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Import Conditions: impacts on industry and potential solutions

1 November 2017

A. Tour Notes

Notes from the DAWR Familiarisation Tour 9-12 October, and from the FIAAA initiative to develop product group standards.

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B. Product Group Standards – FIAAA proposal

Presentation from the DAWR Familiarisation Tour 9-12 October, introducing FIAAA; and, elaboration on the product group standards proposal.

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SUMMARY OF TOUR NOTES

A. Tour Notes

Notes from the DAWR Familiarisation Tour 9-12 October, and on the FIAAA initiative to develop product group standards.

1. Market Failure

Delays or refusals to issue import permits impact the importer's business, with flow on effects to stockfeed, pet food and human food production and further to domestic and export trade.

Comments and examples

Product lines may need to be deleted, delayed or reformulated if import permits can't be obtained as expected

Physical quality may have to be compromised in order to formulate a product, for example if they can only obtain an ingredient with a less than ideal physical form such as a powdered rather than a solid enzyme.

Very low margins in the poultry industry so the business has little tolerance for disruptions in supply.

Importers don't keep a large reserve of products. So there can be significant flow on impacts to industry if they can't supply.

Nestle is a high complexity site. Currently there are 345 SKUs, 166 recipes, 23 pack sizes and 125 raw materials. Despite the large scale and experience of the organization, Nestle still has some problems with import permit applications. Some production stoppages are related to import permits.

2. Permit assessment time

Assessment times are longer than previously. This appears related to the new BICON system, and changed process and new staff at DAWR. Problems are experienced with applications for new products, renewals and variations.

It is understood that applicants can assist by providing good information to allow for efficient assessment. At the same time some delays are out of their control: In the case of variations there seems to be no statutory timeframe; timeframes are extended when assessors seek clarification from the biosecurity team; there needs to be a mechanism for continuity of assessment when assessors are on leave.

Importers request more efficient and predictable timeframes.

Comments and examples

About the time the Biosecurity Act came out, the plant program also changed to include animal biosecurity. This unexpectedly lengthened review times. Several permits were impacted, including:

- A permit for chicory under the old system had taken 1 week to be issued. It now took 6 months due to identification of a biological risk due to potential for porcine disease come through plant based products. The permit process has been somewhat streamlined since.
- Tapioca starch permit took 12 month. As a result the manufacturer to reduce product supply with

consequent impact on trade.

These delays were not related to the new biosecurity act but rather to changed processes and new people.

When assessing officers have to ask for clarification from the biosecurity team there is no standard timeframe for response. Unless the applicant follows up the application doesn't move through the system effectively.

For some products the entire production can be lost if a permit is delayed, for example where an enzyme is only used for a 3 month period each year.

Now that many products go through both the plant and animal streams the assessment times have increased considerably. There are major hold ups on the plant side, particularly when the assessors don't have experience with the material.

Under the ICON system it was quick to make a new case and create conditions. Now a different team creates the case and it can take a couple of weeks.

3. Location

Long shipping times to Australia impact decisions on permit applications

Comments and examples

There is a particular risk for the Australian business because of long shipping times.

The lead time out of Europe is 12 weeks so it is not always possible to have a permit in place before dispatch. This situation is exacerbated when extra data is requested.

4. Consistency in assessment

Inconsistencies in assessments may be alleviated with an upgrade of guidance to applicants and assessors.

Questionnaire updates in BICON have been helpful and could be developed further. There needs to be standardization of both questions and conditions and the use of common language across scenarios.

Mechanisms within DAWR are needed to ensure consistency across assessors. An administrative solution is suggested for minor application faults such as incorrect formatting.

Comments and examples

Some requirements that slow down permit issue appear to be petty, for example requirements around standard formatting and letterheads. Can there be an administrative work around for these?

Production questionnaire has improved but is difficult to find. Could it be included in the document link page?

5. Thermal processing

Meeting requirements for thermal processing is a major issue. Recognition of alternate, equivalent processing would reduce assessment timeframes and permit rejections. There are several options to facilitate this process:

Education of applicants, potentially through FIAAA, on providing adequate data, scientific argument and manufacturing information to justify alternate scenarios.

Inclusion in BICON, of more detailed directions, to provide scientific evidence of the suitability of manufacturing conditions at the time of application.

Development of industry standards for processing of certain materials.

Development of equivalence models for some processing scenarios.

Transparency of DAWR risk assessment process.

Comments and examples

An example where there are difficulties meeting requirements for thermal processing of pelleted stock and pet food:

- Permits refer to core temperature. These are difficult to measure directly because temperature drops immediately when pellets are released from the extruder.
- The product is deemed by the operation to meet requirements based on meeting key controls, including, preconditioning steps (mixing, steam, thermal processing) various airflow configurations and residence time in extruder. These steps can vary considerably across products.
- Time, temperature and other parameters are recorded but there is currently no technology available to measure core temperature.
- Can equivalence to current permit time / temperature requirements be established based on the condition measurements?

If a material undergoes treatment utilizing pH, crushing, sieving, washing and treatment what can be done to establish equivalence to the standard time / temperature requirements?

- Could FIAAA work with members and DAWR to establish standard equivalence data?
- Could FIAAA offer training to members on establishing and collating data to submit at the time of permit application as non-standard proof of treatment suitability?

Across meat commodities there is a 100 deg / 30 min requirement regardless of disease risk. For example, if fish have pH reduction for 30 minutes this is not taken into account. The restrictions are reducing ingredient options.

Some ingredients will lose flavour and nutrients if processed to the required time / temperature. Even though they achieve kill in other ways permits are refused.

Vitamins intended for human use tend to be pure whereas those included in pet food need to tolerate heat and are therefore incorporated in a protective matrix. Although the matrix is heat treated, the regime cannot be as extreme as for those without a vitamin component as the potency would be lost.

For some highly purified ingredients there is no heat treatment; because of the nature of the material there is no microbial risk. A time/temperature profile can't be provided because it is not used. There needs to be acceptance of alternate treatments.

6. Transparency and quality of application

The quality of applications would improve if applicants and assessors worked from the same guidance material (literature, modelling risk matrices). If there was total transparency on how risk was determined, manufacturers could develop processes to achieve a sufficient mitigation of risk. Guidance material could be developed by DAWR in consultation with importers and manufacturers.

Not only would the quality of applications be improved but actual biosecurity risks should diminish.

A flow on impact would be reduced workload for assessors and applicants and a faster assessment time.

Comments and examples
Applicants need to know how DAWR is determining the suitability of manufacturing processes. If this information is shared then applicants can self-assess and ensure products are manufactured to meet requirements.
It would be helpful if there was more guidance in BICON around what will be needed for a successful permit issue.
The department has a list of approved carrier materials. It would be useful if this could be shared with industry.
Can a checklist be developed to help applicants understand and meet requirements?

7. Appropriate risk mitigation

Analysis of whether import conditions are appropriate to the risk could enable reduced pathways in some circumstances.

Comments and examples
An analysis of whether the controls put in place match the level of risk hasn't been undertaken by DAWR but could be useful to reduce workloads and timelines without reducing biosecurity.
There should be a faster pathway for some feed grade ingredients such as dextrose, for example, along the lines of the vet therapeutics excipient list.
If the FIAAA believes that mitigation strategies are excessive for a particular risk, an Import Risk Analysis (IRA) could be requested. A similar approach was taken in the dairy industry. A request would be sent to the assistant secretary of plant and animal biosecurity. The request would be put into the work order and prioritized; it could take years before assessment but nevertheless if the industry believed there was a case then this should be considered In the first instance an approach could be on an informal basis, with FIAAA asking what would be required to get an IRA for, for example, imported stockfeed of microbial origin with plant based carriers or plant based feed.

8. Recognition of quality systems

FIAAA and PFIAA members have high quality standards. In addition to FIAAA certification many companies have ISO quality systems, HACCP systems, traceability systems, third party testing and industry standards that must be met. Recognition of quality systems implemented by importers and manufacturers could fast-track processing of certain permit applications.

Comments and examples

Applicants would welcome investigation of simplified pathways where there are rigorous quality processes in place to minimize business and biosecurity risks.

9. Major scenarios

Several variables have a major impact on the case outcome. If applicants are asked about these up front it will be easier to establish the correct pathway. In particular:

Human vs animal end use

Food vs non-food grade quality

Synthetic vs nature derived.

Comments and examples

The system says starch doesn't need a permit. There is a case for pet food and stock feed but unless the user knows how to navigate the system they will end up with the outcome for starch for human food.

It can be difficult to get information from manufacturers for food grade materials because the import permit requirements are greater for animal food end use. In some cases the requirements should not be greater.

10. Product grouping and industry standards

FIAAA proposes the development of monographs and standards around product groups

Comments and examples

FIAAA has developed a list of product groups that should have similar conditions.
In some cases the need for a permit may be eliminated. For others a group standard would eliminate the need for assessment of individual ingredients within the group, provided they meet the conditions of the standard.
The list of ingredient and additive groups accompanies this document

FIAAA could also work with industry and DAWR to develop information on industry production standards for some individual commodities such as tapioca starch.

Refer to further detail in Part B of this document

11. Approved Arrangements

Information on requirements for Approved Arrangements is needed in BICON at the start of a permit application

Comments and examples

As a manufacturer it is crucial to know if Approved Arrangements are needed because otherwise they may not be in place when an application is made for a permit. Currently importers don't find out until draft permit stage that Approved Arrangements are needed.

12. Pharmacopeia listings

Recognition of the Chinese pharmacopeia would be helpful

Comments and examples

Some amino acids comply to the Chinese pharmacopeia but as this one isn't listed a permit is required. The Chinese pharmacopeia appears similar to other listed versions. Can it be included in the list?

13. Unusual circumstances

Consideration could be given to a mechanism to escalate applications.

Comments and examples

A challenge for urgent cases is that there is no mechanism to escalate or fast track. Circumstances could include a risk to exports.

Applicants could be offered an option to prioritise their own applications when they have several in assessment.

14. Draft permits

Overall draft permits are considered to be a good initiative. A mechanism to minimise changes after the manufacturer has reviewed the conditions would be helpful

Comments and examples

Is there a mechanism for the stream leader to review a draft permit before it is sent to the applicant, so as to minimize the changes made after the manufacturer looks at the draft and before issue?

15. Communication of system changes

Communication of system changes with FIAAA would facilitate efficiencies: the association could disseminate and explain changes to its members.

Comments and examples

If changes in pathways are not well communicated importer and manufacturer operations are disrupted.

16. Access to assessors

The front desk is now more helpful than in the past but unfortunately the 1800 number tends to result in generic answers.

17. Assessment status

The level of detail on the assessment status in BICON could be increased to help businesses plan production.

Comments and examples

Currently the status stays at "assessment" from payment of invoice until issue of permit.

Knowing when the 20 day timeframe starts is critical.

18. Formulation sites

Specification of formulation sites is restrictive and it would be helpful if this information could be removed from permits, assuming other aspects are unchanged.

Comments and examples

Raw material source change. Permit holders tend to send an email to notify of a changed supplier. If there are no biosecurity implication they will be advised by email that they can continue to work under the current permit. It would be better if there was a formal statement that if no change in conditions then no application is required.

19. Physical assessment

Reduction in timeframes for physical assessment of a shipment would minimize production delays

Comments and examples

Booking of assessors for physical audit is difficult – it takes longer than previously to get an assessor on site. Can this be improved.

20. Communication of system changes

Communication of system changes with FIAAA would facilitate efficiencies: the association could disseminate and explain changes to its members.

Comments and examples

If changes in pathways are not well communicated importer and manufacturer operations are disrupted.

21. BICON usability

Applicants find the BICON system easier to use than previous systems

Comments and examples

All companies commented that the BICON system is easier to use than the previous system

It is easier to access conditions with key word search in BICON than in previous system.

22. General BICON user experience

Typical questions and application faults experienced by FIAAA members could be used to inform guidance and training material for BICON users.

Comments and examples

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B. Product Group Standards – FIAAA proposal

1. **Introduction – presentation to DAWR during familiarization tour**
2. **FIAAA proposal for group standards**

1. Presentation

Malcolm Mottram, FIAAA President

i. BICON import conditions review- Stockfeed

FIAAA Introduction and Discussion

ii. Who is the FIAAA?

- Feed Ingredients and Additives Association of Australia.
- Comprises over 50 members who represent most major ingredient and additive suppliers to the stockfeed industry. To be a certified member each company has to be audited to the FIAAA code of practice.
- This does not include bulk materials like soybean meal, grains, rendered products and the like.
- Feed Ingredients and Additives are those micro additives that complete the nutritional and functional performance of the complete feed fed to animals.

iii. Why is the BICON review important to the FIAAA?

- Most imported feed ingredients and additives require an import permit.
- Every product or variation needs a permit.
- With renewal/replacement every 2 years this adds considerable time, resources and red tape for all parties (suppliers, importers, DAWR, industry).
- A review where red tape can be reduced and efficiencies gained without affecting the underlying protection of biosecurity for Australia has obvious implications.
    - Improved efficiencies for all.
    - Lower cost.
    - No impact on risk.
    - Improved trade.

iv. What can be done?

- Grouping the same or very similar product categories under an agreed monograph that is reflective of the use in stockfeed (not human food).
- Even without certain groups there can be sub-groups defined that could be easily rationalised to have its own monograph.
    - Eg. Synthetic versus natural ingredients.
    - Given processing standards for ingredients.

v. FIAAA groupings

Product description	Contains animal material	Contains plant	Contains animal & plant
Amino acids	yes	yes	
Animal protein derived ingredients	yes		
Antioxidants			yes
Antibiotics			yes
Betaine		yes	
Direct fed microbials	yes		
Egg derived products	yes		
Electrolytes			yes
Emulsifiers			yes
Enzymes			yes
Flavours			yes
Ionophores		yes	
Mycotoxin binders & deactivators			yes
Organic acids		yes	
Organic trace mineral			yes
Phytobiotics & essential oils		yes	
Pigments			yes
Protein by-products		yes	
Stabilisers , anti-caking agents		yes	
Sugar based products		yes	
Vegetable Proteins		yes	
Vitamins			yes
Yeast and yeast derivatives		yes	

i. Conclusion

- FIAAA is keen to work through parameters for groups that would meet the criteria of BICON.
- It's important that standards meet the requirements for use in stockfeed.
- Efficiency while maintaining biosecurity is essentially the end game.

2. FIAAA grouping proposal

FIAAA proposes the development of standards for feed ingredients and additive groups. It is expected that the majority of products would fall within group standards. Likely groupings are shown in the previous section.

The application of standards to a product could negate the need for an import permit, reducing the workload of DAWR and importers, and facilitating the use of ingredients and additives in stockfeed.

It is suggested that a DAWR – FIAAA working group be established to develop standards. Initially several could be selected as test cases to build the standard development methodology.

Before FIAAA provides any significant data on processing it would be wise to establish the parameters for acceptance by DAWR. This would involve decisions around the critical control points in production of ingredients and additives.

Amino acids are an example of a group to consider this aspect of a standard:

- A range of amino acids may be used in stockfeed.
- Non-synthetic amino acids are usually produced by microbial processes involving fermentation and/or various enzyme pathways. As a generalization, a microorganism is added to a nutrient system, fermentation takes place and amino acids are formed. In all cases a purification step is required to produce the final amino acid product.
- For each different amino acid the microorganisms are different and the nutrient system varies.
- Beyond the generic differences in organism and nutrient system there are differences between manufacturers, and the final composition of an amino acid broth prior to purification can vary from batch to batch.
- The veracity of the purification step is considered the critical control point of greatest relevance to an amino acid standard.

It is envisioned that a working group would consider a number of points, including:

- Similarities and differences between starting materials and methods of manufacture of amino acids.
- The relevance of the similarities and differences to the outcome, from a biosecurity point of view.
- Critical control points to establish compliance to the standard.
- The possibility of a group standard for part of the manufacturing process.
- The potential to have an all-encompassing amino acid group standard or whether it would be necessary to have separate standards for each.

Amino acids are an example. Other groups that could be early stage test cases are individual amino acids (e.g. lysine hydrochloride), organic acids and phytobiotics with essential oils.

Overall, the working group would need to establish what DAWR is prepared to accept in support of a standard and, at the same time, what FIAAA is capable of providing.

At this point FIAAA is not attempting to provide specific data in support of any of the proposed group standards. It is hoped that DAWR will agree to consider the proposal to establish group standards with a likely process as follows:

- Establishment of a working group comprising FIAAA and DAWR representatives.
- Agreement on timeframes and priority listing for standard development.
- Scoping of components of a group standard.
- Determination of thresholds that DAWR will accept, including whether these are process specific or outcome specific.
- Provision, by FIAAA, of manufacturing process information.
- Writing the group standard.
- Validation of the group standard.
