Implementation of a HACCP based approach for complying with Norwegian biosolids standards for pathogen control

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Sammendrag

I Norge har vi hatt tradisjon for å disponere slam fra avløpsrenseanlegg på jordbruks- og grøntarealer helt siden utbyggingen av renseanleggene startet for fullt på begynnelsen av 70-tallet. Bruk av slam er siden 2003 regulert gjennom en felles forskrift for gjødselvarer av organisk opphav (gjødselvareforskriften), men avløpsslam har vært gjenstand for ulike typer reguleringer helt siden 1975. Dagens forskrift har strenge kvalitetskrav til innhold av tungmetaller og patogener i slammet, og i tillegg er det begrensninger i bruksmengder av slam (tonn tørrstoff pr. dekar pr. 10 år) og type vekster som kan dyrkes der hvor det er spredd slam.

For å komme fram til et praktisk opplegg som avløpsrenseanleggene kan bruke for å dokumentere at de overholder hygieniseringskravet om inaktivering av eventuelle parasittegg i slam, tok Norsk Vann (tidligere NORVAR) initiativet til å få utviklet et kvalitetssystem for slambehandlingen ved renseanlegg basert på HACCP-prinsippene (HACCP = Hazard Analysis and Critical Control Points). Artikkelen beskriver hovedtrekkene i et HACCP-basert kvalitetssystem for hygienisering av slam, med hovedvekt på fastleggelse av kritiske kontrollpunkter og kritiske driftsbetingelser for ulike hygieniseringsmetoder. De kritiske driftsbetingelser er fastlagt for de vanligste hygieniseringmetodene gjennom prosessvalidering, basert på fullskala testing med infektive parasittegg av typen <u>Ascaris suum</u>.

Summary

Norway has a long tradition for land

application of biosolids. The recycling is currently (since 2003) based upon a joint regulation for all organically derived fertilizers, including biosolids, organic household waste, food processing waste, farm waste, animal manure etc., but the treatment and use of biosolids have been regulated in Norway since the mid-seventies. The regulation has stringent standards for pathogen control (close to US EPA Class A standards), in addition to limits for heavy metals in biosolids and soils, and restrictions on the use of biosolids (application rate and type of crops). In order to comply with the standards for pathogen control, the Norwegian Water and Wastewater Works Association has supported the development of a quality assurance (QA) system for sludge treatment plants based upon HACCP principles (HACCP = Hazard Analysis and Critical Control Points). The paper presents the framework of the HACCP based QA-system for sludge hygienisation processes with emphasis on the determination of the Critical Control Points and their Critical Limits (CL) for complying with the pathogen control standards. The CLs have been determined by process validation for most of the sludge hygienisation methods employed in Norway (e.g. pre-pasteurisation, thermophilic aerobic pre-treatment, thermophilic anaerobic digestion, lime treatment). The processes have been validated against their ability to inactivate helminth ova since this is the crucial criteria for pathogen control in the Norwegian regulation. HACCP based QA systems have been implemented at many treatment plants during the last 2-3 years, and some of them have already been audited with good results by the responsible authority.

Introduction

Most of the sewage treatment plants in Norway are built after 1970, and during the seventies and eighties there was a major increase in the number of plants, especially in the parts of the country with discharges to inland waters and narrow fjords. With the increasing number of sewage treatment plants, the amount of sewage sludge increased as well, and there was a need for some guidance to the municipalities about the management of sewage sludge (biosolids).

In 1976 the Norwegian public health authorities presented hygienic guidelines for the recycling of biosolids on agricultural land. These guidelines were further developed to also include environmental matters, and in 1982 the pollution control authorities and the public health authorities jointly issued guidelines for the temporary storage, use and disposal of biosolids in Norway. These guidelines recommended either agricultural use ore use on "green areas" (i.e. parks, road sides, reclamation sites and other types of areas not producing crops for human consumption), while landfilling of sewage sludge should be considered only when the recycling options were not feasible for a specific sewage treatment plant. Land application of untreated sludge was not allowed, but on agricultural land dewatered sludge

(20-25% solids) could be spread after a storage period of minimum six months (of which two months had to be in summer). In addition there were recommendations on application rates and type of crops to be grown, and standards for heavy metals content in biosolids were included. When recycling biosolids on green areas a better hygienic quality of the biosolids was recommended due to the possible exposure to the public in parks etc., and in practice only composted sludge was used for this option.

Storage sites for dewatered untreated sludge prior to agricultural use were either centralised or located on the premises of the farmer receiving the sludge. In the second part of the 1980s the agricultural use of increasing amounts of non-stabilised sewage sludge generated a lot of complaints from residents living close to the sludge storage sites. This situation, combined with an increasing scepticism to the content of potential toxic elements (i.e. heavy metals and organic micropollutants) in sewage sludge, forced the authorities to start reviewing the existing guidelines. In this process there was an open dialogue between the authorities and the sewage treatment plant owners (mostly municipalities and inter-municipal companies), also including consultants and research institutions. A key issue was the treatment requirements for the two main biosolids outlets: farmland and green areas (no food production), since landfilling of sewage sludge should not be allowed under normal circumstances in the future, and incineration was considered too expensive for sludge handling in Norway. The authorities proposed to have the same treatment standards for the two major utilisation alternatives and to include requirements for both sludge stabilisation (to reduce odour nuisances) and hygienisation (to protect animal and human health). There was no risk based background for having the same pathogen control requirements for both utilisation options, but the key argument of the authorities was that they did not believe in two different classes of sludge regarding hygienic quality. They were afraid that farmers and other stakeholders would deny receiving "Class B" biosolids, even if they should be spread on arable land and ploughed down within 24 hours. Also the plant owners realised that having to invest in stabilisation processes anyway, the extra costs for a better pathogen control (hygienisation) could be marginal.

In 1991 the Norwegian public health and environmental authorities presented a proposal for a joint regulation on sewage sludge treatment and use, with a general requirement for stabilisation and hygienisation of all sludge to be recycled on land. The hygienisation criteria were mainly adapted from German guidelines (ATV/VKS, 1986, 1988a, 1988b), which include recommendations on design and operation of sludge treatment processes for pathogen control that had been employed for several years in full scale plants in Europe (Strauch, 1989). After passing public hearings and longlasting legal discussions, the new statutory regulation was launched in January 1995 by the Ministry of Health and Social Welfare and the Ministry of the Environment (1995). At the same time the authorities announced their target of 75% beneficial use on land areas of the total biosolids production within five years, and this was nearly accomplished (Paulsrud et al., 2001).

Even if the regulation had a three years transitional period for implementing stabilisation and hygienisation processes (until 1998), many treatment plant owners had started the upgrading of their sludge treatment processes already in the beginning of the 1990's due to problems with odour complaints. The following processes or process combination have been in operation in Norway since this period of implementation of the new requirements for stabilisation and hygienisation of sewage sludge:

- Thermophilic aerobic digestion
- Thermophilic aerobic pre-treatment + mesophilic anaerobic digestion (dual digestion)
- Pre-pasteurisation + mesophilic anaerobic digestion
- Thermal hydrolysis + mesophilic anaerobic digestion
- Mesophilic anaerobic digestion + thermal drying
- Thermophilic anaerobic digestion
- Composting (windrow or in-vessel)
- Lime treatment (addition of quick lime to dewatered sludge)
- Long-term (min. 3 years) storage of dewatered sludge

Existing regulations of biosolids in Norway

With the increasing amounts of organic waste materials to be recycled on land during the nineties, the Ministry of Agriculture found it necessary to harmonize the parallel regulations for each type of organic waste, considering both agronomic and veterinarian aspects, and consultations including the Ministry of the Environment and the Ministry of Health and Social Welfare were started. This process was completed in 2003 by a new joint regulation covering all organic materials spread on land i.e. farm waste, food processing waste, organic household wastes, garden waste and sewage sludge (biosolids), but with some exemptions for animal manure (Ministry of Agriculture, Ministry of the Environment and Ministry of Health and Social Welfare (2003).

The new regulation was called "Regulation of organically derived fertilizers" with the Ministry of Agriculture as the lead ministry and with their directorate, the Norwegian Agricultural Inspection Service (NAIS), in charge of the enforcement. In 2004 the NAIS was merged with several other directorates, creating the Norwegian Food Safety Authority (NFSA). The regulation of organically derived fertilizers now belongs to this authority.

In the joint regulation of fertilizers of organic origin the requirements on treatment and use of biosolids have only been slightly modified compared to the original 1995 regulation. In this paper, dealing with the pathogen control part of the regulation, only the major components of the regulation will be summarised. More detailed information is given by Walker (2003).

The regulation sets the following major requirements to organically derived fertilizers in general and with some special requirements for biosolids:

- All producers of organic fertilizers (including the production of biosolids) have to implement a quality assurance system.
- Quality criteria of the products include standards for heavy metals content, pathogens, weeds and impurities, in addition to a more general requirement of product stability (linked to odour emissions but no parameters or figures are given). The regulation has no specific limits for organic micropollutants, but there is a general statement about taking reasonable actions to limit and prevent such compounds that may cause harm to health or the environment. In practice surveys of actual content in biosolids are performed every five years since 1991.
- Requirements on product registration, declaration of product quantity and quality and also name and address of all receivers of biosolids.
- Requirements on labelling, marketing and sales of organic fertilizers (only valid for biosolids if they are part of a soil amendment product).
- Requirements on storage of products before use.
- Requirements on use of organic fertilizers with special crop restrictions for biosolids.

All organic fertilizers should meet the following criteria for hygienisation:

- No Salmonella sp. in 50 grams of sludge.
- No viable helminth ova.
- Less than 2,500 fecal coliforms per gram dry solids

This is the same pathogen control criteria as in the original biosolids regulation from 1995.

Framework of quality assurance system for biosolids production based upon HACCP principles

The 2003 regulation required implementation of a quality assurance (QA) system for all sewage treatment plants and sludge treatment plants producing biosolids for recycling on land. This requirement had formerly been included only in the regulation for composting plants treating source separated organic household waste, garden waste and similar organic wastes; one of the regulations that was merged with the biosolids regulation in 2003. The QA system must as a minimum, contain the following elements:

- Documentation of the producer's organization, including allocation of responsibility.
- Identification of the risks for non-compliance with the regulation and establishing preventive measures to reduce the risks.
- Routines to uncover non-conformity, implement corrective actions

and avoid recurrence.
- Systematic reviews of the QA system to ensure compliance with the intentions of the system.

Since 2003 audits of the producer's QA system is the pre-dominant control activity of the authorities (NFSA) to ensure compliance with the regulation of organically derived fertilizers. Dealing with this task the NFSA is taking advantage of the experiences with the previous audits of the composting plants (Katla et al., 2003).

After the final enforcement of the pathogen control criteria for biosolids in 1998, a discussion started between the biosolids industry and the health authorities on how to document that the sludge treatment processes were actually inactivating helminth ova. Most sewage treatment plants in Norway have very low densities of such eggs in the untreated sludge and it can be difficult to find any eggs in the treated sludge (biosolids) to verify that the hygienisation process actually inactivate them. In addition, the analytical procedure for determining viability of the helminth ova takes about 4 weeks and there are only a few laboratories in Norway performing this analysis. To overcome these problem, the Norwegian Water and Wastewater Works Association (NORVAR), on behalf of the biosolids industry, started a project in 2001 to implement the HACCP (Hazard Analysis and Critical Control Points) principles into the QA system that every plant would have to establish from 2003 due to the new regulation.

The HACCP principles were developed by the Pillsbury Company for NASA during the 1960's to reduce the risk of food poisoning to astronauts and to come up with something better than end product testing of food. Since then the HACCP has been used in the food industry to identify potential food safety hazards, so that key actions, known as Critical Control Points (CCP's) can be taken to reduce or eliminate the risk of the hazards being realised. HACCP has been adopted by the World Health Organization (FAO, 1997), the European Union and most national governments as the basis of producing safe food and drinking water. HACCP has also been suggested for use in the UK water industry in a draft revision of their Sludge (Use in Agriculture) Regulations (Davies et al., 2002; Siljehag & Low, 2002) and for compost producers (Evans, 2003).

HACCP is based around seven established principles:

1. Conduct a hazard analysis
2. Identify critical control points (CCP's)
3. Establish critical limits (CL's) for each critical control point
4. Establish and implement effective monitoring procedures at critical control points
5. Establish corrective actions to be taken when monitoring indicates a deviation from an establish critical limit
6. Establish record keeping procedures
7. Establish procedures for verifying the HACCP system is working as intended

Determination of critical control points (CCP's) and critical limits (CL's) for sludge treatment processes to inactivate helminth ova

By implementing the HACCP principles for controlling inactivation of helminth ova by different sludge hygienisation processes, finding the CCP's and CL's for each plant are the key issues. For most of the hygienisation processes employed in Norway (see Introduction), the CCP's will be the process temperature and the exposure time for each sludge particle at that temperature (time-temperature combinations) (Carrington, 2001; US EPA, 2003). Process temperatures can easily be monitored continuously in most plants, and the exposure time (holding time) is a simple measurement as well when dealing with batch or semi-continuous processes. For continuous processes (e.g. thermal drying, in-vessel composting) tracer studies should be performed to determine the real minimum exposure time at actual temperatures in the process.

In the NORVAR project about HACCP implementation (started in 2001) it was soon realised that one of the major issues for the sludge treatment plants was to determine CL's for inactivation of helminth ova by the different hygienisation processes employed in Norway. Some alternatives were discussed with the authorities:

1. Adopting literature data based upon experiences and regulations in other countries
2. Performing validation tests at a typical full scale plant representing a certain hygienisation process operating in batch or semi-continuous mode
3. Performing validation tests at each full scale plant where the operating conditions are difficult to define (varying process temperature and/or exposure time)

A literature review proved that Alternative 1 was difficult to apply since the information from other countries was not consistent (ATV/VKS, 1988b; Carrington, 2001; US EPA, 2003). During the period 2002-2005 several full scale plants, each representing a specific hygienisation process, was validated according to Alternative 2 (Paulsrud et al., 2004; Paulsrud, 2005). In all process validation tests viable eggs of Ascaris suum have been used, employing semi-permeable nylon bags or Sentinel chambers (small plastic cylinders with fine mesh screens in both ends). The test units were inserted into the process under actual process conditions recording the exact temperature of the test units by temperature probes fixed to the units. Exposure time was the only controlled variable during the tests, and different exposure times were selected at each plant to cover both normal operation conditions and shorter exposure times. Three replicate test units were used for each exposure time.

In Table 1 we have summarized the critical limits for inactivation of Ascaris eggs by different sludge hygienisation processes based upon process validation. All processes have been validated in full scale, but for lime treatment and thermophilic anaerobic digestion additional validation tests have been performed in pilot scale. For some processes it is recommended that operating values for process control are set at higher temperatures and/or longer exposure times than the critical limits given by validation. At each individual plant the HACCP team should, in their hazard analysis, propose a safety margin that should be added to the validated CL's.

Norwegian experiences with pathogen control based upon HACCP principles

Since 2003 many sewage treatment plants in Norway have established a QA system in accordance with the new regulation, and eventually the plants are adopting the HACCP principles recommended by NORVAR and the authorities (NFSA). Implementing HACCP into the QA system, the treatment plants are supposed to cover all the quality criteria in the regulation, not only the pathogen standards.

Hygienisation process	Critical Limits (CL's)		Recommended operating values
	Minimum temperature (°C)	Minimum exposure time (min.)	
Pre-pasteurisation	65	30	70°C for 30 min.
Thermophilic aerobic pre-treatment	60	60	60°C for 90 min.
Thermophilic anaerobic digestion (semi-continuous, draw-and-fill mode	55	90	55°C for 120 min.
Lime conditioning + vacuum drying	80	50	80°C for 90 min.[1)]
Lime treatment (quicklime addition to dewatered sludge)	55	120	55°C for 120 min.

1) This is the design operating values for the process equipment

Table 1. Critical limits for inactivation of Ascaris eggs based upon validation tests of different sludge hygienisation processes (Paulsrud et al., 2004; Paulsrud, 2005).

More projects are currently under way to validate long-term storage of sewage sludge and mixtures of sewage sludge and bulking agents under different climatic conditions, and also to validate a certain thermal dryer regarding the inactivation of helminth ova.

One of the major challenges for the pathogen control by HACCP has been to establish corrective measures to be taken when monitoring indicates a deviation from an established critical limit. The solutions have to be site specific and should be included in the QA system for each plant. Examples of solutions are:

- Repeated treatment at the plant (not possible for all hygienisation processes)
- Transportation of the actual amount of sludge to a neighbouring treatment plant for proper hygienisation
- Establishing a contingency process scheme, e.g. based upon long-term storage prior to recycling on land

All treatment plants also need to have a plan for sampling and analysis of the biosolids before they are trucked away. This end product testing is primarily for determining the content of organic matter, nutrients and heavy metals, but they should also be analysed for Salmonella spp. and fecal coliforms in order to discover any recontamination of the biosolids. The experiences so far are that several treatment plants have realized high densities of fecal coliforms and also Salmonella, even if the hygienisation process has been operating according to the relevant critical limits. In almost all such cases it has been possible to find reliable reasons for the high bacteria content, and the most frequent explanations are related to improper hygienic housekeeping at the actual plant. Recontamination by internal streams and leakages originating from the wastewater treatment processes or from the sludge treatment processes prior to the hygienisation step has been experienced several times.

Some of the sludge treatment plants starting early with their HACCP based QA system have already been audited by the NFSA with only minor remarks to their systems and the way they are operated. The treatment plants organization (NORVAR) is very positive to increasing the frequency of the audits, since well operated QA systems is a necessary tool in securing biosolids recycling outlets for the future (Tornes et al., 2007).

Conclusions

Norway has a long tradition for the beneficial recycling of biosolids on land, and this practice has been supported by different national authorities, representing human, animal and plant health as well as agronomic and environmental aspects.

The governmental support has been linked to the stringent standards regulating land application of biosolids. These standards have contributed to improved stakeholder confidence and public perception in general.

A recent (2003) joint regulation for organically derived fertilizers requires all plants producing such fertilizers (including biosolids) to establish and operate a quality assurance system. Both the authorities and the biosolids industry recommends implementing HACCP principles into the QA system. By this approach the treatment plants can document compliance with pathogen standards in the regulation, and especially the criteria of helminth ova inactivation, which is the most stringent of the pathogen criteria.

Crucial parts of a HACCP based pathogen control system are the determination of the critical control points and their critical limits (CL's). The biosolids industry in Norway has spent considerable resources on the validation of actual hygienisation processes in order to come up with CL's for inactivation of helminth ova (mainly time-temperature combinations).

Experiences so far support the assumption that HACCP based QA systems can make a major contribution to the continuing work with maintaining and improving biosolids recycling on land for beneficial use

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