NOTIFICATION

The following notification is being circulated in accordance with Article 10.6.

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| **1.** | **Notifying Member:** SPAIN  **If applicable, name of local government involved (Articles 3.2 and 7.2):** |
| **2.** | **Agency responsible:** *Ministerio de Agricultura, Pesca y Alimentación* (Ministry of Agriculture, Fisheries and Food)  **Name and address (including telephone and fax numbers, email and website addresses, if available) of agency or authority designated to handle comments regarding the notification shall be indicated if different from above:**  *Dirección general de Sanidad de la Producción Agraria* (Directorate-General of Agrarian Health)  Tel.: (+34) 91347 5042  Fax: (+34) 91347 8248  [Bzn-dgspa@mapama.es](mailto:Bzn-dgspa@mapama.es) |
| **3.** | **Notified under Article 2.9.2 [X], 2.10.1 [** **], 5.6.2 [** **], 5.7.1 [** **], other:** |
| **4.** | **Products covered (HS or CCCN where applicable, otherwise national tariff heading. ICS numbers may be provided in addition, where applicable):** HS codes 28, 29 (excluding 29.35, 29.36, 29.37, 29.39 and 29.40), 30.0610, 30.06.20.00 and 38.22. |
| **5.** | **Title, number of pages and language(s) of the notified document:** *Proyecto de Real Decreto por el que se Regulan los Productos Zoosanitarios* (Draft royal decree regulating animal health products). (51 pages, in Spanish) |
| **6.** | **Description of content:** Requirements are established for the authorization, registration, marketing and use of animal health products.  The following items are excluded: veterinary medicines; homeopathic veterinary medicines; medicated feeding stuffs; biocides used in livestock settings; biocidal animal hygiene, care and handling products; animal health supplies and devices; those related to reproduction (except preservatives and diluents for semen, ova and embryos); animal feeding stuffs and animal identification products, which will be subject to specific regulations.  Also excluded are all health products for which there has been a communication or authorization under Royal Decree No. 414/1996 of 1 March, on the regulation of health products, and which are intended for use in veterinary settings or in animals, with the same composition, packaging and labelling as when communicated or authorized by the Spanish Agency for Medicines and Health Products; importation of live animals not subject to harmonized European Union regulations and having Spain as their final destination, including invasive species |
| **7.** | **Objective and rationale, including the nature of urgent problems where applicable:** The reagents used to diagnose animal diseases are a key element in safeguarding animal health and, consequently, food security and public health. To that end, adoption of the notified decree (in the framework of the OIE codes) is necessary to provide adequate assurance of their proper use (appropriate sensitivity and specificity).  Furthermore, adoption of the decree is necessary in order to regulate the authorization procedure for diagnostic products for animal diseases, particularly zoonotic diseases, including for their importation into Spain in the absence of harmonized European Union sanitary regulations. |
| **8.** | **Relevant documents:** - |
| **9.** | **Proposed date of adoption:** 30 June 2019  **Proposed date of entry into force:** 2 July 2019 |
| **10.** | **Final date for comments:** 60 days from the date of notification |
| **11.** | **Texts available from: National enquiry point [ ] or address, telephone and fax numbers and email and website addresses, if available, of other body:**  <https://www.mapa.gob.es/es/ganaderia/participacion-publica/proyecto_rd_productos_zoosanitarios.aspx>  <https://members.wto.org/crnattachments/2019/TBT/ESP/19_0972_00_s.pdf> |