SCIENTIFIC OPINION

Scientific opinion on the modification of authorisation of Deccox® (decoquinate) as feed additive for chickens for fattening[1]

EFSA Panel on Additives and Products or Substances used in Animal Feed (FEEDAP)[2,3]

European Food Safety Authority (EFSA), Parma, Italy

ABSTRACT

Deccox® contains decoquinate as the active substance for prevention of coccidiosis in poultry. The applicant requested a reduction in the withdrawal time from three days to zero days and the introduction of maximum residue limits (MRLs) for liver (1.0 mg/kg), kidney (0.8 mg/kg), muscle (0.5 mg/kg) and skin/fat (1.0 mg/kg). Decoquinate is not genotoxic and is not carcinogenic. The lowest no observed effect level (NOEL) was 15 mg/kg bw per day, observed in a 12-week oral toxicity study in dogs. The acceptable daily intake (ADI) of decoquinate (already established by the FEEDAP Panel in 2003 and since confirmed) is 0.075 mg/kg body weight (bw), based on the above NOEL, applying an uncertainty factor of 200. On the basis of new metabolism/residue studies in chicken and rat, major metabolites appear to be dissimilar in these two species. Nevertheless, the assessment of consumer safety refers to the ADI of decoquinate, considering the limited exposure of consumers to metabolites from chicken tissues. Decoquinate is the marker residue. A conservative estimate of consumer exposure, based on total residues measured after two and six hours withdrawal, indicates that it would be about 2 % of the ADI. Since a withdrawal period of two and six hours corresponds to a zero withdrawal time under practical husbandry conditions, a zero days withdrawal time does not compromise consumer safety. The new residue data submitted confirm that no MRLs are considered necessary.

KEY WORDS

coccidiostats, Deccox®, decoquinate, withdrawal period, MRL, chickens for fattening

[1] On request from the European Commission, Question No EFSA-Q-2013-00343, adopted on 12 September 2013.

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SUMMARY

Following a request from the European Commission, the Panel on Additives and Products or Substances used in Animal Feed (FEEDAP) was asked to deliver a scientific opinion on the modification of the authorisation of the additive in chickens for fattening.

Deccox® contains decoquinate as the active substance for the prevention of coccidiosis in poultry. The applicant requested a reduction in the authorised withdrawal period from three days to zero days and the introduction of maximum residue limits (MRLs) for liver (1.0 mg/kg), kidney (0.8 mg/kg) muscle (0.5 mg/kg) and skin/fat (1.0 mg/kg).

The opinion of the FEEDAP Panel is based on data submitted previously and used in its previous opinion on decoquinate in 2003 and on the results of newly submitted metabolism/residues studies in chicken and rat and of an *in vivo* micronucleus assay in the rat.

Decoquinate is not genotoxic and is not carcinogenic. The lowest no observed effect level (NOEL) was 15 mg/kg bw per day, observed in a 12-week oral toxicity study in dogs.

The acceptable daily intake (ADI) for decoquinate, already established by the FEEDAP Panel in 2003, is confirmed. The value is 0.075 mg/kg body weight (bw), based on the above NOEL, applying an uncertainty factor of 200.

On the basis of new metabolism/residue studies in chicken and rat, major metabolites appeared to be dissimilar in these two species. Nevertheless, the assessment of consumer safety refers to the ADI of decoquinate, considering the limited exposure of consumers to metabolites from chicken tissues. Decoquinate is the marker residue.

A conservative estimate of consumer exposure, based on total residues measured after two and six hours withdrawal, indicates that it would be about 2 % of the ADI. Since a withdrawal period of two and six hours corresponds to a zero withdrawal time under practical husbandry conditions, a zero days withdrawal time does not compromise consumer safety.

The new residue data submitted confirm that no MRLs are considered necessary.

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BACKGROUND

Regulation (EC) No 1831/2003[4] establishes the rules governing the Community authorisation of additives for use in animal nutrition. In particular, Article 13(3) of that Regulation lays down that if the holder of an authorisation proposes changing the terms of the authorisation by submitting an application to the Commission, accompanied by the relevant data supporting the request for the change, the Authority shall transmit its opinion on the proposal to the Commission and the Member States.

The European Commission received a request from the company Pfizer Ltd.[5] for a change of the withdrawal time and the introduction of the Maximum Residue Limits (MRLs) for the product Deccox® (decoquinate), when used as a feed additive for chickens for fattening (category: Coccidiostats and Histomonostats) under the conditions mentioned in Table 1.

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 13(3) (modification of the authorisation of a feed additive). EFSA received directly from the applicant the technical dossier in support of this application.[6] According to Article 8 of that Regulation, 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. The particulars and documents in support of the application were considered valid by EFSA as of 30 April 2013.

The product Deccox® is a feed additive intended for the control of coccidiosis, a debilitating protozoal infection in poultry. The product is currently authorised for use in chickens for fattening until July 2014 (Commission Regulation (EC) No 1289/2004).[7]

Decoquinate is present in the list of Commission Regulation (EU) No 37/2010 as a product for which no MRL is required for use in bovine and ovine species.[8]

EFSA issued an opinion on the safety and efficacy of Deccox® in accordance with art. 9G of Council Directive 70/524/EEC (EFSA, 2003).[9]

TERMS OF REFERENCE

According to Article 8 of Regulation (EC) No 1831/2003, EFSA shall determine whether the feed additive complies with the conditions laid down in Article 5. EFSA shall deliver an opinion on the withdrawal time for the existing additive Deccox® (decoquinate) from three days to zero days and introduction of the MRLs for liver (1.0 mg/kg), kidney (0.8 mg/kg), muscle (0.5 mg/kg) and skin/fat (1.0 mg/kg) when used under the conditions described in Table 1.

[4] 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.
[5] Pfizer Ltd., Ramsgate Road, Sandwich, Kent CT13 9NJ, United Kingdom.
[6] EFSA Dossier reference: FAD-2013-0009.
[7] Commission Regulation (EC) No 1289/2004 of 14 July 2004 concerning the authorisation for 10 years of the additive Deccox© in feedingstuff, belonging to the group of coccidiostats and other medicinal substances. OJ L 243,15.7.2004, p. 15.
[8] Commission Regulation (EU) No 37/2010 of 22 December 2009 on pharmacologically active substances and their classification regarding maximum residue limits in foodstuffs of animal origin. OJ L 15, 21.1.2010, p. 1.
[9] Council Directive 70/524/EEC of 23 November 1970 concerning additives in feeding-stuffs. OJ L 270, 14.12.70, p. 1..

Table 1: Description and conditions of use of the additive as proposed by the applicant

Additive	decoquinate (Deccox®)			
Registration number/EC No/No (if appropriate)	E756			
Category(ies) of additive	Coccidiostats and Histomonostats			
Functional group(s) of additive	Coccidiostats			
Description				
Composition, description	Chemical formula	Purity criteria (if appropriate)		Method of analysis (if appropriate)
Composition: **Decoquinate: 60.0 g/kg** **Colloidal silica: 0.6 g/kg** **Refined deodorised soya oil: 28.5 g/kg** **Wheat middlings: q.s. 1 kg** **Active substance:** **Decoquinate: (ethyl 6-decycloxy-7-ethoxy-4-hydroxyquinoline-3-carboxylate)**	**C24H35NO5** **CAS number: 18507-89-6**	**6-decyloxy-7-ethoxy-4-hydroxyquinoline-3-carboxylic acid: < 0,5 %** **Methyl-6-decyloxy-7-ethoxy-4-hydroxyquinoline-3-carboxylate: < 1,0%** **Diethyl 4-decyloxy-3-ethoxyanilinomethylenemalonate: < 0,5%**		**Feedstuffs:** **Validated HPLC with fluorescence detection.** **Tissues:** **Validated LC-MS/MS method**
Trade name (if appropriate)	Deccox®			
Name of the holder of authorisation (if appropriate)	Pfizer Ltd.			
Conditions of use				
Species or category of animal	Maximum Age	Minimum content	Maximum content	Withdrawal period (if appropriate)
		mg or Units of activity or CFU/kg of complete feedingstuffs (select what applicable)		
Chickens for fattening	-	20 mg	40 mg	Nil
Other provisions and additional requirements for the labelling				
Specific conditions or restrictions for use (if appropriate)	For user safety, avoid direct contact and use in a well-ventilated area. Breathing protection & safety glasses are recommended.			
Specific conditions or restrictions for handling (if appropriate)	Store in original, closed packaging, in cool, dry place (<25ºC).			
Post-market monitoring (if appropriate)	As per EU feed hygiene regulation: traceability, HACCP, formal product/ service complaints procedure, and product recall capability. Field monitoring of resistance to Eimeria spp.			
Specific conditions for use in complementary feedingstuffs (if appropriate)	Not applicable			
Maximum Residue Limit (MRL) (if appropriate)				
Marker residue	Species or category of animal	Target tissue(s) or food products		Maximum content in tissues
Decoquinate	Chicken for fattening	Liver Kidney		1.0 mg/kg

		Muscle Skin/fat	0.8 mg/kg 0.5 mg/kg 1.0 mg/kg

ASSESSMENT

1. Introduction

Deccox® is a coccidiostat currently authorised as a feed additive intended for the control of coccidiosis caused by *Eimeria* spp. in chickens for fattening. Its active substance is decoquinate (ethyl 6-decycloxy-7-ethoxy-4-hydroxyquinoline-3-carboxylate; Chemical Abstracts Service (CAS) No 18507-89-6), produced by chemical synthesis. The additive is a blend of micronised decoquinate (60 g/kg) with colloidal silica (0.6 g/kg) as anticaking agent, soybean oil (28.5 g/kg) and wheat middlings as carrier up to 1 000 g.

EFSA issued an opinion on the safety and efficacy of Deccox® in accordance with Article 9G of Council Directive 70/524 EEC (EFSA, 2003). The present formulation is authorised for use in chickens for fattening until July 2014 (Commission Regulation (EC) No 1289/2004) with an inclusion level of 20–40 mg decoquinate/kg of complete feedingstuff and a withdrawal period of three days.

The applicant is now seeking authorisation for a reduction in the withdrawal time from three days to zero days and the introduction of MRLs in chickens for fattening (liver, 1.0 mg/kg; kidney, 0.8 mg/kg; muscle, 0.5 mg/kg; and skin/fat, 1.0 mg/kg).

Since the composition of the additive in the application is the same as that currently authorised, the data provided by the applicant for characterisation and identity of the product are not considered in this opinion. Any eventual consequences of reducing the withdrawal time and setting MRLs for Deccox®, as proposed by the applicant, would concern consumer safety only.

2. Evaluation of the analytical methods by the European Union Reference Laboratory (EURL)

EFSA has verified the EURL report as it relates to the methods used for the control of decoquinate in animal feed, premixtures, feedingstuffs and tissues. The Executive Summary of the EURL report can be found in the Appendix.

3. Safety for the consumer

In its previous opinion on the use of Deccox® for chickens for fattening (EFSA, 2003), the FEEDAP Panel concluded that "the limited studies made in chickens and laboratory animals effectively preclude any comparison of the metabolic profile of the chicken with those of the rat. However, the limited data available indicates that there are differences in the number and nature of the metabolites produced in the two species. As none of the metabolites have been identified or quantified (in either species) the risk for the consumer exposed to decoquinate residues in chicken tissues cannot be adequately assessed on the basis of the existing data."

The applicant submitted new metabolism/residue studies in the chicken and rat, carried out using more advanced analytical tools (radio-high-performance liquid chromatography (HPLC), liquid chromatography–mass spectrometry (LC-MS) and liquid chromatography–tandem mass spectrometry (LC-MS/MS))[10] than in the former studies (EFSA, 2003).

3.1. Metabolism and residue studies

3.1.1. Chicken

[^{14}C]-decoquinate (quinoline ring labelled), at a dose equivalent to 40mg decoquinate/kg complete feed, was administered orally (by gavage), twice a day for seven days to chickens (three males and three females per group; 1.6–2.1 kg bw). Groups of animals were slaughtered 2, 6, 12 and 24 hours

[10] Technical dossier/Section III/Paragraph 3.2.1/Annexes III.2.1.1.2 and III.2.1.1.3.

after withdrawal and tissues sampled. Metabolic profiling was performed to identify major metabolites, and total radioactivity and decoquinate content were measured.[11]

More than 92 % of the administered radioactivity was recovered from the named tissues at all withdrawal times. Metabolic profiles indicated that unchanged decoquinate was by far the major residue in all tissues at all withdrawal time points. In the liver, two major metabolites, L1 and L2, accounted for 12 % and 8 % of the total radioactivity, respectively, 12 hours after withdrawal. In the kidney, at the same time point, two major metabolites, K1 and K2, accounted for 35 % and 12 %, respectively. L1 and L2 exhibited the same retention times (HPLC) as K1 and K2, respectively. Analysis of the chemical structural of K1 identified it as the 6-*O*-butanoic acid structure derived from decoquinate by β-oxidation of the its alkyl chain. In the muscle, unchanged decoquinate accounted for the majority of the residues (98 %), and in the skin/fat only very minor (< 10 % each) metabolites were observed. The depletion of total residues and decoquinate contents is shown in Table 2. The values in Table 2 show that residue levels remain constant during the first six hours after withdrawal, before depletion occurs. High residues were found in liver and kidney; residue levels in muscle were markedly lower (by a factor of 10). The liver is considered the target tissue. Decoquinate is the marker residue.

Table 2: Decoquinate residues in tissues of chickens following continuous administration of [^{14}C]-decoquinate at a dose of 40 mg/kg feed followed by a withdrawal period

Withdrawal time (h)	Liver		Kidney		Muscle		Skin + fat	
	TR [(a)]	D [(b)]	TR [(a)]	D [(b)]	TR [(a)]	D [(b)]	TR [(a)]	D [(b)]
2	0.399 ± 0.056	0.298 ± 0.053	0.330 ± 0.042	0.158 ± 0.021	0.032 ± 0.006	0.032 ± 0.006	0.125 ± 0.028	0.110 ± 0.023
6	0.315 ± 0.074	0.271 ± 0.067	0.336 ± 0.073	0.137 ± 0.048	0.036 ± 0.015	0.036 ± 0.015	0.169 ± 0.058	0.148 ± 0.059
12	0.216 ± 0.069	0.191 ± 0.063	0.197 ± 0.042	0.087 ± 0.021	0.021 ± 0.004	0.021 ± 0.004	0.104 ± 0.030	0.099 ± 0.033

(a): Total radioactivity: mean values (six animals) ± SD expressed as mg decoquinate/kg wet tissue.
(b): Decoquinate: average content (six animals) ± SD mg/kg wet tissue.

3.1.2. Rat

A study was designed to provide information about the excretion, tissue distribution and biotransformation of decoquinate in urine, faeces and tissues.[12] Two groups of rats (four males and four females per group, six to nine weeks of age) were administered orally (by gavage), twice a day for seven days, [^{14}C]-decoquinate at a dose of 2.4 mg/kg feed.[13] Groups of animals were killed 4 and 48 hours after withdrawal and tissues sampled. Blood was sampled throughout the experimental period in one group, while urine and faeces were collected for 48 hours in the second.

The results relevant to our assessment were the following:

i Most of the radioactivity administered was recovered in the faeces (82–87 %), urine being a minor excretion route (0.2–0.4 %). Decoquinate was the major component in the faeces (51 and 60 % of the dose excreted in male and female animals, respectively).

ii Tissue metabolic profiles showed that decoquinate was the major component in liver, kidney, muscle, skin and fat (accounting for 19.6 % of liver and kidney radioactivity and 23.9 % of muscle, 31.2 % of skin and 76.5 % of fat total radioactivity). Six metabolites, three of which each accounted

[11] Technical dossier/Section III/Annexes 2.1.1.2.
[12] Technical dossier/Section III/Annex 2.1.1.3.
[13] Calculated following the Guidance on selected default values to be used by the EFSA Scientific Committee, Scientific Panels and Units in the absence of actual measured data (EFSA, 2012)

for more than 10 % of total radioactivity, were isolated from the liver. One or more of these metabolites were isolated from the other tissues.

iii In terms of comparative metabolism, it appeared that the absorbed fraction of decoquinate is metabolised more extensively in rat than in chicken, with the production of different metabolites.

3.2. Toxicological studies

The FEEDAP Panel reassessed the package of toxicological studies submitted in the frame of a previous application (EFSA, 2003).

The mutagenicity studies presented for the previous assessment were carried out in accordance with Good Laboratory Practice (GLP) or were published in peer-reviewed journals, and the results suggested that decoquinate is not genotoxic. A mouse lymphoma assay found that decoquinate caused gene mutation *in vitro* at the highest concentration tested in the presence of metabolic activation, but it was questionable whether it should be regarded as a positive result as most of the cells were killed at this concentration. Other *in vitro* mutagenicity tests (*Salmonella*/microsome reverse mutation assay, a bacterial *rec* assay and a cytogenetics test in mammalian cells) gave negative results.[14]

Aa new *in vivo* mammalian erythrocyte micronucleus test were submitted by the applicant.[15] Rats were given two daily intraperitoneal doses of up to 800 mg decoquinate/kg bw in accordance with OECD Guideline 474 and GLP.[16] The study gave negative results for genotoxicity.

Acute oral toxicity was low in rats. The repeated-dose oral toxicity studies and developmental studies reported were done to standards appropriate to the time but some were not in accordance either with GLP or with previous and current OECD guidelines. However, the quality of the studies was considered sufficient for the assessment. Repeat-dose oral toxicity studies were performed in rats (several studies of duration 16 days to 2 years) and dogs (12-week and 2-year studies), with the lowest NOEL seen in these studies being 15 mg/kg bw per day for subdued behaviour in dogs given 62.5 mg/kg bw per day for 12 weeks. No adverse effects were seen in rats at doses of up to 37.7 mg/kg bw per day for up to two years. No carcinogenicity studies were available, but the two-year chronic toxicity study showed no effects on tumour incidences. A three-generation reproduction study in rats showed no adverse effects up to the highest dose tested (60.6 mg/kg bw per day). A rat developmental toxicity study showed fetotoxicity (retarded skeletal development) at 300 mg/kg bw per day, with a NOEL of 100 mg/kg bw per day, but showed no embryotoxicity or teratogenicity. A rabbit developmental toxicity study showed embryotoxicity at 100 mg/kg bw per day, with a NOEL of 60 mg/kg bw per day, but with no fetotoxic or teratogenic effects (EFSA, 2003).

No treatment-related adverse effects were seen in any of the studies at doses of 15 mg/kg bw per day or less and this dose was therefore adopted as the overall NOEL.

3.3. Acceptable daily intake

In its former assessment of Deccox® (EFSA, 2003), the FEEDAP Panel established an ADI of 0.075 mg/kg bw by applying a 200-fold uncertainty factor to a NOEL of 15 mg/kg bw per day for subdued behaviour, reduced activity and emesis in dogs in a 12-week oral toxicity study.

The uncertainty factor of 200 incorporated a factor of 100 to account for intraspecies and interspecies variation and an additional factor of 2 to account for uncertainty about the NOEL due to the fact that the critical dog study and some of the other toxicity studies, including the rabbit developmental study, were not conducted to modern standards. This is confirmed by the present assessment.

[14] Technical dossier/Section III/2.2.
[15] Technical dossier/Section III/Annex 2.2.2.1.
[16] GLP (ENV/MC/CHEM(98)17).

3.4. Withdrawal time

The highest consumer exposure corresponding to two (liver) and six (other tissues) hours withdrawal, and resulting in a withdrawal time, in practice, of zero days, has been calculated on the basis of maximised (average plus two standard deviations) total residue values (see Table 2), using the theoretical consumption figures defined in Regulation (EC) No 429/2008[17] for the different tissues (Table 3).

Table 3: Maximised consumer exposure to decoquinate total residues

	Liver	Kidney	Muscle	Skin/fat	Sum
TRC [(a)] (mg/kg)	0.511	0.482	0.066	0.285	
DITR [(b)] (mg)	0.051	0.005	0.020	0.026	0.102

(a): Total residues concentration expressed as decoquinate (average + 2SD).
(b): Daily intake total residues corresponding to the theoretical consumption figures.

The results indicate that consumer exposure to the total decoquinate residues present in chicken tissues at what would, in practice, be zero days' withdrawal would be about 2 % of the ADI (0.075 mg/kg bw, equivalent to 4.5 mg per person per day). Consequently, the use of decoquinate up to 40 mg/kg complete feed for chickens for fattening does not give rise to concerns regarding consumer safety. Therefore, no withdrawal period would be required.

3.4.1. Maximum residue limits

During the previous evaluation, limited data available on identification and quantification of metabolites (both in chicken and in rats) could not adequately allow the assessment of consumer exposure to residues. As a consequence, the FEEDAP Panel was unable to establish an MRL for decoquinate (EFSA, 2003).

It was noted that, since the EU's Committee on Veterinary Medicinal Products (CVMP) assessed use of decoquinate as a veterinary medicine,[18] Commission Regulation (EU) No 37/2010 advised that the concentrations of residues in muscle, liver, kidney and fat as a consequence of authorised use in cattle and sheep were unlikely to be sufficiently high to be hazardous to consumers.[19] The new residue data submitted confirm that there is also no need to introduce MRLs in chicken tissues to ensure consumer safety.

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[20] and by Good Manufacturing Practice.

CONCLUSIONS

Decoquinate is not genotoxic and is not carcinogenic. The lowest NOEL was 15 mg/kg bw per day, observed in a 12-week oral toxicity study in dogs.

The ADI of decoquinate, already established by the FEEDAP Panel in 2003, is confirmed. The value is 0.075 mg/kg bw based on the above NOEL, applying an uncertainty factor of 200.

[17] 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.
[18] European Medicines Evaluation Agency, 2000, Decoquinate Summary report (2), European Public Assessment Reports, EMEA/MRL/722/99.
[19] OJ L 15, 21.1.2010, p. 1.
[20] 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.

On the basis of new metabolism/residue studies in chicken and rat, major metabolites appeared to be dissimilar in these two species. Nevertheless, the assessment of consumer safety refers to the ADI of decoquinate, considering the limited exposure of consumers to metabolites from chicken tissues. Decoquinate is the marker residue.

A conservative consumer exposure estimate based on total residues measured two or six hours after withdrawal indicates that it would be about 2 % of the ADI. Since a withdrawal period of two or six hours corresponds to a withdrawal time of zero days under practical husbandry conditions, a zero days withdrawal time does not compromise consumer safety.

The new residues data submitted confirm that no MRLs are considered necessary.

DOCUMENTATION PROVIDED TO EFSA

1. Deccox®. March 2013. Submitted by Pfizer Ltd.

2. Evaluation report of the European Union Reference Laboratory for Feed Additives on the Methods(s) of Analysis for decoquinate.

3. Comments from Member States received through the ScienceNet.

REFERENCES

EFSA (European Food Safety Authority), 2003. Opinion of the Scientific Panel on Additives and Products or Substances used in Animal feed on a request from the Commission on the coccidiostat DECCOX® in accordance with article 9G of Council Directive 70/524/EEC. EFSA Journal 2003, 17, 1-40.

EFSA Scientific Committee (EFSA), 2012. Guidance on selected default values to be used by the EFSA Scientific Committee, Scientific Panels and Units in the absence of actual measured data. EFSA Journal 2012;10(3):2579, 32 pp. doi:10.2903/j.efsa.2012.2579

APPENDIX

Executive Summary of the Evaluation Report of the European Union Reference Laboratory for Feed Additives on the Method(s) of Analysis for decoquinate[21]

Deccox® is a feed additive currently authorized in chickens for fattening by Commission Regulation (EC) No 1289/2004 belonging to the group "Coccidiostats and other medicinal substances" listed in Chapter I of Annex B of Directive 70/524/EEC. In the current application a modification of the existing *Deccox®* authorisation is requested, under article 13(3), proposing new Maximum Residue Limits (MRLs) for *decoquinate* in chicken tissues and requesting a modification of the withdrawal period from three to zero days. *Deccox®* consists of 6 % *decoquinate*, 0.6 % colloidal silica, 2.85 % soya-bean oil on a wheat middlings carrier. The *Deccox®* active substance is *decoquinate,* a quinoline coccidiostat, with a minimum purity of 98%. *Deccox®* is a buff-coloured coarse powder formulation to be incorporated in *feedingstuffs* through *premixtures.* The Applicant suggested a concentration of *decoquinate* in *feedingstuffs* ranging from 20-40 mg/kg. Furthermore the Applicant proposed the following MRLs for *decoquinate* in poultry *tissues*: 500 µg/kg in muscle, 800 µg/kg in kidney and 1000 µg/kg in skin/fat or in liver. These MRLs are not covered by the Commission Regulation (EC) No 37/2010 and need therefore to be evaluated by the EURL.

For the determination of *decoquinate* in the *feed additive, premixtures* and *feedingstuffs*, the Applicant submitted the ring-trial validated CEN standard method (EN 16162:2012). Furthermore, the Applicant demonstrated the applicability of the CEN method to *premixtures* and *feedingstuffs* samples containing Deccox by performing a supplementary verification study. The performance characteristics provided are comparable to those of the EN 16162:2012 standard. Based on the experimental evidence provided, the EURL recommends for official control ring-trial validated CEN standard method (EN 16162:2012) based on Reversed Phase High Performance Liquid Chromatography coupled to fluorescence detection (RP-HPLC-FL) for the determination of *decoquinate* in the *feed additive,* in *premixtures* and *feedingstuffs* For the determination of *decoquinate residues* in *tissues*, the Applicant submitted a single laboratory validated and further verified method, based on Reversed Phase High Performance Liquid Chromatography coupled to a triple quadrupole mass spectrometer in electrospray ionisation mode using matrix matched standards (RP-HPLC-MS/MS). The following performance characteristics are reported: precision (repeatability and/or intermediate precision) ranging from 0.9 to 7.2% and a recovery rate ranging from 95 to 110%. Based on the performance characteristics presented, the EURL recommends for official control the RPHPLC- MS/MS method proposed by the Applicant to enforce the *decoquinate* MRLs in the relevant *tissues*.

Further testing or validation of the methods to be performed through the consortium of

National Reference Laboratories as specified by article 10 (Commission Regulation (EC) No 378/2005) is not considered necessary.

[21] The full report is available on the EURL website: http://irmm.jrc.ec.europa.eu/SiteCollectionDocuments/FinRep-FAD-2013-0009-Deccox.doc.pdf