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UK Chemicals Round Table – COVID-19

1 April 2020

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Supply interruptions: what are your options?

Presentation to Chemicals Round Table

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Supply interruptions: what are your options under English law?

- Various options for affected parties;
- "Force Majeure" clause;
- Doctrine of "frustration";
- Other clauses in the contract, such as "MAC" ("material adverse change") and emergency change control provisions.

Force Majeure clauses

- Force Majeure clauses generally allow a party affected by an event beyond the control of that party to suspend performance of its obligations without penalty.
- However, the wording of these clauses is critical.
- Key questions:
 - Does COVID-19 represent an event that triggers the relevant clause?
 - Look at whether the clause lists an exclusive list or non-exclusive list (e.g. a "FM Event includes but is not limited to..."
 - Does the particular event appear on the list, or is it similar to those on the list?
 - What is the impact of that party's actions in contributing to its ability to perform?
 - Generally, clauses specifically state that the event must be "out of the party's reasonable control"
 - But what if a party's travel ban has meant it is unable to perform?

Force Majeure clauses (cont.)

- Must performance be "prevented" (essentially impossible) or is it sufficient for it to be "delayed" or "hindered" for the clause to bite?
- What are the consequences of triggering the clause, in terms of what steps the affected party must take?
 - Generally there will be a notice provision requiring the affected party to provide certain information, often including details of the steps being taken to mitigate;
 - Also an affected party may be required to give regular updates as to the position.
- Will prolonged inability to perform lead to a termination right (for either party)?

Jurisdictional differences

- Common law jurisdictions (e.g. UK, Hong Kong, Singapore) fairly similar.
- Differences in civil law jurisdictions: some imply force majeure into contracts (e.g. France), some do not (e.g. Germany).
- US varies from state to state: Uniform Commercial Code may apply if no FM clause.
- Duty of good faith in civil law jurisdictions and US may be a factor.

Frustration

- The doctrine of "frustration" allows a party to treat itself as discharged from its obligations and to treat the contract as at an end.
- Only applies if it is impossible (not merely more difficult or uneconomic) to perform its obligations.
- Seems unlikely that this will apply other than in quite limited circumstances (e.g. local factory shut down by government).
- Becoming more of an option as restrictions increase.

Other options

- There may be other contractual provisions on which a party can rely to escape consequences from a failure to perform such as:
 - a "MAC" (material adverse change) clause (commonly in finance or acquisition related documents); or
 - emergency change control provisions (often in, for instance, outsourcing and IT project contracts)
- Commercial renegotiation is a possibility: other parties may have cash flow or other reasons for wanting to delay/reprogramme.
- Proactive attempts to mitigate are important in case contractual provisions do not assist or there are commercial reasons for not triggering them.
- Check if insurance applies (e.g. business interruption) and ensure notification requirements are followed.

Summary of practical tips

- Identify contracts that are likely to be affected by COVID-19.
- Review high-priority contracts to assess impact and potential relief available. Priorities might be set both on the importance of the relationship and the potential harm from COVID-19.
- Consider whether (in addition to Force Majeure) other legal avenues are available, such as Material Adverse Change (MAC)/Material Adverse Effect (MAE) clauses, price adjustment clauses or the concept of "frustration" of contract.
- Comply with contractual notice requirements where beneficial, whether in Force Majeure or other relevant clauses. The giving of notice might begin the period of relief of performance obligations or the beginning of insurance coverage.

Practical tips (cont.)

- Identify and consider utilising governance provisions to make plans and work on joint solutions. Today, it is difficult to even get the attention of counterparties, and a contractual right to attention through a governance provision may help.
- Consider communicating with counterparties regarding potential difficulties with performance and possible solutions. For example, consider sending letters to potentially affected counterparties indicating your view that the Force Majeure clause does not apply and that they thus remain fully obligated to perform. This may convince them to fully perform or, at a minimum, be good evidence in later litigation.

Practical tips (cont.)

- Consider what steps could be taken to mitigate the impact of COVID-19 on performance, and how such steps fit with contractual and legal obligations. Many laws and contracts impose upon both parties an obligation to mitigate damages.
- Work closely with other parts of your COVID-19 response team so that steps taken (such as imposing travel ban) to prioritise health and welfare are effected without violating contractual obligations. For example, be cautious about instructing individuals (or giving individuals the option) to work from home if you are contractually obligated to have those individuals working at a specific facility.

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Covid-19: Employment Issues

April 2020

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Some Key Employment Issues

- Sick pay
- Volunteering leave
- Furlough leave
- Annual leave

Sick Pay

- Deemed entitlement to SSP if isolating in accordance with Government guidance
- Payable from Day 1
- Small employers (less than 250 employees) can recover first two weeks

Emergency Volunteer Leave

- New form of unpaid leave
- Employee can take block of 2, 3 or 4 weeks
- 3 days' notice to employer

Furlough Leave

- Coronavirus Job Retention Scheme
- If employee laid off (without work), employer can recover 80% of regular wages up to £2,500
- Minimum 3 weeks lay-off
- Not apply to short-time working
- Must be employed as at 28 February 2020
- Need consent to layoff and reduce pay

Annual Leave

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- Can employers require employees to take leave?
- What if they are on furlough?
- New rules on carry-over of unused leave at the end of the year

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Chemical Round Table

Covid 19-related trade and customs developments in the EU

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Agenda

Agenda

- EU Commission guidance on legal provisions in the customs field.
- EU Commission guidance to facilitate the production of certain sanitary products, including measures taken by the European Chemicals Agency (ECHA).
- EU Commission measures and guidance in the field of the transportation of goods to contribute to supply chain efficiencies.
- EU legal provisions and guidance on the export authorizations required for certain personal protective equipment.
- European Commission Communication with guidance and requests to strengthen foreign direct investment screening by EU Member States.
- Trade barriers adopted by several EU Member States and whether they affect chemicals.

Customs facilitation

Customs-related guidance: where

• Over the last couple of days, the European Commission issued the "Guidance on Customs issues related to the COVID-19 emergency".

See: https://ec.europa.eu/taxation_customs/sites/taxation/files/covid-19-customs-guidance-for-trade.pdf

It is presented as an evolving document to be added to.

I.e.: the site should be checked regularly for new facilitation guidance.

- During the transition period, this guidance applies to the UK.
- Some guidance is referred to by way of illustration below. The illustrative examples provided might not be relevant to all, while others provided in the Guidance may be relevant for importers and exporters. Please check the Guidance.

Customs-related guidance: application for authorizations

A recommendation:

"economic operators are strongly encouraged to only apply for essential customs decisions, so that customs authorities can focus on the most urgent demands"

No clarification on what is "essential".

 This is not really a practical recommendation and will vary companyby-company.

Customs-related guidance: some payment facilities

- Some payment facilities.
- Only in case of economic or social difficulties:
 - Article 45(2) and (3) UCC allows customs to suspend the implementation of a customs decision, even without a guarantee, if it is established on the basis of a documented assessment that such a guarantee would be likely to cause the debtor economic and social difficulties;
 - Article 112(1) and (3) UCC provides that customs authorities may refrain from requiring a guarantee or charging credit interest if it is established on the basis of a documented assessment that this would create serious economic or social difficulties;
 - Article 114(3) UCC allows customs to refrain from charging interest on arrears if it is established on the basis of a documented assessment that it would create serious economic or social difficulties;
 - Article 89(3) UCC DA provides that customs shall suspend under some conditions the time limit for payment of a customs debt in relation to which there is an application for remission. When the goods subject to such application are no longer under customs supervision, customs shall not require a guarantee if it is established that providing such a guarantee would be likely to cause the debtor economic and social difficulties;
 - Article 91(2)(b) UCC DA provides for the suspension of the time limit for payment of a customs debt incurred through non-compliance, even without a guarantee, if it is established that providing such a guarantee would be likely to cause the debtor economic and social difficulties.

Customs-related guidance: some payment facilities (ct'd)

- Note the absence of a general deferment of the payment of customs duties after customs clearance.
- Latvia had announced the possibility to defer the customs duty payment.
- There were some reports that Germany might do the same.
- On 26 March 2020, the Dutch customs authorities stated that they will grant companies deferment of payment of import duties. A company needs to file a formal request if it wants to defer the payment. The deferment will ultimately apply until the 15th day of the month following the month in which the installed measures to deal with the coronavirus are terminated.

See:

https://www.belastingdienst.nl/wps/wcm/connect/en/customs/content/corona-crisis-customs-supports-entrepeneurs

Going further: rumored suspension of tariffs and VAT on protective medical equipment

- EU Governments have asked the European Commission to authorize the suspension of tariffs and VAT on protective medical equipment.
- The European Commission is reportedly considering a temporary suspension of tariffs and VAT on imports of protective medical equipment, such as protective masks and personal garments.
- Reportedly, this EU-wide relief would apply retroactively.
- Not much is known at this stage and caution should however be exercised. In particular, there is no information as to the precise scope of this possible EU-wide relief.
 - See inter alia Mlex, EU to suspend tariffs, VAT on medical equipment to fight Covid-19, 31 March 2020.
- In the meantime, the Guidance states that the present exceptional situation should be considered as a 'disaster' in the terms of Article 221 UCC DA. Therefore, all goods brought to the customs territory of the Union to counter the effects of this 'disaster', i.e. COVID-19, such as ambulances or some support medical equipment, should be eligible to be declared for temporary admission with total relief from import duty.

Going further: facilitation of customs procedures

- Facilitation of entry summary declarations and presentation of goods to customs requirement for medical, surgical and laboratory equipment for emergency treatment.
- For other goods, possibility to use copies of T2L documents when the timely presentation of the originals is impossible (essentially: a document confirming the Community status of goods transported between parts of the customs territory of the Community for carriage of goods between ports in the EU by sea or air).
- Goods in temporary storage for longer than the maximum of 90 days: if the goods fail to be placed under a customs procedure or re-exported due to circumstances related to the spread of COVID-19 disease, the economic operator may invoke force majeure. Customs authorities will assess each situation on a case-by-case basis and, when conditions so justify, apply equity in accordance with Article 120 UCC or regularize the situation of the goods in accordance with Article 124(1)(h) UCC. This should not, however, lead to a situation where the due customs duties are not paid at all for goods remaining in free circulation.

Going further: facilitation of customs procedures (Cont'd)

• In the case of transit, as regards the time-limit to present the goods at destination: economic operators can expect that the customs office of departure will take into consideration possible longer transport times due to anti-corona measures when setting the time-limit within which the goods shall be presented at the customs office of destination.

When the goods are presented to the customs office of destination after expiry of the time-limit, the customs authority may presume that the delay was not attributable to the carrier.

• Time-limits for exportation: normally, if the customs office of export has not received any information or evidence that the goods have left the customs territory of the EU within 150 days from the date of the release of the goods for the export, re-export or outward processing procedure, the customs office may invalidate the declaration concerned, in accordance with Article 248 UCC DA.

Considering the current exceptional circumstances, it is recommended that the customs office of export does not initiate such invalidation, unless it is explicitly requested by the declarant of the declaration concerned.

Facilitating the production of certain sanitary products

Facilitation of production and registration procedures

- While perhaps not directly relevant for the chemical industry, three guidance documents are briefly mentioned to the extent that companies may start producing the relevant products or are producing materials for the products concerned.
- On 30 March 2020, the European Commission made available guidance to assist manufacturers in ramping up production of essential medical equipment and material in three areas:
 - the production of masks and other personal protective equipment:

(see: https://ec.europa.eu/docsroom/documents/40521)

It helps manufacturers to assess the applicable legal and technical requirements before importing new products to the EU or launching new or reconverting existing facilities to PPE like masks, gloves and surgical gowns to satisfy the unprecedented demand including details on the applicable EU legal frameworks and the steps to take in order to be able to place products on the EU market. It also explains the role of national authorities, in particular market surveillance authorities in ensuring an adequate level of health and safety of equipment originating in third-countries, which is placed on the EU market.

Facilitation of production and registration procedures (Cont'd)

- the production of **leave-on hand cleaners and hand disinfectants**:

(see: https://ec.europa.eu/docsroom/documents/40523)

It provides guidance on the applicable legal framework for the placing on the EU market of **hydro-alcoholic gel** (i.e. the Cosmetic Products Regulation or the Biocidal Products Regulation).

the production of 3D printing:

(see: https://ec.europa.eu/docsroom/documents/40522)

It provides guidance on **conformity assessment procedures for 3D printing and 3D printed products** for medical use in the context of the coronavirus outbreak including detailing the applicable EU legal frameworks for those products and setting out examples of technical standards which manufacturers may use in order to place compliant products on the EU market.

- · A guidance on medical devices will also be made available within the coming days.
- These documents also aim to assist manufacturers and market surveillance authorities in making sure these products comply with necessary safety standards and are effective

Facilitation of production and registration procedures – ECHA's role

See the press release by ECHA on 20 March 2020

Helsinki, 20 March 2020 - ECHA is taking measures to support EU action to fight the pandemic caused by the coronavirus disease (COVID-19).

The Agency will, together with the European Commission, support Member States and industry to address shortages with the supply of disinfectants, which has become a critical issue in several EU Member States.

Bjorn Hansen, ECHA's Executive Director says: "It is essential to ensure that there are enough disinfectants available for health professionals and European citizens. The main limiting factor seems to be the availability of active substances used in these biocidal products – in particular isopropanol, 1-propanol and ethanol. We are working, together with the Commission, on special arrangements to help Member States and companies get more disinfectants on the market as soon as possible." More details about concrete actions will follow soon.

Deadlines for certain processes will also be handled flexibly, including the payment of invoices. For certain deadlines that fall between now and the end of May 2020, companies will receive an extension of two months. This applies to cases where companies have initially failed to provide a complete registration for their chemicals and were granted a final deadline between March and May 2020, as well as for requests for further information related to confidentiality claims.

An extension of 30 days will also apply for companies to comment on ECHA's draft decisions in cases where a registration has been considered incompliant with legal requirements.

More information on these arrangements will be published soon and duty holders will also be informed directly through ECHA's IT systems.

See also: https://echa.europa.eu/covid-19

Whats new

- 31 March 2020: Contact information for competent authorities now available. More
- 30 March 2020: Do you already have a disinfectant product authorised under the BPR and want to use additional sources? We are now speeding up technical equivalence assessments for propan-1-ol and propan-2-ol. More
- 27 March 2020: Q&As for companies seeking to place disinfectants on the EU/EEA market. More
- 26 March 2020: ECDC guidance to EU/EEA Member States on environmental cleaning. More
- 24 March 2020: Speeding up the supply of disinfectants. More

Facilitating the transport of goods to ensure supply chain efficiencies

European measures and recommendations in the field of transportation including "green lanes"

• On 16 March 2020, the European Commission adopted *Guidelines for border management measures to protect health and ensure the availability of goods and essential services*. They are guidelines only and not mandatory.

See: https://ec.europa.eu/home-affairs/sites/homeaffairs/files/what-we-do/policies/european-agenda-migration/20200316 covid-19-guidelines-for-border-management.pdf

- Among the Guidelines, we cite the following:
 - 1. The transport and mobility sector is essential to ensure economic continuity. Collective and coordinated action is indispensable. **Emergency transport** services should have **priority** within the transport system (e.g. via 'green lanes').
 - 2. Control measures should not undermine the continuity of economic activity and should preserve the operation of supply chains. Unobstructed transport of goods is crucial to maintain availability of goods, in particular of essential goods such as food supplies including livestock, vital medical and protective equipment and supplies. More generally, such measures should not cause serious disruption of supply chains, essential services of general interest and of national economies and the EU economy as a whole.

and

6. Member States should preserve the free circulation of all goods. In particular, they should guarantee the supply chain of essential products such as medicines, medical equipment, essential and perishable food products and livestock. No restriction should be imposed on the circulation of goods in the Single Market, especially (but not limited to) essential, health-related and perishable goods, notably foodstuffs, unless duly justified. Member States should designate priority lanes for freight transport (e.g. via 'green lanes') and consider waiving existing weekend bans.

European measures and recommendations in the field of transportation (c'td)

 On 23 March 2020, the European Commission issued new practical advice on how to implement its Guidelines for border management, in order to keep freight moving across the EU during the current pandemic.

See: https://ec.europa.eu/transport/sites/transport/files/legislation/2020-03-23-communication-green-lanes_en.pdf

- The core of this advice is phrased as follows:
 - In order to preserve the EU-wide operation of supply chains and ensure the functioning
 of the Single Market for goods, wherever internal border controls exist or have been
 introduced Member States are requested to designate immediately all the relevant
 internal border-crossing points of the trans-European transport network (TEN-T) and
 additional ones to the extent deemed necessary, as "green lane" border crossings for
 land (road and rail), sea and air transport.
 - Going through these "green lane" border crossings, including any checks and health screening of transport workers, should not exceed 15 minutes on internal land borders. The "green lane" border crossings should be open to all freight vehicles carrying any type of goods.
 - Member States should act immediately to temporarily suspend all types of road access restrictions in place in their territory (week-end bans, night bans, sectoral bans, etc.) for road freight transport and for the necessary free movement of transport workers.
 - Transport workers, irrespective of their nationality and place of residence, should be allowed to cross internal borders. Restrictions such as travel restrictions and mandatory quarantine of transport workers, should be waived, without prejudice for competent authorities to take proportionate and specifically adapted measures to minimise the risk of contagion.

European measures and recommendations in the field of transportation (c'td)

- The Commission's advice covers all products:
 - 9. The Commission recognises that some Member States wish to prioritise certain types of freight in this crisis. However, given the complex nature of supply chains and the need to ensure the free circulation of all goods, vehicles carrying any type of goods should be able to use "green lane" border crossings. The Commission is ready to explore if needed whether further measures are necessary to prioritize particular categories of goods, building also on best practices at national level, but underlines that Member States should do their utmost to keep all goods moving. Emergency transport services should be given priority at all times.

And

- 16. On all their territories, Member States should temporarily suspend all types of driving restrictions in place (week-end bans, night bans, sectoral bans, etc.) for freight transport. The suspension of these driving bans will contribute to increase the fluidity of traffic.
- 17. Member States should ensure the availability of adequate sanitary facilities and food supplies / catering for transport workers on the main transport routes. As accommodation facilities along routes are likely to be unavailable, and in order to limit exposure to contagion, Member States should consider urgent suspension of the ban on transport workers spending rest periods in vehicle cabins, in accordance with Article 14 of Regulation 561/2006⁶. For periods exceeding 30 days, in light of persisting problems, the Commission will consider favourably Member State requests for authorisation for extension of such exceptions.

Protecting sensitive industries through tougher controls on foreign direct investments ("FDIs")

The EU only recently adopted a "framework" for screening FDIs

- Regulation (EU) 2019/452 ("FDI Screening Regulation") was adopted on 19 March 2019 and will only **apply as from 11 October 2020**.
- The FDI Screening Regulation does not:
 - Establish an EU-wide screening mechanism (i.e., not U.S. CFIUS);
 - Require Member State to implement a FDI screening mechanism.
- The FDI Screening Regulation is structured around 2 pillars:
 - Minimum procedural requirements, in case Member States decide to implement a FDI screening mechanism;
 - A cooperation mechanism, through which the Member States may provide comments and the European Commission can issue opinions in relation to FDIs taking place in another Member States (whether or not that Member State has a FDI screening mechanism in place).

NB: The Member State in which the FDI is taking place <u>always</u> has the ultimate say.

The FDI Screening Regulation permits screenings on grounds of security or public order

- No general definition of "security or public order".
- The "factors" that may be taken into consideration by Member States or the Commission in determining whether a FDI is likely to affect security or public order cover the following sectors:
 - Critical infrastructure (physical and virtual), including energy, transport, water, health, communications, media, data processing or storage, aerospace, defence, electoral or financial infrastructure, and sensitive facilities, as well as land and real estate crucial for the use of such infrastructure;
 - Critical technologies and dual-use items, including including artificial intelligence, robotics, semiconductors, cybersecurity, aerospace, defence, energy storage, quantum and nuclear technologies as well as nanotechnologies and biotechnologies;
 - Supply of critical inputs, including energy or raw materials, as well as food security;
 - Access to sensitive information, including personal data, or the ability to control such information;
 - The freedom and pluralism of the media.

NB: There are also factors relating to the origin of the FDI, notably whether it is State-backed.

The FDI Screening Regulation also covers FDIs likely to affect projects or programs of Union interest

- "Projects or programs of Union interest" are exhaustively defined in the Annex to the FDI Screening Regulation and relate to:
 - European GNSS programmes (Galileo & EGNOS);
 - Copernicus;
 - Horizon 2020;
 - Trans-European Networks for Transport (TEN-T);
 - Trans-European Networks for Energy (TEN-E);
 - Trans-European Networks for Telecommunications;
 - European Defence Industrial Development Programme;
 - Permanent Structured Cooperation (PESCO).

What is the impact of COVID-19 on FDI screening?

- The COVID-19 outbreak has pervasive economic effects, which weaken EU companies and may result in an artificial lowering of their market value. As a result, EU companies may be more vulnerable to foreign takeovers.
- On 13 March 2020, the European Commission issued its *Communication on the Coordinated Economic Response to the COVID-19 Outbreak*.

This Communication warned Member States "to be vigilant and use all tools available at Union and national level to avoid that the current crisis leads to a loss of critical assets and technology"

See https://ec.europa.eu/info/sites/info/files/communication-coordinated-economic-response-covid19-march-2020_en.pdf

• Building upon this Communication, the European Commission published on 25 March 2020 a *Guidance to the Member States concerning FDIs and free movement of capital from third countries* ("FDI Guidance").

See https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.Cl.2020.099.01.0001.01.ENG&toc=OJ:C:2020:099l:TOC

The FDI Guidance refers primarily, but not only to healthcare-related industries

• The FDI Guidance recognizes that pervasive effects of the COVID-19 outbreak affect notably "healthcare capacities (for example for the productions of medical or protective equipment) or related industries such as research establishments".

Increased scrutiny is recommended in relation to acquisitions of companies in such industries due to the potential risks they may have on the EU's capacity to cover the health needs of its citizens.

NB: This appears as an implicit reaction to rumored attempt by the U.S. to acquire a German company involved in the development of a COVID-19 vaccine.

• At the same time, the FDI Guidance recognizes that potential risks goes well beyond the healthcare-related industries, so that **Member States should** exercise vigilance with regard to all strategic assets.

The FDI Guidance calls for tougher controls on FDI, going beyond the FDI Screening Regulation

- Member States are asked to either:
 - Make full use of existing FDI screening mechanisms, if they have one; or
 - Set up full-fledged FDI screening mechanisms, if they don't.
- FDI Screenings should **not depend on value**, as SMEs can be of strategic importance (notably in the field of research / technology).
- Options to regulate FDIs are <u>not</u> limited to FDI screening and can involve:
 - Mitigating measures (e.g., supply commitments; compulsory licenses; regulatory measures); or
 - Holding of golden shares.

NB: The guidance recalls the case-law relating to restrictions on free movement of capital under Article 63 of the TFEU to assist Member States when implementing restrictions

 Member States are asked to coordinate their actions in relation to FDIs which may affect the EU single market.

What is the impact of the FDI Guidance?

The FDI Guidance is not limited to the COVID-19 outbreak:

NB: In relation to the COVID 19 outbreak, the European Commission stresses that (i) public health concerns can justify screening or restricting FDIs (both under the FDI Screening Regulation and Article 63 TFEU) and (ii) FDIs affecting projects or programs of Union interest, such as future projects in response to the COVID 19 outbreak, will be subject to a closer scrutiny by the European Commission.

- The FDI Guidance is likely to have far broader political and practical effects:
 - Consensus and momentum towards tougher FDI screenings in the EU (the 26 March 2020 EU Summit welcomed the Guidance);
 - The FDI Guidance is a warning for ongoing negotiations: although the FDI Screening Regulation applies as from 11 October 2020, transactions completed in March 2020 can be subject to ex post comments and opinions until June 2021;
 - Listing the possibilities to restrict FDIs encourages Member States to be proactive in their decision to control FDIs.

How can this affect the chemical industry?

- Chemical-related industries are very likely to qualify as strategic sectors targeted by the FDI Guidance and, more generally, covered by the FDI Screening Regulation.
- In particular:
 - Chemical-related industries involved in the supply of raw chemicals for the health-related industries, but also for other critical infrastructures can be considered as supplier of critical inputs;
 - A number of chemicals are used for the development of critical technologies or listed in the Dual-Use Regulation;
 - Chemical-related industries may receive funding in the context of or participate in projects or programs of Union interest.
 - → There are numerous reasons why chemical-related industries could be considered as strategic industries, which would be subject to enhanced scrutiny in line with the FDI Guidance.

Export control restrictions on certain personal protective equipment

A response to Member States' initiatives

- The COVID-19 outbreak resulted in several Member States in a **shortage of personal protective equipment ("PPE")**, such as gloves, face shields and protective garments.
- In order to address these shortages, these Member States had started to implement national bans on exports of PPE. For certain of them, such as Germany and Poland, even transfers to other EU Member States were prohibited.
- In order to prevent further intra-EU restrictions on the free movement of PPE, while addressing the legitimate concerns of EU Member States, the EU adopted **Regulation (EU) 2020/426** on 14 March 2020 ("PPE Regulation"), which provides for EU-wide export controls on PPE.

On 19 March 2020, the European Commission amended the PPE Regulation to exclude certain countries from its scope of application.

The PPE Regulation and its amending Regulation can be found at:

https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.LI.2020.077.01.0001.01.ENG&toc=OJ:L:2020:077I:TOC

https://trade.ec.europa.eu/doclib/docs/2020/march/tradoc_158671.pdf

 On 20 March 2020, the European Commission published a Guidance Note relating to the PPE Regulation ("PPE Guidance").

See https://trade.ec.europa.eu/doclib/docs/2020/march/tradoc_158668.pdf.

The scope of the PPE Regulation

• The PPE Guidance makes clear that the PPE Regulation was adopted "with the understanding that **Member States should revoke any restrictive national actions taken**, formally or informally, concerning either exports to third countries or trade between the Member States within the Single Market, going beyond actions designed to ensure priority access to such material by those who need it most".

E.g., Germany withdrew its export restrictions on PPE as a result.

- The PPE Regulation covers **all PPE listed in Annex 1** ("Covered PPE"). This includes certain:
 - Protective spectacles and visors;
 - Face shields;
 - Mouth-nose-protection equipment;
 - Protective Garments;
 - Gloves.

The scope of the PPE Regulation (Ct'd)

- Exports of Covered PPE outside the European Union are **prohibited**, **unless** subject to an authorization:
 - Authorizations are to be granted in principle within 5 working days based on limited grounds;
 - Where Covered PPE to be exported are located in more than one Member States, all the Member States concerned must be consulted and may object.
- Exports to Norway, Iceland, Liechtenstein, Switzerland, certain overseas territories of the Member States, the Faeroe Islands, Andorra, San Marino and the Vatican City are not covered.
- The PPE Regulation applies for 6 weeks, as from 15 March 2020.
 - Measures may subsequently be extended, based on consultations between the EU Member States and the European Commission within the Safeguard Committee.

How can this affect the chemical industry?

• For the moment, the PPE Regulation **does not cover chemicals**, such as hand sanitizer, testing kits or raw materials for the production of hand sanitizers / testing kits / PPE.

Any development should nonetheless be monitored in case shortages are feared.

Indeed, the **Commission can revise the list of Covered PPE** based on "scarcity of supplies or increased manufacturing capacities allowing to alleviate shortage concerns".

• The PPE Regulation may nonetheless affect logistics and supply chains of companies which produce or source in the EU PPE that are then shipped to their companies outside the EU.

On the other hand, imports of PPE into the EU are not covered by the PPE Regulation.

Trade barriers imposed by several EU Member States

Trade-restrictive measures imposed by Member States in relation to COVID-19: Illustrations

- A number of Member States have imposed trade-restrictive measures, including the seizure of protective medical equipment, but also additional prohibitions on exports:
 - France adopted Decree No 2020-293, which provides inter alia for:
 - (i) Price controls on hand sanitizers;
 - (ii) the seizure of certain protective and surgical masks held by any public and private legal entities, including existing stocks in France, as well as those produced in France until the end of the health emergency situation in France;

Imports can be seized if above 5 million units per guarter per legal entity.

- (iii) The possibility to seize:
- any goods, services or persons necessary for any health establishment or nursing home;
- raw materials necessary for the production of face masks subject to seizures;
- any civilian aerial vehicle, as well as any person necessary for its operation, for the transportation of health products and personal protective equipment necessary to deal with the health crisis.
- (iv) Exports of hydroxychloroquine-based medicinal products and the lopinavir/ritonavir combination are prohibited, but only for wholesale distributors.
- (v) Restrictions on placing on the market / prescription of certain drugs (notably hydroxychloroquine-based medicinal products and the lopinavir/ritonavir combination).

Trade-restrictive measures imposed by Member States in relation to COVID-19: Illustrations (Cont'd)

- **Spain** adopted Royal Decree 463/2020, which provides for the seizure of goods by the Minister of Health. On that basis, the Guardia Civil reportedly seized 150,000 masks.
- The Czech Republic (i) prohibits the sale of all PPE covered by Regulation (EU) 2016 and FFP3 respiratory protection masks other than to the State of the Czech Republic / other State suppliers and (ii) restricts the prescription and dispensing of the medicinal product Plaguenil.
- **Denmark** adopted several Orders, which empower the Danish Medicines Agency to issue instructions in relation to stocks of medicinal products, intermediates, active substances and disinfectants (notably build-up of stocks, but also – for products other than disinfectants – distribution in a specified manner or rationing and rules on price increases).
- **Hungary** restricts the export of the active substance hydroxychloroguine sulphate and of medicinal products and pharmaceutical intermediates that contain the active substance hydroxychloroquine sulphate within the framework of wholesale activities in relation to medicinal products or any other distribution activities on a commercial scale.
- Slovenia adopted measures to inter alia (i) setting maximum prices for safety, protective and other medical equipment, (ii) limit the circulation agricultural products, foodstuffs and animals for the purpose of human consumption, (iii) limit the level of the price of an individual agricultural product or foodstuff, (iv) impose restrictions or prohibitions of the placing on the market of timber, wood chips and wood pellets.
- **Slovakia** restricts the exports of registered medicinal products for human use, medical devices and in vitro diagnostic medical devices, during the state of emergency in Slovakia.

This list is NOT exhaustive. Moreover, changes are frequent and should be monitored regularly. 36

Thank You

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