**To OTC: For Information**

**Trilogue of 7 February 2019 on ‘Compliance and Enforcement’ (market surveillance): a positive outcome for Orgalim**

We are very pleased to inform you that yesterday, the Romanian Presidency of the Council of the EU and the European Parliament have reached in their trilogue with the Commission, a provisional agreement on the “**Regulation on Market Surveillance and Compliance**” – its new name. The European Commission welcomes this provisional agreement, which will be submitted for endorsement to Coreper next week ([more](https://ec.europa.eu/growth/content/single-market-commission-welcomes-agreement-its-proposal-strengthen-controls-products_en)).

According to our information, the state of play appears as a **real success compared to the Orgalim requests😅**. Let’s cross fingers that it remains as follows:

* **Scope:** the **inclusion of counterfeiting** – Rapporteur Danti made it one of its red lines in the negotiations – was eventually left in a recital only. As Orgalime steadily stressed it in its past positions, this Regulation should indeed not mix-up the protection of IPR with the protection of the general interest.
* **Article 3 - Definitions:**the **definition of economic operators** would include now **‘fulfilment service providers’** and “*any other natural or legal person established in the Union and other than a distributor, who warehouses, packages and ships products to or within the Union market subject to obligations in relation to the manufacture of products, making them available on the market or putting them into service in accordance with the relevant Union harmonisation legislation*”. This would exclude parcel and postal services from the scope of this regulation.
* **Article 4 – “Tasks of economic operators regarding products subject to certain Union harmonisation legislation”**: The Commission proposed the appointment of a “person responsible for compliance information” for companies established outside the EU. As requested by Orgalim in its latest position paper, the Council and the EP agreed on assigning this task to any economic operator – including the new ones defined in Article 3 – under the following terms:
  + Lex specialis: NLF provisions of specific legislation apply first
  + Obligation to check ‘only’ that compliance documents have been drawn-up
  + The ‘tasked’ economic operator does not have to hold the technical documentation himself. His name and address should be indicated on the product or on its packaging, the parcel or an accompanying document.
* **Article 5** – **declaration of conformity**: as requested by Orgalim, the obligation for manufacturers to publish their DoC on their web site is deleted
* **Article 8 – activities to promote compliance (formerly ‘memoranda of understanding with stakeholders’):** as requested by Orgalim in its latest position paper, this article has been preserved in its full potential:
  + **MSA could ‘agree’ with “organisations representing economic operators** or end-users **on carrying out joint activities**”…
  + …under the condition that it does not affect the objectivity, independence and impartiality of the parties or creates create unfair competition between economic operators;
  + market surveillance authority may use any information resulting from the joint activities carried out
  + agreement on joint activities, including the names of the parties involved, shall be made available to the general public
  + the Network of MSAs could assist in the drawing up of the agreement on joint activities
* **Article 12 and 14 –** **Powers and activities of Market Surveillance Authorities**: We understand that the provisions on the powers of MSAs have been significantly simplified: as requested by Orgalim, the power to perform audits on companies’ internal procedures or to ask any staff would have been removed from Article 14, and the reference to proportionality principle strengthened. However, MSAs would have “the powers to carry out, without prior announcement, on-site inspections and physical checks” and to “enter any premises, land or means of transport that the economic operator in question uses for purposes related to his trade, business, craft or profession, in order to detect non-compliance and obtain evidence”
* **Article 31-34 –** **Network of Market Surveillance Authorities**: organisations representing the interests at Union level of industry –  such as Orgalim – may be invited to attend the meetings as observers of either the ADCOs or the Network of MSAs on the basis of the subject matter of discussion and to provide written contributions.

For more, please see the note of the Romanian Presidency submitted on 5 February for the preparation of the trilogue – in green, the articles where an agreement was already reached ([more](file:///\\localhost\chrome-extension\::ieepebpjnkhaiioojkepfniodjmjjihl:data:pdf.js:web:viewer.html%3Ffile=https%253A%252F%252Fdata.consilium.europa.eu%252Fdoc%252Fdocument%252FST-5841-2019-INIT%252Fen%252Fpdf)).

The provisional agreement will now be submitted for endorsement to Coreper next week.

We will provide you with our in-depth analysis, when will get hold of the final text, which will be submitted for adoption to the European Parliament, in one of the two plenary sessions scheduled in March, unless the 'action-packed' BREXIT busts MEPs’ agenda, which is already fully booked.

Once formally approved by the European Parliament and Council, **the regulation will start to apply in 2021**.