not possible for them to replace MOCA in the manufacture of their main market sector products before 21 November 2021 (Sunset date + 4-year review period as recommended by the ECHA committees). However, the companies are actively working towards the substitution of MOCA and the steps they take are described in details in this section.

Table 3 presents the utilization grouping of the twelve designated SAGA designated companies. The grouping was based on the answers provided by the companies on the main factors affecting substitution. Due to the diversity of the products manufactured by the companies, some companies may have products in two different groups.

	Utilization 1	Utilization 2	Utilization 3
Company A			Yes
Company B			Yes
Company C			Yes
Company D			Yes
Company E			Yes
Company F		Yes	
Company G	Yes		
Company H		Yes	Yes
Company I		Yes	Yes
Company J		Yes	Yes
Company K			Yes
Company L			Yes

Table 3 Utilization grouping

Utilization group 1:

Utilization group 1 covers utilizations where decommissioning of the existing plant is needed. This applies to Company G, which is specialized in producing one specific type of PU product in large quantities for a large number of industry sectors.

Company G is characterized by their process technology. They have a production line, consisting of fixed installations that are specifically optimized to process MOCA. This allows them to produce the same type of products in high quantities. This is the main hurdle for substitution in this utilization group as the alternatives must be suitable for use in Company G's production line by meeting strict processing requirements in terms of pot-life, demould time and scrap rate.

Despite years of close collaboration with different alternative providers and conducting trials on more than fifteen PU systems, none of the alternatives were suitable to be used in Company G's production line. Many of the alternative systems tested by Company G were MDI-based systems, which are the PU systems that Company G's EEA competitors are using, according to Company G. These are therefore considered as SAGA.

The substitution plan followed by Company G is presented in **Table 4***.*

Stage	Actions	Milestone	Decision point
Early stage R&D	Working with systems providers to develop MOCA-free formulations that are likely to be suitable. Conducting test runs in the laboratory. Conducting preliminary tests on the technical properties of the PU. Assessing the availability of raw materials.	System provider identifies likely candidates or develops a new alternative candidate. Test runs in the laboratory are successful. PU properties are within specification. Raw materials are available in the amounts needed for production.	Management decision to start the upscaling to production scale.
Upscaling to production scale and internal testing	Running test batches on site in the installation and optimizing process parameters to get the right combination of properties. Calculating scrap rate. Measuring pot-life and demould time. Conducting tests on the technical properties of the test parts. Assessing the change in production costs with the alternative.	PU properties are acceptable. Pot-life and demould time are acceptable. Scrap rate is acceptable. Production costs are acceptable.	Management decision to start customer trials with selected customers.
Customer trials	PU products are field tested in customer trials for the specific end use.	PU products pass customer acceptance criteria	Customer commitment to buy PU products Management decision to continue with phased implementation of alternative.
Phase out of MOCA	Scheduled phase out of all production lines using MOCA/TDI to the alternative system	PU products made with the alternative are put on the market	Use of MOCA ends

Table 4 Substitution plan for utilization group 1

All of the alternatives tested by Company G, including the ones considered as SAGA, have failed to pass the second stage of the substitution plan. The alternatives either failed all the milestone criteria or a combination of those. Company G is currently testing two MOCA-free PU systems. The status of the substitution is given in **Table 5**.

	Status	Description
Early stage R&D	In progress	As currently none of the alternatives tested are suitable to be used in Company G's production line, the company is continuing to collaborate actively with systems providers to find new MOCA-free PU systems. Over the years, multiple system providers have been consulted. This phase contains the highest uncertainty component in terms of duration as it is currently unknown when new MOCA-free systems are going to be developed by system providers.
Upscaling to production scale and internal testing	In progress	All the alternatives tested so far have failed to pass this stage. Company G is currently running test batches with two MOCA-free PU systems. Tests are still on-going and additional tests are still needed before a definite conclusion can be drawn. However, based on the tests conducted so far, Company G is not expecting to achieve an acceptable scrap rate with these systems.
Customer trials	Not started	Should an alternative pass the previous stage, customer trials will be conducted. Company G estimated that customer trials would take 1-2 years.
Phase out of MOCA	Not started	Should customers commit to purchase the MOCA-free products, Company G will proceed with the phase out of MOCA.

Table 5 Status of the substitution for utilization group 1

Due to the high number of alternatives tested and the fact that none were compatible with Company G's production line, the company is no longer expecting to find an apt replacement in the current equipment. Thus, in parallel to the substitution plan presented above, Company G is now planning to seek agreement, from senior management colleagues, to take the following steps:

- Step 1: Designing a new concept of process technology, which would be optimized for a MOCA-free system. Prototype moulds would be designed to improve the results.
- Step 2: Conducting tests to determine which alternative, is most suitable, in the new concept.
- Step 3: Carry out an economic appraisal of changing the entire production, moulding machines and moulds, to the new manufacturing system
- Step 4: A decision from the management, would be necessary, to determine if relocation to a non-EEA country is the most cost-effective option. The decision would be based on costs and payback period. Based on the decision, Company G would either (a) relocate to a non-EEA country or (b) fully decommission the MOCA processing equipment and invest in new installations, optimized for a MOCA-free system.

In terms costs and timescale:

(a) Cost of approximately €1M, and 1-2 years to complete

(b) Budget in the region of €4.4M and a 7-10 years time frame

Relocation to a non-EEA country would allow Company G to continue the use of MOCA in the manufacture of their products. Their EEA customers would still have the possibility of purchasing Company G's MOCA-based PU products as the Commission cannot regulate the import of MOCA-based PU products to the EU under Art. 69(2)[18] based on MOCA content. Thus, the customers could keep using the MOCA-based products they are used to purchasing. This would however lead to job losses in the EEA as the current factory would close.

[18] Regulation (EC) No 1907/2006 (REACH)

In summary, despite the extensive R&D work conducted by Company G, none of the alternatives available, including the ones considered as SAGA, are suitable for use in their current production line. Company G is currently testing two MOCA-free systems however, based on the tests conducted so far, they are not expecting to achieve an acceptable scrap rate with these systems. As a result, Company G is no longer expecting to find an apt replacement in the current equipment. Thus, the company is planning to research the possibility of changing to a process technology optimized for a MOCA-free system, in parallel to the substitution plan. Depending on which option is the most cost effective, the management will decide the subsequent phase.

Utilization group 2:

Utilization group 2 covers utilizations where the MOCA product portfolio is extensive, which makes the substitution of MOCA lengthy. This utilization groups concerns four companies and the products covered by this utilization group include:

- Rollers
- Wheels
- Polishing wheels
- Punches, foils and battens
- Pads
- Anvil covers/blankets and rings
- Sheets
- Tubes

The companies have the common characteristic of having large product portfolios, which contains thousands of items made with MOCA. For instance, a company explained to have 40 000 MOCA-based items in their portfolio, another had more than 3000 while another company indicated to have 15 000 moulds in use.

The companies have conducted trials on 3-7 different alternative PU systems. None of the alternatives were suitable to substitute MOCA across their product portfolio. In addition, the alternatives that are generally available are not currently economically feasible for them to implement.

The substitution plan followed by the companies is described in **Table 6**.

Stage	Actions	Milestone	Decision point
Early stage R&D	Working with systems providers to develop MOCA-free formulations that are likely to be suitable. Separating the products into groups based on their size, weight, complexity and mould type. Conducting test runs in the laboratory on products of each product group. Conducting preliminary tests on the technical properties of the PU. Determining the number of products that can possibly be reformulated with the alternative. Assessing the availability of raw materials.	System provider identifies likely candidates or develops a new alternative candidate. Test runs in the laboratory are successful. PU properties are within specification. Multiple products can be reformulated with the alternative based on preliminary results. Raw materials are available in the amounts needed for production.	Management decision to start the upscaling to production scale.
Upscaling to production scale and internal testing	Evaluating the need for new equipment and machines (e.g. casting machines, ovens etc…) Verifying that existing oven capacity is sufficient to maintain production capacity Verifying that existing moulds can be used. If not, the moulds need to be redesigned. Running test batches on site in the installation and optimizing process parameters to get the right combination of properties. Calculating scrap rate. Conducting tests on the technical properties of the test parts. Assessing the change in production costs with the alternative. Validating the production standards. Determining the number of products that can possibly be manufactured successfully at production scale.	All the new equipment needed has been installed. Moulds were successfully re-designed, where needed. Test runs are successful and PU properties are acceptable. The process was validated successfully. Scrap rate is acceptable. Production costs are acceptable. Multiple products can be manufactured successfully at production scale.	Management decision to start customer trials with selected customers.
Customer trials	Convincing customers to test the alternative PU parts during end-use. Determining the technical performance and durability of the alternative PU parts during end-use. Validation and qualification of products. Determining which market sectors can use MOCA-free products.	Customers agree to conduct trials in their installations. PU products pass customer acceptance criteria.	Customer commitment to buy PU products Management decision to continue with phased implementation of alternative.
Phase out of MOCA	Scheduled phase out of MOCA for each product group.	PU products made with the alternative are put on the market	Use of MOCA ends

Table 6 Substitution plan for utilization group 2

Based on their answers to the questionnaire, the companies are currently at different stage of the substitution plan. The progress of the different companies has been aggregated in **Table 7**. In the questionnaire, companies had the possibility to select multiple options for each stage allowing them to describe their situation as precisely as possible. Companies may have multiple stages in progress as they work by product groups.

	Completed	**In progress**	**Not started**
Early stage R&D	2	3	
Upscaling to production scale and internal testing		4	1
Customer trials		3	2
Phase out of MOCA		3	3

Table 7 Status of substitution for utilization group 2

As the companies have large product portfolios, they conduct the substitution work using product groups. Each product group will advance through the substitution plan presented in **Table 6** at a different pace. In addition, each company has different resources available in terms of budget, personnel and time for the substitution work. In practice, it means that it may take companies a different amount of time to complete each stage of the substitution plan. Furthermore, each company have started the substitution work at different times. Therefore, providing a timeline for the progress of the substitution work for utilization group 2 is not meaningful.

It should also be noted that three of the four companies allocated to this utilization group are also allocated to utilization group 3. Thus, their large product portfolios is not the only factor affecting substitution, they also have affordability issues.

Based on the answers to the questionnaires, it would take the companies between 2-5 years to complete stage 1, 2-10 years to complete stage 2, 2-10 years to complete stage 3 and 3-5 years to complete stage 4. The broad ranges come from the reality that they cover four different companies that make different product portfolios to diverse sectors. Although the different product groups will progress through the substitution plan at their own pace, allowing the different stages to be conducted in a staggered manner, the substitution work will be lengthy.

The current lack of drop-in alternatives that would be suitable to replace MOCA across the companies' extensive product portfolio renders the substitution of MOCA complex. This puts the companies in a situation where they need multiple alternatives to substitute MOCA, increasing exponentially the number of production lines required for the manufacture of their products. It is not viable for the companies to have dozens of MOCA-free production lines thus, the alternatives should be suitable to replace MOCA in several product groups to be viable solutions.

In addition, as the result of their large product portfolios, the companies have thousands of formulations to be tested and optimized with the alternative system. This makes stage 2 of the substitution extremely time-consuming as finding the right formulation and optimizing the process parameters consists of trial and error. Several iterations are likely to be needed for each product group. The higher the number of product groups the company has, the longer this step is expected to take. The pace at which a company progresses through this stage will also depend of the amount of resources available for substitution.

Another factor that affect the duration of stage 2 is the number of moulds the company has. The moulds that companies are currently using are optimized for casting with MOCA. As a higher amount of shrinkage is typically observed with MOCA-free systems, the companies would need to re-design and change all their moulds, which is both costly and time-consuming.

The duration of stage 3 is heavily affected by the necessity to revalidate and requalify their products. Depending on sector of end-use, the duration of this task can be shorter or longer, explaining the difference between durations given by moulders. Some products are used in applications with long lifetimes (e.g. for the offshore sector), the companies are required by their customers to test and qualify the durability of products over a long period of time.

In summary, the substitution of MOCA in utilization group 2 is lengthy due to the large product portfolios of the companies. The number of reformulations needed is high and it is also likely that the companies will also need to re-design their moulds to accommodate with the different exothermic profile of the alternatives. Thus, several years will still be needed before MOCA can be substituted. In addition, the alternatives considered as SAGA are not currently economically feasible for the companies to implement. For these reasons, the companies in utilization group 2 are in the process of preparing their own authorisation application.

Utilization group 3:

Utilization group 3 covers utilizations where available alternatives in general are not economically feasible for them. This concerns ten companies and the products covered by this utilization group include:

- Rollers
- Wheels
- Pads
- Anvil covers/blankets and rings
- Polishing wheels
- Punches, foils and battens
- Tubes
- Sheets
- Dowel for fixing beacons to electrical cable
- Floating cell rotors and stators

For these utilizations, affordability is the key issue in terms of substitution. Due to interplay between technical and economic factors, they are unable to take available alternatives into implementation at their sites. As the PU market is very competitive, they do not consider they will be able to compete with non-EU based suppliers in price and performance of products made with alternative systems.

The substitution plan of companies in utilization group 3 is presented in **Table 8**.

Stage	Actions	Milestone	Decision point
Early stage R&D	Working with systems providers to develop MOCA-free formulations that are likely to be suitable. Separating the products into groups based on their size, weight, complexity and mould type. Conducting test runs in the laboratory on products of each product group. Conducting preliminary tests on the technical properties of the PU. Assessing the availability of raw materials.	System provider identifies likely candidates or develops a new alternative candidate. Test runs in the laboratory are successful. PU properties are within specification. Raw materials are available in the amounts needed for production.	Management decision to start the upscaling to production scale.
Upscaling to production scale and internal testing	Evaluating the need for new equipment and machines (e.g. casting machines, ovens etc…) Verifying that existing oven capacity is sufficient to maintain production capacity. Verifying that existing moulds can be used. If not, the moulds need to be redesigned. Running test batches on site in the installation and optimizing process	The investments needed to take the alternative system into full scale production are economically feasible. The space in the manufacturing plant is sufficient. All the new equipment needed has been installed. Oven capacity is sufficient. Moulds were successfully re-designed, where needed. Test runs are successful and PU properties are acceptable.	Management decision to start customer trials with selected customers.

	parameters to get the right combination of properties. Calculating scrap rate. Conducting tests on the technical properties of the test parts. Cost the changes needed to take the alternative system into full scale production. Cost the changes in production costs with the alternative system.	Scrap rate is acceptable.	
Customer trials	Convincing customers to test the alternative PU parts during end-use. Determining the technical performance and durability of the alternative PU parts during end-use. Determining which market sectors can use MOCA-free products.	Customers agree to conduct trials in their installations. PU products pass customer acceptance criteria	Customer commitment to buy PU products Management decision to continue with phased implementation of alternative.
Phase out of MOCA	Scheduled phase out of MOCA for each product group.	PU products made with the alternative are put on the market	Use of MOCA ends

Table 8 Substitution plan for utilization group 3

The companies progress through the substitution plan at different pace based on their resources. Their answers have been aggregated in **Table 9**. As it can be seen, two companies have already completed early stage R&D while this stage is still in progress for others. For the majority of moulders, stage 2 is still in progress and four moulders are currently conducting customer trials.

	Completed	In progress	Not started
Early stage R&D	2	6	
Upscaling to production scale and internal testing	1	5	2
Customer trials	1	4	3
Phase out of MOCA		3	6

Table 9 Status of the substitution for utilization group 3

Due to the number of companies, concerned by this utilization group (10) and the differences in progress in terms of substitution between the companies and considering the number of product types (see **Figure 1**) and the sectors they are supplied to (see **Figure 2**), presenting a common timeline for the substitution work is not meaningful.

Based on the answers to the questionnaires, it would take the companies between 2-5 years to complete stage 1, 2-10 years to complete stage 2, 3-10 years to complete stage 3 and 3-4 years to complete stage 4. As for utilization group 2, the broad ranges reflect the reality that there are ten different companies located in 5 different countries that supply diverse products (10 different product types listed in the survey) to diverse sectors (10 listed in the questionnaire).

Overall, the substitution work is lengthier for the companies also included in utilization group 2 due to the large number of MOCA-based products they need to reformulate. Although the substitution work may be less lengthy for the others, the complete phase out of MOCA depends on factors that are outside their control; the regulatory status of MOCA outside the EU, the absence of restrictions on the imports of TDI/MOCA PU products and the costs of the alternatives supplied by the systems providers. As the PU market is very competitive, the companies consider they cannot compete with imports on product price and performance criteria. As outlined in the Amec report, due to competition from global suppliers and price sensitivity of EU customers, EU moulders who have implemented substitution are also unlikely to have passed on substitution costs to their customers. Most of the companies would qualify as SME and those that do not, are small sites owned by parent companies who may consider off-shoring rather than investing in substitution in the EU. Affordability for SMEs is the key determinant for the companies in terms of their ability to implement substitution. In addition given the competitive nature of the PU market, even indicating to their customers that they have regulatory issues with their current manufacture may have the effect that their customers switch to suppliers that do not have these issues (i.e. imports from outside the EU).

Six of the twelve designated SAGA companies are in the process of submitting their own application to continue use. It is not known what the remaining six companies plan to do once the review period ends for this application. As all are SMEs, the costs of preparing and submitting an application for authorisation may be limiting. It may be that they can neither afford to substitute nor apply for authorisation to continue use while seeking alternatives.

3. MONITORING OF THE IMPLEMENTATION OF THE SUBSTITUTION PLAN

Based on the answers to the questionnaire, nine of the twelve designated SAGA companies indicated to hold an ISO 9001 certification. For these companies, their quality management system (QMS) sets the basis for the execution, monitoring and documenting of the substitution work. This includes for instance the following:

- Assigning a project manager and dedicated team for the substitution work
- Conducting the substitution work according to a defined process, which has defined actors and goal
- Documenting and recording the results of reviews of the progress
- Documenting and recording of management decision at milestones
- Regular meetings between the project manager and dedicated team are held.

The remaining three designated SAGA companies indicated that they did not have ISO certification. In the questionnaire, the companies were given the possibility to select which system(s) they have in place from several given options. The answers from the companies are compiled in **Table 10**.

	Company F	Company H	Company K
Substitution project follows company project governance and quality systems relating to change management			
A project manager and team are allocated to implement the substitution project	YES		
Progress of the substitution project is documented following company policy on project management			
Progress of substitution project is reported to management	YES		YES
Regular monitoring of project milestones and deliverables is done as per company policy on project management	YES	YES	

Table 10 Systems in place at the companies without ISO certification

4. CONCLUSIONS

This report documents the substitution plans for the companies that responded to a questionnaire launched to collect the information needed to fulfil the request received from the Commission relating to this application. The information provided by the twelve companies that were designated as having a SAGA was analysed and compiled to complete the report as per the ECHA template and instructions available in guidance material.

From the information collected, the TDI/MOCA system continues to be used by a limited number of moulders who are unable to take available alternative systems into implementation at their sites. The reasons are based on the interplay between the technical and economic feasibility of the alternative systems and the highly competitive nature of the PU market in the EU and globally. Quality, cost and processing were the main reasons limiting their substitution given by all the companies. All are small sites and most would qualify as SME. Cost is a major concern for all followed by the cost/quality ratio. Ten of the twelve companies designated as having a SAGA have affordability issues that they need to overcome before they can implement substitution. Some of the issues are company specific (e.g. small company size, low profit margin, limited access to investment). Others are not within their power to influence and they will need to work-around them to find a compromise that enables them to be competitive; these are the regulatory status of MOCA outside the EU, the absence of restrictions on imports of TDI/MOCA PU products and the costs of the alternatives supplied by systems providers.

These companies need time to implement affordable solutions to substitute the TDI/MOCA system that does not render them non-competitive and therefore out of the market.

These twelve companies are small scale manufacturing bases located in 6 countries. The Amec report[7] gave as one of the options for companies for whom it is unaffordable to implement substitution was to switch roles from manufacturer to distributor of imports from outside the EU. It is therefore an open question to the Commission on the value they place on retaining manufacturing bases and in turn, manufacturing jobs in the EU. Similarly, what is the value the Commission places on ensuring SMEs do not go out of business due their inability to compete with imports that have a competitive advantage due to lower regulatory requirements outside the EU. There has been a lot of discussion on the cost of applying for an authorisation. The real cost companies face is in their implementation of substitution and it may be unaffordable for small companies.

As outlined in the Introduction, the Commission requested the submission of this Substitution Plan report following a ruling by the General Court[1] that changed the interpretation of the requirement relating to alternatives that are considered to be generally available. There have been other rulings[2,3] relating to the interpretation of the definition of intermediate use as per Art 3(15). We request that the Commission also take this ruling[3] into account in its decision on the application. We consider that the use of MOCA as a reactant in the manufacture of polyurethanes fulfils the definition for intermediate use as given in the legal text and as clarified in the rulings by the courts. Consequently, authorisation is not needed for this use.

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APPENDIXES

Appendix 1 Consultations

We ran information campaigns to collect the information needed to prepare this report from the downstream users. We circulated an information notice to all distributors and downstream users known to us and asked to share it widely. We prepared an online questionnaire in English, Italian, Spanish and French and hosted a webinar on how to complete it in early May. The online questionnaire was open for 6 weeks (up to the end of May 2020). Due to the low response rate, we ran additional information campaigns and accepted responses up to the end of July 2020. At our request, Suzhou also contacted all its customers in early July 2020 and asked them to ensure their customers completed the questionnaires. We had numerous follow-up emails with distributors since July and asked the Commission for an extension of one month to allow their downstream users to complete the survey. We closed the online questionnaire on the 10th September.

As is documented in the “Note on the representative of this report for all MOCA users covered by the application” in the Introduction, the number of survey responses was 24 and 12 of these were designated as having a SAGA and 12 were designated as not having a SAGA.

Additional appendices

Appendix 2

Figure 5 Illustrative examples of PU product types

Note that polyurethanes refer to a very broad family of polymers. The information below is taken from the public domain and the polyurethanes may be manufactured from different systems. The information is given to aid the reader with no background in polyurethanes gain an understanding of where they may be used in practice.

Example	**Description**
Rollers	Polyurethane rollers consist of a metal core surrounded by a polyurethane cover. They are integral parts of modern production lines and they are often involved, for instance, in pressing, assembling or heavy lifting operations.[19] Different types of polyurethane rollers exists, for instance: - Conveyor rollers: are typically used in high-demand manufacturing environments to transport materials from one place to another. - Drive rollers: drive conveyor belts and assembly lines. - V-rollers: have a specific V-shape and are used to transport materials. - Pinch rollers: are used to provide consistent pressure on a material while it is pulled through a machine.
Wheels	Polyurethane wheels typically consist of a metal core surrounded by a polyurethane layer. They are used in industrial settings due to their load-bearing capacity, corrosion resistance and coefficient of friction. They have the advantage of being quiet during use while limiting the stress applied on the flooring.[20]
Polishing wheels	Polyurethane polishing wheels are used in glass processing machines to grind and polish the edges of glass sheets.
Punches, foils and battens	Punches, foils and battens made of polyurethane are used in the ceramic industry. For instance, punches are used in presses to produce ceramic tiles.
Pads	Pads consist typically of a metal plate and of a polyurethane layer. They are often used in the offshore oil and gas industry, for instance, on pipe laying vessels. These vessels are used to install e.g. pipes and cables on the sea bed.
Anvil covers/blankets and rings	Polyurethane anvil covers/blankets and rings are used in the corrugated cardboard industry. For instance, anvil covers are used in rotary die cutters, which are used to cut corrugated cardboard to a given shape at high speed and with consistency.
Timing belts and power transmission belts	Timing belts and power transmission belts made of polyurethane are used in a wide variety of applications such as conveyors, portal robots, textile machines, printing machines, medical appliances, robots and door drives.
Tubes	Tubes made of polyurethane are used in various applications such as in pneumatic control systems, cable jacketing, air lines, powder and granular material transfer, fluid lines, sleeving, low pressure hydraulics and robotics.[21] The main advantages of polyurethane in these applications include its high toughness, flexibility, high load bearing capacity, electrical insulating properties and high resistance.
Floating cell rotors and stators	Polyurethane flotation cell rotors and stators can be found in mechanical flotation cells, which are used in the mining industry. Flotation cells are used to separate selectively valuable minerals from a slurry. The rotor and stator play a key role in the separation by agitating the slurry promoting the formation of fine air bubbles.

19 https://www.poly-tek.com/polyurethane-rollers-advantages-and-uses/

20 https://www.rwmcasters.com/products/wheels/polyurethane-wheels/#filter-wheel-application-any

21 https://www.medicaldesignbriefs.com/component/content/article/mdb/features/technology-leaders/21705

Appendix 3

Tonnage used by designated SAGA companies

The questionnaire collected information on the tonnage used in 2019. The compiled responses for the designated SAGA is given in **Figure 6**. The total tonnage reported was 92 tons. The median, minimum and maximum values of those reported are 6, 1 and 20 tons respectively.

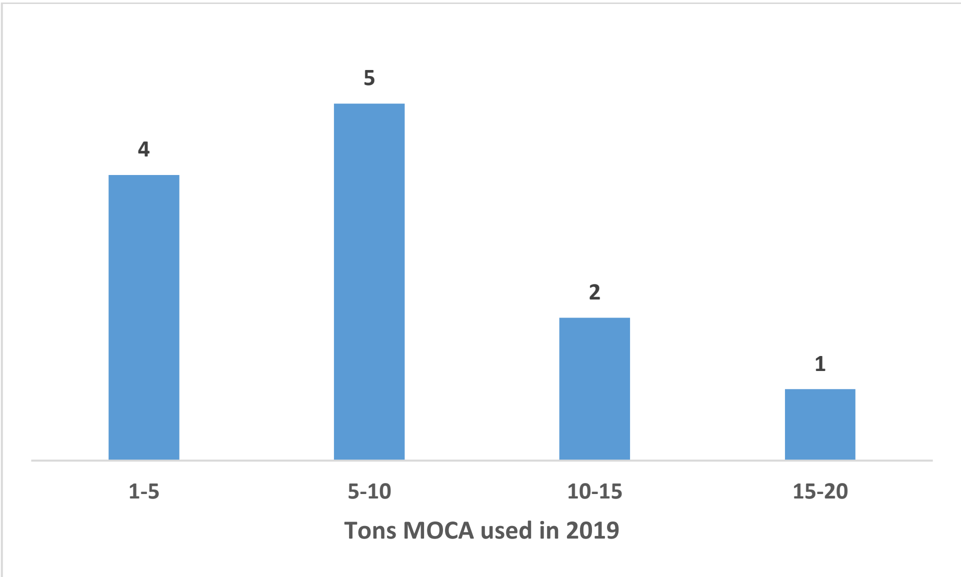

Figure 6 Volume of MOCA used in 2019 by the respondents

Appendix 4

Extracts of a technical brochure available in the public domain[12] from a systems provider that illustrates the MOCA is marketed as a curative for use outside the European Union.

Conventional MDI and TDI prepolymers

Adiprene® and Vibrathane® MDI and TDI prepolymers can be used with Vibracure® curatives to produce elastomers for a range of demanding applications with outstanding toughness, abrasion resistance, load-bearing capacity, cut resistance, and resistance to heat build-up. Selected applications include:

- Mining components where urethane offers abrasion resistance, weight and noise reduction compared to traditional materials like steel and other elastomeric materials
- Wheels where urethane carries higher loads at higher speeds with lower rolling resistance than other elastomers
- Golf balls where urethane withstands cutting by the club and provides superior distance
- Belting where urethane delivers longer lifetime due to outstanding toughness

Adiprene® and Vibrathane® MDI and TDI prepolymers are available with a wide range of polyol backbones. LANXESS scientists can work with you to customize a special formulation to achieve your ideal performance.

Adiprene® TDI Urethane Prepolymers – Selected Grades

Product Grade	Polyol	NCO%	Hardness	
			Vibracure® 2107 curative	Vibracure® A 133 HS curative (MOCA[1])
Adiprene® L42	polyether	2.65-2.95	78A	80A
Adiprene® L83	polyether	3.20-3.40	85A	83A
Adiprene® L100	polyether	3.95-4.30	90A	90A
Adiprene® L167	polyether	6.15-6.55	95A	95A
Adiprene® L200	polyether	7.30-7.70		58D
Adiprene® L315	polyether	9.25-9.65	76D	73D
Adiprene® L325	polyether	8.95-9.25	72D	72D
Vibrathane® 6007	polyester	4.00-4.52	95A	
Vibrathane® 8011	polyester	3.17-3.43	81A	84A
Vibrathane® 8083	polyester	3.20-3.50	83A	84A
Vibrathane® 8050	polyester	5.40-5.80		50D
Vibrathane® 8070	polyester	2.55-2.70		70A
Vibrathane® 8090	polyester	4.35-4.75		90A
Vibrathane® 8095	polyester	3.75-4.05		88A
Vibrathane® 9087	polyester	3.17-3.43	84A	
Vibrathane® 6060	polycaprolactone	3.20-3.50	73A	62A

[1] Note: For use outside of the European Union

Adiprene® LF TDI systems for easy processing and excellent industrial hygiene

Adiprene® LF TDI prepolymers take conventional TDI technology to the next level of performance and safety. By reducing free TDI levels to below 0.1%, these systems greatly improve workplace industrial hygiene and enable the use of PU prepolymer systems with lower viscosity, longer pot life, and faster demolding. Adiprene® LF TDI systems offer strong performance and easy processing for a wide range of applications.

Compared to conventional prepolymers LF TDI prepolymers provide:

- Reduced free TDI levels (<0.1%) greatly improve workplace safety
- Lower process viscosity reduces bubble entrapment making mixing easier
- Longer pour life allows mixed material to properly fill molds and reduce rejects
- Faster demolding improves productivity and reduces costs

Adiprene® LF TDI prepolymers are available with a wide range of polyol backbones. LANXESS scientists can work with you to customize a special formulation to achieve your ideal performance.

Adiprene® LF TDI Urethane Prepolymers – Selected Grades

			Hardness	
Product Grade	Polyol	NCO%	Vibracure® 2107 curative	Vibracure® A 133 HS curative (MOCA[1])
Adiprene® LF 800A	polyether	2.75-3.05	80A	80A
Adiprene® LF 900A	polyether	3.70-3.90	88A	90A
Adiprene® LF 930A	polyether	4.90-5.20	94A	94A
Adiprene® LF 940A	polyether	5.20-5.45	95A	94A
Adiprene® LF 950A	polyether	5.90-6.20	97A	95A
Adiprene® LF 600D	polyether	7.10-7.40	60D	60D
Adiprene® LF 601D	polyether	7.05-7.35	62D	60D
Adiprene® LF 650D	polyether	7.55-7.85		65D
Adiprene® LF 700D	polyether	8.10-8.40	72D	70D
Adiprene® LF 750D	polyether	8.75-9.05	75D	75D
Adiprene® LF 751D	polyether	8.90-9.20	75D	75D
Adiprene® LFG 963A	PPG polyether	5.55-5.85		96A
Adiprene® LFG 964A	PPG polyether	5.80-6.20		96A
Adiprene® LFG 740D	PPG polyether	8.65-9.05		75D
Adiprene® LF 1700A	polyester	2.28-2.58	73A	73A
Adiprene® LF 1750A	polyester	2.45-2.75		76A
Adiprene® LF 1800A	polyester	3.15-3.35	85A	83A
Adiprene® LF 1860A	polyester	3.55-3.85	89A	86A
Adiprene® LF 1900A	polyester	4.05-4.35	92A	92A
Adiprene® LF 1930A	polyester	4.75-5.05	95A	93A
Adiprene® LF 1950A	polyester	5.24-5.54	98A	95A
Adiprene® LF 1600D	polyester	6.10-6.40		60D
Adiprene® LF 2600A	polycaprolactone	3.10-3.50		60A

[1] Note: For use outside of the European Union

Vibracure® curatives & Duracure™ blocked curatives[1]

Curatives are an integral part of the final elastomer, so we give them careful consideration when designing the right system to meet your needs. The final elastomer is what you care about – and LANXESS scientists can work with you to customize a special curative to achieve your ideal performance.

Vibracure® Urethane Curatives & Duracure™ Blocked Curatives[1] – Selected Grades

Product Grade	Type	Usage	Appearance
Vibracure® A 120	Diol	Low hardness, high resilience	Liquid
Vibracure® A 122	Diol	Low hardness, high resilience	Solid
Vibracure® A 125	Diol	Low hardness, FDA wet food approval	Solid
Vibracure® A 133 HS[1]	MOCA[1]	Excellent color stability for TDI prepolymers	Solid
Vibracure® A 134[1]	MOCA[1]	Excellent color stability for TDI prepolymers	Solid
Vibracure® A 157	Aromatic diamine	FDA dry food approval with TDI ether prepolymers	Powder
Vibracure® A 250	Diol	For tough pPDI prepolymers	Liquid
Vibracure® A 260	Diol	Used with MDI and pPDI prepolymers	Solid
Vibracure® A 310	TMP and TIPA	For low durometer TDI prepolymers	Super cooled liquid
Vibracure® 2101	Diol	Used with MDI and pPDI prepolymers	Pellet
Vibracure® 2107	Aromatic diamine	Used with TDI prepolymers	Liquid
Duracure™ C3[1]	MDA[1]	Blocked for controllable working life	Suspension
Duracure™ C7[1]	MDA[1]	Blocked for controllable working life	Suspension
1,4 Butanediol	BDO		Liquid
MCDEA	MCDEA		Solid flake

[1] Note: For use outside of the European Union

Appendix 5

Number of sectors companies reported supplying PU parts to
The questionnaire collected information on the number of sectors where TDI/MOCA PU parts are supplied. 9 sectors were listed in the questionnaire with a 10th for "other" where there was a free text field to include sectors not listed. The answers given by each of the twelve companies is compiled in **Figure 7**. The list of sectors given in the questionnaire is given in **Figure 1**

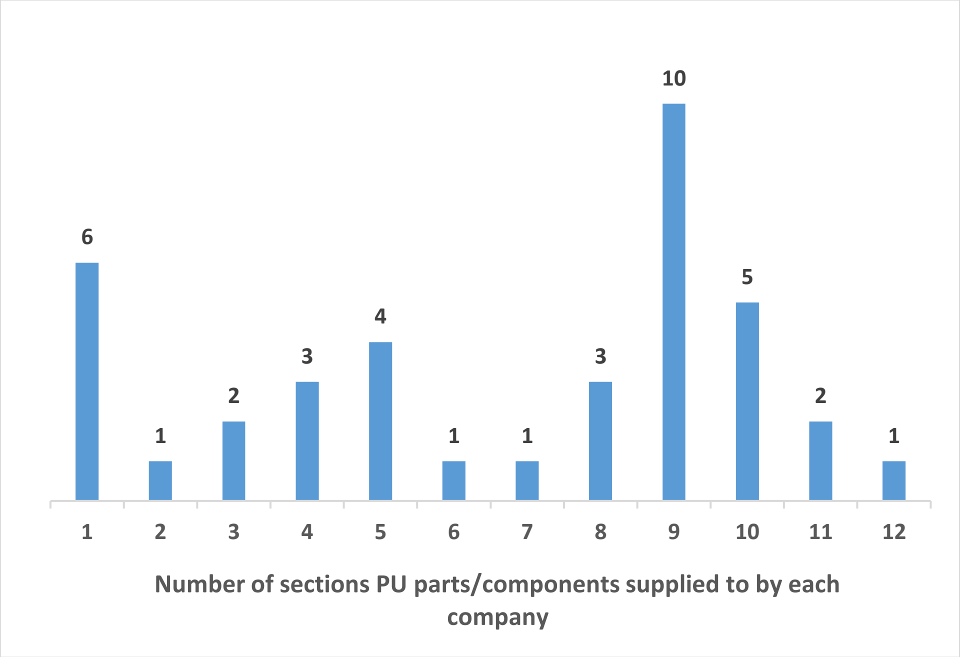

Figure 7 The number of sectors PU parts/components each company reported supplying

Appendix 6

Contribution of TDI/MOCA based PU production to global turnover

The questionnaire also collected information on the importance of TDI/MOCA based PU products to their global turnover. The responses received ranged from 10 % to 90 %. The responses are compiled in **Figure 8**. Two companies reported contributions between 35 and 45 %, three companies between 50 and 60 % and two companies between 70 and 90 %.

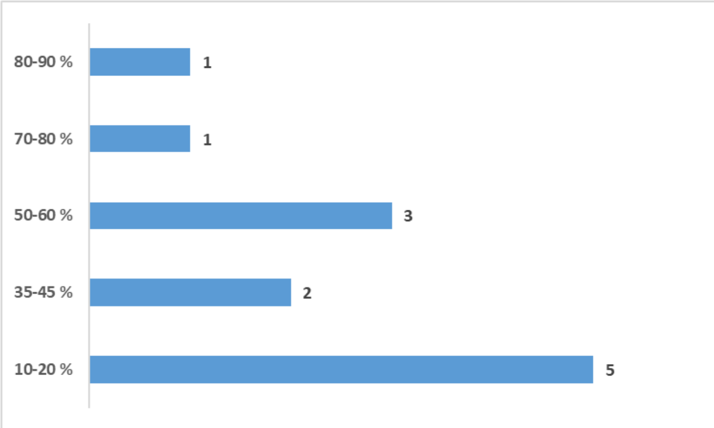

Figure 8 Compiled responses for the % contribution MOCA based products make to the responder's global turnover