BUSINESSEUROPE

Deputy Secretary General
Ms.Celine Gauer
Secretariat General of the European Commission
Rue de la Loi 200
1040 Bruxelles
Belgium

21 March 2019

Re: Brexit contingency measures

Dear Ms. Gauer,

With cliff edge still not off the table less than two weeks before Brexit day, the European business community is getting increasingly concerned by the potential disruptions for citizens and businesses of a no-deal scenario. Although companies have been preparing for the possibility of no-deal, many uncertainties remain.

We appreciate the work the EU has been doing to put in place a number of contingency measures aimed at mitigating the damage of a no-deal Brexit. While these measures cannot and should not replicate the benefits of EU membership or the terms of any transition period, as provided for in the withdrawal agreement, we believe there are shortcomings that should be addressed in case the UK really leaves the EU without a deal on 30 March 2019.

After consultations with our members, we are enclosing a list with the main areas where we believe EU contingency actions and measures fall short of what is needed to limit major disruptions.

We would be happy to have the opportunity to meet you and discuss these issues in more detail.

Thank you in advance for your attention.

Kind regards,

Luisa Santos
CHAIR OF THE BUSINESSEUROPE BREXIT TASK FORCE
DIRECTOR OF INTERNATIONAL RELATIONS

BUSINESSEUROPE
168 AVENUE DE CORTENBERGH
1000 BRUSSELS - BELGIUM
Tel : +32 (0) 2 237 65 28
Fax : +32 (0) 2 231 14 45
l.santos@businesseurope.eu
www.businesseurope.eu

Shortcomings in EU Contingency Measures for a no-deal Brexit

1- Financial Services:

- Memoranda of Understanding between ESMA and the British Financial Conduct Authority must be in place by 29 March to enable financial services firms to continue to operate between the UK and the 27 EU member states. We welcome the agreement of Memoranda of Understanding (MoU) between the BoE and FCA and ESMA and EIOPA but would welcome publication of the details of these MoUs. We ask the Commission to encourage Member State Competent Authorities to follow the recommendations of the European Insurance and Occupational Pensions Authority in order to minimise any detriment to policyholders and beneficiaries from a no deal Brexit.
- The British Financial Conduct Authority (FCA) and Prudential Regulation Authority (PRA) have agreed the Temporary Permissions Regime (TPR) which will enable EEA firms to continue to operate within the UK, in the event of a No Deal, for a limited amount of time. We are concerned about the different approaches taken by EU Member States with respect to reciprocating the TPR. In some jurisdictions, there may still be areas that need to be addressed e.g. mortgages for retail and commercial customers and corporate cash management for EU based corporates.

2- Data Flows:

- As it currently stands, businesses need 'approved safeguards' (e.g. standard contract clauses) in place for third-country personal data transfers in case of a no-deal scenario. Therefore, there appears to be an increased risk of cost for business to put such safeguards in place under a 'no deal' scenario until an agreed mutual adequacy decision on data flows post-Brexit materialises. There may also be insufficient administrative and legal capacities to restructure e.g. existing contracts in time in case of a no-deal Brexit.
- The issue of EU-UK data flows is mentioned in the November European Commission contingency planning note which states that 'In the case of a no deal scenario, as of the withdrawal date, the transfer of personal data to the United Kingdom will become subject to the rules on international transfers in application of the General Data Protection Regulation (EU) 2016/679, Directive (EU) 2016/680 for the law enforcement sector and Regulation (EC) 45/2001'. The

AV. DE CORTENBERGH 168
BE-1000 BRUSSELS
BELGIUM
VAT BE 863 418 279

BUSINESSEUROPE a.i.s.b.l.
WWW.BUSINESSEUROPE.EU
Follow us on Twitter @BUSINESSEUROPE

TEL +32(0)2 237 65 11
FAX +32(0)2 231 14 45
E-MAIL: main@businesseurope.eu
EU Transparency register 3978240953-79

Commission also stated that 'the adoption of an adequacy decision is not part of the Commission's contingency planning [for a no-deal scenario]'. The Commission and European data protection authorities should step up awareness/guidance efforts to help businesses, particularly SMEs who may have less resources in preparing for this issue.

- We would like the EU and UK to work together to deliver a robust mutual adequacy decision on personal data transfers as a sustainable long-term solution (as indicated in the Political Declaration on the Future Framework). Until that decision is taken, a standstill non-enforcement arrangement to avoid a cliff-edge in the movement of personal data needs to be agreed. The Commission could take a lead on this in the political signals it sends to Member State DPAs as it did during the period when Safe Harbour was struck down in 2015.

3- Ownership and Control Rules in Aviation:

- The Commission's actions in this area may not be enough to prevent disruptions in the European aviation sector.
- Under the EU no-deal regulations for aviation safety and connectivity, Member States have a number of responsibilities to implement the regulation. For example, transfer of licences, issuing of route licences and foreign carrier permits where applicable, system for flight plans to be submitted and approved, etc. In its work with Member States in their preparations for no deal, the Commission should monitor quality and timeliness of implementation.
- The potential Brexit consequences due to the current ownership and control restrictions should be monitored.

4- Customs and Borders:

- Governments must continue communicating with businesses of all sizes what the changes on day one will be, what impact this will have on businesses and how they need to prepare. Where possible government should look to support businesses to build customs competence.
- Considering the high level of complexity in this area and the number of measures businesses must take in preparation in a very short period of time, authorities in the EU and the UK should be pragmatic and act in good faith when, though not fault of the business, possible errors and unwanted infringements occur.

- The administrative requirements and steps related to the authorizations granted that will expire and need to be renewed should be clarified.
- Both sides should continue to share trade and customs-related data, potentially via Intrastat to ease the burden on business.
- Regarding border checks on people, measures have been put in place at EU level (e.g. recognition of the UK for the purposes of one-stop security), but the effectiveness of no deal measures will depend on Member States. The Commission should monitor Member State implementation in this area to ensure that borders continue to work smoothly, and business is not obstructed.

5- Workers:

- Posted EU workers in the UK have another legal status than EU citizens in the UK. The same goes for posted UK workers in the EU. This is because posted workers do not change their legal basis to the one of the country they are posted in. They therefore risk having to leave on 30 March with consequences for them and for their company. Thus, it needs to be mutually agreed that they can continue until the end of their posting period or the end of the service contract.
- The European Commission should urge pragmatism on UK nationals falling under EU27 Member State national immigration rules and vice versa.

6- Pharmaceuticals:

- The responsibility for all pharmaceutical products authorised by a UK competent authority must be transferred to the national competent authority of another EU Member State after Brexit.
- It is currently unclear, what will happen if a competent authority will not be able to approve all applications that have been made within the set timelines before March 30th.
- There will likely be a limited number of products at risk of supply shortages as the 30 March deadline will not be met, mainly for reasons outside of companies' control (e.g. lack of suitable testing laboratory facilities within the EU27).
- EU and UK policy makers should take measures to ensure uninterrupted access to medicines. This includes ensuring there are no delays for medicines at the borders (e.g. by encouraging co-ordination of contingency plans; prioritizing lifesaving medicines and treatments with a shelf life of less than 24 hours; exempting

medicines, clinical trial materials and Active Pharmaceutical Ingredients from customs checks; completing paperwork and regulatory checks away from the border, with the necessary infrastructure in place) as well as necessary measures to recognise UK based testing until permanent mutual recognition agreements can be agreed upon.
- Measures should be taken to enable the continued UK participation in key data sharing platforms that protect public health and medicines safety in Europe.

7 Energy:
- EU regulators should approve new Market Access Rules to ensure the bi-directional flow of electricity via interconnectors to and from both Great Britain and Northern Ireland, acknowledging the unique differences between both systems. The former is a non-synchronous DC connection between two wholesale markets, whereas the latter is a synchronous AC connection within a single wholesale market. The current trading rules are therefore quite different.
- The UK should continue to be coupled with the Pan European Day Ahead market for at least 9 more months.
- A substantial portion of Ireland's natural gas supply will continue to be transported through the twinned Moffat Interconnector. Conceivably, gas may one day also need to flow in the opposite direction. Market rules for daily trading between the UK and Irish balancing points therefore need to be robust. The same consideration applies to daily trading between Bacton and Zeebrugge, for instance.

8 Agri-food Industry:
- Simplified customs clearance for agri-food products, which could be held in the operator's facilities.
- Temporary measures to allow goods traded before Brexit to be marketed after 29 March until they are exhausted.
- A grace period providing continued recognition of existing approvals for products of animal origin traded between the UK and EU.
- Keeping the full access of the UK to the Rapid Alert System on Food and Feed (RASFF) and the Administrative Assistance and Cooperation System (AAC) to avoid fraud.
- A grace period of at least 18 months allowing the continued use of EU labelling, certification schemes (SPS – phytosanitary, food safety

and otherwise) and EU proprietary marks including Organic logos, health marks, the EU flag and 'do not eat' symbols for agri-food and drink products traded between the UK and EU.

- Clarification of the legal obligation to "establish a business address" in the EU for use on food and drink product labels.

9 Chemicals:

- More than 1000 substances are only registered by British companies in the European Chemicals Agency. To keep these substances legally on the EU-27/EEA market, UK-based manufacturers and formulators either need to transfer their business to, or appoint an only representative in, one of the EU-27/EEA countries by 29 March. As this may not be sufficient, the EU should grant a grace period of 180 days for this procedure.
- While necessary and helpful, there are some cases in which measures announced by ECHA will not be sufficient. For instance, when there are products imported by British companies and then imported by European companies.
- In these cases, EU27/EEA downstream users will become new REACH importers and will need to register immediately after 29 March, lacking the time and resources to do so. To prevent supply chain disruptions for these users, further adaptation measures from the European Commission need to be taken. These measures should be comparable to those provided for in the UK, e.g.:
    - Notification by EU27/EEA businesses of EU REACH registrations currently held by a UK business within 180 days with full registration at a later date to guarantee continuity;
    - Notification of authorisations currently held by a UK business which EU27/EEA downstream users are dependent on;
    - Notification should not incur any fee.
- Activating the Director's Contact Group solutions for REACH registration deadline could provide some solutions and send an important signal. This has already been done in the past when there was a deadline for registration under REACH, e.g. on 31 May 2018, and requires a political decision without modifying any legislation.

10. Medical Technologies:

- Under existing EU legislation, medical devices need to be certified by a notified body. UK notified bodies play a central role in this certification, covering between 30-40% of medical devices used in the EU. However, in key fields such as emergency and routine care, the role of UK notified bodies is even more important as they cover over two thirds of all devices used in the EU, for instance in: Tests to ensure the safety of the blood supply (IVDs), Orthopaedic implants (knee and hip replacements in particular), Surgical sutures and Ophthalmology. Without a valid certification it would no longer be legal to place these products on the EU market, potentially leading to shortages and disruptions for healthcare delivery and more specifically, blood supply.
- In the absence of a European approach, national authorities across the European Union are taking measures to address the situation and safeguard national healthcare systems. However, these measures are not consistent. Some Member States consider that only specific derogations will be granted and even then, in only in very narrow cases. Other member states seek to implement a systemic approach to mitigate the impact. Such a disjointed approach will inevitably create disparities in patient care across the EU and cause significant disruption of the internal market. We are urging the Commission to advocate for a consistent European approach and recognition of UK notified body certificates in the EU post 29 March.
- Measures should be taken to enable the continued UK participation in key data sharing platform EUDAMED, that protects public health and medical technology safety in Europe.