SUBSTITUTION PLAN

Public Version

Legal name of Applicant(s):	Tata Steel UK Ltd Tata Steel IJmuiden BV
Submitted by:	Tata Steel IJmuiden BV
Date:	November 19th 2019
Substance:	Sodium dichromate, CAS No: 10588-01-9, 7789-12-0 (dihydrate), EC No: 234-190-3, 616-541-6 (dihydrate) (Annex XIV entry number: 18) Chromium trioxide, CAS No: 1333-82-0, EC No: 215-607-8
Use title:	Use of Chromium (VI) Trioxide and Sodium Dichromate for Passivation of Electrolytic Tinplate (ETP)
Use number:	1

This Application has been prepared collectively in APEAL and has been submitted by individual legal entities.

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Table of Contents

1. INTRODUCTION 7

1.1 Critical requirements for use of Cr (VI) 7

1.2 Factors affecting substitution 8

1.3 List of actions and timetable with milestones 11

2. MONITORING IMPLEMENTATION OF THE SUBSTITUTION PLAN 13

3. CONCLUSIONS 15

ANNEX 1: JUSTIFICATIONS FOR CONFIDENTIALITY CLAIMS 16

ANNEX 2: FOOD CONTACT REGULATION IN EUROPE 20

LIST OF ABBREVIATIONS

AoA/SEA	Analysis of Alternatives/Socio-Economic Analysis
Cr (VI)	Hexavalent chromium
Cr (III)	Trivalent chromium
EN	EuroNorm
APEAL	The Association of European Producers of steel for packaging
CFPA	Chrome Free Passivation Alternative
ZrO_2	Zirconium dioxide
TiO_2	Titanium dioxide
B2B	Business-to-Business
R&D	Research and Development
ITRI/ITA	International Tin Research Institute/International Tin Association
WG	Working Group

DECLARATION

Tata Steel UK Ltd and Tata Steel IJmuiden B.V. are aware of the fact that evidence might be requested by ECHA to support information provided in this document.

Also, we request that the information blanked out in the "public version" of the Analysis of Alternatives and Socio-economic analysis is not disclosed. We hereby declare that, to the best of our knowledge as of today (November 15th, 2019) the information is not publicly available, and in accordance with the due measures of protection that we have implemented, a member of the public should not be able to obtain access to this information without our consent.

Signature: 

Date, Place: Ymuiden

November 15th 2019

1. Introduction

1.1 Critical requirements for use of Cr (VI)

As discussed in Section 4.1 of the joint AoA/SEA document, Cr (VI) is used for the passivation tinplate, to form a Cr (III) oxide layer, because of its unique chemical and electrochemical properties for providing corrosion inhibition to ferrous and non-ferrous metals. By applying an electric current, the 'natural' thickness of the layer can be enhanced and a stable tin oxide layer can be formed. Chromate coatings have a high barrier component.

Cr (VI) is, therefore, used to apply a coating that provides the following properties:

- Prevention of additional tin oxide growth
- To ensure a surface amendable to subsequent lacquering, decorative printing and welding of the tinplate
- Prevention of sulphide staining by foodstuffs which contain natural protein and,
- Weldability.

The Table below outlines the key critical technical requirements that a passivating agent must meet, to ensure tinplated steel conforms to accepted industry standards (e.g. EN 10202, EN 10333, etc.).

Key Technical Requirements	**Criticality**
Tin Oxide Growth Resistance	**Critical**
Lacquer Adhesion	**Critical**
Suitability and Compatibility with the can making process	**Critical**
Sulphide Staining Resistance	**Critical**
Market Acceptance	**Critical**
Compliance with FCM Regulations	**Critical**
Ability of the applicants to implement	**Critical**
Temperature Resistance	Important
Tinplate Process Speed Compatibility	Important

With reference to Section 5.3 of the joint AoA/SEA document accompanying this application, APEAL members and their supply chain are in the process of testing and developing an alternative that is composed of a Zirconium / Titanium Fluoride liquid solution system applied by spraying and drying. The protective layer consists of ZrO_2/TiO_2, phosphoric and polymeric compounds – Chrome Free Passivation Alternative (CFPA).

1.2 Factors affecting substitution

Several steps are still required in order to ensure CFPA material performs in an equivalent manner to the current Cr (VI) manufactured material.

1. Completion of Research and Development;

   Research and Development work is on-going in order to build-up the industrial production experience for APEAL members and can-makers.

   The product specification has been set in the draft Euronorm (EN10202) which has been agreed and will be published by Q4 of 2020.

2. Completion of preliminary testing of material for can-making and R&D work;

3. Feedback on preliminary packtesting from the can-makers and identification of further research and development activities;

   APEAL members and their value chain are in regular B2B contact and also at association level. Meetings and teleconferences are organised at association level on a bi-monthly basis to discuss generic feedback on the status of testing.

   For can-makers some of the key requirements are that the coatings must adhere well to the metal body and end sealants. In addition, the coatings[1] must:

   - adhere well to metal, coatings & end sealants;
   - be flexible;
   - have a high resistance to food components;
   - be resistant at temperatures up to 130 °C;
   - have good organoleptic properties; and
   - be inert with low/safe/no migration.

   Up to 500 lacquers are used by a typical can-maker who all have a wide variety of can fabrication methods, produce different can shapes/sizes, with different food/filling types, and food process conditions all contribute to the need for many lacquers.[2]

[1] Coatings are mostly a mix of resins, cross linkers, additives, pigments, and catalysts applied in a carrier then dried and cross-linked in oven at ca 200 °C and results in very high molecular weight impervious film (5-20µm dry film).

[2] A simple example as to why there are so many coatings/lacquers is of a metal coated can that includes an external coating on the top end, an internal base coating, an internal top coating, and a can end sealant. The body includes a base coating, an internal top coating and an internal powder side stripe coating. The bottom end will have an external coating, and internal coating and an internal top coating as well as a can sealant. Each of these coatings differ depending on the filling of the can as well as its shape and design.

In addition, not all can-makers have the same fillings into their cans and they produce varying different products, from general line/decorative products like storage cans, to aerosol cans, food cans, beverage cans, closures including twist off caps etc., etc. All have

different internal conditions based on the filling (of which there are many even within segments e.g. different food products).

Consequently, each can-maker may have their own pack-test qualification protocols based on the products they manufacture and the fillings that their customers will put into the can. This has been confirmed through surveys of can-makers that was carried out as part of this application.

Furthermore, the vast array of packed foodstuffs poses particular challenges, given the number of potential fillings all with unique chemistries (acidity, basicity, sulphur content, whether the food is oily or not, etc.) and differing interactions with the food packaging material; the need to ensure compliance of all of these combinations of packaging/lacquer/foodstuff with European and non-European regulation; and the overriding goal to maintain the continued high level of safety for the consumer.

The final canned food product must be food safe after can making and food processing.

As the base substrate will change from a chromium passivated to CFPA passivated substrate, it will be necessary for can-makers to identify coatings from the currently available catalogue and suppliers, and test these with metal combinations with various fillings in order to determine which combinations may or may not work.

3.1. Reformulation of lacquers, if required;
Feedback during these tests and meetings will, in turn, inform the finalisation of the R&D work, as well as give an early indication as to any issues (major or minor) that can-makers and coatings/lacquers producers might face in shifting to CFPA. This will, in turn, determine the actual time frame for substitution.

3.2. Other issues related to CFPA material for can manufacture;
Feedback from lacquer performances will also be made to the APEAL members, and will inform any actions by them [redacted] # D [redacted]The EN also serves to ensure production of a set CFPA product which is important for can-makers who require consistency in the tinplate that they consume for their own process efficiency.

3 [redacted] # D [redacted]

In addition, APEAL members, in conjunction with their supply chain, are in contact with the CFPA formulation manufacturer in order to ensure that all relevant (global) food contact approvals are either in place or that the process is started. Feedback from can-makers/fillers on their requirements in this area is an on-going process.

3.3. Re-start of Preliminary testing once issues rectified;
[redacted] can-makers will feedback to the APEAL members and coatings manufacturers in order to identify if any issues can be resolved and at what level [redacted] If such an outcome occurs, then Preliminary testing will need to re-commence, [redacted] in order to ensure that these perform as expected and also to ensure that it will not result in compromised safety.

4. Qualification packtesting for products/lacquers for which no issues identified in preliminary packtests;

Substitution in these cases will occur gradually over the 7-year time horizon and could start in 3 to 5 years from now.

4.1. Packtests proceed without issue;
In this instance, the process for canmakers will involve industrial trials, validations with packtest performance approval followed by industrial development scale-up and final (manufacturing) approval.

4.2. Re-start of Packtesting if issues identified;
Similarly to the Preliminary tests, should qualification packtests identify issues with CFPA with some categories of products (general line, aerosol, food cans, etc.) then it will be necessary to re-start these tests.

Qualification packtesting timeframes are up to 5 years. Analysis of the packaging occurs at intervals of for example 3, 6 and 12 months, etc for the entire 5 years. At any point up to an including the final opening at 5 years, a packaging may fail, necessitating investigations into the reasons for the failure. This will include analysis of the best way forward to ensure product and consumer safety [redacted]

5. Re-engineer and adaption of tinplate manufacturer lines planning for the CFPA process;
Currently not all tinplate manufacturing lines are adapted to manufacture CFPA passivated material. It is not presently possible to do this as the chromium passivated tinplate is the qualified standard and CFPA has not yet reached

market acceptance as it has not yet completed pack-tests. Consequently, the vast majority of production output is for chromium passivated tinplate.

Nevertheless, as industrial knowledge, experience and confidence is established for CFPA, more manufacturing lines will be commissioned. This will require infrastructure planning, budgeting and commissioning by both APEAL members and can-makers as they adapt to the new technology.

6. Re-engineering works implementation and line conversion;

   Modification of the tinplate lines will require engineering and building works. Following this, there will need to be testing of the lines and their products in order to ensure the material being produced is of a sufficient standard. Early demand will initially be met by producing CFPA passivated tinplate on swing lines as full conversion progresses.

7. CFPA production ramp-up;

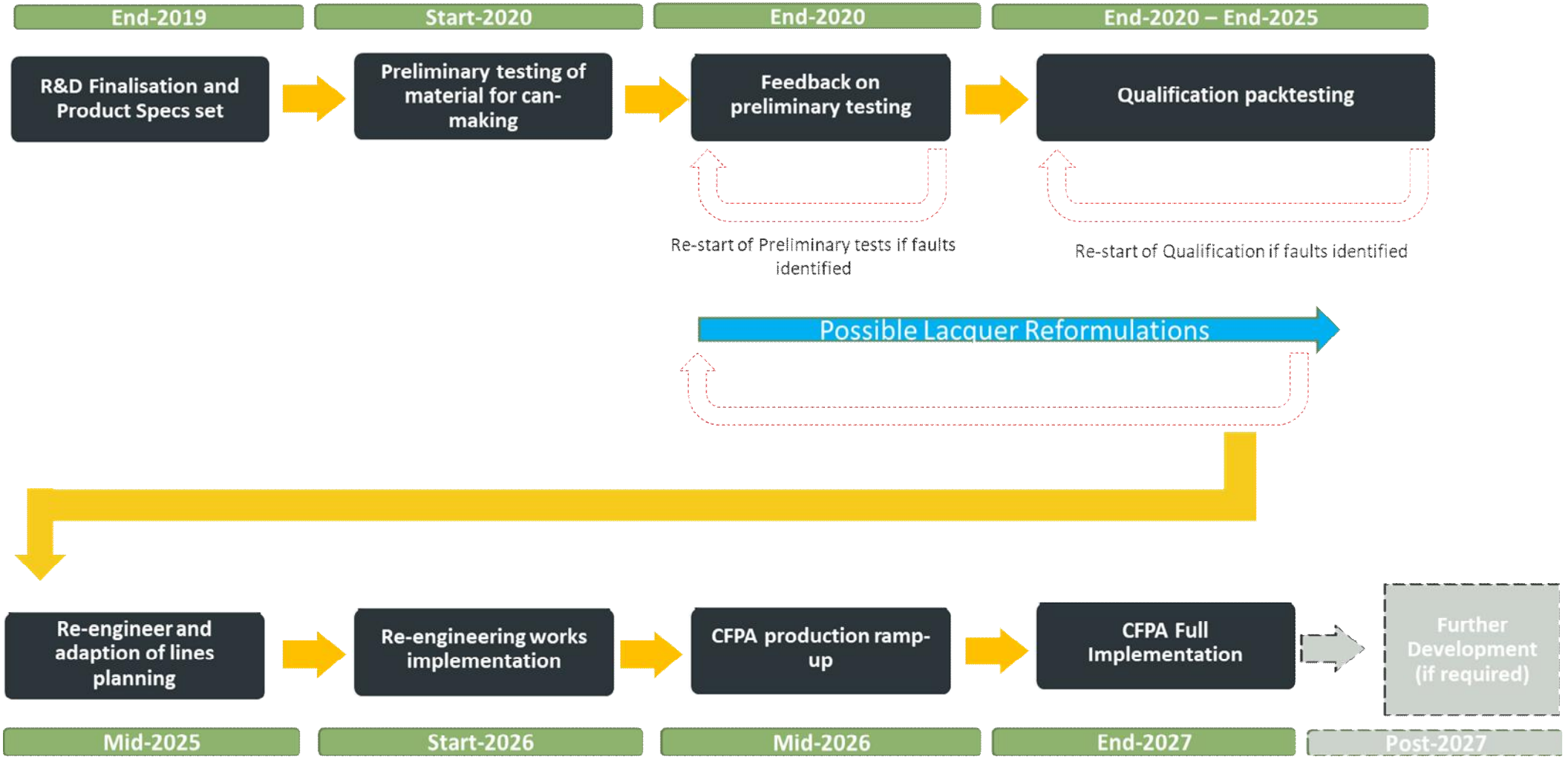
8. Complete replacement of Cr (VI) with CFPA.

   Complete replacement of CFPA is, of course, conditional on the successful completion of qualification packtests, market acceptance and global regulatory approvals to ensure all markets currently accessible for material manufactured using the current Cr (VI) passivation process are accessible for CFPA. As discussed in the AoA/SEA, these approvals are on-going.

1.3 List of actions and timetable with milestones

- Completion of Research and Development by the tinplate manufacturers, can-makers and lacquer suppliers:
  - Reformulation of lacquers, if required,
  - Rectification of other issues that may be identified related to CFPA material performance for can manufacture;
- Qualification of the material for use and ensuring that it maintains the high levels of safety required and that it is in compliance with relevant food contact regulations;
- Market acceptance and implementation; and
- Re-engineering works implementation and new line commissioning.

Figure 1 Flow Diagram of the indicative timetable for complete implementation of CFPA



1. Monitoring Implementation of the Substitution Plan

The CFPA R&D WG was established in 2017[4], is a joint collaboration between all the parties for whom this AoA was prepared. It is coordinated by the APEAL Secretariat and has monthly meetings to provide feedback on production issues related to the development of CFPA that impacts all APEAL members, in as far as compliance with anti-trust regulations and laws allow. It is a separate, but follow-on activity from the work already undertaken under the umbrella of the ITRI/ITA chrome free tinplate R&D that had first commenced in 2006.

Following identification of a viable laboratory alternative, the WG's remit was to scale-up the potential alternative system to mill-product trials with verification of the system through trial programs. The WG will also develop industrial best practices for the CFPA process, provide a forum to exchange information on experiences with members' respective products, and ensure regulatory food contact approvals. It is also responsible for liaising with downstream users and other technical stakeholders.

In order to achieve the desired aims, the R&D working group is sub-divided into 6 subgroups, each with different focuses:

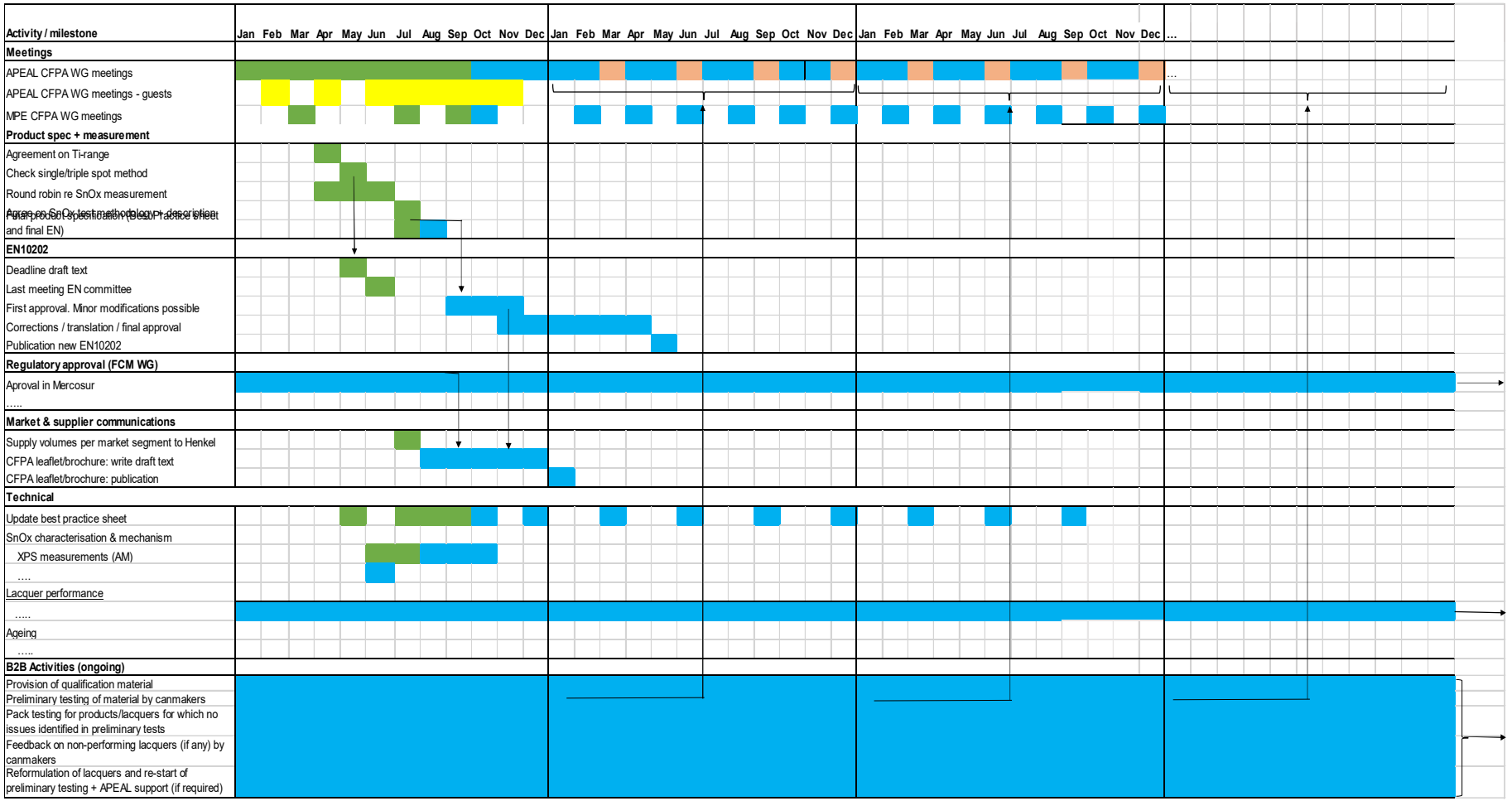
- Core WG – Overall project management and control. It comprises 1 member from each APEAL member company and the APEAL Secretariat.
- Lacquer WG – Evaluation of lacquer performance with CFPA and identification of any issues as well as liaising with lacquer system suppliers. In conjunction with the Core WG, elucidation of solutions to identified issues.
- Detinning[5] WG – Evaluation tinning performance and elucidation of solutions to any identified detinning issues of CFPA material, in conjunction with the Core WG.
- Regulatory Approval WG – Filings and approvals for CFPA globally.
- Product/Process WG – Responsible for identification of best practice manufacturing and, in conjunction with the Core WG, elucidation of solutions to identified issues with production processes.
- Customer/Filler WG – Interface with can makers to gather feedback on material performance which feeds into the other WGs and directs potential R&D in relation to issues identified during can-maker testing.

This group monitors all the developments of CFPA and liaises with the value chain in order to ensure the alternative is implemented in the most efficient and practical way. The following Figure outlines the key milestones that are being monitored and developed by the CFPA WG over the next several years.

[4] The CFPA R&D Agreement was signed on 22/09/2017.

[5] In the context of this application, detinning means the unwanted separation of tin from the can, causing rust.

Figure 2 CFPA WG Project Gantt chart for the next several years



2. Conclusions

APEAL members, and members of their value chains, have been engaged for many years in the identification and development of a suitable alternative to the use of hexavalent chromium in the passivation of tinplate. These investigations pre-dated the REACH Regulation and involved global, as well as, European cooperation.

As discussed in Section 5.3.1 of the joint AoA/SEA, the identified alternative has faced some difficulties in R&D, which has delayed the value chain as a whole in implementing it as an alternative.

As noted in the AoA/SEA and this document, APEAL members and their supply chain have invested significantly in bringing forward CFPA. In addition, APEAL members are fully aligned and committed to the implementation of CFPA as the alternative to the use of hexavalent chromium in the passivation of ETP.

This challenge is being met jointly by the full supply chain (tin-mills, can-makers, coatings suppliers) and we all continue to work intensively towards its successful implementation.

Excluding any significant issues with qualification pack-tests for food fillings that may occur late in the qualification process, and result in the need to re-start the process [redacted], [redacted] # D, G [redacted] it is estimated that full implementation of CFPA could be complete by the end of 2027.

This review period includes the finalisation of R&D work, and allows for the time required by can-makers to complete their qualification protocols to ensure the continued high levels of consumer safety that are required of materials intended to be used in food contact applications.

Annex 1: Justifications for Confidentiality Claims

Table 1–1: Justifications for confidentiality claims			
Reference type	**Commercial Interest**	**Potential Harm**	**Limitation to Validity of Claim**
[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]

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Annex 2: Food Contact Regulation in Europe

When put in contact with food, and depending on their composition and properties, different materials may behave differently and transfer their constituents to food. If ingested in large quantities, Food Contact Material (FCM) chemicals may change the food itself or endanger human health. Therefore, these materials are subject to legally binding rules at EU and Member State level. The main objectives of EU FCM policy are to ensure the effective functioning of the internal market of FCM goods and to secure a high level of protection of human health and the interests of consumers.[6]

Products that do not comply with these regulations cannot be placed on the EU market. Any alternative to Cr (VI) in the production of ETP must, therefore, comply with the EU requirements for food contact materials.

An overview of these regulations is given below. The requirements relate to materials and substances used, as well as the labelling on food contact materials.

REGULATION (EC) No 1935/2004 on materials and articles intended to come into contact with food

This Regulation covers the general requirements for all food contact materials and aims to guarantee a high level of protection of human health and the interests of consumers with regard to the placing on the Community market of materials and articles intended to come into contact with food either directly or indirectly.

FCMs must under no circumstances transfer substances to the food with which they are in contact with in quantities likely to, according to Article 3:

- endanger human health;
- bring about an unacceptable change in the composition of the food; or
- bring about a deterioration in the organoleptic characteristics thereof.

Furthermore, Annex I of this Regulation identifies metals and alloys and varnishing and coatings as materials and articles for which specific measures may be adopted.[7]

REGULATION (EC) No 2023/2006 on good manufacturing practice for materials and articles intended to come into contact with food

FCMs and articles governed by EC 1935/2004 and on Annex I of that regulation are required to be produced in line with good manufacturing practice (GMP) as laid down in Regulation EC 2023/2006.[8]

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6 http://www.europarl.europa.eu/RegData/etudes/STUD/2016/581411/EPRS_STU(2016)581411_EN.pdf accessed 14/01/2019

7 As covered by Article 5 of Regulation EC 1935/2004

This regulation applies to all sectors and to all stages of manufacture, processing and distribution of materials and articles, up to but excluding the production of starting substances.

REGULATION (EC) No 1881/2006 on setting maximum levels for certain contaminants in foodstuffs

This Regulation aims to protect public health and to keep contaminants at levels which are toxicologically acceptable. It sets out maximum levels for certain contaminants in foodstuffs, including inorganic tin.[9]

It sets strict levels which are deemed to be reasonably achievable by following, for example, good manufacturing practices, and takes into account the risk related to the consumption of the food.

REGULATION (EC) No 852/2004 on the hygiene of foodstuffs

Every food business operator along the food chain should ensure that food safety is not compromised.[10] The principal objective of this regulation, therefore, is to ensure a high level of consumer protection with regard to food safety by considering an integrated approach to food safety from the place of primary production up to and including placing on the market or export and states that packaging is not to be a source of food contamination.

Resolution CM/Res (2013)(9) on metals and alloys used in food contact materials and articles from the Council of Europe[11]

The resolution has no legal standing at the time being, but it will likely be adopted as a method of demonstrating that a material complies with Article 3 of the Framework Regulation 1935/2004. Several countries have already informed their intention of adopting the provisions into their national law.

In the absence of specific measures, Member States may maintain or adopt national provisions[12]

Countries having national legislation potentially impacting metal packaging are:

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8 https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32006R2023&from=GA accessed 14/01/2019

9 https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32006R1881&from=EN accessed 14/01/2019

10 https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32004R0852&from=EN accessed 16/01/2019

11 https://search.coe.int/cm/Pages/result_details.aspx?ObjectID=09000016805c8094 accessed 14/01/2019

12 Article 6 of Regulation EC 1935/2004

- Czech Republic: Decree No. 38 of 2001 covering elastomers and rubber, paper and board, metal and alloys, wood, cork, varnishes and coatings, printing inks, glass and enamel.
- Belgium: the overarching legislation regulating food contact materials and articles, is the Royal Decree 25/09/2016 which entered into force on 01 January 2017. This law sets specific requirements for certain food contact materials, but not for coatings, for example, varnishes and coatings intended to come in contact with foodstuff. The legislation applies to, amongst other things, coatings for metal materials and articles.
- France: Decision of 28/06/1912, Decision of 15/11/1945, Decision of 13/02/1976 and Decision of 27/08/1987 on metals and alloys; and Decision of 02/01/2003 on plastics, varnishes and coatings.
- Greece: decision No. 446/98, Greek Food Code, Article 28 on coatings; and decision No. 232/98, Greek Food Code, Article 22 on metals, cans and alloys.
- Germany: BfR Recommendation applies to coatings for food contact materials. Restriction limits apply on maximum quantities or a Specific Migration Limit (SML).
- Hungary: 17/1999. (VI.16.) EüM Regulation on forbidden usage of lead, cadmium, zinc and brass as food contact materials. Limitation of nickel and copper and copper alloys for enamels and metals.
- Italy: Decree of the Ministry of Health of 21 March 1973, as amended, on plastic, rubber, paper, glass, stainless steel and tin.
- Lithuania: Ordinance No. V-371 of 2006 on paper and board and metal.
- Slovakia: Decree No. 1799 of 2003 on Elastomers and rubber, paper and board, glass, metal and alloys, wood, cork, textile products, varnishes and coatings.
- Spain: Resolution of 4/11/1982 on polymers and the country has recently updated its coatings legislation with the enactment of Royal Decree 847/2011.
- Sweden: Decree No. 2005:20 on lead and cadmium in equipment used when handling foodstuffs (other than ceramic articles).
- The Netherlands: Dutch Packaging and Food Utensils Regulations under the Commodities Act (Warenwet) on ceramics, coatings, glass, metals and alloys and paper and board. Ongoing amendment. Most extensive EU MS requirement for food contact coatings.

Food Contact Regulation in the USA

To be able to export materials and empty or filled packages outside the EU, these need to comply to local regulations. Several national regulations exist on food contact materials, which need to be used locally. Next to that, food companies often have their own internal standards, which can be based on the legislation of their country of origin. For many regions and market parties, the food contact regulation of the USA serves as the guiding regulation. Hence, approval by the US Food and Drugs administration (FDA) is an important benchmark for food contact materials.

China

Food related products, for example, food packaging, etc. must comply with the Chinese Food Safety Law. In addition, this law requires the development of Food Safety Standards for food related products, with the General Safety Standard, the metals specific standards

and the Coatings and Coating Layers standards being effective since mid-late 2017. Testing for compliance must also be performed within a recognised laboratory in China.

In 2018, CFPA received successful test results by an approved laboratory and was assessed to be of regulatory compliance for use in China.

Mercosur

The Mercosur region has introduced General Safety Standards for packaging and articles to come in contact with foodstuff which member states transpose into their national law, while member state sanitary authorities issue registrations. These member states are Argentina, Brazil, Paraguay and Uruguay. Once approval is achieved in one of these member states, the approval is mutually recognised within the Mercosur region.

Consequently, the manufacturer of the formulation making up CFPA initiated notification procedures in 2017 through the Brazilian authorities to cover the Mercosur region. This approval process is currently on-going.