

COUNCIL PROPOSAL TO REPLACE REGULATION 2377/90 – DISCUSSION PAPER ON SETTING REFERENCE POINTS FOR ACTION (RPAs)

This paper is to help discussion on this issue, and is not the UK's definitive view.

Introduction

1. The UK recognises that control procedures are needed for detecting the presence of prohibited substances in third country¹ (3C) food entering the EU. The UK considers it essential that a clear strategy is produced which all producers (EU and non-EU) can understand, and which is straightforward to enforce. This must have a level playing field for all producers without compromising consumer protection – in particular it must avoid giving 3C producers (and EU consumers) the impression that RPAs are simply Maximum Residue Limits (MRLs) by another name.

Background

2. In 2002, 3Cs expressed concerns to the Commission that there was no consistency in approach between Member States (MSs) in dealing with imported foodstuffs. This led to the introduction of Minimum Required Performance Limits (MRPLs) for certain substances not authorised for use in food producing animals in the EU (chloramphenicol, nitrofurans metabolites, MPA, and the sum of malachite green/leucomalachite green). The MRPL concept was introduced in Commission Decision 2002/657. MRPLs were set on the analytical performance which Community Reference Laboratories (CRLs) believed could be achieved by all MS laboratories for the respective substances. Although MRPLs were recommended technical limits, they became, in effect, action levels for determining whether the import consignment entered the food chain under the provisions of Commission Decision 2005/34.

3. Commission Decision 2005/34 also requires Member States to report where the presence of certain prohibited substances below the MRPL is persistently detected in food from the same country. The Commission may then take action.

4. Council Regulation 882/2004 (Official Food and Feed Controls) allows MSs receiving consignments with prohibited substances above the MRPL to:

- destroy the consignment,
- subject it to any other appropriate measure necessary to protect human health, or
- re-dispatch it – usually back to the 3C of origin.

Current Situation

5. Not all MS laboratories can analyse to the concentrations set as MRPLs, whereas others can achieve well below them. There are also different approaches taken by MSs (allowed by 882/2004): some destroy the consignments where the presence of prohibited substances is confirmed above the MRPLs and others re-

¹ Third countries are those that are neither members of the EU nor associated states.

dispatch consignments. This has not produced the consistent approach 3Cs said they wanted.

6. Rather worryingly, it seems that some 3C traders see the MRPLs as a type of MRL – believing it is acceptable to use a prohibited substance in produce destined for the EU provided it is below the MRPL when analysed on arrival in the EU. This is contrary to the equivalent guarantees/certification provided by the 3C to the Commission to enable those countries to import into the EU. There is possibly more incentive to use prohibited substances if non-compliant consignments are returned by MSs to the country of origin, rather than destroyed (see paragraph 24).

Proposal for RPAs contained in 2377/90

7. The proposal is to set RPAs for substances for which administration is prohibited in the EU (Article 13(2) (d)) of the draft Regulation. In addition to the “MRPL substances” this can, of course, include all prohibited Group A substances in Annex I of Council Directive 96/23. This is the Directive that sets out surveillance requirements.

8. Article 17 (2)² states that RPAs shall be adapted in accordance with the regulatory procedure with scrutiny referred to in Article 21(3) – the “Comitology” procedure³.

9. Article 17(3) states that RPAs will be reviewed regularly in the light of technological progress (presumably this means analytical methods rather than scientific knowledge). The UK (and others) have suggested that it should also include scientific progress, and notes that Recital 22⁴ indicates that the Community should provide for RPAs at concentrations for which *scientific advice* indicates that consumer exposure is negligible.

10. Article 18(1) provides for RPAs to be set on the analytical performance recommended by CRLs (in the same way the MRPLs were set). Article 18(2)(3)(4) state that the Commission may forward a request to the European Food Safety Authority (EFSA) for a risk assessment, taking account of rules prepared by the Commission in consultation with EFSA, and which are adopted in accordance with Article 21(3) – the Comitology procedure again.

Discussions in Council Working Group Meetings.

11. Whilst all Member States appear content to have control measures for dealing with prohibited substances in foodstuffs, several MSs have expressed concern about how RPAs will be set. The Commission has been asked if the European Food Safety Authority (EFSA) has been consulted on its proposed role, but has replied that systematic involvement of EFSA will “kill the system”.

² Articles 17 and 18 are re-numbered Articles 15 and 16 in the revised proposal 16219/07 ADD1 dated 7-12-07.

³ Refers to the network or procedures of committees designed to oversee the agreement of implementing measures taken by the European Union's executive bodies.

⁴ Recitals are the numbered notes that appear at the start of EU Regulations and Directives.

12. The Commission has stated that MRLs and RPAs are conceptually very different; in that the MRL is a consumer measure and the RPA is a control measure. However, the bottom line is that foodstuffs with prohibited substances (including those for which no safe limit can be set) would enter the food chain without a toxicological assessment, provided they are below the Reference concentration. In this respect, the situation is no different to food that contains a substance with an MRL, except, of course, that the substance with an MRL has undergone a full safety assessment. Some MSs, including the UK, still have concerns that the intention is to set RPAs based on exposure to detectable levels of a hazard rather than on an assessed risk to human health.

13. Setting RPAs which apply to EU countries in addition to 3Cs will have implications for court cases. Prosecuting a producer for using a prohibited substance will be confusing if the residue concentration in the produce is below the RPA. In this case, the produce can enter the food chain in accordance with current legislation. This would send out conflicting messages to the judicial services.

Options for moving forward.

14. The desire to have a level playing field for both EU and 3C producers must incorporate maintaining consumer protection in accordance with the stated principles in the Reflections exercise. There appear to be only two options for achieving a level playing field:

- to move the RPAs as far as possible to ‘zero tolerance’ for importers to come in line with the approach within the EU. Whilst this would be more reassuring for consumers and EU producers, it would be unpopular with 3Cs, which wanted reference limits for imports to enable MSs to take a consistent approach with imported consignments. This option would not give a level playing field in terms of enforcement at points of entry of imports into the EU unless the action level was achievable in all MS laboratories analysing imported food. Otherwise it could encourage some laboratories to engage in a spiral of constantly lowering analytical limits, which would leave less proficient laboratories constantly struggling to keep up unless they are given more help. Consumer protection could be reduced if trade patterns then changed to take advantage of differences between MSs.
- to move EU producers up from “zero tolerance” to the RPA under the same conditions as importers, while setting the RPA as low as practically possible to protect consumers. That is, the prohibited substance should not be present in food produced within or entering the EU, but anything below the RPA is accepted into the food chain, for both EU and 3C produce. This puts less pressure on MS Laboratories to keep improving analytical limits, but, as indicated earlier, it risks sending out the wrong message to EU consumers and the courts about use of prohibited substances. However, enforcement action could still be taken against EU producers for using prohibited substances.

Discussion

15. (Throughout the discussion in setting RPAs, it is recognised that there are two types of substances prohibited for use in food producing animals:

- i) those which are not known to be dangerous, in respect of which no company has sought an authorisation, but, if it did, authorisation might be granted, and
- ii) those substances which are known to be dangerous and for which authorisation will not be granted.

There may be some scope here to help distinguish between those substances that should be referred to EFSA and those that are lower priority at present, but which may still merit attention from EFSA at a later time.)

16. Control measures are needed to detect prohibited substances in 3C produce entering the EU; where malachite green, chloramphenicol and nitrofurans metabolites are the most common problems. The concern is that continuing to base them on recommended analytical performance does not give consumers any information about the potential health risk when their presence in food is reported. This is why there is a desire from many Member States to stipulate that EFSA should consider these substances before RPAs are introduced⁵.

17. The Commission noted at the last meeting that it has information for chloramphenicol. There are also international assessment data. It may therefore be possible for a risk assessment to be carried out by EFSA to see if the current MRPL of 0.3 µg/kg safeguards consumers. The Commission has said it does not have a dossier for malachite green, although the UK notes that the US conducted long-term toxicity studies and work is being done elsewhere which may provide useful background information. It is unlikely that there are up-to-date data for nitrofurans, although these were permitted substances up to the mid-1990s.

18. It has been suggested that a “pilot study” could be carried out by EFSA using one of the prohibited substances with an MRPL. On the basis of the above it appears that chloramphenicol and malachite green are candidates for such a study. Clearly the result from one pilot study cannot read across to all prohibited substances, but, if EFSA agreed with the MRPL for the pilot study substance, it would give consumers more general reassurance about the system than not having any risk assessment done.

19. If MRPLs automatically become RPAs, with or without a risk assessment, consideration should be given to whether this should be stated in the new Regulation. This would probably mean repealing Commission Decision 2005/34 at the same time, otherwise it is difficult to see how MRPLs will become RPAs.

20. Once an RPA is set, the UK recommends that it is not changed for a fixed period (say five years) unless new safety data emerges which suggests that a lower limit is urgently needed. If an RPA is not changed for some time, then that will introduce some stability into the system.

⁵ Article 16(2) now reads “If the basic scientific data on the substance in question is available, the Commission shall forward a request to the European Food Safety Authority for a risk assessment as to whether the reference points for action are adequate to protect human health.”

Role of Community Reference Laboratories⁶ (CRLs)

21. In the UK's opinion, there is a need for a clearer and transparent system to be set up to enable CRLs to help bring less proficient National Reference Laboratories up to the required standard. In discussing the analytical limits recommended by CRLs for Group A substances it was clear that some of the limits are unachievable on a consistent basis even for the most experienced MS laboratories. The more ambitious limits must remain as a goal to be achieved in the future, with a clear coordinated plan to help all MS labs attain them by a defined deadline. The Reflections Working Group discussing CRLs came up with some suggestions for improving communications, and hopefully these can be taken forward together with the proposal to replace Council Directive 96/23.

Dealing with non-compliant imports (in respect of veterinary medicines)

22. The key requirement is a level playing field. At present, different Member States have different levels of analytical proficiency and each can decide its own policy on how to deal with imported consignments of food which are found to contain non-compliant residues. If Member States can adopt a common approach to non-compliant residues in imports, exporting countries can't 'shop' for ports of entry where there is less stringent analysis for residues or where there are less serious consequences if non-compliant residues are found. If Member States can achieve this 'level playing field', we can avoid trade distortions and ensure consumer protection.

23. It is possible that by setting RPAs, based on toxicological grounds and agreeing a common approach for when non-compliant residues are detected we could move toward the level playing field. However, It could mean that there would have to be either a concerted effort to get all EU Member States up to the required standard of analysis, or only allow imports through ports where such analysis is available.

24. What would be the agreed way of dealing with consignments found to contain non-compliant residues above the RPA? We could require all Member States to:

- redispach all such consignments to the country of origin
- destroy all such consignments
- destroy all consignments where substances for which no safe limit can be set are detected, but allow re-dispatch where the non-compliant residues are of substances, which while not authorised in the EU, are not actively banned.

25. To do this it could require a change in the EU legislation. Regulation 882/2004 allows a range of options, which has resulted in the inconsistent approach. But amending this Regulation may not be appropriate, as the options it provides affect many sectors. So it could require specific veterinary residues legislation. Council Directive

⁶ For each substance or group of substances, the EU appoints a CRL, which takes the lead on developing analytical methods and assisting other countries with their methods. NRLs take on responsibility for developing these methods within each Member State.

96/23/EC, which requires Member States to carry out surveillance for such residues, is due to be revised. So, it could be amended to include the agreed way of dealing with non-compliant import consignments.

26. **Redispatch** – Sending all non-compliant consignments back to the country of origin may give the impression that the EU is content for others to consume food that contains a substance “for which no safe limit can be set”. It could also allow 3Cs to resend the consignment to another port in the hope it would not be sampled.

27. **Destruction** - Article 23(2) of Council Directive 96/23 requires Member States to slaughter and destroy animals immediately where illegal treatment is confirmed. If this requirement is continued then there is an argument applying the same sanction on imports where detection of residues of prohibited substances would require destruction of the particular consignment. This would move EU producers closer to a level playing field, and will send out a strong message to third countries that their consignments are not in keeping with their guarantees of equivalence.

28. Destruction also removes the possibility of the consignment being sent to the EU a second time, in the hope that it evades checks this time. Balanced against this, it is recognised that returned goods may not necessarily be used for consumption, and may provide evidence to help some exporting countries address the source of the problem at home.

29. In order to avoid contravention of the World Trade Organisation Sanitary and Phytosanitary Agreement it could be important that our sanctions are supported by the science as a necessary and proportionate measure. If the RPAs are set on toxicological grounds we could defend this approach, but if they are set purely on analytical standards, it would be more difficult.

30. **Redispatch or destruction** – As we have said, not all non-compliant residues are the same. Some substances may be authorised in the country of origin, but not in the EU. Their presence at certain concentrations may not be a risk to human health. However, other substances – such as chloramphenicol – are actively banned, as no safe concentration can be set. It is possible we could require destruction where these banned substances are detected.

Questions

1) Is it the intention to automatically transfer existing MRPLs, based on recommended analytical performance, to RPA status? Would this be stated in the Regulation?

It is our understanding that the existing MRPLs will be transferred to RPA status, with legislation amended accordingly.

2) What are the circumstances under which EFSA will be consulted on a recommended RPA? Will a guidance document be produced to make the process clear and transparent?

3) If MRPLs automatically gain RPA status, will EFSA be consulted on some or all of those RPAs in due course?

Article 16(2) now reads "If the basic scientific data on the substance in question is available, the Commission shall forward a request to the European Food Safety Authority for a risk assessment as to whether the reference points for action are adequate to protect human health."

4) The intention appears to be to set further RPAs on analytical performance recommended by CRLs. How many substance groups will this cover? All prohibited substances?

5) Will there be a strategic and transparent system set up by CRLs to help bring less proficient Member State laboratories up to the required standard? *(Some of the recommended analytical limits for group A substances, banned in the EU, are unachievable on a consistent basis even for the most experienced MS laboratories.*

6) In looking at a list of introduced RPAs, how will it be possible to distinguish between an RPA based on analytical performance and one based on scientific (EFSA) assessment? *This could affect the risk management action taken as a result of RPAs being exceeded.*

7) Will RPAs be set on exposure or risk to consumer health? Setting it on risk to consumer health is more in keeping with Reflections principles regarding consumer protection.

The Commission remains keen to maintain its proposal that risk is based on exposure rather than risk to human health.

8) If the decision is to set RPAs for EU and 3C produce, and allow food below the RPA into the food chain, how do we deal with an EU producer caught using a prohibited substance?

9) Article 23(2) of Council Directive 96/23 requires animals to be slaughtered immediately where illegal treatment is confirmed. Will the introduction of RPAs mean that in future animals are only slaughtered when the residue concentration is above the RPA?

10) Council Regulation 882/2004 allows 3C consignments above the RPA to be destroyed, subjected to any other appropriate measure necessary to protect human health or re-dispatched. This has not achieved the level playing field between MSs or the consistency requested by the 3Cs. Would it be better to specify in legislation which option should be used by all Member States where consignments are above the RPA?