

21 February 2018

TF50 (2018) 32 – Commission to EU 27

Subject: Internal EU27 preparatory discussions on the framework for the future relationship: "Regulatory issues"

Origin: European Commission, Task Force for the Preparation and Conduct of the Negotiations with the United Kingdom under Article 50 TEU

Remarks: These slides are for presentational and information purposes only and were presented to the Council Working Party (Article 50) on 15 February 2018. The contents are without prejudice to discussions on the framework of the future relationship.

In December 2017, the European Council invited the Council (Art. 50) together with the Union negotiator to continue internal preparatory discussions on the scope of the future EU-UK relationship. The slides support those discussions. They are based on the April European Council guidelines which continue to apply in their entirety.

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Internal preparatory discussions on framework for future relationship

Regulatory issues

- **Regulatory issues in context**
- **Regulatory issues in free trade agreements**
 - **Automotive sector**
 - **Chemicals - REACH**
- **Trade in agri-food products, sanitary & phytosanitary provisions**

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15/02/2018

Internal preparatory discussions on
framework for future relationship

Regulatory issues in context

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The EU's and Internal market's Ecosystem

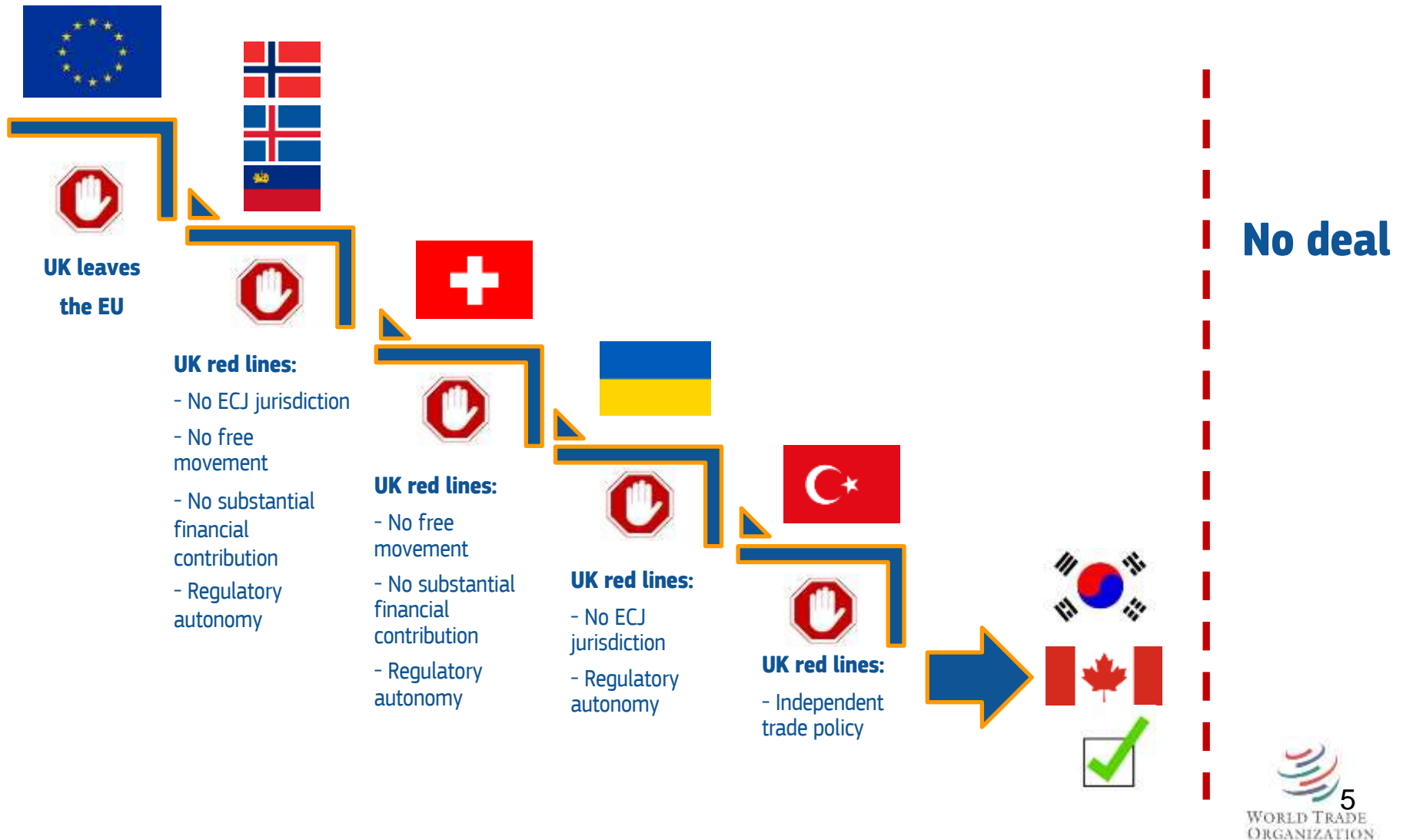
- Union policies and actions, including the Internal market with its four freedoms, form a unique ecosystem underpinned by instruments and structures that cannot be separated from each other
- The EU ecosystem:



European Council Guidelines – principles for the future relationship

- A third country cannot have the same rights and benefits as a member of the Union, as it does not live up to the same obligations.
- A balance of rights and obligations.
- Preserve integrity and proper functioning of the Single Market.
- Preserving the integrity of the Single Market excludes sector-by-sector participation.
- Access to the Single Market requires acceptance of all four freedoms.
- Avoid upsetting existing relations with third countries.
- Ensure a level-playing field.
- Should safeguard financial stability in the Union and respect its regulatory and supervisory regime and standards.
- Preserve Union decision-making autonomy and the role of the CJEU.

Future relationship and UK red lines



Single Market vs Free Trade Agreements

	Single Market	Free Trade Agreement
Scope	Indivisible four freedoms: goods, services, capital, persons	No holistic approach: limited opening, varying per area (goods, services, investment, public procurement)
Integration method	Principle of free movement	Targeted removal of barriers to trade
	Regulatory union (pooled sovereignty) <ul style="list-style-type: none"> - Prohibition of restrictions - Harmonisation of rules - Mutual recognition by default 	Regulatory autonomy (two separate regulatory spaces) <ul style="list-style-type: none"> - Access to market requires full compliance with host State rules - Regulatory cooperation on voluntary basis
	Distinct legal order; primacy and direct effect of EU law	International law; no direct effect
Decision-making	Mostly by qualified majority for secondary legislation	Mutual agreement only
Supervision & enforcement	<ul style="list-style-type: none"> - Commission, EU regulatory agencies, Member State supervisory authorities, cooperation networks - Court of Justice of EU, Member State courts 	<ul style="list-style-type: none"> - Joint Committee, specialised committees - State-to-State dispute settlement - Investment Court System
Remedies	Compliance, lump sum/penalty payments, damages (to private parties)	Suspension of obligations, compensation, damages (to investors)

Single market vs FTA

Illustration - Goods

Single Market

- Free movement
- EU Customs Union
 - No customs duties between MS
- No quantitative restrictions
- Regulatory integration
 - Harmonised areas: full EU-level harmonisation of product rules and compliance methods
 - Non-harmonised areas: mutual recognition of national rules
- No border controls in intra-EU trade
- Integrated regulatory, supervisory, judiciary and enforcement system

Free Trade Agreement

- No general free movement; customs controls and procedures
- Market access
 - Elimination of most duties over time
 - Some quantitative restrictions
- Access requires full compliance with host state rules
 - No harmonisation
 - No mutual recognition/equivalence of substantive rules; limited mutual recognition of conformity assessment results with host rules
- Regulatory cooperation always on a voluntary basis
- Each side retains right to regulate
 - Some general rules framing regulation ("rules on rules")

EU Customs Union vs customs cooperation

Illustration – customs

EU Customs Union

- Borderless internal market through EU customs union and internal market
- Mission of EU customs: supervision of international trade **and** implementation of external aspects of internal market
- Union Customs Code
 - Common customs procedures
 - Common Risk Management Framework
 - Trade facilitating measures, e.g. simplified procedures and authorised economic operators
- Union IT systems and databases

Third country/FTA

- Customs border: customs controls and procedures apply
- Customs Cooperation to mitigate burden of customs controls and procedures
 - Mutual recognition of authorised trader programmes (Japan, USA)
 - Mutually agreed customs security measures (Switzerland, Norway)
 - Mutual recognition of risk management techniques (USA)
 - Establish channels of communication for exchange of information (China) between customs authorities

Single market vs FTA

Illustration – Services

Single Market

- Fundamental freedoms
(*dismantling national barriers*)
 - Services
 - Establishment
 - Capital
 - Persons
- Sectoral liberalisation
 - Services Directive
 - Sector-specific legislation
(harmonising conditions for the provision of services)
 - Country-of-origin approach/mutual recognition

Free Trade Agreement

- Differentiated liberalisation:
 - Open on establishment (but e.g. no direct branching financial services)
 - More limited for cross-border provision of services and movement of staff (only temporary)
 - Based on existing levels of openness
- Sectoral exclusions to market access; reservations; exceptions
- Access requires full compliance with host state rules
 - No harmonisation of rules
 - No mutual recognition of rules
- Each side retains right to regulate
 - Some general rules framing regulations ("rules on rules")

Regulation and access conditions under FTAs - limited differences between goods & services

	GOODS from 3rd countries	SERVICES from 3rd countries
Tariffs	Removal of (most) tariffs	Tariff removal irrelevant (no tariffs)
Rules on goods/ services	EU rules - Host State principle No mutual recognition with 3 rd countries	
Proof of compliance	Conformity with EU products rules (in some cases, authorisation/approval by EU (or EU MS) authorities or certification by 3 rd party, e.g. Notified Bodies, is needed) (host State principle). No mutual recognition of 3rd country certificates (compliance with 3 rd country rules irrelevant), but possible in some cases (e.g. CETA) to accept that 3 rd country conformity assessment body certifies compliance with EU rules.	EU national authorities certify compliance with EU MS professional qualifications (host State principle). No mutual recognition of third country professional qualifications , but framework for possible convergence. EU Member State specific procedures for recognition of 3 rd country professional qualifications.
Licences / authorisations	EU rules on licences or authorisations (where required, e.g. because of high-risk products or wider policy objectives)	
	(e.g. health & safety /environment) <ul style="list-style-type: none"> • Certain chemicals (pesticides etc.); • Pharmaceuticals • Certain manufacturing sites 	(e.g. financial stability) <ul style="list-style-type: none"> • Some financial products • Financial services providers
Competent Authorities	EU (or EU national) authorities deliver licences or authorisations (no mutual recognition with third countries).	
Supervision	EU institutions & bodies and EU national authorities (no reliance on third country authorities).	

European Council guidelines: implications for regulatory issues (1/3)

- **Principles:** cannot have same rights and benefits as a member, as it does not live up to the same obligations. Balance rights / obligations.
- **Implications:**
 - FTA partners do not have obligations derived from Union instruments and structures, such as:
 - Pooling of regulatory autonomy, qualified majority voting;
 - Competition/state aid disciplines;
 - Accepting primacy and direct effect of EU law; and the role of the CJEU.
 - As a result, internal market regulatory tools don't work for FTAs:
 - No harmonisation through new rules to apply between the parties
 - No mutual recognition of substantive rules, autonomy of regulatory approval: e.g. Cars; Chemicals; Pharma; SPS area
 - However, full dynamic alignment with EU acquis, coupled with structures and instruments implying same obligations has been tried
 - EEA → governance adapted to internal market ecosystem for EEA purposes; challenge of backlog (e.g. financial services)
 - EU-Switzerland → unsatisfactory governance; thus need to upgrade before further market access

European Council guidelines: implications for regulatory issues (2/3)

- **Principles:** Integrity and proper functioning of the Single Market. Acceptance of all four freedoms. Preserving the integrity of the Single Market excludes sector-by-sector participation.
- **Implications:**
 - FTA partners may only have access to the Single Market to the extent its integrity and proper functioning are preserved, including across all four freedoms.
 - As a result, internal market regulatory tools are not available in FTAs; full dynamic alignment in only specific sectors or individual Single Market freedoms insufficient to preserve the Single Market:
 - **DCFTA (Ukraine):** no full single market benefits; benefits not applied in practice, and subject to autonomous EU decision. Requires involvement of CJEU for questions of interpretation of EU law. Specific context: convergence towards EU
 - **EU-Switzerland:** unsatisfactory governance, including to ensure full dynamic alignment, thus need to upgrade including regarding role of CJEU before further market access. Specific historical context: convergence towards EU/EEA.

European Council guidelines: implications for regulatory issues (3/3)

- **Principles:** Ensure a level-playing field; safeguard financial stability and respect regulatory and supervisory regime and standards. Preserve Union decision-making autonomy and the role of the CJEU.
- **Implications:**
 - FTA partners may only have access to the Single Market that is commensurate to relevant level playing field risks. Union decision-making autonomy and CJEU are always fully preserved.
 - Agreements with specific level playing field risks contain more ambitious level playing field provisions.
 - FTAs fully preserve Union decision-making autonomy:
 - Mutual recognition of certain conformity assessment results in some areas
 - No mutual recognition of substantive rules, autonomy of regulatory approval
 - FTAs fully preserve role of the CJEU: dispute settlement mechanisms do not interpret EU law or bind EU to particular interpretations

UK views – regulatory issues in the future relationship

- **Objective:** "Greatest possible" tariff-and-barrier free trade in goods and services, while ensuring regulatory autonomy, and no ECJ.
- "...take in single market arrangements in certain areas" such as motor vehicles and financial services (*Lancaster House speech*);
- "Both sides have regulatory frameworks and standards that already match"..."prioritise how we manage the evolution of our regulatory frameworks"(*Article 50 notification*)
- Reference to the "creative arrangements" the EU has developed with neighbouring countries (*Florence speech*)
- "New ways of managing our interdependence" (*Florence Speech*):
 - Areas where the EU and the UK "want to achieve the same goals in the same ways"
 - Areas where the EU and UK "share the same goals but want to achieve them through different means"
 - Areas where the EU and the UK "may have different goals"

Conclusions:

- UK views on regulatory issues in the future relationship including "three basket approach" are not compatible with the principles in the EuCo guidelines:
 - **Autonomy of EU decision-making:** if UK seeks to preserve influence over EU rule- and decision-making → risk to unsettle EU "ecosystem"; no "gradation" possible (in, or out); no "EU-UK co-decision" possible.
 - **Preserving the role of the CJEU:** if reliance on EU law concepts, CJEU must have a role → but even if CJEU role preserved, risk for EU in the absence of full EU "ecosystem"; no same effectiveness in enforcement.
 - **Preserving the integrity and functioning of the internal market, no sector by sector approach/ensure level playing field:** if UK aspires to cherry pick → risk for integrity and distortions to proper functioning of internal market, aggravated by absence of full EU "ecosystem" (including regulatory, supervisory, enforcement tools, with CJEU on top) and by proximity and level of economic integration; predictability for business to suffer.
 - **Avoid upsetting existing relations with third countries:** risk to undermine relations with countries participating in the internal market (EEA)

Internal preparatory discussions on
framework for future relationship

Regulatory issues in free trade agreements

AD HOC WORKING PARTY ON ARTICLE 50 (*Seminar mode*)

15/02/2018

FTAs – Regulatory pillar

Main elements in EU Free Trade Agreements

- Horizontal disciplines and mechanisms
 - Good regulatory practices
 - Regulatory cooperation
- Goods
 - Technical barriers on trade (TBT) chapter
 - Sanitary and phytosanitary (SPS) chapter
 - Sectoral annexes for certain regulated sectors
- Services
 - Limited provisions in sectoral chapters (*cf. Seminar on services*)

→ Building on WTO agreements

FTAs – Good regulatory practices

- Relatively **new** chapter in EU FTAs (e.g. CETA, Japan)
- **Objective:** ensure that all stakeholders are able to anticipate legislative changes and their views are taken into account in the regulatory process
- **Provisions** laying down best practices for the entire regulatory cycle:
 - Publication of regulatory agendas
 - Early information of expected regulatory measures
 - Public consultations
 - Impact assessments
 - Retrospective evaluations

FTAs – Regulatory cooperation

- **Objective:**
 - Create opportunities for cooperation between regulators to enhance compatibility of measures
 - Prevent and address unnecessary barriers to trade and investment
- Fully preserves the **right to regulate**
- **Voluntary** in nature, no binding outcome
- In areas where cooperation is agreed:
 - Exchange of information and discussion during appropriate phases of the regulatory process to increase compatible approaches
 - In relevant international fora: identify common approaches and cooperate

FTAs – Regulatory cooperation in goods

- Voluntary information exchanges and cooperation on upcoming regulatory measures
→ e.g. *EMA-U.S. FDA cooperation on pharmaceuticals*
- Cooperation (e.g. joint initiatives) in international fora
→ e.g. *EU-US-Japan trilateral cooperation in UNECE 1998 in the area of cars*
- Recognition of certain SPS conditions
e.g. food hygiene in food manufacturing

(cf. upcoming sector-specific presentations)

FTAs – Chapter on Technical Barriers to Trade

Builds on WTO TBT Agreement but goes beyond:

- Defines international standards and promotes alignment to them
- Promotes conformity assessment procedures proportionate to the risk (e.g. manufacturer's self-declaration of conformity in low risk areas)
- Sets requirements in cases where third party certification is used
- Provides for limited mutual recognition of results of conformity assessment with the rules of the importing party.
- Increases transparency in the development of technical regulations
- Marking and labelling provisions to facilitate trade
- Consultation mechanism to address specific trade concerns

FTAs – Chapter on Sanitary and Phyto-Sanitary measures

Builds on the WTO SPS Agreement but goes beyond:

- Avoids undue delays for regulatory and administrative market access procedures
- Sets up the basis for recognition of SPS conditions
- Sets up trade facilitation mechanisms: pre-listing of establishments, recognition of regionalisation, export authorisation and certification procedures, limitation of audits and related costs, inspections and checks
- Increases transparency and the exchange of information on SPS measures
- Enhanced bilateral cooperation and consultation mechanism
- Reaffirms the Precautionary principle

FTAs – Sectoral annexes for certain regulated sectors

Cars, Pharmaceutical Good Manufacturing Practices (GMP), Chemicals, Wines and Spirits, Consumer Electronics

→ In no case do these Annexes deliver single market treatment

Generic Objectives:

- Promote compatibility and convergence of regulations based on international standards and enhance regulatory cooperation
- Avoid undue delays for regulatory and administrative market access procedures
- Avoid unnecessary duplication of testing/certification requirements/audits
- Facilitate trade by recognising GMP certificates/inspections/labels
- Prevent the creation of new barriers which could nullify benefits of the FTA
- Limited recognition of home requirements as equivalent to EU requirements

Regulatory cooperation in industrial goods with European and neighbourhood countries

Deep and Comprehensive FTA with Ukraine (1/2):

- **Context: convergence towards EU**; support for necessary domestic regulatory reforms
- Promote **regulatory alignment towards specific parts of EU acquis for industrial goods**:
 - **EU Member State-equivalent requirements, long preparatory process** supported by EU technical assistance (analogy with accessions)
 - Detailed **timetable for alignment** covering **some 30 EU acts**
 - Horizontal (framework) legislation and policies on industrial goods (conformity assessment, standardisation, accreditation, market surveillance, general product safety, product liability, metrology)
 - Vertical (sectoral) legislation: New Approach legislation providing for CE marking (e.g. electrical equipment, machinery, toys, gas appliances, etc.)
 - Similar provisions in DCFTAs with Moldova and Georgia

Regulatory cooperation in industrial goods with European and neighbourhood countries

Deep and Comprehensive FTA with Ukraine (2/2):

- **EU autonomous decision** whether full alignment is achieved
- Possibility to conclude **Agreement on Conformity Assessment and Acceptance of Industrial Products (ACAA)** in aligned sectors:
 - **Products compliant with UA's aligned legislation** covered by ACAA **accepted** in the EU **as compliant with corresponding EU legislation** (and vice-versa)
 - **Full participation in EU regulatory ecosystem, including dynamic alignment and preserving role of CJEU**
 - **No general free movement clause** beyond specific ACAA scope
 - ACAA also available in pre-accession phase and relations with Southern Neighbourhood countries
 - ACAA preparations started with Southern Neighbourhood countries more than 10 years ago based on Association Agreements with EU (but with no detailed roadmap like Ukraine): limited progress, only example so far is ACAA with Israel covering Good Manufacturing Practice for Pharmaceuticals

Regulatory cooperation in industrial goods with European and neighbourhood countries

Trade with Switzerland in industrial goods (1/2):

- **Specific historical context: convergence towards EU/EEA.**
- **Mutual Recognition Agreement in relation to conformity assessment:**
 - **Where equivalence of substantive rules is granted, it is assessed by the EU based on Swiss full alignment with relevant acquis** (horizontal [framework] legislation + vertical [sectoral] legislation)
 - 20 sectorial chapters listing relevant EU and Swiss legislation:
 - 15 New Approach sectors (CE marking legislation, e.g. electrical equipment, machinery, toys, gas appliances, etc.)
 - 5 additional sectors: Motor vehicles, agricultural and forestry tractors, Good Laboratory Practice for the testing of chemicals, Good Manufacturing Practice for pharmaceuticals, biocidal products

Regulatory cooperation in industrial goods with European and neighbourhood countries

Trade with Switzerland in industrial products (2/2):

- **Mutual Recognition Agreement in relation to conformity assessment** (continued):
 - **Products compliant with Swiss aligned legislation** covered by MRA equivalence provisions **accepted** in the EU **as compliant with corresponding EU legislation** (and vice-versa)
 - **Unsatisfactory governance: no provisions on dynamic alignment and preservation of role of CJEU**
 - ❖ Heavy maintenance required: static agreement, each change in relevant EU acquis requires new EU equivalence assessment of amended Swiss legislation by EU side and decision by MRA governing body amending relevant sectorial chapters
 - **No waiving of border controls & no free movement clause** beyond specific MRA scope

Internal preparatory discussions on
framework for future relationship

Automotive sector

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15/02/2018

Internal Market for Automotive: an integrated regulatory area

Scope	Motor vehicles (cars), agricultural and forestry vehicles, light category vehicles, and non-road mobile machinery (NRMM)
Integration method	<p>Full harmonisation of requirements for the approval of vehicles, components, systems and technical units.</p> <p>Ascertainment of conformity with EU law:</p> <ul style="list-style-type: none">• Competent EU national authorities issue "EU Type Approvals"• Manufacturer issues a "Certificate of Conformity" with EU-approved type for each vehicle to be placed on the market. <p>Mutual recognition:</p> <ul style="list-style-type: none">• Nationally-issued EU Type-Approvals valid throughout the EU (as basis for Certificate of Conformity issuance)
Supervision	<ul style="list-style-type: none">• EU Type-Approval authority responsible for conformity of production (wherever production is located) and for the implementation of corrective measures (including recalls) resulting from market surveillance• In-service conformity – ensured by manufacturers• Cooperation networks between Member States
Enforcement & Remedies	<ul style="list-style-type: none">• Member State approval authorities; Commission• CJEU, Member States courts• Withdrawal of approvals, corrective measures, including penalties, recalls.

Consequences of the UK becoming a third country

- UK leaves the EU's integrated regulatory and supervisory system
- UK Type-Approval authority no longer an EU authority:
 - **Can no longer issue new approvals or revisions/extensions of existing approvals (loss of competence under EU law)**
 - **Can no longer perform any supervisory functions or activities in relation to existing approvals (e.g. conformity of production, implementation of corrective measures resulting from market surveillance)**
- End of recognition of UK Type-Approvals – no mutual recognition
- Vehicles placed on the market after withdrawal date must be accompanied by a Certificate of Conformity referring to an EU Type-Approval issued by a competent (EU-27) authority.

Implications of UK withdrawal for the automotive sector

Phases/scenarios

Aspects to consider

TRANSITION

- (Regulatory aspects of) **Market Access** (Certificate of conformity based on EU[27] Type-Approvals)

FUTURE

- **Supervision** (conformity of production, market surveillance)
- **Enforcement** (withdrawal of Type-Approvals, corrective measures, recalls)

PREPAREDNESS

For the UK becoming a third Country,
including in a no deal scenario

Transition (1/2)

If TRANSITION AGREEMENT WITH UK reached
(EUCO guidelines 15/12/2017 and negotiation Directives 29/01/2018)

UK applies **all acquis and keeps participating in the Single Market** for a limited period

- ✓ Status quo would be maintained, i.e.:
 - ✓ Harmonized rules on market access and market surveillance - Mutual recognition of Type-Approvals and tests
 - ✓ Level playing field (e.g. State Aid control)
 - ✓ Single supervision and enforcement (Commission, national authorities, Member State cooperation networks, CJEU)

Transition (2/2)

- **Assimilation of UK to EU Member State** but need to specify precise perimeter:
 - **UK no longer part** of the EU institutions, agencies and bodies
 - UK invitation to meetings of committees or Commission expert groups and other similar entities or of the agencies, offices or bodies where Member States are represented **only exceptionally on a case-by-case basis** and without voting rights
- **External effects** of UK becoming a third country:
 - UK remains bound by the **obligations stemming from EU agreements**
 - UK should no longer participate in bodies set up by those agreements

Options for the future

❌ Internal Market

- EU acquis
 - Motor vehicles – Dir 2007/46/EC
 - Light category vehicles – Reg 168/2013
 - Agricultural and forestry vehicles – Reg 167/2013
 - Non-Road Mobile Machinery – Reg 2016/1628
- Enforcement/CJEU
- Competition rules
- State Aid acquis



✅ External relations

FTA:

- No mutual recognition of non-UNECE based type approvals
- Joint-commitment to UNECE harmonisation work (domestic incorporation of UNECE regulations, promotion of harmonisation work)
- Voluntary bilateral industrial and regulatory cooperation in specific areas of interest

Multilateral (by default):

- UNECE 1958 and 1998 Agreements (WP29) – UN based technical harmonisation (safety, emissions).
- Equivalence of national requirements transposing UNECE regulations.

Future relationship (1/2)

FTA

Partners

- **EU/Korea**
- **EU/Singapore**
- **EU/Vietnam**
- **EU/Canada**
- **EU/Japan**

On-going:

- **EU/Mexico**
- **EU/Mercosur**
- **EU/Chile**
- **EU/Indonesia**
- **EU/Malaysia**
- **EU/Philippines**
- **EU/India**
- **EU/ASEAN**
- **EU/Thailand**

Car annex content

- **Not all vehicle** categories covered, often excludes non-road mobile machinery and agricultural and forestry vehicles
- Promoting **regulatory convergence/harmonisation**:
 - primarily **based on UNECE** 1958 and 1998 Agreements – (e.g. tables of equivalence in case of EU/Korea, EU/Japan and EU/Canada), coupled with research, technical and **regulatory cooperation**
 - Parties keep their **own respective regulatory frameworks** and certification/type approval requirements, including testing and enforcement

Future relationship (2/2)

Multilateral (by default): UNECE

Scope of UNECE technical harmonisation activities

- Safety requirements
- Partial harmonisation of emission requirements
- Type-approval procedures and requirements

Commitments of Contracting Parties under UNECE Agreements

- Domestic regulations of Contracting Parties in the areas of transposed UNECE regulations are presumed equivalent
- Mutual recognition of (non-whole vehicle) type-approvals granted by Contracting Parties applying the same level of stringency of requirements based on UNECE regulations (nb: cover only a subset of requirements under EU type approval legislation)

Preparedness

- **Preparedness** for UK's withdrawal:
 - Need to raise public/stakeholders' **awareness** of need to anticipate and **adjust** (e.g.: notices)
 - Notice to stakeholders on type-approval of motor vehicles published on 8.2.2018
https://ec.europa.eu/growth/content/brexit-%E2%80%93-guidance-stakeholders-impact-type-approval-motor-vehicles_en
 - Similar notices on other categories of vehicles to be published soon
 - 1st EU-27 Technical expert meetings in Dec. 2017
 - Stakeholders should not defer any **adjustment for new vehicles**. This is even more so the case in the absence of certainty of transition period
 - Possible adaptations to EU **law** if needed

Summary

- UK applies **EU *acquis*** and is part of **Single Market**
- **UK bound by obligations** stemming from "automotive" *acquis*
- **UK out of EU Institutions and bodies**

Transition

Future

- UK out of EU type-approval system
- **No general mutual recognition or equivalence of regulatory frameworks**, i.e. approval of systems/components/parts or full vehicle type approvals.
- **Mutual recognition of component approvals and tests under UNECE arrangements** provided Contacting Parties apply the same levels of stringency (but falling short of the full recognition available in the Single Market under EU law)

- **Stakeholders' awareness and adjustment**
- Adaptations of EU law if needed

Preparedness

Internal preparatory discussions on
framework for future relationship

Chemicals - REACH

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15/02/2018

Internal Market for chemicals: an integrated regulatory area

Scope	Chemicals, mixtures and substances as defined by the REACH Regulation (Registration, Evaluation, Authorisation and Restriction of Chemicals)
Integration method	Fully harmonised system Only Member States and EEA countries (as observers) participate in committees / expert groups
Supervision & enforcement	<ul style="list-style-type: none">- Commission, European Chemicals Agency (ECHA) and all its bodies- Member State inspectorates, network of Member State inspectors in a FORUM coordinated by ECHA- CJEU, Member State courts
Remedies	<ul style="list-style-type: none">- Domestic remedies in application of directly applicable Regulations- Infringement procedures

Consequences of the UK becoming a third country

For chemical companies:

- Registration of substances, mixtures and substances in articles under REACH can only be done by registrants established in the EU-27:
 - => **UK manufacturers** and **third country exporters** with "only representatives" in the UK prior to withdrawal **need to establish an "only representative" in the EU-27** to avoid their registrations becoming null and void as from the withdrawal date.

For the UK:

- **No participation in:**
 - **rule-making (REACH committee)**
 - **risk and socio-economic assessments**
 - **enforcement** of EU chemicals legislation
- No access to **ECHA's database**

Overview of withdrawal implications

Phases/scenarios	Aspects to consider
TRANSITION	<ul style="list-style-type: none">• Market Access• Regulatory matters• Enforcement & Supervision
FUTURE	
PREPAREDNESS For the UK becoming a third country, including in a no deal scenario	

Transition (1/2)

If TRANSITION AGREEMENT WITH UK reached (EUCO guidelines 15/12/2017 & negotiating Directives 29/01/2018)

UK applies **all acquis, including new ECHA decisions, and keeps participating in the Single Market** for a limited period

- ✓ Status quo would be maintained, i.e.:
 - ✓ UK continues to be part of the REACH system
 - ✓ Level playing field (e.g. State Aid control)
 - ✓ Single supervision and enforcement (Commission, ECHA, national authorities, Member State cooperation networks, CJEU)

Transition (2/2)

- **Assimilation of UK to EU Member State** but need to specify precise perimeter:
 - **UK no longer part** of the EU institutions, agencies (e.g. ECHA) and bodies
 - UK invitation to meetings of committees or Commission expert groups and other similar entities or of the agencies (e.g. ECHA), offices or bodies where Member States are represented only **exceptionally on a case-by-case basis** and without voting rights
- **External effects** of UK becoming a third country:
 - UK remains bound by the obligations stemming from EU agreements
 - UK should no longer participate in bodies set up by those agreements

Future relationship

Third-country regime:

- Manufacturers and traders exporting chemicals from the UK to the EU must **comply with REACH fully**

FTA solutions?

- "light regulatory cooperation" (e.g. Korea)

but

- no participation in REACH or any form of mutual recognition / equivalence

Preparedness

- **Preparedness** for UK's withdrawal:
 - ECHA has provided information on all possible implications of the UK's withdrawal from the EU: <https://echa.europa.eu/uk-withdrawal-from-the-eu>
 - EU-27 and UK-based companies find comprehensive information in a Q&A document explaining all relevant implications for business continuity as from 30 March 2019: <https://echa.europa.eu/advice-to-companies-q-as/bpr>

Summary

- UK applies **EU *acquis*** and is part of **Single Market**
- **UK bound by EU** chemicals legislation
- **UK out of EU Institutions and bodies**

Transition

Future

- **UK out of the REACH system**; no mutual recognition / equivalence.
- Operators exporting **chemicals from the UK to the EU must comply with REACH fully.**
- **Registration** of substances by an operator established in EU-27 as **pre-requisite for access to EU market.**

- **Stakeholders' awareness and adjustments**
- European Chemicals Agency has provided comprehensive guidance for business actors on all sides as well on general implications of the UK's withdrawal

Preparedness

Internal preparatory discussions on
framework for future relationship

Trade in agri-food products, sanitary & phytosanitary provisions

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15/02/2018

Internal Market for trade in agri-food: an integrated regulatory area

Scope	Trade in live animals, animal products, food, feed, plants and plant products
Integration method	Regulatory conditions on sanitary, animal health and plant health in trade with third countries
Supervision & enforcement	<ul style="list-style-type: none">- Commission, European Food Safety Authority (scientific advice)- Member State supervisory authorities, cooperation networks- CJEU, Member State courts
Remedies	Withdrawal or refusal of authorisation to trade in relevant food products Safeguard measures to restrict trade

Consequences of the UK becoming a third country

Restrictive legal framework governing market access to the EU. For **live animals** and **animal products** in particular:

- **Legal approval** of the third country, the specific commodities and the establishments authorised to export to EU; approval of residue plans for veterinary drugs
- **Commission audits** of the oversight of the third country authorities (entire food production chain)
- Formal **certification by third country services** of compliance with the relevant EU import requirements
- Mandatory documentary, physical and identity **border checks** by Member State authorities (for plants and plant products, risk based controls)
- Compliance with relevant EU requirements on traceability, labelling, packaging, ingredients, etc.

UK withdrawal implications in agri-food/SPS area

Phases/scenarios	Aspects to consider
TRANSITION	<ul style="list-style-type: none">• Integrity of the Internal Market• Protection of EU health status• Transit & transshipment arrangements• Respect of international obligations
FUTURE	
PREPAREDNESS For the UK becoming a third country, including in a no deal scenario	

Transition (1/2)

If **TRANSITION AGREEMENT WITH UK reached** (EUCO guidelines 15/12/2017 & negotiating Directives 29/01/2018)

UK applies **all acquis and keeps participating in the Single Market** for a limited period

- Status quo would be maintained, i.e.:
 - UK continues to be part of the EU SPS system: no need to approve UK as a country, UK eligible products or UK establishments for exports to the EU for the transition
 - Level playing field
 - Single supervision and enforcement (Commission, national authorities, Member State cooperation networks, CJEU)

Transition (2/2)

- **Assimilation of UK to EU Member State** but need to specify precise perimeter:
 - **UK no longer part** of the EU institutions, agencies (e.g. EFSA) and bodies
 - UK invitation to meetings of committees or Commission expert groups and other similar entities or of the agencies (e.g. EFSA), offices or bodies where Member States are represented only **exceptionally on a case-by-case basis** and without voting rights
- **External effects** of UK becoming a third country:
 - UK remains bound by the obligations stemming from EU agreements
 - UK should no longer participate in bodies set up by those agreements

Future Relationship (1/3)

- Models are
 - SPS chapters in Free Trade Agreements (Canada, Chile) or
 - "Veterinary agreements" (New Zealand, USA)
- Both provide for enhanced trading relationship with preferential market access based on "trust", for example by:
 - setting up the conditions for recognition of certain production standards (limited scope)
 - re-affirming guiding principles, including appropriate level of protection and approach towards scientific uncertainty.
 - committing to transparency and exchange of information on SPS measures
 - establishing common principles, e.g. for regionalisation, transparency, co-operation

Future Relationship (2/3)

...but: these agreements do **not**

- amount to "**mutual recognition**" of product standards, labelling of food, food ingredients, etc.
- remove mandatory border controls and country specific approval processes

→ These agreements fall very **far short of EU membership**

- In the absence of an Agreement, trade takes place under WTO/SPS framework as with most third countries

Future relationship (3/3)

Examples

Existing Agreements with USA, Canada, NZ, Chile....

- Recognition of disease status and regionalisation
- Certification procedures
- Information exchange
- Recognition of certain production standards

Multilateral (by default): WTO/SPS

- Commitment that regulatory measures are science-based, proportionate, non-discriminatory and transparent.
- Cooperation with the UK aimed at enhancing trade and averting problems, e.g. in agreeing trade conditions, certification requirements etc. (like any third country)

Preparedness

- **Preparedness** for UK's withdrawal:
 - Need to raise public / stakeholders' **awareness** of need to anticipate and **adjust** (e.g. notices)
 - Extensive advance notice of implications for agri-food sectors (https://ec.europa.eu/info/brexit/brexit-preparedness_en)
 - "Technical expert seminars (EU27)" with Member States & information of stakeholders
 - Academic and trade organisations own reports

Summary

- UK applies **EU acquis** and is part of **Single Market**;
- **UK bound by obligations** stemming from SPS requirements;
- **UK out of EU Institutions and bodies.**

Transition

Future

- UK as a third country with all the relevant rights and obligations, i.e. WTO/SPS;
- FTA with the UK and/or SPS chapter with market access arrangements;
- No escaping from significant impact on trading conditions under either scenario.

- **Stakeholders' awareness and adjustments**;
- Agri-food sector is heavily regulated and divergent regulatory requirements entail **unavoidable trade disruption**;
- Stakeholders need to anticipate that third countries can only trade with the EU under highly restrictive conditions.

Preparedness