Declaration by the High Representative on behalf of the EU on the alignment of certain countries concerning restrictive measures against Iran

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On 4 June 2018, the Council adopted Decision (CFSP) 2018/833[1] amending Council Decision 2010/413/CFSP.

The Council Decision amends the list of entries concerning certain persons and entities set out in Annex II to Decision 2010/413/CFSP.

The Candidate Countries the former Yugoslav Republic of Macedonia*, Montenegro* and Albania*, the country of the Stabilisation and Association Process and potential candidate Bosnia and Herzegovina, and the EFTA countries Iceland, Liechtenstein and Norway, members of the European Economic Area, as well as the Republic of Moldova, align themselves with this declaration.

They will ensure that their national policies conform to this Council Decision.

The European Union takes note of this commitment and welcomes it.

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[1] Published on 06.06.2018 in the Official Journal of the European Union n°. L 140, p. 87

*The former Yugoslav Republic of Macedonia, Montenegro and Albania continue to be part of the Stabilisation and Association Process.

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European Border and Coast Guard: agreement on operational cooperation reached with the former Yugoslav Republic of Macedonia

Today, European Commissioner Dimitris Avramopoulos and Oliver Spasovski, Minister of Interior of the former Yugoslav Republic of Macedonia, initialled a status agreement that will allow teams from the European Border and Coast Guard Agency to be deployed in the former Yugoslav Republic of Macedonia. Once in force, the agreement will allow the Agency to carry out joint operations with and within the former Yugoslav Republic of Macedonia, especially in the event of sudden migratory challenges.

Commissioner for Migration, Home Affairs and Citizenship Dimitris **Avramopoulos** said: *"I would like to congratulate the former Yugoslav Republic of Macedonia on this important operational step forward in our cooperation on the ground. This agreement will allow the European Border and Coast Guard Agency to fully exercise its potential, reacting swiftly to migratory challenges and protecting our common borders. Today's agreement is the second we have now initialled, and I hope for the ongoing negotiations with the other Western Balkans partners to be finalised quickly."*

The Commission has committed to further strengthening the European Border and Coast Guard Agency's role in protecting the EU's borders, including closer cooperation with the EU's neighbours. Status agreements like the one initialled today with the former Yugoslav Republic of Macedonia will reinforce the Agency's ability to act in the EU's immediate neighbourhood, helping to manage irregular migration better and further enhancing security at the EU's external borders.

Closer cooperation between the Agency and Western Balkan partners is also a core element of the Commission's strategy for 'A credible enlargement perspective for and enhanced EU engagement with the Western Balkans', which highlights the Western Balkans' European future and calls for enhanced strategic and operational cooperation on migration and border management.

Next Steps

The draft status agreement initialled today with the former Yugoslav Republic of Macedonia will be formally signed at a later date, after both sides complete the necessary legal procedures. The European Parliament's consent to the agreement is also required.

Once the agreement enters into force, the European Border and Coast Guard Agency will be able to carry out operational activities and deploy teams in the regions of the former Yugoslav Republic of Macedonia that border the EU, in agreement with both the authorities of the former Yugoslav Republic of

Macedonia and the authorities of the bordering EU Member States.

Background

Under its recently reinforced mandate, the European Border and Coast Guard Agency can carry out operations on the territory of neighbouring third countries, subject to prior agreement. The Commission adopted a model status agreement in November 2016 and subsequently requested the Council to first start negotiations with Serbia and the former Yugoslav Republic of Macedonia in January 2017. Later, the Commission was also granted mandates to negotiate agreements with Albania, Montenegro and Bosnia and Herzegovina.

Today's draft status agreement is the second negotiation concluded between the European Union and the EU's partners in the Western Balkans, following an agreement with Albania in February 2018. A draft status agreement with Montenegro was agreed at technical level in April 2018, and negotiations are ongoing with Serbia and Bosnia and Herzegovina.

For More Information

Website: The European Border and Coast Guard Agency

Website: DG HOME

EU and Japan reinforce their collaboration on inspections of medicine manufacturers

18/07/2018

Update of 2004 mutual recognition agreement extends scope to sterile products, active pharmaceutical ingredients and biologicals including vaccines

The European Union (EU) and Japan have agreed to broaden the range of medicines for which they will recognise each other's inspections of manufacturing sites.

The current mutual recognition agreement (MRA) between the EU and Japan has been operational since 29 May 2004. It allows regulators to rely on good manufacturing practice (GMP) inspections in each other's territories, to waive batch testing of medicines that enter Japan from EU countries and vice versa and to share information on inspections and quality defects. Thanks to this agreement, regulatory authorities in the EU and Japan can make better use of their inspections resources by reducing duplication of inspections in

each other’s territory.

The scope of this agreement has now been extended to include sterile medicines, certain biological medicines including vaccines and immunologicals, and active pharmaceutical ingredients (APIs) of any medicine covered in the agreement. This means that authorities from the EU and Japan have agreed that they have equivalent regulatory and procedural frameworks for inspections of manufacturers for these products and can therefore rely on each other’s inspections.

The full scope of the MRA now covers chemical pharmaceuticals, homeopathic medicinal products (as long as treated as medicinal products and subject to the GMP requirements in Japan), vitamins, minerals and herbal medicines (if considered as medicinal products in both parties); certain biological pharmaceuticals including immunologicals and vaccines, APIs for any of the above categories and sterile products belonging to any of the above categories.

In the EU, inspections of manufacturing sites are carried out by national competent authorities from EU Member States. In Japan, GMP inspections are conducted by the Pharmaceuticals and Medical Devices Agency (PMDA) and the 47 inspectorates of the prefectures.

This is the first update of the original MRA agreement. As part of the product scope expansion project, Japan also evaluated and recognised as equivalent all EU competent authorities for human medicines inspection.

Notes

- The biological pharmaceuticals, including immunologicals and vaccines, in the scope of the agreement are: medicinal products produced by cell culture utilising natural microorganisms or established cell lines; medicinal products produced by cell culture utilising recombinant microorganisms or established cell lines; and medicinal products derived from non-transgenic plants and non-transgenic animals.
- The update of applicable legislation and recognition of the equivalence of all EU Member States was formalised through an exchange of Diplomatic Notes with Japan published in the Official Journal of the EU.

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Trade: Commission imposes provisional safeguard measures on imports of steel products

These measures will address the diversion of steel from other countries to the EU market as a result of the recently imposed US tariffs. The safeguard measures will come into effect on Thursday 19 July. Traditional imports of steel products will not be affected.

Commissioner for Trade Cecilia **Malmström** said: "*The US tariffs on steel products are causing trade diversion, which may result in serious harm to EU steelmakers and workers in this industry. We are left with no other choice than to introduce provisional safeguard measures to protect our domestic industry against a surge of imports. These measures nevertheless ensure that the EU market remains open, and will maintain traditional trade flows. I am convinced that strike the right balance between the interest of EU producers and users of steel, like the automotive industry and the construction sector, who rely on imports. We will continue to monitor steel imports in order to take a final decision by early next year, at the latest.*"

The provisional measures concern 23 steel product categories and will take the form of a Tariff Rate Quota (TRQ). For each of the 23 categories, tariffs of 25% will only be imposed once imports exceed the average of imports over the last three years. The quota is allocated on a first come first serve basis, thus at this stage not allocated by individual exporting country. These measures are imposed against all countries, with the exception of some developing countries with limited exports to the EU. Given the close economic links between the EU and the European Economic Area (EEA) countries (Norway, Iceland, and Liechtenstein), they have also been exempted from the measures. These exclusions are compatible with both the EU's bilateral and multilateral Word Trade Organisation (WTO) obligations.

The provisional safeguard measures can remain in place for a maximum of 200 days. All interested parties will now have the opportunity to comment on the findings of the investigation so far. The Commission will take these comments into consideration in order to reach its final conclusion, at the latest by early 2019. If all conditions are met, definitive safeguard measures may be imposed as a result.

The Commission received overwhelming support for these measures from the EU Member States.

Background

The measures announced today are part of the three-pronged response outlined by the European Commission earlier this year. As a result of the import duties applied by the United States as of 23 March under Section 232 the US Trade Expansion Act of 1962, exporting steel to the United States has become less attractive. There are already indications that, as a consequence, steel suppliers have diverted some of their exports from the US to the EU. In order to avoid a sudden increase of imports that would cause further economic problems for EU steel producers – who are already suffering from global overcapacity – the Commission considers that provisional safeguard measures are necessary and justified.

The adoption of the measures follows the initiation of an investigation on 26 March. This investigation covers 28 product categories. Imports for 23 steel categories were found to have increased in the last few years, and a further increase of imports – mostly diverted from the US as a result of the Section 232 steel measures – threatens to cause injury to the EU steel industry which has not yet recovered from the steel crisis. WTO rules allow for the imposition of safeguard measures under these circumstances.

An additional duty of 25% will be levied only after the usual level of imports over the last 3 years has been reached. The 25% tariff has been calculated by using an economic so-called partial-equilibrium model which is a standard tool for trade policy analysis by investigating authorities, including the Commission. On the basis of certain facts and assumptions (exclusion of US imports, expected trade diversion, import substitution, etc.) the model is used to establish an out-of-quota tariff that provides a deterrent for imports that go beyond the historic import level.

According to WTO rules, safeguard measures should apply to all imports, irrespective of their origin. However, the WTO also requires that if the imports of developing countries represent less than 3% of the total imports, these imports should be exempted. The Regulation therefore contains a list of developing countries that are exempted from the measures.

For 12 steel product categories covered by the provisional safeguard measures, imports from e.g. China, Russia, Ukraine are currently subject to anti-dumping and countervailing duties. In order to avoid the imposition of “double remedies”, whenever the tariff quota is exceeded, the Commission will consider the suspension or the reduction of the level of these duties to ensure that the combined effect of these measures does not exceed the highest level of the safeguard or anti-dumping/anti-subsidy duties in place.

Next to the safeguards announced today, the EU three-pronged response to the US tariffs on steel and aluminium includes rebalancing measures targeting US imports, imposed on 20 June and a legal action in the WTO launched on 1 June.

For more information

Regulation imposing safeguards