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Position zu dem Entwurf einer Verordnung zur betrieblichen Herstellung und/oder den Export von in der EU nicht zugelassenen Zusatzstoffen oder Futtermitteln, die diese Zusatzstoffe enthalten, die für den Export bestimmt sind

Dem Ständigen Ausschuss wurde vor kurzem von der Europäischen Kommission ein Vorschlag zu einer Verordnung vorgelegt, der die Herstellung, den Export und die Einfuhr von Futtermittelzusatzstoffen, die in der EU nicht zugelassen sind, kontrollieren und regeln soll. Ziel der Verordnung soll es sein, für Futtermittelzusatzstoffe, die nicht in der EU zugelassen sind sowie Futtermittel, die diese enthalten und für den Export in Drittländer bestimmt sind, eine Harmonisierung von Kontrollmaßnahmen auf EU-Ebene zu erreichen.

Wir verstehen darunter, dass die Verordnung insbesondere dafür bestimmt ist, dass für diesen spezifischen Markt die Einhaltung und Anforderungen an die Futtermittelhygiene und die Rückverfolgbarkeit dieser Produkte auf EU-Ebene einheitlich sichergestellt werden. Denn bisher wurde dieser Bereich hauptsächlich durch die nationale Gesetzgebung geregelt und unterlag demnach mehr oder weniger restriktiven Anforderungen in den unterschiedlichen Mitgliedstaaten.

Demnach begrüßen wir die Initiative der Europäischen Kommission und sehen diese Verordnung als Instrument zur Förderung eines fairen Wettbewerbs und zur Verbesserung der Futtermittelsicherheit entlang der Futtermittekette.

Einige Prinzipien, die in diesem Verordnungsentwurf beinhaltet sind, stehen im Einklang mit dem im Jahr 2012 verabschiedeten FEFANA Code of Practice für den Einsatz von Futtermittelzusatzstoffen, die in der EU nicht zugelassen sind und zur Herstellung von Premixen verwendet werden, die für den Export in Drittländer bestimmt sind. Diesem Code of Practice verpflichten sich die Mitglieder sowohl auf europäischer als auch auf nationaler Ebene.

Dennoch sind die Verbände FEFANA Asbl. und die AWT e.V. der Meinung, dass einige Anforderungen, die im Anhang des nun vorgeschlagenen Verordnungsentwurfes mit aufgenommen wurden, zu einem erheblichen und nicht umsetzbaren Verwaltungsaufwand führen würden. Eine nachhaltige Produktion würde dadurch maßgeblich beeinflussen werden. Das Ausmaß der dort aufgeführten Restriktionen, würde den europäischen Handel von nicht zugelassenen Zusatzstoffen in Drittländer vielmehr beschränken als diesen unterstützen.

Nach sorgfältiger Bewertung des Verordnungsentwurfes sind die Verbände der Zusatzstoffindustrie der Ansicht, dass dieser Vorschlag nicht den Grundsatz der Verhältnismäßigkeit erfüllt. Gemäß diesem Grundsatz gehen die Maßnahmen der EU nicht über das zur Erreichung der Ziele der Verträge erforderliche Maß hinaus. Mit anderen Worten, der Inhalt und die Form der Maßnahme müssen im Verhältnis zum verfolgten Ziel stehen.

Zudem steht der Vorschlag in keiner Weise im Einklang mit dem REFIT Programm der EU Kommission, welches zur Gewährleistung der Effizienz und Leistungsfähigkeit der Rechtssetzung beitragen soll. Das EU-Recht soll einfacher werden und weniger Kosten verursachen. Ziel ist die Schaffung eines klaren, stabilen und vorhersehbaren Rechtsrahmens, der Wachstum und Beschäftigung fördern soll. Auf allen Regierungsebenen soll gewährleistet werden, dass der Nutzen des Verwaltungshandelns zu geringstmöglichen Kosten für die Bürgerinnen und Bürger und Unternehmen erreicht werden soll.

Die vorgeschlagene Verordnung würde insbesondere kleine und mittelständische Unternehmen, die die Mehrheit der FEFANA und AWT Mitgliedschaft ausmachen, unverhältnismäßig beeinflussen und

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schließlich dazu führen, dass diese Unternehmen an wachsenden Märkten, wie es der Export von nicht zugelassenen Zusatzstoffen in Drittländern ist, nicht mehr partizipieren könnten.

Aus diesen Gründen bittet die Arbeitsgemeinschaft für Wirkstoffe in der Tierernährung e.V. die Kommission folgende Kommentare und Begründungen, die nachfolgend aufgeführt sind, zu berücksichtigen. Die FEFANA und die AWT sind gerne bereit zu einer konstruktiven Diskussion beizutragen oder weitere Erklärungen, die als notwendig erachtet werden, den Behörden bereitzustellen.

Text im EU-Verordnungsentwurf (Annex)	**FEFANA /AWT Kommentare/Vorschläge**
Section 2, point 1: *If the manufacturer is not exporting the non-authorized feed additive, or feed containing non-authorized feed additives, information and agreement of the exporter shall be mentioned in the request for approval, providing documentation regarding relationship between the two feed business operators for this purpose.*	This point may result in a heavy administrative burden for both the Feed Business Operators (FBO) and competent authorities (CA). In fact in case the exporter changes, the FBO is supposed to inform the CA and to provide again all the relevant documentation. An alternative wording would ensure a greater flexibility to industry and potentially a lower burden to the CA and would at the same time being in line with the level of control envisaged by the draft Regulation: *"If the manufacturer of non-authorised feed additives or feed containing them is not exporting those products, it can only supply FBOs approved for the activity of importing, manufacturing and/or exporting non-authorised feed additives, or feed containing non-authorized feed additives to third countries."*
Section 2, point 2: *Feed business operators shall always communicate [X days/week??] in advance to the competent authority when is foreseen the manufacturing of a batch of non-authorized feed additives, or feed containing non-authorized feed additives*	We acknowledge that it is relevant to inform the CA on activities related to non-EU authorised feed additives. On the other hand, once a FBO is approved for the manufacturing of these products, no more actions should be envisaged. In the current legislation, approved FBO are not required to inform CA on their daily manufacturing activities. Moreover, the current provisions of the General food law, the Feed Hygiene Regulation and the additions proposed in **section 3** of the Annex of the present draft Regulation already facilitate inspections at the manufacturing site and ensure full transparency of the FBO on formulas produced and country of destination. Anyway, this requirement would only be applicable for products produced in time limited campaigns e.g. 2-3 times a year. In case of continuous production its implementation is not possible in practice, particularly for products that are approved for the EU market and which are intended to be exported to third countries with other conditions of use. Due to logistic aspects, the lead time to produce a premixture or a feed is relatively short, therefore awaiting a feedback from the authorities before producing is not practical.

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	FEFANA kindly requests the Commission and Member states to reconsider this requirement from the draft regulation.
Section 2, point 2(a): *Official documentation issued by the competent authorities of the third country (or justified by another means verifiable by the competent authorities) or declaration of the importer in the third country, guaranteeing that the non-authorized feed additives, or feed containing non-authorized feed additives manufactured can be marketed in the third country.*	In practice obtaining an information from third countries is rather difficult and time consuming. Official documents are not harmonised, may not contain all the relevant information (such as conditions of use) and are normally provided in the local language thus not easily verifiable by a national CA in the European Union. Moreover in some third countries the authorization certificates may not be required hence it may be not possible to receive this document from the authorities. Nevertheless, we believe that the information provided according to **point 5** ensure already a sufficient level of identification of the exported non-authorised products to trigger border controls by third country CA which should be eventually in charge to verify the existence of authorization certificates, import licenses or any other relevant information. FEFANA kindly requests that the EC and Member States reconsider the requirement for provision of third country documentation.
Section 2, point 2(e): *Manufacturer's and exporter's, when appropriate, commitment that the non-authorized feed additive, or feed containing non-authorized feed additives exported will not be returned to EU territory in any case.*	Sometimes exported products are returned to the sender due to administrative errors. If an exported product cannot be returned this would cause a serious economic prejudice, due to the loss of the product itself and the extra costs related to its destruction, the arrangement of additional transports, etc. For these reasons non-authorised products should be allowed for return as long as justifications are properly documented, there is no safety risk to EU consumers and traceability is guaranteed.
Section 2, point 3: *Non-authorised feed additives which are not covered by an authorisation granted in accordance with Regulation (EC) No 1831/2003 shall be manufactured and stored separately from any other feed.*	The establishment of separate production lines and warehouses for non-authorised feed additives would have an unsustainable economic and logistical impact. This is certainly not necessary as according to article 6 of the Feed Hygiene Regulation, FBO are already responsible for putting in place, implementing and maintaining permanent written procedures based on the HACCP principles in order to achieve the highest level of feed safety including the prevention of cross-contaminations and carry-overs (e.g. Copper on feed for ovines, coccidiostats, etc). See also **point 5(b)**.
Section 2, point 4: *Packaging and/or means of transport used to arrive to the exit point shall be closed initially with a seal in such a way that when the packaging is opened for the first time the seal is irreparably damaged. Seal shall not be necessary when packaging non-authorised feed additives for which the conditions for use set out in*	It is not clear what is intended for sealed packaging since any feed is in principle is packed in a sealed package. "Tamper-proof packaging" may be a more appropriate wording. This comment also applies to **point 6(c)**.

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Regulation (EC) No 1831/2003 and in the authorisation are not met.	
Section 2, point 5: *Non-authorised feed additives, or feed containing non-authorized feed additives, shall be stored and transported in such a way to be easily identifiable, in order to avoid any confusion with products intended to be placed on the EU market.*	The implementation of this requirement would only be feasible as long it does not imply that the products shall be physically separated: i.e. transported within the same truck on two different pallets or in another truck (see comments on **point 5(c)** and **point 5(b)**). Normally for logistic and economic reasons, orders from the same costumers are included in the same pallet regardless whether the products are authorized or not according to the EU legislation. Non-Eu compliant products may be easily identified either via the transport documents, or additional stickers on the outer label of cardboard box, bags etc.
Section 2, point 5(a): *labelling shall include indications of the third country of destination. The accompanying label or commercial documents shall include the sentence 'for export to …', followed by the name of the third country of destination.*	We recognize that is important for non-EU authorised feed to be properly identified. Nevertheless reporting the country of destination on the label may raise complications since a given product is likely to be exported to more than one non-EU country. Moreover this would imply the production of one label per each destination country which is even more complicated in case of frequently used pre-printed bags. The possibility to have the country of destination indicated on the commercial documents included with the products is therefore much more appropriate and sufficient. In this case it would be easy to include the sentence "for export to…".
Section 2, point 5(b): *storage areas shall be clearly and unequivocally identified supported by the relevant record keeping and provide with systems to:* *(i) isolate the non-authorised feed additives which are not covered by an authorisation granted in accordance with Regulation (EC) No 1831/2003 and allow access only to specifically authorised staff,* *(ii) separate the non-authorised feed additives for which the conditions for use set out in Regulation (EC) No 1831/2003 and in the authorisation are not met*	This requirement asks to "isolate" rather than "separate" (in contradiction with **point 3**) the non-authorised feed additives which are not covered by an authorisation. While the non-authorised feed additives for which the conditions for use are not met must be kept "separated". We understand that there is a distinction between keeping these products "separated" or "isolated". Again the separation in areas clearly identified by proper signs is reasonable and feasible. On the other hand "isolation" would imply the need for a dedicated warehouse which as stated above bears very high costs and is unnecessary when properly sealed packages already avoid potential cross-contaminations. FEFANA kindly propose to amend the text as follows: *"storage areas for non-authorised feed additives shall be clearly and unequivocally identified and supported by the relevant record keeping"*
Section 2, point 5(c): *Transport shall be exclusive and separate, in order to avoid any confusion with products intended to be placed on the EU market. Transport shall not be exclusive when transporting non-authorised feed additives for which the conditions for use set out in*	While we understand the need to separate non-authorised products from authorised ones for instance by means of proper identification signs, there is a need to better clarify the term "exclusive" transport. Without further specifications "exclusive" transport may mean that dedicated (and sealed according to **point 4**) containers should be used only for transporting feed for which an EU authorization does not exist.

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Regulation (EC) No 1831/2003 and in the authorisation are not met.	Indeed such a solution would entail unsustainable costs, highly impacting transport economy of scale, when separation by proper identification and detailed records ensuring traceability would be more than enough to avoid mistake with products intended to be placed on the EU market. For these reasons FEFANA kindly requests to remove any reference to exclusive transport.
Section 2, point 7: *When non authorized feed additives, or feed containing non-authorized feed additives are exported from a Member State to a third country through a different Member State, feed business operators shall inform competent authorities from both Member States with all relevant information of the consignment, according to Title V of Regulation (EC) No 882/2004, and in particular:*	We consider that the implementation of this requirement is completely unrealistic. No FBO are in a position to access the CA of other Member States (which have different organigrams and speak different languages), mostly when several Member States are involved as it is the case for road transport. This would lead to an unsustainable administrative burden and to appoint staff specifically dedicated to this task. Moreover we doubt this requirement would provide any added value as far as the safety of the feed chain is concerned. FEFANA kindly requests to reconsider this requirement.