



REGULATION OF DISINFECTANTS INTENDED FOR USE IN THE CITRUS INDUSTRY

by

Paul Hardman (CGA), Paul Fourie, Arno Erasmus and Keith Lesar (CRI)

CRI is being regularly asked to conduct trials on new disinfectants and sanitizers that might improve sanitation in the packhouse. Similarly growers often contact the CGA office seeking information about the permissibility and suitability of products being marketed to them for packhouse sanitation. This Cutting Edge seeks to provide clarity around the regulatory framework when considering the suitability of a sanitizer for a particular use in the packhouse. This is deemed necessary because some sanitizers currently on the market result in detectable residues and could lead to the rejection of fruit placed on the market. A final section looks at the current status of Quaternary Ammonium Compounds (QACs) in the European Union in light of recent detections of QACs (DDAC and BAC) on fruit and vegetable products.

When deciding on whether to use a new disinfectant/sanitizer it might be helpful to have the following question in mind:

- Under which Act is the disinfectant/sanitizer registered?
- Is it registered for the intended purpose?
- Are there any toxicological concerns associated with the product?
- Does the product leave a residue (confirmed by an independent source)?
- If a residue is likely, is there a tolerance (Maximum Residue Level) in South Africa or in the importing country?
- Is the product suitable for the intended use? For instance, has it been tested to demonstrate its phytotoxicity risk?

To help answer these questions a brief review of the key strings of legislation are provided here.

Disinfectant Regulation in South Africa

Act No. 5 of 2008: The National Regulator for Compulsory Specifications Act

The National Regulator for Compulsory Specifications Act (Act 5 of 2008) was promulgated in Government Gazette 31216 on 4th July 2008 and took effect on 1st September 2008. The Act transferred the Regulatory Division of the South African Bureau of Standards (SABS) and all regulatory functions of the SABS to a new statutory Department of Trade and Industry (DTI) institution - the National Regulator for Compulsory

Specifications (NRCS) (*Source: www.nrccs.org.za*). In citrus industry circles the SABS regulation was known as "Act 29", which has effectively been replaced now with this Act 5 of 2008.

All disinfectants marketed in South Africa are subject to this compulsory specification. "The intention of this compulsory specification is to ensure that any product that is claimed to be a disinfectant should meet or exceed the performance claimed on the label and supporting publicity material and data sheets. It only covers requirements for disinfectants intended for use on inanimate surfaces. It does not cover antiseptics or bacteriostatic agents" (*Source: www.nrccs.org.za*). Inanimate surfaces are defined as "any substance other than human or animal surfaces" by Public Notice R529 (14th May 1999).

In addition to the requirements in this specification, the requirements promulgated under the Fertilizers, Farm Feeds, Agricultural Remedies and Stock Remedies Act, 1947 (Act No. 36 of 1947), the Medicines and Related Substances Act, 1965 (Act No. 101 of 1965), and the Foodstuffs, Cosmetics and Disinfectants Act, 1972 (Act No. 54 of 1972) also apply. Biocides for use in water treatment are excluded. If a disinfectant complies with the requirements of this compulsory specification, it can be considered to be bactericidal, fungicidal, sporicidal or virucidal, but it should not necessarily be inferred that it is suitable for a defined purpose.

Implications for the citrus industry

- Act 5 of 2008 does not necessarily consider human toxicity or ecotoxicity and is not subject to rigorous evaluation (such as for products registered under Act 36 of 1947).
- Act 5 of 2008 does not consider the level of the resultant residues and whether these would comply with South African or importing countries' Maximum Residue Levels. Unless packhouse managers are sure this product will not leave residues at levels that are problematic, the product should not be considered suitable for use in packhouses. The recent detections of QACs in the EU is a case in point.
- DAFF: Directorate Food Safety and Quality Assurance (FSQA) have indicated a preference for disinfectants coming into direct contact with fruit to be registered under Act 36 of 1947 and not Act 5 of 2008 due to the residue considerations. (Note DAFF: FSQA is a different directorate to Act 36, which falls into DAFF: Directorate Agricultural Inputs Control).

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- While registration of a product under Act 5 of 2008 is less expensive and allows suppliers to bring a product to market more quickly, it provides little assurance to users regarding the suitability of that product on export citrus.
- The question of cross-contamination of disinfectant residues from hard surfaces (e.g. pack lines) onto the fruit is a subject of considerable debate, even in the EU presently. It is unclear how the Commission will interpret detections of residues (at low concentrations) that arise from maintaining sanitary surfaces in the packhouse.

Act 36 of 1947: Fertilizers, Farm Feeds, Agricultural Remedies and Stock Remedies Act

The Registrar of the Fertilizers, Farm Feeds, Agricultural Remedies and Stock Remedies Act, 1947 (Act No. 36 of 1947) is housed within DAFF: Directorate Agricultural Inputs Control. This Directorate was created during restructuring of DAFF in 2011 (previously it was housed under DAFF Directorate: Food Safety and Quality Assurance).

All agricultural remedies are regulated by this Act. However, sanitizers are not necessarily registered under Act 36 of 1947 if they do not make any claims regarding the biocidal properties of the product. CGA was recently in discussion with the Registrar to seek clarity on this matter. The Registrar indicated that he recognized there was some overlap between the various strings of legislation but would, for now, only intervene if claims about the product's agricultural remedial action were being made. In other words, if claims about the product's fungicidal, algacidal, or bactericidal effectiveness were being made for the purpose of improving the quality of fruit then those products would need to be withdrawn from the market or undergo a full Act 36 registration process. The Registrar also indicated that should the citrus industry believe this overlapping of Regulations was leading to confusion then it would be possible to institute clearer rules regarding the definitions of disinfectants, but this would inevitably lead to a reduction in the number of products that could be used in the packhouses (both for hard surface sanitizing and other uses).

Implications for the citrus industry

- Disinfectants registered under Act 36 of 1947 may be used in dump tanks or degreening drenches if registered for such uses (i.e. it is indicated on the label).
- Act 36 of 1947 considers the toxicological and ecotoxicological profile of the active and

it is only registered if these profiles are acceptable.

- Act 36 of 1947 takes into account the South African MRL.
 - NB: Additional usage restrictions may be required to meet the importing countries' MRL.
- Act 36 of 1947 registration applications are typically more expensive than those under Act 5 of 2008 because of the additional toxicological data requirements. The associated benefit of such registration is that users are provided with greater assurance regarding the suitability of the product for use on export citrus (for example, phytotoxicity risk).

Act No. 54 of 1972: Foodstuffs, Cosmetics and Disinfectants Act, 1972

The Foodstuffs, Cosmetics and Disinfectants Act, 1972 (Act No. 54 of 1972) addresses the manufacture, sale and importation of foodstuffs from a safety/public health point of view. It is relevant here because MRLs for pesticide residues (agricultural remedies) are promulgated under this Act. Department of Health Directorate: Food Control implements Act 54 of 1972.

Implications for the citrus industry

- All products registered under Act 36 of 1947 will be subject to a review under Act 54 of 1972 to evaluate the need for MRLs and to set the MRLs for South Africa if required.
- To CGA's knowledge those disinfectants currently registered under Act 36 of 1947 for use in the citrus industry have South African MRLs set under Act 54 of 1972.
- Disinfectants registered under Act 5 of 2008 are not compelled to undergo an MRL review under Act 54 of 1972 specifically, but provision is made that any product to be used on foodstuffs should not cause harm. This is rather a grey area and subject to possible abuse by eager disinfectant marketers because without rigorous review it allows for interpretation around what might be considered an acceptable level of risk for the consumer.

SANS 1853: Disinfectants coming into contact with foodstuff

Some disinfectants meet the SANS 1853 standards for disinfectants coming into contact with foodstuff. This is a voluntary standard administered by SABS. It does NOT set specifications for the performance of the product as a disinfectant or detergent-disinfectant (which is covered under Act 5 of 2008 above) although



any claims made about the performance must be true under SANS 1853. This standard focuses on the safety, quality and consistency of raw materials and final product in addition to appropriate labelling of the product. SANS 1853 does not take into account phytotoxicity, resultant residues and their acceptability when looking at South African and importing country MRLs (in this regard it is similar to Act 5 of 2008).

Implications for the citrus industry

- This standard provides assurance about the safety to users and possibly consumers of the foodstuff and quality of the disinfectant product. This assurance should apply to citrus uses specifically (see certificate to confirm this).
- Since SANS 1853 does not address any possible phytotoxicity, ecotoxicity or residue concerns, it is recommended that additional assurances are provided besides SANS 1853 compliance to determine the suitability of the product for packhouse use.

Biocide Regulation in the EU

Biocide Residues

Regulation EC/396/2005 covers residue tolerances for both pesticide and biocide uses. For example the default MRL of 0.01 mg/kg applies for both DDAC (and the QAC-family in general) irrespective of how the product is used. As such, fruit and vegetables containing residue levels above 0.01 mg/kg may not be placed on the market. It is the resultant residue from biocide uses on fruit and vegetables above the 0.01 mg/kg tolerance that is causing concern in the EU at present (Cutting Edge 143).

Biocide use within the EU

The use of the QACs as a plant protection product (pesticide) on citrus (and food products in general) in the EU is forbidden (i.e. it is not listed under Annex I of EC/1107/2009 or exempt from this regulation). This would apply for all biocides not listed under Annex I of EC/1107/2009. DDAC is authorized at EU-level (EC/540/2011) but is strictly limited to indoor uses on ornamental plants.

Directive 98/8/EC is the key biocide legislation and contains the positive list of biocides. The use of QACs as a biocide in the EU is authorized, even if both QACs and DDAC have not been officially included in the EC/98/8 positive list yet. The basis for this is Article 16, which provides for a derogation allowing the placing on the market of products containing existing substances whilst they are being evaluated under the review programme for existing active substances. Applications have been filed for several QAC-families and DDAC and all of these cover use as food and feed areas disinfectants.

Conclusion

Packhouse managers considering the use of a new sanitizer are encouraged to review the product in light of the questions posed above and by testing its suitability using the information about the three South African Acts and the Standard discussed here. At present, the use of a sanitizer for fruit destined for the EU depends significantly on whether there are any detectable residues and if those residues are compliant with EU MRL requirements.

If there is further uncertainty about the legality or suitability of the product for use in citrus packhouses please contact either CRI (Keith Lesar - keithlesar@cri.co.za) or CGA (Paul Hardman – ph@cga.co.za) for confirmation before proceeding with use of the product.