Safety and efficacy of Alterion NE® (*Bacillus subtilis* DSM 29784) as a feed additive for minor poultry species for fattening and reared for laying

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**Abstract**

Following a request from the European Commission, the EFSA Panel on Additives and Products or Substances used in Animal Feed was asked to deliver a scientific opinion on the safety and efficacy of Alterion NE® when used in feed for chickens for fattening and chickens reared for laying. Alterion NE® is a preparation containing viable spores of *Bacillus subtilis* DSM 29784 intended for use in feed for the target species at the recommended dose of $1 \times 10^8$ CFU/kg complete feedingstuffs. *B. subtilis* is a species considered by EFSA to be suitable for the qualified presumption of safety (QPS) approach to safety assessment, which requires the identity of the strain to be conclusively established, evidence that the strain is not toxigenic and that it does not show resistance to antibiotics of human and veterinary importance. The strain was found to meet the criteria for the QPS approach in the context of a previous opinion and since concerns are not expected from other components of the additive, the additive is presumed safe for all target species, consumers and the environment. In the same opinion, the FEEDAP Panel concluded that Alterion NE® is not a dermal irritant but is irritant to eyes and should be considered a potential respiratory sensitiser. In the absence of data, no conclusion could be drawn on the dermal sensitisation of the additive. Alterion NE® at the recommended dose $1 \times 10^8$ CFU/kg feed has the potential to be efficacious in minor poultry species for fattening and reared for laying. *B. subtilis* DSM 29784 is compatible with the coccidiostats monensin sodium, narasin/nicarbazin, salinomycin sodium, lasalocid sodium, diclazuril, narasin, maduramicin ammonium, robenidine hydrochloride and decoquinate at the respective authorised levels.

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**Keywords:** zootechnical additive, Alterion NE®, *Bacillus subtilis* DSM 29784, minor poultry species, safety, QPS, efficacy

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1. **Introduction**

1.1. **Background and Terms of Reference**

Regulation (EC) No 1831/2003 establishes the rules governing the Community authorisation of additives for use in animal nutrition. In particular, Article 4(1) of that Regulation lays down that any person seeking authorisation for a feed additive or for a new use of a feed additive shall submit an application in accordance with Article 7.

The European Commission received a request from ADISSEO France SAS for authorisation of the product Alterion NE® (*Bacillus subtilis* DSM 29784), when used as a feed additive for minor poultry species for fattening and reared for laying (category: zootechnical additives; functional group: gut flora stabilisers).

According to Article 7(1) of Regulation (EC) No 1831/2003, the Commission forwarded the application to the European Food Safety Authority (EFSA) as an application under Article 4(1) (authorisation of a feed additive or new use of a feed additive). The particulars and documents in support of the application were considered valid by EFSA as of 5 October 2016.

According to Article 8 of Regulation (EC) No 1831/2003, EFSA, after verifying the particulars and documents submitted by the applicant, shall undertake an assessment in order to determine whether the feed additive complies with the conditions laid down in Article 5. EFSA shall deliver an opinion on the safety for the target animals, consumer, user and the environment and on the efficacy of the product Alterion NE® (*Bacillus subtilis* DSM 29784) when used under the proposed conditions of use (see Section 3.1.1).

1.2. **Additional information**

The additive Alterion NE® is a preparation containing viable spores of *Bacillus subtilis* DSM 29784. EFSA issued an opinion on the safety and efficacy of this product when used with chickens for fattening and reared for laying (EFSA FEEDAP Panel, 2017).

It has not been previously authorised as a feed additive in the European Union (EU).

2. **Data and methodologies**

2.1. **Data**

The present assessment is based on data submitted by the applicant in the form of a technical dossier in support of the authorisation request for the use of Alterion NE® (*Bacillus subtilis* DSM 29784) as a feed additive. The technical dossier was prepared following the provisions of Article 7 of Regulation (EC) No 1831/2003, Regulation (EC) No 429/2008 and the applicable EFSA guidance documents.

The European Union Reference Laboratory (EURL) considered that the conclusions and recommendations reached in the previous assessment are valid and applicable for the current application.

2.2. **Methodologies**

The approach followed by the FEEDAP Panel to assess the safety and the efficacy of Alterion NE® is in line with the principles laid down in Regulation (EC) No 429/2008 and the relevant guidance documents: Technical Guidance on the extrapolation of data from major species to minor species regarding the assessment of additives for use in animal nutrition (EFSA, 2008).

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1 Regulation (EC) No 1831/2003 of the European Parliament and of the Council of 22 September 2003 on additives for use in animal nutrition. OJ L 268, 18.10.2003, p. 29.
2 ADISSEO France SAS, Immeuble Anthony Parc II, 10 place du général de Gaulle 92160, Antony, France.
3 FEED dossier reference: FAD-2017-0054.
4 Commission Regulation (EC) No 429/2008 of 25 April 2008 on detailed rules for the implementation of Regulation (EC) No 1831/2003 of the European Parliament and of the Council as regards the preparation and the presentation of applications and the assessment and the authorisation of feed additives. OJ L 133, 22.5.2008, p. 1.
5 The full report is available on the EURL website: https://ec.europa.eu/jrc/sites/jrcsh/files/finrep-fad-2016-0040_alterionne.pdf
3. Assessment

Alterion NE® is a preparation of *B. subtilis* DSM 29784 intended for use as a zootechnical additive (gut flora stabilisers) in feed for minor poultry species for fattening and reared for laying to improve performance.

### 3.1. Characterisation

The additive is a preparation of viable spores of *B. subtilis* DSM 29784 at a minimum declared concentration of $1 \times 10^{10}$ CFU/g additive. The additive was fully characterised in the previous opinion (EFSA FEEDAP Panel, 2017).

#### 3.1.1. Conditions of use

Alterion NE® is intended for use in feed for minor poultry species for fattening and reared for laying at the minimum recommended dose of $1 \times 10^8$ CFU/kg feedingstuffs.

The additive is intended for use in the presence of the permitted coccidiostats: lasalocid sodium, robenidine hydrochloride, maduramicin ammonium, decoquinate, salinomycin sodium, monensin sodium, narasin, diclazuril and narasin/nicarbazin.

### 3.2. Safety

The species *B. subtilis* is considered by EFSA to be suitable for the qualified presumption of safety (QPS) approach to establishing safety for the target species, consumers and the environment (EFSA, 2007; EFSA BIOHAZ Panel, 2017). This approach requires the identity of the strain to be conclusively established and evidence that the strain lacks toxigenic potential and does not show resistance to antibiotics of human and veterinary importance.

In a previous opinion (EFSA FEEDAP Panel, 2017), the identification of the strain and compliance with the QPS qualifications were confirmed. Moreover, in the absence of concerns from other components of the additive, Alterion NE® was considered safe for the target animals, consumer of products from animals fed with the additive and the environment. The Panel considers these conclusions to apply also in the current assessment.

In the same opinion on the use of Alterion NE® in feed for chickens for fattening and reared for laying, the Panel concluded that the additive is not a dermal irritant but is an eye irritant and should be considered a potential respiratory sensitiser. In addition, no conclusion could be drawn on its skin sensitisation potential. The use of the additive in minor poultry species for fattening and reared for laying is considered unlikely to introduce hazards for users of the product not already considered as part of the first assessment. Therefore, the conclusions reached in the previous assessment apply to the current application.

### 3.3. Efficacy

The efficacy of Alterion NE® for chickens for fattening has been established at $1 \times 10^8$ CFU/kg feed (EFSA FEEDAP Panel, 2017). The dose proposed for use with minor poultry species is the same as that demonstrated to be effective in a physiologically similar major species (chickens for fattening) and it can be reasonably assumed that the mode of action is the same. Consequently, the conclusion on efficacy for chickens for fattening can be extrapolated to minor poultry species for fattening and reared for laying.

#### 3.3.1. Compatibility with coccidiostats

In the previous opinion on the use of Alterion NE® in feed for chickens for fattening and reared for laying, the compatibility of *B. subtilis* DSM 29784 with monensin sodium, narasin/nicarbazin, salinomycin sodium, lasalocid sodium, diclazuril, narasin, maduramicin ammonium, robenidine hydrochloride and decoquinate at the highest authorised levels for chickens for fattening was established. Since the maximum authorised doses of the coccidiostats for chickens for fattening are equal or higher than those for the physiologically similar minor species (when they exist), conclusions previously drawn apply to the current application.
3.4. Post-market monitoring

The FEEDAP Panel considers that there is no need for specific requirements for a post-market monitoring plan other than those established in the Feed Hygiene Regulation\(^6\) and Good Manufacturing Practice.

4. Conclusions

The active agent fulfils the requirements of the QPS approach to the assessment of safety and no concerns are expected from other components of the additive. Since no concerns are expected from other components of the additive, Alterion NE® can be presumed safe for the target animals, consumers of products from treated animals and the environment.

Alterion NE® is not a dermal irritant but is irritant to eyes and should be considered a potential respiratory sensitizer. In the absence of data, no conclusion can be drawn on the dermal sensitisation of the additive.

Alterion NE® at the recommended dose \(1 \times 10^9\) CFU/kg feed has the potential to be efficacious in minor poultry species for fattening and reared for laying.

*B. subtilis* DSM 29784 is compatible with the coccidiostats monensin sodium, narasin/nicarbazin, salinomycin sodium, lasalocid sodium, diclazuril, narasin, maduramicin ammonium, robenidine hydrochloride and deconquinate at the respective authorised levels.

**Documentation provided to EFSA**

1) Alterion NE® for minor poultry species for fattening and reared for laying. October 2017. Submitted by ADISSEO France S.A.S.

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**Abbreviations**

| Abbreviation | Description |
|--------------|-------------|
| CFU          | colony forming unit |
| EURL         | European Union Reference Laboratory |
| FEEDAP       | EFSA Panel on Additives and Products or Substances used in Animal Feed |
| QPS          | qualified presumption of safety |

\(^6\) Regulation (EC) No 183/2005 of the European Parliament and of the Council of 12 January 2005 laying down requirements for feed hygiene. OJ L 35, 8.2.2005, p. 1.